FALSE CLAIMS ACT

HEARING

BEFORE THE

SUBCOMMITTEE ON THE CONSTITUTION
AND CIVIL JUSTICE

OF THE

COMMITTEE ON THE JUDICIARY
HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRTEENTH CONGRESS

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MATERIAL SUBMITTED FOR THE HEARING RECORD BUT NOT REPRINTED

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http://www.whistleblowers.org/storage/whistleblowers/RebuttalDocs/final%20fca%20report.pdf

FALSE CLAIMS ACT

WEDNESDAY, JULY 30, 2014

HOUSE OF REPRESENTATIVES

SUBCOMMITTEE ON THE CONSTITUTION
AND CIVIL JUSTICE

COMMITTEE ON THE JUDICIARY

Washington, DC.

The Subcommittee met, pursuant to call, at 1:05 p.m., in room 2237, Rayburn Office Building, the Honorable Trent Franks (Chairman of the Subcommittee) presiding.

Present: Representatives Franks, Goodlatte, DeSantis, Cohen, Conyers, and Johnson.

Staff present:(Majority) Zachary Somers, Counsel; Tricia White, Clerk; (Minority) James Park Minority Counsel; and Veronica Eligan, Professional Staff Member.

Mr. FRANKS. The Subcommittee on the Constitution and Civil Justice will come to order.

Without objection, the Chair is authorized to declare recesses of the Committee at any time.

I will begin by recognizing myself for an opening statement.

We welcome all of you to the Committee hearing today.

Because protecting taxpayer dollars from waste, fraud and abuse is a critical responsibility with which Congress is entrusted, it is important that from time to time we examine how the False Claims Act is working.

It has been 6 years since the Judiciary Committee has held a hearing on the FCA, and in that time three major legislative changes to the FCA have been enacted. So we have called today's hearing to examine areas in which the Act has been effective and potential areas in which reforms could be made to detect and prevent false claims in the future.

The False Claims Act is the Federal Government's primary tool for combatting fraud in federally funded programs, and the Act has proved to be a very successful tool. In each of the last 4 years the government has recovered over $3 billion under the FCA, and since the significant 1986 amendments to the FCA the Federal Government has recovered over $38 billion using the Act.

The FCA has been used to combat false claims in several economic sectors including defense, health care, pharmaceuticals, and finance. However, despite its success, as it is currently structured and enforced, the FCA still fails to prevent massive losses of taxpayer dollars to waste, fraud and abuse.

According to a recent study by the General Accountability Office, over $100 billion in taxpayer money is lost each year to improper payments by the Federal Government. Thus, the government recovers only a fraction of what it loses to false claims every year. This is especially troubling considering Congress has amended the FCA three times in the past 5 years to expand its coverage and enhance the ability of the whistleblowers to bring suit.

So the question occurs, how do we get more recoveries of taxpayer dollars out of the False Claims Act? Some experts who have studied the Act suggest that the answer is all about incentives and encouraging those best able to detect and prevent false claims—government contractors and government program beneficiaries themselves—to self-police and self-report potential FCA violations. The advice of these experts seems to make a great deal of common sense to me.

However, as currently structured, the FCA provides very few incentives for Federal Government contractors and businesses that participate in Federal Government programs to come forward and disclose their own violations. In other words, those with the best knowledge of waste, fraud and abuse are not encouraged to self-police for violations and self-disclose violations if they, in fact, occur.

This is because there is no economic advantage or incentive to do so. FCA violators who self-report generally receive the same exact penalties and face the same damages as those who are caught violating the Act and settle out of court with the government.

This would seem to make little sense. Shouldn't those that come forward and self-disclose violations get better terms than violators who are caught essentially red-handed? The FCA has been as successful as it has because it has provided whistleblowers with tremendous financial incentives for uncovering and disclosing false claims. It seems very appropriate and logical that to complement the current incentives for whistleblowers in the Act with financial incentives for self-disclosure will uncover even more waste, fraud and abuse of Federal taxpayer money. We need to examine ways to give those who do business with the government meaningful incentives to detect wrongdoing and to self-report it to government, and thus return to taxpayers more money than is currently recovered under the FCA.

The Justice Department itself has acknowledged the limitations of the Act as it is currently written. According to the head of the division at DOJ charged with enforcing the FCA, the Justice Department is "well aware of the fact that litigation can only plausibly reach a fraction of the fraud committed against U.S. Government programs, which likewise makes the prevention of fraud a more potent tool for protecting the interests of the United States than efforts to undo the damage of completed schemes. Litigation to recover the costs of fraud is a far inferior option to preventing the fraud in the first place."

Now, I hope through this hearing we can begin to discuss ways to prevent violations of the False Claims Act from occurring in the first place. The Federal Government has benefitted greatly from the increased accountability that has resulted from the False Claims Act and the invaluable help it has received from False

Claims Act whistleblowers. We must make sure, however, that we are doing everything that we can to detect and prevent even more false claims against our nation's hard-earned financial resources, and I look forward to the witnesses' testimony.

And I would yield—I see the Ranking Member is not here, so I am not going to yield to him. How does that sound? And I look forward to hearing, then, from our witnesses. We will now just thank the Committee for being here.

We have two very distinguished panels of witnesses today, and I will begin by introducing the first panel witness.

Our first witness is Senator Chuck Grassley, the Ranking Member on the Senate Judiciary Committee. Senator Grassley has served in the Iowa Legislature and the U.S. House of Representatives before being elected to the Senate in 1980. In 1986, Senator Grassley authored significant amendments to the False Claims Act to empower whistleblowers to file suit on behalf of the Federal Government against those who falsely obtain taxpayer dollars. Senator Grassley has been a leader in combatting waste, fraud and abuse in Federal Government programs and protecting the rights of whistleblowers.

I am wondering now at this point if we might ask the Ranking Member of the full Committee if he has any opening statement or any comments.

Mr. CONYERS. Thank you, Chairman. I do, and I thank you for your generosity.

Senator Grassley, welcome, and to the Members of our Committee.

I merely wanted to read a page or two of my remarks and put them in the record so that we don't detain the distinguished witness that we have today.

The False Claims Act is a longstanding and vital tool for ferreting out fraud against the government and ultimately protecting taxpayer dollars, and since its enactment and in 1986 amendments to this law almost $39 billion have been recovered from those that defrauded the American people, including some large pharmaceutical companies, hospitals, and defense contractors. In fact, more than $3.8 billion was recovered in the Fiscal Year 2013 alone.

While no system is perfect, this Act has worked well, particularly in light of the amendments which were spearheaded by our distinguished witness who is with us today. These amendments revitalize the Act's qui tam provisions. The Act was further strengthened with clarifications to its liability provisions that were made in 2009. Thus, as we consider the state of the False Claims Act, we should keep the following points in mind.

To begin with, qui tam actions are a critical component of the False Claims enforcement scheme, and I think for the interest of brevity I will ask permission to include the rest of my statement into the record and yield back the balance of my time, and thank the Chairman.

[The prepared statement of Mr. Conyers follows:]

Statement of the Honorable John Conyers, Jr. for the Hearing on "Oversight of the False Claims Act" Before the Subcommittee on the Constitution and Civil Justice

Wednesday, July 30, 2014, at 1:00 p.m.
2237 Rayburn House Office Building

The False Claims Act is a longstanding and vital tool for ferreting out fraud against the government and, ultimately, protecting taxpayer dollars.

Since the enactment of the 1986 amendments to this law, $42.3 billion has been recovered from those that defrauded the American people, including some large pharmaceutical companies, hospitals, and defense contractors. In fact, there was $3.8 billion in recoveries in fiscal year 2013 alone.

While no system is perfect, the False Claims Act has worked well, particularly in light of the 1986 amendments, which were spearheaded by Senator Charles Grassley, who is with us today.

These amendments, among other things, re-vitalized the Act's *qui tam* provisions. The Act was further strengthened with clarifications to its liability provisions that we made in 2009.

Thus, as we consider the state of the False Claims Act, we should keep the following points in mind.

To begin with, *qui tam* actions are a critical component of the False Claims Act's enforcement scheme.

Qui tam actions – which allow private parties to sue a defendant on behalf of the United States – are key to the government's efforts to fight fraud for at least two reasons.

Qui tam plaintiffs are often company insiders who can produce evidence critical to establishing liability under the Act.

These insiders are generally in the best position to know about fraud that would otherwise be hidden from the government.

Fraudulent activity by its very nature is concealed. Without the help of insiders, who can provide the government documents and other hard evidence of the fraud, it would be extremely difficult for the government to detect and prosecute the fraud.

It is the relentless, zealous pursuit of *qui tam* litigation that has led to the bulk of recoveries in False Claims Act cases since 1986.

Of the almost $39 billion in recoveries from fiscal year 1987 to fiscal year 2013, more than $27 billion of that amount resulted from litigation initiated by *qui tam* plaintiffs.

While the False Claims Act's *qui tam* provisions are important, they would be ineffective if the Act had weak incentives for *qui tam* plaintiffs to file suit.

After all, such individuals often take on tremendous personal risk in revealing the fraud.

Disincentives that potential plaintiffs face include the fact that the they often suffer job loss or other retaliation by their current or former employers and have difficulty finding employment once news of their whistleblowing activity surfaces.

They also often bear the emotional and psychological stress of being under attack by the defendant and former colleagues.

One of the main points of the 1986 amendments to the Act was to ensure that *qui tam* relators had sufficient incentive to go public with fraud that they knew existed. Prior to 1986, the Act had been applied in such a way that the disincentives to file *qui tam* lawsuits vastly outweighed the incentives.

The Act currently allows a *qui tam* plaintiff to recover 15 to 25% of the government's recovery in cases where the government chooses to intervene in the case, and 25 to 30% when the government does not intervene. The *qui tam* plaintiff can also recover legal fees and expenses from the defendant.

Additionally, the Act allows the government to recover treble its damages, which also factors into the plaintiff's recovery.

Without these kinds of incentives, few would risk filing *qui tam* suits, which, in turn, would undermine the effectiveness of the False Claims Act, as was the case prior to 1986.

Therefore, I am skeptical of efforts to weaken the False Claims Act, and especially its *qui tam* provisions.

The U.S. Chamber Institute for Legal Reform, from which we will hear today, has proposed numerous amendments to the False Claims Act that, in my view, would do nothing to enhance the fight against fraud and, if anything, would weaken it.

For instance, the Chamber has proposed requiring dismissal of *qui tam* actions by employees of a defendant company unless an employee reports alleged misconduct internally at least 180 days before filing the suit.

In my view, this is just an invitation for the company to either intimidate or retaliate against the whistleblowing employee.

The Chamber also proposes to reduce the relator's share of the government's recovery by limiting it to 15 to 25% of the first $50 million recovered, 5 to 15 percent of the next $50 million, and 1 to 3 percent of amounts over $100 million in cases where the government intervenes.

The proposal would similarly reduce the relator's share in non-intervention cases.

Again, this proposal strikes at the heart of what has made the False Claims Act successful.

The False Claims Act has largely been an effective tool at addressing fraud against the government. Rather than maintaining this important tool, the Chamber's proposals appear to go in the opposite direction.

Mr. FRANKS. And I thank the gentleman.

I would now like to recognize Senator Grassley.

Senator Grassley, thank you for your gallant service to the country, and we are pleased to have you here today.

I want to make sure that microphone is on so we can hear you, sir.

TESTIMONY OF THE HONORABLE CHUCK GRASSLEY, A U.S. SENATOR FROM THE STATE OF IOWA

Senator GRASSLEY. The green light is on.

Before I read my 5-minute statement, I would like to, first of all—I thought the green light was on. I would like to thank you for responding to my request to come and testify. Thank you for doing that.

The second thing I would like to say, you gave a nice introduction of me. Thank you for that.

Thirdly, I often speak about whistleblowers as being welcome within an organization kind of like a skunk at a picnic. Now, I kind of feel that there is a lot of special interests in this town who are going to consider me a skunk at this picnic.

Thank you for allowing me to come here today to testify. Today happens to be National Whistleblower Appreciation Day. Whistleblower groups are meeting as we speak to honor some of our colleagues on the Hill for their support of whistleblowers who report waste and fraud.

I am wary when I hear the biggest violators of a fraud law hire people to talk about strengthening that law. Last fall, the Chamber of Commerce released a report on the False Claims Act. It claims the Act "plainly is not getting the job done since the government has recovered only $35 billion since 1987." Now that figure, as you folks have said, is $39 billion, and some people use the term $42 billion. Anyway, this amount of money is nothing to sneeze at where I come from in rural Iowa.

The fact is that since 1986, no other law has been more effective in battling fraud, and you said that, Mr. Chairman, in your opening statement. Before the 1986 amendments, it only brought in about $40 million a year, not billions of dollars. At that rate, it would have recovered only $1 billion in the past 25 years. Thanks to these '86 amendments, it has brought in 39, 40 times that amount of money.

Clearly, the False Claims Act is working, and it is working fantastically. The report that I previously referred to says that the law is "ineffective in preventing fraud." Yet, my staff have met with some of the authors of that report, and they don't have any concrete proposal for preventing fraud more effectively. They talk about "a gold standard compliance certification program," but that just happens to be a pie-in-the-sky idea with no specifics. As they said, "We had to come up with something, so we just put that in." The Chamber clarified to my staff that they were talking about their proposal for internal reporting 180 days before any whistleblower can file a False Claims suit. Yet they also said of the overall certification program, "We deliberately left this vague."

Now, that is a very serious problem. They lack details on who would create the program, who would enforce the program. Basi-

cally everything about it lacks detail, but they want you to believe that once this pipe dream is in place, it will magically increase the amount of taxpayer dollars the government recovers. In exchange, the report proposes hefty concessions for its big corporate sponsors.

For starters, they want to eliminate the use of exclusion or debarment, some of the government's strongest tools on deterring fraud. They would require whistleblowers to report internally, which just puts a huge target on the back of a whistleblower. Internal reporting and a 6-month head-start on retaliation before a whistleblower gets the chance to be heard in court is a recipe guaranteed to reduce disclosures of fraud. Even when a corporation does come forward, the company line is never going to be the complete picture.

That is why the False Claims Act incentivizes whistleblowers, and you see how it has worked. While I believe companies should have strong internal compliance programs, nothing is worth the get-out-of-jail-free pass that this report asks in exchange. Many corporate giants already spend large amounts on compliance but still routinely bilk the government out of millions of taxpayer dollars.

This report's recommendations contradict its assertion that the False Claims Act has failed by not recovering enough money. The report proposes to limit government recoveries across the board regardless of the participation in any compliance certification program. That just makes no sense.

In the last 5 years, the Federal Government has grown larger and larger, and spending has gotten more and more out of control. Whistleblowers using the False Claims Act have played a key role in checking fraud and wasteful spending. Annual recoveries under the False Claims Act have increased dramatically in the last 5 years. State Attorneys General around the country have used state False Claims Act to successfully recover billions of dollars for their states.

For example, last October, then-Virginia Attorney General Ken Cuccinelli recovered $37 million for the State of Virginia from a drug company that was inflating its prices to scam taxpayer dollars from Medicare. The next month, Cuccinelli recovered $21 million in two healthcare fraud settlements with multi-national pharmaceutical giant Johnson & Johnson, which was paying millions of dollars in kickbacks to the nation's largest pharmacy.

Yet, just days before Cuccinelli's announcement of the settlement, Health and Human Services Secretary Kathleen Sibelius also made an announcement. She revealed that this Administration did not intend to treat the Affordable Care Act as a Federal healthcare program, then exempting it from anti-kickback laws. Precisely because of the fraud opportunities under the Affordable Care Act, one provision that Congress added to the law made a violation of the anti-kickback law an automatic violation of the False Claims Act. This Administration has chosen to ignore that part of the law.

Congress must step forward and we must reiterate that the Affordable Care Act is no less subject to the anti-kickback law and the False Claims Act than any other Federal healthcare programs. Additionally, this Subcommittee should strongly consider strength-

ening the False Claims Act's connection with suspension and debarment. That would keep repeat offenders away from taxpayer dollars.

A couple of years ago, the nonpartisan Government Accountability Office discovered serious weaknesses in the suspension and debarment program of numerous government agencies. Chairman Issa and Ranking Member Cummings of the House Oversight Committee have joined together with some proposals on this issue. Chairman Issa stated last fall, "The current process of keeping taxpayer dollars out of the hands of criminals, tax evaders, and the chronically incompetent is stove-piped, fractured and inadequate."

This issue is really about law and order. If we really want to improve the False Claims Act, we should make a judgment or settlement under the law result in an automatic review for suspension or debarment. That would capitalize on the success of the law while increasing its deterrent effect. The False Claims Act has already provided a crucial check during a time of growing government and out-of-control spending. No matter what we do to deter waste and fraud, whistleblowers are the key to the government finding out when that act happens.

Today, on National Whistleblower Appreciation Day, I hope we can honor whistleblowers for the patriotic service that they provide to the taxpayers.

Thank you very much.

[The prepared statement of Senator Grassley follows:]

U.S. Senator Chuck Grassley • Iowa
Ranking Member • Senate Judiciary Committee
http://grassley.senate.gov

Prepared Statement of Senator Charles E. Grassley
Ranking Member, United States Senate Committee on the Judiciary
Hearing Before the House Committee on the Judiciary
Subcommittee on the Constitution and Civil Justice
"Oversight of the False Claims Act"
Wednesday, July 30, 2014

Mr. Chairman, thank you for allowing me to come here today to testify on the False Claims Act.

Today is National Whistleblower Appreciation Day. On this day in 1778, the Continental Congress passed the first whistleblower law in the United States. It read:

> *Resolved,*
> That it is the duty of all persons in the service of the United States . . . to give the earliest information to Congress or other proper authority of any misconduct, frauds or misdemeanors committed by any officers or persons in the service of these states, which may come to their knowledge.

This resolution was passed by the Congress without any recorded dissent. Then and now, Congress's control of the purse strings has given it an obligation to guard against wasteful or fraudulent spending.

Today, whistleblower groups are meeting as we speak to honor some of our colleagues on the Hill for their support of whistleblowers who report waste or fraud. It's too bad that this hearing was scheduled for the precise time that many of them are unable to be here.

Of course, I'm always wary when I hear the biggest violators of a law hire people to talk about "strengthening" it. Last fall, the Chamber of Commerce announced that it was launching a full-fledged campaign to reform the False Claims Act. It called its report "Fixing the False Claims Act." It claims the Act "plainly is not getting the job done" since "the government has recovered only $35 billion since 1987." The current number is actually $42 billion. Either way, that's nothing to sneeze at where I come from. The fact is that no other law in existence has been more effective in battling fraud than the False Claims Act has in the past 25 years. Before the 1986 amendments, it brought in a tiny fraction of what it does today, only about $40 million a year. At that rate, it would have recovered only $1 billion in the past 25 years. Thanks to the 1986 amendments, it's brought back 42 times that much. Clearly, the False Claims Act is working, and it's working fantastically.

This report says that the law is "ineffective at preventing fraud." Yet my staff have met with the authors of the report, and they don't have any concrete proposal for preventing fraud more effectively. They talk about a "gold-standard compliance certification program," but it's just a pie-in-the-sky idea with no specifics. As they put it to my staff, "We had to come up with something, so we just put that in." They are vague on who would create the program, who would enforce the program—basically, everything about it. But they want you to believe that once this pipe dream is in place, it will magically increase the amount of taxpayer dollars the government recovers.

In exchange for this castle in the air, the report proposes hefty concessions for its big corporate sponsors. For starters, they want to eliminate the use of exclusion or debarment, surrendering one of the government's strongest tools for deterring fraud. They want to lower the damages multiplier for those who self-report. And they repackage a detrimental proposal to whistleblowers that has been recycled again and again.

Large corporations have long argued that whistleblowers should be forced to report wrongdoing internally before going to the government. Yet when whistleblowers try to do exactly that and get retaliated against, these large corporations change their stance in court and argue that whistleblowers only have protection if they report *externally*. Those kinds of inconsistent positions make it hard to believe that either argument is made in good faith. This report proposes requiring internal reporting 180 days before any whistleblower can file a False Claims Act suit. Yet in most corporations, reporting internally just puts a huge target on your back. We should trust whistleblowers to use their common sense to know the safest place to report. Anything else would dramatically weaken the False Claims Act and result in fewer whistleblowers coming forward.

Besides, it's ludicrous to think forcing whistleblowers to report internally would add to corporations' incentive to self-report. Instead, the first calculation any corporation would make is whether they could get away with muzzling the whistleblower and paying *no* damages. This report says we need to move from a stick to a carrot approach for corporations, but they're asking for a stick to use against whistleblowers. Internal reporting and a six-month head start on retaliation before the whistleblower gets a chance to be heard in court is a recipe guaranteed to reduce disclosures of fraud. Even when a corporation does come forward, the company line is never going to be the complete picture. That's why the False Claims Act incentivizes whistleblowers—and it's worked.

Now all that I've just discussed is predicated on the mythical gold standard compliance certification. While I believe companies *should* have strong internal compliance programs, nothing is worth the 'get out of jail free' pass this report asks for in exchange. Presumably we are supposed to believe that the model for certification would be the report's multinational corporate sponsors, who are already required by law to have compliance programs. No small- or mid-sized businesses would have the kind of money for a gold standard compliance program that these corporate colossuses do. Since many corporate giants already spend large amounts on compliance, yet still routinely bilk millions in taxpayer dollars, it's hard to imagine how these perks would motivate them to stop. Because this program has no specifics, there is no research showing how it would increase recoveries or prevent fraud.

Yet the specifics that are in the report contradict its assertion that the False Claims Act has failed by not recovering enough money. The report makes multiple proposals to *limit* government recoveries across the board. These limitations would apply regardless of whether the corporation involved participated in any compliance certification program. That just makes no sense.

Further, as the testimony that Stephen Kohn has submitted for today's record illustrates, corporations have already been using compliance programs as a trap for whistleblowers. By making their compliance program an arm of their legal department, anything a whistleblower reports is protected as confidential by attorney-client privilege. Back in March, the Chamber joined others in submitting a strongly-worded *amicus* brief arguing for such confidentiality for whistleblowers who take the internal compliance route. Many corporations also require employees who provide tips to their compliance departments to then sign non-disclosure agreements. In addition to the chilling effect this has on whistleblowers contemplating filing a False Claims Act suit, any whistleblower brave enough to file then finds *themselves* the subject of legal action claiming they have violated attorney-client privilege or non-disclosure agreements. Is this how we want to treat whistleblowers? Internal compliance is *not* the one-size-fits-all solution this report would have you think it is.

In the last five years, the federal government has grown larger and larger and spending has gotten more and more out of control with laws like the stimulus package and Obamacare. The federal government now spends $1 trillion dollars in contracts and grants each year. Inspectors general, the Government Accountability Office, and congressional oversight committees simply haven't been able to keep up. Yet whistleblowers coming forward under the False Claims Act have played a key role in checking fraud and wasteful spending when other oversight resources have failed. Annual recoveries under the False Claims Act have increased dramatically in the past five years. Last year the Justice Department recovered $2.6 billion in health care fraud alone through the False Claims Act. The False Claims Act is clearly doing *exactly* what we intended it to do: recover taxpayer money.

State attorneys general around the country have used state False Claims Acts to successfully recover billions of dollars for their states. For example, last October, then-Virginia Attorney General Ken Cuccinelli recovered $37 million for the State of Virginia from a drug company that was inflating its prices to scam taxpayer dollars from Medicare. The next month, Cuccinelli recovered $21 million in two health care fraud settlements with multinational pharmaceutical giant Johnson & Johnson. One of those settlements related to millions of dollars in kickbacks Johnson & Johnson paid to the nation's largest pharmacy.

Yet just days before Cuccinelli's announcement of the settlements, Health and Human Services Secretary Kathleen Sebelius also made an announcement. She revealed that this Administration did not intend to treat Obamacare health exchanges as a federal health care program, *exempting* them from anti-kickback laws. Precisely because of the fraud opportunities under Obamacare, one provision that Congress added to the law made a violation of the Anti-Kickback Law an automatic violation of the False Claims Act. This Administration has chosen to ignore that part of the law. Given that Obamacare constitutes the biggest expansion of federal health care in our lifetimes, it's alarming that the Administration would try to simply ignore a key anti-fraud provision added by Congress. This is a ripe area for Congress to step forward and

reiterate that Obamacare is no less subject to the anti-kickback law and False Claims Act than other federal health care programs.

Health and Human Services isn't the only part of this Administration that has set this law aside when it didn't suit its interests. As those who sit on this Subcommittee will remember, in May 2013 the full Committee held a joint hearing with the House Oversight and Government Reform Committee. At that hearing I testified about how the Department of Justice had sacrificed taxpayers' interests under the False Claims Act to an ideological agenda. A report I released with Chairman Goodlatte and Chairman Issa found the Justice Department let the City of St. Paul off the hook for false claims worth as much as $200 million to the Treasury. It's extremely disappointing when those who work at the Justice Department don't put the interests of the taxpayer first.

This issue is really about law and order. The real question is: Why is it that some corporations swindle the federal government out of millions upon millions of dollars, yet we allow them to keep coming back for more? This subcommittee should strongly consider strengthening the False Claims Act's connection with suspension and debarment. That would keep repeat offenders away from taxpayer dollars and strengthen the law's deterrent effect. A couple of years ago, the nonpartisan Government Accountability Office (GAO) discovered serious weaknesses in the suspension and debarment programs of numerous government agencies. Six agencies, including the Department of Health and Human Services, "had virtually no procurement-related suspensions and debarments" in 2009. Now remember, 2009 was the same year that this Administration pushed through its $831 billion stimulus package, causing federal spending to skyrocket. The federal government gave out $200 billion more in grants in 2009 than it did in 2008. 2010 also included $50 billion more in grants than usual. Yet remarkably, even with all the billions of dollars being shoveled out the door by the federal government, GAO found that those six agencies again had almost no suspensions and debarments in 2010.

Chairman Issa and Ranking Member Cummings have joined together with some proposals on this issue. Along with several others, including Congressman Jason Chaffetz, who sits on this full committee, they introduced a bill last fall to strengthen the tools of suspension and debarment. Chairman Issa stated at the time: "The current process for keeping taxpayer dollars out of the hands of criminals, tax evaders, and the chronically incompetent is stove-piped, fractured, and inadequate." If we really want to improve the False Claims Act, I believe a judgment or settlement under the law should result in an automatic review for suspension or debarment. That would capitalize on the success of the law while increasing its deterrent effect.

The False Claims Act has already provided a crucial check during a time of growing government and out of control federal spending. No matter what we do to deter waste and fraud, whistleblowers are the key to the government finding out about it when it happens. We have to do all we can to protect them from those who resist the role they play. Today on National Whistleblower Appreciation Day, I hope we can honor whistleblowers for the patriotic service they provide to taxpayers.

Mr. FRANKS. Well, thank you, Senator Grassley. And again, we want to express our gratitude for you making the trip over here and the cogency of your remarks. Thank you very much, sir.

I would now like to turn to the second group of witnesses, if you would like to take your seats.

Our first witness on this panel is Dr. Rachakonda Prabhu. I am going to try that again, sir. Rachakonda Prabhu. I know nobody ever has any trouble with that name, do they?

Dr. Prabhu is a Board-certified pulmonologist—boy, I am having trouble today—pulmonologist and the Founder of Red Rock Medical Group, the largest specialty medical group, multi-specialty medical group in the State of Nevada. He is also a Clinical Associate Professor of Medicine at the University of Nevada School of Medicine. Dr. Prabhu was twice sued under the False Claims Act and both times, at great personal expense, prevailed in the litigation. In one of the cases against him, the court determined that the case brought by the government was without substantial justification.

Our second witness is Patricia Harned—I got that one—President of the Ethics Resource Center, the nation's oldest non-profit organization devoted to the advancement of high ethical standards and practices in public and private institutions. She serves as Consultant to the New York Stock Exchange and is a member in good standing of the Advisory Group of the Public Company Accounting Oversight Board. Dr. Harned has testified before Congress and the Federal Sentencing Commission and has been featured in media outlets including the Wall Street Journal, Washington Post, and USA Today.

Our third witness is John Clark. John, thank you for having a simple name. [Laughter.]

An attorney specializing in False Claims Act litigation. Mr. Clark is testifying today on behalf of Taxpayers Against Fraud. He served as an attorney in the Justice Department's Criminal Division as an Assistant U.S. Attorney and as the U.S. Attorney for the Western District of Texas. Mr. Clark has been a member of legal teams representing whistleblowers in cases that have resulted in recoveries totaling more than $3 billion for the United States and state Medicaid programs.

Our final witness is David Ogden, a partner at WilmerHale. He is testifying on behalf of the Chamber of Commerce's Institute for Legal Reform. Mr. Ogden has held several positions at the Justice Department, including serving as the Deputy Attorney General of the United States from 2009 to 2010, and as Assistant Attorney General for the Civil Division from 1999 to 2001. As head of the Civil Division, he directed the Justice Department's False Claims Act enforcement.

Now, each of the witnesses' written testimony will be entered into the record in its entirety, and I would ask each witness to summarize his or her testimony in 5 minutes or less, and to help you stay within that time there is a timing light in front of you. The light will switch from green to yellow, indicating that you have 1 minute to conclude your testimony. When the light turns red, it indicates that the witness' 5 minutes have expired.

And before I recognize the witnesses, it is the tradition of the Subcommittee that they be sworn. So if you would please stand to be sworn.

[Witnesses sworn.]

Mr. FRANKS. Let the record reflect that the witnesses answered in the affirmative.

I will now recognize our first witness. Dr. Prabhu, please turn on your microphone, sir, before you begin.

TESTIMONY OF RACHAKONDA D. PRABHU, M.D., RED ROCK MEDICAL GROUP

Dr. PRABHU. Thank you, Chairman Franks, for inviting me to testify, and Honorable Congressman Mr. Conyers, Honorable Mr. DeSantis. I am a doctor who has been practicing medicine in Nevada since 1979. I have been sued twice under the False Claims Act. Both times the actions were dismissed and I was exonerated. But the lawsuits were ordeals that had a terrible effect on my medical practice, my finances, my health, my family, on my reputation.

Over 10 years, my wife and I had built a good medical practice with several doctors and employees. In the 1990's, three former employees made a false accusation against me in a qui tam lawsuit. Then they persuaded the Department of Justice to join the lawsuit in 1999, and my life turned upside-down.

They fabricated charges that I had performed unnecessary medical tests and used the wrong billing codes. These allegations were not true, but that did not stop the press from printing them. I was a doctor with a tremendous reputation, a teacher, a humanitarian, and the next day my reputation was tarnished. My medical practice went down. My wife and I had to work without taking any salary. The doctors left and we had to let employees go. I was also emotionally distraught. It was hard for me to get up in the morning, to face people giving you dirty looks in the hospitals. The stress took a toll on me physically and I developed medical problems.

Worst of all, my kids were little, and because of the press, other kids would tease them and make them cry. They would tell me, "Dad, we don't want to go to school." But I never considered giving up or settling even though the government was asking me for millions of dollars for things I had not done. I also knew the government could kick me out of Medicare and Medicaid.

After many years I was finally proven right. The government dropped all of the qui tam lawsuit because it found the allegations were untrue. Eventually, the judge dismissed the entire lawsuit. Although I was vindicated, the financial cost to defend myself was incredible. The total expense was between $4 to $5 million. Almost all of the money we had made was gone.

After the lawsuit ended, I tried to gain my reputation back and build my medical practice. After several years we had grown to 30 doctors and over 100 employees. One of the services I had been providing to my patients with advanced lung disease is known as pulmonary rehabilitation service. Patients would come to our office and we would exercise them under supervision.

When I first started providing this service, there was no Medicare code, so I was doing it for free. Later, I was told that it was

improper under Medicare rules to do anything for free. So we asked Medicare what should we do, and Medicare representative came to our office and told us the billing code that we have to use, and we used that code for 20 years, and a Medicare carrier assured us it was the right code to use.

Then in 2004, we learned the U.S. Attorney's Office was investigating our use of this code. I met with the U.S. Attorney, but he didn't listen. One afternoon a reporter called and said, "Dr. Prabhu, do you know the government filed a False Claims lawsuit against you?" The nightmare started all over again. My medical practice collapsed. Doctors started to leave. We had to let our employees go. We even had to close a clinic in a nearby town that badly needed our doctors. I was so depressed.

This time the government told me that under the False Claims Act I would have to pay $22 million. They said I had billed Medicare for 2,000 tests over 6 years, and they wanted a penalty of $11,000 for every test, which came to $22 million. But we only charged $50 for one test, and we had charged only a few hundred thousand dollars for all the tests. In the process, we even lost money. It just made no sense.

But I knew the government could kick me out of Medicare and Medicaid and I would lose my livelihood. I know that in many cases doctors simply settle when they have to go through what I have gone through. Some lose their patients, their spouses, their children, their houses, their health, and some even commit suicide. But I refused to give in.

Once again, I hired a team of lawyers and experts. In the end, the government's case fell apart and they just dismissed the case. The lawsuit was so unjustified that we filed a motion to recover legal costs. The judge awarded me $500,000 in attorney's fees. But I still spent over $2 million to defend myself.

In conclusion, I went through this ordeal twice. I spent more than $6 million to defend myself. I twice lost my practice, my friends, my partners, my dreams, and my reputation. The False Claims Act should be more fair so that it cannot be used to bankrupt people when they have done nothing wrong. I don't want what happened to me to happen to other citizens of this great country. Thank you.

[The prepared statement of Dr. Prabhu follows:]

Committee on the Judiciary's Subcommittee on the Constitution and Civil Justice Hearing on "Oversight of the False Claims Act"

My Experiences Being Wrongly Sued Under the False Claims Act

Dr. R.D. Prabhu, M.D.

I am a doctor who has been practicing medicine in Nevada for more than thirty years. Twice in that period I have been sued under the False Claims Act, once by *qui tam* plaintiffs and once by the U.S. Department of Justice. Both times, the actions were dismissed, and I was exonerated. But these lawsuits were ordeals that had a terrible effect on my medical practice, my finances, my health, and my family. This is what happened to me.

