

PISC IN THE WIND?
HOLDING HEALTHCARE ORGANIZATIONS
LIABLE FOR PUBLICLY ISSUED
STATEMENTS OF CONDUCT

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INTRODUCTION

Has the moment arrived when we can no longer permit a company, that espouses value statements and ethical programs professing a dedication to help and to heal, to act in ways that are contrary and harmful to individual or collective goods? Fully acknowledging that we, two legally trained business ethics professors, are pursuing a line of inquiry rooted in the aspiration of a more robustly just marketplace,¹ we are convinced that it is time for serious reflection upon the question: Should healthcare companies be held accountable for ways in which they deviate from publicly issued statements of conduct (PISC)?

Observers have long argued that the business of health is particularly complicated in terms of the array of potentially conflicting values and ends being pursued among multiple stakeholders.² Even while corporations

1. See *Piss in the Wind*, FREE DICTIONARY, <https://idioms.thefreedictionary.com/piss+in+the+wind> (“To do something totally pointless, fruitless, or futile; to waste one’s time doing something that will not or cannot come to pass.”).

2. See Joshua E. Perry et al., *Direct-to-Consumer Drug Advertisements and the Informed Patient: A Legal, Ethical, and Content Analysis*, 50 AM. BUS. L.J. 729, 732 (2013) (“The health-care industry’s marketing practices are connected to a broader set of concerns than most other industries. These concerns extend beyond the profitability, productivity, and efficiency priorities of businesses in most industries . . .”); Joshua E. Perry, *Physician-Owned Specialty Hospitals and the Patient Protection and Affordable Care Act: Health Care Reform at the Intersection of Law and Ethics*, 49 AM. BUS. L.J. 369, 374 (2012) (arguing that “[t]he complex relationship between patient-consumer and a physician-provider creates a unique transaction experience with few analogues”). See generally Patricia H. Werhane, *Introduction to Organization Issues in Business Ethics*, in DEVELOPING ORGANIZATION ETHICS IN HEALTHCARE: A CASE-BASED APPROACH TO POLICY, PRACTICE, AND COMPLIANCE 13, 13–18 (Ann E. Mills et al. eds., 2001); Troyen A. Brennan, *An Ethical Perspective on Health Care Insurance Reform*, 19 AM. J.L. & MED. 37, 48 (1993)

rightly pursue profitability, a healthcare corporation necessarily has infused in its very business model the welfare of individuals and populations. The ends of public good and individual wellbeing may not always align perfectly with the economic ends of a for-profit business. In the clinical context, asymmetries of information—even in the age of WebMD—always exist and the unpredictabilities and urgencies of medical care introduce wide-ranging complications when one considers the business of medicine.³ Beyond the clinic, the healthcare landscape in the United States constitutes what one commentator infamously referred to as a “medical-industrial complex.”⁴ With nearly one-fifth of our economy now occupied by pharmaceuticals, medical devices, and the provision of healing arts, engagement with the healthcare industry is pervasive.⁵ Moreover, it is in the healthcare space, where the promise of improved life and flourishing can too quickly deteriorate into prolonged suffering, that the sense of urgency around the question of accountability becomes most pressing.

Take for example the issue of opioid manufacturers and the epidemic that has consumed large sectors of contemporary society. The Department of Health & Human Services has declared that the opioid crisis is a public health emergency nationwide.⁶ A portion of its consequences can be quantified, but numbers reflect only part of the “wicked problem.”⁷

(arguing the ethics of healthcare policy should share similar analogues to medical ethics when considering access to healthcare); Heather Elms et al., *Ethics and Incentives: An Evaluation and Development of Stakeholder Theory in the Health Care Industry*, 12 BUS. ETHICS Q. 413, 425 (2002) (concluding that economic incentives can encourage physicians to behave in ways inconsistent with the ethical norms of the medical profession).

3. See Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941, 948–54 (1963).

4. Arnold S. Relman, *The New Medical-Industrial Complex*, 303 NEW ENG. J. MED. 963 (1980).

5. See Aimee Picchi, *Health Care Spending in America to Consume 1 in 5 U.S. Dollars*, CBS NEWS (Feb. 21, 2019, 12:02 PM), <https://www.cbsnews.com/news/health-care-spending-is-on-track-to-eat-1-in-5-u-s-dollars> [<https://perma.cc/56TB-RX58>] (projecting that healthcare spending will consume almost twenty percent of GDP by 2027).

6. Press Release, Eric D. Hargan, Acting Sec’y, U.S. Dep’t Health & Human Servs., HHS Acting Secretary Declares Public Health Emergency to Address National Opioid Crisis (Oct. 26, 2017), <https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html> [<https://perma.cc/6L82-QRWR>]; see also Maria Puente, *First Lady Melania Trump Calls Opioid Epidemic ‘Worst Drug Crisis in History’*, USA TODAY (Nov. 28, 2018, 1:53 PM), <https://www.usatoday.com/story/life/2018/11/28/melania-trump-says-opioids-worst-drug-crisis-ever-town-hall/2137303002>.

7. NICOLAS P. TERRY ET AL., LEGAL AND POLICY BEST PRACTICES IN RESPONSE TO THE SUBSTANCE ABUSE CRISIS: A PRELIMINARY REPORT 17 (2018), <https://www.in.gov/>

The National Institute on Drug Abuse estimates that, in 2018, nearly 32,000 people died from overdosing on synthetic opioids alone.⁸ When adjusted to include all opioids,⁹ the number of deaths in 2018 alone rises to nearly 50,000.¹⁰ Millions more suffer from opioid-related addiction issues; in just the State of Indiana, one in twelve residents (500,000) has a substance use disorder.¹¹ The crisis involves both the misuse of legally produced, prescribed opioids, and illegally produced opioids. Because about 80% of people who use heroin first misused prescription opioids,¹² these two patterns of use are inextricably linked. The impact of this crisis on individuals, families, communities, our healthcare system, and the economy is substantial.¹³

recovery/files/Full%20Report%20IU%20Grand%20Challenge%20Legal%20and%20Policy%20Best%20Practices-Substance%20Abuse%20Crisis.pdf [https://perma.cc/PT75-QY24].

8. The total number of deaths due to synthetic opioids other than methadone in 2018 was 31,335. *Overdose Death Rates*, NAT'L INST. ON DRUG ABUSE (Mar. 10, 2020), <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates> [https://perma.cc/63SC-7LFJ]. Synthetic opioids, best known by the name “fentanyl,” are like morphine but 50 to 100 times more potent. *Fentanyl Drug Facts*, NAT'L INST. ON DRUG ABUSE (Feb. 2019), <https://www.drugabuse.gov/publications/drugfacts/fentanyl> [https://perma.cc/GP97-NVQP].

9. Opioids include heroin, fentanyl, and painkillers available by prescription, such as oxycodone, hydrocodone, codeine, and morphine. *Opioids*, NAT'L INST. ON DRUG ABUSE, <https://www.drugabuse.gov/drugs-abuse/opioids> [https://perma.cc/4XK6-DRSF].

10. The total number of deaths involving opioids in 2018 was 46,802. NAT'L INST. ON DRUG ABUSE, *supra* note 8.

11. TERRY ET AL., *supra* note 7, at 9. According to the National Institute on Drug Abuse, 1.7 million people in the United States suffered from substance abuse disorders related to opioids in 2017. *Opioid Overdose Crisis*, NAT'L INST. ON DRUG ABUSE (May 27, 2020), <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis> [https://perma.cc/PHM6-6DN7].

12. Pradip K. Muhuri et al., *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States*, CBHSQ DATA REV. (2013), <https://www.samhsa.gov/data/sites/default/files/DR006/DR006/nonmedical-pain-reliever-use-2013.htm> [https://perma.cc/343M-8DXG].

13. See Cardinal Health Foundation, *Cardinal Health Foundation Awards over \$3 Million to More than 70 Nonprofit Organizations to Fight the Opioid Epidemic Across Appalachia*, CISION: PR NEWSWIRE (June 19, 2018, 12:00 PM), www.prnewswire.com/news-releases/cardinal-health-foundation-awards-over-3-million-to-more-than-70-nonprofit-organizations-to-fight-the-opioid-epidemic-across-appalachia-300667993.html [https://perma.cc/RUQ9-JQ7K]; *DEA Raids CVS Stores Tied to Cardinal Health*, COLUMBUS DISPATCH (Feb. 7, 2012, 12:01 AM), www.dispatch.com/content/stories/business/2012/02/07/dea-raids-cvs-stores-tied-to-cardinal-health.html [https://perma.cc/NPJ4-YHBF]; Editorial Board, *Opioid Distributors Flooded Communities with Painkillers. Now They Deny Responsibility*, USA TODAY (May 8, 2018, 7:35 PM), www.usatoday.com/story/opinion/2018/05/08/opioid-distributors-offensive-denials-

The gravity of the opioid crisis and its consequences is not lost on the country's political system. In 2018, Congress passed a bi-partisan, 653-page bill.¹⁴ The bill takes a multi-pronged approach to the crisis and (1) addresses a variety of law enforcement and public health measures, (2) prohibits fentanyl from being sent through mail, (3) allows physician assistants and nurse practitioners to prescribe Medication Assisted Treatments, and (4) over a five-year period permits nurse specialists, nurse midwives, and nurse anesthesiologists to also prescribe

editorials-debates/592089002; Jef Feeley, *McKesson, Cardinal Health Must Face New York Opioid Suits*, BLOOMBERG L. (July 18, 2018, 8:09 AM), www.bloomberg.com/news/articles/2018-07-17/mckesson-cardinal-health-must-face-new-york-opioid-lawsuits; Erika Fry, *Following the Pills: Inside the Government's Investigation of McKesson*, FORTUNE (June 13, 2017, 11:23 AM), <http://fortune.com/2017/06/13/mckesson-drug-distributors-opioid-epidemic> [<https://perma.cc/7BS5-XF6B>]; Robert Gebelhoff, *An Obvious Way to Fight the Opioid Epidemic—and Make Doctors' Lives Easier*, WASH. POST (May 10, 2017, 1:36 PM), https://www.washingtonpost.com/news/in-theory/wp/2017/05/10/an-obvious-way-to-fight-the-opioid-epidemic-and-make-doctors-lives-easier/?utm_term=.c250b2276c79 [<https://perma.cc/9JVD-ASDM>]; John M. Gray, *Don't Blame Pharmaceutical Distributors for Opioid Crisis*, USA TODAY (May 8, 2018, 7:48 PM), <https://www.usatoday.com/story/opinion/2018/05/08/dont-blame-pharmaceutical-distributors-opioid-crisis-editorials-debates/34702647> [<https://perma.cc/E5YQ-VNHN>]; Bruce Japsen, *Opioid Lawsuits Look More like a Tobacco Settlement Every Day*, FORBES (Aug. 25, 2018, 8:15 AM), www.forbes.com/sites/brucejapsen/2018/08/25/opioid-lawsuits-looking-more-like-tobacco-settlements-every-day/#361b19d34f4f [<https://perma.cc/TNK2-G626>]; Brett Kelman, *These Nashville Doctors Were Running Pill Mills. Purdue Pharma Sold to Them Anyway*, TENNESSEAN (July 10, 2018, 10:00 PM), www.tennessean.com/story/news/2018/07/11/oxycontin-lawsuit-purdue-pharma-encouraged-pill-mills-sell-opioids/768322002 [<https://perma.cc/RBX4-XN5N>]; German Lopez, *Trump Just Signed a Bipartisan Bill to Confront the Opioid Epidemic*, VOX (Oct. 24, 2018, 3:13 PM), www.vox.com/policy-and-politics/2018/9/28/17913938/trump-opioid-epidemic-congress-support-act-bill-law; Chuck McCutcheon, *Opioid Addiction*, CQ RESEARCHER (June 14, 2018), library.cqpress.com/cqresearcher/document.php?id=cqr_ht_Opioids_2018 [<https://perma.cc/G492-JKJ5>]; Alysha Palumbo, *Boston Sues Pharma Companies for Alleged Role in Opioid Crisis*, NECN (Sept. 13, 2018), www.necn.com/news/new-england/Boston-Sues-Pharma-Companies-for-Alleged-Role-in-Opioid-Crisis-493198551.html [<https://perma.cc/NKC4-WQAF>]; Sara Randazzo, *Opioid Makers Ask Counties for Proof of Harm*, WALL ST. J. (Oct. 18, 2018, 9:00 AM), www.wsj.com/articles/opioid-makers-ask-counties-for-proof-of-harm-1539867600?mod=djemwhatsnews&ns=prod/accounts-wsj; Ethan Siegel, *Opioid Epidemic so Dangerous, Says CDC, It's Finally Killing as Many Americans as Guns*, FORBES (Mar. 20, 2018, 10:00 AM), www.forbes.com/sites/startwithabang/2018/03/20/opioid-epidemic-so-dangerous-says-cdc-its-finally-killing-as-many-americans-as-guns/#567feb496c21 [<https://perma.cc/M9CY-ZUL9>].

