NEITHER CARROTS NOR STICKS: DOJ'S UNFULFILLED COMMITMENT TO CORPORATE HEALTH CARE COMPLIANCE

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The Department of Justice (DOJ) has for decades sought to encourage four compliant behaviors in corporate actors: maintenance of an effective preexisting compliance program, post-enforcement adoption of an effective compliance program, cooperation with a government investigation, and self-disclosure of misconduct. While DOJ's public statements reflect a claimed commitment to all four behaviors, analysis of DOJ policy and resolved cases makes clear that as DOJ has increasingly prioritized and incentivized the latter three behaviors, the first—maintenance of an effective preexisting compliance program, the only one aimed toward stopping fraud before it occurs—has been cast aside in one of DOJ's highest-profile enforcement areas.

In criminal prosecutions, both DOJ policy and the United States Sentencing Guidelines (USSG) consider preexisting compliance programs in determining whether a business entity should be prosecuted and the amount of a fine if a prosecution does occur. DOJ's Criminal Division has hired compliance experts and enthusiastically publicized internal training aimed at improving prosecutors' ability to evaluate corporate compliance programs. For the health care industry, however, the civil False Claims Act (FCA) is DOJ's primary enforcement tool, and neither that DOJ policy nor the USSG applies. Instead, DOJ guidance in civil cases has been opaque or non-existent, offering little clarity as to how, if at all, DOJ will consider preexisting compliance programs when resolving FCA cases. This is particularly surprising given that health care compliance has evolved over decades into a major industry not only with sophisticated and expensive corporate programs, but also as the subject of increasingly frequent and hands-on DOJ public statements and guidance.

This Article is the third in a series analyzing civil FCA resolutions, looking not only at DOJ's stated policies but also at actual outcomes through review of a data set of resolved cases against health care entities. Until now, those analyzing the extent of benefits for corporate compliance programs have focused on criminal cases, particularly those under the Foreign Corrupt Practices Act, and have focused primarily on the potential for a compliance defense to criminal liability. Surprisingly, the literature has to date failed to analyze this question in the context of the FCA, and thus the health care industry, despite its supremacy as a DOJ enforcement target and despite the fact that the FCA's mens rea standard is more likely to sweep in cases in which applying a compliance benefit would further DOJ's enforcement goals.

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With health care enforcement gaining increased attention in the wake of government spending relating to COVID-19 and additional visibility into DOJ settlement policy now possible due to a change in the tax code, DOJ's current failure to reward preexisting compliance programs in FCA resolutions puts DOJ's enforcement goals at risk, potentially demotivating corporate actors and adding to skepticism about DOJ's motivations and the legitimacy of the enforcement regime, as it prevents DOJ from separating the most culpable corporate actors from those less worthy of condemnation. It is also a missed opportunity, as the large quantity of health care resolutions provides the potential for industry to learn from others' compliance successes and failures and for DOJ to encourage advancements as it claims to desire to do.

INTRODUCTION

For decades, the Department of Justice (DOJ) sought to encourage four compliant behaviors in corporate actors: maintenance of an effective preexisting compliance program, post-enforcement adoption of an

effective compliance program, cooperation with a government investigation, and self-disclosure of misconduct. While DOJ's public statements reflect a claimed commitment to all four behaviors, analysis of DOJ policy and resolved cases makes clear that as DOJ has increasingly prioritized and incentivized the latter three behaviors, the first—maintenance of an effective preexisting compliance program, the only one aimed toward stopping fraud before it occurs—has seemingly been cast aside in enforcement actions against health care entities.

Through repeated public statements and formal criminal policy, DOJ has repeatedly and increasingly sought to encourage corporate entities to invest in internal compliance not only by threatening severe sanctions if wrongdoing occurs, but also by affirmatively rewarding organizations that maintain effective programs. Recognizing that entities are often better than government enforcers at stopping misconduct before it occurs[1] and that achieving just resolutions may require declining to bring cases based on respondeat superior against entities that appear to have put in best efforts to prevent wrongdoing, DOJ has clear guidance in criminal prosecutions to consider preexisting compliance programs when determining whether a business entity should be prosecuted and the amount of any potential fine.[2] The latter is reinforced by the United States Sentencing Guidelines.[3]

But criminal prosecution is not DOJ's weapon of choice in the fight against health care fraud, and the criminal guidance is inapplicable to the civil False Claims Act (FCA)—DOJ's primary mechanism for prosecuting wrongdoing by health care companies. While in civil cases DOJ guidance has been opaque or non-existent, offering little clarity as to how, if at all, DOJ considers preexisting compliance programs when resolving FCA cases, a review of DOJ policy, as well as an in-depth analysis of more than 300 FCA resolutions involving health care entities over the past three years, reveals that DOJ not only fails to reward organizations for maintaining effective compliance programs, but also fails to separate truly bad corporate actors from good corporate citizens.

It is important that this Article's findings not be misunderstood. Substantial motivation remains for organizations to invest in compliance. At the most basic economic level, good compliance makes good business sense to reduce the chances of facing government enforcement action, even if the compliance program itself does not generate specific and direct mitigation from DOJ. The reduction in fraud—and thus organizational exposure from investing in compliance—may itself be sufficient to create an economic incentive to do so. But there is more to motivation than

1. Jennifer Arlen & Reinier Kraakman, *Controlling Corporate Misconduct: An Analysis of Corporate Liability Regimes*, 72 N.Y.U. L. REV. 687, 693 (1997).

2. *See* U.S. Dep't of Just., Just. Manual § 9-28.300 (2020); *id.* § 9-28.500 (2008).

3. U.S. SENT'G GUIDELINES MANUAL § 8C2.5(f) (U.S. SENT'G COMM'N 2021).

economic incentives, and DOJ has more at stake in crafting policy than in ensuring there are sticks and carrots in place.

In *A Path to Data-Driven Health Care Enforcement* and *Health Care Fraud Means Never Having to Say You're Sorry*, analysis of newly unearthed data provided insight into DOJ's long-secret FCA settlement practices and identified threats to the credibility of DOJ's health care enforcement regime.[4] This Article, the third in the series, calls into question whether in reality DOJ's actions match its public statements and claims of sharing and rewarding the values of organizations committed to compliance.

The question of what impact a preexisting compliance program should have in a potential corporate prosecution is not new. Most notably, debate surrounding a potential statutory compliance defense to prosecution has continued, led by those who criticize the current reliance on prosecutorial discretion in criminal cases as insufficient.[5] Scholars, current and former DOJ officials, industry representatives, and white-collar practitioners have debated the need for a compliance defense in congressional hearings, law review articles, and elsewhere.[6] Yet no attention has been given to the issue in the civil context despite the fact that it represents the core of DOJ's health care enforcement regime, and DOJ policy in civil cases provides significantly less benefit than those viewed by critics of criminal policy as insufficient. While attention has focused on policy impacting a small number of Foreign Corrupt Practices Act prosecutions each year, it has eluded a policy impacting more than one hundred civil enforcement actions against health care entities, despite their recovering billions of dollars annually and, according to DOJ, being responsible for billions more in fraud avoided through deterrence.[7]

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4. Jacob T. Elberg, *A Path to Data-Driven Health Care Enforcement*, 2020 UTAH L. REV. 1169 [hereinafter Elberg, *A Path to Data-Driven Health Care Enforcement*]; Jacob T. Elberg, *Health Care Fraud Means Never Having to Say You're Sorry*, 96 WASH. L. REV. 371 (2021) [hereinafter Elberg, *Health Care Fraud Means Never Having to Say You're Sorry*].

5. *See, e.g.*, Mike Koehler, *Revisiting a Foreign Corrupt Practices Act Compliance Defense*, 2012 WIS. L. REV. 609, 611–12, 658–59 (arguing in favor of an FCPA compliance defense in order to better incentivize more robust corporate compliance, reduce improper conduct, and best advance FCPA's objective of reducing bribery).

6. *See, e.g.*, *Foreign Corrupt Practices Act: Hearing Before the Subcomm. on Crime, Terrorism, and Homeland Sec. of the H. Comm. on the Judiciary*, 112th Cong. 19–20 (2011) [hereinafter *Foreign Corrupt Practices Act Hearing*] (testimony of the Hon. Michael Mukasey, Former Att'y Gen. of the United States, Partner, Debevoise & Plimpton LLP); Ellen S. Podgor, *A New Corporate World Mandates a "Good Faith" Affirmative Defense*, 44 AM. CRIM. L. REV. 1537, 1537 (2007) ("[C]orporations with the best of motives, with the best of efforts, and with the utmost in 'due diligence' can still find themselves the subject of criminal prosecution.").

7. Press Release, U.S. Dep't of Just., Justice Department Recovers over $2.2 Billion from False Claims Act Cases in Fiscal Year 2020 (Jan. 14, 2021) [hereinafter DOJ

With DOJ's Criminal Division increasingly touting the importance of compliance programs,[8] the Civil Division for the first time offering increased transparency regarding its FCA policy,[9] and DOJ proclaiming that the FCA will be at the center of its efforts to address COVID-19-related fraud,[10] DOJ's civil policy toward compliance programs can no longer avoid attention.

Part I examines DOJ's policies for considering preexisting compliance programs in the context of criminal investigations and prosecutions, laying out the rationale for DOJ's long-held and recently increasing commitment to incentivizing organizations to invest in compliance, including by committing to analyze and reward preexisting compliance programs. Part II provides an overview of the civil FCA, including the impact of respondeat superior and the FCA's lenient mens rea standard. It explains the FCA's critical role in health care enforcement, providing the necessary background for Part III's analysis of the role of preexisting compliance programs in the FCA system. Part III looks both at DOJ guidance regarding the role of compliance programs in FCA resolutions and at an empirical analysis using a data set of resolved cases against health care entities. Both lead to the conclusion that DOJ fails to reward preexisting compliance programs or to publicly separate which corporate defendants are truly bad actors from those that are good corporate citizens despite some level of wrongdoing for which the entity is responsible under respondeat superior.

Part IV examines the consequences of DOJ's failure to identify whether FCA defendants had in place effective preexisting compliance programs and to issue rewards or punishments based on that analysis. Beyond a missed opportunity to economically incentivize desired behavior, DOJ's practice in this area threatens perceptions of the fairness

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Jan. 14, 2021, Press Release], https://www.justice.gov/opa/pr/justice-department-recovers-over-22-billion-false-claims-act-cases-fiscal-year-2020 [https://perma.cc/P24M-DR4Z].

8. *See, e.g.*, Matthew S. Miner, Deputy Assistant Att'y Gen., U.S. Dep't of Just., Remarks at the 29th Annual National Institute on Health Care Fraud, (May 9, 2019), https://www.justice.gov/opa/speech/deputy-assistant-attorney-general-matthew-s-miner-gives-remarks-29th-annual-national [https://perma.cc/XXN6-YEXK] ("[I]t only makes sense for us to incentivize, and where possible, reward companies that invest in compliance. After all, companies with well-designed and fully-resourced compliance programs are able to detect misconduct early on and, in some cases, prevent the misconduct altogether.").

9. Press Release, U.S. Dep't of Just., Department of Justice Issues Guidance on False Claims Act Matters and Updates Justice Manual (May 7, 2019) [hereinafter 2019 FCA Guidance], https://www.justice.gov/opa/pr/department-justice-issues-guidance-false-claims-act-matters-and-updates-justice-manual [https://perma.cc/4VW9-TRYL]; U.S. Dep't of Just., Just. Manual § 4-4.112 (2019).

10. Michael D. Granston, Deputy Assistant Att'y Gen., U.S. Dep't of Just., Remarks at the ABA Civil False Claims Act and Qui Tam Enforcement Institute (Dec. 2, 2020), https://www.justice.gov/opa/speech/remarks-deputy-assistant-attorney-general-michael-d-granston-aba-civil-false-claims-act [https://perma.cc/TZY8-R3AH].

and legitimacy of the FCA enforcement regime (essentially, DOJ's health care enforcement regime) and fails to capitalize on individuals' desire to do the right thing apart from any potential profit motive.

Part V details challenges to DOJ efforts to change its policies and practices in this area and, with those challenges in mind, examines potential solutions. This Article concludes that DOJ would be best served by employing a team of compliance experts to analyze requests for mitigation based on an organization's compliance program—a structure that borrows from the Civil Division's practice of considering ability-to-pay settlements and the Criminal Division's recent practice of hiring compliance experts to review corporate compliance programs.

I. DOJ POLICY REGARDING THE IMPACT OF PREEXISTING COMPLIANCE PROGRAMS IN CRIMINAL CASES

DOJ has made clear that it is "in the business of promoting compliance programs."[11] This Part examines DOJ's statements and policies regarding the impact of preexisting compliance programs when considering criminal misconduct, as well as the rationales behind those statements and policies. It details decades of DOJ policy in favor of evaluating and considering compliance programs and the extent to which those policies track theories of corporate punishment and incentivization. It then examines DOJ's system of substantial consideration and benefits based on compliance programs and concludes by describing criticism from scholars, policymakers, and practitioners who argue that the benefits should go further by including a statutory compliance defense to prosecution.

The question of whether, and how much, to take an organizational defendant's compliance program into account when deciding how to resolve a case against the organization springs from two sources: one retribution-based and the other rooted in deterrence.

From a retributive perspective, the state of an organization's compliance program at the time of the misconduct is important because of the sweeping power of respondeat superior and the limitations of compliance programs. As a pure matter of law, under respondeat superior, an organization is liable for the misconduct of its employee if the employee was acting within their apparent authority and acted with an intention of aiding the corporation—even if the actor's primary intention was directly contrary to the organization's policies—with no requirement that the organization in any way encouraged, condoned, or rewarded the

11. Claire McCusker Murray, Principal Deputy Assoc. Att'y Gen., U.S. Dep't of Just., Remarks at the Compliance Week Annual Conference (May 20, 2019), https://www.justice.gov/opa/speech/remarks-principal-deputy-associate-attorney-general-claire-mccusker-murray-compliance [https://perma.cc/87ZH-UF69].

misconduct.[12] At the same time, while they are believed to significantly decrease misconduct,[13] even compliance programs that are "effective"[14] are not expected to prevent all wrongdoing.[15] Organizations, DOJ, and the U.S. Sentencing Commission understand that corporations with compliance programs that satisfy rigorous standards will never be perfect.[16]

In combination, the sweeping power of respondeat superior and the limitations of compliance programs mean that, under the law, a sincere and profound commitment to compliance will not universally protect an organization. Put simply, even a good corporate citizen that does everything it can to prevent misconduct will be liable if a rogue employee acts to enrich the corporation in order to enrich themself (for example, by defrauding the government in order to increase sales and increase their personal commission). Thus, without a mechanism for a company's preexisting compliance program to derail or diminish the extent of government enforcement, enforcement without retributive justification will inevitably occur.[17]

From a deterrence perspective, compliance programs effectively supplement the government's enforcement efforts because they themselves are intended to deter wrongdoing. Given superior access and

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12. *See* V.S. Khanna, *Corporate Criminal Liability: What Purpose Does It Serve?*, 109 HARV. L. REV. 1477, 1489–90 (1996); *United States v. Basic Constr. Co.*, 711 F.2d 570, 573 (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.").

