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UNDER THE FDCA, DECIDING WHETHER TO PROSECUTE

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I thank FDLI for the honor of being invited to give this lecture. I had the privilege and genuine pleasure of serving in the Office of Chief Counsel at the Food and Drug Administration ("FDA") with Rick Blumberg in the late 1970s when he was still—arguably—a young lawyer. Even then, he was an ardent protector of the public health and was vigorous in discussions of possible approaches the agency could take to problems, from which discussions I was happy to learn, even at the end of his pointed index finger.

A common definition of "enforcement" is "[t]he act or process of compelling compliance with a law, mandate, command, decree or agreement . . . ."[1] I would add that "enforcement" also includes the act of seeking or imposing a remedy or punishment for past, continuing, or prospective noncompliance with a law, mandate, command, decree or agreement.

Thus, the concept of "enforcement" is broad. In the context of the Federal Food, Drug, and Cosmetic Act ("FDCA"),[2] it includes not only court actions—for product seizure, injunction, or criminal prosecution—but also a wide range of administrative actions, such as FDA Form 483 inspectional observations, warning letters, debarments, product bans, public warnings, FDA-initiated recalls, import refusals, civil monetary penalties, required changes in labeling, refusals to approve a product or an indication or claim for a product, and suspensions or withdrawals of

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[1] *Black's Law Dictionary* 669 (11th ed., Bryan A. Garner, editor in chief 2019).

[2] 21 U.S.C. §§ 301- 399d (2018).

prior approvals.[3] In his Blumberg Memorial Lecture in 2015, Howard Sklamberg, FDA's Deputy Commissioner for Global Regulatory Operations and Policy, discussed a number of FDA's enforcement tools that do not involve going to court—and, thus, do not involve the Department of Justice ("DOJ").[4] Last month, a statement by Acting Commissioner Ned Sharpless and colleagues discussed FDA's expanded investigative and criminal enforcement operations with respect to unapproved, counterfeit, potentially dangerous, or otherwise unlawful products that originate abroad or are sold online.[5]

In addition, some actions in court to enforce the FDCA do not originate with FDA. Under the False Claims Act,[6] a civil enforcement action for violation of the FDCA that has led to

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[3] For descriptions of some types of FDA enforcement actions, *see*, *e.g.*, FDA, Types of Enforcement Actions (Nov. 6, 2017), https://www.fda.gov/animal-veterinary/resources-you/types-fda-enforcement-actions. For statistics relating to FDA's non-criminal enforcement actions during fiscal 2017, *see* FDA Enforcement Statistics Summary Fiscal Year 2017, https://search.usa.gov/search?utf8=%E2%9C%93&affiliate=fda1&sort_by=&query=%22FDA+enforcement+statistics+Summary+Fiscal+Year+2017%22&commit=Search. *See also* Vernessa T. Pollard & Anisa Mohanty, *FDA Enforcement: How It Works*, *in* A Practical Guide to FDA's Food and Drug Law and Regulation 505, 507, 509 (6th ed., Kenneth R. Piña & Wayne L. Pines. eds. 2017).

[4] Howard Sklamberg, Third Annual Eric M. Blumberg Memorial Luncheon Address (Dec. 10, 2015).

[5] Ned Sharpless, M.D., Melinda K. Plaisier, & Catherine A. Hemsen, Expanding Criminal Enforcement Operations Globally to Protect Public Health (Oct. 17, 2019), https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/expanding-criminal-enforcement-operations-globally-protect-public-health.

[6] 31 U.S.C. §§ 3729-3733 (2017). *See generally*, DOJ, The False Claims Act: A Primer (undated), https://search.justice.gov/search?query=False+Claims+Act&op=Search&affiliate=justice; Press Release, DOJ, Department of Justice Issues Guidance on False Claims Act Matters and Updates Justice Manual (May 7, 2019) (with link to new guidance), https://www.justice.gov/opa/pr/department-justice-issues-guidance-false-claims-act-matters-and-updates-justice-manual; Gibson Dunn, 2019 Mid-Year False Claims Act Update (July 16, 2019), https://www.gibsondunn.com/2019-mid-year-false-claims-act-update/.

the submission of a false claim to the federal government can be initiated as a *qui tam* action by a private party; and DOJ can decide whether to intervene in, and take control of, such an action, or to allow it to proceed without DOJ involvement, or to seek dismissal.[7] In addition, the investigation that DOJ conducts in response to the filing of a *qui tam* action can lead to a criminal prosecution under the FDCA and/or one or more other statutes.[8]

FDA's criteria for enforcement actions that are set forth in enforcement policy statements are critically important to enforcement officials at FDA and to private lawyers who represent

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[7] As to DOJ's power to dismiss a *qui tam* action under the False Claims Act, *see* Memorandum from Michael D. Granston, Director, Commercial Litigation Branch, Fraud Section, Civil Division, DOJ to Attorneys, Commercial Litigation Branch, Fraud Section, and Assistant U.S. Attorneys Handling False Claims Act Cases, Offices of the U.S. Attorneys re Factors for Evaluating Dismissal Pursuant to 31 U.S.C. 3730(c)(2)(A) (Jan. 10, 2018), https://www.google.com/search?source=hp&ei=ZpS8Xc-AGa--ggeP0Ja4DQ&q=granston+memo+pdf&oq=Granston+&gs_l=psy-ab.1.1.0l5j0i10j0j0i10j0l2.1400.5360..7563...0.0..0.206.1039.7j3j1.....0....1..gws-wiz.....0i131j0i10i30j0i5i10i30j0i5i30j0i30j0i13j0i13i10.Y9Y_Tcrb8x8#spf=1572893554781; *See also*, *e.g.*, Newsletter and Letter from Sen. Charles E. Grassley, Chairman, Sen. Comm. on Finance, to Hon. William Barr, Attorney General (Sept. 4, 2019), https://www.grassley.senate.gov/news/news-releases/grassley-questions-use-doj-memo-limit-recovery-tax-dollars-lost-fraud; Serra J. Schlanger, *The End May be Here: Court Grants DOJ Motion to Dismiss Whistleblowers' FCA Suit* (Nov. 15, 2019), http://www.fdalawblog.net/2019/11/the-end-may-be-here-court-grants-doj-motion-to-dismiss-whistleblowers-fca-suit/?utm_source=feedburner&utm_medium=email&utm_campaign=Feed%3A+FdaLawBlog+%28FDA+Law+Blog%29; Jeff Overley, 5 Takeaways As DOJ Finds Footing in FCA Dismissal Crusade (Nov. 15, 2019), https://www.law360.com/lifesciences/articles/1217347/5-takeaways-as-doj-finds-footing-in-fca-dismissal-crusade?nl_pk=b0f5ad25-aef2-46ed-aa4d-881291f58159&utm_source=newsletter&utm_medium=email&utm_campaign=lifesciences;Sam Bolstad, *The Granston Memo in Tension: Third Circuit Allows DOJ's Dismissal of FCA Claim without a Hearing; Sen. Grassley Wants DOJ to Pump the Brakes* (Oct. 8, 2019), https://www.jdsupra.com/legalnews/the-granston-memo-in-tension-third-81442/.

