

A PRACTITIONER'S VIEW OF INSTITUTIONAL CORRUPTION THROUGH THE LENS OF THE HEALTH CARE SYSTEM: AN ESSAY

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These interdisciplinary invaders have come to dominate the faculties of the elite law schools and to influence a great many of the other law schools. The interdisciplinarians are valuable additions to law faculties, but they should not be allowed to displace faculty who bring to the teaching of and research into law a rich background of legal practice in lieu of expertise in a scholarly field or fields outside of law.

—Richard A. Posner, *The Federal Judiciary Strengths and Weaknesses*, Harvard University Press 2017

INTRODUCTION

Think about this: some of the largest drug companies in the world—the one's that we rely on for life saving treatments—are convicted criminals.¹ Hospital chains and large entities that distribute drugs to the elderly have been charged with defrauding the government and have paid fines, or entered guilty

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¹ See *GlaxoSmithKline to Plead Guilty and Pay \$3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data: Largest Health Care Fraud Settlement in U.S. History*, U.S. DEP'T OF JUST. (May 22, 2015), <https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report>; *Abbott Labs to Pay \$1.5 Billion to Resolve Criminal & Civil Investigations of Off-label Promotion of Depakote*, U.S. DEP'T OF JUST. (Oct. 22, 2014), <https://www.justice.gov/opa/pr/abbott-labs-pay-15-billion-resolve-criminal-civil-investigations-label-promotion-depakote>; Ransdell Pierson & Jeremy Pelofsky, *Pfizer to Pay \$2.3 Billion, Agrees to Criminal Plea*, REUTERS (Sept. 2, 2009, 11:35PM), <https://www.reuters.com/article/us-pfizer-settlement-sb/pfizer-to-pay-2-3-billion-agrees-to-criminal-plea-idUSTRE5813XB20090903>; E.D. Pa. Crim. Guilty Plea Agreement, <http://online.wsj.com/public/resources/documents/cephalonplea.pdf>; *Pfizer Unit Wyeth Pleads Guilty*, CORPORATE CRIME REPORTER (July 30, 2013, 1:35PM), <https://www.corporatecrimereporter.com/news/200/wyethpleadsguilty07302013/>; *Warner Chilcott Agrees to Plead Guilty to Felony Health Care Fraud Scheme and Pay \$125 Million to Resolve Criminal Liability and False Claims Act Allegations*, U.S. DEP'T OF JUST. (April 28, 2017), <https://www.justice.gov/opa/pr/warner-chilcott-agrees-plead-guilty-felony-health-care-fraud-scheme-and-pay-125-million>; *Johnson & Johnson Unit Pleads Guilty, To Pay More than \$2.2 Billion in Global Settlement*, CORPORATE CRIME REPORTER (Nov. 4, 2013, 11:38AM), <https://www.corporatecrimereporter.com/news/200/johnson-johnson-unit-pleads-guilty-to-pay-more-than-2-2-billion-in-global-settlement/>.

pleas to resolve allegations of conduct that have placed patients at risk.² Healthcare fraud is so rampant that each year the government has recovered billions of dollars under the False Claims Act from companies whose television advertising attempts to portray a different image; an image of a benevolent and caring corporate citizen.

Yet, with so many employees inside the company, how do these entities do what they do for so many years before their wrongful conduct is exposed, perhaps by a whistleblower who wakes up one day and questions what others have never thought about questioning? The answer to this question involves an analysis of how people behave when they are part of an institution—or in this case, a large corporation.

In contemplating this matter, I am reminded of the air raid drills at my grade school in the 1960s. Do stay with me because there is a point to be made here.

In second grade, we were marched in double rows, holding hands, to the edge of the school property where we were told that when “the big one” comes, we should immediately vacate school grounds and walk home. Perhaps it is the influence of three decades of practicing law, but I surmise that this air raid protocol was cooked up by the lawyers and the insurance companies. Why would our school principal—a caring but unwitting fellow—not question why a mere exit from school property would protect little tikes from an enemy onslaught? The answer is obvious; the protocol was unassailable because it came by way of a superior institution, the Board of Education.

It is not so much that I believe that all people are motivated by self-interest or greed; it is that institutions have a way of corrupting even those who are inherently principled, or creating a dynamic where unwitting players—even principals—are lulled into complicity. To very loosely paraphrase a line used by a former Assistant Secretary of Energy in testimony before a House of Representatives oversight committee, institutions have a way of causing individuals to check their brains at the door.

² See *Hospital Chain Pleads Guilty in Settlement*, QUESTIA (Dec. 15, 2000), <https://www.questia.com/newspaper/1P2-5744861/hospital-chain-pleads-guilty-in-settlement>; Nate Raymond, *CVS's Omnicare to Pay \$8 Million to Settle U.S. Probe*, UNION LEADER (May 17, 2017, 3:17AM), <http://www.unionleader.com/apps/pbcs.dll/article?AID=/20170516/NEWS02/170519385/0/NEWHAMPSHIRE14>; *Major Hospital Pleads Guilty to Defrauding U.S.—Nobody Goes to Jail*, QUIT ALCOHOL (Oct. 26, 2016), <https://www.quitalcohol.com/news/major-hospital-defrauding-us.html>.

