A GAP IN THE HEALTH CARE INDUSTRY: RETHINKING THE DEPARTMENT OF JUSTICE'S APPROACH TO CORPORATE COMPLIANCE PROGRAMS AND CIVIL FALSE CLAIMS

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I. INTRODUCTION

An individual or entity charged with criminal or civil violations for corporate wrongdoing or fraud against the government may attempt to use their effective compliance program as evidence to reduce liability.[1] Some scholars and practitioners have suggested that an effective compliance program can essentially be a defense to criminal charges, but there is no comparable defense in civil cases.[2] This dichotomy leaves a significant recognition gap in the health care industry. The reason for this gap is because the majority of the settlements and judgments recovered by the Department of Justice ("DOJ") relate to matters in the health care industry brought under the False Claims Act ("FCA"), and most individuals bring these

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[1] U.S. Deputy Att'y Gen., *Guidance on the Use of the Civil False Claims Act in Civil Health Care Matters* (updated Mar. 3, 2017), https://www.justice.gov/archives/dag/memo-guidance-use-false-claims-act-civil-health-care-matters-june-3-1998; Lewis Morris & Gary W. Thompson, *Reflections on the Government's Stick and Carrot Approach to Fighting Health Care Fraud*, 51 ALA. L. REV. 319, 348 (1999).

[2] Marc S. Raspanti & Gregg W. Mackuse, *What's Really So Important About an Effective Compliance Program?*, THE CHAMPION, May 2007, at 22 ("The conventional belief in some compliance and in most law enforcement and prosecutorial circles is that an effective compliance program may insulate a corporation from criminal charges.").

claims civilly.[3,4] The FCA is a series of federally enacted statutes to address fraud against the government.[5] A person or entity violates the FCA when they falsely obtain "money from the government or [are] improperly relieved from paying money to the government."[6]

Advocating for a compliance program defense in criminal investigations creates an inconsistency in the law for civil investigations. The current framework does not further the DOJ's goal, particularly in the health care industry, of deterring and preventing fraud before it occurs.[7] The current framework also does not enable the DOJ to use the FCA to its full potential as their primary weapon for fighting fraud against the government.[8] Part II of this Comment sets out the history of the FCA, an overview of corporate responsibility, how companies have relied on their corporate compliance programs in reducing criminal charges, and how the DOJ currently approaches civil claims under the FCA. Part III discusses how the differences in

[3] *Justice Department Recovers Over $3 Billion from False Claims Act Cases in Fiscal Year 2019*, U.S. DEP'T. OF JUST. (Jan. 9, 2020), https://www.justice.gov/opa/pr/justice-department-recovers-over-3-billion-false-claims-act-cases-fiscal-year-2019 (stating that more than $3 billion in settlements and judgments was obtained by the government from fraud and false claims against them and, of that amount, $2.6 billion involved matters relating to the health care industry).

[4] *See* Victor E. Schwartz & Phil Goldberg, *Carrots and Sticks: Placing Rewards as Well as Punishment in Regulatory and Tort Law*, 51 HARV. J. LEGIS. 315, 338 (2014).

[5] Jim Moye, *Are We Bulletproof?: A Defensive Business Strategy to Protect Health Care Companies from False Claims Act Litigation and Corporate Integrity Agreements*, 41 U. BALT. L. F. 24, 28 (2010); *see* Katheryn Ehler-Lejcher, *The Expansion of Corporate Compliance: Guidance for Health Care Entities*, 25 WM. MITCHELL L. REV. 1339, 1372 (1999) (noting that the FCA was first enacted in 1863 to aid the defense industry in fighting fraud but was later revived to address all industries).

[6] 31 U.S.C. § 3729; Morris & Thompson, *supra* note 1, at 328.

[7] *Justice Department Recovers Over $3 Billion from False Claims Act Cases in Fiscal Year 2019*, U.S. DEP'T. OF JUST. (January 2020), https://www.justice.gov/opa/pr/justice-department-recovers-over-3-billion-false-claims-act-cases-fiscal-year-2019 (stating that "the significant number of settlements and judgments obtained over the past year demonstrate the high priority this administration places on deterring fraud against the government").

[8] S. REP. NO. 99-345, at 2 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5266; *see* Morris & Thompson, *supra* note 1, at 327.

criminal and civil charges impact the health care field as the industry with the largest number of claims brought under the FCA. Part IV provides a solution by suggesting effective compliance programs as an affirmative defense to civil charges. Part IV also discusses what factors would constitute an effective compliance program. Finally, Part IV addresses the opposition to this new framework.

This comment will argue that the issue in supporting compliance programs as a defense to corporate criminal charges is that it leaves out the widely brought claims from the health care industry under the civil FCA. This paper concludes that individuals should support an argument for an affirmative compliance defense for civil cases, like criminal cases. The DOJ should use its discretionary authority to initiate a new policy that allows companies facing civil liability under the FCA to present evidence of its effective compliance program as an absolute defense to the fines and penalties.

II. BACKGROUND

A. *History of the False Claims Act*

Congress first signed the FCA into law in 1863 to address fraud against the government during the Civil War.[9] The law was largely unused until its revival in 1986 when Congress strengthened the statute due to escalating fraud against the government.[10] Congress first enacted the broadly written FCA to be used for fraud against the military, but it eventually became the government's primary tool to fight fraud against all federally funded programs.[11] In response to increased Medicare and Medicaid fraud, the DOJ began using the FCA to combat health care fraud.[12] The FCA prohibits frauds including, but not limited

[9] S. REP. NO. 99-345, at 4 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5269. The law was passed in response to contractor fraud against the Union Army during the Civil War.

[10] Morris & Thompson, *supra* note 1, at 328.

[11] S. REP. NO. 99-345, at 9 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5273; Morris & Thompson, *supra* note 1, at 327.

[12] *See* Peterson v. Weinberger, 508 F.2d 45, 52 (5th Cir. 1975) (holding that the government directly or indirectly pays for claims of Medicare and Medicaid, thus triggering liability under the FCA for false claims to those programs); Morris

to: (1) knowingly submitting, or causing to be submitted, to the federal government a false or fraudulent claim for payment; (2) knowingly using, or causing to be used, a false record or statement to get a false or fraudulent claim paid by the government; (3) conspiring with others to get a false or fraudulent claim paid by the government; and (4) knowingly using, or causing to be used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the government ("reverse false claim").[13]

Under the FCA, both the DOJ and private individuals may bring an action on behalf of the federal government.[14] Individuals, usually employees of a company, may bring qui tam suits under the FCA, which allow private parties, or "relators" to allege FCA violations on behalf of the government and share in any recovery.[15] When a party files a qui tam complaint, the DOJ launches an investigation into the alleged acts and decides whether to intervene.[16] If the DOJ decides to intervene, it becomes the primary prosecutor on the case, while the relator remains a party.[17] The FCA imposes heightened penalties per violation, treble damages, and debarment as methods to deter illegal conduct.[18] The relator also receives an award for bringing the fraudulent acts to the DOJ's attention and may receive up to 25% of the award if the government intervenes and up to 30% if the government does not intervene.[19] One of the main goals of the 1986 amendments was to enhance the qui tam provision of the law because Congress believed there should be a "coordinated effort" between the government and the relator to oppose those defrauding federal funds.[20] Relators started

& Thompson, *supra* note 1, at 327.

13 31 U.S.C. § 3729(a)(1)-(7).

14 *See* 31 U.S.C. § 3730(a)–(b); *Fixing the False Claims Act: The Case for Compliance-Focused Reforms*, U.S. CHAMBER INST. FOR LEGAL REFORM, 6 (2013), https://instituteforlegalreform.com/research/fixing-the-false-claims-act-the-case-for-compliance-focused-reforms/ [hereinafter Compliance-Focused Reforms].

15 Morris & Thompson, *supra* note 1, at 329.

16 Compliance-Focused Reforms, *supra* note 14.

17 31 U.S.C. § 3730(c); *see* Compliance-Focused Reforms, *supra* note 14.

18 Schwartz & Goldberg, *supra* note 4, at 337–38; *see* 31 U.S.C. § 3729(a)(1).

19 31 U.S.C. § 3730(d)(1)-(2); *see* Schwartz & Goldberg, *supra* note 4, at 345.