[8] *See*, *e.g.*, Press Release, DOJ, GlaxoSmithKline to Plead Guilty & Pay $750 Million to Resolve Criminal and Civil Liability Regarding Manufacturing Deficiencies at Puerto Rico Plant (Oct. 26, 2010), https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-pay-750-million-resolve-criminal-and-civil-liability-regarding.

subjects or targets of enforcement actions and who seek to influence the decisions those officials make as to potential actions; and, of course, they are very important to organizational and individual subjects and targets. Those criteria also matter to all of us, who consume the products FDA regulates.

In what follows, I will discuss one aspect of the overall enforcement of the FDCA—the criteria applied by FDA and those applied by DOJ for initiating a criminal prosecution for violation of the FDCA.

The foundation for misdemeanor prosecutions of individuals under the FDCA consists of two Supreme Court decisions: *United States v. Dotterweich*, decided in 1943,[9] and *United States v. Park*, decided in 1975.[10] In *Dotterweich*, the Court held that the FDCA is of a type of legislation that "dispenses with the conventional requirement for criminal conduct – awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger."[11] In its main brief in *Park*, DOJ stated FDA's and the government's enforcement policy under *Dotterweich*:

> [I]t has . . . been FDA policy to limit prosecutions to continuing violations, violations of an obvious or flagrant nature, and intentionally false or fraudulent violations.
> . . .
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> The standard for prosecution of individual corporate officials, as distinguished from prosecution of their corporations, is based on the reasonable [sic] relationship criterion of *Dotterweich*. The government's policy is to prosecute only those individuals who are in a position and who have an opportunity to prevent or correct violations, but fail to do so. Officials who lack authority to prevent or

[9] 320 U.S. 277, 281 (1943).

[10] 421 U.S. 658 (1975).

[11] 320 U.S. at 281.

> correct violations, or who were totally unaware of any problem and could not have been expected to be aware of it in the reasonable exercise of corporate duties, are not the subject of criminal action. Even if the investigation discloses the elements of liability, and indicates that an official bears a responsible relationship to them, the agency ordinarily will not recommend prosecution unless that official, after becoming aware of possible violations, often . . . as a result of notification by FDA, has failed to correct them or to change his managerial system so as to prevent further violations.[12]

The Court in *Park* reaffirmed and further developed *Dotterweich*'s "responsible relation" standard. Thus, the Supreme Court set an extraordinarily low standard for a misdemeanor prosecution of a corporate officer for violation of the FDCA.[13]

In 1976, Sam Fine, FDA's Associate Commissioner for Compliance, published in what was then The Food Drug Cosmetic Law Journal a classic article entitled "The Philosophy of Enforcement."[14] He focused on enforcement through court actions, and on criminal prosecutions in particular. He said: "I am persuaded that prosecution of firms can have an important and dramatic impact on their peers."[15] Thus, he emphasized the deterrent effect of criminal

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[12] Brief for the United States at 16, 31-32, *United States v. Park*, 421 U.S. 658 (1975) (No. 74-215) (footnote omitted).

[13] The imposition of sentences of imprisonment for three months under the *Park* doctrine was affirmed, over a dissent, in *United States v. DeCoster*, 828 F.3d 626 (8th Cir. 2016), *cert. denied*, 581 U.S. ___, 137 S. Ct. 2160 (2017), https://www.supremecourt.gov/search.aspx?Search=DeCoster&type=Site. There is a large literature on the *Park* doctrine. For a discussion of FDA's and DOJ's application of the doctrine, *see* Jennifer Bragg, John Bentivoglio, & Andrew Collins, *Onus of Responsibility: The Changing Responsible Corporate Officer Doctrine*, 65 Food & Drug L.J. 525 (2010), https://heinonline.org/HOL/LuceneSearch?terms=Onus+of+Responsibility%3A++The+Changing+Responsible+Corporate+Officer+Doctrine&collection=all&searchtype=advanced&typea=text&tabfrom=&submit=Go&all=true.

[14] Sam D. Fine, *The Philosophy of Enforcement*, 31 Food Drug Cosmetic L.J. 324 (1976) ("Fine"), https://heinonline.org/HOL/LuceneSearch?terms=The+Philosophy+of+Enforcement&collection=all&searchtype=advanced&typea=text&tabfrom=&submit=Go&all=true.

[15] *Id.* at 325.

enforcement, in addition to its retributive effect. He identified five "interrelating factors" that FDA considers in deciding whether to recommend prosecution to DOJ:

> (1) the seriousness of the violation;
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> (2) evidence of knowledge or intent;
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> (3) the probability of effecting future compliance by the firm in question as well as others similarly situated as a result of the present action;
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> (4) the resources available to conduct investigations necessary to consummate the case successfully; and (underlying all of these)
>
> (5) the extent to which the action will benefit consumers in terms of preventing recurrences of the violation throughout the industry.[16]

Additional considerations he identified are whether the violation is "of a continuing nature," whether the violation is "so gross that any reasonable person would conclude management must have known of the conditions," whether the violation is "such that it is obvious that normal attention by management could have prevented" it, whether the violation is "life-threatening or injuries have occurred," and whether the violation involves a "deliberate attempt[] to circumvent the law."[17]

Mr. Fine also noted that, in reviewing a prospective referral for prosecution, the Office of Chief Counsel considers legal sufficiency, consistency, and "'winnability.'"[18] Speaking a year after the Supreme Court's decision in *Park*, Mr. Fine addressed whether to recommend prosecution of individuals:

> The general Agency posture is to consider that individuals acting for and within the corporation are responsible for violations of the law, rather than to consider the corporation as acting alone. Therefore, as a rule, the FDA does not recommend

[16] *Id.* at 328.

