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THE FALSE CLAIMS ACT AS FAIL-SAFE IN A DEREGULATED ENVIRONMENT

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I. THE FALSE CLAIMS ACT IS A FAIL SAFE FOR ATTACKING THE OPIOID CRISIS

The Department of Justice has shined a large spotlight on the opioid crisis. Earlier this year, Attorney General Jeff Sessions told a Senate subcommittee that the Justice Department is “going after drug companies, doctors and pharmacists” who are fueling the nation’s opioid epidemic.¹ As the opioid epidemic continues to devastate communities and families across the nation, the Justice Department is responding with innovative and appropriately aggressive approaches and using the full panoply of its enforcement tools. These have included increased staffing, data analytics, new initiatives—sophisticated measures and tried-and-true policing efforts.²

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¹ OPENING STATEMENT OF ATTORNEY GENERAL JEFF SESSIONS BEFORE THE SENATE APPROPRIATIONS SUBCOMM. ON COMMERCE, JUSTICE, SCIENCE, AND RELATED AGENCIES, <https://www.justice.gov/opa/speech/opening-statement-attorney-general-jeff-sessions-senate-appropriations-subcommittee> (last visited Nov. 16, 2018).

² The Department of Justice’s efforts have included:

- Attorney General Sessions announced on February 27, 2018, the launch of the Department of Justice Prescription Interdiction and Litigation (PIL) Task Force to fight the prescription opioid crisis. Through the PIL, the focus is on opioid manufacturers, pharmacies, pain management clinics, drug testing facilities, and individual physicians
- Attorney General Sessions emphasized the importance of using criminal and civil actions to deter misconduct. Press Release, Attorney General Sessions Announces New Prescription Interdiction & Litigation Task Force (Feb. 27, 2018) (on file with Dep’t of Justice).
- Attorney General Sessions announced on April 3, 2018, the results of the first coordinated action by the new Joint Criminal Opioid Darknet Enforcement (J-CODE) team in combatting opioid trafficking by “disrupting the sale of drugs via the Darknet and dismantling criminal enterprises that facilitate this trafficking.” Press Release, Attorney General Jeff Sessions Announces Result of J-Code’s First Law Enforcement Operation Targeting Opioid Trafficking on the Darknet (Apr. 3, 2018) (on file with Dep’t of Justice).
- The Department of Justice joined a wave of state and municipal lawsuits spearheaded by the Ohio Attorney General’s office alleging that opioid manufacturers and distributors used false, deceptive, and misleading marketing to promote opioid painkillers. Katie Benner & Jan Hoffman, *Justice Dept. Backs High-Stakes Lawsuit Against Opioid Makers*, N.Y. TIMES, Feb. 27, 2018, available at <https://www.nytimes.com/2018/02/27/us/politics/justice-department-opioid-lawsuit.html>.

But, let's face it—the Justice Department cannot battle this epidemic alone. As the Attorney General observed, “With one American dying of a drug overdose every nine minutes, we need all hands on deck.”³ The Department has much on its plate right now from terrorism to corporate fraud to cyber security.

Exploiters of the drug crisis extend beyond pharmaceutical companies and their executives who pay doctors to prescribe opioids for unintended uses. There are others who bear responsibility for the crisis—individuals and companies that have criminal and civil culpability. These include doctors who put patients at risk because they are paid handsomely by the pharmaceutical industry to prescribe opioids; laboratories churning out test results that put maximizing billing ahead of patient safety; rehabilitation clinics that admit and discharge addicted patients through a revolving door rather than providing effective treatment options; drug insurance plans that cover opioids with no prior permission required; and pharmacy benefits managers—the middlemen—that make access to opioids easier than less addictive alternative remedies. Holding these providers and companies accountable requires that knowledgeable insiders come forward. There are anti-retaliation laws to protect whistleblowers who provide tips and helpful information to the government.

This country needs ordinary Americans to step forward and step up—individuals who will “do the right thing.” Effective enforcement of our nation's laws to solve the opioid crisis is dependent upon help from individuals with first-hand knowledge of the harmful practices that have brought us to the regrettable circumstances we find ourselves in today. The False Claims Act—the Justice Department's primary civil enforcement tool—provides financial rewards to whistleblowers. It is a legitimate enforcement tool to augment the efforts of the Justice Department. Insiders with personal knowledge of abusive practices that put patients at risk and waste taxpayer dollars can make an enormous difference.