20 *See* S. REP. NO. 99-345, at 2 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 5266, 5266–67.

responding to Congress' action, and the number of qui tam suits increased each year.[21] Notably, anti-fraud efforts in the health care industry became law enforcement's primary focus, with public policymakers and private citizens increasingly seeking to join these efforts.[22] By 1996, most parties bringing qui tam suits were bringing claims against health care providers, and these kinds of claims continue to be the majority today.[23]

B. *Corporate Responsibility*

Traditionally, under the doctrine of respondeat superior, corporations can be held vicariously liable for employee misconduct.[24] Illegal actions by the agents of a corporation, within the scope of their employment, may be imputed to the corporation either criminally or civilly.[25] Even in situations where the employee's actions were explicitly forbidden by the corporation or were contrary to corporate policy, the corporation can still be held liable.[26] Thus, under the current law, a corporation with an effective compliance program can do

21 Morris & Thompson, *supra* note 1, at 329.

22 Morris & Thompson, *supra* note 1, at 329–30.

23 Morris & Thompson, *supra* note 1, at 330.

24 *See* Restatement (Third) of Agency § 7.07 (Am. Law Inst. 2006).

25 N.Y.C. & H.R.R. Co. v. United States, 212 U.S. 481, 493–94 (1909) (holding that tort doctrine of respondeat superior, which holds a corporation liable for actions of its agent within scope of employment, can render corporation criminally liable*);* Lake Shore & M.S.R. Co. v. Prentice, 147 U.S. 101, 109 (1893) (holding that for acts done by agents of corporation, in course of employment, corporation is responsible to same extent an individual is responsible under similar circumstances).

26 Kevin B. Huff, *The Role of Corporate Compliance Programs in Determining Corporate Criminal Liability: A Suggested Approach*, 96 COLUM. L. REV. 1252, 1259 (1996); *see e.g.*, United States v. Twentieth Century Fox Film Corp., 882 F.2d 656, 660 (2d Cir. 1989) (holding that no matter how extensive a corporation's compliance program is, corporation is not immune from liability when an employee fails to comply with the law); United States v. Automated Medical Labs., Inc., 770 F.2d 399, 407 (4th Cir. 1985) (stating that a corporation would still be held liable even when employee's actions were "contrary to corporate policy"); United States v. Basic Constr. Co., 711 F.2d 570, 573 (4th Cir. 1983) (noting that corporation may still be held liable for employee's illegal acts, even if such acts were "against corporate policy or express instructions"). The Restatement notes that even an employee's unauthorized conduct is still within the scope of employment. Restatement (Second) of Agency § 230 (Am. Law Inst. 1958) ("An act, although forbidden[] . . . may be within the scope of employment.").

everything right but is still not immune from liability for an employee's wrongful actions.[27] This system provides little incentive for corporations to effectively regulate their employees' conduct and fails to reward compliance programs.[28]

C. *The DOJ's Approach to Criminal Charges*

For criminal prosecutions of noncompliance, there is a clearly defined and detailed framework surrounding rewards for compliance programs, cooperation credit for self-disclosure, and actual calculations for how compliance will affect criminal fines. An organization may have its criminal penalties reduced after a conviction, or the prosecutor may choose not to proceed due to an effective compliance program.[29] An effective compliance program generally might include "an internal audit of the current processes; a determination of what current practices may be illegal or potentially abusive; a written code of conduct for management and staff; a training program for employees; and a periodic audit to ensure that the adopted standards are being followed."[30] In some law enforcement and prosecutorial settings, it is believed that effective compliance programs should shield a corporation from criminal charges.[31] Under this view, denying corporate charges to companies who have a convincing compliance structure rewards the company and allows prosecutorial resources to focus on those that have ignored the compliance scheme.[32] A strong compliance program can reduce a company's liability because it can show the company had a system in place to comply with the law and that it did not have the requisite intent needed for the government to prove the

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27 Huff, *supra* note 26, at 1254.

28 Charles J. Walsh & Alissa Pyrich, *Corporate Compliance Programs as a Defense to Criminal Liability: Can a Corporation Save its Soul?*, 47 RUTGERS L. REV. 605, 678 (1995); Harvey L. Pitt & Karl A. Groskaufmanis, *Minimizing Corporate Civil and Criminal Liability: A Second Look at Corporate Codes of Conduct*, 78 GEO. L. J. 1559, 1645 (1990).

29 David Favre, Alexander Bodaken et al., *Health Care Fraud*, 57 AM. CRIM. REV. 895, 943 (2020).

30 *Id.*

31 Raspanti & Mackuse, *supra* note 2.

32 Corporate Criminal Liability and Prevention § 14.01.

illegal act.[33]

When determining whether to bring criminal charges against a corporation, prosecutors use the "Principles of Federal Prosecution of Business Organizations" in their investigations.[34] These principles make clear that the DOJ considers compliance significantly in deciding whether to bring charges and negotiating agreements with corporations.[35] The Justice Manual ("JM") lists eleven factors to be considered, but two directly reward behaviors related to compliance programs. "[T]he adequacy and effectiveness of the corporation's compliance program at the time of the offense . . . and the corporation's remedial actions, including . . . any efforts to implement an adequate and effective corporate compliance program or to improve an existing one."[36]

Further, the United States Sentencing Guidelines (hereinafter "Sentencing Guidelines") acknowledge compliance programs in reducing a corporation's sentence and provide a specific framework in calculating their fine based on a "culpability score."[37] The Sentencing Guidelines provide how the court determines the fine by calculating the "base fine" and adjusting it based on the culpability score.[38] The Sentencing Guidelines explicitly grant the court the power to reduce a criminal fine based upon finding an existing compliance program.[39] One of the factors specifically expressed is whether the crime occurred "despite an effective program to prevent and detect violations."[40] A company's culpability score is reduced by three points if the offense occurred regardless of an effective compliance program in place.[41]

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[33] Morris & Thompson, *supra* note 1, at 348; *but see supra* Part II on Corporate Responsibility.

[34] U.S. Dep't of Just., Just. Manual § 9-28.300 (July 2020), https://www.justice.gov/jm/jm-9-28000-principles-federal-prosecution-business-organizations [hereinafter Corporate Prosecution Principles].

[35] *Id.*; *see* Jacob T. Elberg, *A Path to Data-Driven Health Care Enforcement*, 20 UTAH L. REV. 1169, 1172 (2020).

[36] Corporate Prosecution Principles, *supra* note 34.

[37] U.S.S.G § 8C2.5; Huff, *supra* note 26, at 1267–68.

[38] U.S.S.G § 8C2.5.

[39] U.S.S.G. § 8C2.5(f).

[40] *Id.*

[41] *Id.*; Dan K. Webb & Steven F. Molo, *Some Practical Considerations in*

In an April 2019 guidance document, updated in June 2020, the DOJ's Criminal Division issued a robust framework on what companies should address in their compliance programs and the elements necessary to reduce a criminal sentence.[42] A company that is convicted of criminal wrongdoing but meets the requirements for an effective compliance program under the Sentencing Guidelines can receive as much as a 95% reduction of its "base fine."[43] Going beyond reducing the amount of the fines, arguing for a compliance program as a potential defense to criminal charges would allow the DOJ and companies with efficient compliance programs to partner together to combat fraud and corruption.[44]

Beyond the Corporate Prosecution Principles and Sentencing Guidelines, the DOJ has also established additional incentives for compliant behaviors and has continuously increased its guidance and transparency to rewarding compliant behaviors.[45] While focused on the Foreign Corrupt Practices Act ("FCPA"), the DOJ has made formal incentives for cooperation, self-disclosure, and remedial investments in compliance programs through the FCPA Resource Guide in 2012 and formalizing the FCPA Pilot Program into the Corporate Enforcement Policy in the JM in 2018.[46] The Corporate Enforcement Policy is binding in FCPA cases and is "aimed at

Developing Effective Compliance Programs: A Framework for Meeting the Requirements of the Sentencing Guidelines, 71 WASH. U. L. Q. 375, 378–79 (1993).

[42] Dep't. of Just. Crim. Div., *Evaluation of Corporate Compliance Programs*, U.S. DEP'T. OF JUST. (June 2020), https://www.justice.gov/criminal-fraud/page/file/937501/download.

