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Inside This Issue

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Can An Early Discussion Lead to Fewer Malpractice Lawsuits?

by Patricia L. Yeatts, Legal Counsel, Medical Association of Georgia

For decades, tort reform advocates have argued that the medical malpractice model is flawed. While litigation is often protracted, medical malpractice suits can last years – if not decades. This not only interferes with a physician's ability to practice but also hinders and delays a patient's compensation when a legitimate negligence has occurred. In a traditional medical malpractice suit, there must be an investigation of all medical records, an evaluation by medical experts, the filing of complaints and service of summonses, discovery, settlement negotiations, trial and subsequent appeals, and the process goes on and on.

The criticisms of the current system include the lack of a quick resolution, the lack of transparency, and the high costs for all parties (e.g., financial, emotional, psychological, and reputational). Critics maintain that the system creates a "deny and defend" attitude by all involved. While Georgia currently has an apology statute, it is rarely used.[1]

Tort reforms have achieved varying success over the last several decades. Capped awards, capped attorney's fees, shorter statute of limitations, periodic payment, and screening panels are examples of tort reforms that have been used repeatedly, rung out, and hung up to dry. Where advocates in states like Louisiana and Texas see successes, critics of tort reform see failures.

Consequently, some advocates seek extreme reform, such as replacing malpractice litigation with an administrative system. In Georgia, it seems unrealistic to believe that the Supreme Court which decided that noneconomic damage caps are unconstitutional, would support a system that denies access to the courts all together.[2] Because extreme reform is not practical, it is time for true advocates of speedy justice to think outside of the box and consider an early discussion and resolution process.

As the legal counsel for the Medical Association of Georgia, one of the most common patient concerns I hear is that, "I just want to know what happened." An early discussion and resolution process would help solve this dilemma in an innovative way: it would allow the patient or patient's family to reach out to the physician or health care system and attempt to handle the matter privately before beginning a lengthy and costly litigation process. It would also allow health care entities to privately investigate and answer questions without the fear that these comments will come back to hurt them in future litigation. And when appropriate, it would allow physicians or health care system to apologize to the patients and their families and offer just compensation.

The early discussion and resolution process would take place prior to the beginning of the litigation process. When an unanticipated adverse outcome occurs, there would be a mandatory pre-litigation "cooling-off" period that typically lasts for six months, during which the statute of limitations is tolled. During this period there would be full disclosure to patients or families by health care professionals and institutions following internal investigations. And if appropriate and necessary, an apology would be offered in addition to fair financial compensation. The health care entity would then establish systems to improve patient safety and prevent the recurrence of similar incidents and share the changes with the patient or their family.

Following the cooling-off period, the patient would retain their full rights to legal action and access to the courts if the incident were to remain unresolved or if the patient is unhappy with the outcome. All open discussions would be confidential and not subject to discovery or other means of legal compulsion in any subsequent legal proceedings. While not required, lawyers for all parties would be welcome to assist in discussions and settlement offers.

There are many potential benefits to an early discussion and resolution process – the most obvious being quicker resolutions following adverse outcomes and fewer trials. Other potential benefits include fewer claims in court, prompt reporting and investigations, improved practice environments, less physician anxiety, less defensive medicine, and a decreased fear of lawsuits. The early discussion and resolution process would promote communication, transparency and the disclosure of harmful errors by health care professionals. It would also help lower overall health care costs by reducing the risk of huge jury awards while increasing compensation for smaller injuries. And it would offer ample opportunity for apology and reasonable compensation when appropriate.

Medical associations have promoted open communication between physicians and patients for a long time. In its *Principles of Medical Ethics,* the American Medical Association (AMA) states*:*

> *"Physicians must offer professional and compassionate concern toward patients who have been harmed, regardless of whether the harm was caused by a health care error. An expression of concern need not be an admission of responsibility. When patient harm has been caused by an error, physicians should offer a general explanation regarding the nature of the error and the measures being taken to prevent similar occurrences in the future. Such communication is fundamental to the trust that underlies the patient-physician relationship, and may help reduce the risk of liability."*[3]

An early discussion and resolution process would be based upon this policy and the idea that more open communications between physicians and patients will not only strengthen the physician-patient relationship and improve the quality of care that is being delivered, but that it will also help reduce malpractice lawsuits and expedite patient resolutions.