14. SUPPORT for Patients and Communities Act, Pub. L. No. 115-271, 132 Stat. 3894 (2018).

medication for opioid addiction.¹⁵ However, there are no provisions that enhance or define the liability of companies that manufacture, distribute, or sell opioids.¹⁶ Congress's hesitance to address the role of corporate liability in the opioid crisis may come from many factors, but one especially salient one is that there is a real dilemma here. This dilemma lies underneath debates about marketing, FDA approvals, learned intermediaries, and product misuse. The dilemma is that while on the one hand opioids are detrimental to individual and community health, on the other they do effectively assist individuals who suffer from pain, and untreated pain is a serious problem in its own right.¹⁷

Writing in 2004, Kent Durning reported that more than 40–50% of patients do not receive sufficient relief for chronic pain.¹⁸ This can manifest itself at the end of life, where palliative care has become increasingly prominent and useful (even merciful) for patients and their families enduring the difficulties of terminal illness.¹⁹ Controlling pain also has significant benefits for those who have ongoing issues throughout their lives, relieving discomfort and providing patients with the opportunity to live satisfying and productive lives.²⁰ This good

15. Abby Goodnough, *In Rare Bipartisan Accord, House and Senate Reach Compromise on Opioid Bill*, N.Y. TIMES (Sept. 26, 2018), <https://www.nytimes.com/2018/09/26/health/opioid-bill-congress.html>; see also Billy Wynne & Dawn Joyce, *The 660-Page Opioids Bill Is Now the Law. Here's What's in It*, CAL. HEALTH CARE FOUND. BLOG (Nov. 1, 2018), <https://www.chcf.org/blog/the-660-page-opioids-bill-is-now-the-law-heres-whats-in-it> [<https://perma.cc/GK6A-NAAQ>].

16. See Wynne, *supra* note 15 (stating that the Act includes more than seventy bills, none of which address opioid manufacturer liability).

17. DEP'T OF HEALTH & HUM. SERVS., PAIN MANAGEMENT BEST PRACTICES INTER-AGENCY TASK FORCE REPORT: UPDATES, GAPS, INCONSISTENCIES, AND RECOMMENDATIONS 25 (2019) [hereinafter BEST PRACTICES]; see also Linda Searing, *The Big Number: 50 Million Adults Experience Chronic Pain*, WASH. POST (Oct. 21, 2018, 10:00 AM), https://www.washingtonpost.com/national/health-science/the-big-number-50-million-adults-experience-chronic-pain/2018/10/19/30831828-d2e0-11e8-83d6-291fceed2ab1_story.html (citing a CDC study finding 20.4% of the U.S. adult population is afflicted with chronic pain).

18. Kent Durning, Note, *No Pain No Gain?! Who Will Make the Greatest Sacrifices in Curbing Opioid Analgesic Diversion and Abuse?*, 93 KY. L.J. 199, 215 (2004).

19. Cf. Helen Clark, *Opioid Shortages Open up a World of Pain*, FIN. TIMES (June 29, 2020), <https://www.ft.com/content/97c51a2a-e600-402e-9015-95d3ba32ab05> (stating international controlled substance policy and the COVID-19 pandemic have caused a shortage of opioids and other drugs typically used for palliative care, among other things).

20. CENTERS FOR DISEASE CONTROL & PREVENTION, GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN, <https://www.cdc.gov/drugoverdose/pdf/prescribing/>

stands in contrast to the misery experienced by those addicted to opioids, as well as by their families, communities, and the country as a whole.²¹ Because of opioids' crucial role in treating pain, their use and misuse are tightly linked to the medical community. Prescribing physicians are in the best position to provide opioid access to those whose medical condition can be improved by them, while remaining careful not to prescribe pain relievers to those who are addicted.²² But many physicians find themselves caught in a bind in which a patient claims to be experiencing pain, and the physician wants to alleviate it, but there is no apparent medical reason for the patient's allegation of pain.²³ This forces the physician to make a difficult choice: prescribe and risk aiding an addict and ultimately harming the patient's health, or don't prescribe and risk failing to provide the best care for that patient, as well as more personal risks such as receiving a negative patient review or facing legal charges for failing to treat the patient's pain.²⁴ Not all physicians handle these situations ethically—some intentionally overprescribe opioids to those they know to be abusing the drug.²⁵

This tension may pose serious issues for the medical profession, but the dilemma extrudes into legal territory when doctors (intentionally or unintentionally) overprescribe medications and when patients (voluntarily or involuntarily) misuse medication. That extrusion defines an important legal parameter of the opioid crisis. When litigants have sought to hold doctors accountable for their role in prescribing medically unnecessary

Guidelines_Factsheet-a.pdf [<https://perma.cc/HQE3-3BNL>] (stating that though other methods are preferred, opioid therapy may be considered to address chronic pain).

21. See Erika Fry, *As America's Opioid Crisis Spirals, Giant Drug Distributor McKesson Is Feeling the Pain*, FORTUNE (June 13, 2017, 6:30 AM) <https://fortune.com/2017/06/13/fortune-500-mckesson-opioid-epidemic> [<https://perma.cc/K4ZK-5TD2>] (outlining the specific effects of the opioid crisis in McDowell County, West Virginia).

22. See BEST PRACTICES, *supra* note 17, at 26 (explaining how physicians must weigh multiple variables when prescribing opioids due to harmful side effects including user dependence).

23. See Sujata Srinivasan, *Opioids Backlash Leaves Some Struggling with Chronic Pain*, CONN. MIRROR (Nov. 17, 2019) <https://ctmirror.org/2019/11/17/opioids-backlash-leaves-some-struggling-with-chronic-pain> [<https://perma.cc/6SW8-GSZ2>] (detailing the difficulties chronic pain sufferers face to obtain opioid prescriptions, especially since the CDC provided new guidance on the prescription of opioids in response to the opioid epidemic).

24. Kelly K. Dineen & James M. DuBois, *Between a Rock and a Hard Place: Can Physicians Prescribe Opioids to Treat Pain Adequately While Avoiding Legal Sanction?*, 42 AM. J.L. & MED. 7, 8–12 (2016).

25. *Id.* at 12.

opioids to those who abuse their prescriptions, they have been met with impediments.²⁶ Moreover, the extrusion also draws in others who are in the distribution chain of opioid medication. Pharmacists, for example, are the ones who fill the prescriptions and who are also in a position to observe the condition of the customer.²⁷ Yet, pharmacists often find it difficult to differentiate between addiction, physical dependence, analgesic tolerance, pseudo-addiction, and substance abuse.²⁸ Durning argues that only at these latter stages does the use of opioids become a law enforcement concern.²⁹ Moreover, Durning argues that NSAIDs, which contribute to thousands of deaths each year, may be a more serious health problem.³⁰

Of course doctors and pharmacists are not the only actors in the distribution chain.³¹ Manufacturers of opioid medication are, after all, creating a product to be sold and marketed, with reasonable expectations they will reap the profits of their sales. Distributors also have a hand in the selling of a product. While these corporate actors are the focus of this Article, it is also worth bearing in mind that there are several other actors involved in the opioid crisis, including law enforcement, the court system, social services personnel, and of course communities generally and families touched personally by this crisis.³² Thus, while there is clearly a link between widespread opioid addiction and misuse and the role of physicians and the medical profession,³³ the

26. See Alyssa M. McClure, *Illegitimate Overprescription: How Babbage v. United States Is Hindering Punishment of Physicians and Bolstering the Opioid Epidemic*, 93 NOTRE DAME L. REV. 1747, 1749 (2018). In a case seeking to hold “bad doctor[s]” accountable, the Supreme Court ruled that it would not punish doctors for prescribing opioids unless the defendant’s use of the controlled substance was a “but-for cause of death or injury.” *Id.* This “but-for” causation requirement makes it hard to hold doctors liable in opioid litigation. *Id.* at 1760.

27. See Mahita Gajanan, *Netflix’s The Pharmacist Depicts the True Story of Grieving Father’s Fight Against the Opioid Epidemic*, TIME (Feb. 6, 2020, 1:05 PM), <https://time.com/5778759/the-pharmacist-netflix>.

28. Durning, *supra* note 18, at 218.

29. *Id.* at 201–02.

30. *Id.* at 207.

31. Lenny Bernstein, *Major Drugstore Chains Sue Doctors in Sprawling Federal Opioid Case*, WASH. POST (Jan. 8, 2020, 11:30 AM), https://www.washingtonpost.com/health/major-drugstore-chains-sue-doctors-in-sprawling-federal-opioid-case/2020/01/07/3ac9cd70-317d-11ea-9313-6cba89b1b9fb_story.html.

32. TERRY ET AL., *supra* note 7, at 16.

33. See Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 AM. J. PUB. HEALTH 221 (2009); Lilly Dancyger, *OxyContin Maker Granted Patent for Opioid-Addiction Treatment*, ROLLING STONE (Sept. 11, 2018, 2:09 PM), <https://www.rollingstone.com/culture/culture-news/oxycontin-purdue-pharma-patent->

opioid crisis as a whole is not a simple problem of medical abuse, but a “wicked problem”: a crisis that has many causes, diseases, and social determinants.³⁴ Solutions must match the complicated nature of the problem and therefore must go beyond increasing arrests.³⁵ Conferences and special symposia have attempted to begin the conversation necessary to address the multifaceted nature of the problem.³⁶

In addition to a variety of healthcare-related issues,³⁷ solutions may include other legal responses such as legal immunity for “[g]ood Samaritan[s]” who report overdoses,³⁸ changing drug paraphernalia laws,³⁹ increasing the number of safe stations,⁴⁰ implementing criminal

opioid-addiction-treatment-722646; Amanda Higley, *The Opioid Crisis in America*, QUORUM (July 24, 2020), <https://www.advarra.com/the-opioid-crisis-in-america>; Dhruv Khullar & Anupam B. Jena, *Do Incentives Nudge Physicians to Prescribe Opioids for Pain?*, STAT (Aug. 18, 2016), <https://www.statnews.com/2016/08/18/opioids-pain-prescribing-physicians> [<https://perma.cc/ZZA4-HQ66>]; German Lopez, *His Family Helped Cause the Opioid Crisis. Now He Might Profit from Addiction Treatment*, VOX (Sept. 7, 2018, 3:20 PM), <https://www.vox.com/science-and-health/2018/9/7/17831710/richard-sackler-opioid-epidemic-buprenorphine>; Mike Mariani, *How the American Opiate Epidemic Was Started by One Pharmaceutical Company*, WEEK (Mar. 4, 2015), <https://theweek.com/articles/541564/how-american-opiate-epidemic-started-by-pharmaceutical-company>; Barry Meier, *Origins of an Epidemic: Purdue Pharma Knew Its Opioids Were Widely Abused*, N.Y. TIMES (May 29, 2018), <https://www.nytimes.com/2018/05/29/health/purdue-opioids-oxycotin.html>; Alex Morrell, *The OxyContin Clan: The \$14 Billion Newcomer to Forbes 2015 List of Richest U.S. Families*, FORBES (July 1, 2015, 10:17 AM), <https://www.forbes.com/sites/alexmorrell/2015/07/01/the-oxycotin-clan-the-14-billion-newcomer-to-forbes-2015-list-of-richest-u-s-families/#25a64f2775e0> [<https://perma.cc/7P8M-HFBB>]; Jonathan Stempel, *New York Sues OxyContin Maker Purdue Pharma over Opioids*, REUTERS (Aug. 14, 2018, 12:13 PM), <https://www.reuters.com/article/us-usa-opioids-purduepharma/new-york-sues-oxycotin-maker-purdue-pharma-over-opioids-idUSKBN1KZ1WZ>; Patty Wight, *Doctors in Maine Say Halt in OxyContin Marketing Comes ‘20 Years Late’*, NAT’L PUB. RADIO (Feb. 13, 2018, 3:27 PM), <https://www.npr.org/sections/health-shots/2018/02/13/585402385/doctors-in-maine-say-halt-in-oxycotin-marketing-comes-20-years-late> [<https://perma.cc/BVH9-FXNM>]; *Last Week Tonight with John Oliver: Marketing to Doctors* (HBO television broadcast Feb. 8, 2015).

34. TERRY ET AL., *supra* note 7, at 16.

35. *Id.* at 18–19.

36. See, e.g., Symposium, *Law and the Opioid Crisis: An Interdisciplinary Examination*, 46 J.L. MED. & ETHICS 193 (2018) (discussing topics such as the role of courts in national health crises, state responses to the crisis, prescription drug monitoring programs, the use of big data, federal criminal prosecution, suppressing the drug market, and the role of civil commitment).

37. TERRY ET AL., *supra* note 7, at 28–44.

38. *Id.* at 22.

39. *Id.* at 24.

40. *Id.* at 24–25.

intervention models,⁴¹ and considering where settlement monies are directed in litigation, such as toward the variety of these aforementioned initiatives or, instead, to general funds of the government.⁴² In late summer 2019, Johnson & Johnson was found liable in the overdose death of nearly 400,000 of its opioid customers due to the company's deceptive marketing. This decision set a significant legal precedent.⁴³ What we are exploring in the discussion that follows is whether, between the ineffective extremes of exonerating and scapegoating companies for their role in contributing to the opioid crisis, there is a place for appropriate corporate accountability. In short, should companies in the healthcare, pharmaceutical, and life science industries that voluntarily issue public statements of conduct (PISCs) be held to some degree of accountability for not acting in accordance with their own professed values?

I. CORPORATE GOVERNANCE AS ENFORCEABLE DUTY

The incentives for companies to even issue a PISC were significantly different fifty years ago.⁴⁴ That was true with respect to their duties vis-à-vis shareholders, as well as to other constituents such as employees and customers.⁴⁵ This is no longer the case with respect to shareholders,⁴⁶ and there is precedent, as well as normative logic, for recognizing similar duties to employees and customers across all industries.⁴⁷ Indeed, our argument has application well beyond the scope of the pharmaceutical, medical device, or healthcare delivery industries. Suggesting that companies with

41. *Id.* at 38.

42. *Id.* at 42–43.

43. Nate Raymond, *Oklahoma Judge to Rule in \$17 Billion Opioid Lawsuit Against J&J*, REUTERS (Aug. 26, 2019, 6:00 AM), <https://www.reuters.com/article/usa-opioids-litigation-oklahoma/oklahoma-judge-to-rule-in-17-billion-opioid-lawsuit-against-jj-idUSL2N25J1B7>. The judgment in this case awarded \$572 million but was reduced on appeal to \$465 million. Nate Raymond & Jonathan Stempel, *Oklahoma Judge Reduces Johnson & Johnson Opioid Payout to \$465 Million*, REUTERS (Nov. 15, 2019, 3:12 PM), <https://www.reuters.com/article/us-usa-opioids-litigation-oklahoma/oklahoma-judge-reduces-johnson-johnson-opioid-payout-to-465-million-idUSKBN1XP27F>.