[43] The Federal Sentencing Guidelines for Organizations at Twenty Years, 22 ETHICS RESOURCE CTR. (2012), https://www.theagc.org/docs/f12.10.pdf; Marcia Narine, *Whistleblowers and Rogues: An Urgent Call for an Affirmative Defense to Corporate Criminal Liability*, 62 CATH. U. L. REV. 41, 68 (2012); *see generally* U.S.S.G. §§ 8C2.4–2.7.

[44] Schwartz & Goldberg, *supra* note 4, at 319.

[45] Elberg, *supra* note 35, at 1177.

[46] *See* Elberg, *supra* note 35, at 1177; U.S. Dep't of Just. & U.S. SEC, *A Resource Guide To The U.S. Foreign Corrupt Practices Act*, U.S. DEP'T OF JUST. (2012), https://www.justice.gov/criminal-fraud/file/1292051/download; Rod Rosenstein, Deputy Att'y Gen., U.S. Dep't of Just., Remarks at 34th International Conference on the Foreign Corrupt Practices Act (Nov. 29, 2017) *in* JUST. NEWS, Nov. 29, 2017, https://www.justice.gov/opa/speech/deputy-attorney-general-rosenstein-delivers-remarks-34th-international-conference-foreign.

providing additional benefits to companies based on their corporate behavior once they learn of misconduct."[47] Essentially, a company may have done nothing to stop the misconduct, but can still reduce its penalties by cooperating after the wrongdoing occurs.[48] This allows the DOJ to agree to or recommend to a sentencing court a 50% reduction off the low end of the Sentencing Guidelines fines.[49] Additionally, in 2018, the DOJ announced the Corporate Enforcement Policy could be used as "nonbinding guidance" in other corporate criminal areas outside the FCPA.[50] While it is important to provide these types of incentives to companies for their compliant behaviors, it is also important to recognize that the DOJ has the power to further deter any wrongdoing by detecting the misconduct before it reaches the level of prosecution, in criminal and civil cases. This can be accomplished with a compliance program defense which will incentivize companies to invest in their compliance programs and allow criminal and civil cases to be treated consistently.

Additionally, in two instances, the United States Courts of Appeals have concluded that a jury may consider a compliance program to decide whether they are liable for criminal actions of their employees.[51] These cases provide the basis for an argument in favor of a compliance defense. In *United States v. Basic Constr. Co.*,[52] the defendants were charged with conspiring to rig the bidding for state road paving contracts, and the jury received instructions that "[a] corporation may be responsible for the action of its agents . . . even though the conduct . . . may be contrary to the corporation's actual instructions . . . . [but], the existence of such instructions and policies . . . may be considered

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[47] U.S. Dep't of Just., Justice Manual § 9-47.120(1) (2019), https://www.justice.gov/jm/jm-9-47000-foreign-corrupt-practices-act-1977#9-47.120.

[48] *Id.*

[49] *Id.*

[50] John P. Cronan, Principal Deputy Assistant Att'y Gen., Remarks at Practising Law Institute Event (Nov. 28, 2018), in JUST. NEWS, Nov. 28, 2018, https://www.justice.gov/opa/speech/principal-deputy-assistant-attorney-general-john-p-cronan-delivers-remarks-practising-law.

[51] Huff, *supra* note 26, at 1253; *See* United States v. Basic Constr. Co., 711 F.2d 570, 573 (4th Cir. 1983); United States v. Beusch, 596 F.2d 871, 878 (9th Cir. 1979).

[52] United States v. Basic Constr. Co., 711 F.2d 570, 572 (4th Cir. 1983).

by you in determining [liability]."[53] In *United States v. Beusch*,[54] the corporation was convicted for an employee's failure to report receipt of currency in an amount exceeding $5,000 from outside the United States, and the court held that vicarious liability may hold a corporation liable for acts of its employees done against the express instructions and policies, but that the "existence of [] instructions and policies may be considered in determining whether the [corporation is liable for the actions of an employee]."[55] Notably, the court also held that because a compliance program may be weighed in determining a corporation's liability, the corporation is not subject to strict liability.[56]

In other sectors, such as securities law, federal regulatory laws recognize compliance programs as a defense to regulatory offenses and as an affirmative requirement.[57] The securities law, under which controlling persons may be held liable for their employees' illegal actions, provides a "good faith defense" which encompasses compliance programs.[58] The law establishes that an employer, who exercised due care in supervising its employees and can show that they diligently enforced an adequate internal supervision system at the time of the misconduct, can invoke the defense.[59]

The Model Penal Code also establishes a "due diligence" defense to criminal charges for a corporation's regulatory

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53 *Id.*

54 *Beusch*, 596 F.2d at 873, 878.

55 *Id.*

56 *Id.* at 878; *see* Huff, *supra* note 26, at 1266.

57 Huff, *supra* note 26, at 1270–71.

58 *See* 15 U.S.C. § 78t(a)

> Every person who, directly or indirectly, controls any person liable under any provision of this chapter or of any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable, unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action.;

Huff, *supra* note 26 at 1271.

59 *See* 15 U.S.C. § 78t(a) (1994); Huff, *supra* note 26, at 1271.

offenses.[60] The corporation needs to prove by a preponderance of the evidence that a high-level manager attempted due diligence to prevent the crime.[61] This defense would show that the company did not have the requisite mens rea to commit the offense.[62] Scholars argue that this approach furthers the goal of deterrence by "encouraging corporations to engage in self-policing."[63] In many cases where a corporation is able to escape criminal sanctions, they still must pay significant fines under civil liability.[64]

The defenses mentioned above are only available to a corporation facing criminal charges. But there is no guidance or transparency from the DOJ in how they calculate resolutions for civil false claims.[65]

D. *The DOJ's Approach to Civil Charges*

The DOJ's substantial guidance on rewarding compliant behavior in criminal matters, including a robust framework and incentive structure, has led to advocacy for a compliance defense in criminal matters. But there has not been the same kind of discussion among the DOJ or scholars for a compliance defense for civil penalties. This substantially impacts the health care companies facing charges because they are likely to be held civilly liable and are not given the same rewards to reduce their liability as under the criminal structure.[66] In stark contrast to the detailed Corporate Prosecution Principle discussed above, until 2015 it was not clear whether the DOJ even had a policy of rewarding corporations for their compliant behaviors in civil cases.[67] The

60 Model Penal Code § 2.07(5) (1985); Huff, *supra* note 26, at 1273.

61 Model Penal Code § 2.07(5) (1985); Huff, *supra* note 26, at 1273.

62 Huff, *supra* note 26, at 1274.

63 Huff, *supra* note 26, at 1274.

64 Sara Sun Beale, *The Development and Evolution of the U.S. Law of Corporate Criminal Liability and the Yates Memo*, 46 STETSON L. REV. 41, 56 (2016).

65 Elberg, *supra* note 35, at 1187.

66 Jacob Elberg, *Neither Carrots nor Sticks: DOJ's Unfulfilled Commitment to Corporate Health Care Compliance*, WIS. L. REV. (forthcoming 2022) (noting that criminal prosecution is not the DOJ's "weapon of choice" in fighting health care fraud and the criminal guidance is inapplicable to the civil FCA).

67 Elberg, *supra* note 35, at 1187.

issuance of a memorandum from Deputy Attorney General Sally Quillian Yates ("Yates Memo") addressed the DOJ's efforts to increase accountability for corporate wrongdoing and provided that civil prosecutors had to take a corporation's cooperation into account.[68] Yet, following the Yates Memo, scholars recognized that the announcement did not offer any real guidance as to how cooperation should be used in reducing penalties.[69]

In May 2019, the DOJ issued a Guidance Memo and Updates to the JM, which merely discussed taking a company's remedial measures into account to reduce damages and civil penalties.[70] This guidance focuses on corrective actions after the fact and does not specifically offer rewards for pre-existing programs.[71] It also gave little detail on the specific measures necessary to reduce penalties. The DOJ has the discretion to and will often decline criminal prosecution under the FCA, thus leaving even more charges to be brought civilly.[72] Under the prosecutor's control, corporations do not face criminal charges

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[68] Memorandum from Sally Quillian Yates, Deputy Att'y Gen., U.S. Dep't of Just., on Individual Accountability for Corporate Wrongdoing to Assistant Att'ys Gen., Dirs., & U.S. Att'ys (Sept. 9, 2015), https://www.justice.gov/archives/dag/file/769036/download [hereinafter Yates Memo].

