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EFFECTIVE COMPLIANCE MEANS IMPOSING INDIVIDUAL LIABILITY

*Reuben A. Guttman**

Deputy Attorney General Sally Yates said it in a memo dated September 9, 2015, and her successor, Rod Rosenstein, said it in remarks dated October 6, 2017: corporations act through individuals, and compliance enforcement must necessarily account for holding individuals liable for the wrongs they orchestrate under cover of the corporate umbrella.¹

The logic is reasonable and necessary. We blame corporations for catastrophic environmental events², misbranded drugs that cause injury, and financial products that destroy the life savings of those who have toiled for a living; yet at the helm of the corporations—guiding their path of impropriety—are people, many of whom who have benefited handsomely from the corporate misconduct that they have captained. Unfortunately, in comparison to the guilty pleas that are taken by corporations, which cannot be put behind bars, prosecutors—both criminal and civil—barely scratch the surface when it comes to pursuing the individual human culprits.

This is not to say that there have been no criminal prosecutions of individuals for corporate crime. Insider trading cases are quite common, and when the wrongdoing has catastrophic consequences, as in Enron, Tyco, WorldCom, and the Madoff organization, prosecutors have put real people behind bars.³

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¹ See “Individual Accountability for Corporate Wrongdoing,” U.S. Department of Justice (September 9, 2015) <https://www.justice.gov/archives/dag/file/769036/download>; Rod J. Rosenstein, Deputy Attorney General, Keynote Address at the NYU Program on Corporate Compliance & Enforcement (October 6, 2017) https://wp.nyu.edu/compliance_enforcement/2017/10/06/nyu-program-on-corporate-compliance-enforcement-keynote-address-october-6-2017/.

² “Deepwater Horizon,” U.S. Department of Justice: Environment and Natural Resources Division, <https://www.justice.gov/enrd/deepwater-horizon>.

³ See Aaron Smith, “Madoff Arrives at N.C. Prison”, CNN:Money (stating Bernie Madoff, release date November 14, 2139, is inmate 61727-054 at the Butner Medium Security Prison) (July 14, 2009 2:19 PM) (http://money.cnn.com/2009/07/14/news/economy/madoff_prison_transfer/); Marcia Heroux Pounds, “Dennis Kozlowski, former Tyco CEO who went to prison, back in M&A business”, Sun-Sentinel (stating Tyco CEO

There are, however, too many instances where individuals have put a corporation on a destructive tear, and still managed to elude personal liability. Considering that many of the large drug companies have either taken guilty pleas or paid fines to the government for conduct that has placed patients at risk by causing the consumption of powerful, unnecessary drugs, it is astounding that few, if any, pharmaceutical executives have been pursued criminally for conduct tantamount to battery.⁴ Imagine, for example, if an intruder broke into your house, opened your medicine cabinet, and loaded the cabinet with bottles of pills that were either not medically necessary—or worse—could cause physical injury or illness? How far removed is this from marketing schemes that cause doctors to write prescriptions based on misinformation, that cause dangerous products to be placed in medicine cabinets and ultimately consumed? Or what about the drug companies that funnel kickbacks to doctors disguised as “speaker fees” or “consulting agreements” while monitoring prescription data to confirm that the doctors are writing the “scripts” as directed.

In 2012, Abbott Labs, one of the largest pharmaceutical companies in the world, plead guilty to illegally marketing the powerful drug, Depakote, which is a limited indication anti-epileptic. Among other things, Abbott marketed the drug to elderly patients in nursing homes for off-label purposes and for pediatric use, even though Depakote was not approved to treat anyone under the age of 18. After the entry of a guilty plea, the U.S. Attorney for the Western District of Virginia, Timothy Heaphy, noted in a Department of Justice press release that, “Abbott unlawfully targeted a vulnerable patient population, the elderly, through its off-label

Dennis Kozlowski spent six and one half years in prison and was released in 2015) (Jan. 11, 2017 6:26 PM) <http://www.sun-sentinel.com/business/fl-dennis-kozlowski-life-after-prison-20170111-story.html>.”Bernie Ebbbers’ wife files for divorce,” NewsOK (Worldcom CEO, Bernard J Ebbbers, release date July 4, 2028, is inmate number 56022-054 at the FMC Forth Worth Federal Prison) (April 23, 2008 4:48 AM) <http://newsok.com/article/3233823>; Rufus-Jenny Triplett, “Prisonworld View-Corporate CEO Gets Skimmed Sentence,” Dawah Interational, LLC (stating Former Enron CEO, Jeffrey K Skilling, release date February 21, 2019, is inmate number 29296-179 at the FPC Montgomery Federal Prison Camp) (May,15, 2015) <http://prisonworldblogtalk.com/2015/05/15/prisonworld-view-corporate-ceo-gets-skimmed-sentence/>.