Historically, insiders have been responsible for exposing some of this country's most harmful health care practices—prompting legislative reforms, increasing funding for preventative and enforcement initiatives, and leading to improvements in compliance practices of the health care industry. With the help of insiders, attention and publicity to this issue could prompt the following additional actions and much more:

³ Press Release, Attorney General Sessions Announces Director of Opioid Entertainment and Prevention Efforts (Dec. 20, 2017) (on file with Dep't of Justice).

- Legislative efforts
 - Increasing the funding for preventative and enforcement efforts launched by the Department of Justice, executive branch agencies, the states and municipalities.
 - Increase the funding for treatment options such as drug rehabilitation and detoxification services, including for individuals without insurance coverage.
 - Revisiting compliance measures for financial institutions to ensure they are not recklessly or negligently funding and sustaining the opioid epidemic.
 - Limiting the marketing and availability of opioids and other addictive drugs through strengthened oversight and regulation of the pharmaceutical companies that manufacture and distribute the drugs.

- Improved physician-patient practices
 - Ensuring that knowledge and education about substance abuse prevention, detection, and treatment are clinical requirements for physicians, particularly primary care practitioners.
 - Imposing mandates to limit the quantities of prescriptions for opioids and other addictive drugs.
 - Emphasizing the importance of sustained treatment to avoid relapse and overdoses.

The economic effects of this crisis are widespread and sizeable. The Council of Economic Advisers released a report finding that the economic cost of the crisis was over \$504 billion in 2015, largely stemming from health care costs but also including foregone employment earnings, lost productivity, and increased criminal justice costs. Because the mortality rate of this epidemic is most acute for Americans 50 years and younger, the economic impact is even more substantial than other health related epidemics:⁴

In April 2018, the Department of Health and Human Services reported a joint-focus with the Justice Department on those who have played a role in the opioid crisis.⁵

⁴ THE COUNCIL OF ECON. ADVISERS, *THE UNDERESTIMATED COST OF THE OPIOID CRISIS* (2017).

⁵ The Department of Health and Human Services and the Department of Justice Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2017 2017 HCFAC program report issued on Friday (April 6), *THE DEP'T. OF HEALTH AND HUMAN SERVICES & THE DEP'T. OF JUSTICE, HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REP. FOR FISCAL YEAR 2017* (2017).

- Too many trusted medical professionals like doctors, nurses and pharmacists have chosen to violate their oaths and exploit this generosity to line their pockets, sometimes for millions of dollars.
- Pharmaceutical manufacturers have entered into Corporate Integrity Agreements.
- The Justice Department has formed the Opioid Fraud and Abuse Detection Unit, a new pilot program that will use data to help prosecute individuals and entities involved in illegal activities that fuel the crisis.

II. THE FALSE CLAIMS ACT IS A FORMIDABLE ENFORCEMENT TOOL

Consistently, the False Claims Act is the government’s most effective civil tool to weed out fraud and return billions of dollars to taxpayer-funded programs.⁶ Recoveries under the False Claims Act have exceeded billions of dollars annually and help preserve the integrity of vital government programs that enable Americans to purchase homes, provide health care to older Americans and low income families, and ensure our national security and defense. Most industries in the United States are impacted by the False Claims Act. Any company—whether publicly traded or privately-owned—that does business either directly or indirectly with the Federal Government (and numerous state governments) has potential exposure under the False Claims Act and in certain sectors, such as the financial services sector, under the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 (FIRREA). FIRREA provides civil penalties for certain kinds of fraud affecting a federally-insured financial institution.

The False Claims Act is a federal law that imposes civil liability on companies and individuals that defraud government-funded programs. It holds a company liable to pay damages, plus three times the amount of damages that the Federal Government sustains because of the false claim, as well as penalties. The False Claims Act includes a qui tam provision that allows private individuals (known as relators or whistleblowers) to file civil actions in the name of the Federal Government and to recover a percentage of any settlement or judgment under the Act. The media, which avidly reports False Claims Act recoveries and judgments, calls them “whistleblower suits.” Whistleblowers are

⁶ Press Release, Justice Dep’t. Recovers Over \$3.5 Billion From False Claims Act Cases in Fiscal Year 2015 (Dec. 3, 2015) (on file with Dep’t. of Justice); Press Release, Wells Fargo Bank Agrees to Pay \$1.2 Billion for Improper Mortgage Lending Practices (Apr. 8, 2016) (on file with Dep’t. of Justice); Press Release, Just. Dep’t. Collects More Than \$15.3 Billion In Civil and Criminal Cases in Fiscal Year 2016 (Dec. 14, 2016) (on file with Dep’t. of Justice); Press Release, Just. Dep’t. Recovers nearly \$ Billion from False Claims Act Cases in Fiscal Year 2014 (Nov. 20, 2014) (on file with Dep’t. of Justice).

key—and they largely dictate where the Justice Department’s priorities lie.

