

Contacts:

Christopher R. Hall
Chair

Nicholas J. Nastasi
Vice Chair

Brett S. Covington
Newsletter Editor

Patrick M. Hromisin
Contributor

Courtney L. Schultz
Contributor

Aaron J. Kornblith
Contributor

White Collar
and Government
Enforcement
Practice

White Collar Watch

The Newsletter of the White Collar and Government Enforcement Practice

Contents

False Claims Act ruling opens door to large damage awards
pages 1 - 2

Supreme Court asked if state universities are exempt from liability under the False Claims Act
pages 2 - 4

Employee whistleblower tips help Medicare Fraud Strike Force bring charges against Illinois hospice executive
pages 5 - 6

Fourth Circuit: False Claims Act case cannot go forward on allegations of regulatory violations alone
pages 6 - 7

False Claims Act ruling opens door to large damage awards

By Patrick M. Hromisin

IN BRIEF

- Fourth Circuit finds \$24 million penalty award does not violate Eighth Amendment ban on excessive fines despite disproportion to payments at issue.
- Other courts have yet to react and ruling provides no guidance.

A three-judge panel of the Fourth Circuit Court of Appeals has ruled that an award of \$24 million in penalties for violations of the False Claims Act did not violate the constitutional ban on excessive fines, even where the damages had not been proven and the total government payments at issue amounted to just over \$3 million. This ruling may open the door to other large damage awards in similar cases, but its applicability has yet to be considered by other courts.

The federal False Claims Act ("FCA") prohibits fraud in billing the government and allows for whistleblowers to bring suits alleging such fraud and collect a portion of any recovery. In *United States ex rel. Kurt Bunk v. Gosselin World Wide Moving*, whistleblowers alleged that a logistics company had swindled the U.S. Department of Defense by fraudulently manipulating contract prices for services it provided. Gosselin, the defendant, was a subcontractor that was involved in shipping U.S. service members' personal goods and effects to and from locations in Europe. Gosselin had colluded with its supposed competitors to artificially inflate the charges for the services it provided in 2001 and 2002.

Kurt Bunk and another whistleblower plaintiff, Ray Ammons, filed suit in 2002 against numerous companies involved in the scheme, and their claims were consolidated in the Eastern District of Virginia in 2007. All defendants other than Gosselin were dismissed or settled the claims. The U.S. government decided to intervene in the *Ammons* claim, but not the *Bunk* claim; Bunk therefore pursued the case on his own, but as part of a consolidated action with the government. The case was tried before a jury in July 2011. At trial, Bunk chose to forgo proof of actual damages, which meant he was limited to the civil penalties available under the FCA, which the statute sets at no less than \$5,500 per claim. In this case, Gosselin had issued 9,136 invoices to the government pursuant to its fraudulent scheme.

At trial, the jury found in favor of Bunk and the government on various portions of their claims. With regard to the government's claims, the trial court entered judgment of \$5,500, indicating that it saw the

scheme as one single offense. The trial court determined that a per-invoice penalty for Bunk's claims, which would have totaled over \$50 million, was excessive in light of the Eighth Amendment to the U.S. Constitution. The Eighth Amendment is most widely known for its prohibition on cruel and unusual punishment, but it also prohibits "excessive fines." The government had paid a total of roughly \$3.3 million under the contracts that were part of the scheme, so the trial court viewed a \$50 million award as disproportionate to the harm suffered. Bunk proposed an award of \$24 million, but the trial court rejected that because it determined that the FCA did not allow a penalty of anything less than the statutorily-mandated \$5,500 per claim. Because it saw the Eighth Amendment as prohibiting an award of that amount, the trial court awarded no damages to Bunk.

Bunk appealed to the Fourth Circuit, arguing that the trial court should have awarded his proposal of \$24 million. The Fourth Circuit, in a ruling issued in December 2013, determined that Bunk's proposal of a \$24 million penalty was within the discretion the FCA grants to plaintiffs, even though it was a departure from the statutorily-imposed penalty amounts for the invoices at issue.

The Fourth Circuit emphasized that each separate invoice constituted a "claim" under the FCA and noted that "[w]here an enormous public undertaking spawns a fraud of comparable breadth, [that rule] helps to ensure what we reiterate is the primary purpose of the FCA: making the government completely whole." The Fourth Circuit pointed out that "an award of noth-

ing at all because the claims were so voluminous provides a perverse incentive for dishonest contractors to generate as many false claims as possible, siphoning ever more resources from the government."

