Caremark’s Irrelevance

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In re Caremark Int’l Inc. Derivative Litig. is commonly cited as the iconic corporate law case on liability for a failure of legal compliance, but the true source of corporate law as to legal compliance is the higher standard established by other sources of law. For example, the expected cost of liability, both criminal and civil, for violations of federal healthcare regulations by a healthcare firm such as Caremark Inc. is a far stronger determinant of corporate compliance systems than potential liability under Caremark. Caremark’s practical impotence applies not only to healthcare firms, but to all firms because the expected costs of violating federal law, or non-corporate state or municipal law, will almost always exceed the expected costs of violating state corporate law. This article argues that compliance standards such as those mandated by administrative rules and agency enforcement and interpretation of these rules impose substantially higher expected costs on corporations and their principals than Caremark and thereby trump Caremark as to the design and operation of corporate compliance. Indeed, Caremark verges on practical irrelevance. The common exaggeration of Caremark’s significance illustrates a flawed pedagogical overemphasis on state corporate law as a legal determinant of corporate compliance and a broader misconception about the influence of regulatory law in corporate affairs.

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I. INTRODUCTION

In the pantheon of corporate law cases, *In re Caremark Int’l Inc. Derivative Litig.* has assumed iconic status. It established a widely accepted state corporate law standard for directors’ oversight of legal compliance in holding that directors may incur personal liability for a failure to make a good faith attempt to ensure that corporate compliance systems are adequate. The Delaware Supreme Court has adopted the *Caremark* standard, which has been cited approvingly by courts in many other states.

However, the *Caremark* standard plays, as a matter of practice, a small role in the design and operation of corporate compliance programs. In developing and administering compliance programs, rational corporate actors will seek first to mitigate the risks that present the highest expected costs to the firm and its principals. The expected costs of violating federal law, or non-corporate state or municipal law, will almost always exceed the expected costs of violating state corporate law, including the costs of violating the *Caremark* standard. The thesis of this article is that compliance standards, such as those mandated by administrative rules and agency enforcement and interpretation of these rules, impose substantially higher expected costs on corporations and their principals
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than Caremark and thereby trump Caremark as to the design and operation of corporate compliance.

Although Caremark raised the standard for directors’ oversight of corporate compliance under state corporate law, the bar remains too low to challenge other sources of law as the determinants of corporate compliance systems. In practice, Caremark offers little promise of success for the shareholder-plaintiff. Chancellor Allen made it clear that had he been ruling on the merits of the allegations in the instant case, rather than merely approving a negotiated settlement, he would have dismissed the plaintiffs’ complaint. In his view, their “claims found no substantial evidentiary support in the record and quite likely were susceptible to a motion to dismiss in all events.”

The court’s seminal statement of the legal standard that it established was similarly qualified:

. . . a director’s obligation includes a duty to attempt in good faith to assure that a corporate information and reporting system, which the board concludes is adequate, exists, and that failure to do so under some circumstances may, in theory at least, render a director liable for losses caused by non-compliance with applicable legal standards.

Even a failure to satisfy the duty “may” (not will) result in personal liability, and then only “under some circumstances,” and even then only “in theory.” Consistent with Professor Mark Roe’s description of Delaware judges’ “fulminating against breaches of fiduciary duty without finding liability,” Chancellor Allen established a heightened standard of care in Caremark while suggesting that it would very rarely, if ever, result in personal liability.

The Caremark standard reflects the view that state corporate law should, as a general matter, defer to free market forces as determinative factors in corporate conduct. Chancellor Allen expressed this view in noting that “the level of detail

7. See infra text accompanying notes 41-43, 49-52.
9. Id. at 970 (emphasis added).
039612045726819193502420.html (criticizing judge’s criticism of defendants while finding no liability).
11. See In re Citigroup Inc. S’holder Derivative Litig., 964 A.2d 106 (Del. Ch. 2009) (citing Caremark, 698 A.2d at 967) (describing the Caremark standard as “possibly the most difficult theory in corporation law upon which a plaintiff might hope to win a judgment.”).
that is appropriate for [a compliance] information system is a question of business judgment.” 13 In its most extreme form, this free-market approach considers the internal affairs doctrine, which holds that corporations are free to choose which state’s corporate law will apply to them, 14 to create a form of regulatory marketplace in which corporations may adopt a set of corporate rules based on the exigencies of the market. It is this “genius” of corporate law that some argue should be a model for much of the law that regulates corporate conduct. 15 A sibling model of corporate law is the view that a corporation is nothing more than a nexus of contracts, under which even the fiduciary duty applied by Caremark may be negotiated away by investors. 16

Professor Bainbridge articulated this perspective in warning courts against over-extending Caremark:

If, in applying Caremark to risk management failures, courts are perceived as imposing liability on boards for failing to adopt some specific model of risk management, the evolutionary market processes by which optimal best

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practices emerge may be aborted.17

This perspective reflects a popular normative view that it is “evolutionary
market forces” that will result in the “optimal best practices” for corporate
compliance, rather than practices dictated by corporate law legal standards
established by courts and legislators.

This article challenges the virtually universal view of Caremark as an iconic
case in corporate compliance. As a matter of corporate law practice, the
Caremark standard plays a small role in the design and operation of corporate
compliance programs. Its exalted place in corporate law pedagogy is belied by
its insignificance relative to the far greater legal risk created by other sources of
law. A corollary of this thesis is that the determinative view of Caremark as
preserving the role of market forces in the design and operation of corporate
compliance is false. State corporate law does not, in fact, determine whether
corporations are free to make decisions based solely on market forces. Nor does
it, in Chancellor Allen’s words, leave “the level of detail” that is appropriate for
compliance systems to directors’ “business judgment” or, under Professor
Bainbridge’s formulation, leave the development of “optimal best practices” to
“evolutionary market processes.” Their positions incorrectly presuppose that,
where one source of law has deferred to market forces, all other sources of law
have done the same.

While the Caremark standard may be determinative in deciding whether state
corporate law will interfere with market forces in the design and operation of
corporate compliance, it has no say in whether other sources of law do so. As the
Caremark court itself concedes, there are other sources of law that have assumed
the determinant role that state corporate law has abdicated.18 Chancellor Allen
specifically noted that one factor on which the Caremark standard depended was
the “powerful incentives” created by the then recently adopted Organizational
Sentencing Guidelines:19

17. Stephen M. Bainbridge, Caremark and Enterprise Risk Management, 34 J. CORP. L. 967, 982
(2009). See Desimone v. Barrows, 924 A.2d 908, 935 n.95 (Del. Ch. 2007) (“I do not read Stone as
undercutting the discretion given to corporations to address law compliance in a manner that takes into
account the precise circumstances facing the corporation. Rather, I read it as reaffirming the protection
given by Caremark to directors who make good faith judgments about how their corporations should
address law compliance, approaches that will obviously vary because of the different circumstances
corporations confront.”) (Strine, J.).

18. See Lawrence A. Cunningham, A New Legal Theory to Test Executive Pay: Contractual
Unconscionability, 96 IOWA L. REV. 1177, 1198 (2011) (Delaware’s “deferential position” on executive
compensation, its “relaxed waste standard, combined with the business judgment rule, veneration of
formal board independence, and the endorsement of special litigation committees in derivative litigation,
took Delaware courts and corporate law largely out of the policing picture.”). See also Bernard Black, Is

19. In re Caremark Int’l Inc. Derivative Litig., 698 A.2d 959, 961 (Del. Ch. 1996); see U.S.
SENTENCING GUIDELINES MANUAL ch. 8 (2010), available at
[Any rational person attempting in good faith to meet an organizational governance responsibility would be bound to take into account [the Guidelines’] development and the enhanced penalties and the opportunities for reduced sanctions that [they] offer.20

Indeed, the consequences of ignoring the Guidelines are far more likely to motivate corporate actors than the remote, secondary risk of Caremark liability.

If corporate actors are rational, they will design and operate corporate compliance systems to satisfy the source of law that imposes the highest expected costs if disregarded or violated. Thus, if Caremark liability presents the highest expected cost on corporations and corporate actors, compliance systems will conform to the Caremark standard. However, if sources of law other than state corporate law impose the highest expected cost, those sources of law—not Caremark—will be the primary legal determinants of corporate compliance systems and related governance processes.21 In fact, the compliance standards mandated by healthcare regulation and sentencing/prosecutorial guidelines impose substantially higher expected costs than Caremark and thereby trump Caremark as to the design and operation of corporate compliance.

Caremark does not, as regulatory market theorists claim, preserve market forces’ influence over corporate compliance. Caremark may be marginally relevant because corporate compliance may fall so far below federal regulatory standards that it fails the Caremark standard as well, even to the point—as Chancellor Allen put it, “in theory at least”—of triggering Caremark liability for corporate directors. However, this theoretical possibility does not make Caremark an iconic or even significant determinant of corporate compliance. Nor should Caremark be viewed as protecting the authority of market forces in the design and operation of corporate compliance systems. Rather, it evinces state corporate law’s ceding of that determinative role to other sources of law.22

http://www.ussc.gov/Guidelines/2010guidelines/ManualPDF/Chapter8.pdf. The federal sentencing guidelines are intended to establish a uniform sentencing policy for serious offenses under federal criminal law. The Organizational Sentencing Guidelines provide the standards that apply to defendants that are entities.