The Department’s use of the False Claims Act will continue unabated—as history has shown, Presidential Administrations of either political party have vigorously enforced the False Claims Act—and should help to attack the opioid crisis from an enforcement perspective. The Act has always had considerable support from Congress and, most notably, from Republican Senator Chuck Grassley who has called the False Claims Act “hands down, the most effective tool the government has to fight fraud against the taxpayers....the modern-day False Claims Act is now 30 years old. It is the most successful piece of anti-fraud legislation in U.S. history, and it has always enjoyed strong bipartisan support.” Further, as reported by the National Law Journal in June 2016, the United States Supreme Court reinforced the broad scope and power of the False Claims Act.

Other areas of steady and increasing focus of the Justice Department’s False Claims Act enforcement practice include: health care fraud involving pharmaceutical manufacturers, health care providers, hospitals, physicians, physician practice groups, laboratories, managed care providers, pharmacies, hospice and nursing home providers, and various government suppliers, many of which may have a role in perpetuating drug addiction. In fact, any company or institution receiving, or participating in, research grants, subsidy programs, loan guarantee programs, federal building construction, government equipment and information technology purchases, selling goods and services to the military, and foreign aid, all fall within the purview of the False Claims Act. Simply put—the False Claims Act materially affects how companies do business.

III. THE FALSE CLAIMS ACT IS A REPEAT PERFORMER FOLLOWING DE-REGULATION

The False Claims Act is a formidable and necessary enforcement tool to keep participants in every industry that receive federal dollars (directly or indirectly) in check. This is particularly so where there is actual or threatened deregulation and a state of crisis like the one we are currently experiencing. We need not look far in the past for similar examples of this. Ten years ago, we saw the collapse of the financial industry beginning with the fall of the Lehman Brothers.⁷ Wrongdoing in the mortgage industry helped lead to a devastating crisis that

⁷ James Mackintosh, *Lehman’s Lessons, 10 Years Later*, THE WALL STREET JOURNAL, Sept. 7, 2018, available at <https://www.wsj.com/articles/lehmans-lessons-10-years-later-1536255748>.

spanned the globe. We found ourselves in this position because of deregulation coupled with many other factors that have been well-covered by scholars. In the absence of sensible regulation, the Department of Justice used the False Claims Act to correct the regulatory failures that the financial market itself did not address.

By example, one important program of the United States Department of Housing and Urban Development was at risk. In late 2012, HUD was facing the near collapse of its Federal Housing Agency's single family mortgage insurance fund. Under the program, homebuyers obtained FHA-insured mortgages from HUD-approved lenders to purchase homes with low down payments. By insuring commercial lenders against loss, HUD encouraged lenders to invest capital in the home mortgage market. The program was intended to help ordinary Americans realize the dreams of homeownership.

Yet, for the first time in its 80 year history, the FHA was considering a potential taxpayer bailout of a program that was insuring a portfolio of more than \$1 trillion in mortgages. In response, the Department of Justice took swift action under an enforcement program called the "Big Lender Initiative." Armed with the False Claims Act, the Department of Justice investigated dozens of lenders that participated in the FHA's single family mortgage insurance program. JPMorgan Chase was the first to get in line to repay the nearly insolvent insurance fund and admit wrongdoing. SunTrust, U.S. Bank, Bank of America, Wells Fargo, and many others followed. In this way, the False Claims Act acted as a fail-safe after chaos reigned in a deregulated environment. It was the Justice Department with its powerful enforcement tool that held the largest mortgage lenders in the world responsible for years of reckless underwriting of tens of thousands of bad loans that resulted in actual harm to real individuals. Even as recently as fiscal year 2016, the Justice Department collected more than \$15.3 billion in civil and criminal cases, with the largest settlements from cases still related to the effects of the financial crisis.⁸

IV. THE FALSE CLAIMS ACT AS FAIL-SAFE

Make no mistake about it. The False Claims Act is needed to fight the opioid crisis with the help of whistleblowers. While it may be a blunt tool compared to sensible laws aimed at addressing the root causes of addiction, the False Claims Act will once again act as a fail-safe. By some measure, it will address the

⁸ Press Release, Justice Dep't. Collects More than \$15.3 Billion in Civ. and Crim. Cases in Fiscal Year 2016 (Dec. 14, 2016) (on file with Dep't. of Justice).

terrible economic and health effects of opioids wrought by wrongdoers willing to exploit others for financial gain—just as it was used effectively during the financial crisis.