The problem starts with un-checked institutional allegiance. Too often we define ourselves not by our own accomplishments, but by our institutional affiliations. We align ourselves with schools, employers, social clubs, and sports teams and we too often define our own worth by their accomplishments. We even subject ourselves to their branding; we wear school t-shirts, don team hats, carry brief cases and travel bags with the logo of our employers and we otherwise boast about the accomplishments of our institutional affiliations.

There is an externality to all of this; when institutional allegiance checks in, individual moral or ethical compasses too often check out. For some, there is no need to question the conduct of the institution because the beauty of the institution is that someone else—perhaps in the ethics department or general counsel's office—takes care of anything that could be of concern. Affiliation with an institution is a convenient excuse for abdication of individual responsibility.³ And for those who play the odds, this makes complete sense. Rarely are individuals held criminally or civilly responsible in direct proportion to the wrongdoing that they orchestrate under cover of institutional affiliation.⁴ For those who might gather an inkling of suspicion about misconduct within the institution, there is often no incentive to act on the suspicion. In simple terms, why make waves when the institution is good to its members? If everyone encompassed by the institution thinks things are good, then things must be good—especially where the institution has super smart people who exist to ensure compliance with law.⁵ Through years of litigation against large corporations, I theorize that this is the thought process for those within an institution who are confronted with blowing the whistle on wrongdoing.

³ “Plausible deniability” is a common concept with its own Wikipedia listing. *Plausible Deniability*, WIKIPEDIA, https://en.wikipedia.org/wiki/Plausible_deniability (last visited Jan. 24, 2018); *See generally* Ognat, *Woody Allen—The Moose*, YOUTUBE (Aug. 21, 2007), <https://www.youtube.com/watch?v=yiUS5Zf9HRI> (Woody Allen indirectly recognizes the plausible deniability phenomenon in his joke about “The Moose”).

⁴ *See* Memorandum from Sally Yates, Dep. Atty. Gen., Department of Justice, to the Department of Justice (Sept. 9, 2015), <https://www.justice.gov/archives/dag/file/769036/download> (instructing US Attorneys, and others within the Justice Department, not to conclude investigation of corporate wrongdoing absent an investigation and prosecution of individuals who were at the heart of the impropriety. As the memo explained: “[o]ne of the most effective ways to combat corporate misconduct is by seeking accountability from the individuals who perpetrated the wrongdoing”).

⁵ The words “super smart” are meant to apply to academic pedigree; history has shown that white collar criminals can—but not always—be the product of the finest schools; indeed, ones that *US News* would deem top tier. Enron’s Andrew Fastow graduated from Tufts (BA) and Northwestern (MBA) while Enron’s Jeffrey Skilling earned his MBA at the Harvard Business School. Insider trader, Raj Rajaratnam, currently in prison, graduated from the Wharton School of the University of Pennsylvania with an MBA. Former White House Counsel, John Dean, received his law degree from Georgetown University.

Of course, if institutions were truly proficient at compliance with the law, there would be no Enron, WorldCom, or Tyco—and certainly Bernie Madoff would have been sentenced to a life in government housing long before he financed his wrist watch collection with money siphoned from the accounts of his clients.⁶

A continuing pattern of corporate wrongdoing that has caused major publicly traded companies to plead guilty to some form of criminal conduct leads one to infer the obvious; corporations balance the penalties for non-compliance against the potential economic rewards reaped from skirting the law while factoring in the chances of getting caught with some consideration for whether there is any colorable defense for the conduct (albeit if only for public relations purposes and as a mechanism to leverage a favorable settlement). In theory, this formula has generated a long list of convicted criminals, including Pfizer, Abbott, Glaxco-Smith-Klein, and Amgen.

I cannot say the root of my cynicism stems solely from my litigation against the healthcare industry. I spent years representing industrial and service unions and their members; the average working person—or hardcore union member—has no illusions about the power of institutions to corrupt. They often view their own employer and their union with the same gimlet eye.

Yet, my litigation against the healthcare industry has, at the very least, been a policy laboratory for the understanding of institutional wrongdoing and deficiencies in compliance enforcement. While the lessons I have learned are in the first instance about “fraud, waste and abuse,” in the delivery of healthcare, they are transferrable and thus have meaning elsewhere.

I. MOTIVE, MONEY AND PUBLIC REPORTING

Motive is the reason that anyone does anything—and anything includes things that are wrong or just plain illegal. In proving any case, motive can be defined by a set of facts that have a tendency to make the ultimate allegation of wrongful conduct more or less probable.⁷

For publicly traded Pharmaceutical companies, motive starts with Wall Street promises. Too often, promises can only be kept through illegal conduct,

⁶ The analysis is not limited to corporate institutions. The logic applies to government—as in Watergate—and universities—as in Penn State and the child sex scandal. The point is simple; institutional affiliation causes people to check their independent thought and analysis at the door.

