

TESTIMONY

of

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Washington, D.C

before the

House Judiciary Subcommittee on the Constitution and Civil Justice

on

Oversight of the False Claims Act

April 28, 2016

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**Unintended Consequences of *Qui Tam* Litigation for Small Business**

Mr. Chairman and Members of the Constitution and Civil Justice Subcommittee, good afternoon. My name is Jonathan Diesenhaus. I am a partner at the law firm of Hogan Lovells US LLP in Washington, DC. Thank you for the invitation to testify on the False Claims Act ("FCA"). My practice focuses on healthcare fraud and abuse litigation and counseling, FCA litigation, and white collar criminal defense. I have been handling investigations and litigation under federal and state False Claims Acts for nearly 25 years. From 1998 to 2005, I served as a trial attorney and then as Senior Trial Counsel in the Fraud Section of the Civil Division at the Department of Justice.

Today I am here to discuss some of the unintended consequences of the *qui tam* statute, particularly when healthcare companies are the target.

I am proud of my time at the Department, and believe strongly that the FCA and its *qui tam* provisions play an important role in protecting the federal fisc, federal programs and their beneficiaries, federal employees, and the military. I also believe that whistleblowers can and do play an important role in bringing fraud and other misconduct to light, both within corporations and to the government. However, what I've seen in recent years is abuse of the statute and the good offices of DOJ by whistleblowers with less than honorable intentions and by whistleblowers' attorneys who the statute shields from the restrictions imposed on other members of the plaintiffs' bar. The cost and burden of investigations and litigation instigated by such whistleblowers can and is doing substantial damage to small health care businesses across the country, including health care providers and innovative manufacturers of drugs, devices and other technologies. And the negative impact of these cases is felt not only by the corporations and their investors, but by their employees, and the customers and patients they serve.

The *qui tam* provisions allow whistleblowers to spur investigations of wide-ranging allegations of misconduct, with very little evidence to substantiate those allegations. The statute requires the Attorney General to investigate each such allegation. And it allows whistleblowers to pursue those allegations in litigation even when the injured party, the government, determines they lack merit or otherwise decides not to participate.

Those *qui tam* allegations that do lack merit trigger two waves of cost and disruption that, in the case of a small business, can be crippling. In the first wave, a DOJ investigation of *qui tam* allegations usually requires a company – large or small, for profit or charitable – to engage in a resource and time intensive internal investigation, the goal of which is to uncover any evidence of the alleged wrongs. When no such evidence is discovered, to defend itself, the company will engage in the costly exercise of disproving the allegations in presentations or written submissions to DOJ.

The second wave comes when the company succeeds in its defense and the government chooses not to pursue the allegations. Litigation is unpredictable and costly, and the threat of exorbitant fines,

fueled by the treble damages required under the FCA, is a gamble few small business can afford to take. And even if the company takes that gamble and wins, unless the company can prove that the whistleblower violated not only Rule 11 of the Federal Rules of Civil Procedure, but the higher “clearly frivolous” standard of the *qui tam* provisions, the company has no means to recover the costs wrongly imposed on it.

**The *qui tam* statute treats all targets as if they are the most culpable fraudsters.** In a health care case, when a whistleblower files a case alleging that regulatory non-compliance amounts to fraud, the organization targeted by the allegation is often an entity engaged in the low margin business of delivering health care services or supplies. Labeled a “fraudster” by a witness claiming to have inside information, the company first struggles through the disruption, diversion of resources and anxiety of a fraud investigation. With increasing regularity, employees, and especially managers, need separate counsel – counsel the company is often obligated to pay for. Thanks to the wonders of email, servers and the cloud, vast amounts of data needs to be collected and reviewed to respond to the inevitable subpoena for documents, books and records. And throughout, the organization and all its employees come to work each day and try to keep the business running and provide care to patients. And if the company is lucky enough to be among the 80 percent of defendants who DOJ decides, after investigation, not to sue, the company must turn immediately to funding the defense of costly declined *qui tam* litigation in federal court.

