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Deputy Associate Attorney General Stephen Cox Delivers Remarks at the 2019 Advanced Forum on False Claims and Qui Tam Enforcement

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Thank you for that introduction, and thank you to the American Conference Institute and all of its sponsors for hosting me here today.

I serve in the Office of the Associate Attorney General at the Department of Justice. Our office oversees five litigating divisions, including the Civil Division, and I spend most of my time working with the Consumer Protection Branch and the Commercial Litigation Branch on enforcement. Relevant to this audience, I've had the privilege of working closely with the Civil Fraud Section within the Commercial Litigation Branch that is responsible for investigating and litigating violations of the False Claims Act.

The new Administration is two years old this month. My plan today is to offer some thoughts about this Administration's commitment to enforcing the False Claims Act and then describe some of the Department's enforcement principles, policies, and perspectives that guide us.

Fraud on the Taxpayer

Let me begin by describing the Department's commitment to fighting fraud on the taxpayer—and specifically our duty to responsibly enforce the False Claims Act to recover loss to the taxpayer and deter misconduct.

The Act was passed during the Civil War to fight fraud on the Union Army, and it is sometimes called "Lincoln's Law." As Assistant Attorney General Jody Hunt recently noted, there were crooked contractors defrauding the Union Army by selling sick mules, lame horses, sawdust instead of gunpowder, and rotted ships with fresh paint. Lincoln's Law was an answer to those problems one hundred and fifty years ago.

The Act fell into relative disuse over the years, but was revitalized in 1986 through amendments spearheaded by Senator Grassley. For example, the 1986 amendments increased the incentives for whistleblowers to file lawsuits alleging false claims on behalf of the government. Since the 1986 amendments, the False Claims Act has returned over $59 billion to the U.S. Treasury—over $42 billion of which came through *qui tam* actions filed by whistleblowers.

Today, we use the False Claims Act to fight not only contracting fraud, but also healthcare fraud, grant fraud, financial fraud, and many other types of fraud.

Enforcing the False Claims Act is a top priority for the Department—not just for our office.

Last month, we announced that the Department recovered approximately $2.8 billion this past fiscal year. $2.5 billion involved the health care industry, including drug and medical device manufacturers, managed care providers, hospitals, pharmacies, hospice organizations, laboratories, and physicians. This is the ninth consecutive year that the Department's civil health care fraud settlements and judgments have exceeded $2 billion.

This year we settled a number of large and important cases. We settled a case with Amerisource Bergen for $645 million involving improper repackaging and distribution of cancer drugs. The Department's position was that the company circumvented important safeguards designed to preserve the integrity of the nation's drug supply.

We also settled a case with United Therapeutics Corporation for $210 million. This case involved the use of a foundation as an illegal conduit to pay the co-pays of thousands of Medicare patients taking the company's drugs. We settled a similar case with Pfizer for $23.85 million to settle allegations that it was also improperly using a foundation to pay Medicare patient co-pays. Co-pay requirements can serve as an important check on healthcare costs, including the cost of drugs, but these cases show how drug manufacturers can make an end-run around these requirements to facilitate increases in drug prices.

We settled a case with Toyobo for $66 million in a case involving the sale of defective Zylon fiber used in bullet proof vests that the United States purchased for federal, state, local, and tribal law enforcement agencies. Defective Zylon can render bullet proof vests unfit for use and put our men and women in blue at unnecessary risk.

Another important case was the Deloitte & Touche settlement for $149.5 million. Deloitte served as independent outside auditor for an originator engaged in a long-running mortgage fraud scheme involving loans insured by the Federal Housing Authority. The allegations against Deloitte were that they knowing deviated from auditing standards and therefore failed to detect the fraud.

It is also worth highlighting cases where we pursued individuals because individual accountability remains a top priority for the Department. The Department obtained $114 million in judgments against three individuals found to have paid kickbacks to doctors disguised as "handling fees" resulting in medically unnecessary tests that were billed to Medicare.

We also settled our case against Lance Armstrong for $5 million. The allegations in that case were that his cycling team used performance enhancing drugs while making numerous false statements denying it and concealing the drug use during the U.S. Postal Service's sponsorship of the team for the Tour de France.