[17] *Id.* at 329-31.

[18] *Id.* at 327.

> criminal prosecution against a corporation without including charges against responsible individuals as well.[19]

The factors Mr. Fine identified generally remain in place today. In February 2011, FDA revised its Regulatory Procedures Manual ("RPM") to state factors to be considered in deciding whether to recommend to DOJ under *Park* a misdemeanor prosecution of a corporate official. In addition to the official's "position in the company and relationship to the violation" and "whether the official had the authority to correct or prevent the violation,"—elements necessary for a conviction under *Park*—FDA enforcement personnel should consider:

a. whether the violation involves actual or potential harm to the public;

b. whether the violation is obvious;

c. whether the violation reflects a pattern of illegal behavior and/or failure to heed prior warnings;

d. whether the violation is widespread;

e. whether the violation is serious;

f. the quality of the legal and factual support for the proposed prosecution; and

g. whether the proposed prosecution is a prudent use of agency resources.[20]

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[19] *Id.* at 329.

[20] RPM § 6-5-3 Special Procedures and Considerations for *Park* Doctrine Prosecutions (Aug. 2018), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/regulatory-procedures-manual. The promulgation of this set of factors in 2011 is discussed in FDA Law Blog, Anne K. Walsh, *FDA Finally Releases "Non-binding" Park Doctrine Criteria* (Feb. 7, 2011), http://www.fdalawblog.net/2011/02/fda-finally-releases-non-binding-park-doctrine-criteria/. For detailed presentations of FDA's enforcement policies and procedures with respect to advisory actions (warning letters and untitled letters), administrative actions, and judicial actions, *see*, respectively, RPM Chapters 4 (Apr. 2019), 5 (Dec. 2017), and 6 (Aug. 2018), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/regulatory-procedures-manual; Compliance Policy Guide § 101.100: FDA Considerations for Recommending Charges Under 21 U.S.C. §331(a) or (d) for Causing the Introduction of Violative Products into Interstate Commerce[;] Guidance for FDA Staff (Oct. 2016), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/manual-compliance-policy-guides/chapter-1-general.

These factors do not differ significantly from those stated by Sam Fine.

At this Conference two years ago, FDA Chief Counsel Rebecca Wood said that the agency was "exploring whether, consistent with the agency's risk-based approach and public health mission, there are additional ways that we can bring added clarity to [the] issue" of whether, and, if so, when, under *Park*, FDA should seek to impose criminal liability on "apex" corporate personnel "for serious acts or omissions done by subordinates at their firm."[21]

Of course, to Mr. Fine's criteria for *recommending* a criminal prosecution to DOJ must be added DOJ's own criteria for *actually prosecuting* corporations and corporate officers and other corporate employees. Although several of DOJ's criteria are quite similar to the criteria articulated by Mr. Fine, as to matters beyond those he addressed, DOJ's criteria have evolved over the last twenty years.

Two types of resolution of a criminal investigation that, in the mid-1990s, DOJ began applying to some business organization are a deferred prosecution agreement ("DPA") and a non-prosecution agreement ("NPA"). Generally, under a DPA or an NPA, to avoid prosecution, an organization agrees to admit wrongdoing, cooperate with DOJ, pay a financial penalty and/or otherwise remedy the harm its wrongdoing has caused, improve its corporate compliance programs, and hire an independent outside individual to monitor its compliance with the agreement. In return, DOJ agrees to file charges in court but defer further proceedings in court for a specified time period (under a DPA) or not to file charges at all (under an NPA); and, at the end of the period, if the organization has complied with all of its obligations under the

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[21] Rebecca K. Wood, Remarks at the FDLI Enforcement, Litigation, and Compliance Conference 5 (Dec. 6, 2017), https://www.fda.gov/news-events/speeches-fda-officials/remarks-fdli-enforcement-litigation-and-compliance-conference-12062017.

agreement, DOJ declines to proceed with prosecution of the organization.[22] A major reason why an organization regulated by FDA would seek such an agreement, or even a plea agreement in which the organization could negotiate as to the entity that would be subject to criminal charges as well as other terms, is the risk of exclusion from federal healthcare programs under 42 U.S.C. § 1320a-7 (2017) if the organization is convicted of any of certain types of crimes.

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[22] "[A] deferred prosecution agreement is typically predicated upon the filing of a formal charging document by the government, and the agreement is filed with the appropriate court. In the non-prosecution agreement context, formal charges are not filed and the agreement is maintained by the parties rather than being filed with a court." Craig S. Morford, Acting Deputy Attorney General, Memorandum for Heads of Department Components and United States Attorneys re Selection and Use of Monitors in Deferred Prosecution Agreements and Non-Prosecution Agreements with Corporations [and Other Business Organizations] 1, n.2 (Mar. 7, 2008), https://www.google.com/search?source=hp&ei=43vEXc64Bo285gLKw5aoCw&q=doj+morford+memorandum&oq=Morford+Memo&gs_l=psy-ab.1.2.0j0i22i30l3.1435.3376..8648...0.0..1.225.1008.10j1j1.....0....1..gws-wiz.....0i131j0i10.ief3BnU9lwc#spf=1573157868284. *See generally*, *e.g.*, Justice Manual §§ 9.28.200(B) ("In certain instances, it may be appropriate to resolve a corporate criminal case by means other than indictment. Non-prosecution and deferred prosecution agreements, for example, occupy an important middle ground between declining prosecution and obtaining the conviction of a corporation."), 9-28-1100(B) ("where the collateral consequences of a corporate conviction for innocent third parties would be significant, it may be appropriate to consider a non-prosecution or deferred prosecution agreement with conditions designed, among other things, to promote compliance with applicable law and to prevent recidivism. Declining prosecution may allow a corporate criminal to escape without consequences. Obtaining a conviction may produce a result that seriously harms innocent third parties who played no role in the criminal conduct. Under appropriate circumstances, a deferred prosecution or non-prosecution agreement can help restore the integrity of a company's operations and preserve the financial viability of a corporation that has engaged in criminal conduct, while preserving the government's ability to prosecute a recalcitrant corporation that materially breaches the agreement. Such agreements achieve other important objectives as well, like prompt restitution for victims.") (footnote omitted), https://www.justice.gov/jm/jm-9-28000-principles-federal-prosecution-business-organizations. *See also*, *e.g.*, Peter R. Reilly, *Sweetheart Deals, Deferred Prosecution, and Making a Mockery of the Criminal Justice System: U.S. Corporate DPAs Rejected on Many Fronts*, 50 Ariz. St. L.J. 1113 (2018) ("Reilly), https://scholar.google.com/scholar?hl=en&as_sdt=0%2C9&q=%22United+States+v.+Aegerion+Pharmaceuticals%22&btnG=.

