

Association of
Certified Fraud Examiners
Greater Chicago Chapter



www.acfechicago.org

Summer 2008

A Message from the Past President

To my fellow Chapter members:

As I finish out my term as president, I wanted to take the opportunity to thank all of you for your support over the last couple of years. Together we have made the Chicago chapter the best chapter in the organization. It is because of a tremendous group of people who continue to support the chapter and its efforts to bring quality programs and resources to the members.



My special thanks goes to Delena D. Spann who served as Vice President this past year. She has been invaluable to me as President attending nearly all our local meetings and workshops during my busy travel seasons. As your incoming President, Delena has a wealth of experience in the fraud and financial industry as well as the association recently being elected to serve on the **Board of Regents for ACFE National** - one of the highest honors for a member of ACFE. In short, you can be assured that the leadership of this chapter is in good hands with Delena at the helm.

I want to also thank my fellow board members and our administrators for a job well done. Everyone has dedicated themselves to ensuring that the chapter serves its members with great resources and valuable training. I especially want to thank a couple of board members. The most difficult task in the chapter is that of training director. Dave Marshall has done an incredible job of ensuring that we continue to have quality programming. It takes up a lot of his time and we all appreciate it very much. Rebecca Busch and this newsletter - what can you say - it's a tough job. She has really taken our newsletter to the next level and we all appreciate her hard work and that of our regular contributors.

I also want to welcome our newest board member and secretary, Peg Berezewski. She will be joining Delena Spann, our new president, Peggy Daley, our new vice-president and Bill Pollard, our treasurer as an officer on the board. Rebecca Busch, Dave Marshall and Michael Vian will continue to serve as directors. Many thanks also go out to those members who ran for a seat on the board. I hope each of you continue to look for opportunities to get involved.

It's been a fun couple of years this time around. I look forward to seeing so many of the friends I've made at upcoming chapter events. Please join me in my unofficial capacity for our next meeting and networking reception on July 21st at the Rock Bottom Brewery. I'm sure it will be a good time!

All the best,
Mark Sullivan

Mission Statement

The mission of the Association of Certified Fraud Examiners is to reduce the incidence of fraud and white-collar crime and to assist the Membership in its detection and deterrence. To accomplish our mission, the ACFE...

- Provides bona fide qualifications for Certified Fraud Examiners through administration of the CFE Examination
- Sets high standards for admission, including demonstrated competence through mandatory continuing professional education
- Requires Certified Fraud Examiners to adhere to a strict code of professional conduct and ethics
- Serves as the international representative for Certified Fraud Examiners to business, government and academic institutions
- Provides leadership to inspire public confidence in the integrity, objectivity, and professionalism of Certified Fraud Examiners

Inside This Issue

- | | |
|--|---|
| Message from the Incoming President | Advertising |
| Board of Directors | Criminal and Civil Libability to Physicians..... |
| Ring Around the White Collar | Upcoming Events |

Certified Fraud

Examiners

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A Message from the Incoming President

Greetings Greater Chicago ACFE Members,

My name is Delena D. Spann and I'm honored to serve as your new Chapter President.

Summer has finally arrived and there's much to do in our great City of Chicago. With festivals in every neighborhood, thousands of tourists, great restaurants and outstanding shopping. I'm excited to be a part of a city that has the coolest architecture, the hottest jazz and some of the most indictable politicians in the country. It's a fraud examiner's paradise!



So we do indeed truly have a wonderful city. In our transition we can challenge ourselves with a new purpose that will foster innovation, spontaneity and exuberance. Chief among our goals will be serving our members, creating a collegial environment, increasing our membership and developing partnerships with corporations and universities.

In addition, forming a Women's Group will also be a top priority.

We live in interesting times with many challenges ahead. With that being said, I encourage each of you to reflect on all that we've done over the past few years and vision what's to come by keeping in mind that, "OUR BEST DAYS ARE AHEAD OF US"!

It is my hope that you will take into consideration what you, as a member, can contribute to the chapter and our efforts to foster a new and vibrant membership.

Best Regards,

Delena D. Spann, M.S., CFE, CCA

President, ACFE Greater Chicago Chapter

Vision: Let's Go Shopping for Fraudsters!

*ACFE Board of Regents

Ring Around the White Collar

By Robert Quillinan, MBA, CFE

And now from our sister city, Boston...