I trained to become a doctor at Mount Sinai Hospital Services in Elmhurst, New York. After I graduated from my residency and fellowship programs, I passed my boards in both Internal Medicine and Pulmonary Medicine. My wife had also trained in Elmhurst as a nephrologist. We came together to Las Vegas in 1979 to start our practice of medicine.

We started a practice together in 1979, and our practice grew after a few years. We started to expand the practice, and I hired one pulmonologist to join me and then others, so we grew to be a four man practice. My wife also had a good practice and she started a dialysis center to take care of patients with end stage renal disease. I partnered with twelve other doctors to build a medical center known as the Red Rock Medical Center. In short, by the mid-1990s my medical practice was doing quite well.

I was also involved in many other activities by the 1990s. I was active in the Indian-American community in Nevada and nationally. I was also politically involved, trying to educate Indian-Americans about civic responsibilities and the importance of participating in the political process. I was engaged in medical research, working on a new treatment for emphysema, using procedures known as lung volume reduction surgery. I also taught residents in the training program of the University of Nevada School of Medicine. On a personal level, my wife and I had children, who were going to a local school.

In about 1990, my trouble started. I began to hear that the government was investigating me. Patients would tell me that they had been interviewed by the FBI, and I learned that my phones were tapped and my mail was being intercepted. The FBI even put body wires on several people in my office, whose job it was to record conversations with me. I've been told there were dozens of FBI agents involved in investigating me, and I know that they interviewed more than 40-50 people, because they would come back and tell me they were interviewed.

I learned that three of my former employees made false accusations about me violating the False Claims Act, in a *qui tam* lawsuit they filed. The *qui tam* plaintiffs were able to persuade the U.S. Department of Justice to join their lawsuit in July 1993, and that's when my life was turned upside down.

The lawsuit fabricated a lot of charges against me. They said that I had performed unnecessary medical test on hundreds of my patients, that I had billed for services that were not rendered, that I had billed for equipment that was not used, and that we were using the wrong billing codes for services. But the lawsuit did not provide details. And none of these allegations were true. Though the lawsuit did not explain how much money they wanted, because I had

performed thousands of medical tests, I thought they could be asking for hundreds of millions of dollars.

All these allegations were leaked into the press. I was a doctor with a tremendous reputation, who had worked very hard to become a Clinical Assistant Professor of Medicine. I was known as one of the best doctors in town, a great teacher and humanitarian, and the next day my reputation was tarnished. The press started writing articles saying "Dr. Prabhu is under investigation by the FBI, by the United States Department of Health and Human Resources Inspector General . . . ." That really destroyed me.

My medical practice went down. We used to see a large number of patients, but after the *qui tam* allegations became public knowledge we lost a lot of sources of referrals, and the income from our practice went down. My wife and I didn't even have enough money to pay ourselves, so we worked for the medical practice without taking any salary. I had been in the process of recruiting more doctors to increase the practice group, but now I could not recruit these doctors, and the other doctors left one by one. In the end, the practice was down to just me, my wife, and one other doctor who stayed with us. As a result, we had to trim down the number of employees, and we had to cut down on our expansion plans, as well as participation in medical research.

This nightmare took up several years of my life. I was emotionally destroyed. It was hard for me to get up in the morning, to go to the hospitals and face all those people who give you dirty looks. It was really hard to walk around with that cloud hanging over your head. I could no longer enjoy anything in life, like watching football or basketball games or going out to see movies. There was no joy in my life. The stress also took a toll on me physically. Before, I would exercise regularly and take care of myself. Now, I developed a lot of medical problems, like sleep apnea and diabetes, and gained unnecessary weight.

Worst of all, my kids were little, and they would come home crying from school. Some of the other kids had seen the papers, or talked to their parents, and would make fun of my kids, and make them cry. It was very hard on my kids. They would tell me, "Dad we don't want to go to school." It was just a constant struggle.

During this whole time, I never considered giving up and settling with the government. I knew what I was facing. Although I had always believed that the job of the government was to protect its citizens, now the government was bearing down on me and asking for millions of dollars for doing things I had not done. I also knew that the government could kick me out of Medicare, Medicaid, and Tricare, and that if that happened all the insurance carriers would drop me as well. They could ruin my practice and force me out on the street. But I knew in my own heart I had not done anything wrong. I knew these allegations were fabricated and false, and I just couldn't give up in my own conscience.

After many years, I was finally proven right. The government decided to drop out of the *qui tam* lawsuit in September 1995, because the Department of Justice found out that none of the allegations were true. After the government withdrew from the case, one of the *qui tam* plaintiffs dropped out of the suit. The other two plaintiffs went forward, but eventually the judge dismissed the entire lawsuit.

Although I was completely vindicated, the financial cost to defend myself was incredible. I had to hire lawyers, forensic accountants, Medicare specialists, and health insurance experts. Sometimes I would sit around the table with 10 or 11 other people, and I was paying each of them $400 or $500 an hour, so I would be spending $5,000 an hour just for my team to talk about how to bring the truth out. The total expense to me was between four to five million dollars. Although my wife and I had both worked very hard for years and had other doctors working for us, all of the money we had made was gone because of what we had to pay the lawyers and experts to defend ourselves. I think it's totally unfair.

After the lawsuit ended, I slowly tried to gain my reputation back and build up my medical practice again. I just tried to do what I knew best: taking care of patients, helping them restore their health, and stamping out sleep apnea. I also had a vision for a better type of medical practice. I had always felt that a patient needed a one-stop medical practice in a big city like Las Vegas, so that patients would not need to go from place to place. So I decided to get physicians in different specialties to join my group. I was able to get cardiologists, other lung doctors, infectious disease doctors, obstetricians, gynecologists, pediatricians, hematologists, oncologists, and neurologists to join the practice. After several years, we had grown to a large group of 28-30 doctors and between 100-150 employees. We were able to provide great service to our patients. We were the first of the large multi-specialty groups in town, and probably the most successful and well-respected group in town. We were doing well.

One type of service I had been providing to patients since I came to Las Vegas in 1979 is known as pulmonary rehabilitation service. It is a structured medical program we provide to patients who have advanced lung disease or who are recovering from lung surgery or lung transplants. Patients would come to our office and exercise under the supervision of a respiratory therapist or doctor, while we carefully monitor their vital signs and oxygen saturation, to make sure they slowly improve their endurance. It's an essential treatment, and I am very passionate about it.

When I first started providing pulmonary rehabilitation services in 1979, there was no Medicare code for this kind of service. It would cost me a few hundred dollars to provide each session for a patient, because of the equipment I had purchased, the space set aside in the building, and the cost of the therapists. But I provided the sessions to my patients for free, because it was so good for my patients.

Afterwards, in the 1980s, I was told by a billing specialist that it was improper under Medicare to give anything free to patients, because it would be construed as an inducement. We went to the Medicare office in Phoenix, Arizona to explain the situation and ask what we should do. A Medicare representative came to our office in Nevada to see exactly what we were doing and what service we were providing. Part of the service involves the patient exercising on a treadmill for 6 to 10 minutes, while the respiratory therapist watches the patient, monitoring vital signs and oxygen. The Medicare representative said that there was no code for the comprehensive type of service we were providing. But she said that part of the service met the requirements of a pulmonary stress test, and she told us to use the billing code for a pulmonary stress test to get paid. So I started using this billing code.

For more than 20 years I had no reason to think anything was wrong with using this billing code. The government had looked at this code as part of its investigation in the 1990s, and they did not say we were doing anything wrong. We had also contacted our Medicare carrier many times about the code and they had assured us, time and again, it was the right code for the kind of service that we were providing. I had no reason to believe that we were doing anything wrong.

At the same time, we were losing money every time we performed the service. We would receive 50-60 dollars from Medicare each time we performed the service, which covered less than half of the cost. But I felt strongly my patients needed this service provided in a medical office with a doctor's supervision. Many of my patients are sicker than other pulmonary patients, and I felt obligated to see them through their ordeal and provide pulmonary rehabilitation in my own offices. People described it as an act of kindness in providing a service to meet a patient's needs at a fraction of the cost.

Then one day in 2004, we got a letter from the U.S. Attorney's office saying that it was investigating the code that I had been using to bill Medicare for pulmonary rehabilitation services. My lawyers and I met with the U.S. Attorney's office, and we tried to explain that there was no False Claims Act violation, that we were using the right code for the service, and that we had been using the same code for almost 24 years.

The government attorneys did not listen to us. One afternoon, a newspaper reporter called and said, "Dr. Prabhu, do you know the United States government filed a False Claims Act lawsuit against you?" And the next morning it was in the papers again: "Dr. Prabhu is sued by the United States government under the False Claims Act for Medicare fraud." The whole nightmare was starting all over again.

After the lawsuit was filed, I had to stop providing pulmonary rehabilitation services to my patients. I requested that my patients go to other places for rehabilitation, and closed the rehabilitation facility in my office. I knew that those other places were not going to be as effective for my patients, but I had no other choice. In fact, two patients died. I also knew that the other places would bill Medicare ten times more than I had been charging. I was reminded of the saying, "no act of kindness goes unpunished."

My medical practice collapsed again. Doctors started to leave one after the other, and eventually we had very few doctors left in the practice, and we had to trim the services we could offer our patients. We had to terminate many of our employees, and had about 60-65 people employed, down from 100-150 employees. We also had to close a medical center we had opened in Pahrump, a town outside Las Vegas. We had opened a clinic there because it badly needed more good doctors.

While the lawsuit was going on, I was so depressed, I couldn't face people again, so I just stopped going to the hospitals and would hide in my office. I was thinking about the lawsuit day and night, and trying to understand why the government had done this to me. I spent most of my time talking to my attorneys, trying to defend myself. Life became very hard again.

This time, the government told me that under the False Claims Act I would have to pay $22 million. The government calculated this by saying we had billed Medicare for 2000 stress tests, and they wanted a penalty of $11,000 for every test, which came to $22 million. And at the same time, we had charged Medicare only a few hundred thousand dollars for all these tests, and had lost money in performing the tests! It just made no sense. And I also knew that the government could kick me out of Medicare, Medicaid, and Tricare, and all the insurance carriers would also kick me out. I could lose my license, and be out on the street again.

But I refused to give in. I was convinced that we hadn't done anything wrong. We had simply helped our patients, and billed the way we were told to by the governmental agency. I know that in many cases doctors simply settle when they have to go through what I have gone through. Some lose their wives, they lose their children, they lose their houses, they lose their health, and they get depressed. Some end up in the street. Some doctors end up committing suicide, because they can't stand the bad press.

We tried to move forward quickly to have the case dismissed because it was absolutely without merit. Once again, I had a team of lawyers helping me. I had to hire an expert False Claims Act lawyer, a local law firm, and expert medical doctors. In the end, the government's case fell like a house of cards. The government's own expert, at Duke University, agreed that we had done everything right. With all the information that we were able to put together, we filed a motion for summary judgment, and the judge agreed with us and dismissed the entire case.

The government's lawsuit was so unjustified that we filed a motion to recover at least some of the legal costs. The judge agreed that the lawsuit was unjustified, and awarded me about $500,000 in attorneys' fees. This amount did not even come close to the entire amount of money I spent defending myself. I still spent over $2 million to defend myself, and none of this was reimbursed by insurance. And this amount did not cover the damage to my reputation, my mental health, and my family.

I still cannot imagine how something like this could have happened to me. I had worked hard, sixteen or seventeen hours every day. I worked every Saturday and every Sunday, every holiday. I still do that, because I am so obsessed with taking care of patients. That's why I became a doctor. And then the government can come in and file a lawsuit against you and destroy your reputation. They can tell the world, "You stole money from the government, you can't be a doctor, we're going to kick you out, and you have to give up all the money you have made in your whole life."

I went through this ordeal twice. I spent more than $6 million to defend myself. I lost my practice, my friends, my partners, and my dreams. I have been able to rebuild my practice again, up to 7 full-time physicians and about 50 employees. But I had wanted to do something bigger, and all those opportunities were lost forever because of the false accusations against me.

Reputation is so hard to get. What are you without your reputation?

I have come to Washington to testify because I do not want what happened to me to happen to other citizens in this country, and I have thought about how the False Claims Act can be changed. First, in my experience, there is no company or office without a disgruntled

employee. They can use the False Claims Act to ruin their employers' life, and I think that before employees try to file a *qui tam* lawsuit or report something to the government, they should have to tell their employer first.

Second, I think there should be some kind of program available that would benefit the government as well as doctors. The law should say that once doctors find out something is being done wrong, the amounts they owe to the government should be returned. Once a good citizen does that, he should not be afraid of anything further. The government should not be able to file a False Claims Act lawsuit then, because the government has recovered what it is owed without spending a penny.

Third, the government should be required to do a very thorough investigation and make sure all other courses of action are exhausted before filing a False Claims Act lawsuit. In my case, the U.S. Attorney's office did not do its homework, and I was falsely accused even though I was doing exactly what had I had been told to do by Medicare for many years. The government should investigate carefully especially when a disgruntled employee complains about their employer or files a *qui tam* lawsuit. For the defendant, being sued by the government amounts to having his life ruined.

Fourth, the amount of money that is demanded under the False Claims Act is absurd. Every time I used a billing code for a service for which the government paid me $50, they said I should pay $11,000 in penalties. That does not make any sense, and there are no doctors in America who can withstand such a threat. I think the law needs to be made more reasonable.

Finally, doctors who report and cooperate with the government, and give back any money they owe, should not be threatened with being kicked out of Medicare. They should be allowed to continue taking care of their patients, and they should not have their livelihoods taken away if they settle with the government. The punishment should fit the crime.

ATTACHMENTS

2 of 2 DOCUMENTS

UNITED STATES OF AMERICA, Plaintiff, vs. R.D. PRABHU, M.D. and R.D. PRABHULATA SHETE, M.D.'S, LTD., Defendants.

Case No. 2: 04-CV-0589-RCJ-LRL

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEVADA

442 F. Supp. 2d 1008; 2006 U.S. Dist. LEXIS 49690

July 19, 2006, Decided

SUBSEQUENT HISTORY: Costs and fees proceeding at *United States v.* ***Prabhu,*** *2007 U.S. Dist. LEXIS 81306 (D. Nev., Oct. 23, 2007)*

COUNSEL: [**1] For United States of America, Plaintiff: Roger W. Wenthe, U.S. Attorney's Office, Las Vegas, NV.

For R.D. **Prabhu,** M.D., R.D. **Prabhu**-Lata Shete, M.D.'s, Ltd., Defendant: C. Stanley Hunterton, Samuel B. Benham, Hunterton & Associates, Las Vegas, NV; Robert **Salcido**, pro hac vice, Akin Gump Strauss Hauer & Feld LLP, Washington, DC.

JUDGES: ROBERT C. JONES, UNITED STATES DISTRICT JUDGE.

OPINION BY: Robert Clive Jones

OPINION

[*1010] **ORDER**

THIS MATTER is before the Court on Defendants' Motion for Summary Judgment on the Government's Claims that Defendants' Simple Pulmonary Stress Tests Violated the False Claims Act (# 40), Defendants' Motion for Summary Judgment on the Government's Claims that Defendants' Medical Services were not Medically Necessary and Indicated (# 41), and Defendants' Motion for Summary Judgment to Dismiss the Government's Claim that Defendants Were Unjustly Enriched (# 42), all filed on November 9, 2005. A hearing on these motions was held on February 27, 2006. After extensive review of the record, [1] applicable law, and argument of the parties, I find that the Defendants' motion for Summary Judgment on the Government's claims that the Defendants violated the False Claims Act (# 40, [**2] # 41) should be GRANTED, and that the Defendants' motion for Summary Judgment regarding the Government's unjust enrichment claims (# 42) should also be GRANTED.

1 Citations to evidence presented at the oral argument or in prior written submission will be referenced using the following abbreviated citation forms: Exhibits that accompanied Defendants' Motion for Summary Judgment on the Government's Claims that Defendants' Simple Pulmonary Stress Tests Violated the False Claims Act ("Def. FCA Mem. Ex. "); Exhibits that accompanied Defendants' Motion for Summary Judgment on the Government's Claims That Defendants' Medical Services Were Not Medically Necessary and Indicated ("Def. Med. Nec. Mem. Ex. "); Exhibits that accompanied Defendants' Motion for Summary Judgment on the Government's Claims that Defendants' Were Unjustly Enriched ("Def. Unjust En. Mem. Ex. "); Government Complaint ("Gov. Compl."); Government's First Amended Complaint ("First Am. Compl."); Exhibits to Dr. **Prabhu's** Declaration ("Dr. **Prabhu** Decl. Ex: "); Exhibits that accompanied Defendants' Reply to the Government's Opposition to Defendants' Motion for Summary Judgment on the Government's Claims that Defendants' Simple Pulmonary Stress Tests Violated the False Claims Act ("Def. FCA Reply Ex: ")

[**3] **FINDINGS OF FACT**

Introduction

1. In this False Claims Act ("FCA"), *31 U.S.C. §§ 3729-3733 (2003)*, action, the Government alleged that Defendants R.D. **Prabhu,** M.D. and R.D. **Prabhu**-Lata Shete, M.D.'s, Ltd., knowingly submitted false claims to the Government by billing for simple pulmonary stress tests (monitored exercise in a structured setting to evaluate the patient's condition) when performed as part of a pulmonary rehabilitation program. *See* First Am. Compl. P13. Defendant R.D. **Prabhu,** M.D. ("Dr. **Prabhu**") is a Board Certified physician in [*1011] both Pulmonary and Internal Medicine. Defendant R.D. **Prabhu**-Lata Shete, M.D.'s, Ltd. is Dr. **Prabhu's** medical practice which is located at the Red Rock Medical Center in Las Vegas, Nevada.

2. On May 6, 2004, the Government filed its initial complaint against Dr. **Prabhu.** *See* Gov. Compl. In the complaint, the Government alleged that during the relevant time period, from January 1, 1998 to February 2, 2004, pulmonary rehabilitation, which consists of physical exercises by the patient to increase the functional capacity of the patient's lungs, was not a covered benefit under Medicare. [**4] *See* Gov. Compl. P13. The Government further contended that Dr. **Prabhu,** knowing that pulmonary rehabilitation was not covered under Medicare, unlawfully billed for a simple pulmonary stress test, under CPT 94620, instead. [2] *Id* at P16.

3. In February 2005, the Government filed its first amended complaint. *See* First Am. Compl. In this complaint, the Government included two additional allegations to its initial contentions that Dr. **Prabhu** breached the FCA because he billed for CPT 94620 when he provided non-covered pulmonary rehabilitation services. First, the Government alleged that Dr. **Prabhu** did not appropriately bill for a simple pulmonary stress test under Code 94620, because a physician could only bill for this code if he performed a pre and post-exercise spirometry and also prepared a written physician report interpreting the results of these services. *See* First Am. Compl. P13. Second, the Government contended that Dr. **Prabhu** failed to properly document the medical necessity of services to some of his patients. First Am. Compl. P14.

4. The Amended Complaint finally contended that Dr. **Prabhu** had been unjustly enriched by his allegedly unlawful behavior. *Id.* [**5] P25.

2 Regulations require that physicians' services and procedures be entered onto a prescribed Governmental form by using procedure codes published by the American Medical Association ("AMA"), known as Current Procedural Terminology ("CPT"). *Id.* P10. The AMA annually updates its CPT Manual to reflect both the advances in the practice of medicine and the changes in the delivery and definition of the various medical services and supplies.

Regulatory Background Regarding Services In Dispute

Pulmonary Rehabilitation Services

5. There are two basic services that frame the dispute underlying the Government's lawsuit: pulmonary rehabilitation services [3] and simple pulmonary stress tests. "Pulmonary rehabilitation," in essence, is a term of art that includes a number of health related programs and procedures, all of which are designed to increase a patient's pulmonary strength that, in turn, will improve the patient's quality of life and reduce the amount of medical resources needed to treat [**6] the patient's pulmonary disease. *See Pulmonary Rehabilitation,* 112 CHEST 1363 at 1364. Although each pulmonary rehabilitation program varies depending upon a patient's specific needs, each program will typically include exercise, education, and [*1012] monitoring the patient's response to the program. *See, e.g.,* Memorandum from Kathleen A. Buto, Deputy Director, Center for Health Plans and Providers to Director, Office of Clinical Standards and Quality, Def. FCA Mem. Ex. 4.

6. Medicare has long considered pulmonary rehabilitation programs to be a covered service under the "incident to physician services" clause of the Medicare Act, *42 U.S.C. § 1395(x) (2003).* In 1981, the Health Care Financing Administration (now known as the Centers for Medicare and Medicaid Services ("CMS")) Office of Coverage Policy stated that pulmonary rehabilitation services were in fact a covered Medicare service as long as the "reasonable and necessary" provisions indicative of all Medicare coverage are met. *See* American Association of Cardiovascular and Pulmonary Rehabilitation, Cardiac and Pulmonary Issue Paper: Cardiac & Pulmonary Rehabilitation Services, Def. FCA [**7] Mem. Ex. 5.

7. Various Medicare publications also demonstrate that pulmonary rehabilitation has long been an integral part of the diagnosis and treatment of pulmonary disease. *See, e.g.,* CMS Outpatient Physical Therapy Manual § 253.5A, Def. FCA Mem. Ex. 6; CMS Skilled Nursing Facility Manual 230.10C, Def. FCA Mem. Ex. 7.

8. In 1980, Congress established Comprehensive Outpatient Rehabilitation Facilities ("CORFs") as legitimate providers of rehabilitation services to Medicare beneficiaries. *See* Pub. L. No. 96-499, § 933, 94 Stat.

2609, 2637 (1980); *see also Nat'l Ass'n of Rehab. Facilities, Inc. v. Schweiker, 550 F. Supp. 357 (D.D.C. 1982)* (describing legislation). Congress identified pulmonary rehabilitation as one of those covered services. Moreover, consistent with the notion that Medicare has always covered pulmonary rehabilitation and/or its component parts, the Government elected to incorporate pulmonary rehabilitation into the National Emphysema Treatment Trial ("NETT"), a joint National Institute of Health ("NIH") and CMS effort to study lung volume reduction surgery which began on August 1, 1997. *See* Medicare Carrier Manual § 4900.1, Def. FCA [**8] Mem. Ex. 8. Medicare would only cover services that were integral to the NETT study and "[n]ot prohibited from coverage by Medicare statute." *Id.* § 4900.2. Because pulmonary rehabilitation was considered a covered service at that time, CMS elected to reimburse pulmonary rehabilitation services under the trial. *Id.*

9. From 1981-2000, Medicare generally continued to pay for pulmonary rehabilitation services, especially when enunciated through fiscal intermediary Local Medical Review Policies ("LMRPs"). [4] These LMRPs generally provided guidance to hospital outpatient departments that provided pulmonary rehabilitation services, outlining covered services, appropriate qualifying diagnoses and billing procedures. *See* Def. FCA Mem. Ex. 9.

10. Also, during this time period, some carriers permitted coverage for pulmonary rehabilitation by designating a specific code under which the component parts of pulmonary rehabilitation could be "bundled" into a single code. [5]

[*1013] 11. In 1998, the pulmonary medicine community (American College of Chest Physicians, American Thoracic Society, National Association for Medical Direction of Respiratory Care, American Association of Cardiovascular [**9] and Pulmonary Rehabilitation) began vigorous pursuit of the establishment of a national coverage policy for pulmonary rehabilitation to eliminate the differences among the various LMRPs that, in effect, provided different services for different Medicare beneficiaries. *See* Def. FCA Mem. Ex. 5.

12. In March, 2000, CMS circulated a memorandum to fiscal intermediaries that declared that there is no true benefit category for pulmonary rehabilitation programs. At the same time, CMS continued to assert that component parts of pulmonary rehabilitation programs may be appropriately billed under some circumstances:

> In some instances, Medicare may make payment under separate benefits for certain individual services such as certain physical or occupational therapy services that could be reasonable and necessary, assuming all other coverage criteria for physical or occupational therapy services were met. Some other services defined as components of pulmonary rehabilitation could be considered physician evaluation and management services under existing codes for physician services.

Memorandum from Kathleen A. Buto, Deputy Director, Center for Health Plans and Providers to Director, [**10] Office of Clinical Standards and Quality (Mar. 3, 2000). *See* Def. FCA Mem. Ex. 4.

13. Consistent with this CMS pronouncement, some carriers began to revise their policies to clarify that although pulmonary rehabilitation may no longer be covered, its component services may be covered. For example, on April 2, 2001, Empire deleted its May 2, 1998, LMRP, *see supra* note 5, and informed its regional providers that they should no longer use 94799 to bill for pulmonary rehabilitation, but listed fifteen other codes as "some" of the codes that providers could use to bill for the "components of pulmonary rehabilitation which represent the actual service[s] rendered." *See* Medicare News Brief - New Jersey at 3 (Apr. 2001), Def. FCA Mem. Ex. 13.

14. Moreover, consistent with the Government's recognition that pulmonary rehabilitation was medically necessary and appropriate, in late 2001, CMS published, as part of its hospital outpatient prospective payment update, new billing codes to be used primarily by respiratory therapists providing certain pulmonary rehabilitation services providing pulmonary-rehabilitation related services. Specifically, on November 1, 2001, CMS published [**11] an interim final rule which introduced three [*1014] new "G" codes which providers could use to bill for respiratory therapy services. [6]

15. On December 31, 2002, CMS published comments and corresponding responses generated through the publication of the interim final rule regarding the G codes. *67 Fed. Reg. 79,966, 79,999 (Dec. 31, 2002).* In its responses, CMS pointed out that the codes were necessary to provide more "specificity about the [pulmonary rehabilitation] services being delivered" and that the physicians could perform these services in an office setting:

> *Comment:* Commentators asked whether respiratory therapists would be precluded from using additional CPT codes to bill for their pulmonary-rehabilitation related services.

> *Response:* We reiterate that codes G0237, G0238, and G0239 were developed to provide more specificity about the services being delivered . . .

Id. at 79,999-80,000.

16. There is no dispute regarding these facts. The Government's own expert concurs that the Government covered pulmonary rehabilitation services in different settings and in different jurisdictions. *See* Deposition of Dr. MacIntyre, [**12] 14:1-16:17 (hereinafter "Dr. MacIntyre Dep."), Def. FCA Mem. Ex. 1 (pulmonary rehabilitation covered in comprehensive rehabilitation facilities, as part of the National Emphysema Treatment Trial, under the "G" Codes, and under some carrier LMRP). Further, both the Government's expert and the carrier's Medical Director concur that Medicare has always covered the component parts of pulmonary rehabilitation - such as pulmonary stress tests. *See* Dr. MacIntyre Dep. at 16:6-10; *see also,* Deposition of Dr. Mangold, 25:3-20 (hereinafter "Dr. Mangold Dep."), Def. FCA Mem. Ex. 2. Dr. Mangold, the carrier's Medical Director, additionally confirmed that it never issued a LMRP that prohibited physicians from billing for pulmonary rehabilitation or its component services. *See* Dr. Mangold Dep. at 12:4-14; 14:5-17.

3 Pulmonary rehabilitation was originally described by the American College of Chest Physicians in 1974 as follows:

> Pulmonary rehabilitation may be defined as an art of medical practice wherein an individually tailored, multi-disciplinary program is formulated, which through accurate diagnosis, therapy, emotional support and education, stabilizes or reverses both the physical and psychopathology of pulmonary diseases and attempts to return the patient to the highest possible functional capacity allowed by the pulmonary handicap and overall life situation.

See Andrew L. Ries et al., *Pulmonary Rehabilitation,* 112 CHEST 1363, 1364 (Nov. 1997).

[**13]

4 LMRP's, which are now known as Local Coverage Determinations, set regional coverage determinations that govern in the absence of or as an adjunct to a national policy. *See 68 Fed. Reg. 63,692, 63,693 (Nov. 7, 2003).*

5 For example, on May 2, 1998, Empire Medicare Services ("Empire"), the Medicare carrier for New Jersey, adopted an LMRP that allowed physicians within its region to bill Medicare for outpatient pulmonary rehabilitation programs performed in a physician's office using code 94799, which is defined as "unlisted pulmonary service of procedures." *See* LMRP -- Empire Medical Services, Outpatient Pulmonary Rehabilitation Programs, # G-17B ("Outpatient pulmonary rehabilitation should be billed under CPT code 94799 and identified as outpatient pulmonary rehabilitation. Unit billed is one per daily session"), Def. FCA Mem. Ex. 9; *see also* Medicare Xact Medicare Report, Outpatient Pulmonary Rehabilitation Programs (G-17A) (Mar. 1998) (same), Def. FCA Mem. Ex. 10; LMRP [Part B] -- First Coast Service Options, Inc., Pulmonary Rehabilitation 94799 (policy originally established in 1998), Def. FCA Mem. Ex. 11; LMRP [Part B] -- Palmetto GBA -- OH, WV, Pulmonary Rehabilitation # 2002-33LR3 (policy originally established in 1997), Def. FCA Mem. Ex. 12. These LMRPs also provided regional guidelines for providers when billing 94620 -- the simple stress test -- when performed during the course of a pulmonary rehabilitation program. *See* LMRP -- Empire, Def. FCA Mem. Ex. 9.

[**14]

6 CMS acknowledged that the new G codes were necessary because "[i]n the past, services delivered by respiratory therapists or other health professionals often have not been clearly described by existing CPT codes." *66 Fed. Reg. 55,246, 55,311 (Nov. 1, 2001).* Thus, the new G codes were being introduced "[i]n order to clarify coding of these services . . . ." *Id.* The new G codes were:

> G0237 Therapeutic Procedures To Increase Strength or Endurance of Respiratory Muscles, Face to Face, One on One, Each 15 Minutes (including monitoring).
>
> G0238 Therapeutic Procedures To Improve Respiratory Function, Other Than Those Described by G0237, One on One, Face to Face, per 15 Minutes (including monitoring).
>
> G0239 Therapeutic Procedures To Improve Respiratory

> Function, Two or More Patients Treated During the Same Period, Face to Face (includes monitoring).

Id.

Pulmonary Stress Tests

17. In 1991, the AMA defined CPT Code 94620 as follows:

> **94620** Pulmonary stress testing, simple or complex

Current Procedural Terminology, Fourth Edition, [**15] American Medical Association (1991), Def. FCA Mem. Ex. 14. At this point, there was no express indication that a pre and post-exercise spirometry or a written physician report is required.

18. The record reflects that in 1998, the AMA, through its publication, the CPT ASSISTANT, which provides guidance to the physician community regarding the proper scope and interpretation of the CPT, announced that Code 94620 would again be revised to distinguish between [*1015] two common types of pulmonary stress tests: one which would include spirometry and one which would not:

> Code 94620 was revised to more accurately distinguish the two types of pulmonary stress testing. Code 94620 includes a simple exercise test performed with a baseline spirogram, in which the patient walks on a treadmill until dyspnea occurs, with a repeat spirogram obtained for the evaluation of exercise-induced bronchospasm. This procedure may alternatively be performed to include a six-minute walk to evaluate distance, dyspnea, oxyhemaglobin desaturation, and heart rate. This test is usually repeated after a rest period. However, this additional testing when performed is considered inclusive and does not alter the reporting [**16] of code 94620. Physician analysis of data and interpretation of the test are procedurally inclusive components of this code.

Coding Changes, Review of 1999 CPT, CPT ASSISTANT, Nov. 1998:35, Def. FCA Mem. Ex. 15.

19. Consistent with the 1998 announcement, the CPT was revised in 1999 to contain the following descriptor for Code 94620:

> Pulmonary stress testing; simple **(e.g., prolonged exercise test for bronchospasm with pre and post-spirometry)**.

CURRENT PROCEDURAL TERMINOLOGY 1999 (emphasis supplied), Def. FCA Mem. Ex. 16.

20. The record further reflects explanatory comments published at the same time in the CPT ASSISTANT. The CPT ASSISTANT sets forth Vignettes that are intended to guide practitioners regarding circumstances under which they may properly bill Codes identified in the CPT. *See* Current Procedural Terminology (CPT) Assistant, Pulmonary Testing Function, American Medical Association. Def. FCA Mem. Ex. 18. Notably, one of the two Vignettes describing CPT Code 94620 expressly does not include a pre and post-exercise spirometry. Specifically, the CPT ASSISTANT provides the following two Vignettes:

> **Vignette # 1:** A 65-year old woman [**17] is seen because of dyspnea and cough after walking several city blocks. She has a normal physical examination and a spirogram is normal. A simple exercise test is performed with baseline spirogram. She walks on a treadmill until dyspnea occurs and a repeat spirogram is obtained to evaluate for exercise induced bronchospasm.
>
> **Vignette # 2:** A 65-year-old woman with documented COPD is evaluated for entrance into a pulmonary rehabilitation program. A six minute walk is performed to evaluate distance, dyspnea, oxyhemoglobin, desaturation and heart rate. The test is usually repeated after a rest period to eliminate learning bias (but reported as one test).

Id.

21. The undisputed facts indicate that the services that Dr. **Prabhu** provided to his patients during pulmonary rehabilitation treatment sessions are consistent with those described in Vignette # 2: patients received a walk test to evaluate distance, dyspnea, oxyhemoglobin, and heart rate. *See, e.g.,* Aff. of Darrall Mitz P7, Def. FCA Mem. Ex. 19; Aff. of Teida Cark P9, Def. FCA Mem. Ex. 36; Aff. of Adiba Schiefer P11, Def. FCA Mem. Ex. 38.