In deciding whether to enter into a DPA or NPA, DOJ considers principally an organization's cooperation in DOJ's investigation, the collateral consequences of a criminal conviction of the organization and effects on innocent third parties (such as employees, communities, and possibly patients)s, and remedial measures the organization has taken or plans to take, including with respect to its own compliance programs.[23] Because, unlike plea agreements, DPAs and NPAs enable organizations to avoid criminal convictions and are not reviewed substantively by the courts, they have attracted criticism.[24]

The consideration of corporate cooperation, collateral consequences, and remedial measures are outside the scope of the criteria identified by Sam Fine. They reflect the later stage of the process at which DOJ acts. FDA needs to decide, in effect, whether suspected violative conduct warrants a referral to DOJ for a more comprehensive investigation than FDA can conduct and for potential prosecution. Once DOJ has conducted its investigation, it needs to decide whether to proceed with a prosecution (and, if so, what its scope should be), to pursue one or more non-criminal remedies, or to drop the matter altogether. Thus, these three elements--

[23] *See* GAO, Corporate Crime[:] Preliminary Observations on DOJ's Use and Oversight of Deferred Prosecution and Non-Prosecution Agreements 9 (June 25, 2009) (Statement of Eileen R. Larence, Director, Homeland Security and Justice), https://www.gao.gov/products/GAO-09-636T.

[24] *See*, *e.g.*, Reilly, *supra* 1119, n.22; Julie R. O'Sullivan, *How Prosecutors Apply the "Federal Prosecutions of Corporations" Charging Policy in the Era of Deferred Prosecutions, and What That Means for the Purposes of the Federal Criminal Sanction*, 51 Am. Crim. L. Rev. 29 (2014), https://heinonline.org/HOL/LuceneSearch?terms=How+Prosecutors+Apply+the+%22Federal+Prosecutions+of+Corporations%22+Charging+Policy+in+the+Era+of+Deferred+Prosecutions%2C+and+What+That+Means+for+the+Purposes+of+the+Federal+Criminal+Sanction&collection=all&searchtype=advanced&typea=text&tabfrom=&submit=Go&all=true.

cooperation, collateral consequences, and remedial measures—are more relevant to the decision facing DOJ than to the decision that faced FDA.

In 1999, Deputy Attorney General Eric Holder issued a memorandum on federal prosecution of corporations.[25] He emphasized the same general deterrent effect of criminal prosecution of corporations that Sam Fine had emphasized.[26] He stated eight factors to be considered in deciding whether to prosecute, which overlapped with those asserted by Mr. Fine:

> 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 . . . ;
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> 2. The pervasiveness of wrongdoing within the corporation, including the complicity in, or condonation of, the wrongdoing by corporate management . . . ;
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> 3. The corporation's history of similar conduct, including prior criminal, civil, and regulatory enforcement actions against it . . . ;
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> 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 the corporate attorney-client and work product privileges . . . ;
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> 5. The existence and adequacy of the corporation's compliance program . . . ;
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> 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 . . . ;
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> 7. Collateral consequences, including disproportionate harm to shareholders and employees not proven personally culpable . . . ; and
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> 8. The adequacy of non-criminal remedies, such as civil or regulatory enforcement

[25] Memorandum from Deputy Attorney General to All Component Heads and United States Attorneys on Bringing Criminal Charges Against Corporations (June 16, 1999), https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2010/04/11/charging-corps.PDF.

[26] *Id.* at first and second unnumbered pages.

actions . . . .[27]

Mr. Holder commented that "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.'"[28] He also noted: "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."[29] In FDCA cases, that sentiment links to the *Park* doctrine. Mr. Holder further stated: "Prosecution of a corporation is not a substitute for the prosecution of criminally culpable individuals within or without the corporation."[30] Like Mr. Fine, Mr. Holder also called for attention to "the sufficiency of the evidence, the likelihood of success at trial, the probable deterrent, rehabilitative, and other consequences of conviction, and the adequacy of non-criminal approaches."[31] Thus, as to criminal prosecutions under the FDCA, the Holder Memorandum overlapped with Sam Fine's criteria and added considerations that are addressed more appropriately after DOJ's full investigation.

Later Deputy Attorneys General have revised the Holder Memorandum in ways that have not changed the elements that overlapped with Sam Fine's elements. Rather, the revisions have

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[27] *Id.* at third unnumbered page.

[28] *Id.*

[29] *Id.* at fourth unnumbered page.

[30] *Id.* at second unnumbered page.

[31] *Id.* at third unnumbered page.

addressed the requirements for cooperation credit and other factors that DOJ considers at the end of an investigation in deciding how to proceed.