First off let me state that I have nothing but respect for anyone that actually will go into a burning building while everyone else is running out of said burning building. However, fraud is where you find it.

In a story from the April 17 Boston Globe, we find that a statistical anomaly has apparently hit the Boston fire department. Now those of us that have been born and raised in the city of Chicago, county of Cook will look at the following article and think, "I should have taken the old man's advice and joined the fire department". Others may see a statistical impossibility.

Background: The contract that the Boston firefighters have allows disability payments, including permanent disability status, to be based on the rank of the firefighter at the time of the injury. This includes those firefighters that may be working "out of rank". In other words if fire lieutenant Folley is assigned to fill in for captain Flynn while Flynn is on vacation and Folley is injured during the time he is filling in for Flynn, Folley is given disability payments based on a captain's pay. Another nice little kicker is that all the payments are tax free.

Note: Folley and Flynn are fictitious names, actually they are the names of a couple of ex-partners of mine, who both retired honorably from the Chicago PD.

Now if you're permanently disabled, you get 72% of the annual salary, tax free, of the rank you were filling in for, until you reach retirement age. Then your retirement payouts are at the rank that you were filling in for. So let's see, if Folley is

permanently disabled while filling in for Flynn, then he gets 72% of captain's pay, tax free, until he retires, then gets his pension paid at the captain rank.

This wouldn't lead to anything fraudulent, would you think?

Well, the FBI has issued subpoenas to a dozen current and former firefighters and to the city of Boston.

Now for all you probability persons, how do these sound?

Over the past several years, 102 Boston firefighters experienced career ending injuries, requiring permanent disability status and thus tax free income. Now the most interesting thing, all 102,(100 %), were filling in for higher ranking personnel. In one instance, a lieutenant was filling in for a captain for a one day vacation. He injured his back permanently while moving a file cabinet. What are the chances of that?

The Boston Globe reported that in an average week 200 of the 1500 person force is on disability.

Between 2005 and 2007 123 out of 166 retirements were based on accidental disabilities,

What are the odds?

Can I get this on my iPod?

A federal court in Tacoma, Washington has bared a woman, Sharon Kukhahn, from selling her IMF Decoder service. The IMF Decoder allegedly showed that her customers were not required to pay federal income taxes unless they live in a United States territory and that US residents could only be taxed under excise tax law if they owned an income producing business.

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About ACFE

Newsletter

The ACFE Greater Chicago newsletter is published quarterly. Submissions to our newsletter must be sent to the Newsletter Editor for consideration by the deadlines stated below. This is the official publication of the ACFE Greater Chicago Chapter. All rights reserved.

Deadline for Information and Print Schedule. Dates are subject to change:

9.1.08 for 10.15.08
12.1.08 for 1.15.09
3.1.09 for 4.15.09
6.1.09 for 7.15.09

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Body of Newsletter with Web Site Link
\$200.00/issue

Side Bar with Web Link
\$50.00/issue

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in JPG, TIFF, PDF
or TEXT Format

Just a tip to those looking for their own "decoder", do you really want to buy tax advice from a company named Advocates for Justice, Liberty and Freedom? Nice name though Ms. Kukhahn.

First do no harm.

Perhaps we should increase the ethics training of doctors. Just a thought.

First, the US District Court of Providence R.I. recently indicted a doctor for fraudulently billing Medicare and Medicaid for unnecessary or non-performed services. These included chemotherapy treatments. On one day the doctor billed for 87 patient visits, on a day that showed he was only in the office 6 hours. The indictment seeks the forfeiture of bank accounts and several pieces of real property.

Next, Dr. W. Scott Harkone, former CEO of Intermune Inc. was indicted for wire fraud and other Federal charges for his involvement in supporting false claims for a drug owned by Intermune. Dr. Harkone allegedly took clinical trial results that showed that the drug Actimmune, did not improve or extend the life expectancy of patients affected with IPF (idiopathic pulmonary fibrosis), a truly nasty disease. The doctor developed a press release based on the clinical trial that according to the indictment stated, "Intermune announces Phase III data demonstrating survival benefit of Actimmune in IPF. Reduces mortality by 70% in patients with mild to moderate disease." This statement was not supported in any way by the clinical trials. Why would anyone do that? The cost of Actimmune for one year of treatment was approximately \$50,000 per patient. The disease can be fatal, to a patient \$50,000 seems cheap if it means you get to breathe for a while longer. Try holding your breath, how much would you pay for the next one?