⁷ *E.g.* FED. R. EVID. 401.

which may include marketing a drug for unapproved purposes, offering money or things of value to induce utilization, or generating—under color of scholarship—writings that are designed for the purpose of driving prescriptions.

How does this work? Companies make representations to investors about their overall revenue streams, the revenue streams attributable to different drugs, and the bona fides of certain products. These promises are made, for the most part, by business people and not scientists. And sometimes, they are made without proper attention to the scientific details of studies, FDA approved package inserts, and support from the Centers of Medicare and Medicaid Services (CMS), identified “compendia,” which provide some guidance for government reimbursement for uses outside the FDA approved label.⁸

For their part, the Wall Street analysts rarely get into the nitty gritty of the science; they report on company puffery about trials and studies—always noting a share price increase or decline—but seldom drilling down and comparing facts and data with an eye toward inconsistencies. Too often, the obvious is ignored.

PharMerica, for example, is a company that provides long term care pharmacy services to nursing homes. It is an intermediary between thousands of homes, caring for the elderly and the infirm, and the drug industry.⁹ The company's 2016 Third Quarter 10k indicates that it received rebates from Pharmaceutical companies. Rebates are payments based, in general, on the volume of drugs distributed to patients.¹⁰ The matter of rebates is a sensitive issue, opening scrutiny as to whether at least one purpose of such payments—which is all it takes—is to induce the ordering of drugs where “payment may

⁸ *CMS Manual System*, DEPT. OF HUMAN AND HEALTH SERVICES (Oct. 24, 2008), <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R96BP.pdf> (explaining compendia).

⁹ See PharMerica, Quarterly Report (Form 10-Q) (Mar. 10, 2017) (“Formed in 2006, PharMerica Corporation (the “Corporation,” “we,” “us,” or “our”), a Delaware Corporation, is an institutional pharmacy services company that services healthcare facilities, provides pharmacy management services to hospitals, provides specialty infusion services to patients outside a hospital setting, and offers the only national oncology pharmacy in the United States. The Corporation is the second largest institutional pharmacy services company in the United States based on revenues and customer licensed beds under contract, operating 98 institutional pharmacies and 14 specialty infusion centers and 5 specialty oncology pharmacies in 45 states. The Corporation's customers are typically institutional healthcare providers, such as skilled nursing facilities, nursing centers, assisted living facilities, hospitals, individuals receiving in-home care and other long-term alternative care providers. The Corporation is generally the primary source of supply of pharmaceuticals to its customers. The Corporation also provides pharmacy management services to 89 hospitals in the United States”).

¹⁰ These drugs may be paid for by third party payers.

be made in whole or in part under a Federal Health Care program.” This is, in part, the language of the Anti-Kickback Statute,¹¹ which criminalizes payments, or any granting of an in-kind benefit, which has—as one purpose—inducing the use of healthcare “items” or “services” which are in whole or part paid for with Federal dollars.

PharMerica, well aware that its conduct implicates scrutiny under the Federal Anti-Kickback statute (AKS), notes the following in its 2016 Third Quarter 10k: “[w]hile we believe our practices comply with the Anti-Kickback statute, we cannot assure our practices that are outside of a safe harbor will not be found to violate the Anti-Kickback statute.” And the Third Quarter 10k also states: “[w]e believe our contract arrangements with other healthcare providers and our pharmaceutical suppliers and our pharmacy practices are in substantial compliance with applicable federal and state laws. These laws may, however, be interpreted in the future in a manner inconsistent with our interpretation and application.”

A complete reading of PharMerica’s filing with the Securities & Exchange Commission (SEC) reveals three important things. First, rebates are material to financial success. This is the motivation component; the company needs them to thrive. Second, the company says it cannot “ensure” compliance with a criminal law. Third, the company has its plausibility position which is that it has endeavored to comply with the law. The PharMerica 10k disclosures have remained virtually unchanged over the years even though the company has paid millions of dollars to resolve alleged violations of the Anti-Kickback statute.¹²

Ironically, and perhaps as only a parenthetical, PharMerica is a Delaware Corporation incorporated to engage in legal activity. Yet, the company’s own SEC filings disclose that the company cannot guarantee compliance with criminal law, let alone its own corporate charter.¹³

¹¹ See 42 U.S.C. § 1320a-7b.

¹² See *Nation’s Largest Nursing Home Pharmacy to Pay Over \$28 million to Settle Kickback Allegations*, DEPT. OF JUSTICE (Oct. 17, 2016), <https://www.justice.gov/opa/pr/nation-s-largest-nursing-home-pharmacy-pay-over-28-million-settle-kickback-allegations>; *Nation’s Second-Largest Nursing Home Pharmacy to Pay Over \$9.25 million to Settle Kickback Allegations*, DEPT. OF JUSTICE (Oct. 7, 2015), <https://www.justice.gov/opa/pr/nations-second-largest-nursing-home-pharmacy-pay-925-million-settle-kickback-allegations>.