[69] Elberg, *supra* note 35, at 1187; *see* Gejaa Gobena, Mitch Lazris, Peter S. Spivack & Karla Aghedo, *DOJ Embraces a More Realistic Position on Corporate Cooperation*, 33 No. 05 WESTLAW J. WHITE-COLLAR CRIME 2, WL 124214 (2019) ("[T]he impact of cooperation on the calculation of civil FCA settlement amounts remains a mystery."); Laura McLane & Rebecca C. Martin, *Cooperation in the Eye of the Beholder: DOJ Official Bill Baer Elaborates on Cooperation in False Claims Act and Other Civil Enforcement Matters*, MCDERMOTT WILL & EMERY (Oct. 18, 2016), https://www.mwe.com/insights/doj-elaborates-on-cooperation-in-fca/ ("[D]efendants continue to be in the dark about what benefits cooperation genuinely confers.").

[70] *See Department of Justice Issues Guidance on False Claims Act Matters and Updates Justice Manual*, U.S. DEP'T. OF JUST. (May 2019), https://www.justice.gov/opa/pr/department-justice-issues-guidance-false-claims-act-matters-and-updates-justice-manual; *see also* U.S. Dep't. of Just., § 4-4.112 Guidelines for Taking Disclosure, Cooperation, and Remediation into Account in False Claims Act Matters (May 2019), https://www.justice.gov/jm/jm-4-4000-commercial-litigation#4-4.112 [hereinafter Guidelines for Cooperation and Remediation in FCA Matters].

[71] Guidelines for Cooperation and Remediation in FCA Matters, *supra* note 70.

[72] Christopher A. Wray & Robert K. Hur, *Corporate Criminal Prosecution in a Post-Enron World: The Thompson Memo in Theory and Practice*, 43 AM. CRIM. L. REV. 1095, 1167 (2006).

often because the prosecutor may rely on the substantial penalties offered under the civil FCA.[73] These penalties include up to three times the amount of damages the government sustains due to any wrongdoing and currently range from about $11,000 to about $23,000 per violation.[74] Notably, penalties are given for each separate violation of the law and, in some cases, can include a multitude of violations, reaching into the millions of dollars for penalties.[75]

In contrast to the DOJ's Criminal Division guidance regarding reducing penalties for a pre-existing compliance program, the Civil Division guidance does not explicitly state such a program will reduce its penalties. [76] The Civil Division simply states that it will "take into account the prior existence of a compliance program in evaluating a defendant's liability" and that the DOJ "may consider the nature and effectiveness" of the program.[77] As discussed in further detail below, there is insufficient evidence that the DOJ rewards compliant behaviors.[78] Professor Jacob Elberg has analyzed the difference in the DOJ's approaches for rewarding compliance programs in criminal and civil cases, and examined hundreds of recent health care FCA resolutions, finding that the DOJ does not appear to provide benefits for pre-existing compliance programs.[79]

The DOJ must go further than a mere consideration of disclosure, cooperation, and remediation because its goal under civil FCA claims to incentivize companies, without giving value to

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73 Wray & Hur, *supra* note 72; *see* Webb & Molo, *supra* note 41, at 378 (stating that prosecutors often decide that criminal pursuit of the corporation under the FCA would not further public interest).

74 *See* 31 U.S.C. § 3729; Civil Monetary Penalties Inflation Adjustment, 85 Fed. Reg. 37004 (June 19, 2020) (to be codified at 28 C.F.R. pt. 85) (adjusting the FCA penalties for 2020 inflation); David W.S. Lieberman, *2020 False Claims Act Penalties*, WHISTLEBLOWER LAW COLLABORATIVE (July 1, 2020), https://www.whistleblowerllc.com/2020-false-claims-act-penalties/.

75 Lieberman, *supra* note 74.

76 Guidelines for Cooperation and Remediation in FCA Matters, *supra* note 70; *see* Beale, *supra* note 64.

77 Guidelines for Cooperation and Remediation in FCA Matters, *supra* note 70.

78 Elberg, *supra* note 35, at 1172.

79 Elberg, *supra* note 66 (emphasizing the DOJ may be rewarding pre-existing compliance programs, but with no transparency for the public to see those impacts).

its programs and encouraging compliance, will not be strongly accepted without further reward.[80] While the DOJ works diligently to prosecute those who commit fraud against the government, litigation only reaches a portion of the illegal acts.[81] As the acting United States Assistant Attorney General, Stuart Delery, noted, "[l]itigation to recover the costs of fraud is a far inferior option to preventing fraud in the first place."[82] Thus, the government should initiate a consistent standard to aid companies in creating an effective compliance program to counter fraud and preserve the Department's scarce resources. As mentioned above, this was the main goal of the 1986 amendments to combat the "'pervasive' fraud against the government."[83] At the time, Congress believed "only a coordinated effort of both the Government and the citizenry will decrease this wave of defrauding public funds."[84] The government and companies could work together under an incentive system to encourage the expansion of compliance programs if the government also allows pre-existing compliance programs to mitigate civil penalties.[85]

III. ANALYSIS

The FCA relies primarily on private relators to bring lawsuits on behalf of the government alleging a corporation committed fraud.[86] As discussed below, this is commonplace for the health care industry, but the DOJ must increase its transparency and advance its reward structure for FCA matters.[87] The DOJ has the

[80] Guidelines for Cooperation and Remediation in FCA Matters, *supra* note 70; Elberg, *supra* note 66 (noting that the DOJ's failure to publicly reward pre-existing compliance programs undermines their enforcement goals).

[81] Stuart F. Delery, Acting Assistant Att'y Gen., Remarks at the American Bar Association's Ninth National Institute on the Civil False Claims Act and Qui Tam Enforcement (June 7, 2012), https://www.justice.gov/opa/speech/acting-assistant-attorney-general-stuart-f-delery-speaks-american-bar-association-s-ninth.

[82] *Id.*

[83] Morris & Thompson, *supra* note 1, at 329, 329.

[84] *See* S. REP. No. 99-345 at 2 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5267.

[85] Schwartz & Goldberg, *supra* note 4, at 319.

[86] Morris & Thompson, *supra* note 1, at 329.

[87] Elberg, *supra* note 35, at 1214. A data analysis study of more than 115 corporate health care FCA settlements between February 2018 and June 2019

chance to improve its relationship with the health care industry and further encourage compliant behaviors, "far beyond what can be achieved through individual enforcement actions."[88] Thus, health care companies involved in civil FCA disputes should at least be able to evoke the same protections afforded to them in a criminal prosecution to reduce civil fines. But in these scenarios, a concrete and effective compliance program is the company's best protection against the government's obligation to prevent fraud and can allow the company to internally avoid fraud and abuse before they occur.

Compliance programs have become an essential tool in protecting the government from being defrauded by discovering and preventing fraud before it begins.[89] A new approach to the current incentives is necessary because while qui tam suits have allowed for uncovering of substantial frauds, there is a chance that those individuals can exploit the provision for their own financial benefit.[90] There is also a competitive aspect to filing a qui tam suit because only the first individual to file can be the relator in the case.[91] Unfortunately, this has led to wasteful lawsuits under the FCA.[92] A change to incentives is needed to allow for the government to recover the heightened penalties to punish companies who commit fraudulent acts, while also avoiding any speculative lawsuits or minor violations that can be resolved before litigation.[93]

In shareholder derivative actions, an effective compliance program has provided companies a defense against the directors'

revealed a complete "absence of evidence that DOJ rewards compliant behaviors." Elberg, *supra* note 35, at 1172. The study also showed that the DOJ was not more forgiving in cases where defendants cooperated or self-disclosed than when defendants did cooperate or self-disclose. Elberg, *supra* note 35, at 1170. This data raises questions about the DOJ's consistency and the conduct the DOJ actually considers in reducing penalties. The author of the study, Professor Jacob Elberg, argued that a more uniform approach is needed for the DOJ to value compliance programs appropriately to deter fraud before it occurs. Elberg, *supra* note 35, at 1205.