22. The record also reflects that the CPT ASSISTANT recently confirmed [**18] that pre and post-exercise spirometry is not required when billing for a simple stress test. There, in response to a question regarding whether a spirometry must be performed to bill for a pulmonary stress [*1016] test, the CPT ASSISTANT reaffirmed that it does not:

> **Question:** A physician performs a 6-minute walk on a patient to assess oximetry, heart rate, dyspnea, and distance reached in 6 minutes. The physician analyzes the data and interprets the test results. If the physician does not perform a spirometry as a baseline for the procedure, is it still appropriate to report code 94620.
>
> **AMA Comments:** From a CPT coding perspective, code 94620, *Pulmonary stress testing; simple (eg, prolonged exercise test for bronchospasm with pre-and post-spirometry),* may be reported to describe the procedure. Code 94620 includes a simple exercise test performed with a baseline spirogram, in which the patient walks on a treadmill until dyspnea occurs, with a repeat spirogram obtained for the evaluation of exercise-induced bronchospasm. This procedure may alternatively be performed to include a 6-minute walk to evaluate distance, dyspnea, oxyhemoglobin desaturation, and heart rate. [**19] This test is usually repeated after a rest period. However, this additional testing when performed is considered inconclusive and does not alter the reporting of code 94620. Physician analysis of data and interpretation of the test are procedurally inclusive components of this code. Therefore, code 94620 may be reported if either of the testing methods are performed.

Coding Consultation: Questions and Answers, CPT ASSISTANT, Mar. 2004:10, Def. FCA Mem. Ex. 20. [7]

23. The latest explanatory guidance in the CPT ASSISTANT conclusively contradicts the proposition that billing for CPT Code 94620 requires a pre and post-exercise spirometry. Indeed, even the Government's own expert concurred. Specifically, after being asked to review the Government's operative complaint and state whether he agreed or disagreed that CPT 94620 required any pre and post-exercise spirometry, Dr. MacIntyre stated that he believed it was not mandated. *See* Dr. MacIntyre Dep. at 11:10-12:2, Def. FCA Mem. Ex. 1.

Reasonable Persons Can Disagree About Billing Requirements

24. The parties' various contentions demonstrate that at a minimum, reasonable persons can disagree regarding the billing requirements [**20] underlying pulmonary rehabilitation and simple stress tests.

25. The record indicates that Medicare has failed to issue specific guidance regarding the precise type of documentation that must exist to document the provision of pulmonary rehabilitation or the provision of a simple stress test. *See* Dr. Mangold Dep. at 23:2-6 ("Q.Are you aware of any particular guidance that Nevada Part B has issued that requires a prescribed physician interpretation of some form to [*1017] exist in order to bill for 94620? A. No."); *see also* Dr. MacIntyre Dep. at 26:25-27.

26. The record also specifies that there is no physician written requirement for purposes of documenting CPT 94620 claims. *See* Deposition of Scott Manaker at 76:10-14 (hereinafter "Dr. Manaker Dep."), Def. FCA Reply Ex. A. ("Q. With respect to documentation of 94620, is it your opinion that the code requires a specific type of physician written interpretation? A. No.").

27. Indeed, a number of facts demonstrate the general confusion regarding the appropriate circumstances under which a physician could bill for a simple stress test. First, the Government and its own expert disagree regarding the extent that pulmonary rehabilitation [**21] has historically been covered by Medicare. *See* PP 6-16. Second, the Government and its own expert disagree regarding whether a pre and post-exercise spirometry is required to bill under CPT 94620. *See* PP 17-23. Third, the Government's lead medical reviewer, Carol Whitby, and the carrier Medical Director, Dr. Mangold, both misread the CPT ASSISTANT to require a pre and post-exercise spirometry when the CPT ASSISTANT itself clarified that no such requirement existed. *See* Deposition of Carol Whitby at 57:12-64:5 (hereinafter "Whitby Dep."), Def. FCA Mem. Ex. 17; Dr. Mangold Dep. at 18:22-22:14. Fourth, the Government's lead medical reviewer, Ms. Whitby, approved several of Dr. **Prabhu's** claims under CPT 94620 that did not include a pre and post-exercise spirometry and prescribed physician report that should have been disapproved if the Government's allegations had any merit. *See* Whitby Dep. at 28:1-35:5. Fifth, Ms. Whitby confessed that even after completing her written review of Dr. **Prabhu's** medical records that a "fair characterization" would be that she still did not know "everything that a pulmonary stress test entailed" and that even trained certified coding

specialists, [**22] such as herself, can legitimately experience confusion when choosing an appropriate code. *Id.* at 48:2-6, 55:7-16. Sixth, Dr. Mangold, the carrier Medical Director, when asked whether the governing guidance was ambiguous conceded that "yeah, I would agree with that." Dr. Mangold Dep. at 22:11-14. Seventh, the Government's own expert, Dr. MacIntyre, admitted that "there's lots of confusion in this area." Dr. MacIntyre Dep. at 33:20-23.

> 7 In 2005, the CPT ASSISTANT again clarified that no pre and post-exercise spirometry was required to bill for CPT 94620:
>
> > **Question:** In reference to this March CPT ASSISTANT Q&A, our question concerns the word *alternatively* in the answer statement. Specifically, does this mean that a baseline and repeat spirogram are not required when the alternative 6-minute walk test is performed? Our interpretation is that it is appropriate to report code 94620 when a 6-minute walk test is performed to evaluate distance, dyspnea, oxyhemoglobin desaturation, and heart rate even though no pre- and post-spirometry performed. Is our interpretation correct.
> >
> > **AMA Comments:** Yes, your interpretation is correct. A 6-minute walk test is appropriately reported with code 94620. **Spirometry is not required for the reporting of code 94620 with a 6-minute walk test.**
>
> Coding Consultation: Questions and Answers, CPT ASSISTANT, July 2005:13 (emphasis added), Def. FCA Mem. Ex. 21.

[**23] **Medicare Instructed Dr. Prabhu to Bill for Simple Stress Tests When Providing Pulmonary Rehabilitation Sessions**

28. Beginning in the early 1990's, Dr. **Prabhu** and his staff, on multiple occasions, reached out to his carrier to receive instructions regarding billing for the pulmonary stress tests he provided to patients. The record is replete with undisputed evidence of these communications.

29. In approximately August, 1991, a representative from the Medicare carrier visited Dr. **Prabhu's** clinic. *See* Aff. of Dennis Falls, PP 5-8 (hereinafter "Falls Aff."), Def. FCA Mem. Ex. 22. [8] The carrier visited to review Dr. **Prabhu's** billing charts and medical records and to answer any billing questions he, his physicians, or his employees asked. *See* McKeon [*1018] Aff., P4; Schlacter Aff., P4; Nelson Aff., P4. During that visit, Dr. **Prabhu** described the pulmonary rehabilitation services he provided. *See* Falls Aff., PP 6-8; *see also* Mitz Aff., PP 5-7. While describing the pulmonary rehabilitation services, Dr. **Prabhu** walked the carrier representative through the pulmonary lab area so he could show her first hand the exercise and monitoring equipment he used during a pulmonary rehabilitation [**24] session. *See* Falls Aff., PP 6-8. After touring the pulmonary lab and hearing the services described, the carrier representative identified several codes and instructed Dr. **Prabhu** to use those codes when billing Medicare for pulmonary rehabilitation services. One of those codes was 94620, the code for a simple stress test. *Id; see also* Schlacter Aff., PP 8-9; McKeon Aff., PP 5-7. The carrier representative instructed Dr. **Prabhu** that 94620 satisfied the description for the monitored exercise portion of the pulmonary rehabilitation services he provided. After the carrier's visit, Dr. **Prabhu** began scheduling pulmonary rehabilitation sessions for his Medicare patients. *See* Mitz Aff., P9.

30. By 1992, Dr. **Prabhu's** medical and billing records -- records that, as will be described below, were under intense scrutiny by the Government -- clearly identified a "pulmonary rehabilitation program" as a service being provided by Dr. **Prabhu.** *See* 10/22/92 Lung Institute of Nevada Pulmonary Function Scheduling Form, Def. FCA Mem. Ex. 30. Thus, the record indicates that as early as 1992, the Government had a basis to know that Dr. **Prabhu** was providing pulmonary rehabilitation services [**25] and that he was billing Medicare for the component parts of those services. *See id.*

31. The Government's own work papers reveal that it was aware of previous education that Dr. **Prabhu** had received from Aetna, the Government Medicare carrier during this time period. *See* Deposition of Cindy Hicks at 28:1-25, 54:24-55:8, Def. FCA Mem. Ex. 31.

32. Even after the initial contact with the carrier, Dr. **Prabhu's** staff continued to make inquiries to Medicare and its representatives regarding the proper coding for pulmonary rehabilitation services. [9]

33. The stress test billings as part of the pulmonary rehabilitation services continued through 1994, 1995, and 1996. *See* McKeon Aff., PP 6-7; Aff. of Kim Brown, P6 (hereinafter "Brown Aff."), Def. FCA Mem. Ex. 33. In 1997, the carrier again informed Dr. **Prabhu** that he

was authorized to bill Medicare for a simple stress test when performed as a component part of a pulmonary rehabilitation session. [10] [*1019] Moreover, Medicare continued to approve payments for the simple stress tests that were given during a patient's pulmonary rehabilitation program.

34. In 1998, as the simple stress test billings continued, Dr. **Prabhu** retained Silverwood [**26] Management Group ("Silverwood") to process his billing claims, including his Medicare claims. *See* Aff. of Robert Kinkade, P9 (hereinafter "Kinkade Aff."), Def. FCA Mem. Ex. 35. Dr. **Prabhu** chose Silverwood because it had a reputation as a company that employed claims processors who were competently trained and sufficiently experienced to review the claims before submission to confirm that the claims were accurately coded and that Medicare covered the services. *Id.* PP 6-8. After retaining Silverwood as his claims processor, Dr. **Prabhu** decided to revise his standard bill yet again. [11]

35. Medicare's approval of simple stress test billings as a component part of pulmonary rehabilitation came from other sources as well during that time. In 1998, Ms. Kim Williams, Dr. **Prabhu's** former billing manager, attended a seminar Medicare conducted in Phoenix, Arizona. *See* Williams Aff., P7. Medicare scheduled the seminar to discuss billing and coding issues with Medicare providers and their staff. One of the seminar's sessions allowed for a question and answer period by a panel of speakers from Medicare. During that session, one of the attendees sought advice from the Medicare panel [**27] as to which codes to use when billing for pulmonary rehabilitation services. The attendee described the pulmonary rehabilitation services in a manner that was the same as the pulmonary rehabilitation services that Dr. **Prabhu** provided. *Id.* P8. After describing the services, the attendee asked whether the code for a simple stress test could be used to bill for a part of the pulmonary rehabilitation services. The entire panel concurred that it was appropriate to bill for a simple stress test performed as part of pulmonary rehabilitation. *Id.*

36. The record indicates that from 1999 into 2004, Dr. **Prabhu** continued to bill Medicare for the simple stress tests that were performed to monitor patients during their pulmonary rehabilitation session. *See, e.g.,* Clark Aff., PP 7-12. Consistent with the years from 1991 through 1998, from 1999 to 2004, Medicare approved Dr. **Prabhu's** simple stress test claims without question.

37. Based upon inquiries received from the Government's program integrity carrier in 2003, Dr. **Prabhu,** and his billing staff, began to realize, for the first time, that there might be some question or problem [*1020] related to his 94620 billings. As a result, he instructed [**28] his billing staff to yet again contact the carrier to discover whether any problems existed regarding his simple stress test billings. The carrier again informed Dr. **Prabhu** that his billing of 94620 was proper and that he could bill 94620 once per day per patient within the pulmonary rehabilitation setting. *See* Clark Aff., PP 9-12; *see also* Dep. of Teida Clark at 17:19-19:10, 24:5-27:5 (hereinafter "Clark Dep."), Def. FCA Mem. Ex. 37.

38. Notwithstanding the carrier's advice, on February 2, 2004, Dr. **Prabhu** received a letter from the United States Attorneys Office alleging that he was violating the FCA by performing pulmonary rehabilitation and billing for a pulmonary stress test. Upon receipt of that letter, Dr. **Prabhu's** agents again inquired of the carrier regarding whether there were any problems with his stress test billings and were told that they were billing correctly. *See* Clark Dep. 24:5-27:13; Clark Aff. P10.

39. The evidence indicates that Dr. **Prabhu** made one final attempt to seek the carrier's advice on this issue. On May 10, 2004, Ms. Teida Clark, Dr. **Prabhu's** Billing Supervisor, in the presence of Adiba Schiefer, one of her claims processors, again called [**29] the carrier to ask whether simple stress tests could be billed within the context of pulmonary rehabilitation services. After hearing a description of the services, the carrier told Ms. Clark that 94620 was correctly being billed. *See* Clark Aff., P2; *see also* Aff. of Adiba Shiefer, PP 10-14 (hereinafter "Schiefer Aff."), Def. FCA Mem. Ex. 38. The carrier also informed Ms. Clark that the simple stress test could be billed within the pulmonary rehabilitation setting once per day per patient. *See* Clark Aff., P12. When asked whether the carrier was willing to confirm its advice in writing, it declined to do so. *Id.* P14.

40. To summarize, the undisputed facts reflect that for thirteen years Medicare advised Dr. **Prabhu** that he was allowed to bill for the simple stress test component of pulmonary rehabilitation services.

8 *See also,* Aff. of Judy Kanizai, PP 3-5 (hereinafter "Kanizai Aff."), Def. FCA Mem. Ex. 23; Aff. of Maureen McKeon, PP 4-7 (hereinafter "McKeon Aff."), Def. FCA Mem. Ex. 24; Aff. of Dr. Michael Schlacter, PP 4-10 (hereinafter "Schlacter Aff."), Def. FCA Mem. Ex.25; Aff. of Beverly Nelson, P4 (hereinafter "Nelson Aff."), Def. FCA Mem. Ex. 26; Mitz Aff., PP 4-10; Dep. of Siuresh Khilnani at 8:20-10:20(hereinafter "Khilnani Dep."), Def. FCA Mem. Ex. 27.

[**30]

9 For example, in 1993, Dr. **Prabhu's** billing supervisor, DeAnna Sulzinger, traveled to Phoenix, Arizona, to visit with Ms. Sonja Campbell, the Provider Relations/Claims Representative for the Medicare carrier. *See* Aff. of Deanna Sul-

zinger, P9 (hereinafter "Sulzinger Aff."), Def. FCA Mem. Ex. 32. Ms. Sulzinger's discussions with Ms. Campbell focused, in large part, on the pulmonary function tests ("PFT") billings that were being performed in Dr. **Prabhu's** pulmonary lab, including the PFT billings that were used to monitor the pulmonary rehabilitation patients. *Id.*, P11. Ms. Sulzinger recalls describing the pulmonary rehabilitation services to Ms. Campbell, including the monitoring component of the services, such as the simple stress test. *Id.*, P10. After providing the description, Ms. Sulzinger was informed that she could use the simple stress test code when billing for the pulmonary rehabilitation services. *Id.* Although there were questions and issues surrounding various other PFT billing issues, the carrier representative never questioned how pulmonary rehabilitation services were being performed or billed. *Id.*, PP 10-11.

10 The confirmation that he was correctly billing the simple stress test component of pulmonary rehabilitation services occurred during a telephone conversation between Ms. Atkins, Dr. **Prabhu's** respiratory therapist, and the carrier. Ms. Kim Williams, Dr. **Prabhu's** former Billing Supervisor, was present with Ms. Atkins during that conversation. At that time, Ms. Atkins specifically referred to "pulmonary rehab classes," when describing the various services being provided. *See* Atkins Aff., PP 8-11; Aff. of Kim Williams, PP 4-6 (hereinafter "Williams Aff."), Def. FCA Mem. Ex. 34. After listening to the description of the "pulmonary rehab classes" the carrier instructed Ms. Atkins that it was appropriate to bill Medicare using code 94620, the code for a simple stress test. *Id.*

[**31]

11 During the revision process, Ms. Teida Clark, a Silverwood employee, contacted the Medicare carrier to discuss various billing and coding issues, including the billings for the simple stress tests that were performed as a component part of the pulmonary rehabilitation services. *See* Aff. of Teida Clark, P7 (hereinafter "Clark Aff."), Def. FCA Mem. Ex. 36. Although Ms. Clark cannot recall the specifics of the discussions, she does know that if the carrier had not approved the simple stress test billings, she would have immediately ceased submitting any future claims for the simple stress tests when performed as a component part of pulmonary rehabilitation. *Id.*, P8.

The Medical Necessity Of Dr. Prahhu's Claims

41. In its amended complaint, the Government alleged that the pulmonary rehabilitation services provided by Dr. **Prabhu** were "not medically indicated and necessary for the patients involved, because no further improvement in lung function could reasonably be expected for those patients at the time the services were rendered." *See* First Am. Compl. P14. In this regard, [**32] the Government contended that the certifications made on Form HCFA 1500 (that the services provided were medically reasonable and necessary) were false. *Id.*

42. The record is replete with evidence of the medical necessity of the pulmonary rehabilitation services given to Dr. **Prabhu's** patients. [12] To be admitted into Dr. **Prabhu's** pulmonary rehabilitation program, patients must have various types of respiratory diseases such as chronic obstructive lung disease ("COPD"), emphysema, chronic bronchitis, persistent asthma or other type of chronic respiratory system impairment that limit exercise and [*1021] their ability to engage in activities of daily living- such as brushing their teeth, taking a shower or preparing their food. *See* Deposition of Rachakonda D. **Prabhu,** M.D., at 23:20-24:10 (hereinafter "Dr. **Prabhu** Dep."), Def. Med. Nec. Mem. Ex. 1. Even as to the diagnoses listed above, however, Dr. **Prabhu** did not admit all patients who had been diagnosed with respiratory disease. Rather, only a very small percentage of patients were admitted that, among other things: (1) exhibited disabling symptoms which significantly impaired the patient's level of functioning, (2) was physically able [**33] and motivated to participate; and (3) was expected to demonstrate measurable improvement. *See generally id.*, at 23:18-28:19.

43. Dr. **Prabhu** provided patients admitted to his pulmonary rehabilitation program with each of the component parts of pulmonary rehabilitation - education, exercise, and monitoring. As part of the education component, a multidisciplinary team of health care professionals educated patients regarding the anatomy of the disease, the pathology of the disease, and the pharmacology of the disease. *Id.* at 26:1-28:19. As to the exercise component, Dr. **Prabhu** exercised the patients on a treadmill, hand ergometer and bicycle. *See generally id.* at 40:4-40:23. As to monitoring the patient, a professional, certified respiratory therapist and/or Dr. **Prabhu** would be physically present during the exercise to monitor the patient's dyspnea (shortness of breath), oxyhemoglobin desaturation and heart rate and to document and measure the patient's performance to determine whether the patient was making progress toward the ultimate goal of assisting the patient obtain the highest possible level of independent function. *Id.* at 48:6-49:2.

44. After each session, Dr. [**34] **Prabhu** would review the respiratory technician's comments, as well as the time, distance, and how many machines were used.

He would then compare those results to the patient's prior sessions to evaluate the patient's condition in the context of the patient's diagnosis. Dr. **Prabhu** Dep. at 48:6-49:2. Based upon that review, Dr. **Prabhu** decided whether the patient needed another test or another session and would document his findings accordingly. *Id.* In providing pulmonary rehabilitation sessions, Dr. **Prabhu's** goal was for the patient to obtain the highest possible level of independent function. *Id.* at 35:15-35:20.

45. Moreover, even the Government itself did not assert that Dr. **Prabhu** provided ineffective or worthless services to his patients. Dr. MacIntyre, the Government's own expert, for example, and a professor of Medicine at Duke University Medical Center, agreed that "[e]xercise therapy is a major component of a pulmonary rehabilitation process that is effective in improving function and quality of life [for] patients." Gov't Expert Report of Dr. Neil MacIntyre. Additionally, after reviewing Dr. **Prabhu's** patient care records from 1/1/99 to 2/2/04, Dr. MacIntyre ultimately [**35] opined that "[e]xercise therapy [was] ... medically appropriate therapy" for Dr. **Prabhu's** patients. *Id.*

46. A second Government expert, Deborah Grider, however, opined that some services provided to a very small percentage of Dr. **Prabhu's** patients were not appropriately *documented* as medically necessary. *See* Deposition of Deborah Grider (hereinafter "Grider Dep."), Def. Med. Nec. Mem. Ex. 5. Specifically, Ms. Grider opined that as to the 254 patients that received pulmonary stress tests during the time period, that 14 patients, or 5.5% of the total, received pulmonary rehabilitation services that were not sufficiently documented in the medical record.

[*1022] 47. To determine the appropriate documentation standard to determine whether the pulmonary rehabilitation sessions were appropriately documented, Ms. Grider used a California LMRP, because Nevada did not have any controlling standard. *See* Grider Dep. at 20:8-25. Both Ms. Grider and the Nevada carrier Medical Director, Dr. Mangold, state in the record, however, that the California LMRP would never dictate how a Nevada physician should document his service. [13]

48. Although Ms. Grider opined regarding the documentation [**36] standard applicable to a small percentage of Dr. **Prabhu's** patients, she expressly disclaimed the ability to opine regarding whether services were clinically medically necessary and indicated, because she lacks formal medical training and is not a physician. *See* Grider Dep. at 37:24-38:4; 59:2-5 ("Q. But you certainly don't agree with his clinical opinion in here? A. Clinically, I can't - I can't agree or disagree. I'm not a physician"); *see also id.* at 66:7-13; 88:17-21 ("Q. What was the specific issue you were requested to opine upon? A. I was asked to give my opinion regarding medical necessity, documented medical necessity, not clinical medical necessity").

49. Thus, the only issue here is not whether the services were in fact provided or whether they were clinically medically necessary and indicated and benefited the patient but only whether the services provided to fewer than 5.5 percent of all relevant patients should have been documented differently. [14] Ms. Grider stated in the record that general documentation guidelines, such as the 1997 Evaluation and Management Services guidelines, should govern the documentation of the services in dispute in this lawsuit. The [**37] same record reflects that those Guidelines are satisfied even if the service provided is not documented as long as "the rationale for ordering diagnostic and other ancillary services [are] easily inferred." *See* 1997 Documentation Guidelines for Evaluation and Management Services, Def. Med. Nec. Mem. Ex. 7.

50. There is no dispute that services were provided and those services were clinically medically necessary and indicated. There is, for example, no allegation that Dr. **Prabhu** fabricated the hospital (or other medical) records documenting how extremely ill the patients were or that he did not provide pulmonary rehabilitation [*1023] services to these acutely ill patients. There is also no dispute that neither the Nevada carrier nor CMS had issued any guidelines regarding how to document the monitored exercise furnished as part of a pulmonary rehabilitation program.

12 Dr. **Prabhu's** Declaration included excerpts from the records of fourteen patients. *See* Dr. **Prabhu** Decl., PP 7-79. Each excerpt refers to patient diagnoses as well as the reasons that pulmonary rehabilitation therapy was medically necessary and indicated. The record reflects patient improvement in each case, a result of the pulmonary rehabilitation therapy. *See also,* Decl. of Clement Y., Osei, M.D., P6 (hereinafter "Dr. Osei Decl."), Dr. **Prabhu** Decl. Ex. 9; Decl. of Paul A. Stewart, M.D., P4 (hereinafter "Dr. Stewart Decl."), Dr. **Prabhu** Decl. Ex. 4.; *see also* Dep. of Scott Manaker, M.D., Ph.D. at 64:14-65:11 (hereinafter "Dr. Manaker Dep."), Def. Med. Nec. Mem. Ex. 8.

[**38]

13 For example, when asked whether she would "ever inform a client that guidelines from another state are binding on that client," Ms. Grider expressly stated that "[n]o, I would not." Grider Dep. 25:18-21. Similarly, Dr. Mangold, when asked whether "guidance issued by Fiscal Intermediaries Part A [is] ever binding with re-

spect to Part B providers and suppliers," responded "[n]ever." Dr. Mangold Dep. at 36:16-20.

Part A of Medicare authorizes payments primarily for "inpatient hospital services, nursing home and hospice care and, in some instances home health services." *See 42 U.S.C. § 1395c-1395i-4, see generally United States ex rel. Drescher v. Highmark, Inc., 305 F. Supp. 2d 451, 453-54 (E.D. Pa. 2004)*. Part B of Medicare, which is relevant here, pays for physicians' services, outpatient hospital services, and certain durable medical equipment. *See 42 U.S.C. § 1395j-1395w-4*. CMS contracts with private companies to handle claims processing responsibilities. Private insurance companies that process the bulk of Medicare Part B claims are referred to as carriers and private insurance companies that process the bulk of Medicare Part A claims are known as fiscal intermediaries. *See Highmark, 305 F. Supp. 2d at 454* (describing programs).

[**39]

14 Ms. Grider stated that other than the patients she opined received services that were not appropriately documented (that is, the 5.5%), the remainder of patients had services that were appropriately documented (that is, the remaining 94.5%). *See* Grider Dep. at 20:5-7.

Dr. Prabhu Lost Substantial Money in Providing Pulmonary Rehabilitation To His Patients

51. Finally, the unrebutted evidence shows that Dr. **Prabhu** lost substantial money in providing pulmonary rehabilitation to his patients but provided these services because of the substantial health benefit his patients obtained. *See* Def. Unjust En. Mem PP 6-10.

52. Specifically, the record reflects that certified public accountant, George C. Swarts, examined all payments the clinics received from patients, their private insurers, and Medicare during 2002 and 2003. The practice received $ 122,399.83 in payments in 2002 and $ 74,594.43 in 2003. The collected revenue during these two years was $ 196,994.26. *See* Expert Reports of George C. Swarts at Ex. 3, p. 1 (hereinafter "Swarts Ex. Report"), Def. Unjust En. Mem. Ex. 5.

[**40] 53. However, the practice's costs exceeded this revenue. Specifically, Mr. Swarts determined the practice's costs by examining its direct costs (such as purchases & supplies; payroll & payroll expenses; health insurance) and its indirect costs (such as utilities for power and phone; rent; malpractice insurance). The total costs were $ 226,803.03 in 2002 and $ 198,104.75 in 2003. *See* Swarts Ex. Report. Consequently, the analysis demonstrates that as a result of furnishing pulmonary rehabilitation services, Dr. **Prabhu's** practice lost approximately $ 104,403 ($ 122,399.83 in payments versus $ 226,803.03 in expense) in 2002 and approximately $ 123,510 ($ 74,594.43 in payments versus $ 198,104.75 in expense) in 2003. *Id.*

54. In February 2004, as a direct result of this lawsuit, Dr. **Prabhu** ceased providing pulmonary rehabilitation to his patients.

The Government's Criminal and Civil Fraud Investigation During the 1990's

55. During the 1990s, Dr. **Prabhu** was the target of an ongoing criminal investigation. As part of the investigation, Dr. **Prabhu's** Medicare claims were being closely reviewed, including his "PFT" claims, such as the simple stress test. *See, e.g.*, Sulzinger [**41] Aff., P5.

56. Active in that investigation was the Federal Bureau of Investigation, the Health and Human Services Office of Inspector General ("OIG"), and the State of Nevada's Medicaid Fraud Control Unit ("MFCU"). (All three investigations are hereinafter collectively referred to as the "Criminal Investigation"). *See* Def. FCA Mem. P56.

57. During the Criminal Investigation, Dr. **Prabhu's** Medicare and Medicaid medical records and corresponding billing claims were placed under extreme scrutiny. *See, e.g.*, Sulzinger Aff., P5. For example, the FBI recruited potential witnesses to wear body wires so they could secretly record their conversations with Dr. **Prabhu.** *See* Memorandum from Edward Jenkins, Acting Special Agent, FBI to Leland Lufty, Acting United States Attorney, Def. FCA Mem. Ex. 40. Dr. **Prabhu's** telephone lines were tapped and his conversations recorded. *Id.* The FBI, alone, conducted at least forty-two witness interviews seeking information about Dr. **Prabhu's** billing practices. *See* Witness Summary, Def. FCA Mem. Ex. 41.

58. By October, 1992, Dr. **Prabhu** was the target of a grand jury investigation [*1024] into his Medicare billings. *See* Letter from Charles Kelly, [**42] Assistant United States Attorney, to Special FBI Agent, Def. FCA Mem. Ex. 42. Dr. **Prabhu** was required to produce voluminous billing and patient records to state and federal authorities. For example, on one occasion, MFCU subpoenaed "the full and complete medical records" for over four hundred patients of Dr. **Prabhu.** *See* Letter from Frankie Sue Del Papa, Attorney General, State of Nevada to Dr. **Prabhu,** Def. FCA Mem. Ex. 43.

59. With the Criminal Investigation in full swing, an FCA *qui tam* lawsuit was filed, under seal, against Dr. **Prabhu.** *See* Def. FCA Mem. Ex. 45. The allegations of

Medicare fraud in the *qui tam* action included matters from the Criminal Investigation and matters that the press had earlier disclosed. To investigate the allegations in the *qui tam* action, the Government was required to review Dr. **Prabhu's** Medicare and Medicaid billings.

60. After investigating Dr. **Prabhu's** Medicare billings for approximately one year, the Civil Division of the Department of Justice ("DOJ") elected to intervene in the *qui tam* lawsuit. On July 1, 1993, the *qui tam* lawsuit was unsealed and a First Amended Complaint was publicly filed against Dr. **Prabhu.** *See* [**43] Def. FCA Mem. Ex. 46. In its First Amended Complaint, DOJ significantly revised the Original Complaint. However, only one revision is relevant to the present issue. DOJ added an allegation that was specific to PFT's, as opposed to a general allegation that Dr. **Prabhu's** office was improperly upcoding claims. The Government alleged that there was no medical necessity for Dr. **Prabhu** to perform the following tests: spirometry tests; lung diffusion tests; functional residual capacity tests; and maximum breathing capacity tests. *Id.* at P26. The simple stress test was absent from this list of unnecessary "lung capacity tests."

61. In September 1994, DOJ informed the Court that it did "not intend to seek an indictment against Dr. **Prabhu** or his companies." *See* Def. FCA Mem. Ex. 48. Upon completion of the Criminal Investigation, however, DOJ renewed its FCA litigation against Dr. **Prabhu.** At that time, DOJ continued its meticulous review of Dr. **Prabhu's** PFT billings and corresponding medical records. *See, e.g.,* Sulzinger Aff., P13. [15] After additional, exhaustive discovery of Dr. **Prabhu's** medical records and billings, DOJ filed a Fourth Amended Complaint against Dr. **Prabhu.** *See* [**44] Def. FCA Mem. Ex. 51.

62. The Fourth Amended Complaint dropped the allegation that Dr. **Prabhu** had been billing for tests that were not reimbursable under Medicare. *See* Def. FCA Mem. Ex. 51. That allegation was dropped even though, during that time, Dr. **Prabhu** was billing for the simple stress test component of pulmonary rehabilitation. The Fourth Amended Complaint also made the allegations of fraud involving PFT codes specific. *See id.,* PP 32-38. Thus, after years of extensive investigations, discovery, and analysis of Dr. **Prabhu's** PFT billings and corresponding medical records, the only PFT billing codes remaining at issue were: 94010 (spirometry test); 94060 (bronchospasm evaluation); 94200 (maximum breathing capacity test); 94700 (arterial [*1025] blood gas analysis); 82803 (laboratory code for analysis of blood gases); and, 36600 (arterial puncture to draw blood for diagnosis). [16] The CPT Code list reflects that 94620, the simple stress test code, was noticeably absent from this list.

63. DOJ was no longer alleging that Dr. **Prabhu** was billing Medicare for medically unnecessary PFTs. Rather, DOJ was alleging that Dr. **Prabhu** had improperly submitted "unbundled claims" to Medicare. [**45] [17] To make this amendment, DOJ was required to review the medical records for all the PFT billing codes Dr. **Prabhu** submitted to Medicare to determine whether the medical records supported the services that were being billed. Since the simple stress tests were being billed as a part of pulmonary rehabilitation services at that time, and since the pulmonary rehabilitation services were clearly referenced in the medical records, DOJ would have reviewed the simple stress tests/pulmonary rehabilitation claims in its search for any alleged fraudulent billings. [18] Despite this detailed review, the undisputed evidence shows that DOJ never questioned the simple stress test claims.

64. After undergoing such an extensive and thorough review, on September 11, 1995, DOJ - without receiving any payment as settlement - withdrew its intervention in the *qui tam* lawsuit; *see* United States Withdrawal of Appearance, Def. FCA Mem. Ex. 52; thereby effectively acknowledging that its case lacked merit.

15 For example, the Government sought discovery of "all versions of any document used from 1986 to the present [i.e., April 22, 1995] by R.D. **Prabhu** or his medical practice to document those tests he wished the pulmonary . . . technicians to perform on patients . . . ." *See* United States of America's Fifth Set of Requests for Documents to R.D. **Prabhu,** M.D. *See* Def. FCA Mem. Ex. 50.

[**46]

16 The parenthetical code descriptions were taken from the 1991 CPT.

17 Unbundling occurs when a physician submits multiple codes to Medicare for procedures that are contained in a single code, thereby increasing their reimbursement. For example, if there is a single code for setting a broken arm, a physician could not bill for that service by submitting the individual codes for x-rays, office visit, cast, pain medications, etc.

18 As already noted through the attached Exhibits, the codes and medical records would have clearly indicated that Dr. **Prabhu** was providing pulmonary rehabilitation services and he was billing for the simple stress component of those services on the frequency of 2 to 3 times per week.

CONCLUSIONS OF LAW

Summary Judgment Standards

1. Summary judgment is proper if there is no genuine issue as to any material fact. *Fed. R. Civ. P. 56(c)*. The party seeking summary judgment bears the initial responsibility of informing the district court of the basis for its motion and identifying those portions of the [**47] "pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any," which it believes demonstrate the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett, 477 U.S. 317, 323, 106 S. Ct. 2548, 91 L. Ed. 2d 265 (1986)*.

