



**BNA's**

# HEALTH LAW REPORTER



Reproduced with permission from BNA's Health Law Reporter, Vol. 19 No. 4, 01/28/2010. Copyright © 2010 by The Bureau of National Affairs, Inc. (800-372-1033) <http://www.bna.com>

## How Attorney General Eric Holder and Recent Developments May Challenge Corporate Directors, Officers, and Compliance Professionals

BY PATRICK M. FLACHS,  
JOHN E. POWERS II, AND  
NATHAN D. STURYCZ

### I. Introduction

**E**ric Holder's appointment as attorney general of the United States has significant implications for corporate compliance professionals and corporate officers and directors alike. From his early years as a federal prosecutor, U.S. attorney, and deputy attorney general in the Clinton administration, Holder has placed great emphasis on the investigation and prosecution of corporations and their officers.

The Holder Memo, penned by Eric Holder while serving as deputy attorney general, represented the original enforcement codification establishing the Department of Justice's (DOJ) prosecution priorities for charging decisions involving criminal investigations of corporations. Some insight into what we might expect from a Holder Justice Department lies in the relevant section of the original text:

In determining whether to charge a corporation, the corporation's timely and voluntary disclosure of wrongdoing and its willingness to cooperate with the government's investigation may be relevant factors. In gauging the extent of the corporation's cooperation the prosecutor may consider the corporation's willingness to . . . disclose complete results of its in-

*Flachs and Powers are partners and Sturycz is an associate with Husch Blackwell Sanders LLP.*

ternal investigation, and to waive the attorney-client and work-product privileges.<sup>1</sup>

What this means precisely is unclear.

Attorney General Holder now will be able to outline for his deputies and U.S. Attorneys exactly what he expects and we can anticipate he will very likely continue to pursue corporate prosecutions aggressively. It is important to recall that when Holder initially penned the Holder Memo, Enron and WorldCom were corporate imbroglgios in-the-making. One may anticipate that in the wake of the recent economic meltdown and its even broader impact on investors—and with the memory of Enron and WorldCom remaining in the collective consciousness—the time is ripe for Holder's DOJ to pursue a second round of vigorous enforcement efforts against corporations.

Equally significant is the Office of Inspector General for the Department of Health and Human Services's contemporaneous promulgation of the Voluntary Disclosure Policies.<sup>2</sup> The former relationship between the Voluntary Disclosure Policies and the Holder Memo may well be reincarnated, adding even greater importance to the proper crafting, implementation and application of compliance plans. Couple this two-sided enforcement paradigm with recent court decisions<sup>3</sup> and add in an increase in federal involvement in the

<sup>1</sup> Memorandum from Eric H. Holder, Federal Prosecution of Corporations (June 16, 1999), available at <http://www.usdoj.gov/criminal/fraud/docs/reports/1999/chargingcorps.html#Federal%20Prosecution%20of> [hereinafter "Holder Memo"].

<sup>2</sup> E.g., Office of Inspector General Provider Self-Disclosure Protocol, 63 Fed. Reg. 58,399–58,403 (Oct. 30, 1998), available at <http://oig.hhs.gov/authorities/docs/selfdisclosure.pdf>.

<sup>3</sup> See *infra* at Part III.

economy through TARP, stimulus spending, and the widely anticipated health care reform bill,<sup>4</sup> and you have a near “perfect storm” of fiduciary liability for corporations, their directors, officers, and compliance professionals. This article will help readers understand this confluence of recent enforcement developments.

Section II of this article will summarize the evolution of the Department of Justice’s policies toward “cooperation” in corporate prosecutions, as well as legislation pending in the Senate that could make new waves. Section III will review recent litigation where either civil or criminal liability has been imposed on individual corporate officers. Finally, Section IV of this article offers some practical considerations for developing a compliance plan and conducting compliance activities.