13. Rod J. Rosenstein, Deputy Att'y Gen., U.S. Dep't of Just., Keynote Address at NYU Program on Corporate Compliance & Enforcement (Oct. 6, 2017), https://wp.nyu.edu/compliance_enforcement/2017/10/06/nyu-program-on-corporate-compliance-enforcement-keynote-address-october-6-2017/ [https://perma.cc/QYT4-T7FU] ("Compliance programs promote [DOJ's] primary goal, which is to deter wrongdoing.").

14. "Effective" is the word used in the U.S. Sentencing Guidelines, as well as by DOJ in the Justice Manual and in guidance issued in 2020 regarding how the Criminal Division will evaluate compliance programs. U.S. SENT'G GUIDELINES MANUAL § 8C2.5(f)(1) (U.S. SENT'G COMM'N 2021); U.S. Dep't of Just., Just. Manual § 9-28.800 (2019); CRIM. DIV., U.S. DEP'T OF JUST., EVALUATION OF CORPORATE COMPLIANCE PROGRAMS 1, 14 (2020), https://www.justice.gov/criminal-fraud/page/file/937501/download [https://perma.cc/5Q2N-QMLN].

15. DOJ has acknowledged this reality, including in the Justice Manual that "the Department recognizes that no compliance program can ever prevent all criminal activity by a corporation's employees." U.S. Dep't of Just., Just. Manual § 9-28.800 (2019).

16. *See id.*; U.S. SENT'G GUIDELINES MANUAL § 8C2.5(f)(1) (providing for a reduced penalty at sentencing for an organizational defendant based on its "effective" compliance program at the time of the misconduct, thus implicitly acknowledging that programs can be effective despite misconduct having taken place).

17. Whether that mechanism should come through prosecutorial discretion or a statutory defense has been the subject of substantial debate. *See infra* Section I.C.

insider knowledge, "firms often will be better than government officials at monitoring or investigating agent misconduct."[18] Firms' decided advantages lead DOJ to take action to promote compliance programs beyond simply encouraging companies to adopt them to stop misconduct and thus avoid potentially substantial penalties from government enforcement.[19] Because preventing misconduct from occurring is DOJ's primary goal, DOJ has recognized that deterrence can be increased not only by making organizations fear sanctions, but also by encouraging organizations to police themselves through rigorous compliance programs.[20] With that in mind, DOJ has long taken the position that organizations should be explicitly and directly incentivized to invest in compliance in order to stop misconduct before it occurs.[21]

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18. Arlen & Kraakman, *supra* note 1, at 693.

19. *See id.* at 692–93. From an organization's perspective, the threat of government enforcement with substantial penalties creates a powerful economic incentive to adopt an effective compliance program even without DOJ providing additional benefit for adoption of a compliance program or additional penalty for lack of a program. Even if the economic incentive for adoption of a compliance program is only indirect—spending money on a compliance program will reduce misconduct and thus reduce potential enforcement sanctions—it may still be powerful. But DOJ has made clear its desire to go further and add carrots to its pile of sticks. *Id.*

20. *See* Jeff Sessions, Att'y Gen., U.S. Dep't of Just., 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 [https://perma.cc/89N6-RUKK] ("[Misconduct] is what your work seeks to prevent, by building strong cultures of compliance within your companies to deter illegal and unethical conduct. We applaud those efforts. Our department would much rather have people and companies obey the law and do the right thing, so we don't have to see them in court.").

21. Jennifer Arlen and Reinier Kraakman have offered analysis in support of an additional need for DOJ to reward effective compliance programs. *See* Arlen & Kraakman, *supra* note 1, at 745–51. In their work examining various corporate liability regimes, Arlen and Kraakman note that primary enforcement mechanisms through which entity liability deters misconduct include "lead[ing] companies to institute 'preventive measures' that deter" and "induc[ing] the firm to undertake a variety of actions that increase the probability that wayward agents will be sanctioned, which we term 'policing measures.'" *Id.* at 692–93. Both are part of an effective compliance program. Arlen and Kraakman argue persuasively, however, that from an incentive perspective they are distinct. In a system (such as respondeat superior) under which an organization is held responsible for the wrongdoing of its employees even if the organization has not violated a duty, the organization will be incentivized by fear of sanctions to appropriately invest in preventative measures. But the organization may be discouraged from investing in policing measures, as discovering misconduct may lead the organization to be sanctioned for wrongdoing the government may otherwise have never discovered. *See id.* at 707–08; Jennifer Arlen, *The Potentially Perverse Effects of Corporate Criminal Liability*, 23 J. LEGAL STUD. 833, 842–43 (1994).

Arlen and Kraakman thus call for a system that, in general terms, takes the same approach as DOJ and the U.S. Sentencing Guidelines—rewarding organizations for instituting effective compliance programs by reducing the sanction against them. *See* Arlen &

DOJ has both acknowledged the potentially overinclusive nature of respondeat superior and pointed to the deterrent benefits of rewarding compliance both in public statements and official policy, with both rationales contributing to DOJ's consistent messaging surrounding the importance of rewarding organizations that maintain effective compliance programs—even in cases in which misconduct occurs despite those efforts.[22]

A. Principles of Federal Prosecution of Business Organizations

DOJ's Principles of Federal Prosecution of Business Organizations describes the factors prosecutors must consider when investigating and deciding whether to charge, as well as when negotiating potential resolutions.[23] The Corporate Prosecution Principles has been contained in the Justice Manual (JM) since 2008.[24] It is thus publicly available and regularly mark the framework for defense attorneys' presentations to prosecutors and for internal memoranda by DOJ prosecutors seeking approval to charge or resolve cases.[25]

The Corporate Prosecution Principles section of the JM notes that "the prosecutor must 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."[26] But the section also notes that there are additional factors present when considering business organizations.[27] The section goes on to list eleven, including the following: "the adequacy and effectiveness of the

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Kraakman, *supra* note 1, at 745. For a detailed discussion of the DOJ and U.S. Sentencing Guidelines, see *infra* Sections I.A–B.

22. *See* U.S. Dep't of Just., Just. Manual § 9-28.500 (2008); *see also* Sessions, *supra* note 20 ("[Misconduct] is what your work seeks to prevent, by building strong cultures of compliance within your companies to deter illegal and unethical conduct. We applaud those efforts. Our department would much rather have people and companies obey the law and do the right thing, so we don't have to see them in court.").

23. *See* U.S. Dep't of Just., Just. Manual § 9-28.300 (2020). This Article refers to the subsections within U.S. Dep't of Just., Just. Manual § 9-28.000 as the "Corporate Prosecution Principles." For a more fulsome discussion of the history and evolution of the Corporate Prosecution Principles, see Elberg, *A Path to Data-Driven Health Care Enforcement*, *supra* note 4, at 1172–75.

24. *Justice Manual*, U.S. DEP'T OF JUST., https://www.justice.gov/jm/justice-manual [https://perma.cc/9HFJ-VX32] (last visited Mar. 17, 2022) ("The JM was previously known as the United States Attorneys' Manual (USAM). It was comprehensively revised and renamed in 2018."). For simplicity, this Article refers to the document as the "JM" even when referring to time periods during which the document was known as the "USAM."

25. *See* U.S. Dep't of Just., Just. Manual § 9-28.200 (2020).

26. *Id.* § 9-28.300.

27. *Id.* § 9-28.300(A).

corporation's compliance program at the time of the offense, as well as at the time of the charging decision."[28]

Noting that failure to do so would lead to unjust results given respondeat superior, DOJ officially requires criminal prosecutors to consider the existence and effectiveness of a putative corporate defendant's preexisting compliance program when determining whether and in what form to prosecute.[29] The policy also instructs prosecutors that "it may not be appropriate to impose liability upon a corporation, particularly one with a robust compliance program in place, under a strict *respondeat superior* theory for the single isolated act of a rogue employee."[30]

The JM goes on to provide further details about the compliance program factor, making clear that the existence of an effective preexisting compliance program does not automatically create a defense to criminal liability but that it "may result in a decision to charge only the corporation's employees and agents or to mitigate charges or sanctions against the corporation."[31]

DOJ officials have emphasized the significance of this factor repeatedly in public statements over more than two decades. In 1999 then deputy attorney general Eric Holder described it as "long-standing policy" of DOJ to "look favorably on providers that implement effective compliance programs . . . ."[32] A decade later, Acting Deputy Attorney General Gary Grindler described pre-existing compliance programs as "one of the most important factors that we consider under the [Corporate

28. *Id.* § 9-28.300(A)(5). The DOJ amended the Corporate Prosecution Principles in 2019 to make explicit that prosecutors could consider the adequacy and effectiveness of the corporation's compliance program not only at the time of the offense, but also at the time of the charging decision. Prior to this amendment, the factor read, "[T]he existence and effectiveness of the corporation's pre-existing compliance program." *Id.* (2015). Why such an amendment was necessary is unclear, as the earlier version already instructed prosecutors to consider "*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." *Id.* § 9-28.300(A)(7) (emphasis added). That language remains part of the Corporate Prosecution Principles. Regardless, the requirement that DOJ consider a corporation's preexisting compliance program has remained in place since the implementation of the Corporate Prosecution Principles. *Id.* (2020).

29. *Id.* § 9-28.300 (2020).

30. *Id.* § 9-28.500 (2008).

31. *Id*. § 9-28.800(B) (2019).

32. *See* Eric H. Holder, Jr., Deputy Att'y Gen., U.S. Dep't of Just., Remarks to the American Hospital Association (Feb. 1, 1999), https://www.justice.gov/archive/dag/speeches/1999/holderahaspeech.htm [https://perma.cc/FBJ7-AL76].

Prosecution Principles]."[33] After nearly another decade, Deputy Assistant Attorney General Matthew Miner echoed the sentiment, stating that "it only makes sense for us to incentivize and, where possible, reward companies that invest in compliance. After all, companies with well-designed and fully-resourced compliance programs are able to detect misconduct early on and, in some cases, prevent the misconduct altogether."[34]

Notably, DOJ has made clear its intention to use both the carrot of credit and the stick of harsher punishment to reward companies that invest in compliance programs and punish those that do not. As recently as October 2021, Deputy Attorney General Lisa Monaco assured an audience of white-collar defense counsel of the following:

> [C]ompanies serve their shareholders when they proactively put in place compliance functions and spend resources anticipating problems. They do so both by avoiding regulatory actions in the first place and receiving credit from the government. Conversely, we will ensure the absence of such programs inevitably proves a costly omission for companies who end up the focus of department investigations.[35]

Particularly over the past decade, DOJ has stepped up its focus on compliance programs, both in terms of articulating expectations to industry and seeking to improve DOJ's ability to distinguish between more and less impressive programs. In 2015, DOJ's Criminal Fraud Section retained Hui Chen as a full-time compliance expert.[36] In announcing her hiring, DOJ noted,

> Among her duties as a consulting expert, Chen will provide expert guidance to Fraud Section prosecutors as they consider the enumerated factors in the [Corporate Prosecution

33. Gary G. Grindler, Acting Deputy Att'y Gen., U.S. Dep't of Just., Remarks at the 2010 Compliance Week Conference (May 25, 2010), https://www.justice.gov/opa/speech/acting-deputy-attorney-general-gary-g-grindler-speaks-2010-compliance-week-conference [https://perma.cc/BF47-QUEX].

34. Miner, *supra* note 8.

35. Lisa O. Monaco, Deputy Att'y Gen., U.S. Dep't of Just., Remarks at the ABA's 36th National Institute on White Collar Crime (Oct. 28, 2021), https://www.justice.gov/opa/speech/deputy-attorney-general-lisa-o-monaco-gives-keynote-address-abas-36th-national-institute [https://perma.cc/YV6X-YN27].

36. *See* Laura Jarrett, *Justice Department Anti-Fraud Expert Resigns, Disturbed by Trump's 'Stunning' Conduct*, CNN (July 4, 2017, 7:38 PM), https://www.cnn.com/2017/07/04/politics/justice-hui-chen-resignation/index.html [https://perma.cc/MW66-8KHR] ("Chen served as the [Justice Department's] then newly created 'compliance counsel' in the fraud section on a contractor basis since November 2015.").

> Principles], including the existence and effectiveness of any compliance program that a company had in place at the time of the conduct giving rise to the prospect of criminal charges . . . .[37]

In February 2017, with Chen's guidance, DOJ's Criminal Division published guidance as to what DOJ looks for in evaluating corporate compliance programs; the Criminal Division published an updated version of that guidance in April 2019 and then again in June 2020.[38] DOJ made clear that it was not issuing the guidance solely to aid corporations in their efforts at crafting compliance programs, but to provide transparency into DOJ's efforts to judge the merits of compliance programs.[39]

In October 2018, DOJ announced a program to create "a workforce better steeped in compliance issues across the board," through a "combination of diverse hiring and the development of targeted training programs,"[40] in lieu of hiring a replacement for Chen, who resigned in mid-2017.[41] In February 2021, however, DOJ hired a new compliance specialist within the Criminal Fraud Section's Strategy, Policy, and Training Unit.[42]

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37. Press Release, U.S. Dep't of Just., New Compliance Counsel Expert Retained by the DOJ Fraud Section (Nov. 3, 2015), https://www.justice.gov/criminal-fraud/file/790236/download [https://perma.cc/977C-XSG2].

38. *See* CRIM. DIV., U.S. DEP'T OF JUST., *supra* note 14, at 1–17.

39. Shortly after issuing the 2019 updates to the Evaluation of Corporate Compliance Programs document, Deputy Assistant Attorney General Matthew Miner noted, "Given the important role of assessing compliance programs in connection with corporate enforcement, we are also strengthening our tools and collective ability to assess the adequacy of the compliance programs." Miner, *supra* note 8.

40. Brian A. Benczkowski, Assistant Att'y Gen., U.S. Dep't of Just., Remarks at NYU School of Law Program on Corporate Compliance and Enforcement Conference on Achieving Effective Compliance (Oct. 12, 2018), https://www.justice.gov/opa/speech/assistant-attorney-general-brian-benczkowski-delivers-remarks-nyu-school-law-program [https://perma.cc/C6J7-T58F].

41. Following her resignation, Chen issued a statement referencing the administration of President Donald Trump: "Trying to hold companies to standards that our current administration is not living up to was creating a cognitive dissonance that I could not overcome." Joe Mont, *Why Hui Chen Left the Justice Department*, COMPLIANCE WK. (July 5, 2017, 7:45 AM), https://www.complianceweek.com/why-hui-chen-left-the-justice-department/9501.article [https://perma.cc/M9ST-T49F].

42. *See* Dylan Tokar, *Justice Department's Foreign Bribery Unit Adds Prosecutors, Compliance Expertise*, WALL ST. J. (Mar. 8, 2021, 5:30 AM), https://www.wsj.com/articles/justice-departments-foreign-bribery-unit-adds-prosecutors-compliance-expertise-11615199402 [https://perma.cc/F634-6UXA] (noting the hiring of Lauren Kootman, "along with the other attorneys in the strategy unit, appears to fill a hole in the fraud section left by the departure of Hui Chen").