20. Caremark, 698 A.2d. at 970.

21. Cf. John C. Coffee, Jr., Modern Mail Fraud: The Restoration of the Public/Private Distinction, 35 AM. CRIM. L. REV. 427, 432 (1998) (“the Supreme Court has recurrently stressed that the governance of business organizations is to be determined by state law—unless Congress has clearly and explicitly said otherwise”).

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The exaltation of Caremark as an iconic case, not unlike the similarly exaggerated emphasis on Smith v. Van Gorkom, reflects a flawed corporate law pedagogy that inflates the influence of state corporate law in corporate affairs. In practice, corporate lawyers respond to the sources of law that are most determinative of corporate conduct, which more often than not will be law other than state corporate statutes or decisions. The determinative sources of law are more likely to be the law of specific industries, such as healthcare and banking; of particular internal processes, such as compliance systems and whistleblowing procedures; or of generic activities, such as employment and environmental practices.

Far from being the free actor that chooses its corporate law when choosing its state of incorporation, the modern corporation is markedly constrained by a web of sources of corporate law other than state corporate law. This web is so complex as to effectively enlist the large corporation as a kind of self-regulatory organization assigned to oversee the legal compliance of its member units. In this sense, the autopoietic modern corporation has not strayed far from its original role as an extension of state power.

The practical exercise of state power through administrative law and agency enforcement and interpretation reveals a fatal flaw in the market theory of corporate law. The fundamental flaw in corporate law market theory is its failure to posit both law and free markets as ultimately derivative of social policy. Corporate law exists only as part of the mechanism by which society has chosen to identify, amend and enforce social norms—just as free markets exist only as a means by which society has chosen to organize economic activity. Our society can and often does choose other sources of law for establishing social norms and models for organizing economic activity to perpetuate itself. Corporate law is ultimately and necessarily an extension of public policy.
This is not to question the utility of analyzing corporate law and free markets as competing determinants of business conduct; this analytical construct has significant value. However, this construct fails when corporate law and free markets are viewed as vying for an illusory crown of social hegemony over corporate affairs. Corporate law and free markets compete with, and often are secondary to, other social constructs. As to the determinants of corporate compliance, this article argues that both corporate law and free markets generally cede determinative power to the administrative state. The administrative state, through regulatory law, uses internal corporate structures to effectuate public policy, which effectively transforms the large corporation into a quasi-governmental actor that functions as a kind of self-regulatory organization.

The administrative state’s power as a determinant of a wide range of conduct is a dominant component of law practice that should be placed at the core of the law school curriculum. The legal duties created by administrative fiat should be added to or partially replace the standard curriculum’s foundational pantheon of contract, tort and property. This curriculum reflects a bias that can be alternatively framed as a pedagogical overemphasis on common law where code-based law is, in fact, predominant in legal practice.
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however, focus on the broad themes of the fundamental flaws in the market theory of corporate law or the content of corporate law pedagogy.

Rather, this article provides an empirical basis for these broad themes through a corporate law analysis that shows that federal regulatory law is a far more determinative source of law than Caremark in the design and operation of corporate compliance systems. Part II of this article compares Caremark to the parallel federal criminal prosecution of the firm to illustrate the influence of federal law in the design and operation of corporate compliance systems. Part III further discusses the determinative role of healthcare regulation in corporate compliance systems and regulatory trends, and uses recent litigation involving Pfizer Inc. to further elucidate the role of healthcare regulation. Part IV broadens the discussion by considering the role of prosecutorial and sentencing guidelines in corporate compliance generally. Part V suggests that corporate law pedagogy would be well-served by reducing its focus on state corporate law and giving greater prominence to the actual legal determinants of corporate conduct.

II. THE EXPECTED COST OF PRIVATE LIABILITY VERSUS PUBLIC ENFORCEMENT IN CAREMARK

Commentators view Caremark as a determinative source of law in the design and operation of corporate compliance systems. However, if corporate actors are assumed to respond first to the sources of law that present the highest potential expected costs, then they will respond first to the higher expected costs of public healthcare enforcement, not private Caremark liability. The expected costs of Caremark liability under state corporate law will be a secondary consideration. Indeed, Caremark liability becomes superfluous if, after fully responding to the legal risks presented by the possibility of public enforcement actions, the expected costs of Caremark liability have also been addressed.

In Caremark, Chancellor Allen approved a settlement of derivative state claims against the directors of healthcare provider Caremark International, Inc. (“Caremark”). The case followed on the heels of the federal criminal prosecution of the firm. Indicted and charged with multiple felonies, Caremark pleaded guilty to a single felony.32 It had allegedly violated the Anti-Referral Payment Law (“ARPL”),33 which generally prohibits paying kickbacks for referrals of Medicare or Medicaid business, by entering into arrangements with physicians who prescribed or recommended Caremark services.34

32. In re Caremark Int’l Inc. Derivative Litig., 698 A.2d 959, 965. This amount included $45 million paid to states in connection with Medicaid programs and $3.5 million for violating recordkeeping requirements under the Controlled Substances Act. Id.

33. Id. at 961-62.

 Plaintiffs alleged that Caremark’s directors violated their duty of care by failing to oversee adequately the conduct that formed the basis of the criminal prosecution. The parties reached a settlement, which they submitted to the court for approval. In approving the settlement, Chancellor Allen stated that a director has “a duty to attempt in good faith to assure that a corporate information and reporting system, which the board concludes is adequate, exists.” In Stone v. Ritter, the Delaware Supreme Court adopted Chancellor Allen’s standard, holding that “Caremark articulates the necessary conditions for assessing director oversight liability.” Caremark has been followed by other jurisdictions and has been applied to executives as well as directors.

Caremark appeared to raise the standard for directors’ liability with respect to legal compliance that was established in a 1963 Delaware Supreme Court decision, Graham v. Allis-Chalmers Mfg. Co. Allis-Chalmers considered the board’s role in overseeing legal compliance to be similar to its role with respect to the exercise of business judgment generally. As quoted in Caremark, Allis-Chalmers held that “absent cause for suspicion there is no duty upon the directors to install and operate a corporate system of espionage to ferret out wrongdoing which they have no reason to suspect exists.” Caremark raised the Allis-Chalmers obligation not to ignore red flags to an affirmative duty to conclude that an adequate corporate compliance system was in place. Chancellor Allen found that even if Allis-Chalmers’ standard might have been correct in 1963, it was not in 1996.

Caremark stands not only as the leading case on the liability of directors for corporate legal compliance failures, but also as an iconic case in corporate law. Commentators have described it as: a “major statement on the duty of

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Pre_96/June95/342.txt.html.

36. Id. at 961.
37. Id. at 970.
39. See supra note 5.
42. Caremark, 698 A.2d. at 969 (quoting Allis-Chalmers, 188 A.2d at 130)
43. See STEPHEN BAINBRIDGE, CORPORATE LAW 163 (2d ed. 2009) (in Caremark, “Chancellor opined that a board of directors in fact has an obligation proactively to take affirmative compliance measures”); Porcher L. Taylor III & Harris L. Kay, A Green Board as a Climate-Change Imperative: Appointing a Climate-Change Expert to the Audit Committee, U. BALT. J. ENVTL. L. 215, 243 (2011) (Caremark is “high-water mark of the Delaware court's willingness to judicially review business judgments of boards. In that case, the court expanded the board's duty of care with respect to its oversight of operations . . . [and] imposes affirmative duties even greater than those of prior cases for directors to inform themselves about the corporation's information and reporting systems.”).
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oversight,” and “destined to be one of the most prominent Delaware opinions of all time.”

It is featured prominently in most corporate law casebooks and reference works and highlighted in both The Iconic Cases in Corporate Law and Corporate Law Stories.

However, the widespread prominence afforded the Caremark standard is out of line with its practical significance. The actual effects of Caremark were trivial in comparison with the effects of the criminal prosecution of the firm. The Caremark settlement terms, described by Chancellor Allen as providing only “modest benefits” that were “not highly significant,” did little more than confirm that Caremark would comply with the ARPL and otherwise buttress some of the compliance reforms mandated by the criminal settlement. The most significant term in the Caremark settlement terms was probably the payment of more than $800,000 in attorneys’ fees.

Chancellor Allen reduced the fee request on the ground that “there was realistically a very slight contingency faced by the attorneys” due to the

44. BAUMAN, PALMITER & PARTNOY, supra note 3, at 653.
45. EPSTEIN, FREER, ROBERTS & SHEPHERD, BUSINESS STRUCTURES at 224.
46. Hillary Sale, Monitoring Caremark’s Good Faith, 32 Del. J. Corp. L. 719, 719 – 20 (2007) (noting 1608 Westlaw citations to the case to date). As of July 13, 2012, the Westlaw state and federal case databases and law journal database included 77 and 133 opinions, respectively, and 1121 articles in which Caremark have been cited.
50. It has been suggested that the size of the attorneys’ fees may reflect as much an inducement for plaintiffs to choose Delaware as their forum as the merits of the claims. See Alison Frankel, Record $285 Ml Fee Award Is Strine's Message to Plaintiffs' Bar, REUTERS, Dec. 20, 2011, available at http://newsandinsight.thomsonreuters.com/Legal/News/2011/12_-_December/Record_$285_ml_fee_award_is_Strine_s_message_to_plaintiffs__bar/.
“circumstances of the government activity.” In other words, the criminal prosecution had settled almost all doubts about the underlying misconduct, leaving the state law action little to resolve. And *Caremark*—the leading case on directors’ personal liability with respect to their oversight of corporate compliance—did not impose any personal liability, in the form of monetary penalties or other sanctions, on the directors. Considering the actual outcome in *Caremark*, rather than its statement of a higher theoretical standard of liability, it is not clear how it would independently effect material changes in the way corporations approach corporate compliance. Rational directors have little reason to fear what a Delaware court has described as “possibly the most difficult theory in corporation law upon which a plaintiff might hope to win a judgment.”