## II. The Rock—Sentencing Guidelines and DOJ’s Evolving Policies on Cooperation

### A. Sentencing Guidelines

The United States Sentencing Commission adopted Organizational Sentencing Guidelines for business corporations in 1991 as part of the Sentencing Reform Act of 1984. The Organization Sentencing Guidelines provide significant incentive for corporations to implement a corporate compliance program that will “effectively” detect violations of law and provide a mechanism for the corporation to disclose such violations promptly and to effectuate a swift, voluntary remedial response.<sup>5</sup> Corporations facing criminal charges can mitigate the civil monetary fines resulting from improper activities if they have appropriately implemented an “effective” compliance and ethics program.<sup>6</sup>

### B. A Summary of DOJ’s Changing Corporate Cooperation Policy (the Holder Memorandum and Its Progeny)

Serving at the time as deputy attorney general, Eric Holder released what is known today as “the Holder Memo,” which outlined suggested factors for assessing whether to prosecute a suspect corporation.<sup>7</sup> Specifically, the Holder Memo instructed prosecutors to consider: (1) the nature and seriousness of the offense, (2) the pervasiveness of the wrongdoing, (3) the corporation’s history of similar conduct, (4) any voluntary disclosure of wrongdoing and ensuing cooperation, (5) the existence and adequacy of a compliance program,<sup>8</sup> (6)

efforts at remediation, (7) the potential for collateral consequences that could harm innocent third parties, and (8) the availability of civil or regulatory remedies.<sup>9</sup> At the time, Holder suggested that corporate “cooperation and voluntary disclosure” made in a “timely” manner merited leniency from the DOJ.<sup>10</sup> The practical result of the Holder Memo was that prosecutors routinely sought broad waivers of the corporation’s attorney-client privilege by seeking the voluntary disclosure of internal investigations early in the course of the government’s investigation.<sup>11</sup> It is significant to note, however, that because Holder issued his guidance to federal prosecutors by way of memorandum—and *not* as an amendment to the United States Attorney’s Manual—the Holder Memo did not represent “official” DOJ policy and federal prosecutors were not required to follow its precepts.

Since publication of the Holder Memo, the DOJ has revised the policy described in the Holder Memo several times, including revisions described in the Thompson Memo<sup>12</sup> and the McNulty Memo.<sup>13</sup> The DOJ’s practices during the period marked by the issuance of the original Holder Memo and 2008 raised a number of questions concerning whether “cooperation” with a government investigation required a corporation to waive its attorney-client privilege as to both factual and even nonfactual communications, especially those ensuing from an internal investigation.<sup>14</sup>

In response to criticism of a perceived connection between waiver of a corporation’s attorney-client and work product protections and classification of the subject corporation as “cooperative,” Deputy Attorney General Mark Filip set forth revised Principles of Federal Prosecution of Business Organizations as part of the United States Attorney’s Manual.<sup>15</sup> Specifically, the revised manual states that “[t]he critical factor [to cooperative behavior] is whether the corporation has provided the *facts* about the events,” though “waiving the attorney-client and work product protections has never

---

of the False Claims Act In Civil Health Care Matters (June 3, 1998), available at <http://www.usdoj.gov/dag/readingroom/chcm.htm>.

<sup>9</sup> Holder Memo, *supra*, note 1 at II–X, available at <http://www.usdoj.gov/criminal/fraud/docs/reports/1999/chargingcorps.html>

<sup>10</sup> See Holder Memo, *supra*, note 1 at VI. See also Cook & Clark, *supra* note 6.

<sup>11</sup> Cook & Clark, *supra* note 6.

<sup>12</sup> Memorandum from Larry D. Thompson, Principle of Federal Prosecution of Business Organizations (June 20, 2003), available at [http://www.usdoj.gov/dag/cftf/corporate\\_guidelines.htm](http://www.usdoj.gov/dag/cftf/corporate_guidelines.htm) (ultimately encouraging an assessment of the actual concrete steps taken by the corporation to cooperate with the DOJ, stating its goal as “increased emphasis on and scrutiny of the authenticity of a corporation’s cooperation”). See also Andrew Weissmann, A New Approach to Corporate Criminal Liability, 44 American Criminal Law Review 1319, 1338 (2007).

<sup>13</sup> Memorandum from Paul J. McNulty, Principles of Federal Prosecution of Business Organizations (Dec. 12, 2006), available at [http://www.usdoj.gov/dag/speeches/2006/mcnulty\\_memo.pdf](http://www.usdoj.gov/dag/speeches/2006/mcnulty_memo.pdf) (requiring approval in order to require a corporate defendant to waive the attorney-client privilege).

<sup>14</sup> See Cook & Clark, *supra* note 6 at 31, 34–35.

<sup>15</sup> Memorandum from Mark Filip, Principles of Federal Prosecution of Business Organizations (August 28, 2008). See United States Attorney Manual, §§ 9-28.200, 9-28.710, 9-28.720 (2008).

<sup>4</sup> As of this writing, final legislation reconciling the respective bills passed by the House and Senate has yet to emerge.