In *qui tam* litigation today, it doesn't matter that a defendant had independently instituted a compliance program and attempted on its own to prevent not only regulatory non-compliance, but fraud. It doesn't matter that it provides a service, drug, or device that the organization believes benefits the public. And it doesn't matter that a whistleblower makes no allegation that the services provided were medically unnecessary or of poor quality, or that the device, drug, or procedure used was unnecessary or inappropriate. Because the allegation is that the company perpetrated fraud on the government, the government, the defense attorneys and the courts treat the allegation, even an allegation of regulatory non-compliance, with the seriousness such an allegation requires.

**The *qui tam* provisions shield whistleblowers and their attorneys from the risk-reward proposition that governs other litigation in federal courts.** Under the *qui tam* provisions, the rewards can be extraordinary. Whistleblowers stand to gain up to 30 percent of multi-million dollar recoveries.<sup>1</sup> In a quirk of this statute unlike almost any other, whistleblower's attorneys, most of who take a substantial contingency from their client's recovery, *also* recover their fees and expenses from the defendant as soon as the defendant pays \$1 to the government, regardless of whether the payment is made under a settlement or after a trial.<sup>2</sup> Further mitigating the financial risk of litigation, the *qui tam* provisions limit a defendant's pursuit of fees in frivolous cases that would otherwise violate Rule 11 to cases shown to be “clearly frivolous, clearly vexatious, or brought primarily for the purposes of harassment”<sup>3</sup> – a standard so high that few defendants pursue relief and few if any of those prevail.<sup>4</sup> While the stigma of whistleblowing can be painful personally and even derail a

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<sup>1</sup> 31 U.S.C.A. § 3730(d)(2).

<sup>2</sup> 31 U.S.C.A. § 3730(d).

<sup>3</sup> 31 U.S.C.A. § 3730(d)(4).

<sup>4</sup> See *Pfingston v. Ronan Eng'g Co.*, 284 F.3d 999, 1006-07 (9th Cir. 2002) (“The award of fees under the False Claims Act is reserved for rare and special circumstances.”); see *also* *United States v. Purdue Pharma L.P.*, No. 5:10-CV-01423, 2015 WL 2401410, at \*3 (S.D. W. Va. May 20,

career, many whistleblowers are disgruntled former employees who have already been through both. Moreover, those who suffer financial loss are well-protected by the broad anti-retaliation provisions of the statute which provide a remedy even for whistleblowers who do not file a *qui tam*.<sup>5</sup> For those who see a *qui tam* suit as a way to win the lottery or inflict pain on a former employer, the *qui tam* provisions can be an effective weapon.

**Increasingly, *qui tam* litigation is pursued solely by a whistleblower after the government, the alleged victim, has investigated the claim and declined to participate.** The *qui tam* statute is structured to encourage whistleblowers to report wrongdoing to the government. In many cases, after investigating the whistleblowers' allegations, the government declines the claim, deciding that the claim lacks merit or that it does not want to pursue the claim itself. However, the statute allows a whistleblower to continue to litigate even when the government has decided not to participate, in what is known as a "declined" *qui tam*. In fact, DOJ declines to intervene in the vast majority of *qui tam* lawsuits.

Yet, since the current version of the statute was enacted in 1986, the treasury has received 94% of its total *qui tam* recovery in cases where the government intervened.<sup>6</sup> In every year until 2015, which stands out as an anomaly, the treasury recovered ten-fold more (and in some cases up to over a hundred fold more) in FCA cases where DOJ participated than in cases where DOJ chose not to get involved.<sup>7</sup> DOJ's statistics show that in the past three decades only 10% of declined cases resulted in a recovery to the government while 90% of cases where the government intervened resulted in recovery. In these declined *qui tam* suits, a tremendous amount of judicial, corporate, and individual resources are expended, even though the alleged victim – the government – has investigated the allegations and elected not to pursue the claim.