44. Timothy L. Fort & Melissa Latini, *The Duty to Establish, Monitor and Enforce: How Today's Corporate Compliance Standards Provide a Workable Model to Limit Defamation and Protect First Amendment Freedoms*, 33 NOTRE DAME J.L., ETHICS & PUB. POL'Y 35, 37 (2019) (stating the 1960s saw a trend of increased corporate accountability in corporate management cases).

45. *Id.* at 38.

46. *See infra* note 99 and accompanying text (describing a standard where a fiduciary may be held liable when he acts in bad faith).

47. *See infra* note 99 and accompanying text (silent on limiting recourse for a fiduciary's bad faith actions to shareholders).

PISCs should have some degree of accountability for them should arguably be a standard that applies across nearly every industry in corporate America today.

To be clear, the argument is not that values statements and mission statements are necessarily legally enforceable. Often, these statements articulate merely an attitude toward conduct rather than specifying conduct. For example, consider some value statements from specific opioid manufacturers that have been sued.⁴⁸ The “purpose” language of AmerisourceBergen’s mission statement is:

[We] are united in our responsibility to create healthier futures. In fulfilling this purpose, we are guided by these principles: [1] Put people first. The rest will follow; [2] Celebrate individuality. Act as a community; [3] Tell the truth, tell it fast; [4] Be part of the solution; and [5] Be bold and stay humble.⁴⁹

Teva Pharmaceutical Industries’ value statement declares, “We’re applying passion and commitment to improve health. Our culture is about not only what we do, but how we do it.” Its mission “is to be a global leader in generics and biopharmaceuticals, improving the lives of patients.”⁵⁰

To provide one more example, Cardinal Health’s mission statement is:

Providing the necessary partnership to help customers navigate the complex healthcare landscape, Cardinal Health is a global, integrated healthcare products and solutions company. We provide vital products, world-class services and customized solutions for hospitals and health systems, pharmacies, clinical laboratories, ambulatory surgery centers, and physician offices worldwide.⁵¹

In and of themselves, statements about improving patient lives and improving health do not specify a public commitment to conduct that is specific enough to be legally enforceable. These are general aspirations to which the company aims. Nevertheless, this Section will

48. See Danny Hakim et al., *The Giants at the Heart of the Opioid Crisis*, N.Y. TIMES (Apr. 22, 2019), <https://www.nytimes.com/2019/04/22/health/opioids-lawsuits-distributors.html>; Mike Leonard, *Teva Seeks to Consolidate Price-Fixing, Opioid Lawsuits*, BLOOMBERG L. (Dec. 16, 2019, 4:13 PM) <https://news.bloomberglaw.com/mergers-and-antitrust/teva-seeks-to-consolidate-price-fixing-opioid-lawsuits>.

49. AMERISOURCEBERGEN, CODE OF ETHICS AND BUSINESS CONDUCT 1, 7 (2019), https://s24.q4cdn.com/386340686/files/doc_downloads/policies/ABC_CodeofEthics_2019.pdf [<https://perma.cc/V2C3-V85T>].

50. *Our Core Values*, TEVA <https://www.tevapharm.com/our-company/our-values> [<https://perma.cc/88JD-DFEZ>] (emphasis omitted).

51. *Essential to Care*, CARDINAL HEALTH (2019), <https://www.cardinalhealth.com/content/dam/corp/web/documents/fact-sheet/cardinal-health-fact-sheet.pdf> [<https://perma.cc/P8S2-9DVR>].

make the argument that if evidence shows that a company specifically conducted itself to the detriment of the health and well-being of patients, that conduct would be in such direct contradiction of even an aspirational statement as to convert that statement into a legally enforceable false claim.

Let us illustrate this in the case at hand: Reasonable people could claim that opioids have positive and negative impacts on a person's health. Opioids relieve pain.⁵² Opioids are highly addictive.⁵³ The balancing of those two impacts calls for the need for "learned intermediar[ies]" and thoughtful, independent regulation.⁵⁴ Conduct that specifically targets

52. NAT'L INST. ON DRUG ABUSE, *supra* note 9.

53. *See id.*

54. In many jurisdictions, drug makers have enjoyed the protection of a legal shield, i.e., the learned intermediary doctrine, since the 1960s. In *In re Norplant Contraceptive Products Liability Litigation*, the court compiled a chart showing forty-eight states, the District of Columbia, and Puerto Rico all to have either applied or recognized the learned intermediary doctrine. *In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp. 2d 795, 806–09 (E.D. Tex. 2002). *See generally* Richard C. Ausness, *Learned Intermediaries and Sophisticated Users: Encouraging the Use of Intermediaries to Transmit Product Safety Information*, 46 SYRACUSE L. REV. 1185, 1195–99 (1996) (discussing the learned intermediary rule and concluding that only physicians should have the duty to communicate prescription drug risk information to patients in most circumstances); Margaret Gilhooley, *Learned Intermediaries, Prescription Drugs, and Patient Information*, 30 ST. LOUIS U. L.J. 633, 657 (1986) (discussing the development of learned intermediary doctrine and arguing that the emergence of robust informed consent doctrine necessitates changing the physician's role as a learned intermediary); Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 GA. L. REV. 141, 178 (1997) (arguing that direct to consumer (DTC) advertising "encourages active participation by consumers in prescribing decisions, a favorable development that courts should not 'reward' by expanding the tort duties of drug manufacturers and, thereby, discouraging such advertising in the future"); Nancy K. Plant, *The Learned Intermediary Doctrine: Some New Medicine for an Old Ailment*, 81 IOWA L. REV. 1007, 1078 (1996) (noting that changes in the delivery of healthcare justify eliminating the learned intermediary doctrine); Teresa Moran Schwartz, *Consumer-Directed Prescription Drug Advertising and the Learned Intermediary Rule*, 46 FOOD DRUG COSM. L.J. 829, 829 (1991) (concluding that the learned intermediary rule should not apply when prescription drug manufacturers advertise products directly to consumers); Charles J. Walsh et al., *The Learned Intermediary Doctrine: The Correct Prescription for Drug Labeling*, 48 RUTGERS L. REV. 821, 880 (1996) (discussing the durability of the learned intermediary doctrine and arguing that in the case of prescription drugs, information is best directed from the drug companies to medical professionals); Susan A. Casey, Comment, *Laying an Old Doctrine to Rest: Challenging the Wisdom of the Learned Intermediary Doctrine*, 19 WM. MITCHELL L. REV. 931, 958 (1993) ("[T]he learned intermediary doctrine is based on medical paternalism that is inconsistent with the concept of informed consent."); Tim S. Hall, Note, *Bypassing the Learned Intermediary: Potential Liability for Failure to Warn in Direct-to-Consumer Prescription Drug Advertising*, 2 CORNELL J.L. & PUB. POL'Y 449, 450–51 (1993) (concluding that

vulnerable populations to prey on their likelihood of becoming addicted, however, cannot be sustained as being consistent with improving health and patient lives. Furthermore, as we will see, some codes of conduct as well as mission/values statements may actually reach the level of specificity necessary to constitute a public promise to conduct company business in a certain way.⁵⁵ Our argument is not that companies must adopt a certain code of conduct or make specific promises; companies are free to make whatever promises they wish. If they wish to promise to be crooks and act as drug dealers, they are free to make such public covenants. They should, however, live up to whatever public promise they make, including those that do, in fact, claim a commitment to health.

Precedent for this argument comes from developments in corporate governance and the implicit covenants directors have to shareholders as well as occasional enforcement of public statements to employees and to customers.⁵⁶ These enforced commitments to constituents have evolved over the past sixty years, so that the legal landscape of today justifies using them as a way to hold opioid manufacturers, distributors, and retailers legally accountable for the damages opioids cause.⁵⁷

Nearly coterminous with the passage of the 1962 Model Penal Code, which also addresses criminal misuse of drugs (primarily alcohol),⁵⁸ was the beginning of a new era of corporate governance that now strongly incentivizes companies to enact, monitor, and enforce corporate codes of conduct.⁵⁹ Because companies regularly tout their mission statements and codes of conduct, courts should require companies to monitor and enforce whatever codes these companies broadcast.

current FDA regulations do not adequately address consumer prescription drug advertisements but that state law is not preempted from regulating such advertisements); Mae Joanne Rosok, Comment, *Direct-to-Consumer Advertising of Prescription Drugs: After a Decade of Speculation, Courts Consider Another Exception to the Learned Intermediary Rule*, 24 SEATTLE U. L. REV. 629, 629 (2000) (recognizing the impact of DTC advertising on increased product sales).

55. See *infra* Sections III.A.1–2.

56. See *infra* Sections III.A.1–2.

57. See Fort & Latini, *supra* note 44, at 37 (describing the evolution of legal standards tending to require corporations to “enact policies to ensure proper corporate conduct, to monitor compliance with such policies, and to enforce those policies”).

58. MODEL PENAL CODE § 2.08 (AM. LAW INST., Official Draft and Revised Comments 1962).

59. See Fort & Latini, *supra* note 44, at 37 (stating the 1960s started a trend of greater corporate responsibility).

Corporations operate in a legal regime very different than the one we had either in 1996, when OxyContin was first marketed,⁶⁰ or in 1962, when the Model Penal Code was proposed.⁶¹ Because of the development of “reflexive” corporate governance regimes, there are expectations that companies will take the time to enact corporate codes of conduct, associated mission statements, and compliance programs; to monitor adherence to these codes, statements, and programs; and to enforce them.⁶² The failure to do so can result in enhanced criminal sanctions should the corporation face any criminal charges—as many opioid-related companies have realized—as well as serving as a predicate for a shareholders’ derivative lawsuit.⁶³

In this Section, we describe the history of the development of these governance regimes and the reality that a reflexive environment is how companies are governed today. We propose that opioid-related companies should monitor and enforce the mission statements, codes, and programs they rhetorically tout, and should do so with the best understanding of how to foster an “organizational culture” that leads to “ethics and compliance.”

To be sure, there will be—and there has already been—resistance to the idea of enforcing aspirational statements.⁶⁴ We argue that if the legal test is effectiveness, then narrowly law-based compliance programs are risky; an effective program needs an aspirational component as well as

60. See Van Zee, *supra* note 33, at 221 (stating OxyContin was aggressively marketed, promoted, and highly available when it was introduced in 1996, which coincided with a “liberalization of the use of opioids in the treatment of pain”).

61. See generally Paul H. Robinson & Markus D. Dubber, *The American Penal Code: A Brief Overview*, 10 NEW CRIM. L. REV. 319, 319–25 (2007) (detailing the history of drafting the Model Penal Code).

62. See Fort & Latini, *supra* note 44, at 65, 68 (concluding companies are required to enact policies to ensure proper conduct and then enforce those policies).

63. See *In re Caremark Int’l Inc. Derivative Litig.*, 698 A.2d 959, 960–61 (Del. Ch. 1996) (explaining a shareholder lawsuit charging a company with multiple felonies); Katy Baum & Wellesley Anna DuBois, *Opioid Epidemic Trends and Insights: Law Enforcers Are Expanding and Transforming Their Toolbelts to Hold Anyone and Everyone Accountable for this National Emergency*, AM. B. ASS’N (Mar. 5, 2020) https://www.americanbar.org/groups/health_law/publications/aba_health_esource/2019-2020/march-2020/opioid-epidemic [<https://perma.cc/A82B-XA72>] (detailing DEA criminal charges against companies, executives, providers, and pharmacies for the opioid epidemic).

64. Sarah Lightdale et al., *Puffery or Not? Courts Examine Corporate Codes of Conduct*, LAW.COM (July 15, 2020, 10:30 AM), <https://www.law.com/newyorklawjournal/2020/07/15/puffery-or-not-courts-examine-corporate-codes-of-conduct> [<https://perma.cc/HS6K-YHN6>] (discussing the holding in *Singh v. Cigna Corp.*, 918 F.3d 57 (2d Cir. 2019), where the court held statements in a company’s code of ethics were not enforceable).

legalisms. Moreover, if we are seeking effectiveness, aspiration must be tethered to action. If aspiration is mere rhetorical fluff, then it is meaningless. However, we do see a problem with effecting this tethering through the conduit of criminalization. Aspiration articulated only through the negative of criminality loses most of its value. This suggests to us that an effective enforcement mechanism should be more internal than external, but to the extent that external forces (markets, laws) are involved, a softer legal enforcement is in order.

II. CHANGES IN CORPORATE GOVERNANCE SINCE 1962⁶⁵

Congressional and judicial expectations for corporate conduct are very different today than they were in the 1960s. This is true for regulation generally as well as for corporate management and responsibility.⁶⁶ Specifically, legal approaches that have developed since the mid-1960s either require or strongly incentivize companies to enact policies to ensure that employees comply with regulatory law and avoid conduct that could subject the company to civil liability.⁶⁷ Companies bear the onus of “protect[ing] a variety of stakeholders, including employees, customers, local communities, and the government.”⁶⁸ This “reflexive” approach to corporate governance⁶⁹ focuses on the responsibilities of directors to maintain effective compliance programs—that is, programs designed to enforce law abidance and to foster ethical conduct—and see that they also apply to management.⁷⁰ Now, due to the pervasiveness of the reflexive model, corporations operate differently than they did in the 1960s when these approaches first began to take shape and when the Model Penal Code was promulgated.⁷¹ Indeed, there is good reason to expect companies today to behave differently than companies of the

65. The following Section is drawn from Timothy L. Fort & Melissa Latini’s piece *The Duty to Establish, Monitor, and Enforce: How Today’s Corporate Compliance Standards Provide a Workable Model to Limit Defamation and Protect First Amendment Freedoms*, 33 NOTRE DAME J.L., ETHICS & PUB. POL’Y 35 (2019).