In 2003, Deputy Attorney General Larry Thompson issued a revised version entitled "Principles of Federal Prosecution of Business Organizations."[32] The most significant changes were an "increased emphasis on and scrutiny of the authenticity of a corporation's cooperation" and on "the efficacy of the corporate governance mechanisms in place within a corporation."[33] Mr. Thompson also added to the Holder Memorandum's list of eight factors a ninth factor: "the adequacy of prosecution of individuals responsible for the corporation's malfeasance."[34] He stated: "Only rarely should provable individual culpability not be pursued, even in the face of offers of corporate guilty pleas."[35] He also stated that, although his "guidelines" referred to corporations, they also applied to "consideration of the prosecution of all types of business organizations, including partnerships, sole proprietorships, government entities, and unincorporated associations."[36]

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[32] Memorandum from Larry D. Thompson, Deputy Attorney General, to Heads of Department Components and United States Attorneys on Principles of Federal Prosecution of Business Organizations (Jan. 20, 2003), https://www.americanbar.org/content/dam/aba/migrated/poladv/priorities/privilegewaiver/2003jan20_privwaiv_dojthomp.authcheckdam.pdf.

[33] *Id.* at cover page.

[34] *Id.* at 3. This factor was inserted as the eighth factor, and adequacy of non-criminal remedies was re-numbered as the ninth factor, and its text was slightly revised.

[35] *Id.* at 2

[36] *Id.* at 2, n.1.

In 2006, a further revision was made by Deputy Attorney General Paul McNulty.[37] His revision imposed on DOJ prosecutors new restrictions on seeking, as part of cooperation, waivers of the attorney-client and attorney-work-product privileges by business organizations under investigation. It also barred prosecutors from considering as a lack of cooperation a corporation's advancement of legal fees to employees, except where the advancement of fees and other significant facts show that the corporation intended to impede DOJ's investigation.[38]

In 2008, Deputy Attorney General Mark Filip made another revision, and placed DOJ's Principles of Federal Prosecution of Business Organizations in the United States Attorneys' Manual ("USAM"), thereby confirming that they are mandatory for DOJ attorneys.[39] To

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[37] Memorandum from Paul J. McNulty, Deputy Attorney General, to Heads of Department Components and United States Attorneys, on Principles of Federal Prosecution of Business Organizations (undated, but Dec. 11, 2006; released Dec. 12, 2006, https://www.justice.gov/archive/opa/pr/2006/December/06_odag_828.html), https://www.justice.gov/sites/default/files/dag/legacy/2007/07/05/mcnulty_memo.pdf. The McNulty Memorandum also superseded the Memorandum from Acting Deputy Attorney General Robert D. McCallum on Waiver of Corporate Attorney-Client and Work Product Protections (Oct. 21, 2005), discussed in Elkan Abramowitz & Barry A. Bohrer, *Waiver of Corporate Attorney-Client and Work-Product Protection*, 234 N.Y.L.J. (Nov. 1, 2005), https://www.google.com/search?source=hp&ei=_-POXbfqFu2n5wK-mar4DA&q=Memorandum+from+Acting+Deputy+Attorney+General+Robert+D.+McCallum+on+Waiver+of+Corporate+Attorney-Client+and+Work+Product+Protections&oq=Memorandum+from+Acting+Deputy+Attorney+General+Robert+D.+McCallum+on+Waiver+of+Corporate+Attorney-Client+and+Work+Product+Protections&gs_l=psy-ab.3...33917.33917..34603...0.0..0.0.0.....1....2j1..gws-wiz.&ved=0ahUKEwj35d2z4uzlAhXt01kKHb6MCs8Q4dUDCAs&uact=5#spf=1573839906544.

[38] The McNulty Memorandum also clarified that the corporate compliance program to be evaluated under the fifth factor is the corporation's pre-existing program. McNulty Mem. at 4.

[39] Memorandum from Mark Filip, Deputy Attorney General, to Heads of Department Components and United States Attorneys, re Principles of Federal Prosecution of Business Organizations (Aug. 28, 2008), https://www.justice.gov/sites/default/files/dag/legacy/2008/11/03/dag-memo-08282008.pdf. The Manual applies not only to all U.S. Attorneys' Offices, but to all components of DOJ. Deputy Attorney General Rod J. Rosenstein Keynote Address on Corporate Enforcement Policy 2 (Oct. 6, 2017) ("Rosenstein keynote"),

respond to widespread criticisms that previous DOJ policy had led federal prosecutors to exert undue pressure on target organizations to waive privileges and to mistreat employees who were subjects or targets of an investigations,[40] the revised Principles changed DOJ's approach to such aspects of prosecutors' evaluation of a subject or target organization's cooperation and remediation as waiver of privileges, payment of employees' legal fees, joint-defense agreements, and disciplining and termination of employees. Mr. Filip otherwise maintained the nine factors as set forth in the Thompson Memorandum, and they have become known as "the Filip Factors."

In a speech in 2014, Marshall L. Miller, the Principal Deputy Assistant Attorney General for the Criminal Division, strongly emphasized that cooperation credit for a business organization under investigation would depend on providing evidence relating to culpable individuals.[41] Mr. Miller's remarks did not cover criminal investigations or prosecutions under

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https://wp.nyu.edu/compliance_enforcement/2017/10/06/nyu-program-on-corporate-compliance-enforcement-keynote-address-october-6-2017/. "[U]nless the statements are incorporated into the U.S. Attorneys' Manual or issued through a formal Department memorandum, they are not necessarily policies that govern Department employees." *Id.* at 3. On September 25, 2018, DOJ announced the issuance of a new version of the USAM, to be known thereafter as the Justice Manual. Press Release, U.S. Dep't of Justice, Department of Justice Announces the Rollout of an Updated United States Attorneys' Manual (Sept. 25, 2018), https://www.justice.gov/opa/pr/department-justice-announces-rollout-updated-united-states-attorneys-manual. For a commentary on the new version of the Manual, *see*, *e.g.*, Amandeep S. Sidhu *et al.*, *The New Justice Manual: DOJ Updates US Attorney's [sic] Manual for the First Time in Decades* (Oct. 12, 2018), https://www.mwe.com/insights/new-justice-manual-doj-attorney/.

[40] *See*, *e.g.*, McGuire Woods, *McNulty Memo Out, Filip Memo In: DOJ Makes Revisions to Corporate Charging Guidelines* (Sept. 4, 2008), https://www.mcguirewoods.com/Client-Resources/Alerts/2008/9/McNultyMemoOutFilipMemoInDOJMakesRevisionstoCorporateChargingGuidelines.aspx; Mark J. Stein & Joshua A. Levine, *The Filip Memorandum: Does It Go Far Enough?* (Sept. 11, 2008), https://www.law.com/corpcounsel/almID/1202424426861/.