Of course, the government can choose not to pursue a *qui tam* action for a host of reasons, including the vast expenditure of government resources necessary to pursue cases or a departmental judgment about what types of cases it wishes to pursue.<sup>8</sup> But, the government does take seriously its mandate to thoroughly investigate the claims, and has an incentive to pursue claims if they appear they have merit: under the statute, when the government chooses to pursue

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2015) (refusing to award attorneys' fees after a decade of litigation resulting in a dismissal because the suit was barred by the public disclosure bar); *United States ex rel. Atkinson v. Pennsylvania Shipbuilding Co.*, 528 F. Supp. 2d 533, 547 (E.D. Pa. 2007) (refusing to award attorneys' fees in a thirteen-year litigation after defendant was successful on motion to dismiss for lack of subject matter jurisdiction because relator was not an original source).

<sup>5</sup> 31 U.S.C.A. § 3730(h)(1).

<sup>6</sup> Dep't of Justice, *Fraud Statistics – Overview* (Nov. 23, 2015), *available at* <http://www.justice.gov/opa/file/796866/download>.

<sup>7</sup> *Id.*

<sup>8</sup> See *United States' Statement of Interest as to Defendants' Opposition to Plaintiff-Relator's Motion to Leave to File a Second Amended Complaint, United States ex rel. Jose R. Valdez v. Aveta, Inc.*, No. 15-cv-1140-CCC (D.P.R., filed Oct. 16, 2015) ("The United States' decision whether to intervene in any *qui tam* action is based on many factors, including questions of resource allocation and judgments as to which types of cases it chooses to pursue at a given time.")

the claim itself, it secures a larger portion of the final pay-out.<sup>9</sup> With the ranks of DOJ attorneys handling these cases growing nearly every year, declinations because of lack of resources are few and far between. And, in those few cases where the government declines because of lack of resources, the government typically attempts to stay involved in a support capacity.<sup>10</sup>

**The scope of the FCA has been gradually increasing. The Supreme Court is currently considering a case which could rein in this expansion.** In recent years, several whistleblowers have stretched FCA liability using a so-called “implied false certification” theory. The theory holds that by submitting a claim to the government, the claimant is making a series of implied statements about the validity of the claim, including representations that the claimant complied with all rules, regulations, laws, and contract terms governing its business, even if the company has not explicitly agreed to do so or represented that it did. While some rules and regulations arguably do go to the heart of a transaction by, for example, defining key terms written on the claim, thousands if not millions of others do not. The question before the Court is how to distinguish compliance issues that matter from compliance issues that don’t for False Claims Act purposes. Put another way, the question before the Court is how to distinguish rules and regulations that only the government can enforce from those Congress intended whistleblowers to be able to enforce through the *qui tam* statute even when the government chooses not to.

While some circuit courts have upheld this theory, others have explicitly rejected it. The Seventh Circuit stated that “it would be . . . unreasonable for us to hold that an institution’s continued compliance with thousands of pages of federal statutes and regulations incorporated by reference into the [agreement with the government] are conditions of payment for purposes of liability under the FCA.”<sup>11</sup> The Second Circuit stated that the “False Claims Act was not designed for use as a blunt instrument to enforce compliance with all medical regulations . . . and to construe the impliedly false certification theory in an expansive fashion would improperly broaden the Act’s reach.”<sup>12</sup>

Now, the Supreme Court will decide whether the FCA, and its *qui tam* provision, can be used to enforce laws and regulations not clearly related to the transaction.<sup>13</sup> The Court’s decision could influence not only the federal FCA, but will determine the scope of dozens of state false claims acts that closely mirror the federal statutory language.<sup>14</sup> It will also signal whether the Court believes that the FCA has been stretched too far to cover conduct that should not be within the statute.

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<sup>9</sup> If the government intervenes, the whistleblower receives 15 to 25% of the judgment. If the government does not intervene, the whistleblower receives between 25% and 30% of the ultimate judgment. 31 U.S.C.A. § 3730(d).