In contrast, the consequences of the *Caremark* criminal prosecution give good reason for directors and other corporate actors to modify their conduct. *Caremark* agreed to make various payments totaling approximately $250 million, $161 million of which comprised “criminal fines, civil restitution and damages for kickbacks and fraud.” At the time, the settlement amount was one of the largest obtained from a healthcare company. The Department indicted three *Caremark* employees: two vice presidents and a general manager. Although the employees ultimately were acquitted and remained employed during and after the trial, the process they endured far exceeds the relatively minimal burdens that the state law claims placed on *Caremark*’s directors. The announcement of the indictments caused a 10% decline in *Caremark*’s stock price.

The criminal prosecution caused significant upheaval in *Caremark*’s business. The company sold its home infusion business at a loss, cancelled contracts with doctors and other referral sources, expended significant resources in defending the claims and negotiating the settlement and incurred substantial reputational harm. As discussed further in the next section of this article,

51. *Caremark*, 698 A.2d. at 972.
52. *In re Citigroup Inc. S’holder Derivative Litig.*, 964 A.2d 106 (citing *Caremark*, 698 A.2d at 967).
53. DOJ *Caremark* Release, supra note 34.
54. See id.
57. See Freudenheim, supra note 55 (shares declined $2.375 to $21.125).
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Caremark entered into a lengthy and detailed Corporate Integrity Agreement (“CIA”) that dictated the design and much of the operation of Caremark’s compliance system. Chancellor Allen had good reason to acknowledge the “powerful incentives” created by the Organizational Guidelines for corporations to implement effective compliance programs, noting that any “rational person” would be bound to consider “enhanced penalties and the opportunities for reduced sanctions” that the Guidelines offer.59

The principal lesson of the Caremark litigation as a whole is not that practicing lawyers should look first to the Caremark standard when advising corporate clients regarding their compliance systems. It is not Caremark risk that creates the strongest incentives for corporate action.60 Corporate actors are more likely to be affected by the prospects of millions of dollars in fines, a substantial decline in stock price, major disruptions to business operations and personal criminal liability in their decision making61 than by the prospect of private Caremark liability under state corporate law.

Prudent counsel should recognize that administrative law, not corporate law, primarily dictates the operation and design of corporate compliance systems. Caremark’s illustration of the determinative nature of administrative law relative to corporate law reflects the pervasive role of the administrative state in regulating internal corporate structures.62 As discussed immediately below, corporate actors are far more likely to consider the terms of the Caremark CIA in designing and implementing their firms’ compliance systems than the relatively minimal expectations of Caremark.

III. HEALTHCARE REGULATION AND LEGAL COMPLIANCE

A. The Role of Healthcare Regulation

As part of one of America’s most regulated industries,63 Caremark is subject to an especially intrusive regulatory regime. Federal and state law pervasively

60. See William W. Bratton & Joseph A. McCahery, The Equilibrium Content of Corporate Federalism, 41 WAKE FOREST L. REV. 619, 676 (2006) (discussing Caremark: “we have not seen Delaware apply its duty of care so that directors of firms with compliance breakdowns are required to pay money judgments. We are highly unlikely ever to do so.”).
61. See Carrie A. Gonell & Christopher A. Parlo, Managing Wage and Hour Investigations and Litigation, 845 PLI/LIT 381, 387 (2011) (discussing “risk of individual criminal liability for individual officers of the corporation, including members of the Board of Directors, [as] enlarged under the ‘responsible corporate officer’ doctrine” (footnote omitted); Tanina Rostain, General Counsel in the Age of Compliance: Preliminary Findings and New Research Questions, 21 GEO. J. LEGAL ETHICS 465, 489 (2008) (discussing an example of corporate general counsel who “explained that he once or twice resorted to carrying handcuffs into a board meeting to ‘get attention.’”).
62. See supra text accompanying notes 26-30.
regulate healthcare at the federal and state level, and this regulation substantially affects the operations and structure of healthcare firms’ compliance systems. Even prior to the 1996 Caremark decision, Caremark’s discretion in ordering its internal compliance systems was circumscribed by detailed guidelines promulgated by the Department of Health and Human Services (“HHS”). Its compliance system would have operated pursuant to 11 detailed ARPL safe harbors promulgated by HHS in 1991, and 2 additional safe harbors promulgated in 1992. In connection with the allegations underlying Caremark, the firm entered into a CIA with HHS that required detailed changes to Caremark’s compliance and ethics program.65

The Caremark CIA sets forth the components of the program, establishes specific positions and committees within the program, requires a series of compliance reports and training and certification processes, and generally provides a comprehensive compliance structure that largely supplants Caremark’s discretion in the fashioning of its compliance policies and procedures. Chancellor Allen considered the settlement terms in Caremark to be insignificant “in light of the fact that the Caremark Board already has a functioning committee charged with overseeing corporate compliance”—a committee whose makeup and functions were largely dictated by the Caremark CIA. Caremark’s compliance systems continue to be substantially dictated by HHS. It entered into a second CIA in 2008, which it modified in 2011. For the last two decades, Caremark’s compliance system has operated under a form of regulatory receivership.

The determinative role of the CIA in Caremark’s compliance systems is hardly unusual in the healthcare industry, where CIAs are commonplace.68 The

65. See Arlen, supra note 47, at 105.
66. Caremark, 698 A.2d. at 970.
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list of active CIAs on HHS’s webpage has the comprehensiveness of a healthcare industry directory.69 One could say that HHS has become a kind of super-Chief Compliance Officer for the industry.

The dominant role that HHS plays in the design and operation of healthcare compliance is not limited to the implementation of CIAs. As HHS has stated, the effect of the rules that it administers “on providers and suppliers [is] pervasive.”70 The agency estimates that the “various guidance and procedure documents on [its] website number approximately 37,000, comprising over 7 million pages.”71 The HHS website lists more than 40 separate compliance manuals.72 The scope and detail of agency compliance guidelines has increased in part as a result of the Executive branch’s emphasis on regulators providing adequate industry guidance on compliance.73 Like other agencies, HHS has issued small business compliance guides pursuant to the requirements of the Small Business Regulatory Enforcement Fairness Act.74 Some have criticized the promulgation of compliance guidance as a form of back-door lawmaking,75 and courts have

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71. Id.


75. See HOUSE COMM. ON GOV’T REFORM, NON-BINDING LEGAL EFFECT OF AGENCY GUIDANCE DOCUMENTS, H.R. Rep. 106-1009 at 1 (106th Cong., 2d Sess. 2000) (finding “that some [federal agency] guidance documents were intended to bypass the rulemaking process and expanded an agency’s power beyond the point at which Congress should stop. Such ‘backdoor’ regulation is an abuse of power and a corruption or our Constitutional system.”); see generally Conner Raso, Do Agencies Use Guidance Documents to Avoid Presidential Control?, (Gellhorn-Sargentich Law Student Essay Competition 2010), available at http://www.americanbar.org/content/dam/aba/migrated/adminlaw/awardsprogram/Connor_Raso_GS_Essay_Winner.authcheckdam.pdf.
struck down such guidance,\textsuperscript{76} in each case an implicit acknowledgment of the role of agency guidance as a \textit{de facto} source of law.

\subsection*{B. Pfizer Corporate Integrity Agreement}

The CIA entered into by Pfizer Inc. in 2009 ("Pfizer CIA") provides more current insight into the extent to which governmental guidelines shape internal corporate compliance systems.\textsuperscript{77} The Pfizer CIA, its third since 2002,\textsuperscript{78} related to the company’s settlement of the then-largest health care fraud case in history.\textsuperscript{79} Pfizer paid $2.3 billion in civil and criminal fines and penalties, primarily in connection with its marketing of drugs for "off-label" (non-FDA-approved) uses.\textsuperscript{80} Off-label marketing claims have been the centerpiece of a number of HHS enforcement actions.\textsuperscript{81} For example, Eli Lilly had settled claims for $1.42 billion and entered into a CIA similar to Pfizer’s in January 2009.\textsuperscript{82} The prosecution of off-label marketing claims has been so extensive as to trigger an industry effort to dilute this area of regulation.\textsuperscript{83}

Through the Pfizer CIA, HHS effectively dictated much of the design and operation of Pfizer’s compliance system. The CIA, which required that Pfizer retain a Chief Compliance Office ("CCO"), expanded the CCO’s managerial

\begin{footnotesize}\begin{enumerate}
\item See Pfizer CIA, supra note 67.
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authority regarding compliance related matters, requiring direct reporting lines to the CEO and the board’s Audit Committee. The CCO did not report to Pfizer’s general counsel because HHS believed that “upper management should hear both arguments.”84 It also appointed the CCO to chair a Compliance Committee that includes senior executives of Pfizer who are tasked to “support” the CCO’s efforts under the CIA.85 The CIA requires Pfizer to report “any change in the identity of the [CCO], or any actions or changes that would affect the [CCO’s] ability to meet the obligations” of the CIA.86 These provisions reflect an understanding that it is corporate executives who exercise decision-making authority, whereas state corporate law focuses almost exclusively on directors.87