[41] Justice News, Principal Deputy Assistant Attorney General for the Criminal Division Marshall L. Miller, Remarks at the Global Investigation Review Program (Sept. 17, 2014), https://www.justice.gov/opa/speech/remarks-principal-deputy-assistant-attorney-general-criminal-division-marshall-l-miller. *See also* Justice News, Assistant Attorney General for the

the FDCA, which are overseen by the Consumer Protection Branch of the Civil Division rather than by the Criminal Division; but they presaged what would soon become DOJ-wide policy.

In 2015, Deputy Attorney General Sally Yates issued a memorandum entitled Individual Accountability for Corporate Wrongdoing.[42] Ms. Yates asserted that individual "accountability is important for several reasons: it deters future illegal activity, it incentivizes changes in corporate behavior, it ensures that the proper parties are held responsible for their actions, and it promotes the public's confidence in our justice system."[43] She made clear that the guidance provided by her memorandum applied "in any investigation of corporate misconduct," civil as well as criminal.[44] She identified "six key steps to strengthen [DOJ's] pursuit of individual corporate wrongdoing":

> (l) in order to qualify for any cooperation credit, corporations must provide to the Department all relevant facts relating to the individuals responsible for the misconduct; (2) criminal and civil corporate investigations should focus on individuals from the inception of the investigation; (3) criminal and civil attorneys handling corporate investigations should be in routine communication with one another; (4) absent extraordinary circumstances or approved departmental policy, the Department will not release culpable individuals from civil or criminal liability when resolving a matter with a corporation; (5) Department attorneys should not resolve matters with a corporation without a clear plan to resolve related individual cases, and should memorialize any declinations as to individuals in such cases; and (6) civil attorneys should consistently focus on individuals as well as the company

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Criminal Division Leslie R. Caldwell, Remarks at the 22nd Annual Ethics and Compliance Conference 7 (Oct. 1, 2014), https://www.justice.gov/opa/speech/remarks-assistant-attorney-general-criminal-division-leslie-r-caldwell-22nd-annual-ethics.

[42] Memorandum from Sally Quillian Yates, Deputy Attorney General, to the Assistant Attorney General, Antitrust Division, the Assistant Attorney General, Civil Division, *et al.* re Individual Accountability for Corporate Wrongdoing (Sept. 9, 2015), https://www.justice.gov/archives/dag/file/769036/download.

[43] *Id.* at 1.

[44] *Id.* at 2.

> and evaluate whether to bring suit against an individual based on considerations beyond that individual's ability to pay.[45]

This emphasis on proceeding against individuals accorded with Sam Fine's statement that, "as a rule, the FDA does not recommend criminal prosecution against a corporation without including charges against responsible individuals as well."[46] It also accorded with the Filip Factors, as originally stated by Eric Holder and as revised by his successors. What was new in the Yates Memorandum was the strengthening of the incentive for companies under investigation by DOJ to conduct their own investigations to identify all corporate wrongdoers, and to provide to DOJ the information about the culpability of individuals that was developed in those investigations. In a speech the day after issuing her Memorandum, Ms. Yates stated:

> No more partial credit for cooperation that doesn't include information about individuals. . . .

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[45] *Id.* at 2-3 (footnote omitted). Ms. Yates further stated that she had "directed that certain criminal and civil provisions in the United States Attorney's [sic] Manual, more specifically the Principles of Federal Prosecution of Business Organizations (USAM 9-28.000 *et seq.*) and the commercial litigation provisions in Title 4 (USAM 4-4.000 *et seq.*), be revised to reflect these changes." *Id.* at 3. For commentary on the six steps, *see*, *e.g.*, Justice News, Deputy Attorney General Sally Q. Yates, Remarks at the New York City Bar Association White Collar Crime Conference (May 10, 2016), https://www.justice.gov/opa/speech/deputy-attorney-general-sally-q-yates-delivers-remarks-new-york-city-bar-association; Ropes & Gray, *The Yates Memo: Have the Rules Really Changed?* (Mar. 29, 2016), https://www.bing.com/search?q=Marc%20h%2029%2C%202016%20%22The%20Yates%20Memo%3A%20Havethe%20Rules%20Really%20changed%3F%22&qs=n&form=QBRE&sp=-1&pq=marc%20h%2029%2C%202016%20%22the%20yates%20memo%3A%20havethe%20rules%20really%20changed%3F%22&sc=0-63&sk=&cvid=D876F171D563479D9B5DA5D7990C6169.

[46] Quoted on pages 6-7, *supra*. Nevertheless, prior to the Yates Memorandum, there had been criticism that FDA and DOJ were not prosecuting individuals frequently enough to deter criminal conduct. *See*, *e.g.*, Marc A. Rodwin, *Do We Need Stronger Sanctions to Ensure Legal Compliance By Pharmaceutical Firms?*, 70 Food & Drug L.J. 435 (2015), https://heinonline.org/HOL/LuceneSearch?terms=Do+We+Need+Stronger+Sanctions+to+Ensure+Legal+Compliance+By+Pharmaceutical+Firms%3F&collection=all&searchtype=advanced&typea=text&tabfrom=&submit=Go&all=true.

> The rules have just changed. Effective today, if a company wants any consideration for its cooperation, it must give up the individuals, no matter where they sit within the company. And we're not going to let corporations plead ignorance. If they don't know who is responsible, they will need to find out. If they want any cooperation credit, they will need to investigate and identify the responsible parties, then provide all non-privileged evidence implicating those individuals.[47]

In a speech in November, 2015, Ms. Yates further elaborated on this policy:

> [T]here is nothing in the new policy that requires companies to waive attorney-client privilege or in any way rolls back the protections that were built into the prior factors. The policy specifically provides that it requires only that companies turn over all relevant non-privileged information and our revisions to the USAM – which left the sections on the attorney-client privilege intact – underscore that point.
>
> But let's be clear about what exactly the attorney-client privilege means. As we all know, legal advice is privileged. Facts are not. If a law firm interviews a corporate employee during an investigation, the notes and memos generated from that interview may be protected, at least in part, by attorney-client privilege or as attorney work product. The corporation need not produce the protected material in order to receive cooperation credit and prosecutors will not request it. But to earn cooperation credit, the corporation does need to produce all relevant facts—including the facts learned through those interviews—unless identical information has already been provided.[48]

In that speech, Ms. Yates also announced three sets of changes to the USAM to implement the new policy on charging individuals and on when organizations will receive credit for cooperation: (i) revisions of the Filip Factors, (ii) a new section applying the revised Filip Factors to civil as well as criminal cases, and (iii) a revision of the USAM's section on parallel

[47] Deputy Attorney General Sally Quillian Yates, Remarks at New York University School of Law Announcing New Policy on Individual Liability in Matters of Corporate Wrongdoing 3 (Sept. 10, 2015), https://www.justice.gov/opa/speech/deputy-attorney-general-sally-quillian-yates-delivers-remarks-new-york-university-school.