2. Once this burden is met, *Rule 56(c)* mandates the entry of summary judgment unless the nonmoving party adduces evidence "sufficient to establish the existence of [each] element essential to that party's case, and on which that party will bear the burden of proof at trial." *Id. at 322*. The role of the court is to determine whether there is *sufficient* evidence so that a trier of fact could reasonably find in favor of the nonmoving party. The "mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no ***genuine*** issue of *material* fact." *Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986)* (emphases in original). Further, because "[i]t follows . . . [*1026] that if the factual context renders respondents' claim implausible - if the claim is one that simply [**48] makes no economic sense - respondents ***must come forward with more persuasive evidence*** to support their claim than would otherwise be necessary." *See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 587, 106 S. Ct. 1348, 89 L. Ed. 2d 538 (1986)* (emphasis supplied); *see also Eakins v. Nevada, 219 F. Supp. 2d 1113, 1116 (D. Nev. 2002)*.

3. To establish FCA liability, "the Government must prove three elements: (1) a 'false or fraudulent' claim; (2) which was presented, or caused to be presented, by the Defendant to the United States for payment or approval; (3) with knowledge that the claim was false." *See United States v. Mackby, 261 F.3d 821, 826 (9th Cir. 2001)*. Here, the Government has failed to furnish sufficient evidence to establish any genuine material issue of fact so that a reasonable trier of fact could reasonably find in its favor that defendants knowingly submitted a false claim. Accordingly, the Court grants summary judgment in the Defendants' favor and dismisses with prejudice the government's claims under the False Claims Act.

Dr. Prabhu's Claims Cannot be False as a Matter of Law

4. Claims are not "false" under the [**49] FCA unless they are furnished in violation of some controlling rule, regulation or standard. *See, e.g., United States ex rel. Local 234 v. Caputo Co., 321 F.3d 926, 933 (9th Cir. 2003)*; *United States v. Southland Mgmt. Corp., 326 F.3d 669, 674-75 (5th Cir. 2003)* ("[W]hether a claim is valid depends on the contract, regulation, or statute that supposedly warrants it. It is only those claims for money or property to which a Defendant is not entitled that are 'false' for purposes of the False Claims Act") (citation omitted) (en banc); *United States ex rel. Hochman v. Nackman, 145 F.3d 1069, 1073-74 (9th Cir. 1998)* (no falsity when Defendants' acts conformed with Veteran Administration payment guidelines); *United States ex rel. Lindenthal v. Gen. Dynamics Corp., 61 F.3d 1402, 1412 (9th Cir. 1995)* (whistleblower's FCA claims for payment based on work that satisfied contractual obligations "could not have been 'false or fraudulent' within the meaning of the [False Claims Act]"); *United States ex rel. Glass v. Medtronic, Inc., 957 F.2d 605, 608 (8th Cir. 1992)* (a statement cannot be "false" or "fraudulent" [**50] under FCA when the statement is consistent with regulations governing program).

5. Additionally, claims are not "false" under the FCA when reasonable persons can disagree regarding whether the service was properly billed to the Government. *See United States ex rel. Lamers v. City of Green Bay, 168 F.3d 1013, 1018 (7th Cir. 1999)* (holding that "errors based simply on faulty calculations or flawed reasoning are not false under the FCA . . . [a]nd imprecise statements or differences in interpretation growing out of a disputed legal question are similarly not false under the FCA") (citations omitted); *Hagood v. Sonoma County Water Agency, 81 F.3d 1465, 1477 (9th Cir. 1996)* ("How precise and how current the cost allocation needed to be in light of the [Water Supply Act's] imprecise and discretionary language was a disputed question within the [Government]. Even viewing [plaintiff's] evidence in the most favorable light, that evidence shows only a disputed legal issue; that is not enough to support a reasonable inference that the allocation was *false* within the meaning of the False Claims Act").

6. Here, as to the two basic services that frame [**51] the dispute underlying the Government's lawsuit, pulmonary rehabilitation [*1027] services and simple pulmonary stress tests, the record does not support a finding of falsity as a matter of law. As to both services, there is no dispute regarding the facts.

7. The Government's own expert agrees that pulmonary rehabilitation was covered by Medicare in various settings and in different jurisdictions. *See* Dep. of Neil MacIntyre, M.D., at 14:1-16:17. Additionally, both the Government's expert and the carrier's Medical Director further concurred that Medicare has always covered pulmonary stress tests when furnished as a component part of a pulmonary rehabilitation program. *See* Dr. MacIntyre Dep. at 16:6-10; Dr. Mangold Dep. at

25:11-20; 26:1-12. Dr. Mangold further confirmed that his office never issued a rule or policy that prohibited physicians from billing for pulmonary rehabilitation or its component services - such as pulmonary stress tests. *See* Dr. Mangold Dep. at 12:4-14; 14:5-17. In light of this, the Government has failed to prove that Dr. **Prabhu** violated a controlling rule, regulation or standard, for purposes of FCA liability.

8. The Government has also failed to prove falsity [**52] as a matter of law, by failing to dispute the overwhelming evidence that Dr. **Prabhu** was following the instructions he received from his carrier in billing for pulmonary stress tests as part of his pulmonary rehabilitation program. *See supra* PP 28-39. The facts are undisputed that over a period of thirteen years, Dr. **Prahhu** and his associates continually contacted Medicare representatives to determine the appropriateness of their billing practices. During that entire time, Medicare never advised Dr. **Prabhu** that it had revised or amended its policy or earlier instructions. Medicare never advised Dr. **Prabhu** or his staff that its advice had changed, never transmitted any Medicare bulletins or flyers stating that its advice had changed or that his billing practice was prohibited, and never denied simple stress test claims that would have signaled to Dr. **Prabhu** that its advice had changed.

9. The Government also failed to dispute the record evidence that Dr. **Prabhu** undertook efforts to ensure accurate coding. *See* Falls Aff., P9 ("Dr. **Prabhu** was always adamant that all medical services must be documented, coded, and billed correctly"); Kanizai Aff., P7 ("I have worked in the healthcare [**53] field for approximately fourteen years, and I have never known a physician that is more dedicated and committed to doing everything correctly, including the coding and billing, than Dr. **Prabhu**"); Clark Aff., P16 ("Throughout the years that I have been processing claims for various physicians and medical practices, Dr. **Prabhu** is the most particular physician that I have known when it comes to making sure that everything is coded and billed correctly"); Kinkade Aff., P15 ("During the entire time that I have known Dr. **Prabhu,** I have never known him to bill a medical service to Medicare using a code that he did not honestly believe to be correct and accurate in all respects"); Williams, Aff., P4 (Dr. **Prabhu** did not allow the Lung Institute to submit any claims to Medicare until all questions regarding the proper coding of that claim had been resolved through our discussions with Medicare"); Brown Aff., P7 ("During the entire time that I was employed by Dr. **Prabhu,** he was always a stickler for making sure that everything was done right, including the correct coding and billing of all procedures"); McKeon Aff., P8 ("Dr. **Prahhu** was always emphatic that every medical procedure or service must [**54] be coded and billed correctly"); Nelson Aff., P6 (same); Schiefer Aff., P15 (same); Sulzinger Aff., P15 (same); *see also* Atkins Dep. at 104:5-10 ("Q: In your opinion, does Dr. **Prabhu** try and bill [*1028] Medicare to get as much as he can out of Medicare, or is he more concerned with the care of the patients? ... A: The care of the patients").

10. As to the government's contention that Dr. **Prabhu's** simple stress test was not properly billed because it did not include a pre and post-exercise spirometry and prescribed written report, the government's interpretation of the CPT Code for a simple stress test is wrong.

11. The Government's contention that a physician must provide a pre and post-exercise spirometry is expressly refuted by the organization that published the billing code governing the provision of simple stress tests. *See supra* PP 17-23. The Government's own expert similarly concurs that pre and post-spirometry is not required to bill for CPT 94620. Specifically, after being asked to review the Government's complaint and state whether he agreed or disagreed that a physician was required to perform a pre and post-exercise spirometry, the Government's expert stated that no [**55] such requirement existed. *See* Dr. MacIntyre Dep. at 11:10-12:2. In light of this, the Government has failed to prove falsity in claims by failure to include the spirometry tests.

12. The Government's contention that a physician must provide a prescribed written report is also expressly refuted in the record. It is clear from the facts and deposition of Dr. Mangold that no such requirement existed. Dr. Mangold, the Medical Director of the carrier that processed Dr. **Prabhu's** claims, specified that it had published no policy mandating a specific type of physician written report that must accompany the provision of a simple stress test. *See* Dr. Mangold Dep. at 23:2-6. In light of this, the Government has also failed to prove falsity in claims by failure to include a written physician report.

13. Finally, it is worth noting that in the Government's Response to the Defendant's FCA Motion, the government asserted an additional element to its claim that Dr. **Prabhu** did not perform all elements of a stress test. *See* Gov't Response to Defendant's False Claims Act Motion at 7. This third requirement- that dyspnea (i.e., whether the patient was short of breath) be measured- was a [**56] new one to this case at the time. Notwithstanding the fact that it *did* not exist in the Government's complaint and thus should not be considered by the Court for that reason, the undisputed facts in this case reveal that Dr. **Prabhu,** in fact, *did* measure dyspnea. *See* Dr. **Prahhu** Dep., 87:7-88:5, Def. FCA Reply Ex: 1, Tab F; *see also* Ex. 1, at entry 6.

14. For all these reasons, the Government has failed to demonstrate to this Court that Defendant's claims were false for purposes of FCA liability.

Dr. Prabhu did not "Knowingly" Submit Any "False" Claim to the Government

15. For the reasons stated above, there is no proof that any of Dr. **Prabhu's** claims were false. However, even if this Court were to have found that some claims were "false" under the FCA, the Government has proffered no material disputed fact that would demonstrate that Dr. **Prabhu** "knowingly" submitted a false claim.

16. Under the FCA, a person is deemed to have acted "knowingly" when the person "acts in deliberate ignorance of the truth or falsity of the information; or acts in reckless disregard of the truth or falsity of the information." *31 U.S.C. § 3729(b)*. As the [**57] Ninth Circuit has pointed out, the FCA knowledge standard does [*1029] not extend to honest mistakes, but only to "lies." [19] Thus, a Defendant does not "knowingly" submit a "false" claim when his conduct is consistent with a reasonable interpretation of ambiguous regulatory guidance. *See, e.g., United States ex rel. Swafford v. Burgess Med. Ctr., 98 F. Supp. 2d 822, 831-32 (W.D. Mich. 2000)* (where the regulatory terms were undefined and ambiguous and the plaintiff's position "devolves to a dispute over the meaning of the terms governing the delivery of the professional component of physicians services . . ." there was no violation of the FCA because a "legal dispute is ... insufficient" to establish FCA liability), *aff'd, 24 Fed. Appx. 491 (6th Cir. 2001)*; *United States v. Krizek, 859 F. Supp. 5, 9-10 (D.D.C. 1994)* (ruling that because the key term in the billing code was undefined and hence "ambiguous," the Government could not state an FCA cause of action), *aff'd in part, rev'd in part, 324 U.S. App. D.C. 175, 111 F.3d 934 (D.C. Cir. 1997)*.

17. Moreover, a Defendant does not knowingly submit false claims when he follows Government instructions [**58] regarding the claims. *See United States ex rel. Butler v. Hughes Helicopters, Inc., 71 F.3d 321 (9th Cir. 1995)*; *Wang v. FMC Corp., 975 F.2d 1412, 1421 (9th Cir. 1992)* (where the Government knew of Defendant's "mistakes and limitations, and that [Defendant] was open with the Government about them, suggests that while [Defendant] might have been groping for solutions, it was not cheating the Government in the effort").

18. The undisputed record evidence demonstrates that Dr. **Prabhu** did not knowingly submit any false claims because his billing practice conformed to a reasonable interpretation of ambiguous regulations that he, and his staff, believed in good faith were proper. [20]

19. Several facts underscore the regulatory ambiguity: (1) the Government never published a rule supporting its interpretation, [*1030] for example, that to bill for a simple pulmonary stress test, the physician must perform a pre and post-exercise spirometry; (2) pulmonary rehabilitation has been covered continuously in various settings and its component parts, such as a simple stress test, has always been covered, *see supra* PP 6-16; (3) the Government's interpretation of [**59] the code has shifted dramatically during the course of this litigation and its own agents concur that the code is mired in ambiguity and confusion, *see supra* PP 25-27; (4) although the Government contends that Dr. **Prabhu** has committed fraud entitling it to tens of millions of dollars because he did not perform a pre and post-exercise spirometry, its own expert states that no such requirement exists and the Government's interpretation is further undermined by the organization that issued the code, *see supra* PP 17-23. Moreover, there is undisputed evidence that Dr. **Prabhu** has always acted in good faith in seeking to understand the Government's rules. *See supra* PP 28-40. And finally, it is further illuminative that several of the Government's representatives have stated that this is an area rife with confusion. *See* Dr. Mangold Dep. at 22:11-14; Dr. MacIntyre Dep. at 33:20-23; *see also supra* P27.

20. The Government has similarly failed to prove knowledge as well, because Dr. **Prabhu** complied with Government instructions regarding the claims. As the uniform and undisputed sworn testimony of Dr. **Prabhu's** staff in the record states, the carrier was fully aware of Dr. **Prabhu's** [**60] billing practice and, indeed, even advised that he bill for the test. *See supra* PP 28-40; Atkins Dep. at 103:3-16. [21]

21. Moreover, the Government became aware of Dr. **Prabhu's** practices during the course of its extensive criminal and civil investigation of him during the 1990s. *See supra* PP 55-64. As part of the investigation, Dr. **Prabhu's** Medicare claims, including his "PFT" claims such as the simple [*1031] stress test, were closely reviewed. *See, e.g.*, Sulzinger Aff., P5.

22. The record also reflects that additional litigation and discovery continued after DOJ filed its Fourth Amended Complaint in the previous investigation. From the commencement of the Criminal Investigation, through the filing of the Fourth Amended Complaint, it is without question that Dr. **Prabhu's** medical and billing records underwent a very extensive and detailed fraud review.

23. Under these circumstances, the court concludes that the Government cannot demonstrate that the Defendant knowingly submitted false claims. It would be simply irrational for any person subjected to the level of

scrutiny to which Dr. **Prabhu** was subjected to knowingly submit any claim that was questionable or borderline, let [**61] alone flat-out wrong. *See supra* PP 55-64.

24. As the regulatory history underlying pulmonary rehabilitation and simple pulmonary stress tests demonstrate, at worst, all that existed were disputed legal issues regarding whether pulmonary rehabilitation could be billed and under what circumstances the component parts of pulmonary rehabilitation, such as simple pulmonary stress tests, could be billed. During the substantial period in which Dr. **Prabhu** billed for these services, there was a nationwide debate regarding when these pulmonary rehabilitation services could be billed. *See supra* PP 6-16. Congress authorized these services in a CORF setting, CMS authorized these services as part of NETT, various carriers expressly permitted physicians to bill for these services in an office setting, and Dr. Prabhu's carrier furnished no written instructions prohibiting the practice. *Id.* Even when CMS later found that pulmonary rehabilitation was not a benefit category, it stressed that the component parts of the service were covered and CMS then promptly instituted new codes to cover pulmonary rehabilitation services. *See supra* P12; *see also 66 Fed. Reg. at 55,311;* [**62] *67 Fed. Reg. at 79,999-80,000.* Courts have routinely ruled that where, at worst, all that exists are disputed legal issues regarding whether a service was properly billed, the Government cannot prove falsity as a matter of law. [22]

25. Accordingly, the Government has failed to establish that Defendants knowingly lied in presenting claims for simple stress tests to the Government.

19 *See Hagood, 81 F.3d at 1478* ("requisite intent is the knowing presentation of what is known to be false, as opposed to innocent mistake or mere negligence"). Indeed, Congress specifically amended the FCA to include this definition of scienter, to make "firm . . . its intention that the act not punish honest mistakes or incorrect claims submitted through mere negligence." *See also Hochman, 145 F.3d at 1073* (quoting S. Rep. No. 99-345, at 7 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5272). "Known to be false" does not mean scientifically untrue, it means "a lie." *United States ex rel Anderson v. Northern Telecom, Inc., 52 F.3d 810, 815-16 (9th Cir. 1995)* (internal citations and quotation marks omitted).

[**63]

20 *See United States ex rel. Quirk v. Madonna Towers, Inc., 278 F.3d 765, 768-69 (8th Cir. 2002)* (no violation of FCA intent standard because, even though administrators refrained from obtaining guidance regarding the questioned practice, they considered the billing practice to be an "acceptable standard procedure" and the relator did not produce any evidence "suggest[ing] anyone was lying to the Government" or "suspected something wrong"); *United States v. Data Translation, Inc., 984 F.2d 1256 (1st Cir. 1992)* (when supplier's actions conformed with industry practice and were otherwise reasonable, the Government could not state a cause of action under the *FCA); United States ex rel. Perales v. St. Margaret's Hosp., 243 F. Supp. 2d 843, 866 (C.D. Ill. 2003)* (defendant hospital did not bury "its head in the sand and wilfully [sic] ignore[] the law" when, among other things, there was "evidence that [it] received and considered relevant publications in this area of the law, established a corporate compliance committee, and routinely consulted counsel in drafting the contracts and agreements, which is suggestive of an intent to abide by the law"); *see also Krizek, 859 F. Supp. at 9-10, aff'd in part, rev'd in part, 324 U.S. App. D.C. 175, 111 F.3d 934 (D.C. Cir. 1997); United States v. Napco Intern., Inc., 835 F. Supp. 493, 498 (D. Minn. 1993)* (because underlying regulation was ambiguous, the court would not permit the Government to apply "an interpretative afterthought by the agency" against the contractor in a FCA action).

[**64]

21 *See United States ex rel. Costner v. URS Consultants, 317 F.3d 883, 887-88 (8th Cir. 2003)* ("The record shows that the EPA discussed these problems with the defendants and referred the matter to OSHA for investigation and possible sanctions. Although the record indicates that the defendants' performance under the contract was not perfect, the extent of the Government's knowledge through its on-site personnel and other sources shows that ... the Government knew what it wanted, and it got what it paid for . . . . Thus, the district court did not err in finding that the defendants' openness with the EPA about their problems and their close working relationship in solving the problems negated the required scienter regarding these issues") (citation and internal quotation omitted); *United States ex rel. Becker v. Westinghouse Savannah River, 305 F.3d 284, 289 (4th Cir. 2002)* ("we join with our sister circuits and hold that the Government's knowledge of the facts underlying an allegedly false record or statement can negate the scienter required for an FCA violation" and hence the Government's "full knowledge of the material facts underlying any representations implicit in

[the defendant's] conduct negates any knowledge that [the defendant] had regarding the truth or falsity of those representations"); *United States ex rel. David Bennett v. Genetics & IVF Inst., No. 98-2119, 1999 U.S. App. LEXIS 27911 (4th Cir. 1999)* (although the defendant's contract mandated that, in conducting paternity testing, it conduct two tests, it informed the Government entity that it would perform only one test [since DNA testing was more accurate than the previously used serology testing] both before the contract was awarded and after it was awarded but before performance began; the court affirmed the district court's determination that no reasonable jury could conclude that the defendant had the requisite intent under the FCA because the Government knew of defendant's practices and had not objected); *see also Butler, 71 F.3d 321* (concluding that where defendants openly shared all information with the Government and fully cooperated with it during the testing process, that the Government's knowledge defeats any inference that defendant "knowingly" presented false claims to the *Government); Wang v. FMC Corp., 975 F.2d at 1421* (same).

[**65]

22 *See, e.g., Lamers, 168 F.3d at 1018*; *Swafford, 98 F. Supp. 2d at 831-32* (where the relator had contended that, in order to bill for an "interpretation or reading" of the "results of the test" of ultrasound studies, the defendant physicians must do more than merely rely upon the findings of the technologist by independently reviewing the supporting data from which the technologist arrived at his conclusions, the court rejected the relator's claim because it found that those terms were undefined and ambiguous and that the relator's position "devolves to a dispute over the meaning of the terms governing the delivery of the professional component of physicians services" and that such a "legal dispute is ... insufficient" to establish FCA liability because "a defendant's decision in the face of a dispute over the requirements of governing regulations is insufficient, without more, to constitute falsity"), *aff'd, 24 Fed. Appx. 491 (6th Cir. 2001). Cf. In Re Genesis Health Ventures, Inc., 272 B.R. 558, 570 (Bkrtcy. D. Del. 2002)* ("In this murky area in which no specificity exists in the statutory, regulatory or contractual scheme regarding the provision of credits, with no quest by either the state or federal Government for unpaid credit, either by way of the filing of proofs of claim or otherwise, there is insufficient basis to charge the debtors with the requisite scienter required to establish a factually false certification").

[**66] **Dr. Prabhu's Claims Regarding Medical Necessity and Documentation Cannot Be False As A Matter Of Law**

26. When submitting healthcare claim forms, physicians certify that their services [*1032] are "medically indicated and necessary for the health of the patient ..." *See* CMS-1500, *reprinted in* Medicare & Medicaid Guide (CCH) P10,26,1 Def. Med. Nec. Mem. Ex. 12.

27. CMS has not delineated what constitutes "medically indicated" and "necessary" items or services furnished to Medicare patients and the specific documentation required to support medical necessity in individual cases. *See, e.g., Medicare Program: Criteria and Procedures for Making Medical Services Coverage Decisions That Relate to Health Care Technology, 54 Fed. Reg. 4,302, 4,304, 4,308, 4,312 (1989)* ("current regulations are general and we have not defined the terms 'reasonable' and 'necessary,' nor have we described in regulations a process for how these terms must be applied"). In determining medical necessity, courts employ what is known as the "treating physician" rule, which provides that with respect to medical necessity, the judgment of the treating physician should be given "extra weight" [**67] or "a reasoned basis ... [should be supplied] for declining to do so". *See, State of New York v. Sullivan, 927 F.2d 57, 60 (2d Cir. 1991); Klementowski v. Secretary, 801 F. Supp. 1022, 1026 (W.D.N.Y. 1992); Gartmann v. Secretary, 633 F. Supp. 671, 680-82 (E.D.N.Y. 1986)* (noting that "'[t]he physician is to be the key figure in determining utilization of health services.'" (internal citation omitted).

28. Here, based solely upon the undisputed material facts, the Government has not established sufficient evidence to demonstrate that Defendants furnished "false" claims regarding the medical necessity of the services they provided.

29. First, the undisputed record indicates that the claims were, in fact, clinically medically necessary and indicated. As delineated above, in the record entries of fourteen patients, Dr. **Prabhu** determined based upon his evaluation that the questioned patients would benefit from additional therapy. *See* Dr. **Prabhu** Decl., PP 7-78. The Government has failed to adduce any evidence that in light of the patient's complaint, symptom, and illness, that -- from a clinical standpoint -- the services were medically [**68] unnecessary. Hence, because the certification provided on the claim form is literally true -- there are no false claims as a matter of law.

30. Dr. **Prabhu's** claims also cannot be false, as a matter of law, because, as previously mentioned, the

Government has not established any violation of a controlling rule, regulation, or standard in Defendants' provision of pulmonary rehabilitation. As the Government's expert readily acknowledged, Nevada did not have a governing LMRP setting forth the precise manner in which these services must be documented. *See* Grider Dep., 20:8-25. Additionally, as the Government conceded, the California LMRP does not furnish a controlling documentation standard. *See id.* at 25:18-21. Accordingly, because there was no breach of any rule, regulation or standard, Dr. **Prabhu's** claims cannot be held false as a matter of law.

31. Finally, Dr. **Prabhu's** claims cannot be false, as a matter of law, because under the undisputed facts there is no articulated, objective standard that dictates that the documentation underlying the claims is false, inaccurate, or incomplete. Dr **Prabhu's** claims are not "false" - even assuming Ms. Grider's opinions were valid - because [**69] his documentation practices would fall within the range of reasonable medical and scientific judgment regarding how to document the medical necessity of pulmonary rehabilitation services. *See* Dr. **Prabhu** Decl., PP 7-79; Dr. Osei Decl., P6; Dr. Stewart Decl., P4; Dr. Manaker Dep. at 64:14-65:11. To establish [*1033] falsity under the FCA, it is not sufficient to demonstrate that the person's practices could have or should have been better. Instead, plaintiff must demonstrate that an objective gap exists between what the Defendant represented and what the Defendant would have stated had the Defendant told the truth. [23] *See Hagood, 81 F.3d at 1477.* Accordingly, because, at a minimum, reasonable minds may differ regarding whether the documentation underlying Dr. **Prabhu's** claims satisfied some undefined standard, the Government has not establish falsity as a matter of law.

> 23 *See also, Anderson, 52 F.3d at 815-16; United States ex rel. Roby v. Boeing Co., 100 F. Supp. 2d 619, 625 (S.D. Ohio 2000)* ("At a minimum, the FCA requires proof of an objective falsehood . . . . Expressions of opinion, scientific judgments, or statements as to conclusions about which reasonable minds may differ cannot be false"); *United States ex rel. Boisjoly v. Morton Thiokol, 706 F. Supp. 795, 810 (N.D.Utah 1988)* ("[the certification] reflects an engineering judgment. . .It is clearly not a statement of fact that can be said to be either true or false, and thus cannot form the basis of an FCA claim"); *see generally, Luckey v. Baxter Healthcare Corp., 183 F.3d 730, 731 (7th Cir. 1999).*

[**70] **Dr. Prahhu did not "Knowingly" Suhmit Any "False" Claim To The Government Regarding The Medical Necessity Of His Claims**

32. As mentioned above, under the FCA, a person is deemed to have acted "knowingly" when the person "acts in deliberate ignorance of the truth or falsity of the information" or "acts in reckless disregard of the truth or falsity of the information." *31 U.S.C. § 3729(b).*

33. Here, as is stated above, Dr. **Prabhu** did not violate any rule, regulation, or standard and it is undisputed that his services were clinically medically uecessary and indicated. However, even if contrary to fact, the Government could establish some regulatory breach, this would be insufficieut to create FCA liability. This is because the FCA is not intended to be some wide-ranging statute to police all types of regulatory or contractual compliance. *See, e.g., United States ex rel. Willard v. Humana Health Plan, 336 F.3d 375, 381 (5th Cir. 2003)* ("The False Claims Act does not create liability merely for a healthcare provider's disregard of Government regulations or improper internal policies unless, as a result of such acts, the provider knowingly [**71] asks the Government to pay amounts it does not owe") (citation omitted); *United States ex rel. Norbeck v. Basin Electric Power Cooperative, 248 F. 3d 781 (8th Cir. 2001); Lamers, 168 F.3d at 1019-20; Swafford, 98 F. Supp. 2d at 828* (the "FCA is not an appropriate vehicle for policing technical compliance with administrative regulations"; mere violations of administrative regulations are not actionable under the FCA "unless the violator knowingly lies to the Government about them") (internal quotation omitted), *aff'd, 24 Fed. Appx. 491 (6th Cir. 2001).*

34. Instead, as this Circuit has emphasized, to demonstrate that the claims are "known to be false" the Government must demonstrate that there were "lies" - and not merely a scientific or technical dispute. For example, in *Wang v. FMC Corp., 975 F.2d at 1421*, the plaintiff contended among other things, that Defendant's "engineering work" was of "low quality" and that its design was "faulty." The Ninth Circuit ruled that these contentions could not serve as the basis for FCA liability. The Court reasoned:

> Proof of one's mistakes or inabilities [**72] is not evidence that one is a cheat . . . . Without more, the common failings of engineers and other scientists are not culpable under the Act . . . . The weakest account of the Act's "requisite intent" is the "knowing presentation of what is [*1034] known to be false." [Citation omitted.] The phrase "known to be false" in that sentence does not mean "scientifically untrue"; it means "a lie." The act is concerned with ferreting out "wrongdoing," not scientific errors. [Citation omitted]. What is false as a matter of science

> is not, by that very fact, wrong as a matter of morals. The Act would not put either Ptolemy or Copernicus on trial.*Id.*

In applying this standard, and for the reasons mentioned above regarding undisputed evidence regarding medical necessity, the Government cannot establish that Defendants "knowingly" submitted "false" claims.

35. The only factual issue that has been raised in relation to the medical necessity issue is how the need for services should have been documented. Because those rules are ambiguous- compare Ms. Grider's opinion with Drs. Stewart, Osei and Manaker- there cannot be any FCA liability as a matter of law. *See, e.g., Swafford, 98 F. Supp. 2d at 831-32* [**73] (where the regulatory terms were undefined and ambiguous and the relator's position "devolves to a dispute over the meaning of the terms governing the delivery of the professional component of physicians services . . ." there was no violation of the FCA because a "legal dispute is . . . insufficient" to establish FCA liability), *aff'd, 24 Fed. Appx. 491 (6th Cir. 2001); Krizek, 859 F. Supp. at 9-10* (ruling that because the key term in the CPT code was undefined and hence "ambiguous," the Government could not state a FCA cause of action), *aff'd in part, rev'd in part, 324 U.S. App. D.C. 175, 111 F. 3d 934 (D.C. Cir. 1997).* [24]

36. Moreover, Defendants' conduct, applying to only a small percentage of all claims was, at worst, inadvertent, which does not trigger FCA liability. Here, the Government has not questioned the documentation related to approximately 94.5% of all patients. While Defendants contend that their documentation was adequate, the existence of such a low alleged error rate disproves the contention that Defendants "knowingly" engaged in a pattern of submitting false or fraudulent claims that would entitle the Government to treble damages and [**74] substantial civil fines. *See, e.g., United States ex rel. Watson v. Connecticut Gen. Life Ins. Co., No. 98-6698, 2003 U.S. Dist. LEXIS 2054 at *55 (E.D. Pa. Feb. 11, 2003)* (rejecting the plaintiff's contention that the Defendant submitted false claims when 98.6% of the claims were correctly processed because the "high rate of accuracy undermines any contention that [the Defendant] knowingly engaged in a pattern of failing . . . "to adhere to the governing standard regarding claims submission), *aff'd 87 Fed. Appx. 257 (3d Cir. 2004).*

37. At worst, such an allegedly low error rate (even if true) reflects inadvertence or honest mistake, which does not trigger FCA liability. *See Hochman, 145 F. 3d at 1074* (rejecting plaintiff's FCA allegations that physicians at a Veterans Health Administration clinic violated the FCA because, among other things, they hired unnecessary personnel because Defendants believed that the additional personnel was [*1035] needed to advance the clinic's interest and that since "at best plaintiffs ha[ve] only shown an innocent mistake or mere negligence . . . ," their FCA action was dismissed); *see also Madonna Towers, Inc., 278 F.3d at 767* [**75] ("innocent mistakes and negligence are not offenses under the Act") (internal quotation and citations omitted); *Mikes v. Straus, 274 F.3d 687, 703 (2d Cir. 2001)* ("the requisite intent is the knowing presentation of what is known to be false as opposed to negligence or innocent mistake") (internal quotation and citations omitted); *see also Hindo v. Univ. Of Health Sciences/The Chicago Med. Sch., 65 F.3d 608 (7th Cir. 1995)* (no violation of the FCA because Defendant had a good faith belief that it was entitled to payment for the services performed by residents); *In re Cardiac Devices Qui Tam Action, 221 F.R.D. 318, 339 (D. Conn. 2004)* ("The Second Circuit has adopted the Ninth Circuit's standard that the 'requisite intent is the knowing presentation of what is known to be false' as opposed to negligence or innocent mistake") (citation omitted); *Swafford, 98 F. Supp. 2d at 832* (under FCA standard, the "plaintiff must adduce facts that establish more than mere innocent mistakes or negligence on the part of Defendants") (citation omitted), *aff'd, 24 Fed. Appx. 491 (6th Cir. 2001).*

38. Finally, the [**76] Government's case "makes no economic sense," *Zenith Radio Corp., 475 U.S. at 587*, because the undisputed evidence shows that Dr. **Prabhu** lost money in providing these services. *See* Def. Unjust En. Mem. PP 6-10. Hence, Dr. **Prabhu** had no monetary incentive to furnish more pulmonary rehabilitation than was medically indicated and necessary and the Government's evidence -- that documentation standards can be debated -- cannot satisfy the test in *Zenith* requiring that when the nonmoving party's claim is economically implausible that it "come forward with more persuasive evidence to support [its] claim than would otherwise be necessary." *Zenith Radio Corp., 475 U.S. at 587.*

> 24 *See also Napco, 835 F. Supp. at 498* (because underlying regulation was ambiguous, the court would not permit the Government to apply "an interpretative afterthought by the agency" against the contractor in a FCA action); *cf. In Re Genesis Health Ventures, Inc., 272 B.R. 558, 570 (Bkrtcy. D. Del. 2002)* ("In this murky area in which no specificity exists in the statutory, regulatory or contractual scheme regarding the provision of credits, with no quest by either the state or federal Government for unpaid credit, either by way of the filing of proofs of claim or otherwise, there is insufficient basis to charge the debtors with the requisite scienter required to establish a factually false certification").

[**77] **Unjust Enrichment**

39. To establish liability for unjust enrichment, the Government must prove (1) the Government conferred a benefit on the defendant, (2) the defendant retained and appreciated the benefit, and (3) retention of the benefit by defendant under the circumstances would be inequitable. *Leasepartners Corp. v. Robert L. Brooks Trust, 113 Nev. 747, 755, 942 P.2d 182, 187 (1997); United States v. Lahey Clinic Hospital, 399 F.3d 1, 8, 16 n. 17 (1st Cir. 2005).*

40. Defendants do not contest that the Government has established the first of these three elements, the conferring of a benefit on defendants. The Government's Medicare reimbursement payments to defendants satisfy this element.

41. As to the final two elements of the unjust enrichment analysis, the Court finds that even if Dr. **Prabhu** retained and appreciated a benefit, such retention is equitable given the Court's ruling on Dr. **Prabhu's** other Motions for Summary Judgment (# 40, # 41). Otherwise, the Court's ruling would be internally inconsistent. As detailed above, Dr. **Prabhu** is entitled to judgment as a matter of law on both the "knowledge" and "falsity" elements of the False [**78] Claims Act. Accordingly, the Court must also find that his retention of benefits is equitable. Because Dr. **Prabhu** is entitled to summary judgment with respect to the False Claims Act, his retention of any benefit cannot constitute unjust enrichment as a matter of law. Having already determined that Dr. **Prabhu's** Medicare claims were justified under the False Claims Act, the Court cannot find as a matter of law that the retention [*1036] of benefits arising there from is inequitable. Therefore, the Court finds that Dr. **Prabhu** is entitled to summary judgment on the Government's claim for unjust enrichment.