The Pfizer CIA assigns specific responsibilities to the Audit Committee, including that each member sign a “resolution . . . summarizing its review and oversight of Pfizer’s compliance program and compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA.”88 The resolution must include, verbatim, a statement in the CIA that the Committee “has made a reasonable inquiry into the operations of Pfizer’s Compliance Program, including but not limited to evaluating its effectiveness and receiving updates” and has “concluded” that Pfizer has implemented an “effective Compliance Program.”89 If the Committee is unable to reach such a conclusion, then the resolution must include an explanation as to why and identify “the steps it is taking to assure implementation by Pfizer of an effective Compliance Program.”90 Business unit presidents, certain other executives and certain employees who report to them must certify, among other things, their having reviewed various reports, referred potential violations up the chain of command and the signers’ understanding that the certification is being “provided to and relied upon by the United States.”91

Other detailed requirements relate to the following: the substance of Pfizer’s Code of Conduct, receipt of which must be certified by employees; the substance of its policies and procedures, including, for example, detailed requirements relating to information regarding off-label uses of Pfizer’s products; and the

84. See Miller, supra note 78.
85. Pfizer CIA, supra note 68, at 3.
86. Id. Pfizer is also required to report any change in the composition of the Compliance Committee, or any actions or changes that would affect the [CCO’s] ability to “satisfy the requirements” of the CIA. Id. at 5.
87. See Timothy P. Glynn, Taking Self-Regulation Seriously: High-Ranking Officer Sanctions for Work-Law Violations, 32 BERKELEY J. EMP. & LAB. L. 279, 326 (2011) (“state corporate-law focuses almost exclusively on director obligations, largely ignoring officers and other supervisors, except in their capacity as directors or when they exert direct influence over board members.”).
88. Pfizer CIA, supra note 69, at 5.
89. Id.
90. Id. at 5-6.
91. Id.
compliance training and education of its employees, including the number of hours, content, instructor qualifications, and certifications. 92 The CIA requires that Pfizer maintain a Disclosure Program and a Consultant Monitoring Program, and establish a detailed “Field Force Monitoring Program to evaluate and monitor field representatives’ interactions with [health care professionals] and to identify potential off-label promotional activities.” 93

The Pfizer CIA requires the implementation of a Risk Assessment and Mitigation Planning tool (“RAMP”), which entails semi-annual identification of compliance-related risks in accordance with the detailed requirements described in a 6-page appendix to the CIA. 94 These include: identifying a Pfizer “Attorney” to develop a risk mitigation plan for each product, retaining an outside reviewer to evaluate the RAMP and producing a series of assessments and reports. 95 Pfizer must engage an Independent Review Organization (“IRO”) that has extensive responsibility for an extensive set of compliance tasks. 96 The CIA grants the IRO significant authority regarding the evaluation of the effectiveness of Pfizer’s compliance programs, and the IRO may be retained only if not found unacceptable by HHS.

The CIA includes a laundry list of stipulated penalties for various breaches of its terms, generally entailing daily fines of $1,000 to $5,000 for each of a number of failures to meet specific obligations under the CIA (e.g., $2,500 each day Pfizer fails to engage an IRO). 97 Pfizer agreed that a material breach of the CIA would constitute an “independent basis for exclusion from participation in the Federal health care programs.” 98 CIA violations may provide an independent basis for a punitive damages award in private litigation arising from related tortious conduct. 99

Thus, the Pfizer CIA dictates much of the design and operation of its compliance program. It assigns responsibilities to particular employees within the organization and grants them authority to bypass typical lines of authority within the corporate structure. It mandates specific monitoring approaches and creates liability risk, independent of substantive compliance procedures, in the form of attestations, certifications and internal control reports—procedures similar to those required under the Public Accounting Reform and Investor Protection Act of 2002 (“Sarbanes-Oxley Act” or “SOXA”). 100

92. See id. at 7-17.
93. Id. at 22-23, 27-33.
94. See id. at 17.
95. Id. at 20-22, app. C.
96. See id. at 17-20, apps. A & B.
97. See id. at 51-53.
98. Id. at 54.
99. See Maclean, supra note 69.
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leaves little, if any, discretion to corporate actors to develop a compliance system pursuant to the exercise of business judgment that Chancellor Allen and Professor Bainbridge believe Caremark to have preserved.101 As Professor Mark Roe described SOXA’s prescriptions, it is the Pfizer CIA that “creates internal managerial duties and allocates authority inside the firm”102 in derogation of market forces. Healthcare regulation is no different from SOXA, and a bevy of other sources of administrative law, in reflecting the dominant role of the administrative state in U.S. law.103

C. Pfizer Caremark Litigation

The Caremark claim brought against Pfizer also illustrates the irrelevance of Caremark relative to the determinant role of federal healthcare regulation. Like Caremark, Pfizer settled a Caremark claim based on the conduct underlying the federal prosecution.104 But the Pfizer I settlement differed from the Caremark settlement in two significant respects. First, the Pfizer I court found that the compliance aspects of the settlement would “provide significant corporate benefits for Pfizer and its shareholders,”105 whereas Chancellor Allen disparaged the significance of the Caremark settlement terms.106 Second, the Pfizer I court strongly implied that the defendants had violated their fiduciary duty.107 In

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101. See supra text accompanying notes 12-17.
102. Roe, supra note 10, at 598.
103. See infra Part V; see also supra text accompanying notes 27-31.
104. See In re Pfizer, Inc. S’holder Derivative Litig., 780 F. Supp. 2d 336 (S.D.N.Y. 2011) (“Pfizer II”); see also In re Pfizer, Inc. S’holder Derivative Litig., 722 F. Supp. 2d 453 (S.D.N.Y. 2010) (“Pfizer I”) (denying defendants’ motion to dismiss breach of fiduciary claim). In 2007, another Caremark claim against Pfizer was dismissed. See In re Pfizer, Inc. S’holder Derivative Litig., 503 F. Supp. 2d 680 (S.D.N.Y. 2007); see also In re Abbott Labs. Derivative S’holder Litig., 325 F.3d 795 (7th Cir. 2003) (pre-suit demand excused where plaintiffs alleged directors knew of violations of law and took no steps to prevent or remedy the situation); McCall v. Scott, 239 F.3d 808 (6th Cir. 2001) (pre-suit demand excused where plaintiffs alleged directors’ failure to afford adequate attention to potentially illegal corporate activities).
105. Pfizer II, 780 F. Supp. 2d at 343.
107. The court found that there was evidence supporting the view that Pfizer’s directors “all knew of Pfizer’s continued misconduct and chose to disregard it.” Pfizer I, 722 F. Supp. 2d at 460-62. (“Many of these disturbing reports [by Pfizer compliance personnel describing continuing kickbacks and off-label marketing] were received during the same time that the board was obligated by the 2002 and 2004 CIAs to pay special attention to these very problems... To put it bluntly, the allegations of the Complaint evidence misconduct of such pervasiveness and magnitude, undertaken in the face of the board’s own express formal undertakings to directly monitor and prevent such misconduct, that the inference of deliberate disregard by each and every member of the board is entirely reasonable.”).
Caremark, Chancellor Allen emphasized the “weakness of the plaintiffs’ claims” and a record that included “no evidence that the director defendants were guilty of a sustained failure to exercise their oversight function.”

These differences make Pfizer a good candidate to test this article’s claim that Caremark is largely irrelevant as a determinant of corporate compliance because Pfizer I purports to give Caremark a determinative role in corporate compliance. In contrast, Caremark asserts a state corporate law standard while in full retreat. The “centerpiece of the [Pfizer I settlement agreement] was the establishing and funding of a “Regulatory Committee, which will have a broad mandate to oversee the company’s drug promotion and marketing practices and compliance with regulatory requirements applicable to same.” The agreement endowed the Committee with information access and investigative powers, including the authority to order audits and review the incentive structure of employees’ compensation. It also authorized the Committee to make recommendations to Pfizer’s Compensation Committee regarding the “‘clawback’ of previously-awarded incentive compensation” and required the creation of an ombudsman program.

The Pfizer I settlement also required that Pfizer’s insurers pay $75 million toward attorneys’ fees and expenses and the funding of the Committee’s activities, which dwarfs the monetary component of the Caremark settlement. In addition, Pfizer would have incurred the expense of extensive discovery and other litigation activities, which would likely have amounted to tens of millions of dollars.

Thus, the Pfizer I settlement terms present a much stronger case than the Caremark settlement terms for attributing a determinative role to state corporate law. As a matter of practice, the Pfizer I settlement terms reflect a material enhancement of the terms of the CIA, with the principal changes being the shifting of compliance oversight from the Audit Committee under the CIA to the Regulatory Committee, and the clawback and ombudsman provisions. Neither

108. Caremark, 698 A.2d. at 971-72.
109. See supra text accompanying notes 8-11, 49-52.
110. Pfizer II, 780 F. Supp. 2d at 338.
111. See id. at 338-39.
112. Id. at 339-40.
113. See Duff Wilson, Pfizer Plans $75 Million Fund To Address Shareholder Suits, N.Y. TIMES, Dec. 4, 2010, at B2. A Pfizer shareholder objected to the settlement partly on the ground that it did not provide for any “monetary recovery for the shareholders.” Pfizer II, 780 F. Supp. 2d at 341 (citing Objection of Nora Vides to Settlement (Jan. 31, 2011)). The court stated that this was incorrect as demonstrated by the $75 million payment to fund the Committee and pay expenses. Id.
114. See Pfizer II, 780 F. Supp. 2d at 340 (describing “vigorous motion practice and very full discovery that included production of over 12 million documents, dozens of fact and expert depositions, and the exchange of detailed expert reports from highly-qualified experts”).
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the $75 million insurer payment nor the costs of the disruption and fees associated with Pfizer’s defense of the state corporate law claims were trivial. Thus, in contrast with the Caremark settlement, the Pfizer I settlement terms reflect material consequences for counsel to consider in advising healthcare firms regarding their compliance systems.