88 Elberg, *supra* note 35, at 1214.

89 Schwartz & Goldberg, *supra* note 4.

90 Schwartz & Goldberg, *supra* note 4.

91 Schwartz & Goldberg, *supra* note 4.

92 Schwartz & Goldberg, *supra* note 4.

93 Schwartz & Goldberg, *supra* note 4, at 339.

personal liability.[94] An adequate compliance program has been shown to meet the duty of care necessary for corporate directors to stay informed of the operations of the company.[95] In *In re Caremark Int'l*, the shareholders attempted to hold directors personally liable for breach of their duty of care by failing to adequately oversee employees' conduct and costing the company large civil and criminal penalties when employees entered into financial agreements with referring doctors.[96] The Court of Chancery of Delaware held that only a total failure to exercise reasonable oversight would render a director liable and that Caremark did have an adequate internal reporting system at the time of the misconduct.[97] The court recognized a person, in good faith, striving to meet their responsibilities of corporate governance, would be bound to take into account the Federal Sentencing Guidelines' opportunities to reduce such penalties.[98] An analogous standard could be used for corporations undergoing civil investigations such that when a company has an adequate compliance system in place, not only can the innocent directors evade liability, but an innocent corporation can as well. The court reasoned that even a rationally designed compliance structure may nonetheless fail to detect noncompliance with the law, but such a system will assure this type of information is brought to the board of directors' attention in a timely manner and they may rectify the situation as appropriate.[99]

In another case, however, the court made clear that the only two defenses available in a criminal or civil FCA claim are negligence and innocent mistake that the claims were false.[100] The government needs to prove that the company "ha[d] actual knowledge of the information," "act[ed] in deliberate ignorance," or "act[ed] in reckless disregard of the truth or falsity of the

94 In re Caremark Int'l, 698 A.2d 959, 971–72 (Del. Ch. 1996).

95 *Id.* at 970–71.

96 *Id.*

97 *Id.* at 970–71.

98 *Id.* at 970.

99 *Id.*

100 *See* United States ex rel. Hagood v. Sonoma Cnty. Water Agency, 929 F.2d 1416, 1421 (9th Cir. 1991) (holding that in filing a claim under the FCA statute, the "knowingly" provision is emphasized repeatedly and requires at minimum "deliberate ignorance" or "reckless disregard").

information."[101] In instances where the company has an effective compliance program in place and does not meet the standards of negligence or innocent mistake, there must be another option to show that the company took all the necessary steps to prevent fraud and the misconduct still happened anyway.

A. *How this Gap Impacts the Health Care Industry*

Compliance programs are especially integral in the health care industry because instances of fraud and abuse are more frequent in reimbursement and payment areas.[102] It is also a complicated industry because coverage and reimbursement of health care services are driven by inconsistent rules which allow for many ways to abuse the system.[103] As one article put it, "the health care industry provides an environment that is ripe for abuse."[104] Due to the uncertainty surrounding medical care and the government programs involved—such as Medicare and Medicaid, intended to aid vulnerable patients—health care providers have the opportunity to take advantage and defraud the federal programs.[105] Additionally, health care fraud and abuse are a high priority for the federal government. Among all its federal programs, the government accounts for the largest amount of funding for health care services at 29%.[106] Additionally, the Office of Inspector General ("OIG") was originally created largely due to scandals in the Medicare and Medicaid programs.[107] With the government being so intertwined

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101 *See* 31 U.S.C. § 3729(b)(A)(i)-(iii).

102 Jane Kim, *Staying Responsible Within the Healthcare Industry in the Era of the Responsible Corporate Officer Doctrine*, 14 IND. HEALTH L. REV. 129, 157 (2017).

103 Morris & Thompson, *supra* note 1, at 320.

104 Morris & Thompson, *supra* note 1, at 320.

105 Morris & Thompson, *supra* note 1, at 320; *see Medicare and Medicaid*, CTR. FOR MEDICARE & MEDICAID SERV., https://www.medicare.gov/Pubs/pdf/11306-Medicare-Medicaid.pdf (last visited Sept. 20, 2021) (noting that Medicare is intended for people 65 or older, certain people under 65 with disabilities, and people of any age with End-Stage Renal Disease and that Medicaid is for those with limited income and resources).

106 *National Health Expenditures 2019 Highlights*, CTR. FOR MEDICARE & MEDICAID SERV., (2019), https://www.cms.gov/files/document/highlights.pdf. (last visited Sept. 20, 2021).

107 S. REP. 94-1324, at 3 (1976), *reprinted in* 1976 U.S.C.C.A.N. 5420, 5422.

in health care programs, the government has great incentive to protect its programs from fraud and abuse.

In the health care industry, the DOJ's enforcement comes almost entirely from civil FCA cases.[108] More than 75% of health care fraud cases are filed as qui tam suits under the FCA.[109] This is significant because the root of fraud cases is often found within the company, and this shows that the issues can also be addressed within a company's infrastructure. The DOJ reported that, in 2019, it recovered over $3 billion from settlements and judgments under the civil FCA, and of that, $2.6 billion related to matters involving the health care industry.[110] Additionally, the DOJ noted that its health care fraud settlements and judgments have exceeded $2 billion for the past ten years.[111] Health care is an industry where the government accounts for a significant percentage of revenue and, as mentioned above, where such suits are more likely.[112] A compliance defense is particularly necessary for health-related fraud because health care compliance incites a heightened level of complexity and enforcement due to the complicated legal and regulatory requirements.[113] Therefore, a strong compliance program that reflects these heightened standards should be rewarded.

Health care is a heavily regulated industry and is governed by multiple regulators: (1) federal agencies and laws, such as the Food and Drug Administration ("FDA"), the Health Insurance Portability and Accountability Act ("HIPAA"), and numerous fraud and abuse laws;[114] (2) state laws; (3) private payor health care program requirements; and (4) health care providers' own

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108 Elberg, *supra* note 66.

109 Janice M. Symchych, Michael K. Fee, Bryan A. Pennington, & Allison S. Owen, *Settlement of Major Healthcare Fraud Enforcement Proceedings: A Probing and Frank Analysis of the Competing Variables*, 25 HEALTH LAW. 1, 3 (2013).

110 Justice Department Recovers over $3 Billion from False Claims Act Cases in Fiscal Year 2019, U.S. DEP'T. OF JUST. (updated Jan. 21, 2020), https://www.justice.gov/opa/pr/justice-department-recovers-over-3-billion-false-claims-act-cases-fiscal-year-2019.

111 *Id.*

112 Alexander Dyck, Adair Morse, & Luigi Zingales, *Who Blows the Whistle on Corporate Fraud?* 65 J. FIN. 2213, 2215 (2010).

113 Kim, *supra* note 102, at 156.

114 Kim, *supra* note 102, at 131; *see* Health Insurance Portability and Accountability Act, 45 C.F.R § 160.103.

rules and regulations, including their business and ethical principles.[115] Some health-related federal laws not only provide guidance on compliance programs but actually require certain organizations to establish policies and procedures. For example, the Patient Protection and Affordable Care Act ("PPACA") allows the Department of Health and Human Services ("HHS") to require those participating in Medicare and Medicaid to implement compliance programs.[116]

If a company has a robust compliance program in place, it is more likely the wrongdoing will be discovered before charges are brought.[117] This is supplemental to the benefits offered under the qui tam statute for self-disclosure, however, because a compliance program will never be able to catch every instance of misconduct.[118] A company would still want an effective program in place to protect them if misconduct is not caught right away rather than self-disclosing each time and not addressing the root issue. Uncovering the wrongful conduct early allows the company to mitigate the behavior and may prevent qui tam claims.[119] This should serve as enough of an incentive for the DOJ to implement a compliance defense so they can better enforce compliance, be consistent, and deter fraud, but they should not go further to allow them to focus on larger fraud and abuse issues. Also, the greatest incentive for the health care companies to establish an effective compliance program is providing this affirmative defense for civil claims to avoid wasting company and government resources and to forge a better company. Additionally, other industries have a compliance incentive in the criminal realm, which is enough to protect them.[120] But since health care is primarily civil law, the incentive also needs to be for civil offenses, otherwise, it does not serve its

115 Publication of the OIG Compliance Program Guidance for Hospitals, 63 Fed. Reg., 8987, 8988 (Feb. 23, 1998), https://oig.hhs.gov/authorities/docs/cpghosp.pdf [hereinafter OIG Compliance Program Guidance]; Ehler-Lejcher, *supra* note 5, at 1378.

116 Patient Protection and Affordable Care Act, Pub.L. No. 111-148, § 6001, 124 Stat. 119, 751; Kim, *supra* note 102, at 158.