There are several working models for the early discussion and resolution process in use today. The University of Michigan Health Systems (UMHS) established what is considered the nation's first early discussion and resolution program. It has long been touted as "successful".[4] The Michigan model has been implemented statewide in Massachusetts[5], Oregon[6], and Iowa.[7] Well-known hospitals including Johns Hopkins Hospital and the University of Illinois Medical Center in Chicago also utilize similar systems.

Michigan's law requires a cooling-off period, so UMHS implemented a discussion process that occurs during this six-month time frame. The process includes an internal investigation, a peer review, and full disclosure to the patient (and attorney if retained). If the hospital/physician concludes that care was not reasonable, they apologize and make an offer of fair compensation after working with the patient or the patient's attorney. If UMHS concludes that the treatment and care was reasonable, it will still fully discuss the outcome with the patient but make clear that it will vigorously defend the case.[8] This model supplies the foundations for all other early resolution and discussion systems.

While the full extent of benefits provided by the Michigan model are unclear, the early results from UMHS show that it may be an effective way to lower claim frequency and costs. An *Annals of Internal Medicine* article compared UMHS liability claims from 1995-2001 (pre-implementation) and 2001-2007 (post-implementation). Significant changes included a decrease in claim compensation, a decline in both the number of filed claims and claims that resulted in lawsuits, and a decrease in the monthly rate of new claims from 7.03 per 100,000 patient encounters to 4.52 per 100,000 patient encounters after the implementation.[9]

As noted, Massachusetts, Oregon, and Iowa have implemented a version of this model statewide. In August 2012, Massachusetts passed Senate Bill 2400, which includes a mandatory Disclosure, Apology, and Offer Law (DAO). This was a collaborative effort by the Massachusetts Medical Society, the Massachusetts Bar Association, and the Massachusetts Association of Trial Attorneys. It is expected to encourage honesty, protect patient rights, improve patient safety, reduce litigation, and cut costs.[10] The process is similar to the UMHS model.

In Oregon, Senate Bill 483 was developed with recommendations by the Oregon Medical Association and the Oregon Trial Lawyers Association and implemented in July of 2014. The main difference between this and other models is that a compromise was made in the final version that allowed the early discussion and resolution process to be voluntary. This process involves filing a notice to Oregon Patient Safety Commission, a discussion between parties, mediation for settlement, and litigation if no agreement is reached. In Iowa, the "Communication and Optimal Resolution" passed both chambers unanimously in early 2015.[11] Like Oregon, the Iowa law is voluntary – but it differs in that it is initiated by the health care providers.

While early discussion and resolution laws are a novel approach to tort reform and medical liability reform, every program is different. The law is mandatory in Massachusetts and at UHMS, but it is voluntary in Oregon and Iowa. As with medical malpractice screening panels, the effectiveness of these programs may vary greatly. Furthermore, while some laws were passed with the intent of avoiding the National Practitioner Data Bank (NPDB), the U.S. Department of Health and Human Services (HHS) released a ruling in 2014 that clearly stated that all "written demands for payments" under an early compensation model must be reported to the NPDB[12]. HHS, however, clarified that when a compensation offer is initiated by the provider and no written demand for payment is made, no NPDB report is necessary.

Critics of these reforms argue that they would create administrative hurdles, extend lawsuits, and hinder a patient's ability to sue when necessary. While the model does rely on a six-month delay before the trial process can officially begin, the statute of limitations is tolled and, in many models, the parties can choose to waive the early discussion process if they agree to do so. For cases that are likely to require litigation, both parties can agree to skip the six-month cooling-off period to accelerate the process.

While there is little statistical data available to evaluate the long-term effects of the aforementioned state laws, early indications suggest that the benefits of the Michigan model will outweigh the downsides and potentially lead to more early resolutions and less costly and lengthy trials. The early discussion and resolution process may be exactly what Georgia needs to help protect patients, physicians, and other providers while lowering health care costs.