<sup>10</sup> See, e.g., United States’ Statement of Interest in Opposition to Defendant Parke-Davis’ Motion for Summary Judgment, United States *ex rel.* Franklin v. Pfizer, Inc., No. 96-11651 (D. Mass., filed May, 23, 2003) (filing thirty-six page long statement of interest even after declining to participate in the case).

<sup>11</sup> United States v. Sanford-Brown, Ltd., 788 F.3d 696, 711 (7th Cir. 2015).

<sup>12</sup> Mikes v. Straus, 274 F.3d 687, 699 (2d Cir. 2001).

<sup>13</sup> Petition for a Writ of Certiorari, Universal Health Services, Inc. v. United States *ex rel.* Escobar, 15-7 (U.S., filed Jun. 30, 2015).

<sup>14</sup> See Brief of *Amicus Curiae* Catholic Charities of the Diocese of Joliet, Inc. in Support of Petition, United Health Services, Inc., v. United States *ex rel.* Escobar, No. 15-7 (U.S., filed Jan. 26, 2016).

**The cost and risk of defending against *qui tam* allegations effectively deprive health care entities of the ability to challenge overzealous interpretations of government regulations.**

Below, I discuss three examples of organizations whose circumstances compelled them to take different paths to resolve *qui tam* allegations lodged against them. The first has become another cautionary tale that any corporate decision maker must consider before fighting either the government or a whistleblower in FCA litigation.

Tuomey Healthcare operated a hospital in a mostly rural community in South Carolina. Tuomey entered into a financial transaction with a group of physicians. A whistleblower and DOJ asserted that the agreement failed to comply with a series of complex regulatory requirements and as a result amounted essentially to a bribe or kickback. Tuomey disagreed and argued that it had acted in good faith and consulted with counsel before entering into the transaction. Tuomey chose to defend in court, and then lost at trial and on appeal. Judgment was entered against it after a decade-long litigation for \$237 million in damages and penalties. And after that, Tuomey faced the risk that it would be excluded from all federal health care programs because it was found liable – a virtual corporate death penalty even if the hospital had the ability to pay the judgment.

Confronted with that kind of risk, questions of regulatory interpretation that might otherwise be subject to administrative litigation simply become too expensive and too uncertain to dispute. Health care providers and small businesses without the resources of a large manufacturer aren't in the business of funding that kind of fight. They want to get back to their business. They settle, and interpretations of regulation embedded in the settlement go unchallenged.

**For a small business or health care provider that is the subject of a *qui tam* action, the result is often financial distress or even ruin, regardless of guilt.** The stories of three defendants make this point.

- As noted above, Tuomey Healthcare elected to challenge allegations against it in court. After two trials and an appeal, Tuomey settled out from the \$237 million judgment by making a series of concessions, selling its hospital, and entering into a \$72 million settlement with the government. The whistleblower, a doctor, received \$18 million.
- Cylex, Inc. was a private equity-backed diagnostic life sciences company based in Columbia, Maryland that employed nearly 50 people in science related jobs there and across the country. In 2011, Cylex faced down the unfounded *qui tam* allegations of a disgruntled former Vice President of Clinical Affairs who had worked for the Company for less than ten months. Cylex's sole product was a proprietary test that transplant surgeons use to assess the health of organ transplant patients. Although the government declined to press any charges after conducting a criminal and civil investigation of the whistleblower's allegations, the investigation had a devastating financial impact, precluding the company from raising new capital and draining it of reserves earmarked for the commercial operation. Cylex was left with one option – bankruptcy and sale of its assets. In the end, Cylex's assets were sold to a European concern, Maryland lost a life science company and all but two of its employees lost their jobs. The whistleblower dismissed his *qui tam* after the government declined; the bankruptcy court refused his other claims. *(For more detailed information, see Appendix A, attached).*
- Based in Redlands Washington, Endogastric Solutions, Inc. (EGS) manufactures EsophyX, an innovative implantable device used to treat severe acid reflux. Just as new management