117 Ehler-Lejcher, *supra* note 5, at 1379.

118 31 U.S.C. § 3730(d).

119 Ehler-Lejcher, *supra* note 5, at 1379.

120 Huff, *supra* note 26, at 1270–71.

purpose. Although there will always be an incentive for companies to have a compliance program to deter fraud, without a defense companies will always be responsible for illegal conduct regardless of their preventative measures.

IV. THE SOLUTION

The federal government's current approach of post hoc enforcement to recovering the costs of fraud is ineffective at preventing the fraud from the outset.[121] Creating a compliance program as an affirmative defense to civil FCA charges will make it more in line with criminal charges, which provide a significant reduction in penalties for compliance programs, and a defense is often advocated for when criminal charges are brought.[122]

The current damages and penalty structure of the FCA requires, at the very least, a more definitive measurement of rewards. A strong reward system encourages compliance to be taken more seriously and promotes deterrence by increasing the chance that the offender will be caught, thus increasing the cost of committing such fraud.[123] In fact, when the FCA statute was first amended in 1986, Former Assistant Attorney General John R. Bolton noted the "significant deterrent" power of the FCA, stating that the use of civil remedies is an essential element to prevent fraud.[124] Additionally, United States Senator, Chuck Grassley, the primary sponsor of the 1986 amendments, expressed that enforcement of the statute is two-fold:[125] (1) it will allow the government to recuperate fraudulent payments, and; (2) it will deter those who may attempt to defraud the government.[126] When the FCA was amended in 2009, United States Senator Patrick Leahy further emphasized the Act's deterrent value and stated, "[t]he only way you are going to stop [fraud] is to show you are going to stop it."[127] Therefore,

121 Compliance-Focused Reforms, *supra* note 14, at 8.

122 Raspanti & Mackuse, *supra* note 2.

123 Claire Sylvia & Emily Stabile, *Rethinking Compliance: The Role of Whistleblowers*, 84 UNIV. CIN. L. REV. 451, 462 (2016).

124 H.R. REP. NO. 99-660, at 63 (1986).

125 *Id.* at 18.

126 *Id.*; Sylvia & Stabile, *supra* note 123, at 462–63.

127 155 CONG. REC. S4410 (2009) (statement of Sen. Leahy).

establishing an affirmative compliance defense can be accomplished by legislation, but also could be initiated by DOJ's discretionary authority to enact a policy not to pursue charges for companies that actively try to deter fraud and meet a compliance defense standard.[128]

A. *Factors of a Compliance Defense*

A compliance defense to civil charges can be modeled after the suggestions for a defense to criminal charges because they will accomplish the same goal of effectively deterring fraud and promoting companies' compliance efforts. To go further, however, a compliance defense for civil charges must be intricate enough to remedy health care-related fraud.[129] Health care is a very high-risk industry and thus requires reasonably designed programs that include a robust monitoring and reporting system.[130] There are various sources that entities can go to for guidance.

The OIG outlines key compliance program factors specifically for health care providers such as (1) written policies and procedures; (2) the designation of a chief compliance officer; (3) training programs; (4) hotline to receive complaints; (5) appropriate disciplinary action; (6) auditing and monitoring; and (7) investigation and remediation.[131] There are suggestions that although these guidelines are voluntary, the word "guidance" implies the weight of the law and that compliance programs are evidence of adhering to such law.[132]

Given the above guidance from the OIG, a strong regulatory compliance program will consider what actions the company

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[128] Schwartz & Goldberg, *supra* note 4, at 333. Professor Jacob Elberg has also proposed that the DOJ give credit in the form of a reduced multiplier when settling an FCA matter with an organization determined to have had an effective compliance program in place at the time of the offense. Elberg, *supra* note 66.

[129] *See supra* Part III.

[130] OIG Compliance Program Guidance, *supra* note 115 (noting that compliance programs are "especially critical" in the reimbursement and payment areas, where claims and billings are often the source of fraud and abuse and that it is "incumbent" upon the health industry and, especially, corporate officers to assure adequate systems are in place).

[131] OIG Compliance Program Guidance, *supra* note 115, at 8989.

[132] Kim, *supra* note 102, at 157.

takes before and after the violation occurred, including self-reporting, cooperating fully with law enforcement, and taking remedial steps to prevent the recurrence of the act.[133] It is necessary for health care providers and corporate officers to implement effective programs to promote ethical conduct.[134] An effective compliance program accomplishes various important checks for a health care entity. It sets the groundwork for conforming to federal and state laws; it promotes a culture within the business to prevent, detect, and resolve noncompliance; and it fosters adherence to the company's business and ethical principles.[135] The sheer existence of a compliance program will not be enough to negate liability, but protection will be afforded if, proven by a preponderance of the evidence, the company has a functioning program relating to the violation at hand.[136]

While the Sentencing Guidelines do not apply to civil cases, scholars use them as a measure in promoting a compliance defense. Based on the Sentencing Guidelines, scholars suggest that an effective program should have the following elements: "(1) an administrator to oversee its implementation and enforcement; (2) a written set of policies distributed to employees at all levels; (3) a violation reporting process; and (4) a process for disciplining employees who violate company policies."[137] The Sentencing Guidelines direct a company to select a program administrator who is of significant authority.[138] This individual should have "substantial control over the organization or who have a substantial role in the making of policy within the organization."[139] A committee to oversee the compliance program often considers multiple viewpoints on the subject matter to create a balance among the company and allows the person who exercises the administrator function to be widely available to employees.[140] Scholars also suggest the administrator

133 Schwartz & Goldberg, *supra* note 4, at 333.

134 OIG Compliance Program Guidance, *supra* note 115 (noting that corporate officers and managers should provide "ethical leadership" to the company).

135 Ehler-Lejcher, *supra* note 5, at 1378.

136 Walsh & Pyrich, *supra* note 28, at 684.

137 Webb & Molo, *supra* note 41, at 388.

138 Webb & Molo, *supra* note 41, at 388.

139 Webb & Molo, *supra* note 41, at 388.

140 Webb & Molo, *supra* note 41, at 389.

should have the authority to implement and disseminate the policies and procedures through training, monitoring, and disciplining; responding appropriately to violations; and updating and revising the program.[141] The written policies should include the company's general code of conduct that applies to all employees and the supplemental policies and procedures that address certain areas of concern and apply only to affected employees.[142] The process for reporting violations should be accessible to employees at all levels without fear of retaliation.[143] The company must provide a system for employees to comfortably report violations because the validity of the compliance program will hinge on its ability to discover any wrongdoing within the organization.[144] Finally, the organization must have a process to impose sanctions on violators.[145] An organization should have disciplinary guidelines with great flexibility, while still achieving a "deterrent and punitive effect."[146]

Scholars outlined additional elements to an effective compliance program, including timing, subject matter of the program, degree of formality, industry practice, and due diligence.[147] The timing of implementing a compliance program matters, and the program must be established before the offense.[148] This is because the DOJ does not want to see companies wait to invest in their programs to prevent wrongdoing after the offense was committed.[149]

The issues each compliance program will address widely depend on the type of company.[150] An effective compliance program should cover conduct likely to be considered wrongdoing and anticipate any potential problems.[151] The health

141 Webb & Molo, *supra* note 41, at 389.
142 Webb & Molo, *supra* note 41, at 389-90.
143 Webb & Molo, *supra* note 41, at 392.
144 Webb & Molo, *supra* note 41, at 392.
145 Webb & Molo, *supra* note 41, at 393.
146 Webb & Molo, *supra* note 41, at 393.
147 Webb & Molo, *supra* note 41, at 380-82 (*citing* U.S.S.G. Guidelines Manual § 8C2.5(f)).
148 Webb & Molo, *supra* note 41, at 380.
149 Webb & Molo, *supra* note 41, at 380.
150 Webb & Molo, *supra* note 41, at 380.
151 Webb & Molo, *supra* note 41, at 380.

care industry involves the types of companies where compliance is especially complex, and their programs require another level of intricacy.[152] The degree of formality of each compliance program will also depend on the size of the company, and larger organizations should typically have more formal programs.[153] The effectiveness of a compliance program will likely be compared to programs of other companies in the same industry.[154] Additionally, an adequate compliance program will show that the company exercised due diligence when attempting to detect or prevent any misconduct or wrongdoing.[155] Companies need a high incentive to implement a compliance program that is robust and effective in preventing and detecting fraud because they must adhere to various state, federal, and regulatory laws. Many programs suffer from a lack of funds and resources necessary for an effective compliance program.[156]

Under the current structure, the only benefit afforded to a company is the DOJ's consideration of corrective actions taken in response to civil charges under the FCA.[157] The discrepancies in rewards from the government discourage companies from creating a dynamic compliance program that invests in training, auditing, and monitoring of policies and procedures.[158] While companies may be encouraged to have compliance programs to reduce fraud in general, without an established compliance defense, their programs will not adequately protect them. Greater incentives would encourage better detection,

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[152] *See generally* Kim, *supra* note 102; *see also supra* Part III on How the Gap Impacts the Health Care Industry.