The Fourth Circuit also stated that a penalty under the FCA will violate the Eighth Amendment where "it is 'grossly disproportional to the gravity of a defendant's offense.'" The Appeals Court determined that in these cases, the penalty must not be assessed in proportion only to the amount the government actually paid, but that a court "must consider the award's deterrent effect on the defendant and on others perhaps contemplating a related course of fraudulent conduct." The Fourth Circuit viewed a \$24 million award in this case as proportionate to the gravity of Gosselin's offense. The Fourth Circuit therefore amended the trial court's judgment to incorporate the award of \$24 million on Bunk's claims.

Although the Fourth Circuit determined that the award in this case was not excessive, it provided no guidance for other courts to determine what level of FCA penalties the Eighth Amendment *would* prohibit. Other courts have not yet reacted to the Fourth Circuit's ruling here, but given that many such actions involve large numbers of invoices or claims, this may open the door to large damage awards in future FCA cases. That possibility may in turn serve as an incentive for future whistleblower plaintiffs to file suit and pursue such awards. Until courts determine the applicability of *Bunk v. Gosselin*, it may stand as an unwelcome development for defendants in FCA cases.

Supreme Court asked if state universities are exempt from liability under the False Claims Act

By Nicholas J. Nastasi and Brett S. Covington

IN BRIEF

- Fifth Circuit ruling finds University of Texas Health Science Center is an "arm of the state" as part of the University of Texas System and therefore exempt from liability under the False Claims Act.
- Decisions around similar cases in the Fourth and Sixth Circuits set differing standards.

A professor at the University of Texas Health Science Center has petitioned the U.S. Supreme Court to determine the standard for imposing liability on state universities and their related

entities under the False Claims Act. In *King v. University of Texas Health Science Center*, the U.S. Court of Appeals for the Fifth Circuit held that the Health Science Center, a hospital

within the University of Texas System, is an “arm of the state” and therefore exempt from liability under the False Claims Act.

In reviewing this issue as it applies to state universities and such related entities as hospitals and research centers, the federal courts of appeal have reached conflicting conclusions. Because there is a split among the federal circuits, this increases the likelihood that the Supreme Court will grant *certiorari* on this issue.

Background

In this case, a former associate professor at the University of Texas Health Science Center filed a *qui tam* (or whistleblower) claim under the False Claims Act (“FCA”), alleging that the university violated the act by covering up the misconduct of a professor who received federal research grants. Under the FCA, liability will be imposed on “any person who ... knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval” or “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.”

The whistleblower, Professor Terri King, worked in the Health Science Center’s Department of Internal Medicine from 2001 to 2005. In 2001, she began working in a research lab under Dr. Dianna Milewicz’s supervision. According to King’s complaint, she began noticing discrepancies in Milewicz’s data in 2004. King alleges that when she informed Milewicz about the discrepancies, she was retaliated against by receiving a “false and defamatory performance review” from Milewicz. King also alleges that she was retaliated against when she was reassigned to less favorable positions and eventually terminated.

In January 2011, King filed a *qui tam* lawsuit against the Health Science Center, alleging that Milewicz falsified research data and results. King claims that the fraud was in connection with federally-funded research, and that Milewicz used falsified results in order to obtain federal funding. King also alleged that the center covered up Milewicz’s misconduct relating to federal research grants. In addition, King asserted a retaliation and wrongful termination claim under the FCA’s anti-retaliation provision, alleging that she was retaliated against after notify-

ing Milewicz of the alleged fraud. The United States, which has the right under the FCA to intervene in *qui tam* action, declined to do so.

The U.S. District Court dismissed the whistleblower claim, concluding that the university hospital was an “arm of the state” and therefore exempt from the FCA’s *qui tam* provisions. The District Court also held that the plaintiff’s retaliation claim was barred by the Eleventh Amendment’s “sovereign immunity” protection. The District Court’s reasoning was based on the Supreme Court’s decision in *Vt. Agency of Natural Resources. v. United States* (2000), which held that states (as well as state agencies) are not subject to liability under the FCA because they are not a “person” within the meaning of that act.

In November 2013, the Fifth Circuit affirmed the District Court’s ruling that the Health Science Center is an “arm of the state” and therefore is not a “person” that can be held liable under the FCA. The Fifth Circuit applied six factors to determine whether the center qualifies as an “arm of the state,” including:

- whether state law characterizes the agency as an arm of the state;
- the source of funds for the entity;
- the degree of local autonomy by the entity;
- whether the entity is concerned primarily with local, as opposed to statewide, problems;
- whether the entity has authority to sue, and be sued, in its own name; and
- whether the entity has the right to hold and use property.