⁴ See, e.g., “Criminal Resolution”, U.S. Department of Justice: Glaxosmithkline Settlement Fact Sheet, https://www.justice.gov/sites/default/files/usao-ma/legacy/2012/10/09/Settlement_Fact_Sheet.pdf ; “Pfizer to Pay \$2.3 Billion for Fraudulent Marketing,” U.S. Department of Justice: Justice Department Announces Largest Health Care Fraud Settlement in its History, <https://www.justice.gov/opa/pr/justice-department-announces-largest-health-care-fraud-settlement-its-history>; Megan Stride, “Wyeth Paying \$491 M to End Criminal, Civil Rapamune Cases”, Law360, <https://www.law360.com/articles/461203/wyeth-paying-491m-to-end-criminal-civil-rapamune-cases>

promotion.”⁵ Think hard about this statement; a company that holds itself out as a manufacturer of life-saving drugs was knowingly placing patients at risk for the purpose of making a buck.

In 2013, Wyeth Pharmaceuticals agreed to pay \$490.9 million in criminal and civil penalties for engaging in proscribed marketing practices regarding the prescription drug, Rapamune. Rapamune is an immunosuppressive drug—that is, it prevents the body’s immune system from rejecting a transplanted organ. At the time of the guilty plea, Wyeth had merged into Pfizer, and was no longer a standalone entity. Wyeth plead guilty to a criminal information, charging it with a misbranding violation under the Food, Drug, and Cosmetic Act. In characterizing the case, Antoinette V. Henry, Special Agent in Charge of the Metro-Washington field office of the FDA’s Office of Criminal Investigations noted, “Wyeth’s conduct put profits ahead of the health and safety of a vulnerable patient population dependent on life sustaining therapy.”⁶ Also in 2013, pharmaceutical GlaxoSmithKline plead guilty and paid \$3 billion to the government in order to resolve fraud allegations and the failure to report safety data. As part of a global settlement, the company also settled a series of civil claims under the False Claims Act, stemming from marketing derelictions including kickbacks.

Time and time again, large pharmaceutical companies have engaged in conduct that placed patients at risk, and, at times, caused real harm, yet, virtually no individual has been prosecuted or put behind bars.⁷ The idea that misrepresentations, kickbacks, and assorted fraudulent schemes can be employed to cause patients to put drugs in their bodies at personal peril without anyone going to prison is stunning. Our jails have no shortage of inmates sentenced to long terms for selling illegal drugs and/or engaging in various batteries. Yet, when white collar executives engage in schemes to drive revenue by causing the consumption of extra drugs, or the use of drugs for improper purposes, individual liability is rare.

⁵ See “Abbott Laboratories Sentenced for Misbranding Drug”, U.S. Department of Justice (October 2, 2012) <https://www.justice.gov/opa/pr/abbott-laboratories-sentenced-misbranding-drug>.

⁶ See “Wyeth Pharmaceuticals Agrees To Pay \$490.0 Million For Marketing The Prescription Drug Rapamune For Unapproved Uses”, U.S. Department of Justice (July 30, 2012) <https://www.justice.gov/usao-wdok/pr/wyeth-pharmaceuticals-agrees-pay-4909-million-marketing-prescription-drug-rapamune>.

⁷ See Erica Goode, “3 Schizophrenia Drugs May Raise Diabetes Risk, Study Says”, The New York Times (August 25, 2003) <https://mobile.nytimes.com/2003/08/25/us/3-schizophrenia-drugs-may-raise-diabetes-risk-study-says.html>.

Consider that this nation is immersed in battling what the press now calls the “opioid crisis”⁸ or the “opioid epidemic.”⁹ This crisis reared its head at least a decade ago when the U.S. Attorney in the Western District of Virginia prosecuted the drug manufacturer Purdue Pharma, and three corporate executives for illegally marketing the drug Oxycontin. On July 23, 2007, the United States District Court for the Western District of Virginia (James P. Jones, Judge) issued an Opinion and Order approving a criminal plea agreement and summarizing its provisions. Among other misdeeds, during a six-year period, “certain Purdue supervisors and employees with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than any other pain medications.” Among an array of specific derelictions, Purdue representatives “told certain health care providers that Oxycontin did not cause a ‘buzz’ or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to ‘weed out’ addicts and drug seekers.”¹⁰ The court’s opinion noted that “Purdue has agreed that these facts are true, and that the individual defendants, while they do not agree that they had knowledge of these things, have agreed that the Court may accept these facts in support of their guilty pleas.” The plea agreement—accepted by the Court—called for Purdue to pay approximately \$600 million to resolve civil and criminal claims. It also provided that no individual defendant would be incarcerated. In the absence of record proof of their culpability, the Court was left with no choice but to accept the agreement as to no prison time for individuals. Noting what we now know about the opioid problem, the Court made this ominous point:

I would have preferred that the plea agreements had allocated some amount of the money for the education of those at risk from the improper use of prescription drugs, and the treatment of those who have succumbed to such use. Prescription drug abuse is rampant in all areas of our country, particularly among the young people, causing untold misery and harm. The White House drug policy office estimates that such abuse rose seventeen percent from 2001 to 2005. That office reports that currently there are more new abusers of

⁸ Opioid Crisis Fast Facts, CNN: Health, (March 2, 2018 9:25 AM) <https://www.cnn.com/2017/09/18/health/opioid-crisis-fast-facts/index.html>

⁹ M. Scott Brauer, “Inside a Killer Drug Epidemic: A Look at America’s Opioid Crisis, (Jan. 6, 2017) (according to the New York Times, “the opioid epidemic killed more than 33,000 people in 2015) <https://www.nytimes.com/2017/01/06/us/opioid-crisis-epidemic.html>.

¹⁰ *United States v. Purdue Frederick Co.*, 963 F.Supp.2d 561 (W.D.Va. 2013).

prescription drugs than users of any illicit drugs. As recently reported, “Young people mistakenly believe that prescription drugs are safer than street drugs. . . but accidental prescription drug deaths are rising and students who abuse pills are more likely to drive fast, binge-drink and engage in other dangerous behaviors.” Carla K. Johnson, *Arrest Puts Spotlight on Prescription Drug Abuse*, *The Roanoke Times*, July 6, 2007, at 4A. It has been estimated that there are more than 6.4 million prescription drug abusers in the United States.¹¹

Fast-forward eleven years, and the opioid crisis—which commenced with pharmaceutical companies manufacturing and marketing opioids well beyond their legitimate demand—and we have a nation now addicted to drugs, with additional supplies flowing from Mexico and China. The origin of this crisis is not just the drug companies; it starts with the individuals who ran the drug companies, placing revenue generation ahead of medical need—perhaps because bonus structures and stock options made it personally advantageous.¹²

Today, legislators on Capitol Hill grouse about the cost of our healthcare system and debate what level of benefits should be reduced. Yet, few, if any, lawmakers focus on what should be a front-end question: how much money is being wasted through fraud and abuse? Few, if any lawmakers are even contemplating a second question: how much money is spent to treat injuries and illnesses attributable to drugs that should never have been taken? And few, if any, have contemplated how to change behavior by holding individuals accountable. And of course, few, if any, legislators have contemplated making drug companies pay for wide dissemination of honest information about their products as one Federal Judge in the Western District of Virginia contemplated over a decade ago.

At the end of the day, if there is a perception that only a legal fiction will be caught holding the bag (albeit a fiction impossible to imprison), corporations—and those individuals that control their conduct—will view civil and even criminal sanctions as simply the price for a license to break the law. And to company insiders—that is to say, the shareholders, officers

¹¹ *Id.*

¹² See Reuters, *U.S. Senator Sanders Introducing Bill Targeting Opioid Manufacturers*, VOA: USA, (April 17, 2018 10:24 AM) (stating the idea of imposing harsher criminal penalties on drug company executives has been championed by Vermont Senator Bernie Sanders who has proposed the Opioid Crisis Accountability Act of 2018) <https://www.voanews.com/a/us-senator-sanders-bill-opioids-manufacturers/4351732.html>

and Directors—paying this fee for the license to break the law may be worth it if the analysis was simply a matter of dollars and cents.

In 2012, when Pfizer paid \$2.3 billion to settle unlawful marketing claims involving a number of its products, it was a small price to pay for the right to engage in a history of conduct that generated a revenue stream in excess of \$100 billion.¹³ Moreover, it was a small price to pay for the right to poison the market for honest medical information and thus establish a standard of care that would generate a revenue stream in the years to come. Put simply, when companies engage in pervasive misbranding of their products over a period of years, they disseminate misinformation that then becomes the standard of care. While that standard may not be evidence based, it is still hard to undo. Hence, paying a mere dollar fine will not reset or correct the market for honest medical information; and so manufactures get the continued benefit of a standard of care which may encourage use of a product even though it is potentially harmful or not otherwise medically necessary.

It is not just a problem endemic to the pharmaceutical industry. An array of corporations routinely game the system seemingly calculating the penalties for non-compliance. Publicly traded big box stores routinely pollute our navigable waterways with runoffs from parking lots that aggregate toxic hydrocarbons from leaky vehicles. Similarly, manufacturing plants have created a legacy—and continue to do so—of groundwater contamination that will for centuries prevent the safe enjoyment of our aquifers and tributaries. They do so because the cost of preventing the harm may well exceed the fine.