B. United States Sentencing Guidelines

Where a criminal prosecution does take place, the U.S. Sentencing Guidelines are even more explicit than the Corporate Prosecution Principles in rewarding a business organization's preexisting effective compliance program. While the Corporate Prosecution Principles are factors for prosecutors to consider, the U.S. Sentencing Guidelines for Organizations, issued in 1991, provide for a concrete and substantially reduced fine for having an effective preexisting compliance and ethics program.[43]

This mitigation comes as part of the U.S. Sentencing Guidelines' effort at individualized sentencing for entities—an effort to "consider what made one entity more culpable than another beyond just considering the nature of the crime charged."[44] Rachel Barkow has attributed this desire on the part of the Sentencing Commission to a belief that respondeat superior made it necessary "to take extra care to consider the company's relationship to" the crimes committed by its agents, leading to a Sentencing Guideline framework she views as more focused on culpability when sentencing entities than sentencing individuals.[45] This effort in the context of organizational sentencing translates into calculation of a Culpability Score for the entity being sentenced.[46]

The U.S. Sentencing Guidelines' "Determining the Fine" section uses a series of factors to arrive at the Culpability Score, which then translates to a minimum (as low as 0.05) and maximum (as high as 4.0) fine multiplier, each of which is multiplied by the base fine (frequently the gain to the organization from the offense or the loss from the offense caused by the organization) to create the minimum and maximum of the guideline fine range.[47]

The U.S. Sentencing Guidelines include preexisting compliance programs as a stand-alone basis for a deduction to the Culpability Score:

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43. U.S. Dep't of Just., Just. Manual § 9-28.200 (2020) (noting that prosecutors have "substantial latitude in determining when, whom, how, and even whether to prosecute for violations of federal criminal law"); U.S. SENT'G GUIDELINES MANUAL § 8C2.5(f) (U.S. SENT'G COMM'N 2021).

44. Rachel E. Barkow, *Using the Corporate Prosecution and Sentencing Model for Individuals: The Case for a Unified Federal Approach*, 83 LAW & CONTEMP. PROBS. 159, 166–67 (2020).

45. *Id.* at 168–69.

46. *See* U.S. SENT'G GUIDELINES MANUAL § 8C2.5(b) (U.S. SENT'G COMM'N 2021).

47. *Id.* § 8C2.4–2.7.

> (f) Effective Compliance and Ethics Program
> (1) If the offense occurred even though the organization had in place at the time of the offense an effective compliance and ethics program . . . subtract **3** points.[48]

A deduction based on having an effective preexisting compliance program can easily reduce the amount of a fine by tens or even hundreds of millions of dollars in a criminal sentencing. Based on the Minimum and Maximum Multipliers listed in the U.S. Sentencing Guidelines Manual, a three-point deduction would reduce the minimum multiplier by 0.6 and the maximum multiplier by 1.2.[49] Thus, for example, if the defendant organization was determined to have gained $100 million from the offense, the guideline fine range would be reduced by $60 to $120 million were the organization determined to have had an effective compliance and ethics program in place at the time of the offense.

The presence or absence of an effective compliance program has been called "a centerpiece of the Organizational Guidelines," and the framework is credited with incentivizing organizations to invest in compliance programs to the point that it led to the creation of the compliance industry.[50]

Barkow suggests that the U.S. Sentencing Guidelines' focus on culpability in corporate cases may be attributable to a greater focus on deterrence as compared to a greater focus on retribution when sentencing individuals, drawing a direct line for both the Sentencing Commission and DOJ between deterrence theory and rewarding effective compliance programs.[51]

Notably, the U.S. Sentencing Guidelines fine analysis is used not only by judges when determining a corporate sentence after a conviction, but also routinely by DOJ when resolving a case via plea, Deferred Prosecution Agreement (DPA), or Non-Prosecution Agreement (NPA), regardless of whether DOJ seeks court approval of the resolution.[52]

C. Calls for a Compliance Defense

DOJ prosecutors must consider the existence of a compliance program when deciding whether to prosecute a business organization and must consider the concrete benefits for having a compliance program

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48. *Id.* § 8C2.5(f)(1).

49. *Id.* § 8C2.6.

50. Barkow, *supra* note 44, at 168 (citing Diana E. Murphy, *The Federal Sentencing Guidelines for Organizations: A Decade of Promoting Compliance and Ethics*, 87 IOWA L. REV. 697, 710–11 (2002)).

51. *Id.* at 171–72.

52. *See, e.g.*, Deferred Prosecution Agreement at 8–9, *United States v. TechnipFMC plc*, No. 19-CR-278 (E.D.N.Y. June 25, 2019).

when determining a corporate fine.[53] Still, scholars, policymakers, and practitioners, including numerous former DOJ officials, have advocated for an increased benefit—a compliance defense under which an entity would no longer be legally liable for the wrongdoing of its employees if the entity could establish that it had an effective compliance program in place at the time of the misconduct.[54]

Part of this advocacy rests on the reality that while DOJ recognizes that some misconduct by corporate employees may not be appropriate for corporate prosecution because the organization did its best to discourage and prevent misconduct, under the current system the decision not to prosecute is left to what has been described as "unlimited prosecutorial discretion."[55] The Corporate Prosecution Principles, while enumerating the various factors prosecutors consider, also make clear that "[p]rosecutors have substantial latitude in determining when, whom, how, and even whether to prosecute for violations of federal criminal law."[56] The Principles also make clear that they

> provide only Department of Justice guidance. They are not intended to, do not, and may not be relied upon to create any rights, substantive or procedural, enforceable at law by any party in any matter civil or criminal. Nor are any limitations hereby placed on otherwise lawful litigative prerogatives of the Department of Justice.[57]

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53. *See* U.S. Dep't of Just., Just. Manual § 9-28.300 (2020); *id.* § 92-28.800 (2019); U.S. SENT'G GUIDELINES MANUAL § 8C2.5(f) (U.S. SENT'G COMM'N 2021).

54. *See, e.g.*, Podgor, *supra* note 6, at 1537–38 ("[C]orporations with the best of motives, with the best of efforts, and with the utmost in 'due diligence' can still find themselves the subject of criminal prosecution."); Koehler, *supra* note 5, at 611–12 (arguing in favor of an FCPA compliance defense to better "incentivize more robust corporate compliance, reduce improper conduct, and best advance the FCPA's objective of reducing bribery"); Jon Jordan, *The Adequate Procedures Defense Under the UK Bribery Act: A British Idea for the Foreign Corrupt Practices Act*, 17 STAN. J.L. BUS. & FIN. 25, 28 (2011) (analyzing, with prior work experience as a senior investigations counsel with the U.S. Securities and Exchange Commission's Foreign Corrupt Practices Act Unit, the UK Bribery Act and proposing a similar defense under the FCPA); F. Joseph Warin, Daniel P. Chung & Melissa L. Farrar, *Renewing the Call for a Compliance Defense to the Foreign Corrupt Practices Act*, CORP. DISPUTES, July–Sept. 2014, at 2, 3, 6, *reproduced online by* CORP. DISPUTES, https://www.gibsondunn.com/wp-content/uploads/documents/publications/WarinChungFarrar-RenewingCallForComplianceDefence.pdf [https://perma.cc/RG3R-EKKC]; ANDREW WEISSMANN & ALIXANDRA E. SMITH, RESTORING BALANCE: PROPOSED AMENDMENTS TO THE FOREIGN CORRUPT PRACTICES ACT 11–14 (2010).

55. *Foreign Corrupt Practices Act Hearing*, *supra* note 6, at 23–24 (testimony of the Hon. Michael Mukasey, Former Att'y Gen. of the United States, Partner, Debevoise & Plimpton LLP).

56. U.S. Dep't of Just., Just. Manual § 9-28.200 (2020).

57. *Id.* § 9-28.1600 (2015).

Put simply, while a prosecutor would run afoul of DOJ guidance if they failed to consider an entity's compliance program when making a charging decision, a corporate defendant has no recourse if DOJ takes the position that prosecution remains appropriate even if the entity's compliance program was perfect and the misconduct was undertaken by rogue employees.[58]

Against that backdrop, many have argued that organizational defendants should not be reliant on DOJ exercising discretion and that there should instead be a statutory compliance defense. Much of the advocacy in this area has centered on the Foreign Corrupt Practices Act.[59] Former attorney general Michael Mukasey argued for a statutory compliance defense before Congress, which he described as "an affirmative defense that would allow companies to rebut criminal liability for violations if the people responsible evaded compliance measures that were otherwise reasonably designed to identify and prevent such violations."[60]

Others, including DOJ officials, have argued against the creation of a compliance defense.[61] Notably, in arguing that a statutory compliance

58. Given respondeat superior, it is quite possible that evidence of an organizational defendant's effective compliance program would be excluded from trial as irrelevant, and in any event it would not, under current law, provide a basis for acquittal. *See id.* § 9-28.500 (2008).

59. *See, e.g.*, *Foreign Corrupt Practices Act Hearing*, *supra* note 6, at 19–20 (testimony of the Hon. Michael Mukasey, Former Att'y Gen. of the United States, Partner, Debevoise & Plimpton LLP); *see also id.* at 74 (testimony of Shana-Tara Regon, Director, White Collar Crime Pol'y, Nat'l Ass'n of Crim. Def. Laws.) ("[F]rom NACDL's point of view, we would like to foster fairness in the criminal justice system, and having a prosecutor also sort of be judge and jury and being the sole person in that calculation making the determination of how valuable the compliance defense is isn't quite fair.").

60. *Id.* at 20. Mukasey sought to draw a parallel with Title 7 of the Civil Rights Act of 1964, noting the affirmative defense available in hostile work environment cases if a company has, among other things, an antidiscrimination policy and provides a way for employees who have been subject to workplace discrimination to receive redress. *See id.* at 19–20. More recently, advocates for a compliance defense have pointed to the United Kingdom's adoption of it. *See* Bribery Act 2010, c. 23, § 7(2) (UK). The UK passed its compliance defense act in 2010—prior to the 2011 congressional hearing at which former attorney general Michael Mukasey and others testified—but it did not take effect until after the congressional hearing. The UK Bribery Act provides for a compliance defense if a defendant organization is able to satisfy criteria set out by the United Kingdom's Ministry of Justice. *See* MINISTRY OF JUST., THE BRIBERY ACT 2010: GUIDANCE 20–31 (2011), http://www.justice.gov.uk/downloads/legislation/bribery-act-2010-guidance.pdf [https://perma.cc/KKR8-QMBG] (discussing six principles to be considered in analyzing a compliance program).

61. *See, e.g.*, *Foreign Corrupt Practices Act Hearing*, *supra* note 6, at 58–59 (testimony of Greg Andres, Acting Deputy Assistant Att'y Gen., Crim. Div., U.S. Dep't of Just.) (arguing against creation of a compliance defense and noting concern that it "could lead to paper compliance; that is, a company having a compliance program on paper that is not rigorous and doesn't help to prevent bribery"); DAVID KENNEDY & DAN DANIELSEN, BUSTING BRIBERY: SUSTAINING THE GLOBAL MOMENTUM OF THE FOREIGN CORRUPT

defense is not necessary or advisable, DOJ officials have stressed that DOJ does take into account and reward compliance programs. Deputy Assistant Attorney General Greg Andres testified before Congress, "[W]e already take into consideration a company's compliance program. We take it into consideration and review it, and it is a serious consideration."[62]

Scholars, current and former DOJ officials, practitioners, and Congress all have spiritedly debated the appropriateness of a compliance defense in criminal cases. This discussion has focused on the FCPA, where there are at most ten cases per year, and with the operating assumption that even without such a defense, DOJ considers and frequently rewards corporate compliance programs.[63] Yet, to date, there has been no meaningful discussion of the need for even a compliance *benefit*—never mind a defense—in the more than one hundred FCA cases resolved each year against health care organizations.

II. THE FALSE CLAIMS ACT

As debate remains over whether there is a need for a complete compliance defense in criminal cases, there is no dispute that a benefit for maintaining an effective preexisting compliance program is called for under DOJ criminal policy. Notably, however, that DOJ policy applies only to criminal cases, a fact of particular significance in the area of health care fraud, where DOJ's enforcement efforts originate almost entirely from civil FCA cases. While, in criminal, cases questions remain about the extent of the compliance benefit and the form the benefit should take, there is at least clarity that DOJ intends to reward compliance programs. In civil cases, there is no such clarity: an examination of DOJ's stated policy, as well as an analysis of hundreds of civil FCA resolutions over the past three years, sparks doubt as to whether DOJ assigns any preexisting compliance program benefit at all in civil cases.

This Part provides an overview of the civil FCA and its critical role in health care enforcement, providing the necessary background for Part

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PRACTICES ACT 6 (2011) (arguing that companies would be able to hide behind "'fig leaf' compliance"); Howard Sklar, *Against an FCPA Compliance Defense*, FORBES (Oct. 18, 2011, 4:32 PM), https://www.forbes.com/sites/howardsklar/2011/10/18/against-an-fcpa-compliance-defense/?sh=7870a3fa34b5 [https://perma.cc/4RK4-V6EZ].

62. *Foreign Corrupt Practices Act Hearing*, *supra* note 6, at 58–59 (testimony of Greg Andres, Acting Deputy Assistant Att'y Gen., Crim. Div., U.S. Dep't of Just.).

63. *See* FRAUD SECTION, U.S. DEP'T. OF JUST., FRAUD SECTION YEAR IN REVIEW 2020, at 10–16 (2021) [hereinafter FRAUD SECTION 2020 YEAR IN REVIEW], https://www.justice.gov/criminal-fraud/file/1370171/download [https://perma.cc/VQB7-8CE3]; FRAUD SECTION, DEP'T. OF JUST., FRAUD SECTION YEAR IN REVIEW 2019, at 9–17 (2020) [hereinafter FRAUD SECTION 2019 YEAR IN REVIEW], https://www.justice.gov/criminal-fraud/file/1245236/download [https://perma.cc/X53L-Z2WJ].

III's analysis of the role of preexisting compliance programs in the FCA system.

A. The FCA Is the Government's Primary Health Care Fraud Enforcement Tool

For most industries, DOJ's criminal policies are what matter: criminal prosecutions are DOJ's primary enforcement mechanism.[64] In the health care industry, however, that honor has long been held by civil cases brought under the FCA, "the weapon of choice in the federal government's battle against health care fraud."[65] In Fiscal Year 2020, for example, DOJ recovered $1.8 billion from settlements and judgments in FCA cases involving the health care industry.[66] This followed ten consecutive years during which DOJ's civil health care fraud settlements and judgments exceeded $2 billion.[67] Between 2010 and 2020, DOJ recovered $27.2 billion from settlements and judgments in FCA cases involving the health care industry.[68] For decades, FCA recoveries have been DOJ's primary method of targeting organizations for health care enforcement, and that trend is expected to continue. In remarks at the American Health Law Association's annual meeting in June 2021, Deputy Assistant Attorney

64. *See* U.S. Dep't of Just., Just. Manual § 9-28.010 (2015).