¹³ See, e.g., Kent Greenfield, ‘Blood Chocolate,’ *Corporate Law and the ACS*, AMERICAN CONSTITUTION SOCIETY (Mar. 24, 2014), <https://www.acslaw.org/acsblog/blood-chocolate-corporate-law-and-the-acs> (discussing the application of the ultra-vires doctrine to corporate activity that is unlawful. Greenfield’s scholarship is the backbone of this application of the law).

In theory, one could easily task a team of regulators to cull through SEC filings, and other reports, solely for the purpose of analyzing business models that place a company on the fringes of compliance with the law. While agencies presumptively review filings within their orbit of oversight, they seemingly do not review filings outside their orbit of oversight. In other words, to an SEC investigator, PharMerica's representation about its compliance with the Anti-Kickback statute may sound like a perfectly reasoned disclosure. Yet, to a Health and Human Services investigator from the Office of Inspector General (OIG), the representations may be a red flag. Yet, there appears to be no process or internal guidance requiring or even counseling investigators—within a given agency—to routinely look at company filings with other agencies. The benefit of doing this is obvious. The attorneys who prepare the SEC filings—for example—are seemingly focused on spinning a message that is consistent with SEC requirements and may thus provide information that is not totally consistent with FDA regulations or guidance.

Following the money—particularly in financial filings—is always a useful path. Revenue stream projections are one test to determine whether a company should be investigated. And sometimes projections can be both a motivator for and an indicator of impropriety.

Imagine, for example, a situation where the revenue projections for a specific drug greatly exceeded the revenue stream that could possibly be predicated from on-label use. Unless there is some obvious reason why doctors—on their own—decided to write prescriptions for off label purposes, the company is most likely doing something to encourage off label use.¹⁴ At the very least the differential is an indicator counseling further investigation.

How might a company drive off label use without it being overtly obvious? The answer lies in the use of facially neutral drivers including, for example, compensation schemes that bonus sales representatives for both off label and on label utilization. The point; if you pay people to chase a goal that requires crossing a line of impropriety, there is an increased likelihood that they will cross the line. If they do not even know that they are crossing the line, the likelihood further increases.

Facially neutral drivers that cause impropriety are not unique to the healthcare arena. Consider, for example, a University, College, or Graduate

¹⁴ The Food, Drug & Cosmetics Act (FDCA) precludes drugs from being marketed for purposes that are not approved. This means that marketing must be within the four corners of the label or "package insert." Doctors, however, are free to use drugs for off label purposes.

School that strives to meet the criteria established by *US News* in order to be a nationally ranked institution. The pressure to increase in rankings could result in the fudging of qualifications for entering students or the employment statistics for graduates.¹⁵ This would be a knowing crossing of the line. Or there could be a dynamic created where, as part of a recruiting effort, large amounts of tuition money are diverted to finance scholarships as a means to induce attendance by those with high grades and test scores. To make up the deficit, the institution may create less valuable degree programs (not using regular tenured faculty) for foreign students who value a US branded degree.¹⁶ To the extent all of this is accomplished under the auspices of creating a global institution, the line may be crossed without immediate notice. And with individual professors fighting for or benefiting from tenure, how many are going to risk their positions to question the propriety of these practices?

For those engaged in compliance enforcement, the trick is to identify the driver and align the schemes that are often quite subtle and always one step ahead of compliance enforcement. Getting back to the Pharmaceutical industry, companies may challenge sales representatives to compete a product with a competitor drug which may have a more expansive indication than the product being marketed. Imagine a scenario where company “A” tells its representatives to compete their product—which has three indications—with company “B’s” product which has seven indications, three of which overlap with the company “A” product. The result is that the company “A” product will end up being marketed for four indications or applications that have not been approved by the FDA.

Drug companies also employ an array of coaching mechanisms that cause representatives to engage in off label marketing without even being made aware that they are doing so. The molding of the representatives are done at regional and national meetings and by coaching sessions—sometimes called “ride alongs”—where a supervisor spends a day with a representative as he or she visits doctors. Off label sales technique is also reinforced through regular performance evaluations. In addition, “roll plays” are a frequent training method employed to mold strategies that can drive off label sales. Roll plays often train representatives on the concept of the “probe” which is designed to elicit questions that cause the doctor to bring up off label usage.

¹⁵ Morgan Cloud & George Shepherd, *Law Deans in Jail*, 77 MO. L. REV. 4 (2012), <http://scholarship.law.missouri.edu/mlr/vol77/iss4/2>.

¹⁶ The parallel is with high end retail outlets or manufacturers who leverage their brand by creating lower cost lines or outlets which do not always sell or manufacture products consistent with the known quality and reputation of the brand.

II. FROM PLAUSIBLE DENIABILITY TO SCHEMES

In the health care arena many schemes are carried out in ways that are open and exposed to employees at a number of levels within the corporation. Unfortunately, the schemes are subtle and employees are not trained to look for impropriety. It may actually seem counter-intuitive that through corporate compliance and integrity programs, employees seemingly are led to believe that impropriety is actually impossible.¹⁷

Consider this point: Pfizer, GSK, Astra Zeneca, and Amgen have all settled large cases where they have been accused of off label marketing or paying kickbacks to induce utilization of drugs paid for with federal healthcare dollars.¹⁸ Each of these companies had internal rules proscribing off label marketing and the payment of kickbacks. The same can be said of Enron, WorldCom and Tyco. Each of these companies also had internal compliance and ethics programs which did not prevent impropriety.