(Endnotes)

1 Ga. Code Ann. § 24-4-416 (2013)

2 *Atlanta Oculoplastic Surgery, P.C. v. Nestlehutt et al.*, 691 S.E.2d 218 (Ga. 2010)

3 *Liability Claims and Costs Before and After Implementation of a Medical Error Disclosure Program*.

4 A Kachalia, SR Kaufman, R Boothman, et al. *Liability Claims and Costs Before and After Implementation of a Medical Error Disclosure Program*. Ann Intern Med. 153(4):213-221 (2010). See also American Medical Association (AMA), Advocacy Resource Center, *Early disclosure and compensation programs* (2015).

5 Mass. Gen. Laws 231 § 60L (2012)

6 OR Rev. Stat. § 30.278 (2013), 31.250 (2013) and 742.407 (2015)

7 Iowa Code Ann. § 135P.1-4 (2015)

8 Richard C. Boothman, Amy C. Blackwell, Darrell A. Campbell, et al. *A Better Approach to Medical Malpractice Claims? The University of Michigan Experience. J Health & Life Sciences Law* (Jan. 2009), www.med.umich.edu/news/newsroom/Boothman%20et%20al.pdf. See also Richard C. Boothman. Implementing Your Version of the Michigan Model (2010), www.macrmi.info/files/4413/5732/2193/ImplementingMichModel.pdf.

9 A Kachalia , SR Kaufman, R Boothman , et al., *supra* note *iv.*.

10 Debra Beaulieu, The Massachusetts Medical Society, Disclosure, *Apology and Offer: A New Approach to Medical Liability* (June, 2012), http://www.massmed.org/News-and-Publications/Vital-Signs/Back-Issues/Disclosure,-Apology-and-Offer--A-New-Approach-to-Medical-Liability/#.VhV1CvlVhHw. See also, Insurance Journal, *Mass. Embraces 'Disclosure, Apology, Offer' Approach for Med Mal Cases* (August, 2012), http://www.insurancejournal.com/news/east/2012/08/07/258509.htm

11 Nicole Burgmeier, et al. *Medical Liability Reform – Iowa's Communication and Optimal Resolution (Candor) Bill Effective July 1, 2015* (July, 2015).

12 The Dep't of Health and Human Services, *Appropriate Medical Malpractice Payment Reporting to the NPDB in Light of Recent Medical Malpractice Reforms in Mass. And Ore. – DECISION* (May 20, 2014), http://www.citizen.org/documents/2211%20Enclosure.pdf

What does Informed Consent have to do with Undercover Videos, Planned Parenthood and Congress?

by Royce DuBiner, JD, LLM[1]

On Sept. 25, 2015, Planned Parenthood President Cecil Richards testified at a hearing before the House Oversight and Government Reform Committee. Ms. Richards was not called to discuss ethics, religious beliefs, or practices regarding abortion. She was called to testify on whether Planned Parenthood was using federal funds appropriately and, to a lesser extent, whether Planned Parenthood was generating a profit from the sale of human fetal tissue. The hearing was prompted by videos of Planned Parenthood personnel released by The Center for Medical Progress.

On Sept. 29, 2015, the Committee published a memorandum reporting the findings of the Committee's investigation into the federal funding issue. The Committee expressed concerns that Planned Parenthood was comingling and using federal and private moneys to fund abortions, political activities, or Ms. Richard's salary.[2] It also expressed concerns that Planned Parenthood was not furnishing enough mammograms or preventative cancer screenings.[3]

Planned Parenthood responded in a letter to House Speaker Paul Ryan dated October 30, 2015. In that letter, it challenged the validity of the video from The Center for Medical Progress. It also announced that Planned Parenthood would no longer charge for services related to fetal tissue donation.[4]

The Committee's investigation and Planned Parenthood's response are intertwined with the legal issue of informed consent. This is because the federal laws governing informed consent require physicians to attest that abortions are not performed for purposes of harvesting human fetal tissues, and require researchers to attest that the tissues were used only for research purposes. Ultimately, these aspects of the federal informed consent laws are intended, at least in part, to protect the women who undergo the abortion procedures and donate the tissues.