66. Fort & Latini, *supra* note 44, at 37.

67. *Id.*

68. *Id.* at 47.

69. See, e.g., Todd Haugh, *The Criminalization of Compliance*, 92 NOTRE DAME L. REV. 1215, 1224–25 (2017) (“Prior to the 1960s, compliance was largely a matter of business regulating itself.”). A variation of the “reflexive model” is also called “structural reform litigation.” See Brandon L. Garrett, *Structural Reform Prosecution*, 93 VA. L. REV. 853, 869–70 (2007).

70. See U.S. SENTENCING GUIDELINES MANUAL § 8B.2.1(a)(2) (U.S. SENTENCING COMM’N 2008) (specifying the aim of promoting an “organizational culture” that fosters both “ethical conduct and a commitment to compliance with the law”).

71. See Fort & Latini, *supra* note 44, at 47–48.

past with respect to the foreseeable harms associated with the use of their products—this is no different from their obligation to comply with other legal standards of corporate conduct that did not apply in the early twentieth century.

A. *Corporate Governance at the Time of the Model Penal Code*

In 1963, one year after the Model Penal Code was proposed, the Delaware Supreme Court held in *Graham v. Allis-Chalmers Manufacturing Co.*⁷² that unless a board of directors had specific reason to believe there had been suspicious activity, a corporate compliance program was not required.⁷³ In the *Allis-Chalmers* case, the Board of Directors took action when it learned of an employee's suspicious activity with respect to anti-trust laws.⁷⁴ Nevertheless, a shareholder filed a derivative suit arguing that the company should have already had a corporate compliance program in place.⁷⁵ The court, noting that the Board had been responsive once it learned of the violation, held that they were not liable and stated: “[W]e know of no rule of law which requires a corporate director to assume, with no justification whatsoever, that all corporate employees are incipient law violators who, but for a tight checkrein, will give free vent to their unlawful propensities.”⁷⁶ Thirty-three years later, things changed.⁷⁷

B. *Evolution of Corporate Governance to Require Stricter Attention to Enforcing Policy*

An important reason why reflexive models began to emerge was that companies were given benefits for implementing effective compliance programs.⁷⁸ In contrast, in 1963 when *Allis-Chalmers* was decided, companies did not have positive incentives to take steps to root out problems in the workforce; in fact, doing so might signal wrongdoing to an investigator, without providing the company with any of the benefits of self-reporting.⁷⁹ New York University Law Professor Jennifer Arlen provided three reasons for why Delaware changed its approach

72. 188 A.2d 125 (Del. 1963).

73. *See id.* at 130.

74. *Id.* at 128–29.

75. *See id.* at 129.

76. *Id.* at 130–31 (emphasis added).

77. *See In re Caremark Int'l Inc. Derivative Litig.*, 698 A.2d 959 (Del. Ch. 1996).

78. Jennifer Arlen, *The Story of Allis-Chalmers, Caremark, and Stone: Directors' Evolving Duty to Monitor* 9 (N.Y.U. L. & Econ. Res. Working Papers, Working Paper No. 08-57, 2008), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1304272 [<https://perma.cc/KP8K-3N2S>].

79. *Id.* at 6–7.

to director oversight of legal compliance.⁸⁰ First, the court imposed a more active oversight duty on corporate directors in selling their firms. Second, the expansion of federal criminal liability and an increase in sanctions increased the importance of corporate legal compliance.⁸¹ Lastly, a series of corporate scandals revealed that the only way directors would take responsibility for legal compliance was if they were legally required to do so.⁸² Directors were too hesitant to challenge senior officers in blocking legally suspect, though profitable, enterprises.⁸³

According to Arlen, in 1963, criminal fines with respect to companies were lower: sixty percent of corporate fines were less than \$10,000, and the average fine was \$45,790.⁸⁴ Moreover, unlike today, companies had no incentives for adopting a compliance program.⁸⁵ By the mid-1990s, however, not only were there such compliance program benefits via the Federal Sentencing Guidelines, there were also more laws regulating the “environment, consumer and employee safety, and business practices.”⁸⁶ In short, the stakes of corporate criminal fines were getting higher along with the increased opportunity of protective safety valves to limit that liability.

1. *In re Caremark: 1996*

Thirty-three years after *Allis-Chalmers*, Delaware Chancellor Allen considered the scandals at Salomon, Inc., Kidder Peabody, and Prudential Insurance, and asked what was needed to “assure corporate compliance with external legal requirements, including environmental, financial, employee and product safety as well as assorted other health and safety regulations.”⁸⁷ His answer pointed to the Organizational Sentencing Guidelines that the United States Sentencing Commission adopted in 1991,⁸⁸ which created incentives for companies to adopt compliance programs designed “to detect violations of law, promptly to report violations to appropriate public officials when discovered, and to

80. *Id.*

81. *Id.*

82. *Id.*

83. *Id.* at 2–3 (footnotes omitted).

84. *Id.* at 7.

85. *Id.*

86. *Id.* at 7–8 (footnotes omitted).

87. *In re Caremark Int’l Inc. Derivative Litig.*, 698 A.2d 959, 968–69 (Del. Ch. 1996).

88. *Id.* at 969.

take prompt, voluntary remedial efforts.”⁸⁹ Ironically, 1996 also marked the year in which Purdue Pharmaceutical first marketed OxyContin.⁹⁰

Chancellor Allen specifically distinguished the rule he was articulating in *In re Caremark Int’l Inc. Derivative Litigation* from the holding in *Allis-Chalmers*. He stated that the latter’s notion that “a corporate board has no responsibility to assure that appropriate information and reporting systems are established by management—would not, in any event, be accepted by the Delaware Supreme Court in 1996.”⁹¹ He pointed to legal developments through cases such as *Smith v. Van Gorkom*⁹² and *Paramount Communications Inc. v. QVC Network Inc.*⁹³ and the impact of the Federal Sentencing Guidelines, finding that “[a]ny rational person attempting in good faith to meet an organizational governance responsibility would be bound to take into account this development and the enhanced penalties and the opportunities for reduced sanctions that it offers.”⁹⁴ After *Caremark*, corporate boards of directors bore the significant responsibility to adopt compliance programs, at the heart of which are the enacting, monitoring, and enforcing of policies that govern the legal and ethical conduct of employees.⁹⁵

2. *Post-Caremark*

Ten years after the *Caremark* decision, the Delaware courts decided two cases that further delineated standards for director liability. In *In re The Walt Disney Co. Derivative Litigation*,⁹⁶ the Delaware Chancery Court held that intentional dereliction of duty, which the court defined as “a conscious disregard for one’s responsibilities,” falls within the ambit of fiduciary misconduct that would violate a corporation’s obligation to act in good faith.⁹⁷ The court stated that “[d]eliberate indifference and inaction in the face of a duty to act is . . . conduct that is clearly disloyal to the corporation [and] . . . the epitome of faithless conduct.”⁹⁸ While the court acknowledged the impossibility of creating

89. *Id.*

90. *See* Van Zee, *supra* note 33, at 221.

91. *In re Caremark Int’l*, 698 A.2d at 969–70.

92. 488 A.2d 858 (Del. 1985) (en banc), *overruled by* *Gantler v. Stephens*, 965 A.2d 695 (Del. 2009).

93. 637 A.2d 34 (Del. 1994).

94. *In re Caremark Int’l*, 698 A.2d at 970 (emphasis added).

95. *See id.*

96. 907 A.2d 693 (Del. Ch. 2005), *aff’d*, 906 A.2d 27 (Del. 2006).

97. *See id.* at 755 (emphasis omitted).

98. *Id.* (emphasis omitted).

a categorical definition of acts that constitute bad faith, it identified the three “most salient” examples of director bad faith:

[W]here the fiduciary intentionally acts with a purpose other than that of advancing the best interests of the corporation, where the fiduciary acts with the intent to violate applicable positive law, or where the fiduciary intentionally fails to act in the face of a known duty to act, demonstrating a conscious disregard for his duties.⁹⁹

Later that year, the Delaware Supreme Court decided *Stone v. Ritter*,¹⁰⁰ in which AmSouth Bancorporation faced losses, fines, and civil penalties under the Bank Secrecy Act¹⁰¹ and other federal anti-money-laundering regulations.¹⁰² AmSouth’s shareholders brought a derivative action against the board, alleging that the directors breached their oversight duties by failing to enact, monitor, and enforce any information controls that would have allowed them to learn of the problem.¹⁰³ The Court of Chancery dismissed the derivative complaint, and the Delaware Supreme Court upheld the dismissal.¹⁰⁴ Citing *Caremark*, the court held that the imposition of liability on a director required one of two conditions: “(a) the directors utterly failed to implement any reporting or information system or controls; or (b) 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.”¹⁰⁵

In either case, directors must have *known* they were not fulfilling their fiduciary duties.¹⁰⁶ The court reasoned that was not the case here, as AmSouth had a reasonable reporting system in place and employed appropriate monitoring and oversight.¹⁰⁷ The court refused to equate a bad outcome for AmSouth with directors’ bad faith.¹⁰⁸ Following the Chancery Court in *Disney*, the Delaware Supreme Court clarified that knowledge is key, noting that “[w]here directors fail to act in the face of a known duty to act, thereby demonstrating a conscious disregard for their responsibilities, they breach their duty of loyalty by failing to discharge that fiduciary obligation in good faith.”¹⁰⁹

99. *Id.* at 755–56 (footnotes omitted).

100. 911 A.2d 362 (Del. 2006) (en banc).

101. Bank Secrecy Act, 12 U.S.C. § 1951 (2018).

102. *Stone*, 911 A.2d at 365.

103. *Id.* at 364.

104. *Id.* at 364–65.

105. *Id.* at 370.

106. *Id.*

107. *Id.* at 371–72.

108. *See id.* at 372–73.

109. *Id.* at 370 (footnote omitted).

C. *Concurrent Developments in Corporate Management Laws*

Corporations' legal requirement to enact, monitor, and enforce corporate compliance policies goes beyond issues related to directors and extends to "strong legal incentives to enact policies that hold employees to standards of conduct under the penalty of criminal sanctions and civil liability, and to develop organizational cultures that foster legal compliance and ethics."¹¹⁰ Failure to implement such policies and compliance programs potentially subjects directors to civil liability pursuant to shareholder derivative suits.¹¹¹

There are two distinct examples of incentives for corporations to enact policies to reduce civil, but not criminal, penalties. First, pursuant to "The Seaboard Report," the Securities and Exchange Commission (SEC) looks to the presence of compliance programs and corporate policies to determine the level of civil penalties to impose on companies that violate SEC regulations.¹¹² In doing so, the SEC imposes fines on companies themselves.¹¹³ Second, in 1998 the Supreme Court held in *Burlington Industries, Inc. v. Ellerth*¹¹⁴ that a corporation can be financially liable for its employees' sexual harassment.¹¹⁵ The Court ruled that corporations can reduce their exposure to liability for sexual harassment claims if they enact, monitor, and enforce programs and policies designed to prevent harassment from occurring and if they provide an internal dispute resolution mechanism for parties subject to the harassment.¹¹⁶ The reflexive approach to corporate governance is now widespread, covers a wide range of issues, and even merits coverage in legal treatises.¹¹⁷

Also beginning in the 1960s, a similar jurisprudential approach emerged in the "structural reform litigation" cases. Structural reform litigation is a strategy utilized to reform large-scale organizations (public and private) and originated in the civil rights cases of the 1960s in the wake of *Brown v. Board of Education*,¹¹⁸ it has been increasingly utilized since then in both

110. See Fort & Latini, *supra* note 44, at 51.

111. *Id.*

112. U.S. SEC. & EXCH. COMM'N, REPORT OF INVESTIGATION PURSUANT TO SECTION 21(a) OF THE SECURITIES EXCHANGE ACT OF 1934 AND COMMISSION STATEMENT ON THE RELATIONSHIP OF COOPERATION TO AGENCY ENFORCEMENT DECISIONS (2001), <https://www.sec.gov/litigation/investreport/34-44969.htm> [<https://perma.cc/6XKW-5FDR>].

113. *Id.*

114. 524 U.S. 742 (1998).

115. *Id.* at 753–54, 756.

116. See *id.* at 765.

117. See, e.g., DAN K. WEBB ET AL., CORPORATE INTERNAL INVESTIGATIONS § 3.02[1][c], at 3–9 (2003) (noting both the board and management responsibilities for corporate compliance programs).

118. 394 U.S. 294 (1955).

civil and criminal litigation.¹¹⁹ Structural reform litigation generally allows courts to oversee the restructuring of policies and procedures, and calls for organizations to adopt structures that would result in the organization's compliance with various laws.¹²⁰ Rather than limiting a holding to the determination of a monetary damage, courts use structural reform litigation to create comprehensive compliance programs that may include independent monitors, injunctions, training programs, audits, data collection, DOJ cooperation, and restitution payments to victims.¹²¹ It has a broad reach beyond just corporate governance and has affected organizational change in the areas of school segregation, conditions in mental hospitals and prisons, affirmative action, and housing discrimination.¹²²

Structural reform litigation changed the ways corporations managed corporate governance such that now, fifty years later, companies have a cornucopia of knowledge on how to create, monitor, and enforce policies that produce acceptable corporate conduct.¹²³ Structural reform litigation bolsters the reflexive movement that forces companies to understand the gravitas of their policies and to ensure they take adequate steps to monitor and enforce their policies.¹²⁴ Together, the Seaboard Report investigations and structural reform litigation highlight how insistent the legal system is in demanding that corporations ratify standards and policies and how these requirements impact a spectrum of corporate activities.