The lesson to be learned is that where impropriety is orchestrated from the top and is actually integral to the business model, no internal compliance program will be equipped to halt the wrongdoing.¹⁹ To the contrary, the existence of such programs will have the effect of assuaging any concern that impropriety might exist. Against this backdrop, those who might otherwise question impropriety are actually entreated to carry out schemes that have an unlawful purpose.

How does this play out? The Food Drug and Cosmetics Act (FDCA) precludes pharmaceutical companies from marketing drugs for purposes outside the scope of their FDA approved label. In addition, the Anti-Kickback precludes the use of payments, or the giving of things of value, where one purpose is to induce the purchase of a product or service which will be paid for by a federal health care program.

¹⁷ See Reuben Guttman, *Internal Compliance: Is it Really about Compliance?*, HARVARD UNIVERSITY: EDMOND J. SAFRA CENTER FOR ETHICS (Feb. 24, 2014), <https://ethics.harvard.edu/blog/internal-compliance>. My observations along these lines come from three decades representing workers.

¹⁸ See, e.g., Paul J. Zwier & Reuben Guttman, *A Failure of Remedies: The Case of Big Pharma (An Essay)*, 3 EMORY CORP. GOVERNANCE & ACCOUNTABILITY REV. 2 (2016), <http://law.emory.edu/ecgar/content/volume-3/issue-2/essays/failure-remedies-case-big-pharma.html>, for a more extensive list of prosecutions of, and settlements with, the Pharmaceutical Industry.

¹⁹ See Reuben Guttman, *Internal Compliance: Is it Really about Compliance?*, HARVARD UNIVERSITY: EDMOND J. SAFRA CENTER FOR ETHICS (Feb. 24, 2014), <https://ethics.harvard.edu/blog/internal-compliance>; Reuben Guttman, *Do We Really Trust Corporations To Investigate Their Own Profitable Impropriety?*, FORBES (Aug. 15, 2014, 10:32 AM), <https://www.forbes.com/sites/danielfisher/2014/08/15/do-we-really-trust-corporations-to-investigate-their-own-profitable-impropriety/#3f112f8a4f9b>.

Companies including Pfizer, Abbott Labs, GSK, and Amgen violated both of these laws for years. The common thread with all of these companies was that hundreds of sales representatives were integral to carrying out the schemes that implicated liability. With so many people involved, why were the schemes not immediately detectable or transparent?

First, each of these companies trained their sales representatives that off label marketing and kickbacks were illegal. Hence, if any sales representative was approached by a government investigator and asked conclusory questions as to whether off label marketing or kickbacks were occurring, the representative would instinctively say something along the following lines: “this is unlawful and we would be fired if we did it, and so it could not have happened.” Of course, as an aside, this is a lesson in how to question witnesses.²⁰

Undoubtedly, where companies have actually been found liable for paying kickbacks or off label marketing their drugs, the training given to employees did not key them into the common schemes implicating liability. For example, training employees on competitor drugs which carry a different label and asking doctors to consider using “our product” if he prescribes “their product” is a non - direct way of off label marketing. Similarly, drug companies are masters of disguising the payment of kickbacks. The classic example is speaker programs where manufacturers pay doctors to give promotional talks. When the doctors are selected based on the recommendation of the sales representatives with consideration given to a doctor’s prescription writing habits, the question arises as to whether the doctor is being selected because of medical brilliance or as a means to induce the writing of prescriptions. Those who are chosen to give talks are, in the industry, universally known as “key opinion leaders” or “thought leaders.” They are not necessarily bestowed these titles because of their medical prowess as much as because of their ability to influence prescription writing.

Whatever the avenue, the industry seems one step ahead of the regulators in concocting schemes to circumvent regulation and detection. Moreover, because the revelation of an unlawful scheme may occur after years of investigation, recent compliance actions may only be bringing to terms culprits

²⁰ Eliciting facts and not conclusions is fundamental to questioning. Once facts are collected, they can be assembled and employed in questioning to test theories. Conclusory questions at the front end of a witness interview are tantamount to testing a theory before the facts have been established.

for conduct that occurred years ago.²¹ Hence, by the time the scheme is made public, there may be newer schemes at play.

Yet, one common denominator that seems to remain constant from scheme to scheme is the need for it to be facially neutral and thus not readily detectable. And, in case there are questions about the scheme, there must be a plausible rationale for legitimacy. This means that cases must be pieced together from bits of circumstantial evidence and that investigators must consider the impact of facially neutral rules that may have an unlawful purpose.²²

One scheme involves the ghost writing of articles.²³ Often a pharmaceutical company will organize studies and enlist doctors to administer the studies. The doctors may receive compensation for their administration and they may be invited to have their names listed as an author of an article documenting the results of the study.