This article will survey the law of informed consent for human fetal tissue donation, and explain what is meant by informed consent in the clinical research setting.

History of Fetal Tissue Laws and Informed Consent

The legal history of protecting the human subjects of medical research starts with the Nuremburg Code, which was written after the Nuremburg trials of Nazi war criminals. The Nazis conducted cruel and medically unnecessary experiments on prisoners in their concentration camps. To help prevent future abuses, the Nuremburg Code set forth ethical principles for medical research on humans. The first provision of the Nuremburg Code states that every human test subject should, "have legal capacity to give consent, be so situated as to exercise free power of choice, without . . . [coercion, and] . . . should have sufficient knowledge and comprehension . . . to make a understanding and enlightened decision."[5] That is, people should have the capacity to understand the potential risks and benefits of the medical studies they join, and the freedom to take part in, or withdraw from, the studies.

The Belmont Report is the next foundational document on human subject research and informed consent. It is the product of the National Research Service Award Act of 1974, which established a commission to "conduct a comprehensive investigation and study to identify the basic ethical principles which should underline the conduct of biomedical and behavioral research."[6] The Belmont Report substantially clarified the requirements for informed consent, addressing the need for the patient to understand the procedure and weigh the potential harm versus the benefits of the procedure.[7]

The National Research Service Award Act of 1974 then placed a moratorium on the use of human fetal tissue in the United States. Specifically, Section 213 of the Act made it clear that there would be no federal funding of research involving fetuses before or after abortion. The only exception would be for research that aided in the survival of the fetus.[8]

In 1988, the Advisory Committee to the Director of the National Institutes of Health (NIH) released a report entitled "Human Fetal Tissue Transplantation Research."[9] In the report, the Advisory Committee analyzed whether allowing fetal tissue donations would encourage abortions, whether written informed consent was an "inducement," and whether a policy change would affect how abortion clinics conduct business. Ultimately, the Advisory Committee recommended the lifting of the moratorium on using fetal tissue from induced abortions.[10] That recommendation, however, had no legal effect.

The moratorium on the use of human fetal tissue was lifted by the NIH Revitalization Act of 1993, which established an informed consent regime for the collection of human fetal tissue in the United States.[11] Under that regime, a woman may donate fetal tissue only if she gives written informed consent and does not know the recipient of the donation.[12] The physician must make a statement declaring that the tissue was obtained by an induced

abortion, the procedure was not performed to obtain tissue, there was no alteration of the procedure to obtain the tissue, and the abortion was performed in accordance with state law.[13] The researcher who obtains the tissue must make a statement in writing that they are aware they are using fetal tissue harvested from a spontaneous or induced abortion or stillbirth, and the tissue was donated for research purposes only.[14] The States are allowed to maintain their own laws governing the conduct of the research, which are not federally preempted.[15]

The NIH Revitalization Act of 1993 makes the transfer of human fetal tissue illegal under certain conditions. First, purchasing human fetal tissue outright is illegal if done for "valuable consideration. . . [and]. . . in interstate commerce."[16] Solicitation or acceptance of donated tissue is illegal if there is a promise that it will go to a specific individual known by the donor, the tissue will be transplanted into a relative of the donor, or the abortion is being financed by the donated tissues.[17] The penalties for violation of the Act are severe, and include fines and incarceration for up to 10 years.[18]

What is Valid Informed Consent for Participating in Research?

While the NIH Revitalization Act of 1993 created the federal informed consent regime, many of the particulars of that regime are found in regulations promulgated by the U.S. Department of Health and Human Services (HHS) and the U.S. Food and Drug Administration (FDA). The HHS regulations regarding informed consent govern research funded by HHS. When submitting a drug, device, or biologic for approval to the FDA, the FDA's regulations apply. Studies done without informed consent are unlawful under the regulations of both agencies.