Dr. Harkone has not gone to trial and is innocent until proven otherwise. However, his former employer, Intermune Inc. paid \$37 million and entered into a 5 year CIA in a plea agreement with the government earlier.

Lastly, Dr. Robin Motz pleaded guilty in New York State Court to second degree larceny. Dr. Motz in his plea agreement, stated that he had stole \$832,453 while using a power of attorney document. He stole the money from his 92 year

old mother. He then put her in a nursing home where her only income is social security.

Dr. Motz was sentenced to..... 150 hours of community service at a city clinic.

That should serve as a deterrent.

Bullet Points

- The Treasury Department reported that allegations of mortgage fraud increased 42% year to year ending March 31, 2008. Do you think a couple of years from now we will be reporting that reports of price fixing in the oil business will be up?
- Follow up to the report done earlier about the OIG agent who defrauded health care businesses by diverting seized bank accounts of healthcare offenders and transferring them to his own account. Scott Allen Gompert was sentenced to 2 years of prison and forfeiture of \$550,000 cash and several pieces of real estate. This was a pretty good plea agreement since he faced a max of 35 years in prison and \$1.2 million in fines.
- 38 persons, including citizens of Romania, Viet Nam, Cambodia and the US, were indicted in an international computer fraud scheme. They obtained credit and debit card numbers during several "phishing" schemes, including setting up a look alike web site that resembled a bank site and then directing bank card holders to go and change their PIN number at the site for "security" reasons. For more info and scary details see the indictment on the DOJ web site under press releases for May 19, 2008. www.usdoj.gov

Until next time, remember to follow the money.

Robert J. Quillinan, Manager, may be reached at 847.582.6546.

Criminal and Civil Liability to Physicians and Other Health Care Providers For the Off-Label Marketing of FDA-Approved Drugs or Devices: An Emerging Trend?

Kevin E. Raphael, Esq. and Shannon L. Voll, Esq.

The Food and Drug Administration ("FDA") is empowered to determine whether any given drug or medical device will be approved for sale in the United States. The FDA does not, however, have the power to regulate the practice of medicine. For example, once the FDA approves a drug for a particular use, physicians are free to use the drug for any purpose. This practice is routine among physicians. As long as individual physicians are using drugs or devices based on their professional judgment that such use is in the best interest of their patients, the federal government has no right to interfere. This is commonly referred to as "off-label" use.

Consequently, pharmaceutical companies were quick to develop marketing strategies to promote drugs for off-label use. However, the FDA does have the authority to regulate how pharmaceutical and device companies market their products, and has prohibited, in most circumstances, the marketing of drugs or devices for their "off-label" uses. Over the past several years, the pharmaceutical companies have paid a heavy price for this illegal practice, becoming the target of criminal investigations, attendant negative publicity and uncertainty, and hundreds of millions of dollars in settlements.

In addition, the False Claims Act has been used against pharmaceutical companies, resulting in the payment of vast sums of money to the federal government and the "whistleblowers" who initiated the lawsuits. More recently, the government has turned its attention to medical device companies, investigating both their marketing of unapproved uses for their products, and their financial relationships with physicians who use their products. The U.S. Attorney's Office for the District of New Jersey recently settled with five of the largest orthopedic medical device companies for their improper marketing of FDA-approved devices, with four of the five paying hundreds of millions of dollars in criminal and civil penalties and fines.

Physicians and other health care providers, however, should not assume that the federal

government will limit its criminal and civil investigations to only the pharmaceutical and device companies. The last several years have evidenced an emerging, and possibly growing, trend by the government and private health insurance companies: to pursue individual physicians and other health care providers for violating laws and regulations concerning the marketing of FDA-approved drugs and devices.

The Fine Line Between Off-Label Use and Off-Label Promotion

Off-label use is widespread. A study released in May 2006 reported that in 2001, roughly two-thirds of prescriptions written for six common drugs were for off-label use. A 2004 study involving pediatric patients (those 18 and younger) showed that almost 80 percent of pediatric patients have been treated with at least one off-label drug.

While a physician's, or other health care provider's, right to use drug or device for off-label uses is relatively clear-cut, their right to promote the off-label use is not without limits. Yes, doctors can, and indeed frequently do, confer with colleagues about their successes with the off-label use of a particular device or drug. Yet, what if the physician is conferring with his or her colleagues during a conference paid for by the drug or device company? What if the physician is under contract with the drug or device company to perform research or consulting services, and also confers with his or her colleagues about the off-label uses of the company's drugs or devices?