Because these purportedly scientific articles list the names of multiple authors, when any one author sees a draft, he or she may presume that earlier drafts, edits, or modifications were placed in the text by one of the listed authors. In reality, it may be the case that the drug company—which organized the project—enlisted ghost writers to edit or draft portions of the manuscript. When the manuscripts are submitted for publication, it is virtually impossible to track the participation of the ghostwriters. Even where the article is peer reviewed, there is no reasonable means for the reviewer to appreciate what, if any, role a ghostwriter may have played in publication.

That ghost writers are involved in the development of purportedly scientific materials should actually be of no surprise where doctors distribute resumes that take credit for scores of publications. Curiously, where a doctor claims credit for seeing patients, teaching, and conducting research, few, if

²¹ Specifically, many compliance enforcement actions occur under the False Claims Act (FCA), which has a statute of limitations that can be as long as ten years. When FCA actions are initiated by a whistleblower, the cases are filed under seal and remain under seal during the pendency of government investigation. These investigations can take as long as three to four years.

²² See, e.g., *Griggs v. Duke Power Co.*, 401 U.S. 424 (1971).

²³ See, e.g., Matthew Herper, *A Former Pharma Ghostwriter Speaks Out*, FORBES (Aug. 10, 2011, 10:26 AM), <https://www.forbes.com/sites/matthewherper/2011/08/10/a-former-pharma-ghostwriter-speaks-out/#5fac7e4528d6>; Natasha Singer, *Medical Papers by Ghostwriters Pushed Therapy*, THE NEW YORK TIMES (Aug. 4, 2009), <http://www.nytimes.com/2009/08/05/health/research/05ghost.html?pagewanted=all>; Jonathan Leo & Jeffrey Lacasse, *Ghostwriting and Academic Medicine*, THE CHRONICLE OF HIGHER EDUCATION (July 19, 2010), <https://www.chronicle.com/article/GhostwritingAcademic/123613>.

any, individuals ask the obvious question: “where is there time to write 100 articles?”

Publications are no doubt of value to teaching physicians as they try and rise within the hierarchy of their academic institution and the medical community. That pharmaceutical companies can engineer a scheme where doctors can—with minimal if any effort—get the benefit of credit for a publication allows pharmaceutical companies to give doctors a thing of value without overtly triggering scrutiny under the Anti-Kickback statute.²⁴

There is no doubt that government prosecutors should be looking at doctors—particularly those in a university or medical school setting—who claim credit for articles that are in whole or in part ghost written. While the starting point for inquiry should be the Anti-Kickback statute, to the extent that these articles may form the basis for off label marketing schemes at a grassroots level,²⁵ doctors may have exposure for violations of the Federal and State False Claims Act and potentially for conspiracy to violate the Food, Drug & Cosmetics Act.²⁶ Specifically, the FDCA makes it unlawful to market a product for uses outside its FDA approved label.

How does this work? Purportedly “scientific articles” are placed in the hands of sales representatives and distributed to doctors or—in some cases—even given to financial analysts who may be writing about alternative—or off label—uses for existing products. Under these circumstances the so called scientific publication becomes the “Trojan Horse” by which the off label message is delivered. For their part, companies claim that their free speech rights protect scientific communication. Yet, even if this were true—at least as to factually accurate communications—this speech would be tainted—and thus

²⁴ See, 42 U.S.C.S § 1320a-7b. The statute generally prohibits offering, paying, soliciting or receiving anything of value to induce or reward referrals or generate Federal health care program business. The United States Department of Health and Human Services has outlined the proscriptions; *Comparison of the Anti-Kickback Statute and Stark Law*, U.S. DEP’T HEALTH & HUM. SERVS., <https://oig.hhs.gov/compliance/provider-compliance-training/files/StarkandAKSChartHandout508.pdf>.

²⁵ Pharmaceutical representatives may use ghost written pieces in their efforts to convince individual doctors to prescribe a drug for an off-label purpose. Hence, the doctors who generate these pieces are within a stream of potentially wrongful conduct.

²⁶ Federal False Claims Act, 31 U.S.C. § 3729, et. seq. (2012) (the statute exposes individuals and entities to liability for filing or causing to be filed a false claim for payment or approval where the payment involves money which—in whole or in part—has been provided for by the Federal government. At least 20 states have analogues that provide for the recovery of state or municipal dollars). See also *False Claims Act*, GUTTMAN, BUSCHNER & BROOKS PLLC, <http://www.whistleblowerlaws.com/false-claims-act/> (last visited Jan. 25, 2018).

not protected—where there is a failure to disclose the involvement of the ghost writer or the pharmaceutical company.²⁷

There are two other points to be made on this subject. First, to the extent that big pharma attempts to justify the high prices of its drugs because it needs the money to finance Research and Development, this contention is dubious. To secure an indication for a drug, the Food and Drug Administration analyzes raw data. Money spent on studies or trials in support of an FDA approval, or post marketing analysis pursuant to the approval, is legitimate R&D. Money spent on developing anecdotal data to spin off label messages and for ghost writers to draft and place these messages in journals is not legitimate R&D.