Under the HHS regulations, valid informed consent requires a statement that confirms that the procedure falls within the regulatory definition of research, discloses the reasonably foreseeable risks and benefits of the procedure for the subject, explains that participation is voluntary, discloses that the subject may withdraw at any time, and explains the steps taken to protect the patient's data.[19]

The FDA regulations make exculpatory language a red flag for valid informed consent.[20] Exculpatory language is language that would release the investigators from liability. No valid informed consent may contain exculpatory language because such language increases the risk that the investigators will exercise coercion or undue influence over the human test subjects

Conclusion

Informed consent promises to remain an important legal issue so long as abortion remains a hot-button social issue. The framework set forth in this article should provide a foundation for understanding the informed consent issue as it evolves in the future.

(Endnotes)

1 The author has served as a regulatory compliance analyst at Sterling Institutional Review Board in Atlanta, Georgia. The views expressed in this article are his own and not those of Sterling, or its officers, employees, or customers. Sterling does not review studies related to human fetal tissue. Neither the author nor Sterling has a financial interest in Planned Parenthood or human fetal tissue procurement.

2 House Committee on Government Oversight and Reform, Memorandum, Sep. 29. 2015. https://oversight.house.gov/wp-content/uploads/2015/09/Committee-Findings-Planned-Parenthood-Investigation.pdf. (accessed October 28, 2015).

3 *Id*.

4 Planned Parenthood Letter to Speaker Paul Ryan, October 30, 2015. http://ppfa.pr-optout.com/ViewAttachment.aspx?EID=mr9WXYw4u2IxYnni1dBRVpM%2fUKmt5NjDh1xLJJYFdYM%3d. (accessed October 28, 2015).

5 The Nuremburg Code, Department of Health and Human Services, http://www.hhs.gov/ohrp/archive/nurcode.html (accessed October 28, 2015).

6 National Research Service Award Act of 1974, Public Law 93-348 at 349. https://history.nih.gov/research/downloads/PL93-348.pdf (accessed October 29, 2015).

7 The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, "The Belmont Report," Department of Health and Human Services, (1979). http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html#xinform (accessed October 29, 2015)

8 National Research Service Award Act of 1974, Public Law Vol. 933-48 Stat. 354. https://history.nih.gov/research/downloads/PL93-348.pdf (accessed October 29, 2015).

9 Report of the Advisory Committee to the Director, National Institutes of Health, "Human Fetal Tissue Transplantation Research," December 14, 1988. https://repository.library.georgetown.edu/bitstream/handle/10822/559348/fetal_tissue_report.pdf?%20sequence=1&isAllowed=y4 (accessed Oct 28, 2015.)

10 *Id*. at 6.

11 The National Institute of Health Revitalization Act of 1993, Pub. L. No. 103-43, 107 Stat. 122.

12 *Id*.

13 *Id*.

14 *Id*.

15 *Id*.

16 *Id*.

17 *Id*.

18 *Id*.

19 45 CFR 46.116

20 21 CFR 50.20

The Increased Privitization of the False Claims Act

by Scott R. Grubman, Chilivis, Cochran, Larkins & Bever

Anyone who has had the misfortune of watching daytime television has seen them: the endless barrage of commercials from plaintiff's personal injury law firm favorite. Although these advertisements have been running for years, the personal injury firms have recently moved into the world of False Claims Act (FCA) *qui tam* litigation. The result has been a proliferation of both *qui tam* relators and the attorneys who represent them.

By now, it is no secret that the FCA[1] is the federal government's favorite tool in its fight against allegations of fraud, waste, and abuse in federally-funded healthcare programs. According to statistics released by the Department of Justice (DOJ), in fiscal year 2014 alone, the DOJ recovered nearly $6 billion from FCA cases, over half of which related to lawsuits filed by private whistleblowers under the *qui tam* provisions of the FCA. Just under half of the DOJ's total recovery in 2014 came from healthcare-related matters, marking the fifth straight year that the DOJ recovered more than $2 billion in cases involving alleged false claims against federal healthcare programs.