However, the consequences of Pfizer I still pale in comparison with the consequences of the public enforcement actions. Accordingly, the expected costs of liability under state corporate law are unlikely to create incentives that provide material competition for the incentives created by other sources of law. The Pfizer I settlement’s compliance terms were essentially derivative of, or supplemental to, the far more expansive and detailed Pfizer CIA. The settlement did not entail any personal liability on the part of Pfizer’s directors, notwithstanding that the court found that there was evidence supporting the view that Pfizer’s directors “all knew of Pfizer’s continued misconduct and chose to disregard it.”

Corporate actors are far more likely to design their compliance systems in response to the risks created by a federal enforcement action, as illustrated by the $2.3 billion in criminal and civil sanctions paid by Pfizer117 (since overshadowed by $3 billion in criminal and civil sanctions paid by Glaxo for improper marketing118), the adverse effect on the company’s stock price and the potential personal civil and criminal liability of Pfizer employees, than in response to the expected costs of Caremark claims. Given a choice between conforming compliance systems to the common elements of dozens of CIAs imposed on healthcare firms and the compliance terms appearing in state corporate law settlements, corporate actors would be prudent to choose the former.

The Pfizer I court specifically observed that other CIAs that Pfizer had agreed to prior to the federal prosecution “imposed affirmative obligations on Pfizer’s board that went well beyond the basic fiduciary duties required by Delaware law.”

regulatory and compliance oversight to the Audit Committee is inadequate. After the Sarbanes Oxley Act, an audit committee of a large public company is fully engaged with oversight of the company’s financial disclosure. The importance and singularity of this responsibility is reflected by the requirement of qualifications for audit committee membership that focus on financial literacy and experience.”).

116. Pfizer I, 722 F. Supp. 2d at 460-62 (“Many of these disturbing reports [by Pfizer compliance personnel describing continuing kickbacks and off-label marketing] were received during the same time that the board was obligated by the 2002 and 2004 CIAs to pay special attention to these very problems…. To put it bluntly, the allegations of the Complaint evidence misconduct of such pervasiveness and magnitude, undertaken in the face of the board’s own express formal undertakings to directly monitor and prevent such misconduct, that the inference of deliberate disregard by each and every member of the board is entirely reasonable.”).

117. See supra text accompanying note 80.


federal authorities will approve is far more likely to reduce the expected liability costs of public enforcement than doing the same with respect to the kinds of procedures negotiated pursuant to state corporate law settlements. Concededly, legal compliance failures may also have state corporate law consequences, which in Pfizer’s case were reflected in a meaningful enhancement of the compliance terms of the public enforcement settlement and at least the specter of directors’ personal liability. Yet, the incentives created by these consequences are still secondary to the considerably more powerful incentives created by the potential consequences of a federal prosecution.

Pfizer I shows that even the incentives created by a strong-form application of the Caremark standard pale in comparison with the legal determinacy of federal healthcare regulation. It is healthcare regulation, not state corporate law, which creates the strongest impetus for the design and operation of corporate compliance systems. To the extent that healthcare compliance is guided by a rational evaluation of the consequences of legally inadequate compliance systems, it will be dictated primarily by federal healthcare regulation. Healthcare firms will attempt to identify the compliance systems that satisfy federal officials’ view of legally adequate compliance because the expected value to corporate actors of doing so dwarfs the expected value of satisfying Caremark. It may be true that the Caremark standard is so low as to remove state corporate law as an impediment to market-driven compliance systems, but it does not remove other sources of law as potential impediments. Where federal law is supreme, state corporate law cannot remove other sources of law. Nor does the state law of incorporation even have the definitive authority to trump other sources of state or municipal law.120

D. Healthcare Regulation Trends

Recent trends indicate that the role of healthcare regulation in the design and operation of corporate compliance systems will continue to expand. Over the last two decades, federal authorities have dramatically expanded their investigation and enforcement program. The Health Insurance Portability and Accountability Act of 1996 established a national Health Care Fraud and Abuse Control Program under DOJ and HHS to coordinate federal, state and local health care fraud enforcement.121 The Act authorized the use of the Medicare Trust Fund

120. See Anne B. Claiborne, Julia R. Hesse & Daniel T. Roble, Legal Impediments to Implementing Value-Based Purchasing in Healthcare, 35 AM. J.L. & MED. 442, 457 (2009) (citing state anti-kickback laws and noting that federal safe harbors do not necessarily preempt such laws).

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account to finance anti-fraud activities.122

In 2009, DOJ and HHS created the interagency Health Care Fraud Prevention & Enforcement Action Team,123 which recovered more than $4 billion “stolen from federal health care programs” in fiscal year 2010 alone.124 The Patient Protection and Affordable Care Act of 2010 (“PPACA”), which provided $310 million over ten years to fund the prosecution of health care fraud,125 provided for the “enhancement and extension of the federal government’s fraud and abuse capabilities and providers’ program integrity obligations.”126

The use of CIAs in connection with the settlement of healthcare prosecutions has grown steadily, with the total of 32 CIAs from 2002 to 2006 rising to 275 from 2006 to 2011.127 Commentators have described these “not-so-voluntary”128 CIAs as “essentially an administratively enforced compliance program paid for by the company but enforced by the government.”129 As discussed above with respect to the Pfizer 2009 CIA, CIAs dictate the details of corporate healthcare compliance programs. For example, the CIA agreed to by St. Joseph Medical Center in 2010 required the appointment of a “Medical Director of Cardiac Catheterization Laboratory” who was certified by the American Board of Internal Medicine in cardiology.130 The Medical Director would be responsible for “clinical management and oversight” at the Laboratory and making quarterly reports to the Physician Executives and Compliance officer (positions also required by the CIA). He/she also had the authority to report to, among others, the board of directors “at any time.”131

122. See id. at 3.
128. Adrienne Dresevic & Donald H. Romano, The Medicare Enrollment Process – CMS’s Most Potent Program Integrity Tool, 23 HEALTH LAW., no. 4, at 1, 15 (April 2011)
129. Greg Luce, Defending the Health Care Industry Against the Government’s Expanding and Novel Theories of Liability, ASPATORE, 2011 WL 4453324 (Sep. 2011).
131. Id. (also requiring notice to OIG of appointment and change in Director, and “any actions or changes that would affect ability” of the Director to perform duties under the CIA).
The expanding federal enforcement of compliance expectations has not been limited to the exercise of its prosecutorial powers. The administration of the Medicare enrollment process has provided another avenue by which healthcare companies compliance programs are dictated by federal law. In 2010, the PPACA made compliance programs, which had technically been voluntary, mandatory for certain healthcare industry participants when they initially enroll in Medicare and required that programs include “core elements” as determined by HHS. In a proposed rulemaking, HHS requested comment on the core elements requirement, including specifically on whether they should reflect the core elements of the Guidelines. The final core elements have not been adopted, but they are likely to reflect core compliance program elements previously promulgated for particular industry segments. For example, the CMS Prescription Drug Benefit Manual comprises a 70-page guide to the detail of which belies the Manual’s claim that “adoption of the methods suggested within [the Manual] on how to implement a comprehensive fraud and abuse program are left to the discretion” of the benefit plan sponsor.

In summary, healthcare compliance systems are designed and operated in the shadow of a dizzying array of federal mandates and guidelines. Ignoring these sources of law would expose the firm and its employees to substantial enforcement and civil liability risk. The financial risk has increased over time; Pfizer’s record-setting $2.3 billion settlement was recently eclipsed by Glaxo-Kline’s agreement to pay $3 billion to settle off-label marketing and other charges. Federal authorities have steadily expanded their influence in the design and operation of compliance programs, as well as their willingness to prosecute criminally corporate executives.

Thus, it is primarily with respect to these very real liability risks, in contrast with practicably limited Caremark risk, that prudent lawyers should advise their healthcare clients to construct and operate their compliance systems. However, the contingency of Caremark as a determinant of corporate conduct is not solely attributable to the particular healthcare regulatory regime under which similar firms operate. As discussed below, other sources of law play a significant role in guiding corporate policy. Federal sentencing and prosecutorial guidelines that...
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apply broadly to all types of businesses also play a determinative role in deciding the design and operation of corporate compliance systems.

IV. FEDERAL ENFORCEMENT POLICIES AND REGULATORY COMPLIANCE

A. Sentencing and Prosecutorial Guidelines

The influence of federal regulation on corporate compliance systems is not limited to healthcare-specific rules. The Organizational Guidelines apply with respect to the sentencing of all businesses convicted of federal criminal law. It was the Guidelines, not healthcare regulations, that Chancellor Allen cited as providing “powerful incentives” for corporations to implement effective compliance systems.\(^\text{136}\) In addition to the Guidelines, the factors that federal prosecutors use in charging decisions also constitute a determinative source of federal law.