was making headway with regulators and insurers to secure reimbursement for the new procedure surgeons performed to implant EsophyX, a former employee's *qui tam* spurred a government investigation. With low revenue but a promising future, EGS lacked the financial resources to mount an effective response or survive the uncertainty or expense of *qui tam* litigation. EGS chose to tell DOJ its financial story, its compliance story and its plans for securing reimbursement for the new procedure and patient access to EsophyX – and to ask for special consideration. Fortunately, DOJ was willing to employ a unique ability-to-pay settlement model that enables the treasury to share in the Company's success upon the occurrence of certain milestones. Although it came at substantial cost and disruption, a leaner EGS is moving forward and is poised to bring its minimally invasive treatment option to the GERD patients. *(For more detailed information, see Appendix B, attached).*

These cases demonstrate three alternatives for a company faced with the threat of treble damages under the *qui tam* provision of the FCA and the unfortunate results: attempting to fund the investigation and declaring bankruptcy, choosing to settle to avoid the massive costs of litigation, and attempting to fight the allegations in court, resulting in exorbitant legal fees and treble damages. Any option could result in massive costs to the company, even if allegations are completely unsubstantiated, and could limit the valuable medical services the company provides to the community.

## **CONCLUSION**

Given the cost of litigation today and the complexity of the regulatory environment in which health care businesses operate, the balance of risks and incentives Congress sought to achieve in the 1986 amendments to the *qui tam* statute no longer applies. The normal rules of litigation simply do not constrain whistleblowers and their attorneys in the same way that other plaintiffs and their attorneys are constrained. Defendants are left without a remedy when investigations, or more often declined *qui tam* litigation, come up empty. Congress can reset that balance, by (1) creating greater incentives for compliance and self-disclosure, (2) subjecting frivolous whistleblower claims to the same scrutiny as other plaintiffs under the federal rules of civil procedure, and (3) sending a clear message that Congress expects DOJ to evaluate declined *qui tams* for merit and to exercise its statutory authority to dismiss cases that would unjustifiably burden the courts, federal agencies, innovators, small businesses and health care providers.

## Appendix A

### United States ex rel. Paradis v. Cylex, Inc., No. 10-11608 (D. Mass, filed Sept. 21, 2010)

**Cylex developed and commercialized *ImmuKnow*, an important technological advance for transplant physicians and their patients.** Cylex was a venture-backed diagnostic life sciences company headquartered in Columbia, Maryland. Cylex's primary product, *ImmuKnow*, was a clinical assay used to measure markers of the immune system associated with the risk of adverse events following organ transplantation. It was the only FDA-cleared test for post-transplant monitoring. As clinical research continued to validate the utility of *ImmuKnow* data, Cylex was poised for growth. In 2007, the Company was preparing to increase production and its work force.

**Employment disputes emerged and the inevitable *qui tam* followed.** In late 2007, Cylex hired a Vice President of Clinical Affairs and Chief Medical Officer. The new hire wasn't up to the task. During his nine-month tenure, he neglected his duties and inappropriately delegated his work. Cylex terminated him for abandoning his position and refused to pay the substantial severance payment he demanded. In September 2010, while purportedly negotiating a settlement of his wrongful termination claims, the terminated Vice President secretly filed a *qui tam* complaint accusing Cylex of promoting *ImmuKnow* for off-label uses and, significantly, alleging that *ImmuKnow* didn't work and that patients would be harmed if treating physicians relied on the data it produced to adjust immunosuppressive therapies in transplant patients.<sup>15</sup>

**Cylex cooperated fully with a government investigation, depleting its cash reserves.** DOJ opened a criminal and civil investigation, hitting Cylex with a subpoena in July 2011. Cylex cooperated fully, producing documents under the subpoena, paying for attorneys to represent workers in DOJ interviews, coordinating with counsel for its investors, who also received subpoenas, and making substantive presentations, through counsel, to the government. The Company incurred half a million dollars in legal fees and costs.