I could tell you about many more cases, and you might hear about more throughout this conference. But the point is that we just finished another big year demonstrating our commitment to False Claims Act enforcement.

Before I turn to certain principles we apply and reforms that we have brought about, I want to note that our work in the False Claims Act space not only protects the taxpayer, but it serves other important goals. The taxpayer is not the only victim of fraud on the government.

When a company falsely certifies the quality of military equipment, it sends our brave men and women into harm's way with less protection. When medical providers submit false claims to Medicare, they often fail to provide adequate medical care to their patients. Kick-back schemes not only defraud the government, they also drive up consumer costs, undermine competition, and may distort independent medical decision-making.

By effectively enforcing the False Claims Act, we protect the taxpayer, we deter bad actors, we protect victims, and we level the playing field in the markets.

Now let me turn to some of the principles that guide the Department in False Claims Act

enforcement.

Qui Tam Dismissals

Let me first start with an internal memo that has become known as the Granston Memo. Last January, the Director of our Civil Fraud Section issued internal guidelines for our litigators in determining when it is appropriate in a *qui tam* case to exercise our dismissal authority under the False Claims Act.

As I mentioned earlier, the success of the False Claims Act is due in large part to the *qui tam* provisions and the partnership between the federal government and whistleblowers. Of the recoveries last year, more than $2 billion was recovered in qui tam cases.

One of the reasons for this partnership is that whistleblowers are often uniquely situated to bring fraudulent practices to light—particularly in suits filed by corporate insiders, who have frequently disclosed complex corporate wrongdoing that the government would have been hard-pressed to understand and unearth without their assistance.

Qui tam filings have been on the rise for many years. The Department intervenes in only about 1 in 5 cases that are filed. But even the other 4 in 5 cases consume Department time and resources – not only in investigating them initially, but also in terms of monitoring and participating in any ensuing litigation if the relator elects to proceed.

When relators litigate cases in which the Department declines to intervene, the relators essentially stand in the shoes of the Attorney General. Because relators may not always have the same interests as the United States, we take very seriously our responsibility to monitor False Claims Act cases when we decline to intervene. Indeed, the Department serves an important role as a gatekeeper.

The Granston Memo is about our gatekeeping role. Part of the reasoning behind the memo is that when *qui tam* cases are non-meritorious, abusive, or contrary to the interests of justice, they impose unnecessary costs on the Department, on the judiciary, and on the defendants. Bad cases that result in bad case law inhibit our ability to enforce the False Claims Act in good and meritorious cases. And from a resource perspective, when the Department's resources are consumed for other things, we have less time to fulfill our priorities. This is why we have instructed our lawyers to consider dismissing *qui tam* cases when they are not in our best interests. This authority is an important tool to protect the integrity of the False Claims Act and the interests of the United States.

The Granston Memo is not really a change in the Department's historical position. In fact, it reflects the factors that the Department has historically considered in deciding to dismiss a case. But we did think it was important that all of our False Claims Act litigators had the benefit of understanding the Department's practice so that the authority could be used more consistently.

It is true that this authority has been used sparingly. In the past, in a given year, the Department might have dismissed a few cases—if it dismissed any at all—but since 2017, the Department has moved to dismiss about two dozen cases. Our exercise of this authority will remain judicious, but we will use this tool more consistently to preserve our resources for cases that are in the United States' interests.

Subregulatory Guidance

Second, I'll address the Department's reforms concerning the issue of rulemaking by guidance. As you know, when an agency has statutory authority to issue regulations, it normally goes through the notice-and-comment process of rulemaking, which can be cumbersome and slow. Sometimes agencies have instead taken a shortcut by issuing "guidance" in lieu of regulations, knowing that it will achieve a similar effect of changing behavior.

To be fair, subregulatory guidance documents can be helpful in educating the public about statutes, regulations, and legal developments. But it is improper to try to use guidance to bind the public by imposing legal obligations beyond those already enshrined in existing statutes or properly promulgated regulatory provisions. Put simply, *agency guidance should educate, not regulate.*

That is why, in November 2017, former Attorney General Sessions announced that the Department will no longer issue any kind of binding sub-regulatory guidance. In other words, the Department will no longer issue guidance documents that effectively bind the public without undergoing the notice-and-comment rulemaking process.