The Organizational Guidelines provide for a reduction in penalties for a company that, among other things, has established “an effective compliance and ethics program.”\(^\text{137}\) The Guidelines assist companies regarding what qualifies as an effective compliance program by “providing a structural foundation from which an organization may self-police its own conduct.”\(^\text{138}\) This “structural foundation” comprises a fairly detailed vision of how corporation compliance systems should be designed and operated. For example, the Guidelines envision that a firm’s compliance program be implemented through specific channels of authority. Specific “high-level personnel” must “be assigned overall responsibility” for the program.\(^\text{139}\) High-level personnel include “a director; an executive officer; an individual in charge of a major business or functional unit of the organization, such as sales, administration, or finance; and an individual with a substantial ownership interest.”\(^\text{140}\) The procedures must expressly assign “overall responsibility” at the “executive officer” level and reflect the responsibility of the leaders—whatever their titles—of both business units and functional leadership.

The assignment of responsibility to individuals “with a substantial ownership interest” steps outside of the management structure and into the realm of shareholders’ duties that arise as a consequence of their status as shareholders, which directly intrudes into the realm of the allocation of intracorporate power.

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137. See U.S. SENTENCING GUIDELINES MANUAL, supra note 19, at 496 (One purpose of the Guidelines is to create “incentives for organizations to maintain internal mechanisms for preventing, detecting, and reporting criminal conduct.”).
138. Id.
139. Id. § 8B2.1(b)(2)(B).
140. Id. § 8B2.1(b)(3)(B).
and responsibility. The Organizational Guidelines effectively determine high-level decisions regarding aspects of the allocation of compliance authority and responsibility. One commentator notes that the Guidelines “have been credited with helping to create an entirely new job description: the Ethics and Compliance Officer.”\footnote{141. Diana E. Murphy, The Federal Sentencing Guidelines for Organizations: A Decade of Promoting Compliance and Ethics, 87 IOWA L. REV. 697, 710 (2002).}

Yet this is precisely the kind of allocation of power and responsibility that the Caremark standard purportedly reserves to the discretion of the board of directors. Left to their own designs, corporate directors and officers might prefer alternative structures that more efficiently effect compliance and maximize profits. For example, they might conclude that “assigning” a compliance role to an individual with a “substantial ownership interest” or the head of the sales department could weaken compliance, depending on the particular characteristics of the firm. However, the corporation has a strong incentive to conform its compliance program to the Guidelines’ requirements. As Chancellor Allen’s recognition of this incentive reflects, the Guidelines have a higher claim on corporate conduct than any secondary incentives created by potential Caremark liability. Commentators have described the Guidelines as having “drafted [private companies] into a war against corporate crime.”\footnote{142. Ilene H. Nagel & Winthrop M. Swenson, The Federal Sentencing Guidelines for Corporations: Their Development, Theoretical Underpinnings, and Some Thoughts about Their Future, 71 WASH. U. L.Q. 205, 209 (1993) (citing Otto G. Obermaier, Drafting Companies to Fight Crime, N.Y. TIMES, May 24, 1992, at F11); see also supra text accompanying notes 27-31.}


Most federal criminal cases against corporations are settled, which gives the factors considered by the Department of Justice potentially greater direct significance than the Organizational Guidelines in incentivizing corporate actors.\footnote{144. See Rebecca Walker, The Evolution of the Law of Corporate Compliance in The United States: A Brief Overview, 1910 PLI/CORP 87, 104-06 (2011); Kristen K. McGuffey & Thomas C. Soldan, Right-Sizing: Customizing Compliance to the Small Corporation, 1661 PLI/CORP 97, 102-03 (2008).}
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Prosecution Standards reflect the Guidelines’ treatment of effective compliance programs as a mitigating factor.\textsuperscript{145} The Guidelines are cited throughout the Standards in support of factors relating to the pervasiveness of wrongdoing, past compliance history, cooperation and self-disclosure and, particularly, the elements of a well-designed compliance program.\textsuperscript{146} These factors also provide a reference point in the Department’s negotiation of plea agreements.\textsuperscript{147}

Like the Organizational Guidelines, the Prosecution Standards emphasize the role of high-level personnel in effectuating compliance. For example, the most important aspect of the “pervasiveness of wrongdoing” factor is the “role of management,”\textsuperscript{148} and management is expected to enforce the corporation’s compliance program.\textsuperscript{149} Compliance programs should “provide[] for a staff sufficient to audit, document, analyze, and utilize the results of the corporation’s compliance efforts,” and “be designed to detect the particular types of misconduct most likely to occur in a particular corporation’s line of business,” with special standards applying to corporations that operate in “complex regulatory environments.”\textsuperscript{150} The Department encourages the use of internal investigations and voluntary disclosure programs in evaluating its level of cooperation and disclosure, which is also a mitigating factor under the Guidelines.\textsuperscript{151}

The Organizational Guidelines and the Prosecution Standards set forth a model for legal compliance that substantially supplants corporate directors in determining the structure and operation of corporate compliance systems. Both the Guidelines and the Standards allow for significant variations in the details of compliance programs, they effectively make the high-level decisions that, under state corporate law, would otherwise fall to the board of directors and senior executives. Corporations must heed the incentives created by HHS CIAs, the Guidelines and the Prosecution Standards, as Caremark itself suggests they must. State corporate law cannot be said to preserve directors’ freedom in the development and implementation of corporate compliance programs where that freedom has already been substantially curtailed by federal sources of law.

\textsuperscript{145} See PROSECUTION STANDARDS, supra note 143, at § 9-28.800, n.5. See generally Eastman, supra note 143, at 1627-28.

\textsuperscript{146} See PROSECUTION STANDARDS, supra note 143, at §§ 9-28.500(B), 9-28.600(B), 9-28.800(B) & n.7; see also McGreal, The Amended Organizational Sentencing Guidelines: Top Ten Things Attorneys Should Know, 2 HOUS. LAW. 10, 11 (March/April 2005) (influence of Organizational Guidelines in charging decisions).

\textsuperscript{147} See PROSECUTION STANDARDS, supra note 143, 9-28.500(B), 9-28.600(B), 9-28.800(B) & n.7, 9-28.1300(B)

\textsuperscript{148} See id. at § 9-28.500(B).

\textsuperscript{149} See id. at § 9-28.600(B).

\textsuperscript{150} See id.

\textsuperscript{151} See id.
B. Trends in Federal Prosecution and Sentencing

As with the role of HHS, the role of the DOJ in determining compliance has steadily expanded over the last few decades, a trend that portends Caremark becoming even less relevant to healthcare firms’ compliance systems. The original U.S. Sentencing Guidelines provided for fine reductions if the organization had an “effective program to prevent and detect violations of law.” In 2004, the Guidelines were amended to provide a more detailed roadmap for effective compliance programs, requiring, for example, that compliance programs have, at a minimum, seven specific components. The 2004 amendments also assigned specific responsibilities to an organization’s board and high-level personnel, and added requirements for training, internal evaluations and employee incentives. Although in 2005 the Supreme Court held that the mandatory nature of the Guidelines was unconstitutional, it nonetheless has required lower courts to continue to consider the Guidelines as “the starting point and initial benchmark” of a sentence.

In 2010, additional amendments to the Organizational Guidelines further increased their level of detail. These amendments created incentives to have the executive responsible for the compliance program report to the highest authority at the organization. This generally means having the Chief Compliance Officer report to the board rather than the CEO, as reflected in the Pfizer CIA discussed above. The Guidelines create an expectation that the CCO will report to the board at least annually on instances of misconduct and on the implementation and effectiveness of the program. The 2010 amendments also

152. See supra Part III.D.
153. ORGANIZATIONAL GUIDELINES, supra note 19, at § 8C2.5(f).
154. See Walker, supra note 145, at 97 (“The amendments make the Guidelines’ definition of an effective compliance and ethics program substantially more detailed and more rigorous than the 1991 version.”); Eastman, supra note 143, at 1625-27.
156. See Walker, supra note 144, at 100.
158. Gall v. United States, 552 U.S. 38, 49 (2007). See Rita v. United States, 551 U.S. 338, 341 (2007) (appeals court may apply presumption of reasonableness to sentence within Sentencing Guidelines’ range). It is not even clear that Booker applies to organizational defendants because it is not clear that they are entitled to the Sixth Amendment right to a jury trial; see McGreal, supra note 146, at 11 (citing Alan L. Adlestein, A Corporation’s Right to a Jury Trial under the Sixth Amendment, 27 U.C. DAVIS L. REV. 375, 376 (1994)).
159. See Walker, supra note 144, at 101 (citing ORGANIZATIONAL GUIDELINES § 8C2.5(f)(2) & (3)).
160. See supra Part III(b).
161. See Walker, supra note 144, at 101 (citing ORGANIZATIONAL GUIDELINES § 8C2.5, cmt. 11).
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made compliance programs more proactive by requiring that a company take “reasonable steps to respond appropriately to the criminal conduct and to prevent further similar criminal conduct, including making any necessary modifications to the organization’s compliance and ethics program.” These steps include making restitution to victims, self-reporting and cooperation with investigators.