65. Jeffrey B. Hammond, *What Exactly Is Healthcare Fraud After the Affordable Care Act?*, 42 STETSON L. REV. 35, 50 (2012); *see also* Lewis Morris & Gary W. Thompson, *Reflections on the Government's Stick and Carrot Approach to Fighting Health Care Fraud*, 51 ALA. L. REV. 319, 327–30 (1999) (referring to the FCA as "the [g]overnment's [p]rimary [w]eapon [a]gainst [f]raud" and pointing to the FCA's *qui tam* provision as a primary reason for its growth); Pamela H. Bucy, *Growing Pains: Using the False Claims Act to Combat Health Care Fraud*, 51 ALA. L. REV. 57, 59–60 (1999) (concluding that the FCA's *qui tam* provision, lower mens rea requirement, and lower burden of proof, combined with the fact that most health care providers have substantial assets, make the FCA a "potent and appropriate weapon to use against fraudulent health care providers"); Timothy Stoltzfus Jost & Sharon L. Davies, *The Empire Strikes Back: A Critique of the Backlash Against Fraud and Abuse Enforcement*, 51 ALA. L. REV. 239, 247 (1999) (noting DOJ's increasing reliance on the FCA to prosecute health care offenses).

> U.S. Department of Health and Human Services ("HHS") Office of Inspector General ("OIG") maintains a separate authority to bring civil monetary penalty ("CMP") actions based on a wide range of program violations. . . . However, the size of CMP actions and resulting publicity from those actions has paled in comparison to FCA recoveries.

Elberg, *A Path to Data-Driven Health Care Enforcement*, *supra* note 4, at 1182 n.38.

66. DOJ Jan. 14, 2021, Press Release, *supra* note 7.

67. Press Release, U.S. Dep't of Just., Justice Department Recovers over $3 Billion from False Claims Act Cases in Fiscal Year 2019 (Jan. 9, 2020), https://www.justice.gov/opa/pr/justice-department-recovers-over-3-billion-false-claims-act-cases-fiscal-year-2019 [https://perma.cc/MJK6-VVEK].

68. *Id.*; CIV. DIV., U.S. DEP'T OF JUST., FRAUD STATISTICS—HEALTH AND HUMAN SERVICES (2020), https://www.justice.gov/opa/press-release/file/1354316/download [https://perma.cc/2LFF-XXGL].

General Michael Granston observed that DOJ opened 580 new FCA cases involving health care fraud in 2020—a new record.[69]

DOJ has noted that, particularly in the health care arena, FCA cases are primary mechanisms not only for punishing misconduct, but also for deterring fraud. In the January 2021 press release announcing the Fiscal Year 2020 recoveries, DOJ noted that "the Department's vigorous pursuit of health care fraud prevents billions . . . in losses by deterring those who might otherwise try to cheat the system for their own gain."[70]

It is thus notable that then deputy attorney general Holder's 1999 statement about DOJ's "long-standing policy" of "look[ing] favorably on providers that implement effective compliance programs" was made in remarks to the American Hospital Association and that Deputy Assistant Attorney General Miner's statement about the policy "only mak[ing] sense for [DOJ] to incentivize and, where possible, reward companies that invest in compliance" was made in remarks to the National Institute on Health Care Fraud, organizations whose members are far more likely to interact with DOJ in the context of an FCA case than a criminal one.[71]

B. Background and Structure of the FCA

Congress originally enacted the FCA during the Civil War in response to concerns about fraud perpetrated against the government by contractors selling "sick mules, lame horses, sawdust instead of gunpowder, and rotted ships with fresh paint."[72] While the FCA remains an important tool for enforcement in government contracting, over the last thirty years the Act has been used primarily to address health care fraud. In Fiscal Year 2020, for example, the $1.8 billion recovered by DOJ from FCA cases involving the health care industry was roughly eighty-two percent of the $2.2 billion recovered in total by DOJ from FCA cases.[73] This reality, along with health care's well-developed compliance industry, explains why many of the public statements by DOJ officials about the

69. *See* Lydia Wheeler, *Justice Department Reports Record Number of Health Fraud Cases*, BLOOMBERG L. (June 29, 2021, 4:02 PM), https://news.bloomberglaw.com/health-law-and-business/justice-department-reports-record-number-of-health-fraud-cases.

70. DOJ Jan. 14, 2021, Press Release, *supra* note 7.

71. *See* Holder, *supra* note 32; Miner, *supra* note 8.

72. Press Release, U.S. Dep't of Just., Justice Department Recovers over $2.8 Billion from False Claims Act Cases in Fiscal Year 2018 (Dec. 21, 2018), https://www.justice.gov/opa/pr/justice-department-recovers-over-28-billion-false-claims-act-cases-fiscal-year-2018 [https://perma.cc/G4ER-9WYR].

73. *See* DOJ Jan. 14, 2021, Press Release, *supra* note 7.

importance of compliance programs were made at conferences specifically focused on the health care industry.[74]

The FCA imposes penalties on anyone who "knowingly presents . . . a false or fraudulent claim for payment or approval" to the federal government.[75] A violation of the FCA includes four elements: falsity, causation, knowledge, and materiality.[76] Significantly, in the context of the FCA, "knowingly" means that a person "has actual knowledge," "acts in deliberate ignorance of the truth or falsity of the information," or "acts in reckless disregard of the truth or falsity of the information," but this inquiry does not require proof of intent to defraud.[77]

The already-expansive nature of respondeat superior is even more pronounced when combined with the FCA's mens rea requirement.[78] Combining the two, we find that an organization is responsible not only for a rogue employee engaging in intentional conduct, but for an employee whose actions meet nothing more than the "reckless disregard" standard.[79]

The FCA provides that a person who violates the FCA "is liable to the United States Government for a civil penalty of not less than [$11,665]

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74. *See, e.g.*, Holder, *supra* note 32; Miner, *supra* note 8; Brian A. Benczkowski, Assistant Att'y Gen., U.S. Dep't of Just., Remarks at the 20th Annual Pharmaceutical and Medical Device Compliance Congress (Nov. 6, 2019), https://www.justice.gov/opa/speech/assistant-attorney-general-brian-benczkowski-delivers-remarks-20th-annual-pharmaceutical [https://perma.cc/7XLA-X7TB]; Benjamin C. Mizer, Principal Deputy Assistant Att'y Gen., U.S. Dep't of Just., Remarks at the 16th Pharmaceutical Compliance Congress and Best Practices Forum (Oct. 22, 2015), https://www.justice.gov/opa/speech/principal-deputy-assistant-attorney-general-benjamin-c-mizer-delivers-remarks-16th [https://perma.cc/LK4T-X7UB]; Jonathan Olin, Deputy Assistant Att'y Gen., U.S. Dep't of Just., Remarks at the Food and Drug Law Institute's Enforcement, Litigation and Compliance Conference (Dec. 9, 2015), https://www.justice.gov/opa/speech/deputy-assistant-attorney-general-jonathan-olin-delivers-remarks-food-and-drug-law [https://perma.cc/J9XD-A8QA]; Lanny A. Breuer, Assistant Att'y Gen., U.S. Dep't of Just., Remarks at the American Health Lawyers Association and Health Care Compliance Association's 2011 Fraud and Compliance Forum (Sept. 26, 2011), https://www.justice.gov/opa/speech/assistant-attorney-general-lanny-breuer-speaks-american-health-lawyers-association-and [https://perma.cc/RF2Y-GMHR]; Daniel Feith, Deputy Assistant Att'y Gen., U.S. Dep't of Just., Remarks at the FDLI Enforcement, Litigation, and Compliance Conference (Dec. 15, 2020), https://www.justice.gov/opa/speech/deputy-assistant-attorney-general-daniel-feith-delivers-remarks-fdli-enforcement [https://perma.cc/2JVW-KDJQ].

75. 31 U.S.C. § 3729(a)(1)(A).

76. *See United States ex rel. Petratos v. Genentech Inc*., 855 F.3d 481, 487 (3d Cir. 2017) (first citing *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 576 U.S. 176 (2016) (materiality); and then citing *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 304–05 (3d Cir. 2011) (falsity, causation, knowledge)).

77. 31 U.S.C. § 3729(b)(1)(A)–(B).

78. *See* Isaac D. Buck, *Enforcement Overdose: Health Care Fraud Regulation in an Era of Overcriminalization and Overtreatment*, 74 MD. L. REV. 259, 285 (2015) (noting that the "relatively low intent requirement" contributes to the broad nature of the FCA).

79. *See id.*

and not more than [$23,331], plus 3 times the amount of damages which the Government sustains because of the act [of the person violating the FCA]."[80] Damages (referred to as single damages) are generally the amount of money the United States paid as a result of the false claim.[81] Thus, recovering single damages can be seen as making the government whole.[82] And DOJ is not required to demand treble damages (or penalties) in resolving an FCA case.[83] There is no guidance or publicly available information provided by DOJ as to what constitutes a standard settlement or what factors influence what DOJ will demand.[84]

The gap between single damages and maximum recovery (treble damages plus penalties) provides DOJ with an opportunity to offer meaningful rewards for compliant behaviors, such as maintenance of a preexisting compliance program or punishment for failure to maintain a compliance program. Empirical analysis, however, reveals that DOJ has yet to make use of that gap. While DOJ has long trumpeted its ability to obtain treble damages plus penalties, in reality, DOJ offers a tremendous settlement benefit to defendants, making no use of the top end of potential FCA exposure.[85]

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80. 31 U.S.C. § 3729(a)(1); 28 C.F.R. § 85.5 (2020) (providing updated inflation-adjusted figures for penalties after November 2, 2015).

81. *See United States ex rel. Marcus v. Hess*, 317 U.S. 537, 551 (1943) ("The law can provide the same measure of damage for the government as it can for the individual.").

82. *Id.* at 551–52. Because of lost interest and other factors, a recovery must be beyond single damages to truly make the government whole. Elberg, *Health Care Fraud Means Never Having to Say You're Sorry*, *supra* note 4, at 380.

83. Elberg, *Health Care Fraud Means Never Having to Say You're Sorry*, *supra* note 4, at 379–80.

84. *See, e.g.*, Brian C. Elmer & Alan W.H. Gourley, *FCA Settlements: A Practical Guide for Defense Counsel*, CROWELL & MORING LLP, https://www.crowell.com/documents/docassocfktype_presentations_440.pdf [https://perma.cc/96ZL-GARA] (last visited Mar. 20, 2022) ("In settling, DOJ does not insist on treble damages, although it will not acknowledge any specific policy to settle for less than treble damages.").

85. Press Release, U.S. Att'y's Off. E. Dist. of Ky., U.S. Dep't of Just., Medical Equipment Company Agrees to Pay $5.25 Million to Resolve Allegations of Fraudulent Claims for Compounded Medical Creams (Oct. 22, 2018), https://www.justice.gov/usao-edky/pr/medical-equipment-company-agrees-pay-525-million-resolve-allegations-fraudulent-claims [https://perma.cc/5MVA-AZMK] (describing treble damages as the "typical[]" liability under the FCA); Elberg, *A Path to Data-Driven Health Care Enforcement*, *supra* note 4, at 1206–07 (Between early 2018 and June 2019, not only did none of the eighty-nine resolutions analyzed involve the imposition of penalties, but none had a multiplier higher than 2.75, only three were above 2.5, and only eleven were above 2.0.); Elberg, *Health Care Fraud Means Never Having to Say You're Sorry*, *supra* note 4, at 380.

III. DOJ POLICY REGARDING THE IMPACT OF PREEXISTING COMPLIANCE PROGRAMS IN CIVIL CASES

This Part analyzes DOJ policy regarding the impact of an organization's compliance program on resolution of FCA cases, looking at published DOJ guidance and statements, as well as at an empirical analysis of hundreds of FCA resolutions over the past three years.

In contrast to criminal cases, for which the Corporate Prosecution Principles have been in place for decades, until recently there was no guidance as to what factors DOJ takes into account in resolving civil FCA cases. In May 2019, for the first time, DOJ issued formal guidance regarding rewards in FCA cases for what I have termed "compliant behaviors"—maintenance of an effective preexisting compliance program, post-enforcement adoption of an effective compliance program, cooperation with a government investigation, and self-disclosure of misconduct.[86] Prior to issuance of the "Guidelines for Taking Disclosure, Cooperation, and Remediation into account in False Claims Act Matters" (2019 FCA Guidance), there was no transparency from DOJ as to whether any compliant-behavior benefits existed at all in the FCA context.[87]

The 2019 FCA Guidance takes on particular significance because there is no civil equivalent to the U.S. Sentencing Guidelines for Organizations. In the criminal context, statutes include a maximum penalty (and in some cases a minimum penalty), and the U.S. Sentencing Guidelines are the true engine for determining actual sentences. Sentencing is thus individualized, particularly for corporations.[88] In the civil context, the FCA states that a defendant who violates the FCA "is liable to the United States Government for a civil penalty of not less than [$11,181] and not more than [$22,363], plus 3 times the amount of damages which the Government sustains because of the act [of the person violating the FCA]."[89] And where an FCA judgment is determined by a court, that is effectively the end of the analysis: there is no equivalent opportunity at sentencing for a judge to make a determination as to whether the corporate FCA defendant should receive the maximum punishment, as it is not left to the judge's discretion.[90]

In the criminal context, as noted in Section I.B, the U.S. Sentencing Guidelines for Organizations drive DOJ's demands when a case is being

86. 2019 FCA Guidance, *supra* note 9; U.S. Dep't of Just., Just. Manual § 4-4.112 (2019); Elberg, *A Path to Data-Driven Health Care Enforcement*, *supra* note 4, at 1189–91.

87. Elberg, *A Path to Data-Driven Health Care Enforcement*, *supra* note 4, at 1189–91.

88. Barkow, *supra* note 44, at 167.

89. 31 U.S.C. § 3729(a)(1).

90. 28 C.F.R. § 85.5 (2020) (providing updated inflation-adjusted figures for penalties after November 2, 2015).

resolved without court involvement. But there is no equivalent in FCA cases—other than the 2019 FCA Guidance (to the extent that it does so), there is nothing to take culpability into account when DOJ is determining how much to punish an FCA-violating entity.

A. 2019 FCA Guidance and Statements from DOJ

Like the Corporation Prosecution Principles governing criminal cases, the 2019 FCA Guidance "identif[ies] factors that will be considered" based on compliant behaviors—in the FCA context, a potentially reduced FCA multiplier.[91] The FCA Guidance largely mirrors the Corporate Prosecution Principles, but some exceptions are notable. Of the four compliant behaviors, all four have long been listed in the Corporate Prosecution Principles as "Factors to be Considered" in "reaching a decision as to the proper treatment of a corporate target."[92] Only three appear in the 2019 FCA Guidance as a basis for reduction in the FCA multiplier.[93]

Table 1. DOJ Consideration of Compliant Behaviors—Criminal vs. Civil

Compliant Behavior	**Corporate Prosecution Principles (Criminal)**[94]	**2019 FCA Guidance (Civil)**[95]
Maintenance of an effective	"5. [T]he adequacy and effectiveness of	[No multiplier benefit listed.]

91. U.S. Dep't of Just., Just. Manual § 4-4.112 (2019). Like the Corporate Prosecution Principles, the 2019 FCA Guidance maintains enormous discretion for prosecutors, noting that "[t]he discussion in these guidelines does not limit Department attorneys' discretion to consider all appropriate factors in determining whether and on what basis to resolve an FCA matter." *Id.* The FCA guidance concludes that

> [t]he measures set forth in these guidelines are intended solely to guide attorneys for the government in accordance with their statutory responsibilities and federal law. They are not intended to, do not, and may not be relied upon to create a right or benefit, substantive or procedural, enforceable at law by any party.