<sup>5</sup> See U.S. Sentencing Guidelines Manual (2007). See also Leonard Orland, The Transformation of Corporate Criminal Law, 1 Brook. J. Corp. Fin. & Com. L. 45, 48 (2006).

<sup>6</sup> U.S. Sentencing Guidelines Manual § 8B2.1(a) (2007). Though beyond the scope of this article, an informative treatment of “ethics” matters may be found in Usha Rodrigues, *From Loyalty to Conflict: Addressing Fiduciary Duty at the Officer Level*, 61 FLA. L. REV. 1 (2009).

<sup>7</sup> Holder Memo, *supra*, note 1. For additional discussion of the Holder memo see R. Christopher Cook & Joseph W. Clark, “DOJ changes it rule for assessing corporate cooperation,” Health Care Compliance Ass’n, 30, 31 February 2009 [hereinafter Cook & Clark].

<sup>8</sup> In an earlier memorandum discussing his views regarding application of the civil False Claims Act, Eric Holder specifically cited self-disclosure and the existence of a compliance plan as factors to be weighed in the FCA’s scienter determination. Memorandum from Eric H. Holder, Guidance on the Use

been a prerequisite under the Department's prosecution guidelines for a corporation to be viewed as cooperative."<sup>16</sup> Further, the revised manual outlined other advisable ways for corporations to receive credit for being cooperative, including: "providing non-privileged documents and other evidence, making witnesses available for interviews, and assisting in the interpretation of complex business records."<sup>17</sup> The 2008 Filip revisions should increase predictability about what may fall within the attorney-client privilege and what will be subject to disclosure to the government and, as a result, should influence how corporations structure internal investigations or, perhaps, whether such investigations should be conducted at all.<sup>18</sup>

While Filip's revisions may have alleviated (or at least clarified) some of the practices promoted in the Holder Memo, the revisions derive significance from the fact Filip actually incorporated his changes into the manual.<sup>19</sup> As a result, the revisions are distinguished from guidance memoranda, as the manual, including Filip's revisions, embodies official DOJ policy that must be followed by federal prosecutors. It remains to be seen whether Holder will revisit and revise this official policy or whether the DOJ, under Holder's leadership, will enforce this current version of the policy.<sup>20</sup>

What's more, the 2008 revisions to the manual appear to place a new emphasis on the role played by individuals within a corporation. Although the Holder Memo noted that "[a] corporation can only act through natural persons,"<sup>21</sup> it did so only in the context of evaluating the pervasiveness of wrongdoing within a corporation subject to investigation. Filip's 2008 revisions, however, makes a similar observation that "a corporation can act only through individuals," but seems to suggest a more aggressive approach of focusing on individual criminal culpability as a means of curtailing future corporate wrongdoing. Specifically, Filip's revisions note that the "imposition of individual criminal liability may provide the strongest deterrent against future corporate wrongdoing"<sup>22</sup> and state that "[o]nly rarely should provable individual culpability not be pursued, particularly if it relates to high-level corporate officers, even in the face of an offer of a corporate guilty plea or some other disposition of the charges against the corporation."<sup>23</sup> While it remains to be seen whether

Holder will refocus on individual culpability as a primary enforcement tool, recent case law suggests corporate officers should pay close attention to this issue.

### III. Some Hard Places—Recent Individual Civil and Criminal Liability of Directors and Officers

#### A. Civil Liability Under the *Caremark* Framework

In the civil context, dicta from the *Caremark* opinion established an affirmative duty on the part of corporate directors to implement and monitor compliance programs effectively.<sup>24</sup> The *Caremark* opinion requires that a corporation's board of directors implement an "information and reporting system" that is:

reasonably designed to provide to senior management and to the board itself timely, accurate information sufficient to allow management and the board, each within its scope, to reach informed judgments concerning both the corporation's compliance with law and its business performance.<sup>25</sup>

In describing the concept of liability under this standard, the *Caremark* court explained that, "only a sustained or systematic failure of the board to exercise oversight . . . will establish the lack of good faith that is a necessary condition to liability."<sup>26</sup> Significantly, the court in *Caremark* also noted that not only was the standard for finding a director liable under this test "quite high,"<sup>27</sup> but "no rationally designed . . . system will remove the possibility that the corporation will violate laws and regulations, or that senior officers or directors may . . . sometimes be misled."<sup>28</sup> Thus, according to the *Caremark* court, the proper focus for prosecutors and regulators should not be solely on whether an issue of noncompliance occurred, but on whether the corporation and its management and board implemented steps to enhance compliance and to limit, discover and correct any incidents of noncompliance.