In applying these factors, the Fifth Circuit recognized:

- The Health Science Center is part of the University of Texas, and the university is considered, under state statutory law, an “arm of the state.” Texas law also recognizes that the Health Science Center is a “governmental unit.”

- The Health Science Center receives significant funding from state sources.
- The Health Science Center has limited autonomy. A Board of Regents appointed by the Texas governor is responsible for governing the University of Texas System, including the component institutions. All Health Science Center contracts must be in accordance with board rules or specially approved by the Board of Regents. As a state agency, the center is also required to follow specific accounting and financial reporting requirements. In addition, the Board of Regents has the sole and exclusive management over the center's right to hold and use property.
- The University of Texas System has locations throughout the State of Texas. Although the Health Science Center's facilities are confined to Houston, its research and education are created to benefit the citizens of the state, not just the local community.

For some of the above factors (particularly, the local/state factor), the Fifth Circuit framed the "entity" as the University of Texas, rather than the more narrow entity of the Health Science Center. In addition, despite the fact that the Health Science Center can sue, and be sued, in its own name (a fact that King argues is important in demonstrating that the entity was not an "arm of the state"), the court held this factor was outweighed by the others.

The Fifth Circuit also affirmed the dismissal of the FCA retaliation claim, holding that the Health Science Center is an "arm of the state" and therefore entitled to "sovereign immunity" under the Eleventh Amendment. Under the Eleventh Amendment, a state, or "arm of the state," may generally not be sued for monetary relief. Therefore, to the extent King was seeking monetary relief relating to her termination, that claim was barred by the Eleventh Amendment.

On January 31, 2014, King filed a petition with the U.S. Supreme Court for review. While the Supreme Court has complete discretion in deciding whether to review cases, the fact that other federal courts of appeal have applied inconsistent standards in deciding this issue – whether state universities (or related entities) can be held liable under the FCA – increases the likelihood that the Supreme Court will decide this important issue. For example, the Fourth and Fifth Circuits considered whether the entity is concerned primarily with local, as opposed to statewide, concerns, while the Sixth Circuit considers whether the entity's functions fall within the traditional purview of state or local government. While there is some overlap between these criteria, the broader approach by the Fourth and Fifth Circuits would lead to a greater range of entities considered as "arms of the state" and therefore exempt under the FCA.

In her petition for review, King argues that the Fifth Circuit's decision was wrong for the following reasons: (1) the Health Science Center has local autonomy; (2) the center has \$1 billion of its own assets (separate from the rest of the university); and (3) the Health Science Center is mostly concerned with local, rather than statewide, problems. King also argues that the courts incorrectly conflated the Health Science Center with the University of Texas, when the courts should have focused on the Health Science Center specifically rather than the university as a whole. King also asks the Supreme Court to either reverse its prior *Stevens* decision, or at least narrow the decision in order to "minimize the growing fraud in academic research."

Conclusion

Qui tam actions have long been pursued in the defense, pharmaceutical and health care industries. More recently, counsel for plaintiffs have been looking to other industries to target including higher education. With significant federal funds spent on research and financial aid, higher education may be susceptible to such claims. If the Supreme Court grants *certiorari* in this case, the outcome will likely have a significant impact on state universities and their related entities.

Employee whistleblower tips help Medicare Fraud Strike Force bring charges against Illinois hospice executive

By Nicholas J. Nastasi and Courtney L. Schultz

IN BRIEF

- The owner of Passages Hospice is alleged to have set in motion a scheme to move patients into a more intense level of care that netted the company higher Medicare and Medicaid reimbursements.
- Case demonstrates the government's increasing focus on health care-related prosecutions and its reliance on willing whistleblowers.

Hospitals, nursing homes and other medical businesses take note: the fraud case against the owner of Illinois-based Passages Hospice illustrates the government's increasing focus on health care-related prosecutions, particularly those arising from the work of the Medicare Fraud Strike Force ("Strike Force") and information reported by company whistleblowers.

The Strike Force currently operates in only nine cities: Chicago, near Passages' corporate headquarters, along with Baton Rouge, La.; Brooklyn, N.Y.; Dallas; Detroit; Houston; Los Angeles, Miami and Tampa. However, expansion to other "hot spot" cities may not be far off considering its growing caseload.

The Strike Force set record numbers last year with 137 cases filed, 345 individuals charged, 234 guilty pleas secured and 46 jury trial convictions. And, with an 8:1 return for every dollar spent fighting health care fraud, the Strike Force appears to be a sound government investment, which only increases the likelihood that more resources will be allocated to the fight against health care fraud.