**Cylex filed for bankruptcy.** With its investors' relationships apparently under a DOJ microscope and the uncertainty of an open apparently broad investigation, Cylex struggled to raise enough capital even to sustain its operations. The Company had no choice but to encourage employees to find other jobs. Despite these cuts, Cylex projected that it would run out of cash by early 2013. The Company was forced to sell its assets to the highest bidder in bankruptcy, including its most valuable asset, *ImmuKnow*. Shortly after Cylex filed for bankruptcy, the government closed the criminal investigation and declined the *qui tam*.<sup>16</sup> The whistleblower later dismissed the *qui tam* voluntarily.<sup>17</sup>

**The bankruptcy sale closed, the buyer moved Cylex's operations outside of Maryland and the Company's remaining Maryland employees lost their jobs and still, the whistleblower unsuccessfully tried to extract money from Cylex in bankruptcy court.** Even after the government declined and the Company filed for bankruptcy, the whistleblower pressed the bankruptcy estate for money. As with the imaginary conspiracy he alleged in the *qui tam*, he argued that unconsummated settlement negotiations surrounding his termination entitled him to a share of the proceeds of the bankruptcy sale, a bankruptcy triggered by his unfounded allegations. The

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<sup>15</sup> Complaint, U.S. ex rel. Paradis v. Cylex, Inc. (filed Sept. 2010).

<sup>16</sup> Government's Election to Decline, U.S. ex rel. Paradis v. Cylex, Inc. (filed Dec. 21, 2012).

<sup>17</sup> Order of Dismissal, United States ex rel. Paradis v. Cylex, Inc. (filed May 30, 2013).



bankruptcy court rejected his claim. Ultimately, Cylex settled his appeal of that decision for a fraction of his demand.

**Recent clinical trial data demonstrates the product Cylex developed in Maryland significantly improves clinical outcomes.** In 2015, published results from a rigorous clinical trial showed that one-year survival rates among liver transplant patients whose physicians adjusted immunosuppression therapies in reliance on ImmuKnow data were 13 percent higher than survival rates of patients in the control group, liver transplant patients whose physicians didn't use ImmuKnow.<sup>18</sup> The study soundly disproves the whistleblower's core allegation – that ImmuKnow was a worthless in vitro test. But proving, or even debating, that value proposition in the context of an FCA investigation is impossible and, as a result, neither Cylex's employees nor its investors, will have the opportunity to benefit from their effort.

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<sup>18</sup> Ravaioli, et al., "Immunosuppression Modifications Based on an Immune Response Assay: Results of a Randomized, Controlled Trial," *Transplantation* (March 2015).

## Appendix B

### U.S. ex rel. Schmasow v. Endogastric Solutions, Inc., No. 1:12-cv-00078 (D. Mont. 2012)

**Endogastric Solutions, Inc. (EGS) developed an innovative technology to treat acid reflux at far less cost to patients and insurers than traditional therapies.** EGS is a privately-held company headquartered in Washington. EGS markets one platform of products, the EsophyX, an implantable device developed to repair an anatomical cause of chronic acid reflux that presents in patients diagnosed with Chronic Gastroesophageal Reflux Disease (GERD). Surgeons and gastroenterologists use a new form of minimally invasive surgery, Transoral Incisionless Fundoplication (TIF), to implant the device. TIF is a less complex, lower cost alternative to other surgical solutions and cheaper for patients than daily medication regimens that treat the symptoms rather than the cause.

**Prior to the publication guidance specific to TIF in December 2011, EGS provided customers with information on procedure codes potentially available to bill for the procedure.** Medical procedures are reimbursed using Current Procedural Terminology (CPT) codes developed and published by the American Medical Association (AMA). The code assigned to each procedure ties to a reimbursement rate set by insurers and government programs. When EGS launched EsophyX in 2007, there was no clear AMA guidance on the code to use for TIF. EGS shared information with physicians about two codes, one an existing code for a similar, but more complex procedure and the other an “unlisted” code which triggered an insurer review on a claim-by-claim basis and slower, albeit sometimes higher, payment. In December 2011, the AMA issued guidance stating that TIF should be coded (and therefore billed) under the “unlisted” code until it issued a specific code. Shortly thereafter, EGS distributed the new guidance to its existing customers and trained its sales force not to discuss alternatives.