III. THE INTERTWINING OF LAW AND ETHICS

It is important to recognize that while law and ethics are not coterminous, they influence each other. In some cases, they interact as a Venn diagram, with each having separate aspects while also sharing common normative points. This is not only true philosophically; it is important to note that in establishing these corporate governance models, legislatures, commissions, and courts have stressed that companies need to establish ethical cultures that go beyond simply requiring that people in

119. See Garrett, *supra* note 69, at 869, 874 (noting courts have used decrees to address school desegregation, special education, public housing, medical care, prison, disability assistance issues in civil litigation, and used decrees in RICO labor racketeering cases and plea bargains in criminal litigation).

120. See *id.* at 912.

121. *Id.* at 901.

122. *Id.* at 857.

123. See Fort & Latini, *supra* note 44, at 52.

124. *Id.*

the company obey the law.¹²⁵ Indeed, empirical studies demonstrate that in order to be effective—the legal standard—companies must include aspirational dimensions to their programs.¹²⁶ If this is true, then aspiration should not be dismissed as having no legal import. This is not to say that companies should be held accountable for failing to reach their aspirations. However, evidence demonstrating that the company intentionally acted in direct contradiction to its stated objectives, and to what it represents to the market as its process of doing business, should be legally relevant to determining the duties the company owes to constituents who reasonably rely upon such PISCs.

Researchers have found strong empirical support for their hypothesis that a values-based approach is a more potent influence on employee rule-following, especially with respect to the congruence of individual and organizational values.¹²⁷ Employees are more inclined to follow organizational rules in cultures where leadership is considered legitimate, where organizational and individual values are congruent, where there is procedural fairness (e.g., where the decision making processes are neutral, transparent, and fact-based), and where people are being treated with dignity when decisions are made about them.¹²⁸

More subtly and psychologically, the external demand of following a rule can cause individuals to perceive the rule as lying outside their own lived experience, thus making one either resistant to following the rule itself or making it harder to understand the rationale for the rule.¹²⁹ In such cases, the compliance officer needs to facilitate discussions to help people understand what laws affect them, why such laws exist, and how these laws relate to their own individual values.¹³⁰ For a non-lawyer to know what they can or cannot do, the person must often turn to an expert—rather than their common ethical experience—to find out.

125. See Tom R. Tyler & Steven L. Blader, *Can Businesses Effectively Regulate Employee Conduct? The Antecedents of Rule Following in Work Settings*, 48 ACAD. MGMT. J. 1143, 1144–45 (2005) (discussing the self-regulatory approach to fostering corporate compliance).

126. *Id.* at 1144, 1148; see also Lynn S. Paine, *Managing for Organizational Integrity*, 72 HARV. BUS. REV. 106, 106, 111 (1994) (discussing how companies can support their employee's ethically sound behavior through tailored corporate management practices).

127. Tyler & Blader, *supra* note 125, at 1145, 1148.

128. *Id.* at 1153.

129. See Haugh, *supra* note 69, at 1260–61.

130. *Id.* at 1267–68 (noting the importance of allowing employees to discuss their rationalizations of unethical or criminal behavior to combat employees adopting these rationalizations).

Todd Haugh recently made a complementary point.¹³¹ Haugh assessed the amendments to the organizational chapter of the 1991 Federal Sentencing Guidelines.¹³² On the one hand, those Guidelines have been hailed as a significant way to gain corporations' attention to prioritize ethical conduct and to abide by the law.¹³³ Indeed, failing to develop corporate compliance programs not only raises the issue of potential criminal liability if such programs are not in place, but, as we have seen, could also be a potential rationale for a shareholders' derivative suit.¹³⁴

Yet, because violations of compliance programs and the laws those programs are intended to address have occurred, and because those violations have been criminalized, psychological research shows that employees do not apply their ethical intuitions and training to conduct; rather, they address such issues from the rationale of avoiding criminal exposure.¹³⁵ Instead of considering what is good, responsible, and ethical, the language encourages employees to think in terms of alibis and exculpatory arguments to shield themselves from criminal charges.¹³⁶ This does more than simply strip an individual of their moral sentiments; research shows that it delegitimizes the compliance process itself.¹³⁷ Moreover, if compliance constitutes the entirety of the moral values of an organization and the process is not viewed as legitimate itself, conduct can actually become worse rather than better.¹³⁸ More directly, and building from the research of Tom Tyler and others, Haugh argues that:

Criminalized compliance, by delegitimizing the compliance function in the eyes of corporate employees, creates opportunities for the adoption of [their most] powerful rationalizations. These rationalizations not only limit the effectiveness of compliance, they actively facilitate the behavior compliance is intended to eliminate.¹³⁹

Criminalizing behavior thus may actually undermine the goal of compliance itself. To the extent a conscientious employee may want to be in compliance, rather than to game the criminal system, the employee's

131. *Id.* at 1227–30.

132. *Id.*

133. *Id.* at 1228–29.

134. *See, e.g., In Re Caremark Int'l Inc. Derivative Litig.*, 698 A.2d 959, 967 (Del. Ch. 1996).

135. Haugh, *supra* note 69, at 1259–61.

136. *Id.* at 1260.

137. *Id.* at 1260–61.

138. *See id.* at 1261.

139. *Id.* at 1259.

only real option to determine what is acceptable conduct is to act on a legal interpretation, something which the individual may not even be able to provide and instead has to be provided by outside counsel. Put otherwise, introducing criminal sanctions into an organizational environment does not necessarily make things clearer; it may instead make things more frightening, influencing conduct outcomes in a negative way. This situation in itself threatens to erode the enterprise of ethics.

More recently, scholars strongly argue that the optimal way to achieve ethical organizational culture—and the conduct that proceeds from such a culture—is through a mix of compliance and aspiration. Organizational culture theorists Kim Cameron and Robert Quinn, for example, argue that once an organization relies on externalized values based in responding to laws and markets, it is very difficult for the organization to return to a values-based, internally driven culture that has more of a communal or entrepreneurial orientation.¹⁴⁰ Once guided by external rather than internal values, they propose, employee conduct becomes increasingly minimalistic, an insight exactly predicted by Haugh, Tyler, and Blader.¹⁴¹

Legal and ethical scholar Lynn Sharp Paine makes a similar point in her work on organizational integrity. Paine argues that compliance-based models of ethics always fall short because, psychologically speaking, employees are never inspired enough to even comply with the law itself.¹⁴² She offers a model that combines both aspirational quests for good and compliance.¹⁴³

140. KIM S. CAMERON & ROBERT E. QUINN, *DIAGNOSING AND CHANGING ORGANIZATIONAL CULTURE* 39–40, 92 (3d ed. 2011).

141. See Haugh, *supra* note 69, at 1261; Tyler & Blader, *supra* note 125, at 1153.

142. Lynn S. Paine, *Managing for Organizational Integrity*, 72 *HARV. BUS. REV.* 106, 106, 111 (1994).

143. *Id.* at 106–07. This is similar to Fort's model of Total Integrity Management, which argues that corporate culture is best enhanced through a blend of Hard Trust (articulating, becoming aware of, and following the external law and internal organizational policies), Real Trust (building reputation with core constituents and providing rewards and incentives for desired behavior instead of behavior that, in reality, cuts against rhetorical expressions or organizational aims and objectives), and Good Trust (those aspirational quests for moral excellence that result in passion for moral excellence and that are elicited by building on the neurobiological capabilities of employees through small organizations with substantial face-to-face interaction, and building peace by showing a commitment to good). TIMOTHY L. FORT, *THE DIPLOMAT IN THE CORNER OFFICE: CORPORATE FOREIGN POLICY* 149–53 (2015). In particular, the dimension of Good Trust calls for the presence of "mediating institutions" within the organization. *Id.* at 154. These institutions are small and there are face-to-face consequences of one's actions. *Id.* Not only do these institutions follow basic principles of natural law, they accord with the

Aspiration is thus a central component of effective compliance. In order to inspire employees within companies to orient themselves toward good conduct, aspirational quests are important: they connect the dots so that employees see how daily work is personally fulfilling as well as potentially globally impactful.¹⁴⁴ Our argument is that between the mistake of dismissing values statements and mission statements as mere unenforceable rhetoric and the mistake of criminalizing the failure to live up to them lie the levers of civil liability appropriate for governing the interaction of companies with key constituents such as shareholders, employees, and customers.

Thus, from a corporate governance perspective, companies already have a fiduciary duty to shareholders to enact, monitor, and enforce an effective ethics and compliance program.¹⁴⁵ If a board fails to do so, it is grounds for a shareholders' derivative suit.¹⁴⁶ A hallmark of an effective program includes aspirational as well as compliance dimensions. To the extent pharmaceutical companies claim that they do operate according to certain values and, in fact, do not, there is ample precedent and reason to hold them legally accountable.

A. *Corollaries to Upholding Enforceability of Blanket Contracts Against Companies*

The shareholder may not be the only constituent to whom there lies a duty. Employees stand as an additional stakeholder, and, indeed, there is precedent for holding companies liable for their PISCs with respect to employees.¹⁴⁷ There is also precedent and logic for holding companies liable for their PISCs with respect to customers.¹⁴⁸ Unlike the duty to shareholders, however, the duty to these other constituents does not include a fiduciary element.¹⁴⁹

neurobiological capabilities of human beings, which anthropological and psychological studies show are relatively small, with breaking points of six, thirty, and one hundred and fifty. *Id.* at 21–22, 154. In such organizations, there are cultural feedback mechanisms to encourage moral behavior beyond what is enforced from a regulatory, command-and-control perspective. *Id.* at 154.

144. See generally ALEXANDRA CHRISTINA & TIMOTHY L. FORT, *THE SINCERITY EDGE: HOW ETHICAL LEADERS BUILD DYNAMIC BUSINESSES* 34, 37 (2017).

145. See Fort & Latini, *supra* note 44, at 51; Haugh, *supra* note 69, at 1229.

146. See Fort & Latini, *supra* note 44, at 51.

147. See *infra* Section III.A.1.

148. See *infra* Section III.A.2.

149. See Matthew T. Bodie, *Employment as Fiduciary Relationship*, 105 *Geo. L.J.* 819, 855 (2017) (“[E]mployers have not traditionally been treated as fiduciaries.”).

1. *Employment manuals*

Although the U.S. is generally known as an employment-at-will legal system, there are times and places where there are restrictions. For example, collective bargaining agreements can restrict the system, as do anti-discrimination laws.¹⁵⁰ Specific employment agreements do so as well, and that raises the question of whether an employee handbook becomes part of an employment agreement. The answer, not surprisingly, is that it depends.

In *Toussaint v. Blue Cross & Blue Shield of Michigan*,¹⁵¹ for example, Blue Cross handed a manual of policies to the plaintiff; the manual stated that employees would be released “for just cause only” and therefore reinforced the oral assurances the company had given the plaintiff that he would be with the company “as long as [he] did [his] job.”¹⁵² Other cases have held that unless a disclaimer conspicuously indicates that the manual is not part of the employment agreement, the manual can indeed be part of the contract,¹⁵³ but with a disclaimer, the manual is not.¹⁵⁴

In both Europe and the United States, legislatures and courts have created corporate governance regimes that incentivize companies to design corporate compliance and ethics programs in which companies take on a first-order responsibility to foster ethical organizational cultures and legal compliance.¹⁵⁵ Companies devote significant resources to creating, monitoring, and enforcing such programs for a variety of reasons, including the commitment of leadership to the importance of ethical, law-abiding culture as a good in its own right, and to the expectation that such a commitment will result in beneficial economic competitiveness that satisfy legal authorities.¹⁵⁶ The stakes for such programs are high, for legal reasons, with significant attention given to auditing, reporting, and training as well as to more general reputational

150. Michael Z. Green, *Opposing Excessive Use of Employer Bargaining Power in Mandatory Arbitration Agreements Through Collective Employee Actions*, 10 TEX. WESLEYAN L. REV. 77, 77–78 (2003).

151. 292 N.W.2d 880 (Mich. 1980).

152. *Id.* at 884.

153. *See, e.g.*, *Staschiak v. Certified Logistics, Inc.*, 60 N.E.3d 824, 829 (Ohio Ct. App. 2016).

154. *See, e.g.*, *Fleming v. Borden, Inc.*, 450 S.E.2d 589, 596 (S.C. 1994); *Bouwens v. Centrilift*, 974 P.2d 941, 946 (Wyo. 1999); *Michelin Tire Corp. v. Goff*, 864 So. 2d 1068, 1076 (Ala. Civ. App. 2002).

155. *See* Simon Deakin, *Reflexive Governance and European Company Law*, 15 EUR. L.J. 224, 225, 230–31 (2009); Fort & Latini, *supra* note 44, at 38.

156. *See* Fort & Latini, *supra* note 44, at 51.

concerns.¹⁵⁷ In addition, there is an advantage to companies that foster an ethical culture in attracting and retaining talented employees.¹⁵⁸

In 2017, Deloitte University Press published a comprehensive study that looked at “the rules for the digital age.”¹⁵⁹ In its report, Deloitte examined the new, optimal ways that “reflect the shifts in mind-set and behavior that we believe are required to lead, organize, motivate, manage, and engage the 21st-century workforce.”¹⁶⁰ The scope of Deloitte’s project is large, but there are some key, salient findings.

157. *Id.* at 151–52.