Conclusion

The Government has failed to establish a genuine issue of material fact concerning its allegations that Dr. **Prabhu** violated the False Claims Act. Accordingly, Defendant's motions for Summary Judgment as to the False Claims Act and Medical Necessity (# 40, # 41) are GRANTED.

Defendants' motion for Summary Judgment as to Unjust Enrichment (# 42) is also GRANTED.

DATED: July 19, 2006.

ROBERT C. JONES

UNITED STATES DISTRICT JUDGE

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GOVERNMENT

Court vindicates Nevada doctor in latest twist of fraud case

¦ A federal judge ruled that a physician was abiding by Medicare's advice in submitting claims for pulmonary stress tests. The government is pursuing an appeal.

By AMY LYNN SORREL — Posted Sept. 4, 2006

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Wired witnesses, tapped phones and whistle-blowers. This may sound like plot features in a spy movie, but it's real life for Nevada physician R.D. Prabhu, MD. The federal government has been investigating the internist and pulmonology specialist on and off for more than 13 years.

Dr. Prabhu's story just took a new turn. A federal court in July found that the government's fraud charges didn't hold up because the doctor was just following Medicare instructions.

The Justice Dept. accused Dr. Prabhu of knowingly submitting unlawful bills for simple pulmonary stress tests as part of a pulmonary rehabilitation program. The government alleged that the doctor had violated the False Claims Act because the tests were not covered by Medicare and because he had failed to document their medical necessity for some patients.

But the U.S. District Court for the District of Nevada found that "Dr. Prabhu has always acted in good faith in seeking to understand the government's rules ... in an area rife with confusion."

The decision is a rare victory for doctors, said Robert S. Salcido, a Washington, D.C.-based attorney for Dr. Prabhu. Physicians are often forced to settle such disputes with the government, even when they believe they are acting appropriately, because the financial stakes are so high.

"The case is a beacon of light for doctors," said Salcido, a former Justice Dept. civil fraud lawyer. The decision is significant because it demonstrates that "where there is no government standard letting [doctors] know their conduct is wrong, there is a strong likelihood they will prevail."

The U.S. Attorney's Office for the District of Nevada declined to comment on the ruling. But spokeswoman Natalie Collins said the office was awaiting approval from the Justice Dept. to file a motion for appeal to the 9th U.S. Circuit Court of Appeals.

The odyssey unfolds

Dr. Prabhu's troubles began in 1992, when federal investigators opened a Medicare fraud inquiry into billing practices for various pulmonary tests.

During the probe, the FBI wired potential witnesses to secretly record

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conversations with the doctor, tapped his phone lines and subpoenaed more than 400 patient medical records.

In July 1993, the government joined a false claims whistle-blower lawsuit against the doctor. But in 1994 the Justice Dept. told the court that it "did not intend to seek [a fraud] indictment against Dr. Prabhu." In 1995, the department also dropped out of the whistle-blower case, which was later dismissed, court documents said.

The government resumed its case against Dr. Prabhu in 2004 with a new complaint, saying that the doctor had submitted false claims for simple pulmonary stress tests from 1998 to 2004.

But in July the Nevada federal court found that in the course of the investigation, Dr. Prabhu and his medical staff regularly had consulted Medicare and the local carrier for guidance. "For 13 years Medicare advised Dr. Prabhu that he was allowed to bill for the simple stress test component of pulmonary rehabilitation," the opinion states.

"A defendant does not knowingly submit false claims when he follows government instructions," wrote Judge Robert C. Jones.

The court also determined that the Centers for Medicare & Medicaid Services did not have an express requirement for additional medical documentation to show medical necessity. In its absence, the court found, Dr. Prabhu in his claim forms met the "reasonable and necessary" provisions to show that the simple stress tests would clinically benefit his patients.

Without a specific rule to determine medical necessity, the courts will give "the judgment of the treating physician ... extra weight,' " Jones wrote. To prove that claims are deliberately false, the government must show that they were "lies and not merely a technical dispute," the ruling states.

Samuel B. Benham, a Las Vegas-based attorney for Dr. Prabhu, said the government often pursues false claims complaints because it can recuperate three times the amount of payment. If found guilty, Dr. Prabhu would be liable for more than $20 million in damages, he said.

To protect themselves, "Doctors need to document communication with the Medicare carrier and ask the [carrier's] medical director to answer any billing questions," Benham said.

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SEPTEMBER 2

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AMA readies campaign for Medicare SGR

Mr. FRANKS. Thank you, Dr. Prabhu.

I now recognize our second witness, Dr. Harned, and please turn on your microphone, if you would, Dr. Harned.

TESTIMONY OF PATRICIA J. HARNED, Ph.D., PRESIDENT, ETHICS RESOURCE CENTER

Ms. HARNED. Good afternoon, Chairman Franks, Ranking Member Cohen, and Members of the Subcommittee. Thank you for the opportunity to testify today.

I am President of the Ethics Resource Center, America's oldest non-profit dedicated to independent research on workplace ethics. Our center generates the U.S. benchmark on business ethics known as the National Business Ethics Survey. We also consult with companies to assess their ethics and compliance programs and cultures. And finally, ERC educates public officials on new insights coming from our research. For example, very recently we shared our work with the OIG from the Department of Justice, the Department of Housing and Urban Development, and also the Interagency Suspension and Debarment Committee.

It is important to note that while ERC's research was cited in the report that has been the impetus for today's hearing, our center was not involved in the writing of the report itself. Neither am I an expert on the False Claims Act. The views I express today are based on the objective findings from ERC's research.

A central focus in today's discussion is the proposal for accrediting rigorous compliance programs, so I would like to address a few questions that are fundamental to that proposal. For example, if a company has invested in an ethics and compliance program that actually works, can we expect that the number of instances of fraud will go down? When fraud does occur, will the reporting of violations go up? And finally, if standards are established to define state-of-the-art programs, is there evidence that industry practices will improve?

First and foremost, ERC has found that when an ethics and compliance program is well implemented within a corporation, there is demonstrable impact on the conduct of its employees. Employees and companies with well-implemented ethics and compliance programs are more likely to say that they work in strong ethics cultures. And when a strong program and a strong culture are in place, misconduct decreases by more than half.

Similarly, in organizations with strong programs and cultures, the potential for wrongdoing is lessened. Forty-four percent fewer employees and companies with strong programs say they feel pressure to break the law in order to do their jobs. And in the same vein, 90 percent of employees in those kinds of organizations with strong programs and cultures say they know how to appropriately handle wrongdoing if it were to arise. And importantly, when wrongdoing does occur, the rate at which employees step forward to report increases by 94 percent.

In 2013, more than 1 in 5 U.S. business employees said that they observed at least one incident that might be considered a False Claims Act violation. That percentage dropped by 71 percent when employees said they worked in a strong ethics culture. Yet you

could ask, if ethics and compliance programs have such a significant impact on business conduct, why does fraud continue to occur?

Part of the reason is that misconduct is a reality in every corporation, and in every organization for that matter. But it is also the case that as of 2011, only one-quarter of U.S. employees said that their company had a compliance program that was well implemented, meaning that it had all of the elements in place that we know improve and encourage ethical conduct, and that is where a certification process has the potential to play an important role.

Standards for certification or the like do shift corporate behavior provided the entity establishing the standards is trustworthy and free from conflicts of interest; standards are established with significant input from industry leaders and enforcement officials; the criteria take into account differences in organizational size, industry, and the context in which an organization is operating; and the standards are living and breathing, meaning they evolve with new insights from research and practice.

Finally and perhaps most importantly, it is imperative that any definition of an effective program focus on compliance but also ethics. Companies that merely comply with the law check the box when they have met expectations and move on to other priorities, and that is the danger of a certification standard without the dimension of ethics. It is the commitment to ethics and culture that perpetuates right conduct in a company and diminishes the need for enforcement due to violations of the False Claims Act.

Thank you again for the opportunity to address you today. I welcome your questions.

[The prepared statement of Ms. Harned follows:]

Testimony before the U.S. House of Representatives
Committee on the Judiciary
Subcommittee on the Constitution and Civil Justice

"Oversight of the False Claims Act"

Testimony of
Patricia J. Harned, Ph.D.
President
Ethics Resource Center

July 30, 2014

1:00pm, Rayburn House Office Building, Room 2237

Good afternoon Chairman Franks, Ranking Member Cohen, and Members of the Subcommittee. Thank you very much for the opportunity to testify today regarding the Oversight of the False Claims Act.

I am president of the Ethics Resource Center (ERC), America's oldest nonprofit organization dedicated to independent research and the advancement of high ethical standards and practices in public and private institutions. ERC was established in 1922, and has become widely known for our rigorous research and our analysis of emerging issues in workplace ethics.

Most notably, our center generates the US benchmark on business ethics: a longitudinal cross-sectional survey of employees known as the *National Business Ethics Survey (NBES)*.[1] Findings from the NBES study reveal the most effective steps that business leaders can take to improve conduct and avoid overstepping the law. We've been fielding the survey since 1994; therefore, the longitudinal nature of the data tracks the progress of Corporate America in addressing their ethics and compliance issues.

Our center also consults with companies to assess and help improve their ethics and compliance programs and cultures. When it comes to fraud, we have worked with organizations at both ends of the spectrum; we've helped companies that are taking a preventative step to avoid problems before they happen, and we've also provided support to organizations after misconduct has occurred.

Finally, ERC educates officials within the federal government on new insights stemming from our research and practice. For example, we have shared findings from our research with the Office of the Inspector General (OIG) for the U.S. Department of Justice and the OIG for the U.S. Department of Housing and Urban Development; we have discussed what research has to say about the hallmarks of an effective ethics and compliance program with the Interagency Suspension & Debarment Committee; and we've presented data on whistleblowing to the Securities & Exchange Commission's Whistleblower Office as well as other agency officials tasked with oversight of federal whistleblower ombudsman programs.

It's important to note that while ERC's research was cited in the *Fixing the False Claims Act* report that has been the impetus for today's hearing, our center was not involved in the writing of the report itself. Neither am I an expert on the False Claims Act. The views I express today are based on the objective research findings and observations of the ERC, and not any other entity.

A central focus in today's discussion of the False Claims Act is the proposal for the establishment of a voluntary system for accreditation of rigorous compliance programs, as an incentive for businesses to prevent fraud. I'd like to address a few questions that are

[1] Since 1994 the Ethics Resource Center has conducted the *National Business Ethics Survey;* a survey of employees in business workplaces across the US. We ask employees to tell us about the work their companies have done to address ethics and compliance; the violations that they have observed; and the extent to which these violations were addressed. See: www.ethics.org/nbes.

fundamental to that proposal; namely what research has to say about whether it is reasonable to expect that businesses can prevent and detect fraudulent activity in the first place. If a company has invested in an ethics and compliance program that actually works, can we expect that the number of instances of fraud will go down? When fraud does occur, should we anticipate that the reporting of violations will go up? Finally, if a set of standards are established to define "state of the art" programs, is there evidence to suggest that industry practices will improve?

My testimony today can be summarized as follows. First, the Ethics Resource Center's research has shown that when companies establish well-implemented ethics and compliance programs, not only do they successfully reduce the frequency of fraudulent activity; they establish cultures that decrease the likelihood that such misconduct will take place, and increase the likelihood that any incident that does occur will be handled responsibly. Second, we know from the input of employees across the country that fraud is a frequent occurrence in U.S. workplaces, and while some companies have elements of an effective program in place, many more have work to do before they can say that they have well-implemented programs. And finally, while there is some precedent that an effort to incentivize "gold standard" or "state of the art" programs will provide strong incentive for businesses to focus on the most effective activities that improve their ethics and compliance programs. Yet it is also important to note that unless certification standards reflect the complexities of organizational ethics and culture (in addition to compliance), and if care is not taken in the selection of the certifying entity (or entities), the process may have the unintended consequence of reducing rather than raising standards of business conduct.

Before I go any further, I'd like to offer one technical note. As I speak today, I will use the term "effective," "well-implemented" and "strong" ethics and compliance program. I recognize that there is a legal element to the term "effective" when it comes to the matter of program design. ERC is the business of understanding the difference that these programs make when it comes to employees and their conduct. So when I refer to an "effective" program, I am saying that a program encourages employees to do right, and to follow the rules. Similarly, a "well-implemented" or "strong" program is one that employees know about, and make use of when violations occur.

The Efficacy of Effective Ethics and Compliance Programs

First and foremost, ERC has found that when an ethics and compliance program is well-implemented within a corporation,[2] there is a demonstrable impact on the conduct of its employees.

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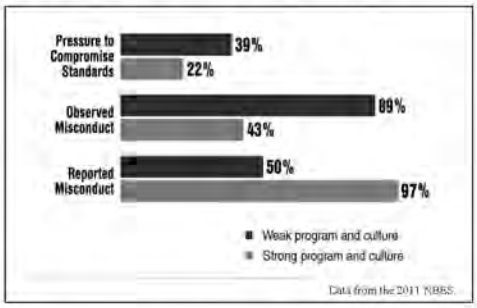
[2] In ERC's research, a well-implemented (effective) program provides the elements of a program as defined by the Federal Sentencing Guidelines for Organizations, and the program is used by employees in their daily activities. They seek advice in uncertain situations, receive positive feedback from their supervisor for ethical conduct, they feel prepared to handle ethics issues that arise, they can raise issues to management without fear of retaliation, they are rewarded for their ethical conduct, and questionable means are not rewarded even if they produce results.

Our research has consistently shown the important dynamic that takes place within businesses that have effective ethics and compliance programs in place. Employees in organizations with well-implemented ethics and compliance programs are more likely to say that they work in companies that have strong ethical cultures – in other words, their business leaders care about ethics, their supervisors support the tone coming from the top, and the values and standards of the organization are observed in everyday business decisions.

Together, these well-implemented programs and strong cultures make a substantial difference. For example, when a strong program and culture are in place, misconduct decreases by more than half (52 percent) compared to companies where the program and culture are weak.

Similarly, the data suggest that in organizations with strong programs and cultures, the *potential* for wrongdoing is lessened as well. For example, 44 percent fewer employees in companies with well-implemented programs say that they feel pressured to compromise standards or break the law in order to do their jobs. In the same vein, 90 percent of employees in organizations with strong programs and cultures say that they know how to appropriately handle a violation of wrongdoing if it were to arise. This compares to only 63 percent who do not work in such an organization.[3]

Figure 1. Impact of Well-Implemented Ethics and Compliance Programs on Employee Conduct



Also importantly, when wrongdoing does occur, the rate at which employees step forward to report a violation increases by 94 percent. They are less likely to doubt that action will be taken. Business leaders in these companies are therefore more aware of wrongdoing that has taken place.

The Need for – and Prevalence of – Effective Ethics and Compliance Programs

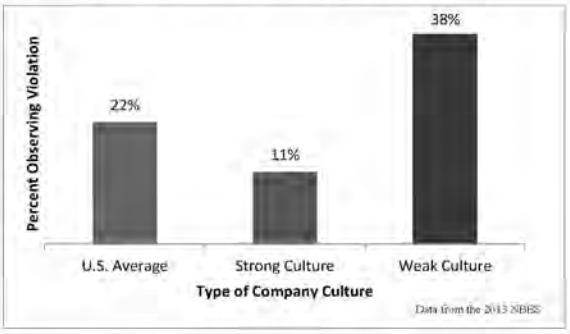
There is a need for effective corporate ethics and compliance programs, particularly when it comes to the False Claims Act. In 2013, more than one in five US business employees (22

[3] Ethics Resource Center. (2011). *National Business Ethics Survey.* Arlington, VA: ERC.

percent) said that within the past twelve months they observed at least one incident that might be considered a False Claims Act violation.[4]

The prevalence of potential FCA violations is also linked to ethics culture. The percentage of employees who observed an incident that might be considered an FCA violation drops by seventy-one percent where employees say they work in a strong ethical culture.

Figure 2. Prevalence of Potential FCA Violations (2013)[5]



Yet if effective ethics and compliance programs have such a significant impact on business conduct, it is reasonable to ask why it is that fraudulent business activity continues to occur. Certainly part of the reason is that misconduct is a reality for *every* organization.[6]

Even in organizations with the strongest of programs and cultures, misconduct does occur. Interestingly, though, the nature of the problem tends to be more isolated to an individual actor, and a single incident. Fraudulent activity in these organizations is more likely to be a matter of a bad apple, as opposed to a bad tree. But misconduct does still take place.

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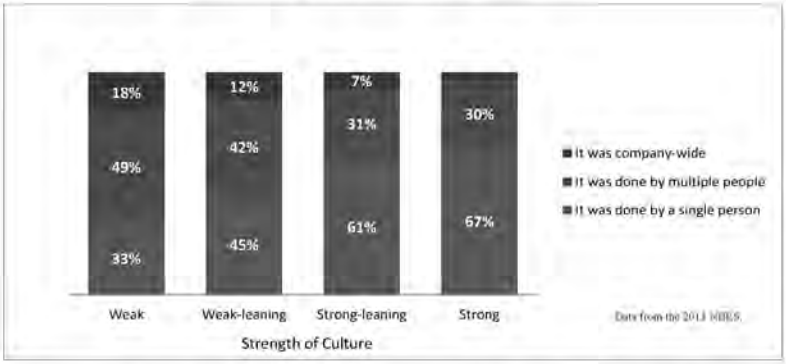
[4] As a part of the *National Business Ethics Survey*, ERC asks employees if they have observed specific types of behavior within the past twelve months. No attempt is made to determine the extent to which violations were knowingly or willfully committed. For purposes of this testimony, the types of violations that could be considered FCA violations were combined to generate an overall statistic. However, it is unknown whether the incidents were actual violations of the FCA. Metrics included: Delivery of substandard goods or services; Lying to customers, vendors, or the public Falsifying and/or manipulating financial reporting information; Falsifying invoices, books, and/or records; Falsifying time reports or hours worked; Violating contract terms with customers or suppliers; Falsifying time reports or hours worked.

[5] Ibid.

[6] In 2013, 41 percent of employees across the US indicated that they observed some sort of violation that they considered to be a violation of the law or their organization's standards for business conduct. Ethics Resource Center. (2013). *National Business Ethics Survey*. Arlington, VA: ERC.

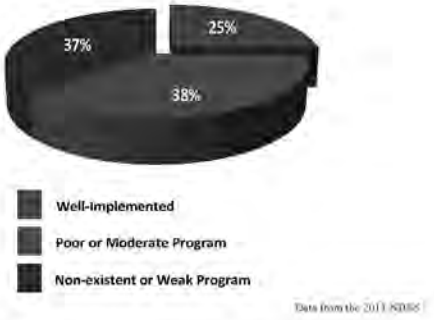
Figure 3. Strength of Culture and Scope of Misconduct



Another reason fraudulent activity continues – sometimes in egregious ways – has to do with the extent to which businesses have actually implemented programs that are fully effective.

A predominance of companies in the US have established codes of conduct, and nearly as many have put into place hotlines to receive whistleblower reports. Training on ethics and compliance is a growing trend, too.[7] Nevertheless, as of 2011 only one quarter (25 percent) of US employees indicated that their employer had a comprehensive program that was operating effectively; that is, a program that could significantly improve the conduct of their workforce. This is where a certification process has the potential to play an important role.

Figure 4. Percentage of Well-Implemented Ethics and Compliance Programs in U.S. Corporations (2011)



[7] Ethics Resource Center. (2011). *National Business Ethics Survey.* Arlington, VA: ERC.

Standards for Certification of Effective Ethics and Compliance Programs

Standards for certification (or the like) do shift corporate behavior. Even further, if the standards are based on criteria that are known to encourage good conduct, they will in turn prompt ethical corporate behavior.

Take, for example, the Federal Sentencing Guidelines for Organizations (FSGO).[8] Promulgated by Congress in 1991, the guidelines were put into effect by the U.S. Sentencing Commission to help federal judges impose fair and consistent sentences when corporations violated U.S. law. The guidelines identified seven elements for effective ethics and compliance programs, and created a "carrot and stick" regime for assessing corporate culpability and giving credit, including sharp reductions in penalties, when an effective compliance and ethics program was in place to "prevent and detect violations of law." The FSGO also imposed severe penalties for companies that "tolerated, encouraged or condoned" improper behavior.

In 2011 (the 20th anniversary of FSGO), the ERC empanelled an independent Advisory Group of distinguished former law enforcement officials, federal judges, prosecutors, academics, and compliance/ethics experts to examine the FSGO, its successes and failures, and to identify possible areas of improvement. The group found that from a judiciary and enforcement perspective, the FSGO were at best seldom utilized and inconsistently applied. But remarkably, the FSGO had achieved significant success from the standpoint of the ethics and compliance industry. In essence, the introduction of the FSGO encouraged vigorous efforts by many U.S. companies and other organizations to adopt comprehensive ethics and compliance programs.

The Advisory Group concluded that the seven elements of an effective program, as outlined in the FSGO, had become the de facto framework for U.S. corporations and have also come to serve as a reference point for many U.S. regulatory and enforcement agencies.[9] Even further, all of the research by the ERC that I have been discussing today is based on metrics that test the presence of an ethics and compliance program as defined in the FSGO. So not only do the FSGO provide a standard for companies to implement effective programs, we actually know that they *work*.

The proposal raised in *Fixing the False Claims Act* varies in some significant ways from the intent and application of the FSGO. It's beyond my scope to address the legal and regulatory specifics of defining and certifying a "gold standard" for an ethics and compliance program. Nevertheless, from ERC's perspective, an effort to review and certify ethics and compliance programs could have a tremendous influence on corporate priorities, provided:

- The entity establishing the standards is trustworthy, transparent, and free from conflicts of interest;

[8] See www.ussc.gov.

[9] Ethics Resource Center. (2012). *The Federal Sentencing Guidelines for Organizations at Twenty Years: A Call to Action for More Effective Promotion and Recognition of Effective Ethics and Compliance Programs.* Arlington, VA: ERC.

- Standards are established with significant and ongoing input from ethics and compliance practitioners, industry leaders, and enforcement officials;

- Criteria for a "gold standard" take into account differences in ethics and compliance program design because of organizational size, industry, and the context in which an organization operates; and

- Standards are living and breathing; meaning that they evolve with new insights from research and innovation in program practices.

Finally, and perhaps most importantly, it is imperative that any definition of an effective program include not only a focus on compliance, but also on ethics. Throughout my remarks today I have used the terms "culture" and "ethics"; this is for a specific reason. Companies that merely comply with the law aim for the minimum standard; they check the box when they've met expectations and they move on to other priorities. And that is the danger of a certification standard without the dimension of ethics.

ERC's research has shown that when employees perceive that their company leadership is genuinely committed to ethical conduct, misconduct is reduced by as much as 56 percent. In cultures where supervisors support employees for doing what is right, employee reporting of wrongdoing rises by more than a third (33 percent). While compliance standards and controls are essential, it is the commitment to ethics and culture that perpetuates right conduct in a company, and diminishes the need for enforcement through the False Claims Act.

Conclusion

By comparison to many other professions, the field of ethics and compliance is relatively young. Yet so long as corporate scandals occur, it is good and right to periodically ask whether the efforts by Corporate America to monitor their own conduct make any difference.

After more than two decades of research, I am pleased to report that there is good news. Companies that implement effective ethics and compliance programs, and also focus on establishing ethical cultures where standards are taken seriously, do prevent and detect fraudulent activity. Even further, they actually improve the conduct of their employees. And there is reason to expect that an effort to assess and certify effective corporate programs – if carefully and thoughtfully done – will improve corporate conduct even further.

Thank you again for the opportunity to address you today. I welcome your questions.

Research Reports by the Ethics Resource Center

The following research reports in the *National Business Ethics Survey* series were recently released by the ERC. Our research is available to the public for free at www.ethics.org.

- 2011 and 2013 *National Business Ethics Surveys*
- *Inside the Mind of the Whistleblower*
- *Retaliation: When Whistleblowers Become Victims*
- *Generational Differences in Workplace Ethics*
- *National Business Ethics Survey of Social Networkers: New Risks and Opportunities at Work*
- *National Business Ethics Survey of Fortune 500® Employees*
- *National Business Ethics Survey of the Construction Industry*

Mr. FRANKS. Thank you, Ms. Harned.

Mr. Ogden, we will get back to you.

I now recognize our third witness, Mr. Clark. And if you would turn on your microphone, sir.

TESTIMONY OF JOHN E. CLARK, OF COUNSEL, GOODE CASSEB JONES RIKLIN CHOATE & WATSON, TAXPAYERS AGAINST FRAUD

Mr. CLARK. Thank you, Mr. Chairman. I appreciate the opportunity to express my views on this important law. It has enjoyed overwhelming bipartisan support for 28 years now.

I come from a small firm of nine lawyers. Two of us represent whistleblowers. The other seven are busy with things like real estate transactions and municipal law and insurance defense litigation.

Representing whistleblowers is the most professionally satisfying thing I have done since I was the U.S. Attorney in Texas, investigating and prosecuting corrupt public officials in an historically corrupt Texas county. We live in an era of ever-growing government and ever-proliferating programs that spend mind-boggling sums of taxpayer money. Big industry groups love big government programs because they have all that money to spend, and we have a resulting phenomenon that I call the Washington merry-go-round. Others call it crony capitalism. Bright, able people get on the merry-go-round and they enter government service, most as administrators or lawyers. They make policy, administer programs, deal with legal issues. They are regulators, and they learn how the government works from the inside.

Later, the same government officials get off the merry-go-round and they are eagerly recruited by industry groups as counsel or as lobbyists, or both. They become part of a community that they used to regulate, and now the regulated industry group's interests are their interests to protect.

One of their goals is to undermine incentives for whistleblowers who take risks when exposing fraud. The goal of the former regulator, now an industry lobbyist, is to make it more difficult for the government to succeed in making False Claims Act cases against their clients' interests.

The Department of Justice does a lot with limited resources. They work hard to enforce the False Claims Act and recover America's stolen billions. One way the False Claims Act might be amended to help the Department of Justice, and it could be accomplished without cost, is to embrace a provision that we now find in 15 of the 29 state False Claims Acts. Under those 15 state False Claims Acts, the state can recover its attorney's fees in a successful case. The United States should have the same right, but that is a right that is now lacking under the Federal False Claims Act. Those fees and a percentage of all False Claims Act recoveries should be specifically allocated to funding False Claims Act enforcement.

I suggest we should also add tax fraud enforcement to the False Claims Act. The IRS now has a whistleblower incentive program, but that program is not working. But again, the states provide a working model that the Federal Government might copy. New York

has added taxes to its False Claims Act, and it is already recovering millions of dollars.

And one more thing. Just as no company should be too big to fail, no individual should be too important to incur personal consequences for fraud against the government. Personal consequences are a strong deterrent to fraud.

Let me conclude by saying I am struck by the wisdom of Senator Grassley's skepticism and caution about buying into a fanciful, untested, gold-plated, certified compliance program. The key to compliance is integrity. It is not just a matter of paperwork, as evidenced by the multiple offenders under the False Claims Act. Justice Oliver Wendell Holmes said it best for all of us, and in just 11 words. When he wrote for the Court in *U.S. v. Rock Island Central Railroad* in 1920 he said, "Men must turn square corners when they deal with the government."

Thank you, Mr. Chairman.

[The prepared statement of Mr. Clark follows:]

TESTIMONY OF JOHN E. CLARK
BEFORE THE HOUSE JUDICIARY COMMITTEE
SUBCOMMITTEE ON CONSTITUTION AND CIVIL JUSTICE

July 30, 2014

I respectfully submit this testimony from my perspective as an attorney representing whistleblowers in *qui tam* actions under the False Claims Act and its state counterparts for more than 20 years. My views on government and law enforcement are informed by my previous service in the public sector, as well as by my experience as counsel for whistleblowers. I have been a licensed attorney since 1961.

From 1969 to 1977 I was in federal government service; first as a litigation attorney in the Justice Department's Criminal Division, next as an Assistant U.S. Attorney in Texas, and finally as the U.S. Attorney for the Western District of Texas. In those capacities, I handled and oversaw a wide variety of civil and criminal litigation for the United States. I served as the U.S. Attorney for the Western District of Texas from 1975 to 1977.

In 1981-1982 I served as a Justice of the Texas Court of Appeals (Fourth District), the state's counterpart to the federal circuit courts.

While engaged in the private practice of law I have also served as an appointed board member or commissioner of the National Institute of Corrections (a Bureau of Prisons agency), the Texas Commission on Law Enforcement Officer Standards and Education, and the Texas Ethics Commission.

Since 1992 my law practice has consisted almost exclusively of representing private parties who bring *qui tam* cases on behalf of the United States under the False Claims Act and on behalf of Texas and other states under their similar Medicaid fraud statutes. Those parties are commonly referred to as "whistleblowers" or "relators."

In the course of my *qui tam* practice I have been a member of legal teams representing whistleblowers in cases that have resulted in recoveries totaling more

than three billion dollars ($3,000,000,000) for the United States and state Medicaid programs. The cases have involved both health care fraud and defense contracting fraud, the two primary areas of fraud against the government today. Many of the defendants have been publicly traded companies with familiar names, such as GlaxoSmithKline, HealthSouth Corporation, SmithKline Beecham Clinical Laboratories, SAIC, Boeing, Baxter International, Abbott Labs, and Actavis.

Those clients who, as employees, first reported the fraud to their employers, were all adversely effected in their employment, and the fraud continued. Even the octogenarian physical therapy patient tried first, without success, to get the corporate provider to reform its conduct voluntarily.

Currently, I am Of Counsel at Goode Casseb Jones Riklin Choate & Watson, a San Antonio, Texas law firm I participated in founding in 1991. I also serve on the Board of Directors of Taxpayers Against Fraud (TAF) and Taxpayers Against Fraud Education Fund (TAFEF), the non-profit public interest organizations dedicated to combating fraud against the United States through the promotion and use of the False Claims Act and its *qui tam* provisions.

- **If fraud were easy for government programs to detect and prevent, it wouldn't be so successful.**

With depressing regularity, government agencies estimate how many tens or hundreds of millions – or even billions – of dollars their programs have lost to fraud in a particular reporting period. Not surprisingly, the largest programs, such as Medicare and Medicaid, report the largest losses due to "improper payments," with the most recent estimate, for FY2013, listed as almost $50 billion and $20 billion respectively, and an estimated $125 billion a year lost across all government programs.[1]

A government agency that knows its program is a prime target for fraud doubtless tries to sniff it out. The clumsy, the obvious, and the unlucky sometimes get caught; we see those successes from time to time in the six o'clock newscasts,

[1] [1] See: http://www.gao.gov/assets/670/662845.pdf and http://www.gao.gov/assets/660/652386.pdf and http://www.gao.gov/new.items/d11575t.pdf

complete with film of government law enforcement agents wheeling file cabinets out of storefront, fly-by-night health care businesses. But the more sophisticated fraudsters, knowing their government-program target is expected to be wary, look for unsuspected chinks in the regulatory and administrative armor and fashion clever schemes - some simple, some complex - to exploit them. The more carefully thought-out schemes often fly under the radar for years unless they're exposed by someone outside of government, with inside knowledge about the scheme. Also, some of the most costly schemes result from corporate cultures that nurture and rationalize practices that violate the False Claims Act, but exist because responsibility is spread among many and diluted beyond accountability.

- **Whistleblowers provide valuable aid to law enforcement by exposing frauds government agencies don't know about.**

When the False Claims Act became law in 1863, and again when it was revitalized in 1986, most of the fraud against the government was thought to be in the arena of defense contracting. But since the 1986 amendments became law, about 68% of False Claims Act recoveries have involved health care. Moreover, new fraud schemes against an ever-proliferating array of increasingly large federal programs have been uncovered by whistleblowers – huge government-insured mortgage schemes, construction contract schemes, oil royalty schemes, and frauds against veterans' education, mortgage, and health care programs, to name only a few.

By encouraging whistleblowers to step forward and expose fraud, the False Claims Act has increased the government's awareness of new vulnerabilities in federal programs and assisted in recovering taxpayer funds and restoring integrity to the affected systems. But law enforcement is inherently reactive, while skilled fraud planners are inventive. Thus law enforcement must often play catch-up to learn about, and learn how to detect, new schemes. Whistleblowers are invaluable to that effort.

- **The False Claims Act enhances the government's defenses against fraud without increasing the size or the cost of government.**

Not only do whistleblowers expose fraud schemes otherwise unknown to the government, but through their attorneys they take the necessary steps to initiate damage recovery actions on the government's behalf – the time-intensive tasks of screening cases, interviewing witnesses, analyzing and organizing available evidence, evaluating legal merit, preparing and filing complaints – thereby augmenting the government's resources without any cost to taxpayers. Moreover, after a recovery the whistleblower's attorney fees are paid by the wrongdoer as costs of the legal action.

- **How and why the False Claims Act works.**

The False Claims Act is designed to incentivize integrity. A company or an organization that defrauds the United States is subject to treble damages and penalties for its perfidy. Those remedies are intended to recover the government's losses, pay for whistleblower awards, and deter similar fraud by the same wrongdoer and by others.

When a fraud scheme goes undetected – or is not responded to – by the administrators of an affected program, the role of the whistleblower is vital. The assistance of a non-government source with knowledge of the facts – a whistleblower – is the key to discovering and excising a secret infection. To obtain that assistance, the statute provides an incentive for a whistleblower to come forward, in the form of a "relator's share" of the total amount recovered. The net result is that the wrongdoer is exposed and punished, the government recoups its losses, and the whistleblower is rewarded for making that possible – all paid for, appropriately, by the wrongdoer.