In the Passages case, owner Seth Gillman was charged on January 27, 2014 with federal health care fraud based on alleged fraudulent elevation of hospice patients to improper levels of care. He allegedly caused ineligible Passages' patients to be placed on general inpatient care ("GIP") in order to increase funds received per patient from Medicare and Medicaid. To effectuate this scheme, the government alleges Gillman:

- trained and caused to be trained Passages nurses to look for signs that would qualify a patient for GIP;

- paid bonuses to Passages directors tied directly to the amount of GIP under their supervision; and
- provided kickbacks to at least eight nursing homes in the amount of \$250 per day for each patient on GIP.

To illustrate the benefit of such a scheme, consider, during fiscal year 2012, Medicare paid \$671.84 per day for a GIP hospice patient versus only \$151.23 for patients receiving routine care.

According to claims data received by the government, Passages was paid approximately \$95 million by Medicare and \$30 million by Medicaid based on the nearly 4,769 patient claims submitted from January 2006 through late 2011. Of this \$95 million in Medicare payments, Passages received approximately \$23 million for claimed GIP services over a three-year period.

The government also hired an independent expert to audit 13 files of Passages patients. Of those 13 files, 10 patients' admissions exceeded six months, which is very unusual as typically hospice patients have a life expectancy of six months or less.

According to Section 1861 of the Social Security Act, hospice care is defined as the provision of specified items or services to a patient who is terminally ill. To be terminally ill, a patient must be certified by the medical director of the hospice provider and by the patient's attending physician as having a terminal prognosis with a life expectancy of six months or less.

In 2009, on average, only 11.8 percent of hospice patients received more than six months of care. By contrast, Passages' Medicare claims data revealed approximately 22 percent of Passages' patients between 2006 and 2011 had more than six months of hospice care – nearly double the average.

Passages employees came forward with information relating to alleged fraudulent billing and marketing practices to both Medicare and law enforcement before being contacted by Strike Force agents.

This pattern of employees reporting wrongdoing prior to being approached by the government in connection with health care fraud investigations is becoming an increasingly common form of whistleblowing.

So what can employers do to be proactive? Employers would be wise to review internal compliance policies, ensure appropriate channels are available for employees to report any suspected wrongdoing internally, and encourage employees to report internally before going outside the company.

Fourth Circuit: False Claims Act case cannot go forward on allegations of regulatory violations alone

By Aaron J. Kornblith

IN BRIEF

- Case alleges that a whistleblower's former employer processed drugs in violation of safety regulations and, therefore, caused those drugs to be ineligible for reimbursement by Medicare and Medicaid.
- The decision closes a potentially lucrative avenue for False Claims Act cases against pharmaceutical companies and others based solely on regulatory non-compliance.

The U.S. Circuit Court of Appeals for the Fourth Circuit dealt a significant blow in February to efforts to use the False Claims Act ("FCA") against pharmaceutical companies who sell contaminated products to the government in violation of federal safety regulations. The whistleblower, or *qui tam*, claim at issue alleged that the defendant, Omnicare, Inc., had violated the FCA by processing its drugs in violation of Food and Drug Administration ("FDA") safety regulations and then placing those adulterated drugs in the stream of commerce where Medicare and Medicaid provided reimbursements for them. The Court of Appeals upheld the dismissal of the claim, holding that the whistleblower failed to allege either that his former employer had made a false statement or that it had acted with the requisite knowledge.

Omnicare ran two operations in a building in Toledo, Ohio: Heartland Repack Services, LLC, a drug repackaging operation, and a pharmacy. Barry Rostholder, a licensed pharmacist who worked for Heartland, discovered that although Heartland did not repackage penicillin, the pharmacy that shared the building with Heartland did. This violated FDA regulations requiring that penicillin repackaging operations be conducted in

separate facilities from those for drugs that do not contain penicillin. Drugs that do not comply with the regulations are considered "adulterated" under the Food, Drug, and Cosmetic Act ("FDCA").

Rostholder resigned from Heartland in 2006 and contacted the FDA concerning Omnicare's apparent violations. An investigation by the FDA uncovered the presence of penicillin throughout the Heartland facility, leading the agency to issue a warning letter to Omnicare and threaten various other actions. Omnicare subsequently disposed of \$19 million of likely contaminated inventory.