[48] Justice News, Deputy Attorney General Sally Quillian Yates, Remarks at American Banking Association and American Bar Association Money Laundering Enforcement Conference 3 (Nov. 16, 2015), https://www.justice.gov/opa/speech/deputy-attorney-general-sally-quillian-yates-delivers-remarks-american-banking-0.

proceedings.[49] The revised Filip Factors "emphasize the primacy in any corporate case of holding individual wrongdoers accountable and list a variety of steps that prosecutors are expected to take to maximize the opportunity to achieve that goal."[50]

The Yates Memorandum's emphasis on proceeding against individuals and to apply pressure to business organizations to contribute to the prosecution of individuals has continued under the current administration. In April 2017, Attorney General Jeff Sessions stated: "The Department of Justice will continue to emphasize the importance of holding individuals accountable for corporate misconduct. It is not merely companies, but specific individuals, who break the law. We will work closely with our law enforcement partners, both here and abroad, to bring these persons to justice."[51] In a speech in October 2017, Deputy Attorney General Rod Rosenstein said:

> In recent years, experts have debated the question, "Can a company be too big to jail?" That question focuses on the wrong issue. We will seek appropriate corporate penalties when justified by the facts and the law. The primary question should be, "Who made the decision to set the company on a course of criminal conduct?" Our investigations will continue to focus on those people.[52]

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[49] *Id.* at 4.

[50] *Id.* at 2. The revisions are discussed in DLA Piper, *DOJ revises USAM "Filip Factors" – focus on prosecuting individuals, cooperation credit, privilege and coordination* (Nov. 19, 2015), https://www.dlapiper.com/en/us/insights/publications/2015/11/doj-revises-usam-filip-factors/.

[51] Justice News, Attorney General Jeff Sessions, Remarks at Ethics and Compliance Initiative Annual Conference (Apr. 24, 2017), https://www.justice.gov/opa/speech/attorney-general-jeff-sessions-delivers-remarks-ethics-and-compliance-initiative-annual.

[52] Rosenstein Keynote 9. *See also* Justice News, Deputy Assistant Attorney General Matthew S. Miner, Remarks at the 6th Annual Government Enforcement Institute 2 (Sept. 12, 2019), https://www.justice.gov/opa/speech/deputy-assistant-attorney-general-matthew-s-miner-delivers-remarks-6th-annual-government. *See also* Thomas L. Kirsch II & David E. Hollar, *Prosecution of Individuals in Corporate Criminal Investigations*, 66 DOJ J. of Fed. Law & Prac., no. 5, 3 (Oct. 2018), https://www.justice.gov/usao/page/file/1106771/download.

In a February 2018 speech, Ethan Davis, Deputy Assistant Attorney General for the Consumer Protection Branch discussed his Branch's enforcement priorities.[53] He referred to off-label promotion (the subject of the conference he was addressing) and, in particular, whether the promotional speech at issue was false or misleading and whether it led to harm to patients.[54] He also referred to the opioid crisis, and, in particular, to non-compliance with Risk Evaluation and Mitigation Strategies or good manufacturing practice requirements.[55] He added, in accordance with established FDA and DOJ policy: "Where appropriate, we will seek to hold accountable those individuals who are responsible for the wrongful conduct."[56]

In November 2018, Deputy Attorney General Rosenstein announced further refinements of DOJ's policies as to enforcement actions against business organizations and individuals. The changes maintained, but softened somewhat in light of practical experience, the Yates Memorandum's focus on pressuring companies for information about possibly culpable individuals. Mr. Rosenstein's summary of the changes included the following elements:

> Under our revised policy, pursuing individuals responsible for wrongdoing will be a top priority in every corporate investigation.
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> . . .

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[53] Justice News, Ethan P. Davis, Deputy Assistant Attorney General for the Consumer Protection Branch, DOJ, Remarks to the FDAnews Off-Label Communication: Top Tips for Compliance Conference (Feb. 28, 2018), https://www.justice.gov/opa/speech/deputy-assistant-attorney-general-ethan-p-davis-delivers-remarks-fdanews-label.

[54] *Id.* at 2, 4. The emphasis on false or misleading statements reflects *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012), where truthful, non-misleading off-label promotion was held protected by the First Amendment.

[55] *Id.* at 4-5.

[56] *Id.* at 6.

[A]bsent extraordinary circumstances, a corporate resolution should not protect individuals from criminal liability.

Our revised policy also makes clear that any company seeking cooperation credit in criminal cases must identify every individual who was substantially involved in or responsible for the criminal conduct.

In response to concerns raised about the inefficiency of requiring companies to identify every employee involved regardless of relative culpability, however, we now make clear that investigations should not be delayed merely to collect information about individuals whose involvement was not substantial, and who are not likely to be prosecuted.

. . .

Civil cases are different. The primary goal of affirmative civil enforcement cases is to recover money, and we have a responsibility to use the resources entrusted to us efficiently. Based on the experience of our civil lawyers over the past three years, the "all or nothing" approach to cooperation introduced a few years ago was counterproductive in civil cases. When criminal liability is not at issue, our attorneys need flexibility to accept settlements that remedy the harm and deter future violations, so they can move on to other important cases.

. . .

[W]e are revising the policy to restore some of the discretion that civil attorneys traditionally exercised – with supervisory review.