Second, there is a distinction between evidence based medicine—medical decision making based on results from the scientific method—and what may be called the standard of care. The two are not always the same, but are often confused as synonymous. Simply said, the standard of care is what most doctors may do, but it does not mean that it is the proper thing to do for a patient in all cases.

Through its messaging and kickbacks, which can be disguised and tendered in various forms, the pharmaceutical industry has manipulated the standard of care to suit marketing goals. The consequences have broad impact on both patient decision making and the application of the rule of law where a patient seeks redress for alleged medical malpractice.²⁸

Patients often have a window of opportunity to review a doctor's recommendation, perhaps seek second opinions, and authorize treatment. During this period, patients are often bombarded with analysis along the lines of “this is now standard practice,” or “many doctors do this,” or “we have great results but we don't exactly know why it works.” Where the treatment is “off label”—or outside the indication listed on a drug's package insert—even an acutely analytical patient will have a hard time distinguishing whether the recommendation is based on science or spin.²⁹

²⁷ See also *United States v. Coronia*, 703 F.3d 149 (2nd Cir. 2012) (the Court noted some protection of off label speech to the extent that it is truthful. Yet, it is—as a practical matter—impossible for a sales representative to be truthful when he or she is marketing a product outside its approved indication). See also *Universal Health Servs. Inc. v. United States ex rel. Escobar*, 136 S.Ct. 1989 (2016) (the proposition that half-truths can be the bases fraud allegations); Caroline Poplin, *The First Amendment: Not one Size Fits All*, 3 EMORY CORP. GOVERNANCE AND ACCOUNTABILITY REV. 30 (2016).

²⁸ See generally Reuben Guttman & Traci Buschner, *Commentary: Give Big Pharma a Dose of Strong Regulatory Medicine*, MARKET WATCH (Aug. 7, 2013), <https://www.marketwatch.com/story/patients-suffer-from-drug-industrys-chronic-greed-2013-08-07>.

²⁹ To be clear, sometimes the scientific method may involve treating the symptoms of an illness as the

Worse yet, the prescribing physician similarly may be unable to make that determination. From his or her vantage point, the recommended usage came from someone who was respected in the field whom the industry might term a key opinion leader or just “KOL”.³⁰ The doctor may have heard the KOL speak at an industry sponsored dinner or maybe the KOL spoke at a university hospital at an event sponsored directly or indirectly by a drug manufacturer. For his or her part, the KOL may believe in the message. Why question it when you are making money from the industry—paid for speaking engagements, getting research grants, having the use of editors for publications and having a company paid marketer help place papers in colorably legitimate publications?³¹ Industry dollars can influence KOLs and this is why the industry keeps spending money to influence them.

Buying influence over the standard of care is the goal and—unfortunately—at the end of the day, the patient or prescribing doctor is making a decision based on a standard of care that is tainted. And worse yet, perhaps unwittingly, the doctor may have placed the patient at unnecessary risk for minimal—if any—benefit.³² Consider this; when a doctor writes a prescription for an off label use, he or she is doing so without tested and approved instructions for the use.

If the patient is injured through a treatment that is the product of the standard of care and not evidence based medicine, legal redress is complicated and may come down to a battle between the expert who relies on the industry-manipulated standard of care, and the expert who is testifying as to evidence based medicine. To the extent that the over-arching framework for evaluating the reliability of expert opinions is articulated in *Daubert v. Merrell Dow Pharmaceuticals*, 509 US 579 (1993), a plaintiff may find him or herself seeking relief from a practice that has indeed secured wide spread acceptance in the medical community but is otherwise quite wrong. Undoubtedly, this notion may be lost on first year law students who, in learning the rules of

quickest path to addressing a problem while avoiding batteries of tests. Doctors may, for example, treat symptoms of pneumonia with antibiotics without seeking a chest x-ray.

³⁰ Of course KOLs are no more than those who are paid by the pharmaceutical industry to promote a drug.

³¹ See also Charles Ornstein, *Drug-Company Payments Mirror Doctors' Brand-Name Prescribing*, NPR (Mar. 17, 2016, 5:00 AM), <https://www.npr.org/sections/health-shots/2016/03/17/470679452/drug-company-payments-mirror-doctors-brand-name-prescribing> (payments to doctors does impact their decision making); and Alex Spiegel, *How to Win Doctors And Influence Prescriptions*, NPR (Oct. 21, 2010, 4:11 PM), <https://www.npr.org/templates/story/story.php?storyId=130730104>.

³² Doctors—but not drug companies—are sworn to the Hippocratic Oath and the notion of “first do no harm,” which has been associated with the oath, but does not appear directly in the oath.

negligence, read cases about breach of the standard of care and assume—in common parlance—that the Defendant deviated from the proper way that something should be done. In the world of pharmaceuticals, the drug industry has so poisoned the market for honest medical information, that the proper way and the standard of care are just not always the same. At the end of the day, and after the litigation process exposes the facts, both the prescribing doctor and the manufacturer should have liability.