In the specific case of *Caremark* and its board of directors, the court found that *Caremark's* board had made a good faith effort to prevent further violation of the law by implementing appropriate compliance systems.<sup>29</sup> The court appears to have based its reasoning on the fact that, after the HHS Office of the Inspector

<sup>16</sup> United States Attorney Manual, § 9-28.710 (emphasis added). Compare Holder Memo, *supra*, note 1 at VI (Opining that "the prosecutor may consider the corporation's willingness to identify the culprits within the corporation, . . . to make witnesses available, to disclose the complete results of its internal investigation, and to waive the attorney-client and work product privileges" while later stating that the DOJ does not "consider waiver of a corporation's privileges an absolute requirement, and prosecutors should [it] . . . only as one factor in evaluating the corporation's cooperation.").

<sup>17</sup> United States Attorney Manual, § 9-28.720 n.2.

<sup>18</sup> Cook & Clark, *supra* note 6.

<sup>19</sup> See United States Attorney Manual, § 9-28.

<sup>20</sup> It also remains to be seen whether Congress may take action of its own on this point. As of this writing, legislation has been introduced in both the House and Senate. See "Attorney-Client Privilege Protection Act of 2009," H.R. 4326, 111th Cong. (2009), introduced in the House Dec. 16, 2009; "Attorney-Client Privilege Protection Act of 2009," S. 445, 111th Cong. (2009) introduced in the Senate on Feb. 13, 2009.

<sup>21</sup> Holder Memo, *supra*, note 1 at IV.

<sup>22</sup> United States Attorney Manual, § 9-28.200.

<sup>23</sup> *Id.*

<sup>24</sup> *In re Caremark Int'l Inc. v. Derivative Litig.*, 698 A.2d 959 (Del. Ch. 1996) (finding that corporate directors may be held liable for breaches of their duty of care by failing to adequately monitor corporate employees whose misconduct caused the corporation to violate the law). See also *Stone v. Ritter*, 911 A.2d 362 (Del. 2006) (where the Delaware Supreme Court adopted the *Caremark* duty of care standard and clarified that bad faith is one of the *Caremark* elements).

<sup>25</sup> *In re Caremark*, 698 A.2d at 970.

<sup>26</sup> *Id.* at 971 ("an utter failure to attempt to assure a reasonable information and reporting system exists," for example, would constitute such a sustained or systematic failure).

<sup>27</sup> *Id.*

<sup>28</sup> *Id.* at 970.

<sup>29</sup> *Id.* at 971. One might also note that in a situation similar to that in *Caremark*, the claim was dismissed, in part, for the fact that the defendant's certificate of incorporation contained a provision as authorized by Section 102(b)(7) of the Delaware General Corporation Law, waiving director liability for due care violations and thus requiring pre-suit demand on the board in that case. *Id.* at n.28 (citing *In re Baxter Int'l, Inc. S'holders Litig.*, 654 A.2d 1268, 1270 (Del. Ch. 1995)). It is doubtful that this procedural play would provide a defense in a criminal case.

General initiated an investigation of its predecessor's business practices for suspected kickback contracts, Caremark took several preventive steps aimed at reining in its previously "decentralized" management.<sup>30</sup> These affirmative steps included: (1) requiring regional officers to approve each new contractual relationship, (2) designing an internal audit plan, (3) requiring comprehensive review of compliance policies, (4) ensuring ongoing education of its sales force, and (5) issuing a new ethics manual requiring employees to report all illegal conduct on a confidential ethics hotline.<sup>31</sup> The *Caremark* court reasoned that such efforts signified a good faith attempt by Caremark's Board of Directors to be informed of relevant facts.<sup>32</sup>

The Delaware Supreme Court reviewed the *Caremark* "sustained or systematic failure"/good faith standard in its 2006 opinion *Stone v. Ritter*.<sup>33</sup> The *Stone* court explained that a derivative plaintiff seeking to establish director oversight liability under the *Caremark* framework must show either that "(a) the directors utterly failed to implement any reporting or information system or controls; or (b) having implemented such a system or controls, [they] consciously failed to monitor or oversee its operations thus disabling themselves from being informed of risks or problems requiring their attention."<sup>34</sup> The court pointed out that, "[i]n either case, imposition of liability requires a showing that the directors knew that they were not discharging their fiduciary obligations."<sup>35</sup> In light of evidence that the corporation maintained a longstanding compliance program, the *Stone* court concluded that, "[i]n the absence of red flags, good faith in the context of oversight must be measured by the directors' actions 'to assure a reasonable information and reporting system exists' and not by second-guessing after the occurrence of employee conduct that results in an unintended adverse outcome."<sup>36</sup>