Id. Where the 2019 FCA Guidance does purport to give benefits, it is thus open to the same criticisms levied by those advocating for a compliance defense in criminal cases.

92. U.S. Dep't of Just., Just. Manual § 9-28.300 (2020).

93. *Id.* § 4-4.112 (2019).

94. All of the numbered sections in this column are listed among "Factors to be Considered" in "reaching a decision as to the proper treatment of a corporate target." *Id.* § 9-28.300 (2020).

95. All of the references in this column are listed among bases for earning credit, most often in the form of "reducing the penalties or damages multiple sought by the Department." *Id.* § 4-4.112 (2019).

preexisting compliance program	the corporation's compliance program at the time of the offense . . . ."[96]	
Post-enforcement adoption of an effective compliance program	"7. [T]he corporation's remedial actions, including but not limited to, any efforts to implement an adequate and effective corporate compliance program or to improve an existing one . . . ."[97]	"Department attorneys will [] consider whether an entity has taken appropriate remedial actions in response to the FCA violation. Such remedial actions may include . . . implementing or improving an effective compliance program designed to ensure the misconduct or similar problem does not occur again."[98]
Cooperation with a government investigation	"4. [T]he corporation's willingness to cooperate, including as to potential wrongdoing by its agents . . . ."[99]	"[A]n [] entity can earn credit by taking steps to cooperate with an ongoing government investigation."[100]
Self-disclosure of misconduct	"6. [T]he corporation's timely and voluntary disclosure of wrongdoing . . . ."[101]	"Entities [] that make proactive, timely, and voluntary self-disclosure to the Department about misconduct will receive credit during the resolution of a FCA case."[102]

Unlike the other three compliant behaviors, the 2019 FCA Guidance treats maintenance of an effective preexisting compliance program differently. It is not listed as a basis for obtaining a reduced multiplier, and

96. *Id.* § 9-28.300 (2020); *see also id.* § 9-28.800 (2015).
97. *Id.* § 9-28.300 (2020); *see also id.* § 9-28.1000 (2015).
98. *Id.* § 4-4.112 (2019).
99. *Id.* § 9-28.300 (2020); *see also id.* § 9-28.700 (2018).
100. *Id.* § 4-4.112 (2019).
101. *Id.* § 9-28.300 (2020); *see also id.* § 9-28.900 (2015).
102. *Id.* § 4-4.112 (2019).

it is not even included in the body of the guidance. Instead, a footnote attached to the section announcing a benefit for *post-enforcement* adoption of an effective compliance program notes, "[T]he Department may take into account the prior existence of a compliance program in evaluating a defendant's liability under the False Claims Act. For example, the Department may consider the nature and effectiveness of such a compliance program in evaluating whether any violation of law was committed knowingly."[103] More significant than its placement in a footnote is the form of the potential benefit. Unlike the other three compliant behaviors, under the 2019 FCA Guidance, a preexisting compliance program is not a basis for a reduced multiplier.[104]

Neither the updated Justice Manual language nor the statement from Assistant Attorney General Jody Hunt announcing the changes provides an explanation as to why maintenance of an effective preexisting compliance program—the only one of the four compliant behaviors aimed directly at stopping misconduct before it occurs—is excluded from this benefit.[105] Nor do they provide any explanation as to what the footnote reference is intended to convey. From a legal analysis perspective, the footnote makes little sense. Significantly, the footnote does not suggest DOJ will use the organization's compliance program to evaluate whether an employee's conduct was in fact taken for the benefit of the organization—the typical basis under which evidence of a compliance program would be relevant.[106] Nor does the footnote track language from the Corporate Prosecution Principles noting that "it may not be appropriate to impose liability upon a corporation, particularly one with a robust compliance program in place, under a strict *respondeat superior* theory for the single isolated act of a rogue employee."[107] The Corporate Prosecution Principles language speaks in terms of prosecutorial discretion, while the 2019 FCA Guidance language speaks in terms of legal analysis.

The 2019 FCA Guidance's reference to the question of whether the violation of law was committed "knowingly" suggests the footnote may be making only a minor point—one DOJ has made for more than two decades.[108] Under the FCA, "knowingly" is defined as "ha[ving] actual

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103. *Id.* n.1.

104. *See id.*

105. *See* 2019 FCA Guidance, *supra* note 9; U.S. Dep't of Just., Just. Manual § 4-4.112 n.1 (2019).

106. *See United States v. Beusch*, 596 F.2d 871, 878 (9th Cir. 1979) ("[A] corporation may be liable for 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.").

107. U.S. Dep't of Just., Just. Manual § 9-28.500 (2008).

108. That this is the most likely reading is supported by the similarity in the language to that of then deputy attorney general Eric Holder in a 1998 memorandum. Memorandum from Eric H. Holder, Jr., Deputy Att'y Gen., U.S. Dep't of Just., Guidance

knowledge of the information," "act[ing] in deliberate ignorance of the truth or falsity of the information," or "act[ing] in reckless disregard of the truth or falsity of the information."[109] Where a case is predicated on the "reckless disregard" standard, it may be that the organization's compliance program would be relevant to show that the organization was not "reckless." This would apply, however, only to that small subset of cases and would be true from the perspective of the legal analysis without any give from DOJ.[110] Under this reading, the footnote solely summarizes the law and does nothing to reward compliance programs not already rewarded by statute.

While seemingly adopting this view in a May 2019 speech, Principal Deputy Associate Attorney General Claire McCusker Murray, whose areas of responsibility included the Civil Division but not the Criminal Division,[111] assured an audience of compliance professionals that "the Department is in the business of promoting compliance programs and . . . [is] doing [things] to get better at that task."[112] McCusker Murray stated that affirmative civil enforcement attorneys "will often take a deep dive into the company's compliance programs" because "a company's compliance efforts [are] relevant to its culpability. For that reason, a fair resolution frequently requires an understanding of the compliance function at the time of the conduct at issue . . . ."[113]

McCusker Murray went on to link the civil enforcement strategy to the principles laid out in the explicitly criminal Corporate Prosecution Principles. She noted that "about a dozen" attorneys from the Commercial Litigation Branch had attended Criminal Division training to learn about compliance programs in order to "develop expertise" in evaluating such programs, and she suggested the Civil Division would be following the path of the Criminal Division (taken by the Criminal Division in the wake of Hui Chen's resignation) in using hiring and training to improve the Civil Division's compliance program expertise.[114]

As I noted shortly after DOJ issued the 2019 FCA Guidance, it was unclear upon issuance whether the statement was simply DOJ explaining

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on the Use of the False Claims Act in Civil Health Care Matters (June 3, 1998), https://www.justice.gov/archives/dag/memo-guidance-use-false-claims-act-civil-health-care-matters-june-3-1998 [https://perma.cc/EWQ3-63A9] (noting that DOJ lawyers "must . . . evaluate whether [a] health care provider 'knowingly' submitted. . . false claims or 'knowingly' made false statements to get the false claims paid," and that "factors that must be considered" when evaluating whether the knowledge requirement has been satisfied include compliance plans in place, whether they were followed, and the relationship between the existing plans and conduct at issue).

109. 31 U.S.C. § 3729(b)(1).

110. *See* Bucy, *supra* note 65, at 59.

111. *See* Murray, *supra* note 11.

112. *Id.*

113. *Id*.

114. *See id.*; Mont, *supra* note 41; Benczkowski, *supra* note 40.

the relevance of a "pre-existing compliance program for a legal determination of whether the conduct was committed 'knowingly'—an element under the FCA"—or was meant to imply a benefit available to defendants "whose conduct is deemed to meet the elements of the FCA despite having a meaningful pre-existing compliance program."[115]

B. Analysis of Civil Settlement Agreements

Since the 2019 FCA Guidance was issued, however, I have collected and analyzed hundreds of FCA resolutions dating back to early 2018, all of which support the conclusion that it is solely the former—that DOJ does not offer a reward for FCA defendants for maintaining an effective compliance program. I first published results of this empirical analysis based on cases between early 2018 and June 2019 (then focused on the variation in multipliers). I have continued to review the Civil Settlement Agreements (CSAs) from civil-only FCA settlements between health care business organizations and DOJ, as well as the accompanying DOJ press releases and other public statements of DOJ or the settling defendants.[116] Among other things, I have tracked the dollar amounts of the resolutions and the restitution amounts, where indicated, and whether DOJ claimed to credit the settling defendants for engaging in compliant behaviors.

A review of civil-only FCA settlements between health care business organizations and DOJ from early 2018 to August 30, 2021, found that none of the more than 300 Civil Settlement Agreements (CSAs) nor associated DOJ press releases made positive reference to a defendant's preexisting compliance program or noted that the defendant had received a reduced multiplier based on its preexisting compliance program.[117]

The lack of reference to preexisting compliance programs in the CSAs and associated press releases is particularly notable, as recent press releases have increasingly identified instances whn the other three compliant behaviors purportedly led to reduced multipliers.[118] Dozens of

115. Elberg, *A Path to Data-Driven Health Care Enforcement*, *supra* note 4, at 1190.

116. *See id.* at 1171–72, 1193.

117. To be clear, this does not definitively establish that DOJ is not rewarding preexisting compliance programs. It may be that DOJ is taking preexisting compliance programs into account—for better or for worse—but without transparency that would allow the public to see those impacts. Even if it is solely an issue of transparency, however, given DOJ's focus on general deterrence in FCA matters, that lack of transparency would have effectively the same impact as not taking compliance programs into account at all. *See* DOJ Jan. 14, 2021, Press Release, *supra* note 7 ("[T]he Department's vigorous pursuit of health care fraud prevents billions . . . in losses by deterring those who might otherwise try to cheat the system for their own gain.").

118. *See, e.g.*, Press Release, U.S. Att'y's Off. Middle Dist. of Tenn., U.S. Dep't of Just., Jacksonville Radiology Practice Agrees to Pay $1.4 Million to Resolve Health Care Fraud Allegations (Nov. 20, 2020), https://www.justice.gov/usao-

resolutions referenced defendants' cooperation, often including self-disclosure.[119] Consistent with the goals of the 2019 FCA Guidance, DOJ has recently sought to use press releases announcing FCA resolutions to encourage compliance by pointing out the presence of one or more of the three compliant behaviors and assuring the public that defendants were rewarded with a reduced multiplier.[120]

DOJ's clear policy statement that self-disclosure, cooperation, and improvements to a preexisting compliance program are worthy of a potentially reduced multiplier, along with DOJ's recent demonstrations of those benefits in action, makes DOJ's treatment of preexisting compliance programs more noticeable and more surprising. There are only a few possible explanations for DOJ's failure to call out and reward any preexisting compliance programs in the more than 300 CSAs reviewed for purposes of this analysis. First, it is possible that DOJ actually is rewarding preexisting compliance programs and that the issue is solely one of transparency.[121] Given DOJ's willingness to identify other compliant

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mdfl/pr/jacksonville-radiology-practice-agrees-pay-14-million-resolve-health-care-fraud [https://perma.cc/JD3J-PJQQ] (noting that the defendant "successfully reduced the amount owed to the government through diligent and effective cooperation"); Press Release, U.S. Att'y's Off. Dist. of Vt., U.S. Dep't of Just., United States Attorney's Office Resolves False Claims Act Investigation into Improper Submission of Federal Health Care Claims by Health Care & Rehabilitation Services of Southeastern Vermont (June 29, 2021), https://www.justice.gov/usao-vt/pr/united-states-attorney-s-office-resolves-false-claims-act-investigation-improper [https://perma.cc/JD7N-WLZE] ("The settlement amount reflects a cooperation credit in light of HCRS's self-disclosure of the violation, assistance with the investigation, and voluntary adoption of remedial measures to guard against improper employment and claim submission in the future."); Press Release, U.S. Dep't of Just., Northern Ohio Health System Agrees to Pay over $21 Million to Resolve False Claims Act Allegations for Improper Payments to Referring Physicians (July 2, 2021), https://www.justice.gov/opa/pr/northern-ohio-health-system-agrees-pay-over-21-million-resolve-false-claims-act-allegations [https://perma.cc/XUZ8-DPZD] ("The Clinic voluntarily disclosed to the government its concerns with these compensation arrangements, which were put in place by AGHS's prior leadership, and received credit for its cooperation in the resolution reached by the parties.").

119. *See, e.g.*, *supra* note 118 and accompanying text.

120. While my prior work called into question whether DOJ was properly rewarding self-disclosure, cooperation, and remedial measures, anecdotal evidence suggests DOJ may be improving in that area in the wake of that criticism. *See* Elberg, *A Path to Data-Driven Health Care Enforcement*, *supra* note 4, at 1201–05; Civil Settlement Agreement, *United States v. Health Care & Rehab. Servs. of Se. Vt.*, D. Vt. (2021), https://www.justice.gov/usao-vt/press-release/file/1413426/download [https://perma.cc/7GXM-B9BN] (reflecting a reduced multiplier of 1.50 based on self-disclosure, cooperation, and remedial measures); Civil Settlement Agreement, *United States v. Akron Gen. Health Sys.*, N.D. Ohio (2021) (reflecting a reduced multiplier of 1.25 based on self-disclosure and cooperation).

121. It may also be that individual DOJ components are rewarding preexisting compliance without transparency while others are not. For a further example of the lack of consistency revealed by the analysis of FCA multipliers, see Elberg, *A Path to Data-Driven Health Care Enforcement*, *supra* note 4, at 1212–13.

behaviors and note their impact, there is reason to be skeptical of this possibility. And for the reasons discussed below, such lack of transparency still would be a substantial problem.

Second, it may be that DOJ has taken the position that none of the more than 300 organizations had in place effective compliance programs—essentially, that the organizations must not have had effective compliance programs in place because if they had, the misconduct would not have occurred. This possibility is discussed in further detail in Part V. Such a position would represent a failure to understand the realities of compliance within large organizations despite DOJ statements recognizing that even an ideal compliance program will not necessarily stop all misconduct. The Corporate Prosecution Principles acknowledge that fact explicitly, stating, "[T]he Department recognizes that no compliance program can ever prevent all criminal activity by a corporation's employees . . . ."[122] And notably, it is not the case that all FCA resolutions represent widespread misconduct. While periodic eight- and nine-figure settlements dominate FCA headlines and discourse, the vast majority of FCA cases settle, with a multiplier included, for below $5 million, with a significant percentage settling for less than $1 million, multiplier included.[123]

Third, it is possible that DOJ takes the view that even effective preexisting compliance programs are not supposed to be rewarded in FCA resolutions. Such a view would presumably be premised on the idea that compliance programs carry with them sufficient intrinsic rewards (they reduce fraud and thus the organization's exposure to enforcement actions and consequences) such that it is unnecessary for DOJ to provide additional benefits. This might make sense from an economic analysis perspective but would be impossible to square with DOJ's policy of rewarding post-enforcement adoption of an effective compliance program in FCA resolutions.[124]

DOJ's failure to reward (or at least publicly reward) preexisting compliance programs in FCA cases is surprising in that there are additional reasons to take into account such conduct in civil cases beyond the reasons present in criminal cases. The Corporation Prosecution Principles language that "it may not be appropriate to impose liability upon a corporation, particularly one with a robust compliance program in place, under a strict *respondeat superior* theory for the single isolated act of a rogue employee"[125] seemingly would apply with equal force to civil cases, at least in the health care context, where the FCA serves as DOJ's primary

122. U.S. Dep't of Just., Just. Manual § 9-28.800 (2019).

123. *See* Elberg, *Health Care Fraud Means Never Having to Say You're Sorry*, *supra* note 4, at 380–81.