Whistleblowers and their attorneys are compensated only if their cases result in a recovery, and there are serious sanctions for bringing a frivolous case. As a result, cases filed by knowledgeable *qui tam* attorneys tend to be carefully chosen and well developed, providing the government's attorneys with a substantial foundation on which to build a successful case. If the Department of Justice exercises its statutory option to intervene in the case and take the lead in prosecuting it, the whistleblower remains a party and she and her counsel continue in a supporting role and assist the government's attorneys in the litigation. The

value of that assistance is a factor in the Department's decision on the amount of the whistleblower's award, which serves as a further incentive to aid the government effectively in enforcing its rights.

For more than 25 years this idea – making fraud expensive for cheaters, and rewarding whistleblowers who expose them – has worked remarkably well. Since the statute was amended in 1986, False Claims Act cases have returned more than $45 billion to the U.S. Treasury and nearly $10 billion to the states. Over half of that total has been recovered in the last eight years, during which time the law has been strengthened and clarified by further amendments, and appreciation of its effectiveness has increased. In a growing number of meritorious cases, the Department of Justice leaves it entirely up to the relator and its counsel team to pursue the action and recover the taxpayers' funds from the fraudster. In these cases, the augmentation of scarce government resources contemplated by the FCA is most realized.

Today nearly 80 percent of False Claims Act recoveries result from cases initiated by whistleblowers.

An analysis by Taxpayers Against Fraud Education Fund of the return on federal investments in investigation and prosecution of health care fraud cases shows that the United States gets back more than $20 for every $1 invested in qui tam cases.

In addition to direct asset recovery, the False Claims Act also has a powerful deterrent value. National fraud schemes related to drug pricing, hospital upcoding, oil and gas fraud, laboratory bill padding and more, have been exposed and reigned in thanks to whistleblower-driven False Claims Act cases.

The False Claims Act is so effective that 29 states and the District of Columbia have adopted similar statutes, and the SEC, the CFTC, and the IRS now have their own whistleblower programs with reward systems modeled on the Act.

Since Virginia adopted its Fraud Against Taxpayers Act in 2002, the Commonwealth's Medicaid Fraud Control Unit has returned an average of $228 million per year, or more than $3.1 million per Fraud Unit employee.

From 2006 through Fiscal Year 2012, Texas recovered more than $821 million for state and federal taxpayers under its Medicaid Fraud Prevention Act - net of the awards paid to whistleblowers and the state's attorney fees and costs. Under the state-federal cost sharing formula for Medicaid, more than $348 million of this amount was retained for the benefit of Texas taxpayers and over $473 million was paid into the United States Treasury. It should be noted, also, that nearly half of these recoveries – more than $394 million – resulted from fraud cases in which Texas led the investigation and prosecution of the case under the Texas Medicaid Fraud statute – the Texas state version of the False Claims Act.[2]

- **Whistleblowers are natural adversaries for crony capitalism and inaction by overgrown government bureaucracies.**

A *qui tam* case under the False Claims Act cannot be ignored by the government. The United States is not required to join the case, but the Department of Justice must exercise due diligence to determine whether it is in the government's interest to intervene in the case and conduct the litigation. In that process the affected agency will learn that it may have been cheated, perhaps by a contractor with which it has dealt extensively. Because agencies do not relish the embarrassment of revelations that they have been taken advantage of, or have been lax in guarding the public fisc, the availability of whistleblower actions serves as an added incentive for them to be vigilant against fraud.

The GAO estimates that "improper payments" by federal programs total more than $125 billion a year, and that in Fee for Service Medicare the ratio of overpayments to underpayments is 20:1 in favor of companies, many of which systematically exploit government billing and payment protocols to price-gouge, pad bills, and sell defective or unnecessary goods and services.[3] Fraud schemes can be facilitated by commercial kickbacks, or by too-trusting relationships, or by

[2] http://www.taf.org/publications/reports/fighting-medicaid-fraud-texas
[3] http://www.cms.gov/apps/er_report/preview_er_report.asp?from=public&which=long&reportID=15&tab=3#582

regulatory indifference, or by failure to comprehend the problem, or through plans carefully calculated to deceive unwary regulators. But when government, for any reason, cannot – or will not – act to protect the taxpayers, determined whistleblowers and their private attorneys can still protect the public interest and aid the cause of law enforcement by seeking a remedy under the False Claims Act.

A case in point is an extensive and complex course of *qui tam* litigation in which I was a member of a legal team combating a scheme by drug manufacturers nationwide to cause government health care programs to grossly over-reimburse pharmacies for dispensing their drugs. The initial case, asserting fraud by multiple manufacturers, was filed in Miami in 1995, and a similar federal case against additional defendants was filed in 2000 in Boston. The facts – and the truly shocking over-reimbursements being paid by government health care programs because of the false prices reported by manufacturers and relied on by government agencies – were compelling. Top federal officials deferred to the Department of Justice, which delayed making a decision whether to intervene in the cases while continuing to investigate the massive fraud and reaching settlements with a number of the defendant drug manufacturers. Without a decision by the Department of Justice, the cases remained under seal, and we could not pursue active litigation in them. Meanwhile, government health care programs began to address the problems exposed by the cases, but this was a long and complex process during which taxpayers continued to bear the burden.

While the United States continued to pursue resolutions while the cases remained under seal, our team of private lawyers filed similar *qui tam* cases beginning in 1997 under similar state False Claims Acts against many of the same drug companies, alleging they were using the same false pricing scheme to defraud the individual state Medicaid programs. Litigation began in earnest in state courts in Austin, Texas, beginning in 1999, when then Texas Attorney General John Cornyn intervened in our *qui tam* case filed under the Texas Medicaid Fraud Prevention Act. When all of the litigation, both state and federal, was over, more than $3 billion had been recovered for Texas, the United States, and other states; the drug price reporting protocol had been reformed by Congress; and state Medicaid programs, Medicare, and other government health care programs were able, at last, to get drug manufacturers' truthful prices.

The United States finally did elect to intervene and conduct active litigation against three of the manufacturers named in the federal cases. It happened in 2006, 11 years after the 1995 case was filed, and after several federal settlements and many of the state court cases had already been concluded successfully. The cases actively pursued by the Department of Justice generated roughly one-third of the total federal recoveries in the drug pricing cases, with the remainder coming from cases settled without active litigation or by the relator/counsel team proceeding after DOJ declined to intervene.

- **The False Claims Act has been a bipartisan success.**

The False Claims Act was forged during the Civil War at President Lincoln's urging and was designed to combat price-gouging and the sale of defective munitions and supplies to the Union army.

In 1943, the statute was almost completely gutted by the Attorney General, who in 1942 had created a "War Frauds Unit," thinking DoJ could fight fraud against the government on its own from offices here in Washington, D.C.

In 1986 Senator Charles Grassley (R-IA) and Congressman Howard Berman (D-CA) realized the government was paying a high price for not having fraud-fighting assistance from private citizens. Hoping to remedy that situation, they authored legislation to revitalize "Lincoln's Law" with strong, new provisions to encourage whistleblowers to step forward and help once again. Their efforts received overwhelming bipartisan support in both Houses, and President Reagan signed the bill into law.

Reagan-era False Claims Act reforms have been incredibly successful. False Claims Act returns have risen steadily for the last 20 years, and massive fraud schemes against many government programs have been exposed and ended.

- **Nevertheless, government programs remain a target for fraud, and additional efforts are needed to combat it.**

Government programs, with their enormous sums of money to be paid to contractors, providers and suppliers, will always attract those who are willing to take it by fraudulent means from bureaucratic systems ill equipped to discover that they are being cheated. Fraud will never be eradicated completely; but if the government is serious about combating fraud, more needs to be done.

- **The government's litigation resources are inadequate.**

A lack of adequate litigation resources in the Department of Justice's Civil Division and in some United States Attorneys' Offices is one of the reasons why the Department declines to intervene in some meritorious False Claims Act cases. That is also a reason why the Department's decision whether to intervene typically is made only after several six-month extensions of the 60-day statutory "under seal" period that allows the government to conduct its due diligence analysis of the whistleblower's claim discreetly and without interference. And it is a reason why major cases often take years to conclude, even after intervention. The Department often is under-resourced in comparison to the huge law firms typically arrayed against it in major cases More litigation attorneys for the Civil Division and the Affirmative Civil Enforcement (ACE) teams operating in key United States Attorneys' Offices would enable the government to move cases toward resolution more quickly and arm it with more credibility for going to trial – a key factor properly affecting both the government's, and a defendant's, approach to settlement negotiations.

Considering the demonstrably high rate of return on the government's investment in the prosecution of health care fraud cases alone, and the need for additional resources to manage the sizeable inventory of FCA cases effectively, a portion of the government's recoveries in False Claims Act cases should be directed specifically to increasing Justice's litigation resources for FCA cases. That investment would quickly return substantial dividends, and it could be accomplished without additional cost.

- **Congress should allow the United States to recover its attorney fees and expenses in a successful False Claims Act case.**

Under the False Claims Acts of 15 states, including Texas, the state is entitled to recover its reasonable attorney fees from the wrongdoer when it prevails in a fraud case. That is eminently fair, given that the state's damages include not only the money it lost, but also the value of its attorneys' services in effecting a recovery. The federal False Claims Act should be amended to provide the same relief for the United States.

Without the right to recover its attorney fees, the United States - unlike those 15 states - is not fully compensated for the expense of enforcing the statute and the wrongdoer is not held fully responsible for the damage he caused.

Consideration should be given to requiring attorney fees and/or a portion of all funds recovered by the United States in False Claims Act cases to be applied specifically to offset the expenses of the Department of Justice's Civil Division in administering and enforcing the False Claims Act. The False Claims statutes of eight states and the District of Columbia make specific provisions for a portion of the funds recovered by the government to be used in aid of investigating and prosecuting fraud under the statute.[4]

- **The False Claims Act should be clarified to confirm that "damages" caused by fraud means "gross damages."**

The False Claims Act should be amended to clarify that "damages" must be calculated as gross damages rather than net damages, consistent with the Department of Justice's current practice; *i.e.*, without deduction for compensatory value received by the government from any source. For example, defendants sometimes argue that a product they provided to the government was of some value, although it was not what they fraudulently represented it to be and received payment for, and that the government's damages are only the net difference between the two. A few courts have questioned the Department's practice, and clearer legislative language is needed to ensure that the cost of defrauding the government is not reduced to the cost of doing business.

[4] http://www.taf.org/taf-ef-state-fca.pdf

- **Tax fraud should be covered by the False Claims Act**

When the False Claims Act was revitalized in 1986 it was thought that tax fraud cases might be too complex to be dealt with under the law, so those claims were not included. In 2010 New York added tax fraud as an eligible claim under its False Claims Act, and since then several tax fraud cases have been successful under the statute. While the Internal Revenue Service has had its own whistleblower program since 2006, that program is sadly lacking in performance and results. Because it does not include a private right of action if the IRS does nothing, there is no pressure on the agency to resolve cases in order to avoid embarrassment. Civil tax fraud cases are not too complex for federal courts; they manage to deal with the complexities of criminal tax evasion cases without undue difficulty. Including tax fraud cases under the False Claims Act is a simple matter of striking the language in the statute that excludes those cases from its coverage.

- **Big fraud cases should result in personal consequences for the individuals responsible, just as they do in small cases.**

A "small" fraud against the government is not necessarily small in absolute numbers. Because so many frauds against the government involve tens or hundreds of millions, or even billions, of dollars, frauds involving "only" a million, or a few million, are thought of as "small," and the perpetrators are dealt with much more directly and much more severely than those who conceive, manage, conceal, or turn a blind supervisory eye to the big fraud schemes that make headlines in legal and financial journals.

The perpetrators of small frauds typically are often confronted individually with the full panoply of the government's remedies, including damages, penalties, seizure of business and personal assets, prison, and exclusion from doing business with the government in the future.

But in cases where hundreds of millions of dollars, or more, have been taken by fraud, and even when such serious consequences as endangerment of patient safety and health have resulted, personal responsibility is rarely a consideration.

In the typical large fraud case, no one goes to prison, and no one loses their job. Bonuses that resulted from the fruits of the scheme are not clawed back and promotions are kept.

But fraud schemes don't invent or implement themselves. Just as some individual was responsible for the small fraud, some individual - or perhaps more than one - was responsible for the big one. It may be more difficult to determine who was responsible for the big fraud, but it is no less important. Indeed, it may be more important.

The bottom line is that if fraud is to be deterred, there must be personal consequences. Penalties levied against publicly traded corporations may repay the government's cash losses, but those penalties are sometimes inadequate to defer corporate misconduct. This fact is painfully proven by the growing number of large public corporations who are recidivists that repeatedly enter huge – sometimes multi-billion dollar – settlements to resolve False Claims Act violations.

Occasionally a corporate wrongdoer will plead guilty to a criminal offense and pay a fine as part of a global resolution of the case, but typically this is an essentially meaningless gesture the only purpose of which is to allow the government to say it got a criminal conviction. As a practical matter, however, a corporate criminal plea has very little consequence. And without consequence, there is no deterrent effect.

It has been said that we live in an era in which many companies are "too big to fail."

At the same time it is very clear, from reading the newspaper alone, that we also seem to be living in an era in which some individuals are being treated as if they are "too important to go to jail."

What can be done? How can we impose very real personal sanctions on those responsible for fraud against the government?

Fortunately, a sanctioning mechanism already exists.

Federal agencies have authority under existing law to administratively exclude, suspend or debar individuals and entities, for cause, from doing business with the agency.

For example, the Office of Inspector General of the Department of Health and Human Services can exclude individuals or companies "making false statements or misrepresentations of material fact" or who engage in "fraud, kickbacks, and other prohibited activities" in connection with their business with the agency. Any company doing business with the agency that hires an excluded person in a management position is subject to civil monetary penalties, and "no payment will be provided for any item or service furnished, ordered, or prescribed by an excluded individual or entity."

The Department of Health and Human Services excludes about 4,000 people a year. The Department of Defense and the General Services Administration exclude, suspend, or debar a similar number of people and contractors annually.

Remarkably, however, individual and corporate exclusions are rarely levied in cases involving really big frauds.

An orthodontist in Dallas may be excluded, go to prison, and forfeit all of his assets to pay a fine for defrauding Medicaid with false billings; but if a large medical appliance manufacturer engages in a nationwide kickback scheme to increase its sales, no individual consequence is imposed.

No single sanction causes as much concern among individuals who plan and execute large-scale fraud schemes as the prospect of being exposed and held personally accountable.

- **False Claims Act cases are not about accidents or mistakes**.

Every successful False Claims Act case is either the failure of a company or organization to have a compliance program, or the failure of the program. Fraud is dishonest. Fraud is stealthy.

Fraud is not negligence.

Fraud is not an "honest mistake," or a "misunderstanding of complex and confusing regulations."

Fraud that is actionable under the False Claims Act arises only from a legally culpable state of mind ("knowingly"), as defined by the Act.

In a company or organization, fraud typically manifests itself in the planning and active participation of some -- and the tolerance, or ignorance, of that fraud by others.

Because frauds under the False Claims Act are organized, planned, and carried out by company insiders, they are often difficult for company outsiders to detect.

That said, the same planning and organization needed to carry out a fraud often provides the evidence needed to show that a company was knowingly engaged in wrongdoing.

For example, companies may track kickback programs to make sure they are working well and the company is not overpaying or over-gifting.

Spread sheets may be created to detail to doctors and hospitals how they can benefit financially from wasting Medicare and Medicaid money.

Internal emails may show how the company isolated, humiliated, and eventually terminated those who objected to selling the government substandard goods and services.

Price-gouging, double billing, and price manipulations tend to leave a paper trail.

- **Compliance programs do not ensure compliance.**

While companies and organizations may have impressively written compliance programs in place, the reality is that the compliance officers in charge of these programs almost never have the power to change business practices that result in significant profits.

Any competent attorney can write a compliance program that will allow the right boxes to be checked on government forms, but whether the compliance program actually accomplishes compliance with the law depends on whether it is actively administered to enforce an unyielding and thoroughly ingrained institutional culture of integrity.

- **Whistleblowers are not welcome in organizations that lack an institutional culture of integrity.**

Most big fraud schemes are carefully planned and orchestrated for-profit schemes.

When employees in fraud-feasing companies raise their hands internally to question or challenge fraudulent practices, they are not applauded or rewarded. Instead, they are branded as troublemakers and reassigned to other duties and locations in order to limit their access to information and stored data.

The role of compliance officers in these situations is often illuminating. Rather than standing shoulder-to-shoulder with the whistleblower and in support of protecting taxpayer dollars, compliance officers are often part of the management team working on "papering over" the problems while working to terminate the "problem" employee.

- **Education of employees about the False Claims Act should be a requirement of all federal contracts.**

Most corporate fraud schemes that succeed for a significant period of time within an organization do so because of three factors.

First, the scheme itself, whether simple or complex, is not easy to detect, and only a few employees are likely to understand the full scope of it.

Second, those employees who do understand it are likely to be fearful that they will be fired, demoted, or otherwise punished if they question its propriety.

Third, employees see no possible benefit to them or their family for speaking out, either internally or externally.

The False Claims Act was designed to change the last part of this equation, and that part was given a turbo boost by the Deficit Reduction Act of 2005.

In 2005, Congress made education of employees about the False Claims Act a condition of participation for companies that billed Medicare and Medicaid more than $5 million a year.

That part of the law became effective January 2, 2007 and since then False Claims Act recoveries in the health care industry have doubled. *This doubling of False Claims Act recoveries did not occur in any other sector of federal spending.* This experience suggests that a similar requirement, to educate the employees of all federal contractors about the False Claims Act, would have a similarly beneficial effect in the continuing war on fraud.

- **Critics of the False Claims Act would turn back the clock by undermining its effectiveness.**

As awareness of the False Claims Act has increased steadily since Congress revitalized it with the 1986 amendments, so has the Act's effectiveness in exposing

fraud against a broad spectrum of government programs and facilitating the recovery of billions in taxpayers' lost dollars.

It is ironic, but true, that the growth of a well-funded lobby seeking to undermine the law's incentives for whistleblowers is itself evidence that the law works, and that it works because of the whistleblower provisions of the law.

To be clear, the corporate defense lawyers that appear before you today are not here because they seek to save the U.S. government money.

The pharmaceutical companies and hospital associations that are represented here today did not call for smaller government when the Affordable Care Act was being debated.

Military contractors have never led the charge for a smaller footprint on foreign soil when it comes to overseas military interventions.

The banking industry did not rush to Capitol Hill to say they did not want Uncle Sam to relieve them of hundreds of billions of dollars in toxic assets.

It is only in the arena of fraud-fighting that they evince a concern for America's taxpayers.

Their solution to the problem is patently absurd – to reduce the penalties for corporations that have FAILED compliance programs.

Simply put, if government rewards companies for having failed compliance programs, it is sure to get more failed compliance programs, more fraud, and less fraud recovery.

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Top False Claims Act Recoveries

- Cases with an asterisk (*) are cases in which criminal penalties were also assessed.
- Cases with a diamond (♦) are state cases.

Company	Civil Fine ($)
GlaxoSmithKline*	2,000,000,000
Johnson & Johnson*	1,720,000,000
Pfizer*	1,000,000,000
Bank of America	1,000,000,000
Tenet	900,000,000
Abbott*	800,000,000
HCA*	731,400,000
Merck	650,000,000
HCA*	631,000,000
Merck*	628,000,000
JPMorgan Chase	614,000,000
Amgen*	612,000,000
GlaxoSmithKline*	600,000,000
Serono Group*	567,000,000
TAP Pharmaceuticals	559,483,560
New York State and NYC	540,000,000
Astra Zeneca	520,000,000
Ranbaxy Laboratories*	500,000,000
Pfizer*	491,000,000
Schering Plough	435,000,000
Eli Lilly	438,000,000
Abbott Labs*	400,000,000
Fresenius Medical Care of N. America*	385,000,000
Cephalon	375,000,000
United Technologies	365,000,000
Bristol-Myers Squibb	328,000,000
Northrop-Grumman	325,000,000
SmithKline Beecham Clinical Labs	325,000,000
HealthSouth*	325,000,000
National Medical Enterprises*	324,200,000
Gambro Healthcare	310,000,000
Schering-Plough*	292,969,482
Mylan	280,000,000
Roxanne	280,000,000
AstraZeneca*	266,127,844
St. Barnabas Hospitals	265,000,000
Rapamune*	257,400,000
Bayer Corp.*	257,200,000
Schering Plough	250,000,000
Quest Diagnostics♦	241,000,000
First American Health Care Of Georgia (only fractional payment actually made after bankruptcy)	225,000,000
Amerigroup	225,000,000
Deutsche Bank	202,000,000
Actavis (global settlement after verdict)	202,000,000
Oracle	200,000,000
McKesson	190,000,000
BankAmerica*	187,000,000
Laboratory Corp. of America*	182,000,000
Aventis Pharmaceuticals	180,000,000
Endo Pharmaceuticals*	171,900,000
Beverly Enterprises Inc.*	170,000,000

Zimmer Inc.	169,500,000
Purdue Frederick Co	160,000,000
Citigroup	158,000,000
Johnson & Johnson♦ (verdict)	158,000,000
Par Pharmaceutical	154,000,000
Pfizer/Warner-Lambert*	152,000,000
Medco	150,000,000
Sandoz	150,000,000
Amedisys	150,000,000
United Technologies	150,000,000
Maxim	150,000,000
GlaxoSmithKline	150,000,000
Blue Cross Blue Shield Illinois*	140,000,000
Wellcare	137,500,000
Caremark	137,500,000
Mario Gabelli et. al	130,000,000
NetApp	128,000,000
King Pharmaceutical	124,000,000
Northrop Grumman	111,200,000
Shell Oil Company	110,000,000
Sanofi	109,000,000
Vencor Inc./Ventas Inc.	104,500,000
National Health Labs	100,000,000
Oracle / PeopleSoft	98,500,000
Burlington Resources/ ConocoPhillips	97,500,000
Quorum Health Group Inc.	95,500,000
Boehringer Ingelheim Pharmaceuticals	95,000,000
Chevron	95,000,000
Staten Island University Hospital	88,000,000
Lucas Industries*	88,000,000
GlaxoSmithKline	87,600,922
PacifiCare Health Systems	87,300,000
Teledyne	85,000,000
Depuy Orthopaedics	84,700,000
Damon Clinical Laboratories*	83,700,000
Litton Settlement Amount	82,000,000
Northrop Grumman	80,000,000
FMC	80,000,000
Watson Pharmaceuticals	79,000,000
Staten Island Community Hosp.	76,500,000
General American Life Insurance	76,000,000
Kyphon/Medtronics	75,000,000
Boeing Company	75,000,000

Mr. FRANKS. Thank you, Mr. Clark.
And now we will recognize our fourth witness, Mr. Ogden.
Sir, if you will make sure that microphone is on.

TESTIMONY OF DAVID W. OGDEN, PARTNER, WILMERHALE, U.S. CHAMBER INSTITUTE FOR LEGAL REFORM

Mr. OGDEN. Thank you, Mr. Chairman. Thank you, Chairman Franks, Ranking Member Cohen, and Members of the Committee. I appreciate the opportunity to appear before the Subcommittee today to testify on this important issue.

The False Claims Act has been a focus of both my government service and my private practice for over 15 years now, and so I know from direct experience in both places that its unique provisions play a catalytic role in unearthing evidence of fraud and in recovering monies lost to fraud. But there is no doubt, and we have heard some of them today from Dr. Prabhu, that there are costs, and harmful and counter-productive effects of the law as well.

I believe in the False Claims Act. Indeed, as Assistant Attorney General, I personally defended the constitutionality of its critical qui tam provisions before an en banc court of appeals; and as Deputy Attorney General, I helped implement and design the HEAT program which has effectively addressed hard-core fraud in the healthcare industry. But I also believe that we have a real opportunity to enhance the Act's effectiveness and fairness while using it more effectively to prevent fraud before it occurs, as you, Mr. Chairman, identified, as a goal, an important goal.

I start with four basic points. First, the FCA helps uncover fraud against the United States and helps return ill-gotten gains to the Federal Government. Those functions should be preserved and enhanced, and nobody is suggesting otherwise.

Second, encouraging whistleblowers with valid concerns to come forward is critical to the Act, and that is a very good thing. Indeed, I believe the Act can do much more to encourage and protect legitimate internal whistleblowers by incentivizing companies to do more of that themselves.

I heard and understand Senator Grassley's concerns and, to be clear, we strongly support the function of whistleblowers and the role the FCA has played in incentivizing them to come forward.

Third, however, at the present time, the Act is generating a stampede of weak and frivolous claims—we heard about a couple of them earlier—that unproductively burden the government, the courts, private businesses, and individuals alike.

And fourth, the Act as construed by the courts often mandates punishments so far in excess of any real-world harm that defendants are often deprived of meaningful access to the courts to test the most aggressive theories of liability because settlement for many businesses in that situation is effectively the only option. Dr. Prabhu identified some of the ways in which that works where the potential penalties so far exceed the consequences at issue.

I discuss in my written testimony the way these virtues and vices are caused by the FCA's unique features that make it entirely different from other enforcement schemes and call for, I think, some intelligent adjustments.

As outlined in my testimony, I believe there is a sensible way forward, one that aligns government and business alike to prioritize preventing fraud before it diverts Federal dollars from their intended uses, truly making compliance the first line of defense.

First and foremost, we should be encouraging and incentivizing all companies to implement and maintain state-of-the-art compliance programs, programs that promote the highest levels of corporate ethics and legal compliance, encourage and protect internal whistleblowers, and voluntarily report any violation promptly to government authorities. Dr. Harned has talked about how that works.

Under reforms I helped develop for the U.S. Chamber of Commerce and its Institute for Legal Reform, certain rules would apply differently to entities that have been independently certified as maintaining state-of-the-art compliance programs, including the strongest protections for whistleblowers consistent with standards approved by the government. These proposed reforms were the product of my years of work thinking about the Act and the good ideas of my co-authors.

We put pen to paper after months of discussion and consideration, eventually producing the white paper "Fixing the False Claims Act." Our compliance-based approach is not, with all due respect, pie in the sky. Dr. Harned's research shows that state-of-the-art compliance systems work. They reduce fraud, they encourage and protect whistleblowers, and they result in prompt self-disclosure of violations to the government.

So what we propose are incentives for companies and whistleblowers to do these things. The proposed adjustments would by no means remove deterrence and jeopardy associated with civil False Claims Act liability. They would do nothing to change the criminal penalties for individual accountability that were talked about earlier. But they would create differences sufficient to incentivize the adoption of first-rate compliance programs by recognizing their significance in assessing any entity's culpability and recidivism risk.

These reforms are designed to incentivize individual employees to report wrongdoing internally and companies to act quickly to identify and halt wrongdoing and report it to the authorities. They are also designed to make the potential consequences more proportionate to the circumstances, including taking into account whether an entity has programs in place to prevent fraud. There is every reason to believe that the increased self-policing and voluntary disclosure that these reforms would encourage will mean less fraud, less harm, and less need for lawsuits.

There is more detail in my written statement, Mr. Chairman. I appreciate the time and welcome your questions.

[The prepared statement of Mr. Ogden follows:]

Statement of the U.S. Chamber Institute for Legal Reform

ON: Oversight of the False Claims Act

TO: U.S. House of Representatives Committee on the Judiciary Subcommittee on the Constitution and Civil Justice

BY: David W. Ogden, WilmerHale

DATE: July 30, 2014

Improving the False Claims Act

Originally enacted during the Civil War, the False Claims Act (FCA) remains one of the government's most important tools for combating fraud in government programs. With critical amendments in the 1980s, it is innovative and unique in many ways. As interpreted and currently employed, however, the FCA is also less effective than it could be at reducing fraud and too often a spur for specious litigation and coercive out-of-court settlements.[1] Its unique features can be improved to enhance its core mission while reducing its negative side-effects.

Deterring genuine fraud in government programs is an absolutely critical public mission; recouping moneys lost to fraud is as well. I am proud to have contributed to those missions when I oversaw False Claims Act litigation for the Justice Department as head of the Civil Division in the Clinton Administration and again as Deputy Attorney General in the Obama Administration. Today, I am testifying on behalf of the U.S. Chamber Institute for Legal Reform ("ILR"). ILR is an affiliate of the U.S. Chamber of Commerce dedicated to making our nation's overall legal system simpler, fairer, and faster for all participants. The U.S. Chamber of Commerce is the world's largest business federation representing the interests of more than three million businesses and organizations of every size, sector, and region and dedicated to promoting, protecting, and defending America's free enterprise system. I also wish to make clear that the views I am expressing today are my own and based on my experience.

[1] My testimony draws on the analysis and recommendations in U.S. Chamber of Commerce, Institute for Legal Reform, "Fixing the False Claims Act: The Case for Compliance-Focused Reforms," a white paper I co-authored with several colleagues. The paper is *available at* http://www.instituteforlegalreform.com/uploads/sites/1/Fixing_The_FCA_Pages_Web.pdf.

Indeed, the FCA has long been a focus for me. As Assistant Attorney General I met with representatives of both the relators' bar and the defense bar to try to get a better understanding of its operation and effects, and to try to ensure it was as effective and fair as possible. I personally defended the constitutionality of its *qui tam* provisions in oral argument before an *en banc* court of appeals.[2] As Deputy Attorney General, I worked with colleagues at the Departments of Justice and Health and Human Services to create and implement the Healthcare Fraud Prevention and Enforcement Action Team program, or "HEAT," which has targeted hardcore fraud using both criminal and civil enforcement tools. On the defense side, I have also defended and succeeded in obtaining dismissals of *qui tam* actions brought by relators against my clients in the federal courts when the United States has chosen not to intervene, and have helped resolve federal investigations of other clients. So I have seen the Act in operation from different perspectives and I very much believe, based upon some experience, that False Claims Act investigations and litigation are critically important anti-fraud tools but also cause serious problems.

Both proponents and detractors of the law would agree, I think, that it is unique and powerful. One of its great virtues is the incentive it creates for individuals with knowledge of fraud to come forward with that information. True whistleblowers do a great service, sometimes at significant personal risk. The statute encourages them to come forward and great good comes from that. I believe we can and must preserve this function. Similarly, the Act creates a powerful deterrent against defrauding the government, and any reform of the Act must retain that powerful deterrent effect. We can and must do that. But at the same time, we can and must

[2] *Riley v. St. Luke's Episcopal Hospital*, 252 F.3d 749 (5th Cir. 2001) (en banc) (noting intervention of United States to defend the constitutionality of the FCA).

reduce the perverse incentives for non-meritorious claims to clog our courts and burden the Department of Justice, replace the irrational penalty structure that in some cases coerces unjust settlements, and provide greater protections for true whistleblowers in the workplace.

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Understanding the FCA requires understanding its uniqueness, because the good and harm it does both stem from its several unique features. First, virtually nowhere else in the law today is a person who cannot claim personal injury permitted to file suit to remedy the injury to someone else—here, the United States. The requirement that one have been injured as a condition of filing suit—and leaving it to injured persons to vindicate their own rights—generally serves the important goal of regulating use of the courts and limiting it to real parties in interest, which obviously reduces the potential harms of duplicative or vexatious litigation. The FCA, through its *qui tam* mechanism, jettisons that fundamental limitation, opening the courts to hundreds of suits by private citizens who have not been harmed by the conduct they complain of. In most of those cases, the government declines to intervene, typically deeming them unworthy of government lawyers' time. Fully ninety percent of the cases in which the government declines to intervene are dismissed or abandoned, reflecting the fact that a great many of these hundreds of new *qui tam* suits each year are meritless. Yet these suits impose costs on the government, which must consider whether to intervene, and on private enterprise, which must address and defend them, and on our courts.

Second, just as the *qui tam* feature is virtually unique, other federal statutes generally do not create civil liability for mandatory penalties without regard to the size of the plaintiff's injury, the defendant's wrongful benefit, or the wrongfulness of the conduct. But the FCA requires courts to impose not only three times the government's injury but additional civil

monetary penalties of between $5,500 and $11,000 per false claim that can make the effective fine literally thousands of times greater than the harm or improper benefit and potentially many multiples of the federal dollars originally at stake, with the result that the punishment very frequently does not fit the offense. Courts have interpreted the penalty provision as requiring a separate penalty for each invoice submitted to the government, even if there was only one false statement in a more general contracting document, and regardless of the value of the individual invoices. Because each invoice or prescription can constitute a "claim" under this interpretation, the total penalty mandated by the FCA can easily reach hundreds of millions of dollars, even if the violation is technical and the government has sustained little actual harm.[3]

To cite just two examples:

- In *Gosselin World Wide Moving v. United States ex rel. Bunk*,[4] the Fourth Circuit approved a $24 million penalty against the defendant even though the relator did not even seek to prove any actual damages at trial.
- In *United States ex rel. Smith v. Gilbert Realty Co.*,[5] a case involving government housing, the mandatory penalties amounted to 178 times the damages proven.

Of course, in addition, violations of the FCA carry the risk of debarment or exclusion from government programs, a consequence that would ruin many businesses or individuals.

Other places in our law also do not impose such draconian penalties without the typical hallmarks of fraud, such as making a *knowingly* false statement or omission. But at the urging of

[3] Edward P. Lansdale, *Used As Directed? How Prosecutors Are Expanding the False Claims Act to Police Pharmaceutical Off Label Marketing*, 41 NEW ENG. L. REV. 159, 177 (2006) ("While actual damages collected by the government might be relatively modest, the sheer volume of prescriptions written along with attendant reimbursement requests, which easily number in the tens of thousands, can quickly translate into hefty fines.").

[4] 741 F.3d 390 (4th Cir. 2013), *petition for cert. filed* (May 15, 2014).

[5] 840 F. Supp. 71, 74-75 (E.D. Mich. 1993).

relators and the Justice Department, some courts have dramatically expanded the so-called "implied certification" theory of liability, whereby these enormous penalties are attached when a defendant has arguably violated a regulation and had little or no reason to know that non-compliance would be deemed to be a fraud. Under this theory, any violation of any fine-print regulatory requirement can provide a basis for treble damages and these enormous penalties, even if compliance with the regulatory requirement was never stated in the contract or invoice to be material to the government's willingness to pay. As one federal court of appeals has declared, the problem with this theory—aggressively pursued by the government in many cases—is that "the FCA is not an appropriate vehicle for policing technical compliance with administrative regulations. The FCA is a fraud prevention statute."[6] Regulatory violations have their own enforcement schemes, and the government should rely on those schemes to deal with such violations, rather than turning them into an enormous windfall having little to do with traditional notions of fraud.