Recently, courts have taken a more expansive view as they have fleshed out the reach of the *Caremark* framework.<sup>37</sup> One Delaware bankruptcy court held that the *Caremark* fiduciary duties applied equally to corporate officers—here, the officer was the vice president and general counsel<sup>38</sup>—as well as to directors.<sup>39</sup> Similarly,

<sup>30</sup> *Id.* at 962–63.

<sup>31</sup> *In re Caremark*, 698 A.2d at 963.

<sup>32</sup> *Id.* at 971.

<sup>33</sup> *Stone v. Ritter*, 911 A.2d 362 (Del. 2006).

<sup>34</sup> *Id.* at 370 (first emphasis in original, second emphasis added). Contrast these elements for civil liability with those required for criminal culpability discussed *infra* p. 9.

<sup>35</sup> *Id.*

<sup>36</sup> *Id.* at 373. *Accord. David B. Shaev Profit Sharing Plan v. Armstrong*, 2006 WL 391931 (Del. Ch. Feb. 13, 2006), *aff'd*, 911 A.2d 802 (Del. 2006) (unpublished) ("The court accepts, in principle, that a director could be found liable for remaining ignorant of a large fraud occurring in plain sight, even if the director is able to show that the company had established a full set of supervisory controls. . . . But Delaware law requires only diligence, not heroism").

<sup>37</sup> In dictum, the *Caremark* court indicated that the duties it articulated applied both to "senior officers or directors," though the case considered by the court was limited to considering only director liability. *In re Caremark*, 698 A.2d at 970.

<sup>38</sup> Note also that as an attorney, a general counsel may face professional responsibility duties as well as *Caremark* duties. See, e.g., Model Rules of Prof'l Conduct R. 5.3(b) (2007) ("a lawyer having direct supervisory authority over the nonlawyer shall make reasonable efforts to ensure that the person's con-

duct is compatible with the professional obligations of the lawyer").

in the context of a nonprofit corporation, the Delaware Court of Chancery has held that nondirector officers are subject to the same fiduciary duties standards as corporate directors.<sup>40</sup> Certainly, the possibility that directors or officers may be held personally liable on a civil or criminal level demands that a prudent board create, implement, and maintain an adequate compliance program that enhances compliance with applicable laws and addresses risk factors particular to the corporation or inherent to the industry in which it operates. Despite the benefits that a corporation may derive from such plans, such programs may create their own special set of problems. Under current DOJ policy,<sup>41</sup> a corporation may be required to disclose to the government the internal workings of its compliance plans and the results of internal investigations in order for the corporation to receive "credit" for these actions and to be deemed "cooperative." Now more than ever, corporations, and their officers, directors, and compliance professionals must utilize compliance techniques that provide corporations with all of the benefits of an "effective" compliance program but limit substantially the detrimental effects that such compliance efforts may have on the corporation should an investigation ensue.

## B. Individual Criminal Culpability for Corporate Officers

Individual criminal culpability also warrants discussion in light of the increased emphasis on personal liability for corporate officers in the updated manual and recent enforcement efforts. While corporations have commonly been held criminally responsible for illegal conduct, the individuals behind such conduct have often avoided criminal liability.

Notwithstanding this, corporate officers may face direct criminal culpability. Most often, the personal criminal responsibility of officers, directors, or other persons involved in the control and management of a corporation derives from specific acts committed by such individuals or by other corporate agents under the direct supervision of such individuals.<sup>42</sup> But, corporate officers also may face derivative criminal culpability. For instance, corporate officers in a supervisory position may be held vicariously liable pursuant to the Responsible Corporate Officer (RCO) doctrine if they fail to exercise their authority to prevent or remedy criminal violations committed by subordinates under their supervision or operating within the scope of the officer's authority.<sup>43</sup> Most often used in the context of public welfare offenses such as environmental crimes, liability under the RCO doctrine depends upon an individual's corporate position, the individual's knowledge (or willful disre-

duct is compatible with the professional obligations of the lawyer").

<sup>39</sup> *Miller v. McDonald*, 385 B.R. 576 (Bkrtcy. D. Del. 2008).  
<sup>40</sup> *Midland Grange No. 27 Patrons of Husbandry v. Walls*, 2008 WL 616239 (Del. Ch. Feb. 28, 2008) (unpublished).