124. *See* U.S. Dep't of Just., Just. Manual § 4-4.112 (2019).

125. *Id.* § 9-28.500 (2008).

enforcement mechanism.[126] The FCA's more lenient mens rea standard, however, presumably makes it more, rather than less, necessary to use preexisting compliance programs as governors to prevent over-aggressive prosecutions of organizations without moral culpability and that have already been sufficiently incentivized to put in place the type of compliance program DOJ would like to encourage.[127]

IV. DOJ'S FAILURE TO SPECIFICALLY REWARD COMPLIANCE IN CIVIL CASES UNDERMINES ITS ENFORCEMENT GOALS

Whether intentional or not, DOJ's failure to reward preexisting compliance programs in FCA cases not only represents a departure from long-standing DOJ policy, but also undermines DOJ's enforcement goals.[128] This Part examines the consequences for DOJ's practices in this area, which range from economic incentives to less concrete, but no less important, risk to the perceptions of fairness and legitimacy of DOJ's enforcement regime.

To be clear, as noted above, a compliance program's ability to reduce corporate misconduct, and thus enforcement exposure itself, provides a powerful economic incentive for organizations to invest in compliance if sanctions are being set appropriately.[129] Were the goal only to create the

126. Elberg, *A Path to Data-Driven Health Care Enforcement*, *supra* note 4, at 1182–83.

127. 31 U.S.C. § 3729(b)(1).

128. As recently as November 2019—six months after the 2019 FCA Guidance was issued—the assistant attorney general responsible for the Criminal Division stated, "The corporate compliance function is in some ways more important than the prosecution function. It can actually prevent misconduct in the first place through robust systems of controls, and by fostering a culture where compliance is valued and rewarded." Benczkowski, *supra* note 74.

129. The American Law Institute's Principles of Corporate Enforcement note that benefits for adopting an effective compliance program should include not only (1) preventing misconduct and thus reducing organizational exposure, but also (2) increasing the chances of detecting misconduct and obtaining the benefits of self-reporting, (3) facilitating investigations and obtaining credit for full cooperation, and (4) obtaining a reduced criminal fine and avoiding having an outside monitor imposed as part of a criminal resolution. PRINCIPLES OF THE L. OF COMPLIANCE & ENF'T FOR ORGS. § 6.17 (AM. L. INST., Tentative Draft No. 2, 2021). It is unclear, however, whether these incentives are in place under DOJ's current practices for resolving FCA cases.

It may be that DOJ's current enforcement of the FCA applies insufficient penalties to deter misconduct. Elberg, *A Path to Data-Driven Health Care Enforcement*, *supra* note 4, at 1206–07 (quoting Jost & Davies, *supra* note 65, at 308) ("[A] large number of FCA settlements [between early 2018 and June 2019] recovered no more—and often less—than the amount of damages plus interest. No complex analysis of economic incentives is necessary to conclude that such settlements . . . 'undermine even optimal deterrence and . . . risk encouraging improper billing.'"). Whether DOJ enforcement is deficient in that way, however, is an issue separate and apart from DOJ's treatment of preexisting compliance programs.

proper economic incentives, it might be unnecessary for DOJ to separately reward organizations for maintaining effective compliance programs or punish them for failure to do so. But there is more to motivation than economic incentives, as described below.

A. Failure to Capitalize on Noneconomic Incentives to Encourage Compliance

Because corporations can act only through individuals, a purely economic analysis is insufficient—even corporations are thus not motivated by economic incentives alone. Through a body of research and scholarship, John Braithwaite has argued that corporate actors are motivated not solely by economic incentives, but often by a desire to do the right thing separate and apart from any potential impact on profits, reputational concerns, and other non-monetary factors.[130] Through a course of research in which he and colleagues, among other things, conducted interviews with pharmaceutical company executives, nursing home workers, and others, Braithwaite concluded that "[c]orporate actors are not just value maximizers . . . . They are also often concerned to do what is right, to be faithful to their identity as a law abiding citizen, and to sustain a self-concept of social responsibility."[131] While Braithwaite does not deny that business actors frequently are motivated by economic concerns, he argues against an enforcement strategy based solely on punishment and economic incentives. Notably, Braithwaite concludes that "a strategy based mostly on punishment will undermine the good will of actors when they are motivated by a sense of responsibility . . . a more noble calling than making money."[132] In no industry is that as likely to be true as in health care—the source of Braithwaite's paradigmatic example.[133]

Braithwaite urges an enforcement regime that is "contingently ferocious and forgiving."[134] Of course, that requires distinguishing between truly bad corporate actors and those that have made their best efforts but have been less than 100% successful—a near inevitability given the complex nature of health care regulations and the broad reach of the FCA.

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130. IAN AYRES & JOHN BRAITHWAITE, RESPONSIVE REGULATION: TRANSCENDING THE DEREGULATION DEBATE 22 (1992).

131. *Id.* at 23 ("We should not scoff at a top pharmaceutical executive who says that concern for improving human health motivates her and her staff to maintain high standards more than the fear of regulatory sanctions, where this is a company that can be observed to maintain fairly high standards in a Third World country that effectively has no pharmaceuticals regulation.").

132. *Id.* at 24.

133. *See id.* at 23.

134. *Id.* at 27.

The failure to identify which FCA defendants had devoted resources to an effective compliance program is perhaps the most significant part of DOJ's failure to identify which entities have committed misconduct truly worthy of moral condemnation and those that have not.[135] Given the broad reach of respondeat superior and the wide range of conduct the FCA's mens rea standard covers, FCA resolutions inevitably capture both types of defendants.

Take, for example, two hypothetical cases: Company One invests only minimally in compliance and makes little effort to discourage, identify, or stop fraud from occurring. Inevitably, fraud occurs. Company Two devotes substantial resources and maintains what would by even tough standards be considered an effective compliance program. Still, inevitably, in the context of health care's complex regulations and the FCA's broad reach, a violation of the FCA occurs. Under the current system, the public, the health care industry, the defense bar, and even employees of the defendant companies are unable to tell which of DOJ's announced FCA settlements falls into the former category, the latter, or somewhere in between. Of the more than 300 civil-only resolutions I have reviewed, none gave any clear indication.

Failure to clarify for each of those audiences brings its own concerns. For the public, the result is that although the FCA is DOJ's primary means of health care fraud enforcement, FCA resolutions carry with them virtually no social opprobrium. With multiple FCA resolutions announced against health care entities on a weekly basis and insufficient details to separate the good actors from the bad, every company is guilty, so no company is guilty.[136] This matters both to the public, which is deprived of the ability to learn which entities should be trusted and which should be avoided, and to defendants, many of whom likely care a great deal about their reputations.[137] Having conducted case studies and interviews with

135. This is also a problem with DOJ's failure to require FCA defendants to admit wrongdoing and DOJ's settlement model, which prevents the public, in most cases, from differentiating allegations that the government could clearly prove from those that were largely speculative. Elberg, *Health Care Fraud Means Never Having to Say You're Sorry*, *supra* note 4, at 385.

136. *See* BRENT FISSE & JOHN BRAITHWAITE, THE IMPACT OF PUBLICITY ON CORPORATE OFFICERS 265 (1983). DOJ's failure to comment on the state of corporate FCA defendants' preexisting compliance programs is "particularly problematic . . . because the mechanics of DOJ's settlement model [already] prevents the public, in most cases, from differentiating allegations which the government could clearly prove from those which were largely speculative." Elberg, *Health Care Fraud Means Never Having to Say You're Sorry*, *supra* note 4, at 385. And it is further exacerbated by DOJ's practice of allowing large numbers of health care defendants to deny wrongdoing when their settlements are announced. *Id.* at 382.

137. *See* FISSE & BRAITHWAITE, *supra* note 136, at 246–47. Failure to properly educate the public is a particularly notable loss in the area of health care because providers, patients, and insurance companies are regularly making choices about which health care entities to deal with. *See* Cindy R. Alexander & Jennifer Arlen, *Does Conviction Matter?*

executives of large corporations and having reviewed opinion surveys, Braithwaite concluded that "individual executives and the corporation collectively generally valued a good reputation for its own sake" separate and apart from any economic impact resulting from reputation.[138]

DOJ's current FCA enforcement regime sends the message to executives that even if they do everything DOJ would hope—ex ante—that they would do, these executives will be labeled as bad corporate citizens if misconduct occurs and DOJ discovers it (whether through a bounty-seeking whistleblower or otherwise) before the organization's compliance program. This fails to capitalize on the likelihood that executives and their organizations would be substantially motivated to enact effective compliance programs if they trusted their reward will not vanish when an inevitable failure occurs.[139]

For the health care industry and the defense bar, the demotivating impact is clear: if DOJ will neither recognize nor reward investments in compliance, the only enforcer-imposed reason to make them is the economic calculus that the investments will reduce enforcement exposure. In that scenario, the good will of actors motivated by social responsibility is wasted. If DOJ prosecutors appear to forget that "the existence of misconduct does not, by itself, mean that a compliance program did not work or was ineffective at the time of the offense," they will be viewed as far apart from health care executives who surely do not.[140]

The Reputational and Collateral Effects of Corporate Crime, *in* RESEARCH HANDBOOK ON CORPORATE CRIME AND FINANCIAL MISDEALING 87, 101–03 (Jennifer Arlen ed., 2018) (noting that unlike in other situations, such as environmental crime or antitrust, customers may rationally avoid doing business with a corporate entity found to have committed health care fraud given increased fear of being defrauded by the entity in the future, and that outsiders "may take into account the prosecutor's determination of whether the firm's compliance program was effective" when that information is provided).

138. FISSE & BRAITHWAITE, *supra* note 136, at 248 ("One should never underestimate the importance to senior business executives (who, more often than not, are status-conscious people) of being perceived by their middle class peers as working for a prestigious company. And quite apart from these extrinsic rewards, for most people there is basic satisfaction in the feeling they are working with a reputable team.").

139. Miriam Baer has posited that DOJ's FCPA Pilot Program (which provides leniency, including potential declination of prosecution in qualifying cases, where a corporation has self-disclosed misconduct) has been successful in part because it

> allow[s] corporate actors to maintain their self-perceptions as law-abiding people, and to maintain the perception of the firm as a 'good corporate citizen[]' . . . [in part] because [in addition to providing reduced or eliminated charges] it also imbued [companies] with a valuable *intangible* benefit, which was the government's imprimatur of good corporate citizenship.

Miriam H. Baer, *Designing Corporate Leniency Programs*, *in* CAMBRIDGE HANDBOOK OF COMPLIANCE 351, 364 (Benjamin van Rooij & D. Daniel Sokol eds., 2021).

140. CRIM. DIV., U.S. DEP'T OF JUST., EVALUATION OF CORPORATE COMPLIANCE PROGRAMS 14 (2020), https://www.justice.gov/criminal-fraud/page/file/937501/download [https://perma.cc/RR6W-T5FV].

B. Undermining Perceptions of Fairness and Legitimacy

DOJ's failure to separate good from bad corporate actors is a failure from both deterrence and retributive perspectives. DOJ's failure also undermines perceptions of fairness and legitimacy—a problem with potentially far-reaching consequences.

DOJ's health care enforcement regime through the FCA has faced decades of criticism and cynicism from the health care industry. Examining the health care "industry's distrust of FCA enforcement [and its] important implications for the future of the health care anti-fraud agenda" two decades ago, Joan Krause pointed to theorists' arguments that "the perceived *legitimacy* and *moral credibility* of the law are crucial to effective crime control because they influence conduct through normative—rather than coercive—forces."[141] Even where there is seemingly sufficient enforcement to create deterrence, Krause concluded, "lack of legitimacy is likely to lead to greater noncompliance."[142] Studies have shown that legal authorities can motivate compliance when the public views the law and law enforcement as legitimate and thus feels an obligation to follow the rules, as well as when individuals believe "legal authorities share the values, purposes and goals of the community."[143]

The importance of public perception has not been lost on DOJ. As noted in the Justice Manual, public perception of DOJ's enforcement actions depends not only on results, but also on the manner in which DOJ arrives at those results.[144] The Justice Manual reminds prosecutors that they "should be mindful of the common cause [they] share with responsible corporate leaders who seek to promote trust and confidence."[145]

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141. Joan H. Krause, *Health Care Providers and the Public Fisc: Paradigms of Government Harm Under the Civil False Claims Act*, 36 GA. L. REV. 121, 127 (2001) (first citing PAUL H. ROBINSON & JOHN M. DARLEY, JUSTICE, LIABILITY AND BLAME: COMMUNITY VIEWS AND THE CRIMINAL LAW 202 (1995) ("Our conclusion is that the moral credibility of the criminal law is its single most important asset."); and then citing TOM R. TYLER, WHY PEOPLE OBEY THE LAW 22–24 (1990) ("Two such bases [for securing public compliance with the law] are commonly noted: social relations . . . and normative values.")).

142. *Id.* at 212.

143. Tom R. Tyler & Jonathan Jackson, *Popular Legitimacy and the Exercise of Legal Authority: Motivating Compliance, Cooperation, and Engagement*, 20 PSYCH. PUB. POL'Y & L. 78, 79–87 (2014).

144. U.S. Dep't of Just., Just. Manual § 9-28.100 (2015) ("Prosecutors should also be mindful that confidence in the Department is affected both by the results we achieve and by the real and perceived ways in which we achieve them. Thus, the manner in which we do our job as prosecutors . . . affects public perception of our mission. Federal prosecutors must maintain public confidence in the way in which we exercise our charging discretion.").

145. *Id.*

Krause expressed concern that the health care industry would come to view enforcement as illegitimate due to expanding theories of FCA liability and the perception that innocent defendants settle FCA matters with DOJ because of the potentially exorbitant penalties under the FCA (as well as potential exclusion from participation in government health care programs).[146] I expressed a similar concern with regard to DOJ's willingness to allow large numbers of FCA defendants to deny wrongdoing at the time of settlement.[147]

The FCA's whistleblower program only adds to potential cynicism, as it allows relators to bring *qui tam* actions even if they have not first reported wrongdoing internally through their companies' compliance programs, and the program does not incentivize internal reporting the way the SEC's whistleblower program does.[148] While an exhaustion requirement is inadvisable for numerous substantial reasons, including potentially chilling whistleblowers, without a mechanism for DOJ to reward preexisting compliance programs, the health care industry understandably may view the system as one set up to create FCA cases against well-meaning corporate actors that had in place systems designed to stop or promptly address any instances of wrongdoing.[149]

The same concern is present here and raises questions about whether DOJ views the purpose of the FCA to be maximizing monetary recoveries rather than rewarding good corporate citizenship. Where DOJ is perceived as treating truly bad actors no more harshly than those who undertook best efforts to ensure compliance, that perception cannot be squared with DOJ's claims that enforcers share a set of values with the compliance industry.[150]

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146. Krause, *supra* note 141, at 204–05.