The externalities of corporate greed are not only imposed on consumers. Labor lawyer, Jon Karmel, in his recent book, *Dying to Work*,¹⁴ raises awareness of unsafe working conditions that have resulted in death and/or injury to workers. Karmel traveled the country to interview victims and their families and his book highlights how corporations have simply not placed a premium on protecting their workers from harm. Unfortunately, our laws make it too easy for employers to game out the penalty for unsafe workplaces. Workers compensation systems designed to provide injured workers with quick relief also cap liability by preventing direct causes of action for significant actual and punitive damages. There is

¹³ See Gardiner Harris, “Pfizer Pays \$2.3 Billion to Settle Marketing Case”, *The New York Times* (September 2, 2009) <https://www.nytimes.com/2009/09/03/business/03health.html>.

¹⁴ Karmel, Jon, *Dying to Work*, Cornell University Press (2017)

no shortage of reports of coal miners toiling in unsafe mines replete with regulatory derelictions, who have lost life and/or limb in pursuit of company profit.¹⁵ Yet, compensation systems cap the employer's economic exposure and—again—at the end of the day, few, if any, individuals are held personally accountable.¹⁶ For the corporation, the fix or preventative measures are often considered more expensive than the penalty.

Over the past year, the nation has come to realize what many have known as true for some time; that discrimination based on class, race, gender, and national origin festers in our workplaces. There may be few, if any, visible cross burnings in this century, but the internet and cyberspace are overflowing with evidence that the most vulgar forms of racism and gender discrimination are thriving even in the 21st century. Perhaps, some had thought, that the civil rights legislation of the 1960s struck a blow to discrimination, causing its demise. Although we sing the praises of this legislation, it too caps liability and limits the rights of the aggrieved. Consider Title VII of the 1964 civil rights act¹⁷—that statute requires that claims of discrimination be brought within six months.¹⁸ Punitive damages are capped, and the courts have impeded plaintiffs from seeking redress on a class basis for wrongful conduct.¹⁹ Other than damage to brand and reputation, employers can easily calculate the fee for the license to discriminate. Before the #MeToo movement, which now seemingly causes consumers to factor in a company's compliance with laws proscribing discrimination in evaluating the integrity of a brand, derelictions of employment laws had less severe consequences for corporate wrongdoers.

¹⁵ See, e.g., Dana Ford, "Don Blankenship, ex-Massey Energy CEO, sentenced to a year in prison," CNN, (April 6, 2016 11:29 PM) (explaining it was the explosion at Massey Energy's Upper Big Branch mine which killed 29 people. Massey CEO Don Blankenship was ultimately convicted of a misdemeanor with regard to the skirting of safety regulations. He served one year in prison and is now a candidate for the United States Senate in West Virginia) <https://www.cnn.com/2016/04/06/us/former-massey-energy-ceo-don-blankenship-sentenced/index.html>; Nicole Gaudiano, "Don Blankenship, convicted ex-Massey CEO now Senate candidate, calls for more mine safety," USA Today: OnPolitics, (April 4, 2018 6:43 PM) <https://www.usatoday.com/story/news/politics/onpolitics/2018/04/04/don-blankenship-convicted-massey-ceo-senate-candidate/487230002/>.

¹⁶ See "Dying to Work: Death and Injury in the American Workplace", Cornell University Press (December 2017).

¹⁷ 42 U.S.C § 2000e (1964).

¹⁸ Dov Ohrenstein, "Limitation Periods—What's the Limit," Healys LLP, http://www.radcliffchambers.com/wp-content/uploads/2010/02/Limitation_seminar_-_Dov_Ohrenstein.pdf (Explaining in comparison to claims for contracts and most torts, six months is a very limited statute of limitations. Undoubtedly many claims die on the vine because they were not brought in time)

¹⁹ See *infra* note 18.

For years, Wal-Mart battled claims of pervasive gender discrimination without any significant impact on its brand.²⁰

Against this backdrop, the regulators and those enforcing compliance routinely tout million, multi-million, and even billion-dollar settlements as evidence of efforts that change corporate behavior. But do these settlements really change behavior? The answer is no. If our laws are structured to allow corporate defendants to game out the penalty, corporate insiders will gauge the cost of noncompliance as the cost of doing business. Penalties that appear to be massive may be minimal when compared to the profits the corporation secured through wrongful conduct. If corporations can game out the price of non-compliance and individual wrongdoers can hide behind the corporate cloak and continue to collect bonuses based on unlawful corporate conduct, business will continue as usual. And this is the lesson for both regulators and lawmakers.

²⁰ *Wal-Mart Stores, Inc. v. Dukes, et al.*, 564 U.S. 338 (2011) (explaining the case is one of several cases impacting the ability to certify class action discrimination cases).