In May 2007, Rostholder filed suit under the False Claims Act against Omnicare. He argued that Omnicare had submitted false claims to Medicare and Medicaid by knowingly or recklessly repackaging drugs in violation of the FDA regulations, where the violations caused the drugs to be ineligible for coverage under those programs. The government declined to intervene. The U.S. District Court for the District of Maryland dismissed the claim. It held that Rostholder failed to allege that Omnicare, by merely selling the contaminated drugs, had

made a false statement or acted with the requisite knowledge, two elements required to state a claim under the FCA.

The Fourth Circuit affirmed. It acknowledged that failure to follow the FDA's safety regulations classified Omnicare's products as "adulterated" under the FDCA. To qualify as a "covered outpatient drug" under the Medicare and Medicaid statutes, however, a drug need only be approved by the FDA, not comply with its processing regulations. Because such compliance is not required for reimbursement by Medicare and Medicaid, the court said, "the submission of a reimbursement request for [an approved] drug cannot constitute a 'false' claim under the FCA on the sole basis that the drug has been adulterated as a result of having been processed in violation of FDA safety regulations." Similarly, because Omnicare's alleged conduct did not amount to submitting a false claim, the court held that Rostholder could not plausibly allege that Omnicare had done so knowingly, defeating the scienter element, or fraudulent intent, needed for an FCA claim.

The court lauded the correction of regulatory infractions as a "worthy goal" but explained that such violations are "not actionable under the FCA in the absence of actual fraudulent

conduct." Further, endorsing the whistleblower's theory would "sanction use of the FCA as a sweeping mechanism to promote regulatory compliance, rather than a set of statutes aimed at protecting the financial resources of the government from the consequences of fraudulent conduct." The court pointed to the broad remedial powers possessed by the FDA to enforce its own regulations – powers that the agency had used in its proceedings against Omnicare – as evidence that "Congress did not intend that the FCA be used as a regulatory-compliance mechanism in the absence of a false statement or fraudulent conduct directed at the federal government."

Given the myriad statutes and regulations that govern the pharmaceutical industry, the court closed a potentially wide avenue for FCA claims by holding that selling drugs that violate safety regulations and for which government reimbursement will be sought does not, by itself, constitute making a false claim. The decision also warded off the broader, more dangerous proposition that any regulatory slip-up by a defendant could create grounds for an FCA suit. Without an allegation of actual fraudulent conduct related to procuring government funds, it appears that such claims will have little chance of success going forward.

The Saul Ewing White Collar and Government Enforcement Practice

Christopher R. Hall, Chair
215.972.7180
chall@saul.com

Nicholas J. Nastasi,
Vice Chair
215.972.8445
nnastasi@saul.com

Jennifer L. Beidel
215.972.7850
jbeidel@saul.com

Andrea P. Brockway
215.972.7114
abrockway@saul.com

Brett S. Covington
202.295.6689
bcovington@saul.com

Marisa R. De Feo
215.972.1976
mdefeo@saul.com

Jennifer A. DeRose
410.332.8930
jderose@saul.com

Justin B. Ettelson
215.972.7106
jettelson@saul.com

Patrick M. Hromisin
215.972.8396
phromisin@saul.com

Aaron J. Kornblith
202.295.6619
akornblith@saul.com

Keith R. Lorenze
215.972.1888
klorenze@saul.com

Timothy J. Lyon
412.209.2516
tlyon@saul.com

Brittany E. McCabe
215.972.7125
bmccabe@saul.com

David R. Moffitt
610.251.5758
dmoffitt@saul.com

Joseph F. O'Dea, Jr.
215.972.7109
jodea@saul.com

Christine M. Pickel
215.972.7785
cpickel@saul.com

Courtney L. Schultz
215.972.7717
cschultz@saul.com

Gregory G. Schwab
215.972.7534
gschwab@saul.com

Brian P. Simons
215.972.7194
bsimons@saul.com

Matthew J. Smith
215.972.7535
mjsmith@saul.com

Nicholas C. Stewart
202.295.6629
nstewart@saul.com

Meghan Talbot
215.972.1970
mtalbot@saul.com

Chad T. Williams
302.421.6899
cwilliams@saul.com

This publication has been prepared by the White Collar and Government Enforcement Practice of Saul Ewing LLP for information purposes only. The provision and receipt of the information in this publication (a) should not be considered legal advice, (b) does not create a lawyer-client relationship, and (c) should not be acted on without seeking professional counsel who has been informed of specific facts. Please feel free to contact Christopher R. Hall, Esquire of the Philadelphia, Pa. office at chall@saul.com to address your unique situation.

©2014 Saul Ewing LLP, a Delaware Limited Liability Partnership.
ALL RIGHTS RESERVED.