147. Elberg, *Health Care Fraud Means Never Having to Say You're Sorry*, *supra* note 4, at 409.

148. Dodd-Frank Rulemaking, 76 Fed. Reg. 34,329, 34,366 (June 13, 2011) (codified at 17 C.F.R. § 240.21F-6(a)(4) (2021)) (The SEC "will assess whether, and the extent to which, the whistleblower and any legal representative of the whistleblower participated in internal compliance systems.").

149. David Freeman Engstrom has analyzed the significant debate regarding "how to harmonize bounty regimes with internal corporate compliance systems to achieve the 'right' mix of internal and external whistleblower reports," including the question of whether an internal reporting mandate would positively or negatively impact compliance. David Freeman Engstrom, *Bounty Regimes*, *in* RESEARCH HANDBOOK ON CORPORATE CRIME AND FINANCIAL MISDEALING, *supra* note 137, at 334, 343–44.

150. *See, e.g.*, Brian A. Benczkowski, Assistant Att'y Gen., U.S. Dep't of Just., Keynote Address at the Ethics and Compliance Initiative (ECI) 2019 Annual Impact Conference (Apr. 30, 2019), https://www.justice.gov/opa/speech/assistant-attorney-general-brian-benczkowski-delivers-keynote-address-ethics-and [https://perma.cc/PC42-2KCN] (noting that "the interests of the Department and private industry to root out corporate crime are very much aligned" and referring to their "collective efforts").

C. The Civil Problem Extends Beyond Civil Cases

The harm from failing to properly reward compliance programs in the context of civil cases cannot help but spill over to other areas, as efforts to incentivize corporate actors through the Corporate Prosecution Principles and the U.S. Sentencing Guidelines inevitably are diminished when those same corporate actors make decisions taking into account contradictory rewards and incentives offered by different enforcers.[151] The problem is especially stark here, where those enforcers with contradictory rewards and incentives are housed within the same agency.

DOJ's Criminal Division has made great efforts to convince corporations that their compliance programs matter not only for stopping wrongdoing from occurring, but also for impacting how DOJ will treat such corporations if there is misconduct.[152] Much of that effort centers on the Foreign Corrupt Practices Act,[153] an area in which health care companies have been frequent defendants.[154] At least for the health care industry, the message from DOJ's Criminal Division is undercut by the fact that companies know they are far more likely to interact with DOJ's civil attorneys, who offer a far different message.[155]

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151. *See* Veronica Root, *Coordinating Compliance Incentives*, 102 CORNELL L. REV. 1003, 1046–47 (2017) (noting that the "incentivizing of corporations to adopt ethics and compliance programs" is harmed by "the coordination and responsibility challenges associated with inter- and intra-agency coordination").

152. *See supra* Sections I.A–B.

153. In 2020, for example, the Criminal Division's Fraud Section entered into thirteen corporate resolutions. Eight were FCPA resolutions. FRAUD SECTION 2020 YEAR IN REVIEW, *supra* note 63, at 6.

154. *See, e.g.*, Press Release, U.S. Att'y's Off. Dist. of N.J., U.S. Dep't of Just., Novartis AG and Subsidiaries to Pay $345 Million to Resolve Foreign Corrupt Practices Act Cases (June 25, 2020), https://www.justice.gov/usao-nj/pr/novartis-ag-and-subsidiaries-pay-345-million-resolve-foreign-corrupt-practices-act-cases [https://perma.cc/8HUV-CU6D]; Press Release, U.S. Dep't of Just., Fresenius Medical Care Agrees to Pay $231 Million in Criminal Penalties and Disgorgement to Resolve Foreign Corrupt Practices Act Charges (Mar. 29, 2019), https://www.justice.gov/opa/pr/fresenius-medical-care-agrees-pay-231-million-criminal-penalties-and-disgorgement-resolve#:~:text=KGaA%20(Fresenius)%2C%20a%20German,FCPA)%20in%20connection%20with%20Fresenius's [https://perma.cc/2BTJ-JPMM].

155. In fact, the health care FCPA defendants from 2019 and 2020 settled FCA cases with DOJ both before and after their FCPA resolutions. Press Release, U.S. Dep't of Just., Novartis Pharmaceuticals Corp. to Pay More than $420 Million to Resolve Off-Label Promotion and Kickback Allegations (Sept. 30, 2010), https://www.justice.gov/opa/pr/novartis-pharmaceuticals-corp-pay-more-420-million-resolve-label-promotion-and-kickback [https://perma.cc/ENK3-H3KG]; Press Release, U.S. Dep't of Just., Novartis Pays over $642 Million to Settle Allegations of Improper Payments to Patients and Physicians (July 1, 2020), https://www.justice.gov/opa/pr/novartis-pays-over-642-million-settle-allegations-improper-payments-patients-and-physicians [https://perma.cc/ADP8-ANRS]; Eric H. Holder, Jr., Deputy Att'y Gen., U.S. Dep't of Just., Announcement of Criminal Pleas and

D. A Missed Opportunity to Educate Industry

DOJ's failure to consider preexisting compliance programs in resolving FCA cases has another more concrete and direct harm. Government enforcement actions provide a rare opportunity for industries to learn from the compliance successes and failures of others because individual entities have little incentive to share such information themselves and corporate compliance activity is "overwhelmingly *non*transparent."[156] The information sharing thus occurs only when it is forced through government action, and then only if industry knows not only the wrongdoing that occurred, but also the compliance context in which it took place.

In the criminal context, DOJ has sought to educate companies about compliance expectations not only through issuing guidance documents, but also to some degree through its resolutions. Assistant Attorney General Leslie Caldwell encouraged industry to look to resolutions for guidance about what works and what does not, stating,

> In addition to their use as enforcement tools, our plea agreements, DPAs and NPAs provide a transparent explanation of the department's expectations when it comes to compliance programs. Companies seeking to measure their own compliance programs need look no further than many of the resolutions we have made publicly available.[157]

In FCA cases, however, that information is absent. Because DOJ does not share any information publicly regarding the compliance programs in place at the time of misconduct, organizations lack the opportunity to engage in the evaluation suggested by Assistant Attorney General

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Civil Settlements *United States v. Fesenius* (National Medical Care) (Jan. 19, 2000), https://www.justice.gov/archive/dag/speeches/2000/nmichaelhealthremarks.htm [https://perma.cc/TU3V-RUVH] (last visited Mar. 21, 2022); Press Release, U.S. Att'y's Off. Dist. of Mass., U.S. Dep't of Just., Fresenius Agrees to Pay $5.2 Million to Resolve Allegations that It Overbilled Medicare for Hepatitis B Tests (Oct. 9, 2019), https://www.justice.gov/usao-ma/pr/fresenius-agrees-pay-52-million-resolve-allegations-it-overbilled-medicare-hepatitis-b [https://perma.cc/T89Y-3GUJ].

156. Baer, *supra* note 139, at 358; Brandon L. Garrett & Gregory Mitchell, *Testing Compliance*, 83 LAW & CONTEMP. PROBS. 47, 69–70 (2020).

157. Leslie R. Caldwell, Assistant Att'y Gen., U.S. Dep't of Just., Remarks at New York University Law School's Program on Corporate Compliance and Enforcement (Apr. 17, 2015), https://www.justice.gov/opa/speech/assistant-attorney-general-leslie-r-caldwell-delivers-remarks-new-york-university-law [https://perma.cc/YS7Q-PV95]. This is not to say DOJ's current criminal model is perfect. Many, including Garrett and Mitchell, have criticized DOJ for sharing insufficient levels of detail regarding its assessments of corporate compliance programs in criminal resolutions. Garrett & Mitchell, *supra* note 156, at 63–64; *see also* Baer, *supra* note 139, at 363.

Caldwell.[158] This missed opportunity is particularly noticeable given the sophistication of the health care compliance industry.

V. CHALLENGES AND PATHS FORWARD

Fortunately, there is cause for optimism. DOJ is in the midst of making substantial changes to its FCA policies, offering increased transparency for the first time.[159] With this increased transparency comes an opportunity to address DOJ's failure to analyze and reward compliance programs. But fixing the problem will not be easy. This Part details challenges to DOJ efforts to change its policies and practices in this area and with those challenges in mind examines potential solutions. This Part concludes that DOJ would be best served by implementing a structure that borrows from the Civil Division's practice for considering ability-to-pay settlements and the Criminal Division's recent practice of hiring compliance experts to review corporate compliance programs.

A. Challenges to Rewarding Preexisting Compliance Programs

First, the current compression in FCA resolution multipliers makes it difficult to apply any economic reward in a meaningful way. The empirical analysis referenced in Section III.B now reflects 264 CSAs for which the restitution amount and thus the multiplier could be determined.[160] For the 264 CSAs, the mean multiplier was 1.78, and the median multiplier was 2.0. Of those 264 CSAs, 228 (86%) were at or below double damages—104 were at double damages, and 124 were between 1.0 and 1.9—while only 36 CSAs were above 2.0.[161]

158. The availability of Corporate Integrity Agreements with Health and Human Services, Office of the Inspector General in many health care cases, which do outline compliance requirements going forward and are valuable tools analyzed by the health care industry, are not a replacement for information regarding the state of the compliance program at the time the misconduct occurred. OFF. OF THE INSPECTOR GEN., DEP'T OF HEALTH & HUM. SERVS., CRITERIA FOR IMPLEMENTING SECTION 1128(B)(7) EXCLUSION AUTHORITY (2016), https://oig.hhs.gov/exclusions/files/1128b7exclusion-criteria.pdf [https://perma.cc/23VP-X8SH].

159. *See* Elberg, *A Path to Data-Driven Health Care Enforcement*, *supra* note 4, at 1189.

160. The more-than-300 figure with regard to lack of references to preexisting compliance programs includes resolutions that did not reference a restitution figure or that contained arrangements that made determination of the intended multiplier impossible. *See supra* Section III.B.

161. Additional details regarding the analysis's methodology can be found at Elberg, *A Path to Data-Driven Health Care Enforcement*, *supra* note 4, at 1193–94. There has been little change in the distribution of CSA multipliers between May 31, 2019 (the final date for the previously published analysis), and June 30, 2021 (the final date for this analysis). The previously published analysis, based on 89 CSAs for which the multiplier

Table 2. Multipliers

Multiplier	# of CSAs
> 2.0	36
2.0	104
< 2.0	124

When the mean multiplier is 1.78—and all resolutions must be sufficiently above 1.0 so that the government is made whole when considering lost interest, cost of investigation, and relator's share (in the case of a *qui tam*)—there is very little room for reward.[162] It will be difficult for DOJ to meaningfully reward good corporate citizens when misconduct occurs despite their best efforts *unless* DOJ begins using higher damages multipliers to deal more harshly with the truly bad corporate actors.

The compression evident in the settlement multipliers represents not only a failure to reward good corporate citizens, but also a failure to more severely punish truly bad corporate actors. Both failures are problematic and are best solved in tandem through a more nuanced—and more fulsome—use of the range permitted under the FCA. While rewarding preexisting compliance programs necessarily will mean a reduction in recoveries in appropriate cases, the effort should not reduce overall recoveries, as conducting the analysis will leave DOJ better prepared and more motivated to extract harsher (larger) settlements from those entities that DOJ determines did not have effective preexisting compliance programs.

Second, DOJ remains largely reliant on *qui tams* to further its FCA enforcement initiatives, and the structure of the *qui tam* system may disincentivize individual U.S. Attorney's Offices (which handle more than sixty percent of FCA cases without the involvement of the Commercial Litigation Branch in Washington, D.C.) from providing settlement-lowering deductions.[163] Individual U.S. Attorney's Offices are incentivized to compete for the attention of potential relators' counsel, who frequently are repeat players, largely control the distribution of cases among U.S. Attorney's Officers by deciding where to file their cases, and file their cases where the resolution is likely to be highest (as relators' share is a percentage of the government's recovery).[164] Civil prosecutors

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could be determined, found a mean multiplier of 1.78, a median multiplier of 2.0, and 88% of CSAs at or below double damages. *Id.*

162. *See generally* 2019 FCA Guidance, *supra* note 9; *see also* Elberg, *A Path to Data-Driven Health Care Enforcement*, *supra* note 4, at 1195–96.

163. Elberg, *A Path to Data-Driven Health Care Enforcement*, *supra* note 4, at 1199–1200.

164. *See* David Freeman Engstrom, *Harnessing the Private Attorney General: Evidence from Qui Tam Litigation*, 112 COLUM. L. REV. 1244, 1249 (2012) (analyzing *qui*

may face resistance to rewarding compliance programs: any reduction in the government's settlement demand means less money for relators and their counsel.[165]

But these problems apply with equal force to DOJ's efforts to reward the other compliant behaviors—self-disclosure, cooperation, and post-enforcement adoption of an effective compliance program—and DOJ has been willing to make those rewards a matter of official policy.[166] This raises the question of what else makes DOJ reluctant to judge compliance programs.

The answer likely was implicit in the DOJ Criminal Division's hiring of compliance experts to aid in evaluating compliance programs. The hiring of these experts can be seen as an admission of something already apparent: DOJ lacks the internal expertise necessary to confidently pass judgment on complex corporate compliance programs. DOJ made this admission explicitly decades ago in the Corporate Prosecution Principles, noting, "Many corporations operate in complex regulatory environments outside the normal experience of criminal prosecutors."[167] Even the most experienced health care prosecutors are not compliance experts by virtue of that work, and many corporate health care cases are not handled by DOJ attorneys who specialize in corporate health care matters.[168] The task of determining whether an organization's compliance program is both properly structured and resourced and is more than a "paper program" is a difficult one that DOJ attorneys are largely unqualified to undertake, leading DOJ to bring in compliance experts to work alongside DOJ criminal attorneys not only to develop compliance guidance, but also to examine and pass judgment on compliance programs in individual cases.[169]

Adding to the lack-of-knowledge problem is a challenge of imagination and lack of understanding of what can be expected of even the best compliance programs. Because of their role, DOJ prosecutors are necessarily reviewing compliance programs when they have failed.[170] It is

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tam filings and noting superior litigation outcomes in the large number of *qui tams* filed by repeat players); *see also* 31 U.S.C. § 3730(b)(2), (d).

165. Elberg, *Health Care Fraud Means Never Having to Say You're Sorry*, *supra* note 4, at 410–11 (noting that the same disincentives apply when U.S. Attorney's Offices are considering demanding admissions of guilt from FCA defendants).

166. *See* 2019 FCA Guidance, *supra* note 9.

167. U.S. Dep't of Just., Just. Manual § 9-28.800 (2019).

168. *Cf.* Miriam H. Baer, *Compliance Elites*, 88 FORDHAM L. REV. 1599 (2020) (discussing the specialized field of compliance separate and apart from subject-matter expertise).

169. U.S. Dep't of Just., Just. Manual § 9-28.800 (2019). DOJ's initiatives to hire compliance experts, to hire DOJ attorneys with prior compliance experience, and to train current DOJ attorneys all indicate an awareness by DOJ that its attorneys currently are unprepared to confidently do the necessary analysis. Benczkowski, *supra* note 40.