A more in-depth analysis of the DOJ's data shows not only that more and more FCA *qui tam* actions are being filed by private whistleblowers (nearly 1,000 new healthcare-related *qui tams* were filed in fiscal years 2013 and 2014 combined), but also that recoveries in "declined" *qui tams* (i.e., matters in which the government opts not to pursue on its own behalf) have increased significantly over the past couple of years. As to the latter category, in FY 2014, the government recovered over $70 million in healthcare-related declined *qui tams*.[2] In FY 2013, that number was over $146 million. In contrast, (the average annual recovery in declined *qui tams* between 2003 and 2007 was just under $37 million, and between 2008 and 2012 was just over $42 million. This financial trend lends support to the proposition that, unlike in days of old, the government's declination of a *qui tam* is no longer necessarily the death knell of a whistleblower-initiated FCA suit.

The FCA's *Qui Tam* Provisions

The FCA makes it unlawful for an individual or entity to, among other things, present (or cause to be presented) false or fraudulent claims for payment or approval to the federal government; to make, use, or cause to be made or used, a false record or statement material to a false or fraudulent claim; or to knowingly conceal or knowingly and improperly avoid or decrease and obligation to pay or transmit money or property to the government.[3] FCA actions can be brought directly by the DOJ, or by a private whistleblower known as a "relator."[4] Once a relator files a copy of the *qui tam* complaint under seal in federal district court, the government has sixty days (and any extensions supported by good cause and granted by the court) to investigate. The DOJ typically asks for at least one extension of six months and, by department policy, typically aims to finish its investigation within nine months, although pre-intervention investigations very often last significantly longer, sometimes several years.[5]

The Intervention Decision

Pursuant to the text of the FCA, at the end of the sixty-day seal period or any extensions granted by the district court, the government has two options: proceed with the action (i.e., "intervene" in the action), or decline to intervene.[6] Where the government intervenes, it conducts the action on its own behalf and the relator is entitled to between fifteen and twenty-five percent of the eventual recovery.[7] Where the government declines to intervene, the relator has the right to proceed with the action on the government's behalf, and is typically entitled to between twenty-five and thirty percent of the eventual recovery.[8] Although the relator has the right and responsibility to move forward with declined *qui tam* actions, the DOJ typically monitors the litigation. In such matters, upon the government's request, the relator must serve the government with copies of all pleadings filed and all deposition transcripts.[9] Further, regardless of whether the government intervenes, relator's counsel is entitled by statute to reasonable attorneys' fees in addition to any contingency fee arrangement.[10]

Despite the fact that the FCA itself gives the government only two options when it comes to intervention, in recent years, the DOJ has begun to exercise a "middle-ground" approach that is not specifically sanctioned by the statute itself—issuing notices of "no decision". Those notices typically inform the court that the government has been unable to reach an intervention decision, but request that the matter be unsealed and purport to reserve the right to intervene at a later date.[11] Although relators are permitted to proceed with a *qui tam* action if the government declines to intervene, the FCA provides the government with the right to dismiss a *qui tam* action over the objection of the relator, as long as the relator is notified of the dismissal "and the court has provided the person with an opportunity for a hearing on the motion."[12] As discussed below, however, this right is rarely exercised.

Breathing Life into Declined *Qui Tams*

For the first seven years after 1986 (the year in which President Reagan signed into law several major amendments to the FCA designed to increase the use of the FCA), the government's recovery in healthcare-related *qui tams* where the government had declined intervention was

zero. Even through 2000, average recovery for such cases barely exceeded $1 million dollars. In just several years, that number has drastically increased, largely in part to a number of massive recoveries in declined *qui tams* – nearly $25 million in 2002, over $150 million in 2007, and over $145 million in 2013. Last year (2015) will be the highest yet, with DaVita Healthcare Partners agreeing to pay $495 million to settle an FCA *qui tam* filed in the Northern District of Georgia, the largest settlement ever reached in a declined *qui tam*.[13]

There are several reasons for this recent trend. First, more and more plaintiffs lawyers are willing to move forward with declined *qui tams* where such cases would have typically been dismissed by the relator (or resolved with a "nuisance settlement") after declination. Indeed, at a recent conference panel on which the author was a panelist, Atlanta's own Marlan Wilbanks – who is widely regarding as one of the nation's most preeminent relator's lawyers and one of the relator's lawyers in the DaVita matter – stated that although intervention is still the hope and goal in every case that he files, declination is typically no longer the end of a *qui tam*. Mr. Wilbanks stated that he now teams up with high-profile trial lawyers to pursue and litigate declined *qui tams* when necessary.[14]