Finally, few if any laws, and no law with such draconian penalties, operate without any statute of limitations. But some courts have held that the FCA's statute of limitations is stayed so long as the use of military force is authorized with respect to Al Qaida or the Taliban, even if the claims have nothing to do with those military actions. As a result, according to some federal courts, FCA claims may be pursued however stale they are or however unavailable necessary

[6] *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1019 (7th Cir. 1999) ("[V]iolations of [f]ederal . . . regulations" should not be treated as "fraud unless the violator knowingly lies to the government about them."); *see also United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 268 (5th Cir. Tex. 2010) (internal quotation marks omitted) (the FCA was not intended to be "a general enforcement device for federal statutes, regulations, and contracts."); *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1265 (9th Cir. 1996).

evidence may have become, and the traditional safeguard of fairness represented by statutes of limitations is abandoned.[7]

Some of these unique features contribute to incentivizing whistleblowers and earning just compensation for the government. But all of them have also combined to create a uniquely litigious environment, in which many valuable but also a great many frivolous claims are filed. Serious frauds are addressed, of course. But it is also true that borderline regulatory violations are bootstrapped into enormous settlements and these settlements accomplish little, contribute to a perception of unfairness in our legal system, and unnecessarily raise the costs of products to consumers and the government alike. The coercive threat of outsize judgments and related risks such as debarment drive settlements of even these borderline claims, which deprives courts of the critical ability to check the power of the executive or to contribute to a sound development of the law. As one court explained, "[b]ecause the risk of loss in a False Claim Act case carries potentially devastating penalties, however, unlike most litigation or even an administrative recoupment action," defendants are discouraged from even attempting to defend themselves in court.[8]

And it is also true that relators incentivized by the prospect of huge financial rewards file extraordinarily weak claims, which must be investigated and litigated (sometimes at length) before they are finally dismissed. "Qui tam relators are . . . incentivized to file suit even if their case is weak and unlikely to succeed at trial. FCA suits frequently end in settlement because of

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[7] *United States ex rel. Carter v. Halliburton*, 710 F.3d 171, 180-81 (4th Cir. 2013), *cert. granted* (July 1, 2014) (applying Wartime Suspension of Limitations Act, 18 U.S.C. § 3287, to suspend the statute of limitations even on civil claims brought by private *qui tam* plaintiffs, apparently even as to claims that do not involve war-related fraud).

[8] *Ohio Hosp. Ass'n v. Shalala*, 978 F. Supp. 735, 740 n.6 (N.D. Ohio 1997), *aff'd in part, rev'd in part*, 201 F.3d 418 (6th Cir. 1999); *see id.* (litigating in court "is a risk the hospitals feel they cannot take—even if they believe their chances of prevailing would be great").

the heavy penalties and potential for disqualification from federally funded programs, such as Medicare and Medicaid."[9] The result is that companies "lack the benefit of precedent and reliable information on which to base decisions about the legitimacy of the DOJ's use of the False Claims Act" against them.[10]

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For all of these reasons, I hope in my testimony today to suggest relatively modest changes that would preserve the False Claims Act's virtues, correct the Act's flaws, and improve its effectiveness at preventing fraud before it happens. These proposals have the goal of preserving the FCA's incentives to come forward with evidence of fraud and preserving severe punishments for true fraud, while also promoting maximally effective corporate compliance, corporate protection and encouragement of internal whistleblowers, and corporate self-reporting. This should mean less fraud and less harm to the government. As Stuart F. Delery, my successor as head of the Justice Department's Civil Division and a fine former colleague and friend, made clear not long ago: "[l]itigation to recover the costs of fraud is a far inferior option to preventing fraud in the first place." Businesses, he urged, should adopt "forward-looking compliance measures" and "join with the [government] in establishing structures that help prevent fraud—

[9] Sharon Finegan, *The False Claims Act and Corporate Criminal Liability: Qui Tam Actions, Corporate Integrity Agreements and the Overlap of Criminal and Civil Law*, 111 PENN ST. L. REV. 625, 674 (2007).

[10] Vicki W. Girard, *Punishing Pharmaceutical Companies for Unlawful Promotion of Approved Drugs: Why the False Claims Act Is the Wrong Rx*, 12 J. HEALTH CARE L. & POL'Y 119, 153 (2009); *see also* Nicole Huberfeld, *Pharma on the Hot Seat*, 40 J. HEALTH L. 241, 245 (2007) ("From an industry perspective, one major disadvantage of settlements (as opposed to judgments) is that the precedential and informational function that case law serves in a common law system is largely absent. . . . [E]ach new investigation presents legal uncertainty for the company subject to inquiry because the bounds of the law remain unknown.").

and the need for lawsuits to combat it—in the first instance."[11] The FCA should encourage such measures.

Presently, the Act focuses more on punishment and deterrence than compliance, but with modest adjustments, the Act could preserve its deterrent functions, while incentivizing strong and effective compliance. The government has recently recognized the emergence of a health care compliance industry.[12] And extensive study, including by the Ethics Resource Center, has identified the components of meaningful compliance and ethics programs, as well as ways to assess the effectiveness of programs as a whole.[13]

Although many companies have good programs, with appropriate guidance and strong incentives, there are opportunities to improve compliance within companies and across industries. The FCA should, and can, create incentives to adopt the hallmarks of a truly effective system: one that promotes a culture of compliance, encourages whistleblowing and protects whistleblowers, and promotes early correction and self-reporting of violations. And it can do so in a form that removes some of the most counterproductive elements of the current FCA.

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[11] Stuart F. Delery, Acting Assistant Attorney General, U.S. Department of Justice, "Acting Assistant Attorney General Stuart F. Delery Speaks at the American Bar Association's Ninth National Institute on the Civil False Claims Act and Qui Tam Enforcement" (June 7, 2012), *available at* www.justice.gov/iso/opa/civil/speeches/2012/civ-speech-1206071.html.

[12] Inspector General Office Health and Human Services Department, Request for Information and Recommendations: Non-Binding Criteria for Implementing Permissive Exclusion Authority under Section 1128(b)(7) of the Social Security Act, *available at* http://www.regulations.gov/#!documentDetail;D=HHSIG_FRDOC_0001-0397 (requesting comment regarding, among other things, whether guidelines for permissive exclusion should consider a defendant's existing compliance program).

[13] *See, e.g.*, ERC's National Business Ethics Surveys, *available at* http://www.ethics.org/.

To accomplish this, ILR has proposed, and I suggest you consider here, a few adjustments to the FCA and its enforcement—each predicated on a company's adoption and maintenance of a gold standard, certified, compliance program:

- Ensure that for companies with certified compliance programs, a factor in considering damages would be the relative culpability of the company;
- Encourage companies with certified compliance programs to report misconduct to the government to reduce exposure to inefficient *qui tam* actions;
- Incentivize whistleblowers to report internally through certified compliance programs before filing a *qui tam* action, allowing companies to respond quickly and comprehensively; and
- Preserve the prophylactic remedies of debarment and exclusion for companies likely to pose continuing harm to government programs—those without certified compliance programs or individuals with personal involvement in fraud—but appropriately limit their use against companies that do have certified compliance programs.

Let me briefly describe each incentive and the problem it is designed to address.

Adding Fairness to Damages: Currently, a company that violates the FCA is liable for three times the amount of damages the government sustained. This is so regardless of whether the company deliberately intended to defraud the government or was later found to have been reckless, or whether the company had programs in place designed to prevent fraud.

For companies with certified compliance programs, the FCA should instead differentiate among (1) companies that are truly bad actors and have intentionally defrauded the government, which would still face treble damages; (2) companies whose employees have engaged in misconduct that does not rise to the level of intentional fraud, which would be liable for double

damages; and (3) companies that promptly disclose any wrongdoing to the government, which would face 1.5 times actual damages. For companies who adopt state-of-the-art compliance, this approach would maintain the deterrent and punitive aspects of the FCA, while also creating industry wide incentives for investment in meaningful compliance programs and prompt self-disclosure. [14]

Incentivizing Self-Reporting: Under the current FCA, a *qui tam* plaintiff who files suit after the defendant has already disclosed the same conduct to an agency inspector general is nevertheless entitled to proceed with the suit and receive a full bounty. This possibility exists even though the disclosure has been made to the government authority responsible for investigating fraud and even though the party making the disclosure is typically required to cooperate fully in the investigation. When a corporation has made a disclosure of fraud to an agency inspector general or other investigative office, the FCA should clearly foreclose later *qui tam* actions based on the same allegations of fraud. Making this amendment available only to companies with certified compliance programs would provide a further strong incentive to companies to develop and maintain programs that encourage discovery and disclosure of wrongdoing.

At the same time, this "self-disclosure bar" would leave open critical avenues for whistleblowers to file *qui tam* lawsuits. First, the self-disclosure provision advocated here would not foreclose actions filed by whistleblowers that provide the government with information about fraud before a corporation makes a self-disclosure. Second, the proposed self-disclosure bar

[14] This approach would also bring the FCA into alignment with the graduated damages structures of many other penal regimes—including Internal Revenue Service penalties for fraudulent and negligent errors on tax returns; U.S. Customs and Border Protection enforcement of import controls under the Tariff Act of 1930; and the Model Penal Code—in imposing its harshest punishment for the most reprehensible conduct, namely actions undertaken with specific intent to defraud.

would not foreclose *qui tam* actions when the corporation had made a disclosure to any government employee other than an inspector general or other investigative office. This would address any concern that companies could make sham disclosures of information to a non-investigative government official or office that is unlikely to act on the information or vindicate the government's interests. Third, the proposed self-disclosure bar would not interfere with an employee-relator's ability to file a *qui tam* action even after a company's self-reporting to the government, so long as the employee reported internally first and waited at least 180 days before going to court. Fourth, the bar would not apply in situations in which a relator comes forward with valuable *new* information related to a company's activities after the company has disclosed its violation to the government.

Finally, this change would have no impact with respect to companies lacking certified compliance programs.

Incentivizing Internal Reporting, Optimal Whistleblower Protection: The FCA currently provides no incentive for employees to report concerns about potential fraud to their employers. To the contrary, the Act contains a structural disincentive to internal reporting in the form of the "first-to-file" provision, which specifies that only the first relator who files suit is eligible for a bounty. This provision—which is necessary to prevent multiplicitous litigation—also creates a "race to the courthouse," with the problematic effect that a potential relator has no incentive to take the extra step of reporting internally first since doing so might reveal information to other employees, one of whom might beat the initial discoverer of the problem to court. The FCA thus encourages employees to "circumvent internal reporting channels altogether." [15]

[15] Michael D. Greenberg, RAND Corp., *For Whom the Whistle Blows: Advancing Corporate Compliance and Integrity Efforts in the Era of Dodd Frank* 18 (2011) *available at* http://www.rand.org/pubs/conf_proceedings/CF290.html.

Moreover, the current approach misses a valuable opportunity to incentivize companies across all industries to develop and maintain certified compliance programs that encourage internal reporting and provide meaningful protections to whistleblowers. In addition, the FCA's disincentives for prompt internal reporting are out of sync with modern statutory and regulatory mechanisms that encourage internal reporting and more robust corporate compliance programs. To be sure, dispensing with internal reporting may certainly be justifiable where an employee reasonably fears retaliation for making an internal report. But where a certified compliance program is in place with substantial protections for whistleblowers, a prerequisite for this proposal, that rationale falls away.

So to align the FCA with modern approaches, and to maximize the FCA as a means of prevention through effective compliance, the Act could be modified as follows: If an employee of a company with a certified compliance program (or any other individual with a contractual or legal obligation to make reports to such a company) fails to report the alleged misconduct internally at least 180 days before filing a *qui tam* suit, that court would be required to dismiss the action. The 180-day window would afford the employer sufficient time to investigate the allegations and make a determination whether to self-disclose a violation to the government and/or take corrective action.

In order to ensure that a person who uses the internal reporting mechanism is not disadvantaged, a person who reports internally and triggers a prompt disclosure by the company to the government should still be eligible for up to 10 percent of any government recovery that results from the company's disclosure, by following administrative procedure to be established by the U.S. Department of Justice. If the whistleblower reports internally, but the company does not promptly self-disclose and the whistleblower proceeds with a *qui tam* action, then the

whistleblower will be deemed to have filed an action for purposes of the FCA's "first-to-file" bar dating back to the time of the internal report. This change would ensure that an employee's internal reporting would not disadvantage the employee in the "race to the courthouse."

Focusing Exclusion and Debarment: The government has the enormous authority to exclude or debar companies from government reimbursement or contracting. For companies in the healthcare space, for example, exclusion may effectively be a death penalty given the enormous market share of federal healthcare programs. For many government contractors, a prohibition on contracting with the federal government is similarly threatening. With the threat of exclusion and debarment, the government has generated huge settlements from health care, pharmaceutical, and government contractors. But it is appropriate to question whether the current system is fair or effective. As the government has acknowledged, debarment may not "deter or punish wrongdoing," and in the case of mandatory debarment, may be actively counterproductive because it likely "decrease[s] incentives for companies to make voluntary disclosures, remediate problems, and improve . . . compliance systems."[16]

Exclusion and debarment may be necessary as preventative measures with respect to companies that pose continuing risks to federal programs, or pose a particularly high risk of recidivism. That rationale no longer holds, however, when a company diminishes these risks through the implementation of a certified compliance program. Exclusion and debarment should be limited to companies that have failed to institute certified compliance programs.

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[16] Examining Enforcement of the Foreign Corrupt Practices Act: Hearing Before the Subcomm. on Crime and Drugs of the S. Comm. on the Judiciary, 111th Cong. 25 (2010) (written responses of Assoc. Deputy Att'y Gen. Greg Andres, Criminal Div., U.S. Dep't of Justice, to Sen. Coons' questions for the record).

Two final reforms that would make the False Claims Act more fair and more effective in its application to all companies would focus the severe penalties in the FCA on real fraud—where entities and individuals knowingly make false statements or omissions of clearly material facts—by clarifying that the FCA should not be extended to regulatory or contract violations not stated in advance to be material to the government's willingness to pay; and would eliminate the irrational windfalls driven by civil monetary penalties in cases where multiple damages are also recovered.

As noted above, the False Claims Act has been interpreted very broadly to impose liability not only when a claim is false on its face but also when the claimant has "impliedly certified" compliance with regulatory requirements and failed to comply with these requirements. To ensure that the statute remains focused on true fraud on the government, the FCA should include a new definition of "false or fraudulent claim" that would impose FCA liability only when a claim is "materially false or fraudulent on its face," or when a claim is presented or made "when the claimant has knowingly violated a requirement that is expressly stated by contract, regulation, or statute to be a condition of payment of the claim." This approach would reserve FCA liability for true frauds on the government and not apply them to contractual, regulatory or statutory violations that do not rise to that level. Such violations of course would be punishable under existing administrative or judicial regimes that establish proportional and appropriate penalties for such violations.

And finally, civil monetary penalties should be available only where the government has sustained no damage, and thus where multiple damages are not also imposed. And in any event, where the government has not been harmed the civil monetary penalties should never exceed the size of the benefit wrongfully obtained by the defendant from the government.

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I end this testimony where I began—I have long supported the False Claims Act and congratulate those who framed and improved it over the years. Even more, I admire the dedication and courage of true whistleblowers. I believe that we can preserve the best of the FCA and many of its unique aspects, while also increasing dramatically its power to encourage companies to adopt and maintain certified compliance programs and making it more fair. Recouping moneys lost to fraud after the fact is of course critically important. But preventing fraud from happening in the first place should be a far more central feature of federal policy than it has been to this point.

I appreciate the opportunity to testify on this important subject and look forward to your questions.

Mr. FRANKS. Well, I thank all the witnesses.

We are told that they may call votes any moment, and that will give us a short period of time to respond. But if we proceed with questions quickly, we might actually get past this and not have to hold all of you over here. If we can do that, we will.

So, Dr. Harned, I will begin with you. It seems sort of counter-intuitive that we should attempt to rely on the perpetrators of False Claims Act violations to self-report when they violate the Act. Can you explain to me how it would be reasonable to expect businesses to detect and report their own violations of the FCA to the Federal Government?

Ms. HARNED. Thank you, Mr. Chairman. One of the things that we have seen in our research as we have looked at different kinds of organizations and what motivates them to implement ethics and compliance programs, it is the case that the majority of companies want to implement very good programs because it is a preventive measure for themselves. The majority of companies that have good programs and strong cultures in place have leaders that are very committed to ethical conduct. They want to avoid overstepping the law, and that is why those programs are very effective.

So it is not so much a case of the perpetrators monitoring themselves so much as it is the case that most companies that are implementing these good programs are doing it for all the right reasons.

Mr. FRANKS. Mr. Clark, I might ask you, do you think that the efforts that have been discussed related to trying to get self-compliance by these companies could bring harm to the existing protocol?

Mr. CLARK. Mr. Chairman, compliance programs are fine. I certainly have no quarrel with compliance programs. But we have seen that quite a number of entities that have resolved False Claims Act cases, which means that they entered into a corporate integrity agreement, and that required a strong compliance program, went right back to the same bowl and were lapping at it again. I think compliance programs certainly can help, but if a company plastered Justice Holmes' admonition over their entrance as their motto and lived up to it, that would help.

Integrity is the key, and law enforcement, which is my background, is what enforces that.

Mr. FRANKS. Mr. Ogden, you had suggested that there was clear evidence that these compliance programs could work, and I know that you have authored some programs in that vein. Can you tell us what would be the top anecdotal or clear evidence that you would report that would indicate that these programs do work and don't harm the private whistleblower enforcement?

Mr. OGDEN. Absolutely, Mr. Chairman. I think Dr. Harned's work for the Ethics Resource Center is extremely strong support for the proposition that these programs work. As she says, no program can entirely eliminate wrongdoing in any institution. The key is to have measures in place—and as Dr. Harned says, we know what these measures are that are working well—have measures in place at a company that make clear that Justice Holmes' admonition is the rule of the day there, that empower employees to come forward, encourage them to, make clear to them they are going to be protected, make clear that when they report wrongdoing it will

be taken seriously, investigated and, where valid, reported, and that there is prompt reporting.

We know these systems work, and where they are in place——

Mr. FRANKS. You say we know these systems work. What evidence would you cite, just briefly?

Mr. OGDEN. I would rely first on the evidence that Dr. Harned has put forward, the research of the Ethics Resource Council.

Mr. FRANKS. All right.

Well, listen, I am going to yield to the Ranking Member of the Committee for 5 minutes. We might actually beat the vote here.

Mr. COHEN. Thank you, Mr. Chair. I apologize for coming in a little late. Sorry I missed Senator Grassley. I have read his testimony, and it was certainly compelling, and I commend him for the work he has done on this issue.

The False Claims Act has been responsible since 1987 for bringing in $39 billion in recoveries from corporations that cheated the American taxpayer, according to the Justice Department, and $27 billion came from qui tam plaintiffs. So it seems like a lot of money we are talking about, and if we are talking about concern for the budget deficit, we would be giving up a lot of money that is involved, and money is an effective way of seeing that people do comply with the law, and Senator Grassley is to be commended for his work in bringing this to the fore.

I would like to ask Mr. Clark—and I appreciate your testimony. Mr. Ogden suggests that his reforms are sufficient to correct the injustices that he sees and yet keep the program strong. Do you believe if we adopt the amendments that have been proposed here and that Mr. Ogden endorses, and I presume Dr. Harned does as well, that the qui tam law and the False Claims Act will remain as strong a deterrent to government fraud?

Mr. CLARK. Sir, I do not think so. I think it would have two effects, or maybe one effect and one non-effect. I am skeptical about the degree of help that some kind of reliance on a compliance program would bring. But I am also cognizant that whistleblowers and the counsel who represent them have to make tremendous investments of time. The whistleblower has to take a big risk to come forward, a big risk of retaliation, and some of these proposals would increase the whistleblower's risk and diminish the whistleblower's incentive to go forward.

These cases can take—I spend months and months and months sometimes after I interview a client deciding whether the client is a reliable and trustworthy and straightforward person, investigating for myself as best I can to find out what the facts are. I invest—any qui tam lawyer does—months of time often, and lots of money to investigate these cases. To diminish the incentives, which some of these things would do, I think would be a step backward.

Mr. COHEN. I missed most of the testimony of the doctor, even though I read some of it, and I just wonder, Mr. Clark, if there were oversteps or improprieties by the attorneys in an action against an individual, as I guess the doctor suggests there might have been in his case, does not Rule 11 bring an adequate and appropriate sanction against an attorney for pursuing a claim that is not appropriate?

Mr. CLARK. There are several rules and several entities that hold sanctions for things like that. A lawyer who files a frivolous case first of all is going to be in trouble with the judge in whose court the case was filed. Federal judges have no patience with frivolous lawsuits.

The statute allows the defendant, like the doctor, to recover his attorney's fees, and Rule 11 applies, and the attorney would also be in trouble with his bar association. He might lose his license over something like that.

Mr. COHEN. Thank you, sir.

Dr. Harned, your group is—what is the name of your group? The Ethics——

Ms. HARNED. The Ethics Resource Center.

Mr. COHEN. Who are the major funders of the Ethics Resource Center?

Ms. HARNED. About 95 percent of our funding comes from the private sector, not for lack of trying to see if we can get public support for our work. The companies that invest in us, they tend to do it for one of three reasons. They ask for our help in assessing their ethics and compliance programs, or they are a part of a fellows program that we have for chief ethics and compliance officers, along with academics and government officials, and then a portion of our funding comes from research to do the work that we do through the National Business Ethics Survey and other studies.

Mr. COHEN. And you are an attorney, or are you not?

Ms. HARNED. No, I am not.

Mr. COHEN. You are not. I see.

Mr. Ogden, you are, I know, and you have a distinguished career. Have you ever brought any actions on behalf of whistleblowers?

Mr. OGDEN. I have not brought actions as a private lawyer on behalf of whistleblowers, Congressman Cohen. I have brought any number of actions as a public official, intervening in actions brought by whistleblowers on behalf of the United States in pursuing their claims. And as I mentioned, as Assistant Attorney General I defended the constitutionality of the Act that gives whistleblowers the right to bring these claims.

Mr. COHEN. Senator Grassley said that your proposal for gold standard compliance certification program was "pie in the sky ideas with no specifics," and that it is a "pipedream" to suggest such a program would magically increase the amount of taxpayer dollars the government recovers. The Senator also said that his staff was told by the Chamber regarding the proposal for compliance certification program that "we had to come up with something, so we just put it in."

How do you respond to Senator Grassley on those assertions?

Mr. OGDEN. Thank you, Congressman. I have the highest respect for Senator Grassley and what he has done with this statute. What we are trying to do is build on that statute. With respect to the "pie in the sky idea," as I said, effective compliance programs that protect and encourage internal whistleblowers, companies that have fine ethics cultures and report violations to the government, that is not pie in the sky, as the work that Dr. Harned and her group has done shows.

The fact is good companies do try very hard to comply with the law, and we can encourage them. We can set standards. We can encourage more companies to perform that way.

As far as Senator Grassley's report of his staff's comment, I wasn't present for the meeting that was had with his staff, but I can tell you we didn't just put this forward and just come up with something. I have spent a lot of time on this statute. I have a great belief in it. I believe in whistleblowers. I believe in the incentives of the Act. But I think it does a lot of harm, and it does harm in the ways we have described.

Dr. Prabhu is not the only one. The Act can be improved, and we are suggesting some very structured ways. They are not going to interfere with the Act's effectiveness, but they are going to ameliorate some of these effects.

Mr. COHEN. I want to thank you and everybody else. This is an outstanding panel.

I would like to ask for unanimous consent to allow my opening, which has become my midterm, statement to be put in the record.

Mr. FRANKS. Without objection.

[The prepared statement of Mr. Cohen follows:]

Statement of the Honorable Steve Cohen for the Hearing on "Oversight of the False Claims Act" Before the Subcommittee on the Constitution and Civil Justice

Wednesday, July 30, 2014 at 1:00 p.m.
2237 Rayburn House Office Building

The False Claims Act is one of the most potent weapons in the fight against fraud and is a vital means of protecting taxpayer dollars.

From fiscal years 1987 through 2013, the False Claims Act has been responsible for $39 billion in recoveries from corporations that cheated the American taxpayer, according to the Justice Department.

Of that number, more than $27 billion resulted from litigation initiated by *qui tam* plaintiffs, many of whom are employees of corporate wrongdoers who are in the best position to know of fraudulent activity and to bring it to light.

Since 2009 alone, matters pursued under the False Claims Act have resulted in recoveries of more than $20.3 billion for taxpayers, with more than $16 billion resulting from *qui tam* complaints

The fact that almost 70 percent of recoveries since 1987, and more than 78 percent since 2009, stemmed from *qui tam* suits highlights the central role that *qui tam* plaintiffs play in the False Claims Act's enforcement regime and in the fight against fraud.

We need only look at the state of the False Claims Act prior to 1986 to get a sense of how weak *qui tam*-related provisions can undermine the False Claims Act's purpose.

Prior to 1986, the Act had been interpreted and applied in such a way that all the disincentives that potential whistleblowers faced in coming forward vastly outweighed whatever minimal incentives they may have had to pursue litigation on behalf of the government and bring fraud to light.

As a result, the number of False Claims Act *qui tam* suits declined dramatically and fraud against the government ran rampant.

The 1986 amendments to the Act, spearheaded by Senator Charles Grassley and our former colleague, Representative Howard Berman, dramatically strengthened incentives for the pursuit of *qui tam* actions and greatly enhanced the False Claims Act's effectiveness.

It is perhaps no surprise, then, that those who are the target of fraud allegations are now seeking to undermine the False Claims Act, and, in particular, its *qui tam* and penalty provisions.

The U.S. Chamber of Commerce has put forth a set of recommended changes to the False Claims Act regime that can only be characterized as solutions in search of a problem, unless one defines the "problem" as an effective False Claims Act regime.

For instance, the Chamber proposes to limit the share of damages that *qui tam* plaintiffs are able to recover in False Claims Act cases, weakening a major incentive for whistleblowers to come forward.

Further weakening the incentives for whistleblowers are the Chamber's proposals to bar *qui tam* actions under several circumstances. For example, the Chamber suggests barring such suits by an employee of a corporate wrongdoer if the employee did not report the fraud internally to his or her employer within 180 days prior to filing suit.

This proposal almost invites a corporate wrongdoer to intimidate or retaliate against the potential whistleblower employee and gives the company the opportunity to further hide the fraud.

Another example of how the Chamber's proposals weaken the Act is its proposal to bar *qui tam* actions if a corporate wrongdoer has disclosed its own fraud to a government agency inspector general or other investigative office.

For one thing, companies should be already be reporting any fraud that it discovers within its operations without any additional incentives.

Additionally, this proposal appears only to reward the corporate wrongdoer by lessening the legal consequences that it could face for its fraudulent activity.

The Chamber would also reduce the availability of treble damages based on so-called "gold standard" certifications of a company's compliance program done by third parties, in a process where it would be in the interests of the certifying entity – itself a profit-making business – to give the necessary certification, with no way of verifying the accuracy of the certification.

Finally, the Chamber would also make it substantially harder for any plaintiff, whether a *qui tam* relator or the government, to prevail in a False Claims Act case by amending the Act to impose the very high "clear and convincing" standard of proof to demonstrate any violation of the Act, rather than the current "preponderance of the evidence" standard.

In short, while nothing is perfect, the False Claims Act by and large works, and we should be wary of attempts to undermine it.

Mr. COHEN. Thank you.

Mr. FRANKS. Mr. DeSantis?

Mr. DESANTIS. Thank you, Mr. Chairman.

Dr. Prabhu, what happened to your patients when you had these False Claims Act filed against you?

Dr. PRABHU. Well, my patients were very sick. They had a lung transplant and a lung volume reduction surgery, after which they would come back to our office for specialized, structured rehab program. After I was forced to shut down, I had to send my patients to outside facilities which are just not as good. As a matter of fact, two of my patients died. I also had to stop going to a clinic we had in the Town of Parum, which was very under-staffed and they needed us to help them out.

Mr. DESANTIS. Now, are you against—are you just against—you are not against whistleblowers generally. You just think that this statute can lead to bad consequences for innocent people. Is that your correct position?

Dr. PRABHU. I am not—I am basically here to tell you my story and what happened to me.

Mr. DESANTIS. Right.

Dr. PRABHU. Just based on my experience, if those three people, my employees, came to me and told me what problems they detected, I would have addressed it right away and the government wouldn't have lost so many millions of dollars, and I wouldn't have lost millions of dollars.

Mr. DESANTIS. Now, do you—what were your litigation costs in dealing with these two claims?

Dr. PRABHU. Six million dollars.

Mr. DESANTIS. Okay. And were you able to recover any of those costs?

Dr. PRABHU. Well, the second case was so unjustified. So we were able to file a motion to recover attorney costs, but the judge only gave us $500,000 out of $6 million I spent.

Mr. DESANTIS. So you got a judgment for $500,000. Have you actually been able to collect that money?

Dr. PRABHU. Yes. The government paid us a check.

Mr. DESANTIS. Okay, so they have given it to you?

Dr. PRABHU. Yes.

Mr. DESANTIS. Okay. So you actually won your cases, basically, but it doesn't seem like those were victories.

Dr. PRABHU. Well, I wouldn't call it victory. My life is ruined. I can't get all the time back that I have lost in the last 20 years, one case after the other. My reputation is damaged. A lot of things I wanted to do in life. I was doing medical research, working with lung volume reduction surgery. I was advancing in my profession while taking care of a large number of patients, and I had some political ambitions, and nothing was possible.

Mr. DESANTIS. So basically, this detracted from your ability to help sick people?

Dr. PRABHU. Yes.

Mr. DESANTIS. How did the civil penalties and damages the government sought from you compare to the actual amount of money you received that allegedly violated the False Claims Act?

Dr. PRABHU. That is so absurd. They basically said every time I submitted an invoice and got paid—I got $50, they wanted me to pay them back $11,000. They calculated that over 6 years I submitted the code 2,000 times. They said I had to pay them $22 million.

Mr. DESANTIS. Wow.

Mr. Clark, I guess the criticism I have heard about how this operates in practice is that 90 percent of the cases in which the U.S. doesn't ultimately intervene when individuals are bringing the qui tam cases, that they are just abandoned or dismissed. So how would you address—is that a misallocation of resources, that cases that, once the government makes a decision, are going to kind of wither on the vine? Or do you think that everything should continue to go the way it is going?

Mr. CLARK. Well, I think there are a number of reasons why, in the first place, why the Department of Justice declines cases. Part of it is lack of resources. They have to prioritize what they are going to do because of the resources they have to do it with. I am sure that they concentrate first on the larger, the cases that look like they are going to be the biggest to intervene in. And whenever they decline one, they write a letter to the court and to everybody concerned not to take this as an indication of the merit of the case. They have declined it and they don't have to state their reasons.

Mr. DESANTIS. But is that, in fact, happening, though, given the statistics that it is over 90 percent?

Mr. CLARK. I would say it probably is. I don't know. I don't have the statistics on that. I don't know that they are published any place. A lot of them are declined. Probably three out of four, anyway, are. But why they don't go forward could be for any one of a number of reasons.

The Department of Justice may have discovered something in doing its due diligence survey of the case after it is filed during the period it is under seal that makes it clear that the case is not going to succeed for one reason or another, and that may be apparent to the attorney who filed the case after Justice declines it.

Second, going forward with a False Claims Act case against a Fortune 500 company when you are a 9-man law firm that has two lawyers who do False Claims Act work is not an enticing prospect, and the client has to be apprised of that, and the client has to make a decision, do you want to continue to fight this thing, here is what it is going to entail, because it takes years to get one of these cases litigated.

Mr. DESANTIS. Great.

I am out of time. I thank the witnesses. I appreciate your comments.

I yield back.

Mr. FRANKS. And I thank the gentleman.

And I would now recognize Mr. Conyers, the distinguished Ranking Member of the full Committee.

Mr. CONYERS. Thank you, Chairman Franks, and I thank the witnesses.

I would like to have someone explain why the False Claims Act penalties that allow for treble damages and additional penalties for each violation is important. Let me just start with you, Mr. John

Clark, and then I will ask the others, at least two of the witnesses the same question.

Please.

Mr. CLARK. Thank you, Mr. Conyers.

Mr. CONYERS. Is your mic on? It is? Pull it up closer, then.

Mr. CLARK. Thank you, sir. Both damages and penalties are important as deterrents. Penalties are not sought in all cases. Penalties are sought in some cases, the egregious cases, and there are constitutional limits on the amounts that can be assessed in a False Claims Act case. The Eighth Amendment protects someone from excessive penalties. But they are important because they can be invoked. And when they are invoked, then they are a powerful deterrent.

They are not invoked in all cases, but they are there. That is a tool that the government can use if it chooses and if the court agrees with it, but they are not assessed in all cases.

Mr. CONYERS. So it isn't that they are identified at the beginning of the case. It is after a determination and a conviction has been arrived at. Is that the case?

Mr. CLARK. That is correct.

Mr. CONYERS. So do you think that they are excessive or that they are used in a way that is not beneficial for us protecting the government against false claims and fraud?

Mr. CLARK. Sir, I think penalties should remain as a deterrent, and as I say, they are not always imposed. Particularly if a case is settled, they are not going to be imposed, typically.

Mr. CONYERS. Mr. Ogden, do you share approximately the same view?

Mr. OGDEN. I don't, Ranking Member Conyers, and thank you for asking. First of all, it is required under the statute that in a case that goes to judgment these civil monetary penalties be imposed in addition to treble damages. So we have not only the treble damages required under the statute, as under antitrust law, for example, but in addition to that there is a requirement that for every so-called claim, between $5,500 and $11,000 be assessed. That is what is required if you go to judgment. It is simply not true that they are not applied in every case. They are applied in every case that goes to judgment.