[153] Webb & Molo, *supra* note 41, at 381.

[154] Webb & Molo, *supra* note 41, at 381.

[155] Webb & Molo, *supra* note 41, at 381–82.

[156] *See generally* Hui Chen & Eugene Soltes, *Why Compliance Programs Fail—and How to Fix Them*, 96 HARV. BUS. REV. 116 (2018).

[157] *Department of Justice Issues Guidance on False Claims Act Matters and Updates Justice Manual*, U.S. DEP'T. OF JUST. (May 2019), https://www.justice.gov/opa/pr/department-justice-issues-guidance-false-claims-act-matters-and-updates-justice-manual (stating that "remedial measures may include undertaking a thorough analysis of the root cause of the misconduct, appropriately disciplining or replacing those responsible for the misconduct, accepting responsibility for the violation and implementing or improving compliance programs"); *see* also Guidelines for Cooperation and Remediation in FCA Matters, *supra* note 70.

[158] Narine, *supra* note 43, at 46.

documentation, and investigation of activities that companies may otherwise choose to ignore.[159] Comparatively, the United States' approach to corporate liability, and specifically in the criminal context, differs from other countries.[160] One article cites Representative Bobby Scott, a member of Congress, arguing that with global businesses being so interconnected today, the United States should not be disadvantaged by "over-aggressive" corporate penalties.[161] This could also be applicable to civil FCA claims because corporations should not be subject to harsher treatment when facing claims under the FCA. In the criminal context, a fine imposed on an organization will be reduced if the compliance program was implemented prior to the violation.[162] But, the influence of an effective compliance program is not limited to criminal law; it also helps fight civil lawsuits.[163] The notes to the amendment of Chapter Eight of the Sentencing Guidelines provide that the section is influenced by the federal criminal law, but an effective compliance program will also facilitate compliance with all applicable laws.[164]

Proponents of an affirmative compliance defense to criminal charges argue that the factors considered to prevail are just as applicable to civil charges.[165] The company must prove it established a compliance program designed to deter, detect, punish, and disclose illegal behavior.[166] The organization must also present evidence of the program in action during the particular issue at hand, such as whether the employee was trained, their reward system, and auditing and monitoring procedures.[167] The DOJ, as well as judges, will be able to assess an effective compliance program based on the standards set by

159 Narine, *supra* note 43, at 46.

160 Narine, *supra* note 43, at 81.

161 Narine, *supra* note 43, at 81 (citing *Foreign Corrupt Practices Act: Hearing Before the Subcomm. on Crime, Terrorism, and Homeland Security of the H. Comm. on the Judiciary*. 112th Cong. 19-45 (2011)).

162 *See* U.S.S.G. § 8C2.5(f)(1).

163 Raspanti & Mackuse, *supra* note 2, at 24.

164 Raspanti & Mackuse, *supra* note 2, at 24 (*citing* U.S.S.G. Manual app. C, Amendment 673).

165 Narine, *supra* note 43, at 81.

166 Narine, *supra* note 43, at 81.

167 Narine, *supra* note 43, at 81.

the Sentencing Guidelines and be able to identify any deceiving or artificial programs.[168] The program must show its effectiveness and that it prevents some misconduct.[169] The programs can also be assessed based on their reasonableness when compared to other similar companies.[170]

Another aspect of the defense is the burden on the government, and ideally, if a prosecutor cannot show an organization's compliance program was ineffective in detecting and preventing fraud, they should not pursue the matter further.[171] Existing caselaw illustrates that the existence of an effective compliance program will be a factor in determining civil liability for an organization and the potential consequences.[172] The court in *United States ex rel. Hunt v. Merck-Medco Managed Care*, provides that a corporation's ineffective compliance program could establish the "knowingly" factor of a false claim.[173] In the case, two pharmacists filed a qui tam suit against Medco Health Solutions alleging violations of the FCA.[174] The government argued that Medco failed to have an effective compliance program in place to detect and prevent false claims and thus knowingly submitted false claims.[175] The court agreed that such evidence of non-existent or insufficient compliance programs satisfies the requirements under the FCA.[176] The case was settled before trial, so the question of ultimate consequences for failure to implement an effective compliance program is left open;[177] nonetheless, it follows that when there is significant civil exposure for lack of an effective program, there should be an affirmative defense for the successful implementation of an effective program.

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168 Amitai Aviram, *In Defense of Imperfect Compliance Programs*, 32 FLA. ST. UNIV. L. REV. 763, 769 (2005).

169 *Id.*

170 Narine, *supra* note 43, at 47–48.

171 Narine, *supra* note 43, at 86.

172 *See* United States ex rel. Hunt v. Merck-Medco Managed Care, L.L.C., 336 F. Supp. 2d 430 (E.D. Pa. 2004).

173 *Id.* at 441.

174 *Id.* at 434.

175 *Id.* at 441.

176 *Id.*

177 *Id.*; Raspanti & Mackuse, *supra* note 2, at 26.

The main argument that an organization should espouse in using their compliance program as a defense is that the entity is a "good corporate citizen," and the misconduct was the result of a rogue employee.[178] Also, an incentive for a concrete compliance defense will foster an environment that discourages wrongdoing.[179] Although wrongdoing can still occur despite an effective compliance program, a company will be able to address the issue swiftly and minimize any risks or consequences.[180] Establishing a formal compliance defense will initiate a shift in companies' deterrence mechanisms from fear to social responsibility.[181] To accomplish this, some scholars suggest that a compliance defense requires not only a law enforcement approach, but also a community-based approach.[182] The idea is to change current employee perceptions of compliance programs—that they are not in their best interest—to reflect that compliance programs are a valuable and necessary component of companies.[183] The DOJ will want to signal to the health care community that they have made fighting fraud and corruption priorities and that compliance is for the common good.[184]

B. *Benefits of Implementing a Compliance Program*

Implementing and maintaining compliance programs are expensive and time-consuming tasks.[185] A company may weigh

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178 Webb & Molo, *supra* note 41, at 376.

179 Webb & Molo, *supra* note 41, at 376.

180 Webb & Molo, *supra* note 41, at 376.

181 Schwartz & Goldberg, *supra* note 4, at 337.

182 Schwartz & Goldberg, *supra* note 4, at 337.

183 *See* David Hess, *Enhancing the Effectiveness of the Foreign Corrupt Practices Act Through Corporate Social Responsibility*, 73 OHIO ST. L. J. 1121, 1137 (2012)

> A compliance program implemented solely to meet external, regulatory demands can lose legitimacy with employees within the corporation who grow to see the program as not 'valued, necessary, or useful' and not in their best interests. Not only does the program lose legitimacy, but so do the ethical values the program is designed to further.

184 Schwartz & Goldberg, *supra* note 4, at 337; Elberg, *supra* note 66 ("DOJ's failure to separate good from bad corporate actors is a failure not only from both a deterrence and a retributive perspective, but in undermining perceptions of fairness and legitimacy").

185 Walsh & Pyrich, *supra* note 28, at 679.

the significant costs against the inability of a compliance program to yield a significant benefit.[186] Under the current framework, a company may refuse to implement a compliance program, but as discussed below, with an affirmative defense in place, the company would not be penalized for self-policing, but instead rewarded for it.[187] A compliance program will allow management to have a better view of employees' behaviors, decrease exposure to legal action, improve morale among employees, and improve communication.[188] The defense can also encourage good corporate citizenship and long-term cost-effectiveness.[189] Employee liability of misconduct can serve to improve corporate conduct within the company, and creating a compliance defense will further this goal of internal monitoring.[190] An effective compliance program can also present a positive public image and show that the company is taking the steps necessary to mitigate the misconduct.[191] In turn, this creates a reputation that is useful for the company and its business.[192] Overall, companies may not invest in a compliance program because of its huge expense unless there is a huge reward. By implementing these changes, companies will realize the investment is worth it.