The DOJ’s increased use of deferred prosecution agreements (“DPAs”) has further expanded the federal role in dictating the design and operation of corporate compliance. Under a DPA, the DOJ agrees to dismiss criminal charges at the expiration of the agreement if the company has complied with its terms. The terms often include compliance program requirements. For example, a 2007 DPA with Baker-Hughes Inc. included compliance requirements relating to the assignment of compliance responsibilities to specific officers, communication of compliance policies to personnel, training of personnel, a reporting system for suspected violations, disciplinary procedures, record retention policies, specific contract terms relating to the prevention of bribery, and independent audits.

While the pervasiveness of healthcare regulation may make Caremark a beacon of the practicable limits of state corporate law, healthcare regulation reflects only one example of sources of law that are the true determinants of corporate compliance policy. Federal prosecutorial and sentencing guidelines, which apply to a broad swath of corporate conduct, constitute a significant source of corporate law. The importance of state corporate law in determining corporate policy is greatly overstated in many more areas than the compliance practices covered by Caremark.

V. Regulatory Compliance as Corporate Law

The determinacy of non-Caremark sources of law in corporate compliance policies and procedures recommends a systematic re-assessment of corporate law pedagogy. The dominance of state law in corporate law pedagogy misleads students and practitioners as to the true dynamics of corporate law practice. As discussed in this article, the contrast between the practical irrelevance of Caremark and its treatment in the corporate law literature is striking, but not

162. Id. at 102 (citing Organizational Guidelines § 8B2.1(b)(7)).
163. See id. (citing Organizational Guidelines § 8B2.1(b), cmt. 6).
164. See id. at 106-09.
166. See Rustain, supra note 61, at 467 (“The emphasis on compliance pervades every sphere of corporate regulation, including environmental protection, occupational health, health care regulation, anti-terrorism legislation, and employment discrimination.” (footnotes omitted)).
unique. Commentators have previously noted the practical unimportance of *Van Gorkom*, which for decades has been the most prominently featured judicial opinion in corporate law casebooks but plays a very small role in actual corporate decision making.167

The claim that *Caremark* is an iconic case is true only within the very narrow category of state corporate law. However, the foundation of a corporate lawyer’s practice should be understood as the solving of corporate clients’ legal problems, and for very few of these problems is state corporate law the starting point for the corporate lawyer.168 A more promising way to organize corporate law would be to focus on the sources of law that actually determine business practices. In this sense, *Caremark* is not iconic; it is virtually irrelevant.

The *Caremark*- and Pfizer-related litigation discussed above illustrates the importance of sources of law that regulate specific industries, such as healthcare. As discussed in the remainder of this article, other useful starting points for re-organizing corporate law pedagogy may be regulation that is process-based or activity-based in the sense of addressing, respectively, corporations’ internal structures and generic business activities.

### A. Corporate Law as Industry-Based Regulation

Many industries, in addition to healthcare and banking, are subject to regulatory oversight that creates greater incentives for corporate conduct than *Caremark*. This oversight is often designed to cover particular businesses. Particularized regulatory regimes predominate over state corporate law in a variety of industries, including financial services, media, telecommunications, mining, energy and transportation. Some regulatory fields break down into distinct areas – *e.g.*, financial services into banking, insurance and securities – that break down further into sub-areas – *e.g.*, securities into broker-dealers, investment advisers and investment companies. It may be true for each industry that the *Caremark* standard determines directors’ liability under state corporate law, but it is too facile a leap from this narrow position to assume that a low state corporate law conduct standard results in the field of legal compliance being left to directors’ judgment. In none of these industries could the *Caremark* standard reasonably be said to be determinative of the design or operation of corporate legal compliance.

For example, *Stone v. Ritter*, the second most prominent corporate law case on directors’ liability with respect to compliance oversight,169 illustrates how

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167. See, *e.g.*, Hammermesh, *supra* note 23.
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banking regulation acts as a source of law in corporate legal compliance. In Stone, shareholders of AmSouth Bancorporation sued its directors in connection with AmSouth’s and a subsidiary’s payment of $50 million in fines and penalties for failures to file suspicious activity reports and other violations of the Bank Secrecy Act and anti-money laundering regulations. As with Caremark, AmSouth was subject to a settlement setting forth detailed requirements regarding compliance with federal regulations, in this case relating to money laundering. AmSouth agreed to retain an approved consultant to conduct a comprehensive review of its compliance systems and to submit a compliance program that satisfied specific structural, reporting, training and personnel requirements. Its Cease and Desist Order includes a requirement that the board of directors submit a detailed compliance system review that identifies specific steps that the board proposes to take to improve AmSouth’s anti-money laundering, customer due diligence and fraud detection programs.

The Stone court and federal enforcement officials took very different views of the efficacy of the company’s compliance systems. Stone found that the directors had met their Caremark obligations, citing a consultant’s report as having established that the directors “discharged their oversight responsibility to establish an information and reporting system.” Thus, state corporate law as applied created no formal legal incentive to do more than what the AmSouth board had done.

In contrast, FinCEN and the Federal Reserve Board found that AmSouth had failed to “establish an adequate anti-money-laundering program” and that “systemic defects in AmSouth’s program with respect to internal controls, employee training, and independent review resulted in failures to identify, analyze and report suspicious activity occurring at the bank.” The AmSouth Order left no doubt as to which source of law would rule AmSouth’s future compliance practices. Banking, like healthcare, is a heavily regulated industry, and banking regulation, like healthcare regulation, is far more influential as a determinant of corporate compliance systems than state corporate law.

Chancellor Allen’s standard, holding that “Caremark articulates the necessary conditions for assessing director oversight liability.” Id. at 370. The court found that the plaintiffs did not adequately allege that the directors “utterly failed to implement any reporting or information system or controls; or “having implemented such a system or controls, consciously failed to monitor or oversee its operations thus disabling themselves from being informed of risks or problems requiring their attention.” Id. 170.


If banking regulators’ requirements or expectations dictate the design and operation of AML compliance systems, it makes no difference that the Caremark standard protects directors’ discretion in their oversight of compliance. Again, another source of law has effectively stripped the directors of that authority. The legal guidance provided to corporate actors regarding corporate compliance systems will be driven primarily not by Caremark liability risk, but by liability risk arising from authority other than state corporate law. As the facts in both Caremark and Stone illustrate, a board’s satisfying of its Caremark duties reveals little or nothing about the sources of law that actually guide companies’ and their executives’ successful management of their legal compliance duties. Equating the absence of state corporate law constraints with the supremacy of “evolutionary market forces” in corporate compliance is a false equation.

B. Corporate Law as Process-Based Regulation

Sources of law that trump state corporate law are not limited to industry-based regulation; they include other forms of regulation that effectively exploit internal corporate processes – the heart of corporate law – to cause the internalization of the full social costs of corporate activity.173 The Guidelines and DOJ Prosecution Standards are examples of what might be called “process-based” regulation in that their effect is on the generic processes used by corporations to effect compliance, rather than arising, for example, from regulation that is specific to a particular industry or business activity.

Whistleblowing regulation is another example of process-based corporate law, the influence of which has expanded substantially in corporate processes.174 Whistleblower provisions have been incorporated into a wide variety of regulatory schemes, with the most prominent recent additions appearing in SOXA and the Dodd-Frank Act. Section 302 of SOXA requires that public company audit committees “establish procedures for the confidential, anonymous submission by employees of the issuer of concerns regarding questionable accounting or auditing matters.”175 Section 922 of the Dodd-Frank

173. See Beate Sjåfjell, Internalizing Externalities in E.U. Law: Why Neither Corporate Governance Nor Corporate Social Responsibility Provides the Answers, 40 GEO. WASH. INT’L L. REV. 977, 988-89 (2009) (distinguishing corporate internalization of externalities (social costs) through the corporate self from internalization through incentives to act as if prompted by the corporate self).


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Act effectively mandated specific structures and procedures for corporate compliance systems.176

The recent debate regarding the SEC’s promulgation of whistleblower rules under the Dodd-Frank Act illustrates how process-based regulation can exceed even the intrusiveness of industry-based regulation in dictating the design and operation of corporate compliance systems. The Dodd-Frank Act substantially increased whistleblower’s economic incentives to report original information regarding corporate wrongdoing to the SEC, but did not require that whistleblowers first exhaust, or even initiate, internal reporting processes as a condition of receiving a reward.177 The SEC’s rules adopted under these whistleblowing provisions reduced the incentives to report misconduct outside of the corporation by excluding directors, officers, compliance personnel and employees of the firm’s public accountant from eligibility to receive awards.178 The SEC also provided that whistleblowers would receive full credit for original information provided internally as long as that information was reported within 120 days of the internal disclosure. It also decided that internal reporting would constitute a plus factor in determining the size of the whistleblower’s award.179 Each of these factors creates an incentive for whistleblowers to report internally and to wait up to 120 days to receive the results of the internal report before taking the information to regulators.