As Dr. Prabhu said, it is for that reason possible for you to have merely a couple of hundred thousand dollars, in his case, of business with the government. The total possible damage the government would have suffered in his case if he had done anything wrong, which he did not, would have been a couple of hundred thousand dollars. And yet the penalties, because they are assessed at $5,500 to $11,000 per invoice, per prescription, can amount to $22 million in a case of $200,000 in business. For a corporation with $50 per prescription, for example, a total amount of business around $10 million can result literally in penalties of over $1 billion. That is completely irrational.

A similar offense, no different, that has a single invoice issued to the government for the same amount of money would be $11,000, in this other case $1 billion. It is irrational and it drives companies to settle frivolous, weak cases, and it should be changed.

It doesn't make any sense. There is no other law like it that I am aware of.

Mr. CONYERS. Well, Attorney Ogden, are there cases that we can name in which this kind of extreme result has happened?

Mr. OGDEN. There are cases, and I mentioned a couple of them in my testimony. But the very important function is connected to what Mr. Clark correctly said. Frequently what happens is that these penalties are threatened and a company that actually took a case to trial would suffer them if it lost, but the government settles the case without them. So that you face a billion dollars of liability if you take it to trial and lose. But you can settle it for $20 million. Companies do that even if they think the claim is worth nothing, as would be rational. Dr. Prabhu bravely fought it and won, but many companies don't, and that is not good for the country.

Mr. CONYERS. Dr. Harned, where do you stand on this subject?

Ms. HARNED. Congressman, my center is a research organization. Our task and our mission is to better understand how to improve workplace conduct. So in many ways, the specifics of the legislation and enforcement of it is beyond the scope of what our center's expertise is.

Mr. CONYERS. I see. Do you have any further comments, Attorney Clark?

Mr. CLARK. Just one matter. Thank you, sir. Penalties, if a case goes to trial, and I have seen this happen, a judgment can be structured so that if the penalties would amount to more than the Constitution would allow, I have seen judges and attorneys on both sides work those things out so it does not happen that way. But the penalties are important as a deterrent. They are there, and if it is proper to invoke them, they can be invoked.

Mr. CONYERS. Thank you, gentlemen and lady.

My time has expired, and I yield back, Mr. Chairman.

Mr. FRANKS. Well, I want to thank—I am sorry, Mr. Johnson. I didn't mean to look past you, sir.

Mr. Johnson?

Mr. JOHNSON. I am sorry. I am just getting to the hearing, just getting a little acclimated here.

I would ask Mr. Clark—well, I would ask Dr. Prabhu, do you consider yourself to be a free market economic adherent?

Dr. PRABHU. No, sir. I am just a physician. I am not a policy expert. I just came here to share my experience with you.

Mr. JOHNSON. Well, you know the difference between a free market and a regulated market? Economics? Perhaps not.

Let me move on to Dr. Harned. Do you consider yourself to be a free market person, or do you believe in government regulations on the economic sector?

Ms. HARNED. Certainly I do what I do because I am interested in trying to promote productive and effective and ethical business and government and non-profit organizations. It is the case that for many organizations misconduct is a reality, and there should be regulation so that we are able to promote better practice.

Mr. JOHNSON. How about you, Mr. Ogden?

Mr. OGDEN. I am certainly a believer in government regulation. I think it is critical in a free-market economy.

Mr. JOHNSON. And Mr. Clark?

Mr. CLARK. Sir, I am a believer in as big a government as is necessary, but no bigger than necessary. Government has to regulate some things for our safety and to protect itself, but I am not an advocate of over-reaching government regulation.

Mr. JOHNSON. Well, let me ask this question. When we are cutting government in the name of establishing a free market economy and we are cutting out the ability of government to ferret out fraud, doesn't it follow that private whistleblowers would be consistent with a free market approach to the economy?

Mr. CLARK. Sir, I think whistleblowers are the essence of preserving the free market economy. They look for the things or they encounter the things that distort a free market. They look for things that happen, they find things that happen to them, for example, things that they experience on the job that are just not right, cheating the government, and that employer, if it is cheating the government, is probably cheating its competitors as well and distorting the market.

Mr. JOHNSON. So, thank you, Mr. Clark.

Mr. Ogden?

Mr. OGDEN. On behalf of the Chamber and our proposals here, we support whistleblowers, and I totally agree that their function is essential. What we are proposing——

Mr. JOHNSON. But you want to cut down on the economic incentive for whistleblowers to come forward.

Mr. OGDEN. We want to preserve the economic incentive for them to come forward. We want to create along with that an incentive for their companies to implement state-of-the-art compliance that will protect them when they do report internally to create increased compliance and self-reporting in addition to the enforcement regime and incentives we have for whistleblowers.

Mr. JOHNSON. So you would want to limit the whistleblowers and put the fox in charge of securing the chicken coop.

Mr. OGDEN. What we would like to do is to ensure that the way entities are operated encourages whistleblowers, protects them to come forward, and we see that compliance programs, here they would be certified by independent authorities under standards approved by the government. We know that they work to protect internal whistleblowing. When an internal whistleblower comes forward to the company, the company can stop anything wrong that is happening right away.

Mr. JOHNSON. Without firing the employee?

Mr. OGDEN. Absolutely without firing the employee.

Mr. JOHNSON. I will tell you, the U.S. Chamber of Commerce now is in favor of cutting government. They are in favor of cutting off access to the courts. And I am sure that you would agree with me that those are the things that the U.S. Chamber holds dear. So when we start cutting the ability of a private citizen or cutting the incentive for a person to put their livelihood on the line to ferret out fraud in a private sector that would create financial disincentives for every other stakeholder involved, I don't see where that—I see whistleblowing as being consistent with free market principles, and I find that if there is some inconsistency in terms of—you can't have it one way. You can't have it all.

The Chamber is going to have to have some kind of a check and balance. It is going to have to have either government with the ability, the financial resources to investigate and ferret our fraud, or there is a need for the private whistleblower to come along. If you don't have either one of those and you put the fox in charge of the henhouse, then we know exactly what is going to happen there. There won't be any fraud ferreted out, and the free market will be distorted. Competition will be eliminated, and that is just not good for our economy.

Mr. FRANKS. The gentleman's time has expired. The witness will be allowed to answer the question.

Mr. OGDEN. Thank you. Thank you, Congressman. Thank you, Mr. Chairman.

I hope that, Congressman, you will take a very hard look. I know you already looked at it, but I hope you will look hard at these proposals. Our goal here really is not to disincentivize whistleblowers. Our goal is to remove fear of retaliation, to ensure that companies protect and encourage whistleblowers to come forward, and to preserve these incentives for them to bring claims where the company hasn't self-reported. That is really the spirit of these changes, and to make the Act a little more rational, so things don't happen like what happened to Dr. Prabhu.

Mr. JOHNSON. Thank you, sir.

Mr. FRANKS. Well, this concludes today's hearing, and I want to thank all of the witnesses for attending. I know you folks have many things that you have to do, and we appreciate you coming here today.

Without objection, all Members will have 5 legislative days to submit additional written questions for the witnesses or additional materials for the record.

And again, I thank the witnesses. I thank the Members and the audience.

This hearing is adjourned.

[Whereupon, at 2:22 p.m., the Subcommittee was adjourned.]

APPENDIX

Material Submitted for the Hearing Record

Response to Questions for the Record from John E. Clark, Of Counsel, Goode Casseb Jones Riklin Choate & Watson, Taxpayers Against Fraud

1. In your testimony you said some corporate defendants have resolved more than one False Claims Act case – in other words, some companies have been "repeat offenders." Can you provide some examples of companies that have resolved two or more False Claims Act cases involving allegations of similar or related miscondnct?

Yes. If we think of fraud as an infection, the False Claims Act can be thought of as a kind of antibiotic that boosts the powers of the white blood cells (whistleblowers) inside the corporate body. As with all infections, the first shot of antibiotic tends to have a salient effect, but very often the infection adapts, evolves, and develops "resistance" by becoming ever-so-slightly different.

Much the same occurs with corporate fraud, where companies are loath to give up effective, million- and billion-dollar profit techniques simply because they violate the law. If one fraud is dropped, another is often developed to replace it.

Though most companies never see a False Claims Act case, companies with corrupt or seriously deficient ethical cultures tend to be repeat players. What follows is a short sampling of repeat offender companies under the False Claims Act.

GlaxoSmithKline:

- On July 2, 2012, GlaxoSmithKline agreed to pay $3 billion in criminal and civil fines, penalties and damages to settle allegations the company defrauded Medicare, Medicaid and other government funded health care programs in connection with its market practices for Advair, Wellbutrin, Paxil, Lamictal, Zofran, Imitrex, Lotronex, Flovent and Valtrex and Avandia. >> Read More.
- In October 2010, GlaxoSmithKline and a subsidiary agreed to pay $750 million to settle charges that between 2001 and 2005, they distributed adulterated versions of the drugs Kytril, Bactroban, Paxil CR, and Avandamet made at GSK's manufacturing facility in Cidra, Puerto Rico. Former GSK employee Cheryl Eckard filed the case. >> Read More.

Merck:

- On February 7, 2008, Merck & Company agreed to pay more than $650 million to resolve allegations the company failed to pay proper rebates to Medicaid and other government health care programs and paid kickbacks to health care providers to induce them to prescribe the company's products. >> Read More.
- On November 22, 2011, Merck agreed to pay $628 million to resolve allegations that it marketed Vioxx for an unapproved use and that the company made false statements about the drug's cardiovascular safety. >> Read More.

Tenet:

- On June 29, 2006, Tenet Healthcare Corporation, agreed to pay the United States more than $900 million to resolve several "whistleblower" lawsuits and investigations alleging that Tenet knowingly submitted false claims to the Medicare program and other federal health insurance programs over the past decade. The qui tam suit alleged Tenet paid kickbacks to physicians to get Medicare patients referred to its facilities, billed Medicare for services that were ordered or referred by physicians with whom Tenet had an

improper financial relationship with, and engaged in "upcoding," or the assignment of improper diagnosis codes to patient records in order to increase reimbursement. >> Read More.

- On November 15, 2005, Tenet Healthcare Corporation, which owned Redding Medical Center at the time of the alleged violations, agreed to pay $54 million to settle allegations that the company defrauded the government through the unnecessary heart surgeries performed at the hospital. >> Read More.
- In 1994, then operating under the name National Medical Enterprises, Tenet agreed to pay $379 million in criminal fines, civil damages, and penalties to settle a False Claims Act case in which the company was allegedly paying kickbacks and engaging in fraud at NME psychiatric and substance abuse hospitals in more than 30 states.

Schering Plough:

- On August 26, 2006, Schering-Plough Corporation agreed to pay $435 million to settle allegations it engaged in the illegal sale and marketing of the drug Temodar, for treatment of brain tumors, and Intron A for use in treatment of bladder cancer and hepatitis C. Schering allegedly misrepresented best price information to federal healthcare programs, paid kickbacks to physicians, and knowingly promoted the off-label use of the drug Temodar. >> Read More.
- On July 30, 2004, Schering-Plough agreed to pay more than $292 million to resolve False Claims Act liabilities in connection with the illegal and fraudulent pricing of its allergy drug, Claritin. Schering-Plough subsidiary Schering Sales Corp. pleaded guilty to violating the Anti-Kickback Act in the same matter. >> Read More.
- On December 17, 2009, Schering-Plough agreed to pay $69 million to settle False Claims Act lawsuits allegations that the company inflated the price of the asthma drug Albuterol and other products in order to collect millions of dollars in overpayments from California and Florida's Medicaid programs. The settlement resolved allegations that Warrick Pharmaceuticals, a subsidiary of Schering-Plough, deliberately inflated the Average Wholesale Prices (AWPs) it reported to California and Florida. >> Read More.

HCA, Columbia HCA, Quorum:

- In October of 2000, Quorum Health Group, a wholly owned subsidiary of HCA The Healthcare Company (formerly known as Columbia HCA), agreed to pay the United States $95.5 million to settle a whistleblower-initiated case under the False Claim Act, alleging the company systematically upcoded and price-gouged Medicare and Medicaid. >> Read More.
- In December 2000, HCA The Healthcare Company (formerly known as Columbia HCA), pled guilty to criminal conduct and agreed to pay more than $840 million in criminal fines, civil penalties, and damages for unlawful billing practices. Of this amount, $731,400,000 was recovered under the False Claims Act. HCA's frauds included: billing for lab tests that were not medically necessary and not ordered by physicians, "upcoding" medical problems in order to get higher reimbursements, billing the government for advertising under the guise of "community education," and billing the government for non-reimbursable costs incurred in the purchase of home health agencies around the country. >> Read More.
- In June 2003, HCA Inc. (formerly known as Columbia/HCA and HCA The Healthcare Company) agreed to pay the United States $631 million in civil penalties and damages

arising from false claims submitted to Medicare and other federal health programs. This settlement resolved allegations of cost report fraud, and the payment of kickbacks to physicians. In a separate administrative settlement with the Centers for Medicare & Medicaid Services (CMS), HCA agreed to pay an additional $250 million to resolve overpayment claims arising from its cost reporting practices. >> Read More.

Abbott:

- On May 7, 2012, Abbott Laboratories agreed to pay $800 million to the federal government to resolve claims it unlawfully promoted Depakote for unapproved uses and offered and paid illegal kickbacks to health care professionals and long-term care pharmacy providers to induce them to promote and/or prescribe Depakote. >> Read More.
- In July of 2003, a unit of Abbott Laboratories, Inc. pled guilty to obstructing a criminal investigation and defrauding the Medicare and Medicaid programs and agreed to pay $400 million to resolve civil claims. In addition, a subsidiary of Abbott Labs, CG Nutritionals, Inc., agreed to a criminal fine of $200 million. The Abbott/CG Nutritionals scheme involved the sale of enteral products which pump special foods into the stomachs and digestive systems of patients who, because of disease or some other disorder, are not able to ingest and digest meals in a normal manner.

Northrop-Grumman:

- On April 2, 2009 Northrop Grumman Corp. and subsidiaries, agreed to pay $325 million to settle False Claims Act allegations that Northrop provided and billed the National Reconnaissance Office (NRO) for defective microelectronic parts, known as Heterojunction Bipolar Transistors (HBTs). The government's investigation in the HBT Action concluded that Northrop failed to properly test and qualify certain HBTs manufactured from 1992 to 2002. As a result, Northrop integrated into NRO satellite equipment certain defective HBTs. The investigation further concluded that Northrop made misrepresentations about, and concealed certain material facts regarding the reliability of the HBTs. >> Read More.
- On June 9, 2003, Northrop Grumman Corporation agreed to pay $111 million to settle a FCA lawsuit claiming that TRW Inc. (a subsidiary of Northrop) improperly billed the government on several projects from 1990 to 1997. >> Read More.

Johnson & Johnson:

- On January 19, 2012, Johnson & Johnson paid the state of Texas $158 million for the Illegal marketing of anti-psychotics to schoolchildren. After 140 depositions, 10 million pages of documents, and voluminous court motions, Johnson & Johnson caved a week into trial and agreed to pay Texas $158 million to settle a whistleblower lawsuit which charged the company with off-label marketing of Risperdal to Texas school children. >> Read More.
- On November 4, 2013, Johnson & Johnson agreed to $2.2 billion to resolve civil and criminal allegations involving the off-label marketing and unapproved uses for three prescription drugs. Allegations involve alleged kickbacks to doctors and pharmacies to promote the antipsychotic drugs Risperdal and Invega, and a heart drug, Natrecor. >> Read More.

Bank of America:

- In 2012, Bank of America agreed to pay $1 billion in fines to settle allegations that the bank knowingly made loans insured by the Federal Housing Administration (FHA) to unqualified home buyers. The settlement will entail an immediate payment of $500 million to provide a recovery for the harm done to the FHA by Countrywide's conduct. Payment of the second $500 million will be deferred to fund a loan modification program for Countrywide borrowers across the nation with underwater mortgages. >> Read More.
- In 2008, Bank of America paid $187 million to the state of California for improperly retaining unclaimed municipal bond revenue. At the time, this was the largest State False Claims Act case to date.

2. Mr. Ogden says that the False Claims Act has been a failure at preventing fraud and is, therefore, in need of amendment. What is your response?

Some failure! The government's recoveries under the statute since its 1986 overhaul to make whistleblower cases viable again total more than $40 billion, and the law has been widely recognized as the government's most important tool to combat fraud. Mr. Ogden's recipe for improving the law's effectiveness is (i) reduce the penalties for committing fraud, (ii) reduce the incentives for whistleblowers to expose fraud, and (iii) rely on unspecified "gold standard" compliance plans to make fraud go away.

The amendments that reduced whistleblower incentives in 1943 resulted in only a handful of whistleblower cases being filed over the next 43 years and few cases being brought by the Department of Justice.

The current statute serves the government well, as evidenced by the recoveries, more than 80% of which are obtained from actions filed by whistleblowers, and by the bipartisan support it has enjoyed in the Congress. Additionally, a growing number of states, having realized that fraud against government programs is not exclusively a federal phenomenon, are adopting broad-spectrum false claims acts of their own and using them to return ill-gotten taxpayer funds to their state treasuries.

The effectiveness of the federal statute could be improved, however, by (i) allowing the United States to recover its legal and investigative costs when cases are settled or adjudicated successfully, as do the similar laws of 15 states; (ii) adding tax fraud to the scope of the law's coverage, in recognition of the unfortunate fact that the IRS false claims program has proved to be an abject failure; (iii) clarifying the statute to confirm that the government's "damages" from fraud are its "gross damages"; and (iv) administering the law to impose personal consequences on responsible individuals in large fraud cases, as is done now in smaller cases.

3. Why is it problematic to rely on companies to self-report and self-regulate against fraud?

In two words: because of "human nature." Greed is a powerful motivator; and whenever a pot of "federal funds" is available to claimants, some will succumb to the temptation to obtain more than their lawful share by connivance, manipulation, and falsehood – especially if the fiscal

success of the scheme may enhance one or more careers. The impersonal nature of "federal funds" administered by a faceless bureaucracy doubtless makes it easier to rationalize stealing from the government than stealing from an individual. Thus a company that might never countenance the adulteration of its product because that could harm an individual consumer may find it much easier to rationalize gaming-the-system to obtain more money than it is entitled to from an impersonal government program.

As illustrated by the history of repeat violators of the False Claims Act, even a strict compliance plan imposed by a settlement agreement with the United States and explicitly agreed to by the corporate offender is no guarantee of honest behavior in the future. The key to self-regulating against fraud is a true corporate culture of integrity, a dedication to Justice Holmes's admonition about the imperative of "turning square corners" when dealing with the government. And self-reporting is, if anything, even less predictable than self-regulation, in the absence of an ingrained culture of integrity; it's tempting to calculate that the fraud, after all, might never be noticed.

4. **Mr. Ogden says that 90 percent of all qui tam cases in which the government declines to intervene are dismissed or abandoned and that this reflects the fact that most qui tam suits are without merit. What is your response?**

First, I know of no statistical studies supporting that figure; but anecdotal evidence suggests that many non-intervened cases are dismissed, most of them voluntarily. Whatever the number or percentage, however, it does not reflect that "most qui tam suits are without merit."

The United States declines to intervene in *qui tam* cases for many reasons; accordingly, as the Department of Justice advises the court and the parties when it does so, its declination is not to be taken as a comment on the merits of the case. Some declinations are based on statutory or factual obstacles to success discovered by the Department of Justice in its due diligence investigation; and because the Department of Justice and federal agencies do not have unlimited enforcement resources, some result from policy and priority decisions by the affected government agency or by the Department of Justice.

Because all *qui tam* cases must be filed under seal and often remain under seal for years, a relator and his counsel cannot know if their newly filed case is already subject to dismissal under the statute's "first to file" provision. Similarly, the question whether the defendant's alleged misconduct has already been "publicly disclosed" within the meaning of the Act – another ground for dismissal – often cannot be known by the relator at the time of filing.

A declination by the Department of Justice puts the relator and his counsel to a crucial election: to proceed without the government's help, or to dismiss the case. If the government has found a serious flaw in the case, the decision is easy. When the declination is based on priorities, the decision can be more difficult. If, as is typical of *qui tam* cases, the defendant is sizeable and well-funded, the prospect of a pitched legal battle with such an adversary and a big law firm – with no help at all from the government – can be sufficiently unattractive to the relator and his (often solo) counsel to prompt a decision to dismiss the case, *regardless of merit*.

Attorneys who practice in our federal courts are required to know the rules. By filing a lawsuit,

an attorney certifies to the court that it is not presented for any improper purpose, such as to harass; that the claims made are warranted by existing law or by a non-frivolous argument for extending or modifying the law; and that the factual contentions have evidentiary support. *Fed. R. Civ. P. 11(b)*. Sanctions for violations of that rule may be imposed by the court *sua sponte* or in response to an adversary's motion. *Fed. R. Civ. P. 11 (c)*. As a result, few attorneys would risk knowingly filing a case without merit. Moreover, fraud must be alleged with particularity in federal courts, and a *qui tam* complaint must meet that factual standard without any opportunity to develop additional facts through discovery procedures before it is challenged by the defendant. If a case is genuinely without merit, the rules provide measures for an early and expeditious dismissal by dispositive motion. *See, e.g., Fed. R. Civ. P. 12(b)(6)*.

It should be noted, in the context of Mr. Ogden's proposed reliance on self-regulation for companies that federal courts rely instead on strict rules and the ready availability of sanctions to ensure compliance with court rules by attorneys.

5. Mr. Ogden takes issue with staying the application of the False Claims Act's statute of limitations during the use of military force, particularly when the allegations at issue have nothing to do with those military actions. What is your response?

The Wartime Suspension of Limitations Act (WSLA) is law that has been embraced by Congress for 70 years. Whether or not it applies to False Claims Act cases, and under what circumstances, are questions currently before the courts. Assuming the WSLA does apply, any new restrictions on its application will, over time, result in billions of dollars in lost fraud recoveries to the government. At a time when the United States is struggling with a rising, multi-trillion dollar debt, those proposing to change the current law should be required to specify what taxes or user fees will be raised to offset that gap. So far, the Chamber of Commerce has been silent on this matter.

6. **Mr. Ogden suggests that when a corporation has disclosed fraud to an agency inspector general or other investigative office, the False Claims Act should foreclose qui tam actions based on the same fraud allegation. What is your response?**

As phrased, this question begs other questions; *e.g.*, what resulted from the disclosure? Was there a settlement and release, which would bar a claim for the same fraud? Did the agency consider the disclosure and take no action? That could result in a policy decision to decline a subsequent False Claims Act action for the same fraud, depending on the reason for the agency's original decision and the similarity of the facts alleged; but it should not preclude reconsideration of the agency's original inaction. Was the disclosure an instance of true self-reporting, or was it an attempt to limit exposure to damages after learning that it was under investigation?

True "self-reporting" of fraud occurs when a culpable party takes the initiative to voluntarily disclose conduct for which it is not already under investigation or litigation. In that circumstance, assuming full disclosure, settlements and accompanying releases from liability occur routinely. In my experience, executive branch agencies have self-disclosure protocols designed to encourage true self-reporting by members of their contracting community, with the incentive of a settlement for a reduced multiple of the government's damages.

Fraudsters often attempt to portray themselves as "self-reporting" fraud to the government after a False Claims Act case and a resulting Civil Investigative Demand (CID) letter or a subpoena has alerted them that "the government knows and there may be a whistleblower case." Since the company would otherwise have made no such disclosure, it should get no benefit from posing as a self-reporter, and the whistleblowers should be rewarded, not penalized, for their action-forcing integrity. Because qui tam cases require the government to actually investigate frauds, take actions, and make decisions that are reviewable by the courts, they are an antidote to the kind of "crony capitalism" inaction that pervades the world of government contracting.

UNITED STATES HOUSE OF REPRESENATIVES
COMMITTEE ON THE JUDICARY
SUBCOMMITTEE ON THE CONSTITUTION AND CIVIL JUSTICE

"Hearing: Oversight of the False Claims Act"

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Chairman Franks, Vice Chairman Jordan, and Members of the Subcommittee:

Thank you for this opportunity to submit written testimony regarding the False Claims Act ("FCA" or "Act") and the validity of "reforms" to the FCA proposed by the U.S. Chamber of Commerce.[2] As outlined in the National Whistleblowers Center's report, *"Saving America's 'Most Important Tool to Uncover and Punish Fraud:' 25 Facts that Rebut the Chamber of Commerce's Proposals to Undermine the False Claims Act*," the Chamber's proposals, taken together, would cripple a key "tool" for uncovering and punishing fraud against the taxpayers.

According to the Chamber, Congress should amend the FCA to create incentives for companies to enhance corporate internal compliance programs. However, the Chamber's vision of a compliance program is highly misleading.

The Chamber does not use the term "compliance" as it is ordinarily understood. Instead, the "compliance" programs advocated by the Chamber are merely part of a company's law department, and they are designed to protect the company from liability. The Chamber's vision of a "compliance" program increases the ability of a company to cover up fraud from government investigators. Chamber-backed compliance programs operate in secret and are permitted to use information obtained from the compliance investigation to discipline or discredit the very whistleblowers that raise concerns within the company.

THE CHAMBER'S POSITION ON CORPORATE COMPLIANCE PROGRAMS

Most members of the public are unaware that the structure for compliance programs advocated by the Chamber of Commerce would ensure that the program operate in secrecy and have as its

[1] Stephen M. Kohn is the Executive Director of the National Whistleblowers Center and a partner in the law firm of Kohn, Kohn and Colapinto, LLP. He is the author of seven books on whistleblower law, including, *The Whistleblower's Handbook: A Step-by-Step Guide to Doing the Right Thing and Protecting Yourself* (Lyons Press 2013, 3rd ed.). Since 1984 Mr. Kohn has represented numerous whistleblowers in a nonpartisan manner.

[2] These proposals have been widely publicized by the Chamber in its report: *Fixing the False Claims Act: The Case for Compliance-Based Reforms*.

goal the protection of the company from liability. Under this structure, compliance programs report through or to a company's Office of General Counsel and are, effectively, arms of the law department.

Just this year, the Chamber of Commerce had the opportunity to clarify its position on such programs in a major court case decided by the U.S. Court of Appeals for the District of Columbia Circuit. In that case, a major Iraq defense contractor, Kellog-Brown & Root ("KBR") operated a compliance program. A whistleblower had provided information to the compliance program, but later alleged that the company had covered up the instances of fraud. The company claimed that all its compliance records were secret simply because the program was supervised by a lawyer.[3]

The Chamber of Commerce supported KBR's position on secrecy and strongly urged the court to recognize that compliance programs, such as the KBR program, were simply arms of a corporation's legal department. The Chamber aggressively argued that documents created as part of a corporate compliance program are "attorney-client privileged," even if no attorney ever interviewed the whistleblower and no legal advice was requested or received. The Chamber, which filed an *amicus* brief in support of KBR, successfully argued that even if a company is required, under federal law, to operate a compliance program, that program is still an arm of its corporate attorneys.

Chamber-supported compliance programs are not designed to independently investigate internal whistleblower concerns. Instead, as a matter of law, they serve as investigators for the company's legal department and serve the "best interests" of the executives who manage the company. These compliance programs are under no duty whatsoever to protect whistleblowers, and, in fact, companies are fully permitted to use these programs to obtain evidence that can be used as a basis to discredit or terminate the whistleblower.

Corporate compliance programs advocated by the Chamber are so anti-whistleblower that persons who work within such departments are required to give "warnings" to any employee who contacts them. These warnings are required because of the built-in conflicts of interest between the corporation's interest in protecting itself and its executives, and the interests of whistleblowers/employees who reported the fraud and who thought that the compliance department was required to do its job.

Given these conflicts, Chamber-supported compliance programs are required under many local attorney ethics rules to give warnings to employees that: (a) the program was in fact run by the corporate attorneys, not some independent ethics or compliance office; (b) because the corporate lawyers ran the program, there existed potential conflicts of interest between the whistleblower, who reported the misconduct, and the compliance program that served the interest of the corporation and its executives; (c) the compliance program did not represent the employee and that

[3] *In re Kellogg Brown & Root, Inc.*, No. 14-5055 (D.C. Cir. June 27, 2014) (reversing *United States ex rel. Barko v. Halliburton Co.*, 2014 U.S. Dist. LEXIS 36490, at 10 n. 33 (D.D.C. March 6, 2014). Cases reprinted at http://bit.ly/2014-06-27Opinion. Petition for en banc review filed on July 28, 2014, and available at http://bit.ly/PetitionEnBanc.

information provided to the compliance program could be used against the employee/whistleblower.[4]

The anti-whistleblower/anti-independent nature of the Chamber-endorsed compliance programs was highlighted in a paper delivered to the ABA Section of Litigation Corporate Counsel for which Senior Counsel for General Electric co-authored. The paper advised corporate lawyers who managed compliance programs to provide strong warnings to employees who contacted these programs:

> *What is clear is that counsel who fail to give the warnings . . . expose themselves to criticism by the courts, professional discipline and even civil liability. Given these realities, it is imperative that all counsel internal and external scrupulously inform employees at all levels of the organization of the potential conflicts of interest and do so in a way where the warnings cannot be contested. Warnings are a time for plain language.*

"Avoiding the Perils and Pitfalls of Internal Corporate Investigations: Proper Use of *Upjohn* Warnings," ABA Section of Litigation (Feb. 11-14, 2010).

The compliance programs advocated by the Chamber are so riddled with conflicts of interest, that the New York State Bar Association published guidance for attorneys who worked for such programs. *See* New York Ethics Op. 650, a copy of which is available at http://bit.ly/NYbarEthicsOp650.[5] The guidance was not intended to ensure that the programs were independent or provided protection against fraud. Instead, the guidance focused on the need for attorneys who worked in such programs to give very explicit warnings to employees in order to avoid being disbarred for unethical activity.

The "warning" upheld by the New York Bar stated as follows:

> "'I want to caution you that I am an attorney for the Company and not for you or other employees. Therefore, while I can record your complaint, I cannot and will

[4] These warnings were commonly known as "corporate Miranda" warnings or *Upjohn* warnings. *See U.S. v. Int'l Broth. Of Teamsters*, 119 F.3d 210, 217 (2nd Cir. 1997) ("attorneys in all cases are required to clarify exactly whom they represent, and to highlight potential conflicts of interest to all concerned as early as possible"); *In re Grand Jury Subpoena*, 415 F.3d 333, 336 (4th Cir. 2005)(court noted that an *Upjohn* warning stated "We represent the company. These conversations are privileged, but the privilege belongs to the company and the company decides whether to waive it. If there is a conflict, the attorney-client privilege belongs to the company"); *Sandra T.E. v. S. Berwyn*, 600 F.3d 612, 620 (7th Cir. 2009)("*Upjohn* warnings" emphasized that the attorney represented the School Board "and not the employee and that the School Board had control over whether the conversations remained privileged"); *Admiral Ins. v. U.S. Dist. Ct.*, 881 F.2d 1486, 1492 (9th Cir. 1989), quoting with approval *U.S. v. Nicholas*, 606 F.Supp.2d 1109, 1117 (2009)("An *Upjohn* warning is given to advise the employee that he is not communicating with his personal lawyer, no attorney-client relationship exists, and any communication may be revealed to third parties if disclosure is in the best interest of the corporation.").

[5] Also see, ABA WCCC Working Group, "Upjohn Warnings Recommended Best Practices when Corporate Counsel Interacts with Corporate Employees," a copy of which is available at http://bit.ly/ABAbestpractices.

> not give you legal advice, and you should not understand our conversation to consist of such advice. I do advise you to seek your own counsel, however, as your interests and the Company's may differ. Having said this, I would be happy to listen to your complaint, etc.'"

As these warnings make clear, the compliance programs advocated by the Chamber are an alternative to a strong False Claims Act. Given the ability of the company to keep the whistleblower's disclosures secret from government inspectors and to use the information obtained from whistleblowers to discredit the whistleblower, these programs are often traps for employees.

The compliance program upheld at the urging of the Chamber also required employees who provided information to the program to sign broad nondisclosure statements.[6] This Chamber-endorsed nondisclosure agreement was aimed only at silencing employees. It threatened the employees with termination if they discussed their concerns outside of the compliance investigation. Employees were threatened with termination if they provided "anyone" with information related to the frauds for which they were reporting. Employees were not informed of their right to inform federal authorities that fraud had been committed in government-sponsored programs.

The compliance program for which the Chamber of Commerce aggressively defended in the 2014 *In re KBR* court case also permitted the company to classify evidence of fraud as confidential attorney-client materials. The information could be kept secret from whistleblowers and government investigators. Even a criminal Grand Jury subpoena could not force the disclosure of the "compliance" materials. This right to secrecy, in the corporate context, was upheld in *In re KBR*, even though the lower court judge who reviewed the documents *in camera* had determined that the compliance documents contained strong evidence of fraud, including double billing, failure to complete work, and bid-rigging.

As reflected in the Chamber's report, *Fixing the False Claims Act*, these programs usually appear on their face to be "independent." For example, in the case for which the Chamber defended the compliance program, the company's internal corporate compliance program never publicly mentioned that the corporate lawyers ran the program, and that these lawyers could keep secret from the government the evidence of fraud reported by the whistleblowers. The program was marketed as if it was designed to promote integrity and ethics. Its true nature was hidden.

The False Claims Act creates a safe, effective, and highly successful method for employees to disclose fraud in government programs to the appropriate authorities. Compliance programs advocated by the Chamber of Commerce do not provide a reasonable substitute for this law.

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[6] The broad nondisclosure agreement upheld by the Court in the *KBR* decision was reprinted in full in *United States ex rel. Barko v. Halliburton Co.*, 2014 U.S. Dist. LEXIS 36490, at 10 n. 33 (D.D.C. March 6, 2014). *See* http://bit.ly/kbrPrivilegeOrder.

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