Furthermore, *qui tam* lawyers have begun to realize that declination by the government does not always mean that the case lacks merit. With the pace of *qui tam* filings increasing drastically – there were over 750 new *qui tams* filed in 2013 and another 713 in 2014 – the DOJ and its law enforcement partners are busier than ever and simply cannot intervene in every *qui tam*, even if otherwise worthy of intervention. This is particularly true in districts where judges are reluctant to give the government more than a couple of months to investigate. Combined with the fact that the relator share increases where the government declines to intervene, and relator's counsel is entitled to both statutory attorneys' fees and a contingency fee, relator counsel are becoming less reluctant to pursue a declined *qui tam* on the government's behalf.

This trend not only affects whistleblowers and their attorneys, but healthcare fraud and abuse defense lawyers as well. Where the ultimate goal of defendants and defense lawyers used to be government declination, at which point defense counsel could typically be comfortable advising their client that the case would likely either be dismissed or resolved with a nuisance settlement, defendants and their attorneys now have to be prepared to litigate against high-profile, experienced trial lawyers even after they convince the government to decline intervention. This often changes the dynamic throughout the entire course of an FCA investigation and settlement discussion.

Conclusion

As long as the FCA incentivizes private whistleblowers to pursue declined *qui tams* on the government's behalf with the promise of an increased relator's share and statutory attorneys' fees, the trend of relator counsel moving forward with such matters will likely. Massive resolutions of declined *qui tams* like the one in DaVita will only increase this trend. Although the government has the right to dismiss a *qui tam* over the relator's objection in any case, the government has historically been reluctant to exercise its veto right, and will likely remain reluctant for fear of discouraging relators and their counsel from filing *qui tam* actions in the future. This trend has, and will likely continue to, change the way that attorneys on both sides of a *qui tam* action proceed through the course of an FCA investigation, settlement discussions, and litigation, and will ensure the FCA's place as the government's favored fraud-fighting tool for a long time to come.

(Endnotes)

1 31 U.S.C. § 3729 *et seq.*

2 The DOJ's FCA statistics are available at http://www.justice.gov/file/fcastatspdf/download.

3 31 U.S.C. §3729.

4 *Id.* § 3730.

5 Within the last couple of years, a trend began to emerge wherein district court judges became more reluctant to extend the seal period in *qui tam* actions, particularly where the government had already been granted one or two extensions. *See, e.g., U.S. ex rel. Martin v. Life Care Centers of America, Inc.*, 912 F. Supp. 2d 618, 624 (E.D. Tenn. 2012) (holding that "the Government's habitual requests for extensions of the [seal] period were wholly inappropriate."). Significantly, however, on March 10, 2015, at the specific request of the DOJ, the Judicial Conference of the United States amended the provision of Civil Justice Reform Act ("CJRA") requiring the Administrative Office of the Courts to prepare semi-annual reports showing, among other things, civil cases pending more than three years. The Conference agreed to amend the CJRA reporting instructions to provide that the pending date for a *qui tam* case is now the date on which the case is first unsealed by the court. In other words, while pending under seal, a *qui tam* no longer counts towards a court's pending matter report. This change has the potential to increase the length of pre-intervention FCA investigations.

6 31 U.S.C. § 3730.

7 *Id.*

8 *Id.*

9 *Id.* at § 3730(c)(3).

10 *Id.* at § 3730(d); *see also, e.g., United States v. Cooper Health System*, 940 F. Supp. 2d 208, 214-15 (D.N.J. 2013) (holding that a settlement agreement did not supersede the relator's contingency fee agreement with his lawyer).

11 Although the FCA does not expressly contemplate a "notice of no decision", these notices are generally treated by courts as declination notices. The FCA provides that, even where the government initially declines to intervene, the court "may nevertheless permit the Government to intervene at a later date upon a showing of good cause." 31 U.S.C. § 3730(c)(3).

12 *Id.* § 3730(c)(2)(A).

13 Of the $495 million, $45 million were for attorneys' fees alone.

14 Printed with express permission from Mr. Wilbanks.