III. THE FIX

If a manufacturer markets a snow boot as a product that will last a lifetime, there is limited and quantifiable harm if the boot only lasts one winter. The boot can be replaced, or the buyer can get his or her money back.

Health care fraud is different. It is dependent on spinning or manipulating purportedly scientific findings in ways that taint the market for honest medical information while placing humans at risk in ways that cannot always be quantified in monetary terms. Indeed, where there is physical or mental injury, dollars cannot make people whole.

When patients are placed at risk or harm is sustained, the financial burden is placed on third party payers—including the Medicare and Medicaid system, insurance companies, Taft-Hartley, and public employee health and welfare funds—which must subsidize the cost of treatment. To the extent that these funds actually seek redress from the pharmaceutical manufactures, they may be litigating against entities that serve as investments for Taft Hartley and public employee Pension funds.³³ This places company owners in the ironic—if not conflicts ridden—paradox of seeking redress by litigating against their own investments.

While the government itself, or under the auspices of False Claims Act³⁴ whistleblower litigation, has recovered billions of dollars from pharmaceutical industry wrongdoers, the settlement amounts pale in comparison to the revenue secured through wrongful marketing practices.³⁵ The net result is that any penalty paid through settlement has been perhaps the fee for a license to break

³³ Who invests in pharmaceutical companies? The answer is pension funds.

³⁴ False Claims Act, *supra* note 23. See generally EmorySchoolofLaw, *A Conversation on Whistleblowers and the False Claims Act*, YOUTUBE (May 11, 2016), <https://www.youtube.com/watch?v=yiUS5Z9HRI>.

³⁵ See also Paul J. Zweir & Reuben Guttman, *A Failure of Remedies*, 3 EMORY CORP. GOVERNANCE & ACCOUNTABILITY REV. 42 (2016).

the law.³⁶ This is not to say that the industry is not aware of the potential for compliance enforcement; it is to say that current litigation brought on behalf of the government has not had a perfect, or even close to perfect, deterrence effect.

And, to the extent that compliance enforcement has focused on monetary damages, current compliance enforcement efforts have not accounted for injury to the market for honest scientific information. While corporate compliance agreements may require or proscribe conduct, the agreements—many of which are boilerplate—do not require programs to educate the market on the proper use of a particular drug. Absent a corrective educational effort, a company pays a sum to settle while getting the benefit of a non-evidence based standard of care which remains in place uncorrected even after settlement.

One possible solution is to use False Claims Act settlement monies to finance education campaigns that re-adjust or correct the market for honest medical information.³⁷ There are several ways to accomplish this goal. First, State Attorney Generals and the Department of Justice, with the help of respective agencies, can issue a settlement white paper fully documenting the findings of any investigation underlying a settlement. Of course, if a case is litigated, prosecutors should press to ensure that briefs and trial transcripts are matters of public record. Either of these steps can be accomplished by federal prosecutors or State Attorneys General.

Second, to the extent that pharmaceutical marketing derelictions are analogous to a train wreck, Congress should establish a National Transportation Safety Board analogue to investigate and issue reports on the marketing impropriety and the proper use for the drug or the product.³⁸ The overarching purpose for this is to correct the market for honest medical information and to document the schemes. Fully documenting and publicizing the schemes makes it difficult for companies to engage in the wrongful conduct absent detection.

³⁶ See also Reuben Guttman & Jennifer Williams, *Controlling Government Contractors: Can the False Claims Act be More Effective?*, 14 SEDONA CONF. J. 1 (Sept. 2013).

³⁷ While one possible solution is to run these programs through universities, this is not a solution because the drug industry—through payments to doctors and teaching institutions—has in part corrupted these entities as well.

³⁸ See also Reuben Guttman & Traci Buschner, *Taking the Next Step in Pharma Fraud*, ACS BLOG (May 8, 2012), <https://www.acslaw.org/acsblog/taking-the-next-step-in-pharma-fraud>; and Reuben Guttman, *Just Another Pharma Settlement?*, ACS BLOG (Aug. 1, 2013), <https://www.acslaw.org/acsblog/just-another-pharma-settlement>; and Guttman, *Commentary*, *supra* note 28.

Third, settlement monies should in some larger measure be spent to reinforce compliance efforts. Monies recovered in False Claims Act cases are mostly channeled back to the treasury. A material portion of the recovery should be earmarked to bolster compliance enforcement through added investigators and attorneys.

Most importantly, individuals need to be held accountable for the economic damage and injury to humans done through marketing practices that have over-ridden medical diligence. Though institutions have a way of corrupting and coopting humans, it is humans—in the end—who must be held accountable through both civil and criminal prosecution.

CONCLUSION

For reasons perhaps inherent in the human condition, institutions have a way of corrupting the conduct of individuals. The consequences of corruption are significant where the institution is charged with lifesaving functions. Regulators, consumers, and employees can no longer rely on bona fides of these institutions, and a degree of hyper diligence is necessary—especially where the schemes are both complex and subtle.