<sup>41</sup> See United States Attorney Manual, § 9-28.200.

<sup>42</sup> See, e.g., *United States v. Gibson*, 690 F.2d 697, 701 (9th Cir. 1982), *cert. denied*, 460 U.S. 1046 (1983). See also Linda A. Baumann et. al., *Potential Liabilities for Directors and Officers of Health Care Organizations*, in *HEALTH CARE FRAUD AND ABUSE: PRACTICAL PERSPECTIVES* 403, 406–407 (Linda A. Bauman ed., 2002).

<sup>43</sup> See, e.g., *United States v. Dotterweich*, 320 U.S. 277 (1943).

gard) of the improper conduct and concomitant authority to control activities of subordinates.<sup>44</sup> While shareholders, officers, and directors typically enjoy limited personal liability for corporate liabilities absent a compelling argument to “pierce the corporate veil,” the RCO doctrine analysis focuses more on the personal conduct of the individual to determine whether such conduct rises to level of aiding and abetting the criminal conduct committed by the subordinate individual. With the federal government actively expanding its involvement in various facets of our economy, the number of possible public welfare offenses likely is increasing and the RCO doctrine may provide prosecutors with an additional tool for protecting the public.

Recently, another case was decided more on a theory of individual involvement in the improper conduct than on the RCO doctrine. In *United States v. Caputo*, a chief compliance officer of a medical device manufacturer, AbTox, was convicted of conspiracy, fraud, and introduction of an altered or misbranded device into interstate commerce and received a six-year sentence.<sup>45</sup> Judge Ruben Castillo noted that defendant was “one of only a few Chief Compliance Officers ever tried and convicted in federal court”<sup>46</sup> and emphasized the prominent role that officers, specifically, compliance officers, play in the modern corporate environment. Specifically, Judge Castillo stated that:

[c]orporate compliance officers are very much today’s corporate ‘fire personnel.’ They are often the company’s ‘first-responders’ and must focus on both proactive and reactive efforts to be effective. Proactive efforts need to emphasize the complimentary goals of crime prevention and corporate ethical behavior. Reactive efforts measure how well a corporation reacts when it learns that questionable and potentially illegal corporate conduct has occurred.<sup>47</sup>

While there is little doubt that the defendant’s behavior epitomized “sustained and systematic” bad faith (the defendant played an active role in withholding test data from the Food and Drug Administration (FDA)<sup>48</sup>, in marketing a device *in excess* of the FDA’s limited approval<sup>49</sup>, in avoiding inquiries from the FDA<sup>50</sup>, and in disputing consumer complaints about AbTox’s products<sup>51</sup>) the dicta found in *Caputo* reflects a mind-set that is likely to become more prevalent among prosecutors investigating alleged corporate misconduct. *Caputo* and other recent cases show compliance personnel

<sup>44</sup> See, e.g., *United States v. McDonald & Watson Waste Oil*, 933 F.2d 35, 55 (1st Cir. 1991); *United States v. White*, 766 F. Supp. 873, 895 (E.D. Wash. 1991).

<sup>45</sup> 456 F. Supp. 2d 970, *affirmed in part, rev’d and remanded as to restitution calculations*, 517 F.3d 935 (7th Cir. 2008), *cert. denied*, 129 S. Ct. 94 (2008).

<sup>46</sup> *United States v. Caputo*, 456 F. Supp. 2d 970, 972 (N.D. Ill. 2006).

<sup>47</sup> *Id.* at 984–85.

<sup>48</sup> *Id.* at 973.

<sup>49</sup> *Id.* at 973–75.

<sup>50</sup> I.e., the *Caputo* defendant neither investigated claimed injuries, nor did he open a complaint file as required by FDA regulations. *Id.* at 977. In the court’s words, he “did nothing.” *Id.*

<sup>51</sup> *Id.* at 976–77.

that prosecutors may be increasingly willing to seek individual criminal liability for compliance failures.<sup>52</sup>

#### IV. Practical Considerations

When it comes to mitigating liability for corporations, directors, officers, and compliance professionals, there is no substitute for a comprehensive and “effective” compliance plan. While the concept of what constitutes an “effective” corporate compliance plan has been thoroughly discussed, regulators, courts, and commentators appear to be thinking anew about the role individuals play in designing, implementing, and monitoring such plans and on the role individual liability may play in deterring and eliminating illegal corporate conduct. On this point there seems to be universal agreement—corporations and the individuals that run them would be wise to consider the ramifications of corporate as well as personal liability in the course of designing, implementing, and monitoring compliance plans.<sup>53</sup>