158. Indeed, the topic is something that has caught the attention of many business writers and scholars. *See, e.g.*, Laura D. Adams, #16 Match Your Personal Values with Your Work, LAURA D. ADAMS (Aug. 14, 2016) <https://lauradadams.com/richer-life-lab/16-personal-values-work> [https://perma.cc/XG7R-NW8H]; Kate Ashford, How to Assess Company Culture to Find the Best Fit, MONSTER (2020), <https://www.monster.com/career-advice/article/assess-company-culture-best-fit> [https://perma.cc/262Y-4H3H]; Daniel Bortz, How to Answer the Job Interview Question: Describe Your Ideal Work Environment, MONSTER (2020), <https://www.monster.com/career-advice/article/ideal-work-environment-question> [https://perma.cc/9E6V-E6WW]; Susan Bryant, The Corporate Culture Conundrum, MONSTER (2020), <https://www.monster.com/career-advice/article/the-corporate-culture-conundrum> [https://perma.cc/WR6Z-AND7]; Tomas Chamorro-Premuzic, How to Find a Job that Aligns with Your Values, FAST COMPANY (Nov. 10, 2015), <https://www.fastcompany.com/3053241/how-to-find-a-job-that-aligns-with-your-values> [https://perma.cc/LB3Q-T7BT]; Tom Cooper, Is that Employer a Great Place for You to Work?, JOB-HUNT, https://www.job-hunt.org/job_interviews/match-personal-and-employer-values.shtml [https://perma.cc/P9G3-6SFA]; Louis Efron, Why You Can’t Find a Job You Love, FORBES (Sept. 13, 2013, 10:23 AM), <https://www.forbes.com/sites/louisefron/2013/09/13/why-you-cant-find-a-job-you-love/#d45fd651b0b7> [https://perma.cc/83LW-3EPQ]; Shannon Gausepohl, Hiring for Culture Fit? Here’s What to Look for, BUS. NEWS DAILY (Oct. 23, 2017), <https://www.businessnewsdaily.com/6866-hiring-for-company-culture.html> [https://perma.cc/X5CJ-X7R8]; Holly E. Ojalvo & Katherine Schulten, Would You Quit if Your Values Did Not Match Your Employer’s?, N.Y. TIMES (Mar. 15, 2012, 5:17 AM), <https://learning.blogs.nytimes.com/2012/03/15/would-you-quit-if-your-values-did-not-match-your-employers> [https://perma.cc/YYH3-57RE]; Kerry Schofield, Culture Fit in the Workplace: What It Is and Why It’s Important, GOOD & CO. (June 14, 2016) <https://good.co/blog/cultural-fit-in-the-workplace-what-it-is-and-why-its-important> [https://perma.cc/YV4B-5DG8]; Lauren Vesty, Millennials Want Purpose over Paychecks. So Why Can’t We Find It at Work?, GUARDIAN (Sept. 14, 2016, 3:25 PM), <https://www.theguardian.com/sustainable-business/2016/sep/14/millennials-work-purpose-linkedin-survey> [https://perma.cc/7NHL-39AC]; Jolita Vveinhardt & Evelina Gulbovaitė, Questionnaire of Personal and Organizational Values Congruence for Employee (Q-POVC), RESEARCHGATE (Jan. 2015), <https://www.researchgate.net/publication/305728562>.

159. DELOITTE, REWRITING THE RULES FOR THE DIGITAL AGE: 2017 DELOITTE GLOBAL HUMAN CAPITAL TRENDS 1 (2017), <https://www.deloitte.com/content/dam/Deloitte/us/Documents/human-capital/hc-2017-global-human-capital-trends-us.pdf> [https://perma.cc/LL3W-APCM].

160. *Id.* at 2.

First, with respect to the “organization of the future,” Deloitte suggests that the “old rules” focused on efficiency within a more rules-based, hierarchical structure founded on business functions and clearly defined roles.¹⁶¹ Leaders created through promotion and lead by direction indicated a process-driven environment.¹⁶² The culture would be ruled by the fear of failure as perceived by others.¹⁶³ In contrast, the “new rules” organizations emphasize learning and innovation, with the company viewed as a network, empowered by people who become leaders by creating followers.¹⁶⁴ Advancement occurs through different assignments and experiences. The culture is one of safety, abundance, risk-taking and innovation, with teams clearly defined but roles rotating, resulting in a more orchestrated model of leadership that is project-based.¹⁶⁵

Second, the new rules versus old rules analysis applies to talent acquisition as well. Deloitte argues that the old rules feature recruiters using the internet to find candidates whereas the new rules find recruiters expanding their use of social media sites.¹⁶⁶ Under the old rules, recruiters run the process, whereas under the new rules, they partner with hiring managers. Job descriptions change from what the organization demands from a potential employee to focusing on the needs of candidates.¹⁶⁷ Technologically, the old rules rely on an applicant tracking system, in contrast to the new rules’ expanded use of video interviewing, candidate relationship management, and onboarding.¹⁶⁸ Acquisition processes that were once defined by their focus on efficiency, speed, and effectiveness now focus on the candidate and the hiring manager to tailor the process to the candidate’s experience with the company.¹⁶⁹

Third, the factors that contribute to a positive employee experience include:

- “Meaningful work”: “autonomy, small, empowered teams,” [and] time for slack,” among others.
- “Supportive management”: “clear and transparent goals, coaching, and “agile performance management,” among others.
- “Positive work environment”: flexibility, a humanistic workplace, recognition, and being fair and inclusive, among others.

161. *Id.* at 5, 25.

162. *Id.* at 25.

163. *Id.*

164. *Id.* at 25.

165. *Id.* at 25.

166. *Id.* at 46.

167. *Id.*

168. *Id.*

169. *Id.*

- “Growth opportunity”: “training and support on the job,” mobility, self-directed and high impact learning, among others.
- “Trust in leadership”: “mission and purpose, continuous investment in people, transparency and honesty, [and] inspiration,” among others.¹⁷⁰

2. *Consumer: Public advertisements*

Two famous cases, often the bane of law students, suggest that a PISC can be construed as an offer leading to a binding contract. Of course, with a binding contract, there is then a corresponding duty to perform according to the terms of the agreement.

In *Lefkowitz v. Great Minneapolis Surplus Store, Inc.*,¹⁷¹ the defendant had advertised that it would sell three brand new fur coats worth \$100 for \$1, first come, first served, and, three days later, advertised a similar sale with respect to scarves and a stole.¹⁷² The plaintiff was, in fact, the first person at the store’s opening, but was twice refused the sale by the defendant on the grounds that the sale was only for women (the first time) and that, on the second occasion, the plaintiff knew that such were the rules.¹⁷³ Finding that there was a valid offer from the PISC, the court enforced the contract.¹⁷⁴

Similarly, in *Steinberg v. Chicago Medical School*,¹⁷⁵ the plaintiff submitted a \$15 admission fee for consideration to attend medical school.¹⁷⁶ After being rejected, he filed a class action suit against the school, not for the decision of not being admitted per se, but on the grounds that the school did not follow the criteria that it had set out in its admissions bulletin, which specified academic criteria such as grades and MCAT exam scores.¹⁷⁷ Instead, the plaintiff showed that the admissions standards used by the school varied from the school’s stated criteria by including “monetary considerations.”¹⁷⁸ The court held that in accepting the \$15 fee, the school was bound by the criteria it had provided as to how the application would be evaluated.¹⁷⁹

170. *Id.* at 55. Additionally, the article contrasts interesting new rules versus old rules in terms of performance management, leadership, and diversity and inclusion. *Id.* at 72, 83, 114.

171. 86 N.W.2d 689 (Minn. 1957).

172. *Id.* at 690.

173. *Id.*

174. *See id.* at 691.

175. 371 N.E.2d 634 (Ill. 1977).

176. *Id.* at 638.

177. *Id.*

178. *Id.* at 640.

179. *See id.* at 640.

Of course, not all advertisements create such enforceable offers and contracts. In some cases, the “offer” is so outlandish that no reasonable person would think it was legitimate.¹⁸⁰ That was the case in *Leonard v. Pepisco, Inc.*¹⁸¹ where a television viewer submitted fifteen Pepsi points and approximately \$700,000 to Pepsi in exchange for a Harrier fighter jet.¹⁸² The court held that such an offer (which was noted to be redeemed 7,000,000 points and/or their cash equivalent) was made in jest and that no reasonable person would actually believe it to be an enforceable offer.¹⁸³ The court noted that an advertisement is not typically an offer, but an invitation to enter into negotiations.¹⁸⁴ In support of this rule, the court cited a case in which the U.S. Mint advertised Statue of Liberty commemorative coins, but the demand exceeded the supply; the court held that the Mint did not have to fulfill the possible contracts.¹⁸⁵ The court acknowledged *Lefkowitz*, but distinguished the Pepsi case by noting that there, the terms were “clear, definite, and . . . [left] nothing open for negotiation.”¹⁸⁶

3. *Why are companies making PISCs?*

Companies have legal incentives to adopt ethics and compliance programs, such as the inducements provided by the Federal Sentencing Guidelines and *Burlington Industries*, among others.¹⁸⁷ Yet legal concerns are not the only reason companies adopt such programs. They are also valuable marketing tools.¹⁸⁸ A 2001 study by the Organisation for Economic Co-operation and Development (OECD) that reviewed codes of conduct concluded that:

The statements made by some of the codes suggest that economic motivations related to the desire of organisations to compete successfully in the marketplace can also play a role in an organisation’s decision to develop a code of conduct. Relatively often mentioned considerations are the

180. See *Leonard v. Pepisco, Inc.*, 88 F. Supp. 2d 116, 127 (S.D.N.Y. 1999), *aff’d*, 210 F.3d 88 (2d Cir. 2000).

181. 88 F. Supp. 2d 116 (S.D.N.Y. 1999).

182. *Id.* at 119.

183. See *id.* at 119, 127, 132.

184. *Id.* at 122–23.

185. *Id.* at 123 (citing *Mesaros v. United States*, 845 F.2d 1576, 1580 (Fed. Cir. 1988)).

186. *Id.* at 124.

187. See *Burlington Indus., Inc. v. Ellerth*, 524 U.S. 742, 754 (1998) (discussing an employer’s vicarious liability in harassment cases), remanded, 165 F.3d 31; U.S. SENTENCING COMM’N, GUIDELINES MANUAL 509–53 (2018) (detailing sentencing of organizations).

188. Org. for Econ. Co-operation & Dev. [OECD], *Codes of Corporate Conduct: An Expanded Review of Their Contents*, at 2 (May 2001), https://www.oecd.org/daf/inv/investment-policy/WP-2001_6.pdf [<https://perma.cc/HK93-J6AG>].

protection or enhancement of an organisation's reputation and stronger customer loyalty.¹⁸⁹

In the past twenty years, management scholars have argued for “strategic” corporate social responsibility in which specific attention is given to deploying corporate assets mindfully toward specific social goals that enhance a company's reputation with constituents that matter to them.¹⁹⁰ Empirical studies and meta-studies have demonstrated that there is a weak correlation between corporate social performance (sometimes labeled good ethics) and corporate financial performance (sometimes labeled good business).¹⁹¹

Others have argued that corporate culture matters—often in significant ways—to corporate performance.¹⁹² In short, while there may be somewhat both altruistic and legal reasons for companies to attend to ethical and social issues, there are also reputation and business reasons for doing so.¹⁹³ Codes of conduct provide a signal to a company's commitment to ethical and socially responsible corporate behavior and, strategically deployed, are specifically pointed toward constituents that matter, constituents such as shareholders, employees, and customers interested in the company's products and services.¹⁹⁴ If this is the case, however, then a PISC is being offered as a reason for a constituent to maintain a relationship with the company. This further reinforces the notion that those constituents have reason to rely on the statements made by companies and create an obligation for the company to at least not directly act in contradiction to the statements made in a PISC.

Ethics programs generally provide a number of concrete advantages for business organizations.¹⁹⁵ The Josephson Institute of Ethics, for example, has outlined ten primary ways in which an ethics program is able to provide an additional benefit to a corporation outside of the

189. *Id.*

190. *See, e.g.*, Jennifer J. Griffin & Aseem Prakash, *Corporate Responsibility: Initiatives and Mechanisms*, 53 *BUS. & SOC'Y* 465, 466–67 (2013); Marc Orlitzky et al., *Corporate Social and Financial Performance: A Meta-Analysis*, 24 *ORG. STUDS.* 403, 405 (2003).

191. *See, e.g.*, Joshua D. Margolis & James P. Walsh, *Misery Loves Companies: Rethinking Social Initiatives by Business*, 48 *ADMIN. SCI. Q.* 268, 274 (2003).

192. *See, e.g.*, KIM S. CAMERON & ROBERT E. QUINN, *DIAGNOSING AND CHANGING ORGANIZATIONAL CULTURE* 5 (2006).

193. Orlitzky et al., *supra* note 190, at 406–07.

194. *Id.* at 407.

195. We are grateful to research assistant Dakota Coates for drafting an initial version of the following seven paragraphs.

regular aim of boosting ethical behavior.¹⁹⁶ Accordingly, they highlight that these codes: provide guidance in “gray-area” situations; communicate company expectations to employees, vendors, and customers; reduce the level of subjective standards in the workplace; build and reinforce public trust; enhance one’s reputation; and enhance employee morale/loyalty/recruiting.¹⁹⁷

Alternatively, Tara Duggan writing in the *Houston Chronicle* provides a narrower outlook on the financial implications of having a strong ethics program at a firm.¹⁹⁸ They note that companies that promote (and hopefully adhere to) healthy ethics programs are able to benefit from stronger economic performance in the long run.¹⁹⁹ This is heavily rooted in the fact that these organizations are able to avoid unnecessary risks and negative PR—while at the same time remaining in alignment with public opinion.²⁰⁰ Furthermore, this commitment to having an ethical culture will ensure that the company maintains a strong hiring pool as it both ensures job stability and implies that the employee “will be treated with dignity, respect and fairness.”²⁰¹ Similarly, these codes help to bolster customer trust and allow for higher levels of customer satisfaction and brand loyalty.²⁰² Lastly, Carter McNamara also highlighted that these programs can act as a legal shield and a fine reducer when it comes to facing lawsuits and government investigations.²⁰³

In particular, many of the benefits an organization receives from a code of ethics also arise in relation to mission/vision statements. Bain has noted that these statements help to “establish a framework for ethical behavior[s],” guide employees through periods of hardship or change, reinforce PR, and help to create a stronger connection with

196. JOSEPHSON INST. OF ETHICS, *Ten Benefits of Having an Ethics Code*, BUS. ETHICS BLOG, <http://josephsononbusinessethics.com/2010/11/ten-benefits-of-having-an-ethics-code> [https://perma.cc/5AHR-XGSZ].