A compliance program serves as a signal to the company's employees of the company's clear intention to abide by the law.[193] Not only does a strong program provide employees with clear expectations that may prevent them from unintentionally deviating from the law or guidelines, but it will also discourage an employee from intentionally engaging in misconduct because they are aware that the company will disapprove and discipline them.[194] While many hold compliance defense arguments as pertinent in criminal charges, they are just as applicable to civil charges and will greatly assist the health care industry in proving

186 Walsh & Pyrich, *supra* note 28, at 679.
187 Walsh & Pyrich, *supra* note 28, at 680.
188 Ehler-Lejcher, *supra* note 5, at 1381–82.
189 Walsh & Pyrich, *supra* note 28, at 680.
190 Walsh & Pyrich, *supra* note 28, at 680.
191 Walsh & Pyrich, *supra* note 28, at 680.
192 Walsh & Pyrich, *supra* note 28, at 680–81.
193 Walsh & Pyrich, *supra* note 28, at 680.
194 Walsh & Pyrich, *supra* note 28, at 680.

compliance when parties bring claims under the FCA.[195] Structuring an effective compliance program helps health care providers achieve their premiere goal of providing quality care to patients and customers.[196] Ultimately, a compliance program will become cost-effective for the corporation and law enforcement by saving money and resources.[197]

Although a compliance program will cost time and money in legal fees and employee productivity time, a compliance defense as an incentive will make the costs worthwhile.[198] Handling misconduct without a compliance program will cost far more in financial penalties, litigation, employee productivity time, and efforts to remedy their reputation than if a program was established in the first place.[199] Additionally, the benefits are two-fold because the company will not have to expend additional time or money, and the government will not have to prosecute further, thus saving their money and resources.[200] If an employee does commit a fraudulent act, a compliance program can detect the misconduct that otherwise may have slid under the radar of management and law enforcement.[201] Even if companies do not reveal the misconduct right away, compliance programs are still important because companies will want to address the root cause of the issue to prevent it from happening again, rather than receiving a reward for self-disclosing the wrongdoing, but not mitigating the principal cause further. Adding an affirmative compliance defense into the current standard of liability aligns with the goals of the law that attempt to "measure, encourage, and reward" lawful behavior.[202] An affirmative defense would also serve the public in making the standards fair and more predictable while limiting prosecutorial discretion.[203]

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195 Narine, *supra* note 43, at 81; Kim, *supra* note 102, at 157 ("Compliance programs are 'evidence' of complying with the law.").

196 OIG Compliance Program Guidance, *supra* note 115, at 8987–88.

197 Walsh & Pyrich, *supra* note 28, at 681.

198 Walsh & Pyrich, *supra* note 28, at 681–82.

199 Walsh & Pyrich, *supra* note 28, at 681–82.

200 Walsh & Pyrich, *supra* note 28, at 684.

201 Walsh & Pyrich, *supra* note 28, at 679.

202 Pamela H. Bucy, *Corporate Criminal Liability: When Does it Make Sense?*, 46 AM. CRIM. L. REV. 1437, 1442 (2009).

203 *Id.* at 1445–46.

C. *Opposition*

Opponents to an affirmative compliance defense posit that it would be a futile effort because companies will not want to finance litigation until the end or will push to settle in fear of losing at trial.[204] To resolve those issues, some scholars suggest that companies could seek a declaratory judgment or pretrial motion after charges have been filed to establish their ability to utilize the defense at the outset and will not be required to endure costly litigation if it is not necessary.[205] Another approach is to raise the defense at the earliest stages of negotiations with the government so they would not prosecute any further nor attach any penalties or fines.[206]

One scholar argues that with a compliance defense at a company's disposal, they may elect to establish the bare minimum of a compliance program, labeled as "window-dressing," which will not be truly effective, yet they will still be able to take advantage of the defense.[207] Although "window-dressing" is of concern with this type of defense, the standard for evoking the defense will be a high bar to meet. A company will have to show "by a preponderance of the evidence that it has implemented a practical, functioning program relating to the . . . violation."[208] Top management will have to testify that their company implemented the program correctly and they reasonably believed they were meeting all standards to prevent the misconduct.[209] Companies should also have to show evidence of training, anything that could have led to the wrongdoing, and the auditing and monitoring systems.[210] Others have suggested preventing companies from persuading a court or agency of the strength of their compliance program but not investing additional resources to prevent wrongdoing, a third-party or government entity should audit the program before raising the

204 *See* Schwartz & Goldberg, *supra* note 4, at 333–34.

205 Schwartz & Goldberg, *supra* note 4, at 333.

206 Narine, *supra* note 43, at 47.

207 Kimberly D. Krawiec, *Organizational Misconduct: Beyond the Principal-Agent Model*, 32 FLA. ST. UNIV. L. REV. 571, 572, 574 (2005).

208 Walsh & Pyrich, *supra* note 28, at 684.

209 Schwartz & Goldberg, *supra* note 4, at 332.

210 Narine, *supra* note 43, at 47.

defense.[211]

Additionally, some scholars argue that judges or juries are not equipped to assess a compliance program and its effectiveness on corporate misconduct.[212] One response to this opposition is that even if courts cannot identify the most favorable compliance program, they can determine those that are helpless.[213] Also, the company's goal is to invoke the compliance defense to prove to prosecutors early on that they had the proper measures in place, thus ideally avoiding court.[214] This would allow the DOJ and experts who are more equipped with the proper knowledge to determine its effectiveness.

Another counterpoint to those who think companies will invoke the defense without a truly effective program is that legal liability is not the only harm a company may face for corporate wrongdoing.[215] The publicity effects may harm the company far worse than legal penalties, providing another incentive to adhere to an effective compliance regime, to show the public that they comply with the law.[216] Furthermore, there is a whole arsenal of benefits to implementing a compliance program beyond its use in a legal proceeding.[217] Some of these benefits include "increasing the social welfare" of the company, such that it deters any wrongdoing and presents to the public the image of compliance, and in turn, creates a perception to the employees that the program works.[218] A robust compliance defense would encourage companies to monitor their business and employees internally, timely mitigate risks, and cooperate with law enforcement after a violation is discovered; it ultimately would enable a company to make a deliberate decision to invest in its compliance program.[219]

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211 Narine, *supra* note 43, at 47.

212 Krawiec, *supra* note 207, at 580–81.

213 Aviram, *supra* note 168, at 769.

214 Narine, *supra* note 43, at 81–82.

215 Aviram, *supra* note 168, at 765.

216 Aviram, *supra* note 168, at 765.

217 Aviram, *supra* note 168, at 765; *see supra* Part IV on Benefits of Implementing a Compliance Program.

218 Aviram, *supra* note 168, at 768, 774.

219 Narine, *supra* note 43, at 49–50.

V. CONCLUSION

The DOJ should implement a policy allowing for an affirmative defense of a company's compliance program as evidence of innocence in civil cases. Amending the statute could also accomplish this goal; however, the DOJ can also use its authority to create a new policy without needing to go through legislation. A consistent base across criminal and civil actions with a compliance defense is necessary to decrease the uncertainty regarding the prosecutor's discretion and create a more predictable objective process. While a compliance defense is widely structured and argued for in criminal cases, this approach has been left out of cases involving civil violations under the FCA.[220]

This type of discrepancy greatly impacts the health care industry because most of the fraud violations brought under the FCA are health-related frauds.[221] With excess claims filed within the health care industry, companies need a valuably larger incentive to create an effective compliance program and an incentive for the DOJ to protect the federal programs.[222] This kind of change will better allow health care providers to partner with the government in fighting fraud and create consistency among FCA charges.

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[220] Raspanti & Mackuse, *supra* note 2, at 22.

[221] *Justice Department Recovers Over $3 Billion from False Claims Act Cases in Fiscal Year 2019*, U.S. DEP'T. OF JUST. (January 2020), https://www.justice.gov/opa/pr/justice-department-recovers-over-3-billion-false-claims-act-cases-fiscal-year-2019.

[222] *See* Morris & Thompson, *supra* note 1, at 319–21, 326.