The rules will dictate, in effect, detailed aspects of corporate compliance systems. They create incentives, for example, for corporations (1) to structure internal reporting procedures to provide that initial reports are made to an excluded person (i.e., rather than to a non-excluded supervisor) and (2) to ensure that results of internal investigations that are adverse to the whistleblower are not

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Cunningham, The Sarbanes-Oxley Yawn: Heavy Rhetoric, Light Reform (And It Might Just Work), 35 CONN. L. REV. 915, 954-55 (2003) (SOXA “makes express some federal incursions into territory once governed exclusively by states”); E. Norman Veasey, Corporate Governance and Ethics in the Post-Enron WorldCom Environment, 38 WAKE FOREST L. REV. 839, 848 (2003) (former Chief Justice, Delaware Supreme Court, discussing SOXA’s “new requirements that reach into corporate internal affairs”). Notwithstanding that in virtually all Caremark scenarios (e.g., Stone), state corporate law generally has been found not to have been violated where federal prosecutors have found federal standards to have been violated, some commentators seem to view state corporate law as creating the source of law through which federal standards are, in practice, enforced. See O’KELLEY & THOMPSON, supra note 22, at 947 (querying whether a violation of SOXA’s Section 404 mandate would support Caremark claim); Allen, Knakman and Subramanian, supra note 47, at 285 (consideration of compliance in federal prosecutorial charging decision means that “the logic that underlies Caremark remains important under federal law as well.”); Chiappinelli, supra note 47, at 538 (characterizing federal law as enforcing state corporate law standards: pursuant to SOXA CEO/CFO certifications, executives “must also certify that they are responsible for establishing and maintaining internal controls that, in effect, conform to Caremark requirements.”).


179. See id.
released until after the 120-day period has passed so as to eliminate the whistleblower recovery eligibility. The details of a variety of whistleblower regulations, as well as sibling self-reporting procedures under various regulatory regimes, create similar incentives to incorporate specific design and operational characteristics into corporate compliance systems.

C. Corporate Law as Activity-Based Regulation

A third form of compliance regulation could be characterized as “activity-based.” These rules address conduct that is generally generic to businesses, such as capital-raising and employment activities, in contrast with regulations that apply only to a particular industry. Activity-based regulations, such as in the areas of environmental hazards, workplace safety, labor relations, antitrust, and discrimination in employment and public accommodations, play a significant role in the compliance practices of virtually every business.

For example, any business engaging in international transactions is affected

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183. See id. at 1765-67 (describing EPA and OSHA incentive-based compliance policies); Brett H. McDonnell, *Two Cheers for Corporate Law Federalism*, 30 J. CORP. L. 99, 103 (2004) (“Federal rulemakers such as Congress and the SEC can and sometimes do create what is effectively corporate law, although labeled securities law, if they are unhappy with the Delaware status quo. Other areas of law as well, such as labor, employment, banking, consumer protection, and environmental law, help regulate corporations and protect the interests of various constituencies.”); Lloyd C. Anderson, *Interpretation of Consent Decrees and Microsoft v. United States I: Making Law in the Shadow of Negotiation*, 1 U. PITZ. J. LAW & TECH. 1 (2000) (discussing making of public law through consent decrees); Maimon Schwarzschild, *Public Law by Private Bargain: Title VII Consent Decrees and the Fairness of Negotiated Institutional Reform*, 1984 DUKE L. J. 887, 890 (discussing “quasi-legislative character of public law remedies).
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by the risk of liability under the Foreign Corrupt Practices Act of 1977 ("FCPA"), which generally prohibits the payment of bribes to foreign government officials for the purpose of obtaining or retaining business, and requires public companies to adopt specific accounting and recordkeeping procedures. The DOJ has steadily increased its enforcement activity under the FCPA and thereby the importance of FCPA compliance pursuant to the Organizational Guidelines and the Prosecution Standards. Corporate and individual enforcement liability in FCPA cases, which for firms often includes compliance agreements requiring the appointment of an external compliance monitor, has substantially exceeded the liability for the underlying conduct under state corporate law claims.

The argument that federal securities laws have substantially displaced state corporate law is well-traveled in the academic literature.

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186. The Department has instituted a formal procedure through which a business can obtain an opinion from the Department as to the permissibility of conduct under the FCPA, which provides a source of FCPA-specific compliance guidance. See Foreign Corrupt Practices Act Opinion Procedure. 28 C.F.R. § 80 (2012).


188. See, e.g., Larry Ribstein, Ideoblog (Feb. 27, 2008), http://busmovie.typepad.com/ideoblog/200 8/02/the-most-import.html (citing the federal securities law case Basic v. Levinson, 485 U.S. 224 (1988), as the most important corporate law decision of the 20th century ("what case has more impact on actual corporate behavior . . . the ‘most important corporate law decision’ has to be a federal securities law case. Surely no one can deny that this is ‘corporate law,’ even if the feds have chosen to shear off what it chooses to call ‘disclosure’ from state law. The federal securities laws drive internal corporate behavior, and even state law decisions, as much as state law."); Roe, supra note 10, at 598, 619 ("Lawyers who work on corporate voting and proxy solicitations operate primarily not under state law but under the 1934 Securities and Exchange Act’s federal proxy law, which transformed most voting rules into federal rules"); "With the all-holders rule, the SEC demolished the specifics of state law on a selective stock buyback. Nothing was uncertain about it: the SEC said its purpose was to reverse Delaware’s jurisprudence." (footnotes omitted)); Robert B. Thompson & Hillary A. Sale, Securities Fraud as Corporate Governance: Reflections upon Federalism, 56 VAND. L. REV. 859, 860 (2003) ("federal securities law and enforcement via securities fraud class actions today have become the most visible means of regulating corporate governance."); Donald C. Langevoort, Seeking Sunlight in Santa Fe’s Shadow: The SEC’s Pursuit of Managerial Accountability, 79 WASH. U. L. Q. 449 (2001). The public securities law case that most directly displaces Caremark as a source of law may be the W. R. Grace & Co. proceedings in which the Commission found violations of the federal securities laws by independent directors based on their having failed to take
social activists have routinely sought to co-opt internal corporate accounting and disclosure processes to insinuate the consideration of social costs into the exercise of internal business judgments.\footnote{189} Even international law has been determinative of corporate compliance systems. Congress enacted the International Anti-Bribery and Fair Competition Act of 1998\footnote{190} to implement the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions.\footnote{191}

Considered in the aggregate, federal regulation plays a substantial role as a legal determinant of corporate compliance. Federal regulatory law provides far greater incentives than state corporate law for the corporation and corporate actors to follow prescribed compliance approaches. These federal incentives derive from a variety of industry-, process- and activity-based compliance directives and create potential criminal and civil liability that dwarfs the potential consequences of failing to meet state corporate law standards. If “corporate law” in regards to legal compliance is considered to comprise the sources of law that are the strongest determinants of corporate compliance, then federal regulation has a far stronger claim as the determinative source of law than Caremark.

VI. CONCLUSION

This article challenges some of the conventional wisdom in corporate law pedagogy. Principally, it challenges the orthodoxy of Caremark’s iconic status on the ground that other sources of law are actually stronger determinants of corporate compliance. A healthcare firm such as Caremark would pay much greater attention to potential liability under federal law than to the risk of Caremark liability because the expected costs of liability under federal law are much greater than under Caremark. Rational actors will seek first to mitigate the risks that present the highest expected cost. Caremark’s practical impotence applies not only to healthcare firms, but to all firms because the expected costs affirmative steps to ensure corporate legal compliance, notwithstanding the lack of evidence of bad faith. See In the Matter of W. R. Grace & Co., Exchange Act Rel. No. 39156 (Sep. 30, 1997) (21C order finding violations of proxy and reporting rules by independent directors) available at http://www.sec.gov/litigation/admin/3439156.txt; Report of Investigation Pursuant to Section 21(A) of the Securities Exchange Act of 1934 Concerning the Conduct of Certain Former Officers and Directors of W.R. Grace & Co., Exchange Act Rel. No. 39157, at 1 (Sep. 30, 1997) (“Officers and directors who review, approve, or sign their company's proxy statements or periodic reports must take steps to ensure the accuracy and completeness of the statements contained therein, especially as they concern those matters within their particular knowledge or expertise.”).


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of violating federal law, or non-corporate state or municipal law, will almost always exceed the expected costs of violating state corporate law.

This article also challenges the view that state corporate law preserves the authority of market forces in corporate actors’ decision-making. Some argue that the Caremark standard, by making it difficult to prove that corporate actors violated their fiduciary duties, protects their discretion to respond to market forces and their freedom to maximize shareholder wealth. It is correct that state corporate law can interfere with market forces as determinants of corporate action when it is the source of law that establishes the highest standard of conduct, such as is arguably the case with respect to the evaluation of defensive tactics in hostile takeovers. However, state corporate law cannot protect corporate actors from the influence of other sources of law when potential violations of such law present higher expected costs than violations of state corporate law. When states lower the risk of state corporate law liability, they simply cede more ground to sources of law that present greater liability risk.

Finally, this article suggests that the flawed corporate law pedagogy that reinforces this exaggeration of the role of state corporate law in corporate law practice could be remedied by a return to the fundamental question of what sources of law actually determine corporate conduct. The answer to this question might be organized into areas of law that regulate specific industries, such as healthcare and banking; specific corporate processes, such as federal sentencing guidelines and whistleblowing rules; and generic business activities, such as employment and environmental practices. The modern corporation is no longer the free-wheeling enterprise that was unshackled by the corporate charter competition among states in the late 19th century. The modern corporation has become a quasi-governmental vehicle through which the post-World World II administrative state effectuates much of public policy.

192. See Roe, supra note 10, at 625 (“Today takeover law is perhaps the last important domain of corporate law where states have nearly full authority.”). Federal law can trump state law and enforce a lower standard. See, e.g., Riegel v. Medtronic, Inc., 552 U.S. 312 (2008) (FDA approval preempts state common law defective device claims).