Changes to our legal and regulatory framework will like provide increased reinforcement, both positive and negative, for both businesses and “C-Suite” executives to reconsider the role each plays in crafting an “effective” compliance plan. On the heels of multiple financial bailouts, stimulus spending, and the prospect of wide-ranging health care reform, it is quite natural to expect our government to revisit and refine old enforcement tools<sup>54</sup> and to create new ones that will demand

<sup>52</sup> DOJ revives the “responsible-corporate-officer doctrine,” settlement with Purdue Frederick Co. executives requires president, chief legal officer, etc. to plead guilty, pay over \$600 million, 16 HLR 621, 5/17/07; *SEC v. Tenet Healthcare Corp.*, No. CV-07-2144 (C.D. Cal.) (action against Christi R. Sulzbach, Tenet’s former general counsel and chief compliance officer who allegedly failed to disclose scheme to fraudulently inflate Medicare payments to Tenet hospitals). In the case of Cardinal Health Inc., after settling in 2007 with the SEC—in its capacity as a corporation—over allegedly improper accounting and disclosures by the pharmaceutical and medical products distribution company, Cardinal reported that five of its top executives, including Executive Chairman of the Board Robert D. Walter, received “Wells” notices. See Cardinal Health Inc., Current Report (Form 8-K), at 3 (Jan. 25, 2007), available at <http://www.secinfo.com/d14D5a.uC5f.htm>.

<sup>53</sup> Andrew Weissman, *A New Approach to Corporate Criminal Liability*, 44 AM. CRIM. L. REV. 1319, 1341–42 (2007) (encouraging the adequacy of compliance programs as a factor of criminal as well as civil corporate liability); *United States Attorney Manual*, § 9-28.800; *Caputo*, 456 F. Supp. 2d 970, 982 (N.D. Ill. 2006) (supporting criminal convictions for the chief executive officer and the chief compliance officer of a medical device company where, in part, the company’s compliance programs were deficient).

<sup>54</sup> For example, honest services fraud cases under 18 U.S.C. § 1346 have been resurgent. See, e.g., *United States v. Bruno*, No. 1:09-cr-00029, 2009 WL 2601249 (N.D.N.Y. Dec. 7, 2009) (denying motion to dismiss indictment where former majority leader of the New York state Senate was found guilty of two counts of honest-services mail fraud in connection with improper business activities involving entities that had interests before the state legislature).

Once rendered a nullity by the U.S. Supreme Court, see *McNally v. United States*, 483 U.S. 350 (1987), the honest rights doctrine appears to have been revived in the time since Congress enacted 18 U.S.C. § 1341 *et seq.* in response to *McNally*. Recently, courts have categorized honest services fraud cases as either “bribery” or “self-dealing.” See *United States v. Rybicki*, 354 F.3d 124, 139-41 (2d Cir. 2003). Section 1346 of

greater accountability from businesses and the individuals that run them.<sup>55</sup> These new and improved tools may come in the form of longer statutes of limitations, new self-disclosure protocols, stronger civil and criminal penalties or other forms. Regardless, these enforcement mechanisms will no doubt substantially increase the tension that exists between a corporation's decision to incorporate sound principles of corporate compliance into an "effective" corporate compliance program and the fact that the documents, investigations, and reports produced as part of such a program may become the government's best chance at successfully prosecuting a civil or criminal action against the corporation.

It is within this context that one must consider the benefits and risks posed by compliance plans both to the business enterprise, as a whole, and to the individuals that serve as directors, officers, and compliance professionals. Even if a corporation is not required by enforcement authorities to waive the attorney-client or work-product privileges to be viewed by those authorities as "cooperative," it will likely be in the best interest of a corporation under investigation to self-disclose at least some information obtained through internal compliance efforts—to both show that the corporation's compliance plan is "effective" and to seize the advantages provided by self-disclosure. With this likelihood in mind, corporations and their responsible officers, directors, and compliance professionals should consider the following questions when developing, implementing, monitoring, and improving their compliance programs:

- Does the corporation promote a working environment that encourages, supports, and rewards a commitment to compliance and sound ethical behavior from its directors, officers, and employees?
- How formal should the corporation's compliance program be? Does the plan have realistic expectations for the company, its compliance professionals, and its employees? Is the program "scalable"—that is, does it fit the current size of the organization and will it grow with the company?
- What risks are inherent to the industry in which the corporation operates? What risks are specific to the corporation? How have these risks changed with time? How and how quickly will a corporation's compliance efforts adapt to these changes?
- Does the corporate compliance plan require those responsible for directly overseeing compliance

(i.e., a compliance officer) to report solely to the president or the chief executive officer, or does the plan require or permit such individuals to report directly to the corporation's board of directors on a regular basis? Are such reports made in writing or in person?