We hoped to serve as an example for other agencies to follow, and shortly after the policy was announced, then-Chairman of the Senate Judiciary Committee, Senator Grassley, sent a letter to the President praising the Attorney General's policy and suggesting that other agencies follow its commonsense principles.

Last January, in the affirmative civil litigation context (which includes the False Claims Act), then-Associate Attorney General Rachel Brand instructed Department attorneys not to use our affirmative civil enforcement authority to convert other agencies' sub-regulatory guidance into rules that have the force or effect of law. In other words, noncompliance with a nonbinding guidance document cannot be used to establish a violation of law. This policy has been called the "Brand Memo." Its principles have been codified in the Justice Manual, and they apply not only in False Claims Act and civil enforcement cases, but also in criminal actions now.

Let me make a few points about how these principles might apply in False Claims Act cases. As we have noted before, there are, of course, circumstances where it may be appropriate to rely on agency guidance, including to show the defendant's awareness of an agency's interpretation of a particular requirement or the agency's views on the materiality of that requirement. This is not to say that the guidance will carry the day—just because a company knows an agency's nonbinding interpretation of the law does not mean it's correct or that the company's interpretation is unreasonable.

Some guidance documents may be relevant to professional standards that are incorporated into statutes. For example, there are statutory and regulatory requirements that procedures billed to Medicare and Medicaid be medically "reasonable and necessary," and there may be guidance documents discussing an agency's non-binding views on what is medically reasonable and necessary. The guidance document might be probative, even if it isn't binding. Of course, we must be careful not to run afoul of first principles. Agency guidance cannot be dispositive on what a statute or regulation means—it is not a thumb on the scale—and it cannot create binding requirements. But just like other statements of medical standards—such as professional standards from the medical industry or expert testimony—the guidance may have some probative value. It's not necessarily more probative than guidance from the industry, but it can have probative weight.

A particular guidance document may also be relevant if it is expressly incorporated into a contract or a certification. For example, if a party and the government agree in a contract that compliance with some specified guidance document is required, the guidance document will be contractually binding on the party and noncompliance will be relevant under principles of contract law.

Of course, all of these examples need to line up with the general principle that we're not going to use "violations" of nonbinding guidance documents to establish a violation of law. Guidance is not law. It's not binding. And it shouldn't be given the force or effect of law.

As I mentioned earlier, we hope that the Department's policies on subregulatory guidance have been informative to other agencies, and we see evidence of that. Last September, six of the banking regulators followed the Department's lead and announced limits on the issuance and enforcement of sub-regulatory guidance. In December, with similar principles in mind, the

Department of Transportation issued an important memo clarifying and updating its procedures for guidance documents. We hope other agencies follow suit. These policies keep government restrained and promote the rule of law, fair notice, and due process.

Piling On

Third, let me turn to a Department policy discouraging what we think of as "piling on." This policy was announced by the Deputy Attorney General last summer, and it applies across the board, including in False Claims Act cases.

As you know, often the same conduct can violate multiple statutes.

When multiple law enforcement and regulatory agencies pursue a single entity for the same or substantially similar conduct, and then impose unwarranted and disproportionate penalties for that conduct, this is what we mean by "piling on." This can be seen as inconsistent with the concepts of fair play and the need for certainty and finality.

To avoid piling on, we are promoting coordination within the Department and with other agencies to apportion penalties and fines where appropriate. Under the same policy, we are also reminding our attorneys not to use our criminal enforcement authority for purposes unrelated to the investigation and prosecution of a possible crime. For example, we are not going to invoke the threat of criminal prosecution just to persuade a company to pay a larger settlement in a False Claims Act case or any other civil case.

The most prominent example of this policy in action was a $680 million Foreign Corrupt Practices Act settlement in June with Société Générale, a global financial services institution based in Paris, for FCPA violations in Libya and for LIBOR manipulation. This was handled by the Department's Criminal Division, which is not supervised by our office, but the Department's press release made clear that it credited $292 million that the firm paid to the French Authorities, an amount equal to 50% of the total criminal penalty otherwise payable to the United States.