The most important aspect of our policy is that a company must identify all wrongdoing by senior officials, including members of senior management or the board of directors, if it wants to earn any credit for cooperating in a civil case.

If a corporation wants to earn maximum credit, it must identify every individual person who was substantially involved in or responsible for the misconduct.

. . .

I want to emphasize that our policy does not allow corporations to conceal wrongdoing by senior officials. To the contrary, it prohibits our attorneys from awarding any credit whatsoever to any corporation that conceals misconduct by members of senior management or the board of directors, or otherwise demonstrates a lack of good faith in its representations.[57]

[57] Justice News, Deputy Attorney General Rod J. Rosenstein, Remarks at the American Conference Institute's 35th International Conference on the Foreign Corrupt Practices Act 4-5 (Nov. 29, 2018), https://www.justice.gov/opa/speech/deputy-attorney-general-rod-j-rosenstein-

These comments leave some uncertainties, including the following: how the *Park* doctrine affects the assessment of which individuals are "substantially involved in or responsible for the criminal conduct" and what kinds of "extraordinary circumstances" would warrant protecting individuals as part of a corporate settlement. Because the facts considered in such assessments generally are not publicly disclosed, it will be impossible or very difficult for people outside DOJ to develop an understanding of how these assessments are being made by DOJ prosecutors generally.

In December 2018, James Burnham, Deputy Assistant Attorney General for the Consumer Protection Branch, summarized his Branch's approach to enforcement of the FDCA:

> So let me tell you what kind of conduct will get the Consumer Protection Branch's attention. We focus on practices that hurt people—practices like marketing a product for a potentially dangerous or untested purpose. Even if no one has been hurt, we look for activity that poses an unacceptable risk of harm if it continues, like maintaining insanitary conditions. We also target fraud, like lying to the public about what diseases a product is effective in treating.[58]

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delivers-remarks-american-conference-institute-0. A link to a redlined version of the provisions in the Justice Manual showing the changes announced by Mr. Rosenstein appears in the first paragraph of John C. Richter, Brandt Leibe, & William S. McClintock, *Insight: Individuals Remain Focus After DOJ Revisions to Yates Memo on Individual Accountability* (Jan. 24, 2019), https://news.bloomberglaw.com/white-collar-and-criminal-law/insight-individuals-remain-focus-after-doj-revisions-to-yates-memo-on-individual-accountability. *See also*, *e.g.*, *Gejaa Gobena et al.*, *DOJ embraces a more realistic position on corporate cooperation* (Jan 18, 2019), https://www.hoganlovells.com/~/media/hogan-lovells/pdf/2019/2019_01_18_doj-cooperation-policy_westlaw-article_jan-2019.pdf?la=en.

[58] Justice News, James M. Burnham, Deputy Assistant Attorney General for the Consumer Protection Branch, DOJ, Remarks to the 2018 Food and Drug Law Institute Conference 2 (Dec. 13, 2018), https://www.justice.gov/opa/speech/deputy-assistant-attorney-general-james-m-burnham-delivers-remarks-2018-food-and-drug-law.

The particular areas of current FDCA enforcement he emphasized largely overlapped with those previously identified by his predecessor, Ethan Davis.[59]

So, that is where we are. I will end by commenting on how the version of the Filip Factors that currently appears in the Justice Manual[60] has changed from the original formulation in the Holder Memorandum.

Whereas the Holder Memorandum listed eight factors, the current Justice Manual lists ten. The first three current factors—the nature and seriousness of the wrongdoing, its pervasiveness within the corporation and complicity in it or condoning of it by management, and the corporation's history of misconduct and prior enforcement actions against it—remain the same as in the Holder Memorandum. The fourth factor—timely and voluntary disclosure of wrongdoing and willingness to cooperate—has been revised to delete the reference to waiver of privileges, and to move the element of disclosure to a separate, sixth factor. The fifth factor—the corporation's compliance program has been revised to make clear that the focus is on both the compliance program at the time of the offense and the compliance program at the time of the charging decision.[61] The sixth factor—timely and voluntary disclosure--was part of the Holder

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[59] *Id.* at 3-6.

[60] Justice Manual § 9-28.300 (updated Nov. 2018), https://www.justice.gov/jm/jm-9-28000-principles-federal-prosecution-business-organizations#9-28.300.

[61] *See also*, *e.g.*, DOJ, Criminal Division, Evaluation of Corporate Compliance Programs (Updated April 2019), link available at https://www.justice.gov/opa/pr/criminal-division-announces-publication-guidance-evaluating-corporate-compliance-programs; John Nassikas, John Tan, & Lindsey Carson, Arnold & Porter Kaye Scholer LLP, *New DOJ Compliance Program Guidance*, Harvard Law School Forum on Corporate Governance and Financial Regulation (June 10, 2019), https://corpgov.law.harvard.edu/2019/06/10/new-doj-compliance-program-guidance/; OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731 (May 5, 2003)

Memorandum's fourth factor. The seventh factor—remedial actions by the corporation—is substantively the same as the Holder Memorandum's sixth factor. The eighth factor— collateral consequences of a criminal conviction—refers to additional types of collateral consequences. The ninth factor—non-criminal remedies—is a little more detailed than the Holder Memorandum's eighth factor. The tenth factor—the adequacy of prosecution of responsible individuals—is new.

I have spent many more years as a defense lawyer than as an enforcer of the FDCA, so my I have a bias as to the appropriateness of the criteria I have been discussing. With one significant exception, I think those criteria generally are appropriate. The exception relates to what is required for cooperation credit. Sally Yates expressed the requirement as to "turn over all relevant non-privileged information" and "to produce all relevant facts—including the facts learned in [privileged] interviews." Mr. Rosen stein expressed it as "identifying every individual substantially involved in or responsible for the criminal conduct." Even though cooperation credit is a special benefit, this outsourcing of parts of the traditional prosecutorial roles of investigating facts and assessing whether individuals were substantially involved in or responsible for wrongdoing places inappropriate burdens on organizations under investigation. An adequate discussion of the benefits and costs of cooperation under DOJ's policy would require another talk.

Unless you are an enforcement official or a criminal defense lawyer, may you never have to consider this subject again.