- Is compliance education conducted on a regular basis and is it tailored to the specific needs of each director, officer, and employee in light of such individual's responsibilities to the corporation? Does the plan incorporate reporting mechanisms that permit employees to raise compliance concerns with their superiors and that allow for such information to filter-up to more than one individual at the officer or director level? Does the plan emphasize that neither the corporation nor its employees will retaliate against any individual that raises a compliance concern in good faith?
- Is there a well-established plan for auditing compliance on a regular basis? Does the plan address the benefits of conducting auditing activities on a real-time, prospective basis rather than on a retrospective or reactive basis? How will the process be documented? Will the results be documented or will the results be communicated in some other fashion? Will the documents be privileged or discoverable?
- Is there a well-established plan for conducting an internal investigation? How will the process be documented? Will the results be documented or will the results be communicated in some other fashion? Will the documents be privileged or discoverable?
- Does the plan weigh the benefits of using external legal counsel to conduct auditing activities or to coordinate internal investigations?
- Does the plan "dove-tail" with other corporate policies and programs, such as a record retention program, quality assurance and applicable privacy policies?
- Does the compliance plan incorporate procedures that encourage communication among the corporation's officer and directors concerning the results of compliance audits and internal investigations? Does the plan formulate appropriate decision-making procedures for determining what actions the corporation will take (including whether to self-disclose compliance issues) following the completion of its auditing activities or an internal investigation?

It bears special emphasis that any effective compliance plan must be followed. The DOJ specifically references *Caremark* by directing prosecutors to evaluate whether a corporation's compliance plan is effective or "merely a 'paper program.'"<sup>56</sup> Following the compliance program and carefully documenting compliance efforts will lend strength to an argument for the former. Indeed, the existence of a compliance program that directors, officers, and employees do *not* follow may be used as evidence that a subsequent violation of law was performed "knowingly."

Title 18 of the United States Code prohibits devising "a scheme or artifice to deprive another of the intangible right of honest services." Courts have recently held that "the misuse of office (more broadly, misuse of position) for private gain is the line that separates run of the mill violations of state-law fiduciary duty . . . from federal crime." *United States v. Kerik*, 615 F. Supp. 2d 256, 265 (S.D.N.Y. 2009).

One must also make note that the Supreme Court has recently granted certiorari in three cases involving honest services fraud, each of which presents an argument by the petitioner that Section 1346 is unconstitutionally vague. See *United States v. Weyhrauch*, 129 S.Ct. 2863 (June 29, 2009); *Black v. United States*, 129 S. Ct. 2379 (May 18, 2009); and *Skilling v. United States*, 130 S.Ct. 393 (Oct. 13, 2009).

<sup>55</sup> See, for example, the recently enacted Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, § 4, 123 Stat. 1618, 5-9 (2009), which drastically expands the scope of the Federal False Claims Act, 31 U.S.C. §§ 3729-33 (2000).

<sup>56</sup> United States Attorney Manual, § 9-28.800. Compliance documents from the Office of Inspector General also make specific reference to *Caremark* as a type of benchmark. See, e.g., Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8987, 8988 (Feb. 23, 1998).

---

## V. Conclusion

In the wake of recent political transition, economic volatility, and legal developments, the function of corporate compliance plans will be of ever-increasing significance. A thorough compliance plan will, of course, maximize a corporation's ability to monitor the activities of its agents and to discover possible misconduct as early as possible. Further, a rigorously enforced compliance plan that satisfies the *Caremark* standards will help protect individuals responsible for overseeing corporate compliance activities from personal liability. It

is, however, imperative that compliance professionals design and implement compliance plans with the understanding that the inner-workings of that plan and the documents produced in accordance with its mandates likely will be disclosed during the course of any investigation of the corporation. In the end, these professionals must carefully weigh the merits of each component of the compliance program to ensure the program functions as a shield to potential liability and not as a sword that can be turned on the corporation, or its officers, directors, or compliance professionals.