But let me give you one example in the False Claims Act context: In November, the Department announced a global resolution with three South Korea-based fuel companies for their involvement in a decade-long bid-rigging conspiracy that targeted contracts to supply fuel to U.S. military bases in South Korea. This was a global resolution of criminal Sherman Act violations, civil claims under the Clayton Act, and civil claims under the False Claims Act. I can tell you that the Antitrust Division's criminal and civil sections and the Civil Division's Fraud Section worked together effectively with the policy in mind so that they could reach coordinated global settlements that were equitable and proportionate to the defendants' conduct, and they were careful not to impose fines, penalties, or damages that are unnecessarily duplicative of each other.

Cooperation Credit

Finally, let me turn to the issue of cooperation and policy initiatives of relevance to the False Claims Act.

As the Deputy Attorney General has made clear in other contexts, and as senior officials from our office and the Civil Fraud Section have echoed in the False Claims Act context, the Department is committed to rewarding companies that invest in strong compliance programs and who cooperate with our investigations into wrongdoing.

In November of 2017, the Department announced a corporate enforcement policy that takes voluntary disclosure, cooperation, and compliance into account in criminal cases. This policy was, in a sense, a culmination of the FCPA Pilot that was announced in early 2016, but the corporate enforcement policy has been applied in criminal cases outside the FCPA space.

In November of 2018, the Deputy Attorney General announced changes to Department's policies

on awarding cooperation credit based on, for example, whether a company identifies the individual wrongdoers. Much ink has been spilled about the changes, and I won't go into each and every one of them. But for this audience I would like to focus on one change in particular relating to civil cases.

There is no longer an "all or nothing" approach to awarding credit for cooperation in civil cases. You don't have to boil the ocean in an effort to identify every employee who played any role in the conduct in order to receive any credit for cooperating. If a corporation wants to earn maximum credit, it must identify every individual person who was substantially involved in or responsible for the misconduct. But when a company honestly does meaningfully assist the government's investigation, our civil attorneys now have discretion to offer some credit even if the company does not qualify for maximum credit.

In announcing these changes, the Deputy Attorney General gave a False Claims Act example: "A company might make a voluntary disclosure and provide valuable assistance that justifies some credit even if the company is either unwilling to stipulate about which non-managerial employees are culpable, or eager to resolve the case without conducting a costly investigation to identify every individual who might face civil liability in theory, but in reality would not be sued personally."

In short, the policy changes return discretion to our civil lawyers to resolve each case consistent with relevant facts and circumstances.

Last June, then-Acting Associate Attorney General Jesse Panuccio made clear that False Claims Act investigations are no exception to the Department's policy of incentivizing cooperation. Corporate defendants can receive a more favorable resolution for cooperating with our False Claims Act investigations – from voluntary disclosure, which is the most valuable form of cooperation, to other efforts such as sharing information gleaned from an internal investigation and making witnesses available. He also made clear that we will reward companies that invest in strong compliance measures.

As you know, strong compliance programs are good for business and fair competition, they raise awareness of legal obligations, they mitigate risk of legal jeopardy, and they promote reporting up. When there's been a case of overbilling Medicare or Medicaid, for example, we want you to know that having an effective and robust compliance program in place is something we will consider at the outset in determining whether it was a mistake or an anomaly or whether there was a knowing violation. And that in turn will inform whether a False Claims Act case is merited, or whether pursuing another remedy is appropriate to make the government whole.

We also want you to know that, if there's a problem, the Department welcomes and will reward companies that make voluntary disclosures and provide meaningful, candid assistance in False Claims Act investigations.

The Department has significant discretion under the False Claims Act to resolve cases in a way that provides a material discount based on cooperation while still making the government whole. Stay tuned on this front.

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It is a privilege working at the Department of Justice on False Claims Act enforcement, and you should know that our lawyers are committed to exercising the Department's enforcement discretion consistent with the rule of law.

I hope that my remarks today have given you a better understanding of how we do our work, so that you can feel more confident that you know the rules of the road and the priorities of the Justice Department.

Thank you.

Topic(s):
False Claims Act

Component(s):
Office of the Associate Attorney General

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