170. *See* Garrett & Mitchell, *supra* note 156, at 49–50.

difficult in that context to conclude anything other than "the compliance program must not have been effective—it didn't work." DOJ policy acknowledges that a compliance program may be effective even if wrongdoing has occurred, but it remains far easier to credit post-enforcement improvements to a compliance program (which by their very nature are so new that they have not had time to fail) than to defend to the public rewarding a compliance program while simultaneously denouncing the misconduct that occurred under its watch.[171] When outcome bias is combined with lack of compliance expertise, it would be understandable for civil prosecutors around the country to shy away from rewarding preexisting compliance programs. This is perhaps the only explanation for DOJ's seemingly indefensible policy in FCA cases of rewarding post-enforcement remedial measures to implement or improve a compliance program but not rewarding an organization whose compliance program was already effective before remediation.[172] Perhaps DOJ is ill-equipped to find in practice what it has acknowledged in theory—that a compliance program can be effective and still not prevent all misconduct.

B. Weighing the Potential Paths Forward

The question then becomes how to fill that knowledge gap. The Criminal Fraud Section presumably could rely on an individual expert in seeking to resolve a few dozen cases per year. With all Criminal Fraud Section prosecutors reporting up to leadership in Washington, D.C., the structure is well-suited to having all defendants seeking a resolution sit for a compliance meeting or meetings with a DOJ compliance expert in attendance.[173] Differences in the structure of civil enforcement, however, make such a system unworkable. The handling of civil FCA cases involves many more cases and is far less centralized.[174] That more than sixty percent of FCA resolutions are handled by individual U.S. Attorney's Offices without the involvement of the Commercial Litigation Branch in Washington, D.C., has profound implications for any DOJ effort to systematically and consistently evaluate compliance programs.[175] The

171. U.S. Dep't of Just., Just. Manual § 9-28.800 (2019) ("[T]he Department recognizes that no compliance program can ever prevent all criminal activity by a corporation's employees . . . ."); *see also id.* § 9-28.500 (2008) ("[I]t may not be appropriate to impose liability upon a corporation, particularly one with a robust compliance program in place, under a strict *respondeat superior* theory for the single isolated act of a rogue employee.").

172. *See supra* Sections III.A–B.

173. FRAUD SECTION 2020 YEAR IN REVIEW, *supra* note 63, at 1–3; FRAUD SECTION 2019 YEAR IN REVIEW, *supra* note 63, at 1–2.

174. *See* Elberg, *A Path to Data-Driven Health Care Enforcement*, *supra* note 4, app. 1, at 1216.

175. *See id.*

large number of FCA cases DOJ-wide may appear to provide ample opportunity for DOJ to build an expertise in evaluating compliance programs, but as the system is currently structured, that is easier said than done: cases are spread throughout the country so that dozens of different U.S. Attorney's Offices are involved in resolving FCA matters, many handling only one or two cases per year.[176] Even were development of this expertise to be done by the Commercial Litigation Branch based on the significant volume of cases in which it is involved, that expertise would be applied only to the fewer than forty percent of FCA resolutions in which the Commercial Litigation Branch is involved, creating a problematic disparity. The problem is thus not only lack of policy, but also lack of the structure necessary to implement a policy of rewarding compliance programs. Without a significant structure in place, troubling inconsistency in application of any policy would be likely if not certain.[177]

One possible solution would be for DOJ to make use of the expertise already employed by the federal government at the Department of Health and Human Services. The Justice Manual directs criminal prosecutors to "consult with relevant federal and state agencies with the expertise to evaluate the adequacy of a program's design and implementation[—f]or instance . . . the Department of Health and Human Services . . . ."[178] There would be some clear synergies with this option, as Health and Human Services' Office of Counsel to the Inspector General (OCIG) is already involved in most civil FCA cases, including completing a compliance evaluation as part of determining whether to impose a corporate integrity agreement and, if it does so, what that agreement will entail. But this solution has several problems. It would require significant additional work for OCIG and would amount to an unfunded mandate from DOJ. OCIG's current compliance evaluation is focused not on the program in place at the time of the offense, but instead on the program in place at the time of the resolution.[179] For the same reasons, it would risk pulling OCIG

176. *Id.* at 1198–99.

177. As I have previously written, data analysis reveals that a lack of guidance has resulted in a lack of uniformity across the country, with U.S. Attorney's Offices seemingly calculating FCA resolutions differently when the Commercial Litigation Branch is not involved. *Id.* at 1212. This prompts the question of how (or whether) DOJ is evaluating defendants' post-enforcement improvement to compliance programs in order to reward that conduct consistent with the 2019 FCA Guidance. *See id.*

178. U.S. Dep't of Just., Just. Manual § 9-28.800 (2019).

179. Notably, when conducting its risk assessment for purposes of determining whether to exclude an entity from participation in federal health care programs, require a corporate integrity agreement (CIA) in lieu of exclusion, or decline exclusion without requiring a CIA, OCIG considers self-disclosure, cooperation, and remedial measures but explicitly notes within "History of Compliance" that "[t]he existence of a compliance program . . . does not affect the risk assessment." OFF. OF THE INSPECTOR GEN., *supra* note 158, at 7. Thus, as with DOJ, health care entities cannot currently expect to receive from OCIG a benefit for having an effective compliance program in place at the time of the

personnel away from their current important functions.[180] It would still be insufficient to achieve consistency, as not all health care FCA matters involve OCIG. And perhaps most fatal to this solution, the Criminal Division's hiring of compliance experts evinces DOJ's preference for directly employing and supervising the people involved in this important work.

Considering the magnitude of DOJ's FCA recoveries and the importance of this issue, a preferable alternative solution would be to hire a team of compliance experts and implement a policy whereby those experts should be consulted before all resolutions in which the defendant seeks a preexisting compliance program benefit, even if the case is handled without the Commercial Litigation Branch. The team would be large enough to have an expert evaluate every case in which a defendant claimed entitlement to a preexisting compliance program benefit, but small enough to achieve consistency.

Adding compliance experts—while also issuing guidance regarding what information they will consider[181] and what benefits defendants may receive—would in many respects mimic the structure currently in place for evaluating FCA defendants' claims that they lack sufficient resources to satisfy the payment sought by DOJ.[182] In a September 2020

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wrongdoing. It will not increase the likelihood of avoiding a CIA. OCIG's exclusion criteria guidance notes that it determines neither exclusion nor a CIA are generally necessary in cases of small-dollar losses or where the settling entity is a successor owner, is not based on compliant behaviors, and particularly is not based on a finding of an effective preexisting compliance program. *Id.* Given OCIG's exclusion criteria, focusing on preexisting compliance programs would require OCIG to expand on its current role and analysis.

180. [The OCIG] provides timely, accurate and persuasive legal advocacy and counsel to the Inspector General and OIG's other components. The OCIG, which acts as a full-service, in-house legal counsel, also:

- Offers advice and representation on HHS programs and operations, employment, administrative law issues, and criminal procedure;
- imposes program exclusions and civil monetary penalties on health care providers;
- represents OIG in the global settlement of cases arising under the civil False Claims Act, develops and monitors corporate integrity agreements, develops compliance program guidance; and
- renders advisory opinions on OIG sanctions and issues fraud alerts and other industry guidance.

Office of Counsel to the Inspector General, HHS-OIG, https://oig.hhs.gov/about-oig/office-counsel-inspector-general/ [https://perma.cc/CH8U-76PM] (last visited Mar. 21, 2022).

181. Ideally, there would be coordination between those creating civil FCA policy for evaluating compliance programs and those responsible for DOJ's Criminal Division compliance guidance.

182. *See* Memorandum from Ethan P. Davis, Acting Assistant Att'y Gen. Civ. Div., U.S. Dep't of Just., to All Civil Division Employees 1–3 (Sept. 4, 2020),

memorandum, DOJ laid out a general policy regarding inability to pay, listed factors DOJ will consider when making an assessment of a defendant's inability to pay, and noted that "in evaluating such an assertion . . . [DOJ will] typically [use] the assistance of a qualified financial expert," who will consider information from a financial disclosure form along with additional factors.[183] In evaluating compliance programs for purposes of an FCA resolution benefit, DOJ could similarly create a standard form, to be adjusted for the unique circumstances of each case and health care subsector, as a consistent starting point for DOJ's evaluation.

Even with a team of five or more experts, the cost would be negligible compared to DOJ's billions of dollars in health care FCA recoveries, never mind the "billions more in losses" DOJ claims to prevent through deterrence.[184] Given the impact of this issue on deterrence and promoting compliance, it would seemingly be money well spent.

A final, less desirable option would be to promote transparency, acknowledging that DOJ does not separately reward preexisting compliance programs in resolving FCA cases. As noted above, there are already substantial economic incentives for organizations to adopt compliance programs even without their being singled out for a benefit.[185] And DOJ could (and, as I have argued previously, *should*) increase those economic incentives by increasing the settlement multiplier used in cases in which the defendant organization does not have applicable mitigating factors.[186]

DOJ also can increase economic incentives for maintaining an effective compliance program by increasing and publicizing benefits for self-disclosure. Because an effective compliance program will increase the chances that an organization will be in a position to make a self-disclosure, providing clear and meaningful benefits for self-disclosure will provide an economic incentive not only to self-disclose, but also to invest in compliance in the hopes of making self-disclosure possible.[187] As noted

https://www.justice.gov/civil/page/file/1313361/download [https://perma.cc/55VH-NZBP].

183. *Id.*

184. DOJ Jan. 14, 2021, Press Release, *supra* note 7.

185. *See supra* Part IV.

186. Elberg, *A Path to Data-Driven Health Care Enforcement*, *supra* note 4, at 1206–07.

187. The inverse of this also must be kept in mind if DOJ adopts a system of rewarding preexisting compliance programs in FCA resolutions. It remains crucial that DOJ not reward entities that, through their effective compliance programs, discover misconduct, yet fail to self-disclose and cooperate. Benefits for maintaining an effective preexisting compliance program are significant where, despite the company's best efforts, they fail to detect the wrongdoing. In that situation, a reduction is necessary to avoid treating the entity the same as one who failed to invest in compliance. Where the wrongdoing is detected, however, self-disclosure and cooperation should be a prerequisite

above, DOJ may now be making strides in this area—a positive development regardless of what happens with treatment of preexisting compliance programs.[188]

And the benefits for compliance programs go beyond just avoiding financial penalties from government enforcers. Braithwaite and others have written about the extent to which avoiding reputational harm is, for many corporate executives, a substantial motivator.[189] As noted, these incentives would be far more significant if DOJ used public evaluation of compliance programs to separate the truly bad actors from good corporate citizens,[190] but failure to do so does not mean DOJ announcements of FCA resolutions lack any reputational impact.[191]

A separate incentive may come not from potential reputational harm, but from the impact of effective compliance programs even in the absence of government enforcement. Surveys have shown that, particularly among younger workers, mission and values are important draws and may aid in corporate recruitment and retention. A 2018 survey found that 71% of professionals said they would be willing to accept less money to work for a company "that has a mission they believe in and shared values."[192] The percentage was even higher (86%) among younger employees.[193] Nearly 40% of respondents said they would leave their current job "if their employer were to ask them to do something they have an ethical or moral conflict with."[194] It seems likely these perspectives are especially true in health care, a field those seeking a calling beyond profit and income frequently seek to enter.[195]

Where this transparency-only option fails, ultimately, is not in the need for increased incentives for organizations to invest in compliance

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for obtaining any compliance benefit. *See* Jennifer Arlen, *Corporate Criminal Enforcement in the United States: Using Negotiated Settlements to Turn Corporate Criminals into Corporate Cops* 12–14 (N.Y. Univ. Sch. of L., Working Paper Nos. 17-12, 17-09, 2017), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2951972.

188. *See supra* Section III.B.

189. FISSE & BRAITHWAITE, *supra* note 136, at 247–49.

190. *See, e.g.*, *id.* If, for example, DOJ is regularly (or even occasionally) declining to bring a potential FCA case despite a clear violation because DOJ is exercising its discretion based on the entity's maintenance of an effective compliance program, such decisions should be publicized.

191. *See supra* Section IV.A.

192. Nina McQueen, *Workplace Culture Trends: The Key to Hiring (and Keeping) Top Talent in 2018*, LINKEDIN (June 26, 2018), https://blog.linkedin.com/2018/june/26/workplace-culture-trends-the-key-to-hiring-and-keeping-top-talent [https://perma.cc/HSN2-MYPY].

193. Zameena Mejia, *Nearly 9 out of 10 Millennials Would Consider Taking a Pay Cut to Get This*, CNBC (June 28, 2018, 2:24 PM), https://www.cnbc.com/2018/06/27/nearly-9-out-of-10-millennials-would-consider-a-pay-cut-to-get-this.html [https://perma.cc/BJ2X-XH7U].

194. McQueen, *supra* note 192.

195. *See, e.g.*, AYRES & BRAITHWAITE, *supra* note 130, at 22–23.

programs, but in the messages sent about what DOJ values and the impact of those messages on perceptions of fairness and legitimacy of the enforcement regime. Transparency about what DOJ is not doing would be preferable to the current lack of clarity, which may lead to cynicism and lack of trust from those who feel DOJ's practice does not match its public statements and purported values.[196] But actually making DOJ's practice match its public statements and purported values would be even better and is necessary to show that DOJ's values match those of good corporate citizens.

CONCLUSION

With DOJ ramping up its claimed commitment to encouraging corporate compliance programs and the increased focus on DOJ's FCA practices due to recent policy changes, DOJ's failure to directly reward corporate compliance programs in FCA resolutions is indefensible and is a threat to the health care industry's views of the enforcement regime's fairness and legitimacy. Although DOJ has recognized that industry trust and faith in the values of its enforcers impact industry's commitment to compliance, DOJ thus far has not done what is necessary to properly reward—both economically and publicly—the actions of good corporate citizens to invest in compliance and attempt to stop misconduct before it occurs.

By all indications, DOJ's failure in this area is not based on a lack of desire to incentivize investments in compliance programs, but is based instead on a lack of resources currently in place to enable DOJ to perform the necessary analyses—and do it well. Fortunately, given the scope and consistency of DOJ's recoveries in FCA cases, the limited cost of a solution should not be an obstacle, and models already are in place with the Criminal Division's hiring of compliance experts and the Civil Division's use of experts to analyze ability to pay claims. As DOJ has recognized that deterrence and compliance programs prevent billions of dollars in fraud each year, a combination of the two—a team of compliance experts to analyze requests for mitigation based on an

196. *See, e.g.*, Marcos D. Jiménez & Dana Foster, *The Importance of Compliance Programs for the Health Care Industry*, 7 U. MIA. BUS. L. REV. 503, 504 (1999) (stating that if a compliance program's "preventative function somehow fails it can reduce the penalties imposed in a . . . civil proceeding" in an article written by a law firm partner whose practice focuses on such matters and who serves on the board of trustees of an entity controlling four hospitals and other health care entities); *see also* Jack Pirozzolo & Doreen Rachal, *Expect Aggressive Health Care Scrutiny From Mass. U.S. Atty.*, LAW360 (Mar. 30, 2021, 5:56 PM) https://www.law360.com/articles/1370431/expect-aggressive-health-care-scrutiny-from-mass-us-atty [https://perma.cc/6BXB-R8NM] (asserting that an organization being investigated for potential FCA violations "will find itself in a far better position" if it can show it had a "genuine commitment to providing adequate resources and expertise" in matters of compliance).

organization's compliance program—would require a small investment with an anticipated substantial reward both in fraud prevented and improvement in the fragile relationship between DOJ and the health care industry.