197. *Id.*

198. Tara Duggan, *How Do Ethics Affect the Financial Results of a Company?*, CHRON, <https://smallbusiness.chron.com/ethics-affect-financial-results-company-51280.html> [https://perma.cc/QFH4-2H64].

199. *Id.*

200. *See id.*

201. *Id.*

202. *Id.*

203. Carter McNamara, *10 Benefits of Managing Ethics in the Workplace*, BLOG: BUS. ETHICS, CULTURE & PERFORMANCE (Oct. 23, 2010), <https://managementhelp.org/blogs/business-ethics/2010/10/23/10-benefits-of-managing-ethics-in-the-workplace> [https://perma.cc/Z6D7-T2NP].

employees.²⁰⁴ However, much of the literature acknowledged that one of the greatest benefits of creating (and adhering to) these statements was that it gives the organization purpose.²⁰⁵

Forbes points to the fact that by simply drafting these statements, you are allowing the company to at least market what the perceived benefit/purpose of the company is.²⁰⁶ In their article, *A Model of the Impact of Mission Statements on Firm Performance*, Christopher Bart, Nick Bontis, and Simon Taggar examined how this sense of purpose applied to employees. They found that it helped to influence and guide actions; helped align employee behavior with the overall company culture; and that the clearer the statement the greater the employee satisfaction.²⁰⁷ David Mosoma, who performed a similar analysis on Tanzanian banking, also found each of these purpose-tied benefits—and noted that a strong mission/vision statement enhanced an employee’s general workplace performance.²⁰⁸

Shelley Kirkpatrick tied these to more theoretical concepts.²⁰⁹ Accordingly, she contends that the use of a company vision statement is strongly connected with transformational and charismatic leadership theory, “as it provides meaning and context to employees about the purpose of the organization.”²¹⁰ She also pointed to the International Society for Performance Improvement’s human performance technology model,

204. *Mission and Vision Statements*, BAIN & CO. (Apr. 2, 2018), <https://www.bain.com/insights/management-tools-mission-and-vision-statements> [https://perma.cc/4CED-KRCQ].

205. See, e.g., Christopher K. Bart et al., *A Model of the Impact of Mission Statements on Firm Performance*, 39 MGMT. DECISION 19, 30, 32–33 (2001), https://www.researchgate.net/publication/240258617_A_Model_of_the_Impact_of_Mission_Statements_on_Firm_Performance [https://perma.cc/QV49-5LKS].

206. Jeff Bradford, *Bolstering Your Brand Through Vision and Mission Statements*, FORBES (Aug. 24, 2018, 9:00 AM), <https://www.forbes.com/sites/forbesagencycouncil/2018/08/24/bolstering-your-brand-through-vision-and-mission-statements/#4b228b722176> [https://perma.cc/PGX7-GZT4].

207. Bart et al., *supra* note 205, at 30–33; see also Glenn Smith, *7 Reasons Your Company Needs a Clear, Written Mission Statement*, GLENN SMITH EXECUTIVE COACHING (Mar. 29, 2016), <https://www.glennsmithcoaching.com/7-reasons-your-company-needs-clear-written-mission-statement> [https://perma.cc/V48L-GT86].

208. David Mosoma, *The Significance of Effective Mission Statements in Business Performance: The Case of the Banking Sector in Tanzania*, 6 EUR. J. BUS. & MGMT. 92, 98–99 (2014), <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.674.9583&rep=rep1&type=pdf> [https://perma.cc/48NZ-D9YA].

209. Shelley A. Kirkpatrick, *Toward a Grounded Theory: A Qualitative Study of Vision Statement Development*, 18 J. MGMT. POL’Y & PRAC. 87 (2017), http://www.na-businesspress.com/JMPP/KirkpatrickSA_Web18_1_.pdf [https://perma.cc/7YUQ-AL2G].

210. *Id.* at 87.

which suggests that in order to improve performance one must start “by identifying the vision, mission, values, goals, and strategy that the organization wants to achieve.”²¹¹ Therefore, having a company (hopefully with a sufficient assortment of stakeholders) craft a unified mission/vision statement for the entire firm increases organizational and individual performance while also establishing uniform ways of measuring improvement.²¹² She also suggests that by creating a clear “why” for your organization, you are able to enhance the customer trust in your organization while clarifying what benefits you have to offer to new customers.²¹³

In a 2015 article, Benjamin Inyang and others offered another assortment of various benefits that come from a clear and effective mission statement.²¹⁴ A few additional benefits that they highlighted were that it: improves internal and external communication; strengthens the public image of the company; helps clarify who the target customer is; legitimizes the company and its purpose; and can increase performance up to 50%.²¹⁵ However, the authors noted that some of the suggested benefits of mission/vision statements are not all fully grounded in actual empirical data, and instead may be more of a perceived benefit.²¹⁶ In assessing their example’s connection between mission statements and higher profitability, they asserted the results were mixed at best.²¹⁷

Adopting and publicly announcing ethics programs and their associated mission statements is valuable to companies. Forbes highlights that companies want to aim for mission statements that target “[a]uthenticity and transparency.”²¹⁸ This is due to the fact that these types of mission statements help build customer trust in an organization—and “[o]rganizations high in trust are 2.5 times more likely to function as a high-performance organization with revenue growth than lower performance organizations.”²¹⁹ Furthermore, this will also enhance general stakeholder

211. *Id.*

212. *Id.* at 87–88.

213. *Id.* at 96.

214. Ekpe Oyono Ekpe et al., *Leveraging Organizational Performance Through Effective Mission Statement*, 8 INT’L BUS. RES. 135, 139 (2015), <http://www.ccsenet.org/journal/index.php/ibr/article/download/52602/28149>.

215. *Id.* at 135–36, 138.

216. *Id.* at 138.

217. *Id.*

218. William Craig, *The Importance of Having a Mission-Driven Company*, FORBES (May 15, 2018, 8:00 AM), <https://www.forbes.com/sites/williamcraig/2018/05/15/the-importance-of-having-a-mission-driven-company/#25f0c9033a9> [https://perma.cc/ZL6X-RXM6].

219. *Id.*

trust in the company leadership team, with “eighty-one percent of those working for companies with a strong mission” trusting their leadership team compared to only 54% at firms without a strong statement.²²⁰

Gallup suggested that mission/vision statements are often an “underused asset” at firms that could be used to increase overall “performance and profitability.”²²¹ Their research—an analysis involving almost 50,000 business units, 192 different organizations, across 49 different industries in 34 countries—revealed that employees who were given strong mission statements were better able to connect with customers.²²² Accordingly, this allowed for companies to enjoy improved brand differentiation, garner more passionate and loyal customers, and increase brand engagement from new and returning customers.²²³ Having a clearer mission also allowed for firms to create better metrics for monitoring customer services and helped to define what they would look for in employee—customer interactions.²²⁴

The authors of “Mission Statement Theory and Practice: A Content Analysis and New Direction” offered more subtle ways in which a mission statement can be used to connect to customers.²²⁵ First, they suggest that these statements can allow for a company to “create an ‘emotional bond’ and a ‘sense of mission’ between an organization and its employees.”²²⁶ Mission statements written from the customer’s perspective can encourage employees to provide laudable customer service, which would in turn augment customer loyalty and convert to customers “on a mission” to proclaim the benefits of the firm’s services and products.²²⁷ Additionally, a customer-focused mission statement will also allow for more effective marketing efforts due to the fact that customers will be more likely to build strong, healthy, and extended bonds with the organization.²²⁸

Peter Forstmoser and Nikodemus Herger wrote extensively about the various reputational benefits that come from a strong mission

220. *Id.*

221. Chris Groscurth, *Why Your Company Must Be Mission-Driven*, GALLUP (Mar. 6, 2014), <https://www.gallup.com/workplace/236537/why-company-mission-driven.aspx> [<https://perma.cc/HK5V-2ANV>].

222. *Id.*

223. *Id.*

224. *Id.*

225. Meredith E. David et al., *Mission Statement Theory and Practice: A Content Analysis and New Direction*, 7 INT’L J. BUS., MARKETING & DECISION SCI. 95, 96 (2014), <http://strategyclub.com/wp-content/uploads/2014/09/David-pdf-file.pdf> [<https://perma.cc/W3J6-DVCY>].

226. *Id.* at 97.

227. *See id.* at 98.

228. *Id.*

statement.²²⁹ They started by pointing to the fact that it provides the customer with an initial positive image of the company from which the organization can work to build and maintain a strong reputation.²³⁰ A firm with a customer-focused mission statement is also likely to experience higher levels of customer satisfaction and loyalty, and their customer relationships will generally be healthier all around.²³¹ This is then amplified by the fact that a strong mission statement allows for easier customer acquisition and simplifies new product launches, thus ensuring an ever-growing customer pool.²³²

B. The Ethical Rationales for Identifying a Duty to Enforce the Mission Statement/Code of Conduct Claims a Company Makes

Beyond the legal arguments for why we believe there should be a cause of action against companies that have violated specific claims in their PISCs, there are ethical rationales for doing so. Not only do those rationales provide additional, non-legal reasons for companies to uphold their specific promises to the public, they also bolster the rationale for the legal system to hold companies accountable for them.

1. Opioid values statements

Companies remain free to choose what mission statements and codes of conduct they wish to implement. Should a company decide to enact a mission statement that touts the company's willingness to be corrupt, deceptive, and dishonest and then post that statement on its website, it is free to do so. Obviously, that would likely not be an optimal public image to broadcast, and, in reality, companies don't do this. Instead, they offer positive statements about their conduct as a way to be more appealing to stakeholders, including shareholders, customers, and employees.²³³ Indeed, the management literature cited above demonstrates the clear business/contractual calculation that companies make in publicly issuing their mission and values statements.

Opioid manufacturers are not shy about touting the integrity with which they promise to conduct themselves, as well as the care with which they treat

229. Peter Forstmoser & Nikodemus Herger, *Managing Reputational Risk: A Reinsurer's View*, 31 GENEVA PAPERS 409 (2006).

230. *Id.* at 415.

231. *See id.* at 418.

232. *Id.* at 415.

233. *See, e.g., Purpose Statement and Values*, PURDUE PHARMA, <https://www.purduepharma.com/about/ethics-and-compliance/purpose-statement-values>; AMERISOURCEBERGEN, *supra* note 49, at 4; *Mission Statement*, *supra* note 51; *Our Core Values*, *supra* note 50.

their customers. For example, consider Purdue Pharmaceuticals' Purpose Statement and Values:

Compassion for patients and excellence in science inspire our pursuit of new medicines.

Integrity:

We do what is right.

Courage:

We challenge convention and embrace change.

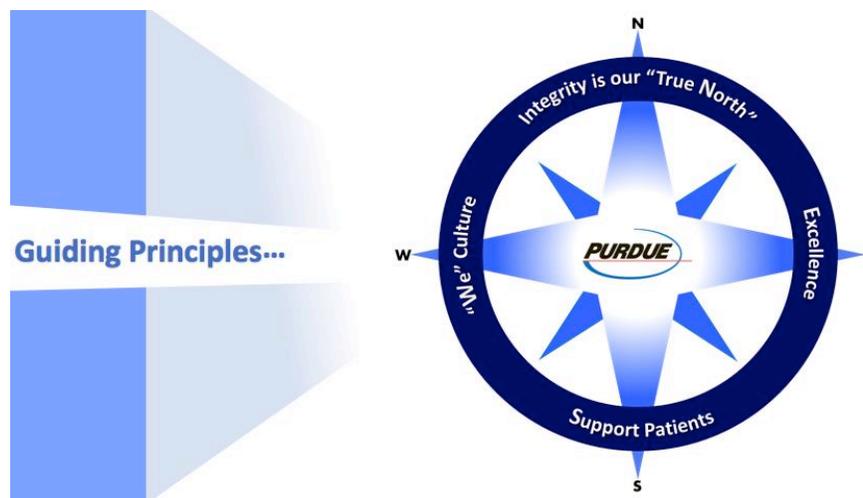
Innovation:

We apply creative and agile thinking to generate solutions.

Collaboration:

We work together to meet our commitments and goals.²³⁴

The company also espouses four guiding principles, graphically presented in the form of a compass:



234. *Purpose Statement and Values*, *supra* note 233.

<p>Integrity is our "True North"</p> <p>We are committed to upholding the highest ethical standards throughout our business. As an important stakeholder in pain management, we embrace responsible stewardship and are dedicated to combating opioid abuse, diversion, addiction, and overprescribing. Every decision matters.</p>
<p>Support Patients</p> <p>We are relentlessly passionate about our mission to identify, develop, and supply innovative medicines that meet the evolving needs of patients as well as their families, healthcare providers, and society. The health and safety of patients is our #1 priority.</p>
<p>Excellence</p> <p>We have pioneered meaningful technologies and medicines that support patients. With this heritage, we are working toward a future of novel approaches to pain management and other therapeutic areas. We are dedicated to innovation and uphold the highest scientific, commercial, and regulatory standards. We will always strive to do better.</p>
<p>"We" Culture</p> <p>We actively seek, value, and draw on colleagues who are diverse in opinions, backgrounds and experiences to challenge the status quo and succeed as a team. We operate as a family, where everyone's ideas and concerns are explored. The voice of every colleague is essential to our progress.</p>

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To be sure, some of these goals are truly aspirational, and they are too open-ended to be deemed enforceable. Valuing colleagues of diverse backgrounds and pioneering new technologies and medicines fall into that category. So too integrity, a virtue that is holistic, ranging beyond mere honesty, and something that reasonable people can hold differing views about. Nevertheless, the language “the health and safety of patients is our #1 priority” is specific enough that evidence showing that the company specifically targeted individuals prone to misusing opioids and/or doctors prone to overprescribing, would be grounds for finding that the company has utterly failed to uphold a principle held out to the public. The company could have chosen to make a different commitment, but it chose—for whatever reason, but presumably with some anticipation of cultivating a favorable reputation—to make this commitment.