**EGS completely restructured the Company to focus on reimbursement and a new CPT code.** In 2011, after recognizing that predictable and timely reimbursement would be essential to broader utilization of EsophyX and TIF, EGS hired a new CEO to guide the Company through a transition. The new CEO dramatically reduced the Company’s focus on sales and shifted resources to collecting data to prove the value of EsophyX and support a new CPT code for TIF. While the Company knew sales would be limited until a final code was adopted, it implemented a strategy to conserve resources in the interim.

**Government investigation of *qui tam* allegations depleted EGS’s reserves.** In June 2012, a former sales representative, who had worked for EGS for only three months, filed a *qui tam*.<sup>19</sup> The government began investigating the claims, and in December 2015 issued a civil subpoena requesting information, documents and electronic data from EGS. Through counsel, EGS cooperated fully and provided thousands of documents, responded to written interrogatories, and interacted frequently with DOJ. Soon, the cost of complying with the government’s requests for data proved unsustainable. In mid-2013, EGS began a reduction in force that brought its workforce to a mere 56 employees (from a high of over 120 in 2010). In June 2013, the CFO recommended that his own position be eliminated, as the leaner company no longer needed both a controller and a

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<sup>19</sup> Complaint, United States *ex rel.* Schmasow v. Endogastric Solutions, Inc. (filed June 26, 2012).

CFO. Shortly thereafter, EGS informed the government that it no longer had the financial resources necessary to aid the government in its investigation.

**EGS cried “uncle”.** EGS asked DOJ to consider disposing of the *qui tam* under an ability-to-pay settlement – a framework that shifts the analysis from an evidence-based assessment of liability to a financial analysis of payments a defendant can afford to make over time. Even though EGS faced unsubstantiated allegations of fraud – allegations which had nothing at all to do with the effectiveness or safety of its product, and had clear defenses to the *qui tam* allegations, EGS could no longer fund the defense and would be unable to pay litigation expenses. Facing a risk of treble damages and penalties, and costly litigation, EGS chose to move on and to take steps to preserve resources.

**DOJ adopted an innovative settlement model.** Given EGS’s precarious financial situation, even a traditional settlement agreement could have been fatal to the Company. Apparently recognizing the potential value of EsophyX and EGS’s planned path to profitability, DOJ implemented a novel framework form of structured settlement – scaling the amount of the fine to be paid overtime to the Company’s achievement of certain milestones.<sup>20</sup> The arrangement gave EGS the ability to maintain its operations, retain over 50 employees, and develop the information necessary to support the need for a CPT code. It also gave the whistleblower a “reward” that could approach \$1 million.

**EGS is on a compliant path to success.** DOJ’s decision to implement a novel framework form of structured settlement appears likely to have had the desired impact on EGS. Shortly after guiding the Company through the settlement, EGS’s CEO resigned and served as a consultant to the Board. Under a new CEO since May 2014, whose charge was to ensure that EGS fully incorporated compliance into its core DNA, the Company focused a vast majority of its limited resources on product iterations (R&D) and building robust clinical evidence in order to gain medical society support for and sponsorship of a reimbursement code. In the last 18 months, EGS has published three randomized clinical trials and numerous peer reviewed studies, earned a Category 1 CPT code (effective January 1, 2016) and received FDA clearance on two new device iterations. The Company is now positioned to offer their minimally invasive TIF treatment option to a subset of GERD patients who will benefit from this procedure.

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<sup>20</sup> Settlement Agreement, United States *ex rel.* Schmasow v. Endogastric Solutions, Inc. (filed Feb. 25, 2014).