The same criticism can be made in terms of the values statement claiming “compassion for patients.” It is certainly possible that different people could propose differing ways to demonstrate compassion. It is hard to envision an argument whereby targeting vulnerable populations and unscrupulous doctors would be among them, however.

Similarly, Johnson & Johnson, at one time considered (including by the authors) to be a standard-bearer of good corporate ethics, attributes much of its reputation to its famous Credo:

We believe our first responsibility is to the patients, doctors and nurses, to mothers and fathers and all others who use our products and services. In meeting their needs everything we do must be of

235. *Code of Ethics*, PURDUE PHARMA (2017), <https://www.purduepharma.com/wp-content/pdfs/CBE.pdf> [<https://perma.cc/5DB3-6F39>].

high quality. We must constantly strive to provide value, reduce our costs and maintain reasonable prices. Customers' orders must be serviced promptly and accurately. Our business partners must have an opportunity to make a fair profit.

We are responsible to our employees who work with us throughout the world. We must provide an inclusive work environment where each person must be considered as an individual. We must respect their diversity and dignity and recognize their merit. They must have a sense of security, fulfillment and purpose in their jobs. Compensation must be fair and adequate and working conditions clean, orderly and safe. We must support the health and well-being of our employees and help them fulfill their family and other personal responsibilities. Employees must feel free to make suggestions and complaints. There must be equal opportunity for employment, development and advancement for those qualified. We must provide highly capable leaders and their actions must be just and ethical.

We are responsible to the communities in which we live and work and to the world community as well. We must help people be healthier by supporting better access and care in more places around the world. We must be good citizens—support good works and charities, better health and education, and bear our fair share of taxes. We must maintain in good order the property we are privileged to use, protecting the environment and natural resources. Our final responsibility is to our stockholders. Business must make a sound profit. We must experiment with new ideas. Research must be carried on, innovative programs developed, investments made for the future and mistakes paid for. New equipment must be purchased, new facilities provided and new products launched. Reserves must be created to provide for adverse times. When we operate according to these principles, the stockholders should realize a fair return.²³⁶

Like Purdue's statement, the Johnson & Johnson Credo contains many fine aspirations that provide general notions of how the company will conduct itself. Many of those would not be legally enforceable because they are not specific enough. People will differ as to what an "inclusive work environment" may entail and what it means to pay a "fair share of taxes."²³⁷ However, when the first paragraph contains a commitment "to the patients, doctors and nurses, to mothers and fathers and all others who use our products and services,"²³⁸ it is hard

236. *Our Credo*, JOHNSON & JOHNSON, <https://www.jnj.com/credo> (last visited Oct. 8, 2020).

237. *Id.*

238. *Id.*

to see how that squares with conduct of overprescribing to vulnerable populations. Indeed, it was exactly the concern for the safety and health of consumers that led Johnson & Johnson to remove Tylenol from the shelves nationwide in 1982.²³⁹ When later asked why the company made such a bold move, Johnson & Johnson CEO, James Burke, said, “[W]e couldn’t live up to our Credo.”²⁴⁰

Like Purdue, Johnson & Johnson can choose whatever code of conduct or mission/values statement it wishes. Its choice reflects a decision of how it wants to present itself to the market. Based on the preceding analysis with respect to public statements to shareholders, employees, and customers, the time has come for companies to be held accountable for their choice of public commitments. That is reinforced by the legal and economic reasons companies make such public commitments.

2. *The ethical rationale for holding companies accountable for their PISCs*

Applications of leading business ethics theories, such as shareholder, stakeholder, and virtue theory, provide different visions of responsibility, but would support this position. It is true that one advocating for a short-term version of shareholder theory would suggest that maximizing profits, especially for a legal product, is a manager’s duty to the shareholders.²⁴¹ Of course, this assumes that the legal approval of a product has been obtained through proper procedures and that deceptive marketing of the product has not occurred.²⁴² As already noted in this Article, both of these assumptions may be in error, meaning that even under a short-term version of shareholder theory, we conclude the intentional marketing of opioid medication to vulnerable populations is suspect.²⁴³ Moreover, nothing in shareholder theory—either the long-term or the short-term version—would countenance violating promises to act to protect health.²⁴⁴

239. See Judith Rehak, *Tylenol Made a Hero of Johnson & Johnson: The Recall that Started Them All*, N.Y. TIMES (Mar. 23, 2002), <https://www.nytimes.com/2002/03/23/your-money/IHT-tylenol-made-a-hero-of-johnson-johnson-the-recall-that-started.html> [https://perma.cc/VFJ6-2C9F].

240. *60 Minutes: Interview of James Burke*, (CBS television broadcast 1982).

241. See *Dodge v. Ford Motor Co.*, 170 N.W. 668, 671 (Mich. 1919) (noting Ford’s financial maneuver to reduce stockholder returns); Milton Friedman, *The Social Responsibility of Business Is to Increase its Profits*, N.Y. TIMES MAG. (Sept. 13, 1970) (“[A] corporate executive . . . has a direct responsibility to his employers . . . to conduct the business in accordance with their desires . . . to make as much money as possible while conforming to their basic rules of the society . . .”).

242. Friedman, *supra* note 241, at 6.

243. Cf. ROBERT PHILLIPS, *STAKEHOLDER THEORY AND ORGANIZATIONAL ETHICS* 4 (2003).

244. *Id.*

Business ethics theories are even clearer with respect to nearly any other leading assessment. A person advocating a long-term version of shareholder theory might factor in the negative impact on companies of being in the opioid business because of the potential costs imposed on firms, ranging from the costs of lawsuits, regulation, and reputation that could more broadly taint the company.²⁴⁵ The reputation of opioid companies has suffered considerably given the awful consequences of the crisis.²⁴⁶ Even a company often lauded for its ethical conduct, Johnson & Johnson, faced the embarrassment of having its famed Corporate Credo introduced into evidence in Oklahoma court with the question of whether the company's actions lived up to the Credo.²⁴⁷ F. A. Hayek, a free market economist who won the Nobel Prize for Economics, argued that companies and the market itself thrive with promise-keeping and truth-telling; such conduct lubricates the market with trust as opposed to relying on expensive police-keeping methods to make sure people are living up to promises.²⁴⁸ As evidence of the wreckage of reputation, consider how non-profits today are refusing to accept donations—or, in some instances, even giving back prior donations—from the Sackler family, owners of Purdue Pharmaceuticals.²⁴⁹

Shareholder theory is one of three leading frameworks for business ethics today.²⁵⁰ Compared to the other two theories, shareholder theory—which focuses on following the lawful directives of the shareholders, with profit-seeking typically being the strongest such directive—is the most likely to countenance the sale of opioids as it has thus far been conducted.²⁵¹ Nevertheless, shareholder theory provides little resistance to the argument of this Article. The other two leading theories, stakeholder and virtue, are far more prone to support.

245. *Shlensky v. Wrigley*, 237 N.E.2d 776, 777–78 (Ill. App. Ct. 1968); see Per Saxegaard, *Are You Businessworthy?*, in TIMOTHY L. FORT, *THE VISION OF THE FIRM* (2d ed. 2017).

246. See Navreet Pabla, *Pharma Companies Struggling to Maintain Reputation*, HEALTHCARE WKLY., (Mar. 21, 2019), <https://healthcareweekly.com/pharmacy-opioid-epidemic-lawsuits> [<https://perma.cc/5C9C-GEH8>].

247. Source: confidential conversation.

248. F. A. HAYEK, *THE FATAL CONCEIT: THE ERRORS OF SOCIALISM* 70–71 (W.W. Bartley III ed., 1988); see also *Friedrich von Hayek Facts*, NOBEL PRIZE ORG., <https://www.nobelprize.org/prizes/economic-sciences/1974/hayek/facts> [<https://perma.cc/MGB3-GRXY>] (providing background on Hayek's life, work, and accomplishments).

249. See, e.g., Alex Marshall, *Museums Cut Ties with Sacklers as Outrage over Opioid Crisis Grows*, N.Y. TIMES (Mar. 25, 2019), <https://www.nytimes.com/2019/03/25/arts/design/sackler-museums-donations-oxycotin.html> [<https://perma.cc/N7KR-PRP6>].

250. See, e.g., FORT, *supra* note 245, at 93–112.

251. *Id.*

Those advocating for protection of stakeholders would likely focus on whether the basic rights (defined as things without which life would be intolerable) are impacted.²⁵² In the opioid crisis, there are many such devastated individuals and communities, yet if we also acknowledge that the experience of chronic pain is something that makes life intolerable, we face the challenge of balancing of multiple kinds of basic rights.²⁵³ Of course, this directly impacts how individuals are affected by the crisis; it would also support the argument that a company should not violate the promises it makes to the health of its constituents while operating in a way that is opposite.

The same might be true in a distributive justice model in which one seeks to protect the most vulnerable stakeholders or at least not make them worse off.²⁵⁴ The determination of who is most vulnerable and how to protect them could itself be a contested argument; after all, opioids can help patients in pain, who surely are vulnerable stakeholders. Assuming the truth of the reality of multiple, vulnerable stakeholders, there is little reason to believe that the intentional targeting of those most likely to misuse—or to prescribe misuse—would qualify as an action protecting vulnerable populations. Moreover, perhaps the most famous distributive justice argument in business ethics, the Integrative Social Contracts Theory framework of Donaldson and Dunfee, contemplates both extant and theoretical social contracts.²⁵⁵ Within that framework is the notion of a social contract between business and society in which business exists at the permission of society; actions that undermine the well-being of that society would violate the social contract,²⁵⁶ as would be the case both with the sale of opioids as described in this Article and with respect to violating a PISC (exactly a form of a social contract).

The final aspect of the triad of stakeholder theory is utilitarianism, which argues for acts or for norms (depending on whether one follows act-utilitarianism or rule-utilitarianism) that create the greatest good for the greatest number of stakeholders.²⁵⁷ Here again, based on how the opioid crisis has unfolded, a utilitarian analysis would condemn both the intentional marketing toward vulnerable populations and a window-dressing approach that promises one set of conduct while

252. Werhane, *supra* note 2, at 7.

253. *Id.*

254. PHILLIPS, *supra* note 243, at 29.

255. THOMAS DONALDSON & THOMAS W. DUNFEE, TIES THAT BIND: A SOCIAL CONTRACTS APPROACH TO BUSINESS ETHICS (1999).

256. *Id.*

257. See WILLIAM C. FREDERICK, VALUES, NATURE AND CULTURE IN THE AMERICAN CORPORATION 220–21, 240 (1995).

acting in a different way. Thus, stakeholder theory is consistent with the approach taken in this Article.

The final theory, virtue theory, also supports this argument in two ways. The first way is straightforward in that virtuous individuals and companies would, by definition of virtue, necessarily exert efforts to live up to the aspirations and virtues that the companies claim to possess.²⁵⁸ One could go further and argue that those claims should be those that make for a better society,²⁵⁹ but even if one took a more process-oriented approach, empirical studies demonstrate that the most effective compliance programs result when a company follows the standards that it sets out to its stakeholders, whatever those standards are.²⁶⁰ In other words, stakeholders (in this case, particularly employees with respect to compliance programs) may be able to accept different standards of conduct as long as they know what those standards are and as long as those standards are enforced.²⁶¹ In either respect, the failure to live up to stated aims of conduct in a PISC violates virtue theory.

Moreover, an additional argument—expressed in terms of virtue theory but expressly claiming to integrate both shareholder and stakeholder theory as well—provides that while companies cannot be managed in such a way as to take into account all stakeholders, they can take three key constituents into account: shareholders, employees, and customers.²⁶² This is a “mediating institutions” argument that exactly supports the argument of this Article that companies have particular duties to shareholders, employees, and customers in carrying out the promises made via their PISCs.

The argument that companies should be held accountable for whatever mission or values statement/code of conduct they enact and advertise does not mandate any particular statement. At the same time, if companies use such statements as a mode of enhancing their business by attracting employees and customers and by living up to their fiduciary duties to shareholders, then they should be held accountable for whatever claim the company makes as long as it is reasonably specific and ascertainable.

258. *Id.* at 220–21.

259. Robert C. Solomon, *The Corporation as Community*, 4 *BUS. ETHICS Q.* 271, 284 (1994); *see also*, Edwin M. Hartman, *Can We Teach Character? An Aristotelian Answer*, 5 *ACAD. MGMT. LEARNING & EDUC.* 68, 71 (2006).

260. *See* Linda Klebe Treviño & Gary R. Weaver, *Compliance and Values Oriented Ethics Programs: Influences on Employee's Attitudes and Behavior*, 9 *BUS. ETHICS Q.* 315, 316 (1999).

261. *Id.*

262. FORT, *supra* note 143, at 152–53.

CONCLUSION

To be sure, our argument is an early step in providing a rationale for holding health companies—here, especially as related to those in the chain of opioid sales—accountable for failing to adhere to specific public statements of conduct. We have been careful to limit our argument to such specific statements rather than to attempt to articulate a theory of liability for more vague statements that could be dismissed as marketing puffery. As an early step in making this argument, we acknowledge that a wide legal and ethical framework would helpfully support our theory, a framework that would range beyond opioids and health care companies per se. At the same time, we believe we have offered a compelling case for considering strong legal enforcement of PISCs issued by companies and upon which multiple corporate stakeholders rely.