These and similar situations may indeed expose the individual physician to criminal and civil liabilities, particularly given the government's emerging focus on investigating medical device companies' marketing efforts and relationships with physicians.

Continued.....

Criminal Prosecution of Individual Physicians or Other Health Care Providers for Off-Label Marketing

The government has been very active in past years investigating and prosecuting physicians and other individuals for their roles in the off-label marketing of FDA-approved drugs and devices. Several examples serve as cautionary tales.

Dr. Peter Gleason believed that Xyrem, approved by the FDA to treat patients with narcolepsy, was also an effective treatment for patients suffering from insomnia and severe depression, conditions not approved by the FDA. Dr. Gleason's off-label prescribing caught the attention of Xyrem's manufacturer, Orphan Medical, Inc. At the request of Orphan, Dr. Gleason started speaking to other physicians about his experiences with Xyrem, specifically its off-label uses. Orphan paid Dr. Gleason for his time.

In April 2005, after a tip from a whistleblower inside Orphan Medical, the government began investigating Dr. Gleason and in April 2006, the U.S. Attorney's Office for the Eastern District of New York filed a criminal indictment against Dr. Gleason. The government alleges that Dr. Gleason conspired with Orphan sales representatives to promote off-label uses of Xyrem in violation of the Food, Drug, and Cosmetic Act.

In its indictment, the government attempts to portray Dr. Gleason as a puppet for the drug manufacturer, rather than an unbiased physician exercising his right to practice medicine freely. The government bases this allegation, in part, on the fact that Dr. Gleason received tens of thousands of dollars from Orphan. The government also alleges that Dr. Gleason told physicians to provide an incorrect diagnosis to the insurance companies to ensure payment for the off-label use.

In July 2007, Jazz Pharmaceuticals, successor to Orphan, agreed to pay \$20 million to settle civil and criminal proceedings concerning its off-label marketing of Xyrem. Charges against Dr. Gleason are still pending.

Further, on March 18, 2008, W. Scott Harkonen, M.D., the former CEO of biopharmaceutical firm InterMune Inc., was indicted for his alleged role in illegally promoting one of the company's drugs for off-label use. The government alleges that Dr.

Harkonen proceeded with an extremely successful marketing campaign that promoted the drug Actimmune as a safe and effective treatment for idiopathic pulmonary fibrosis (IPF), even though early studies of the drug to treat IPF had failed. The government claims that sales of the drug increased from \$11 million to \$141 million between 2000 and 2003, and contends that the off-label promotion was a scheme to defraud doctors and patients.

InterMune had previously agreed to pay over \$36.9 million to resolve civil and criminal allegations that it illegally promoted Actimmune for off-label use.

Finally, the Seventh Circuit recently upheld the conviction of two executives of a medical device company, AbTox, who, among other things, promoted AbTox's FDA-approved sterilizer of medical instruments for unapproved uses. *United States v. Caputo*, 517 F.3d 935 (7th Cir. 2008). The Court upheld the two executives' sentences of six and ten years, respectively, but remanded to the District Court to recalculate restitution owed to the hospitals and other entities that purchased AbTox's sterilizer.

The Civil Risk to Physicians or Other Health Care Providers Who Engage in Off-Label Marketing/Promotion

The federal and state governments, through administrative means and/or the federal or individual state false claims acts have pursued, and will continue to pursue, civil sanctions against physicians, other health care providers, and executives for the off-label marketing of FDA-approved drugs or devices. Further, insurance companies are increasingly aggressive in their attempts to recover monies paid to health care providers. In turn, they are increasingly willing to pursue civil actions against providers to recover those monies, including the use of state insurance fraud statutes that provide an affirmative right of action to insurance companies. Off-label marketing allegations provide an avenue by which insurers can pursue health care providers. There has been at least one action commenced under this theory.

Dr. David Longmire, an Alabama neurologist, discovered that his use of Neurontin for the FDA-approved use of treating seizures had the non-indicated effect of reducing pain. He told his colleagues about his findings and soon Parke-

Davis, the division of Warner-Lambert responsible for Neurontin, was paying Dr. Longmire to share his findings with other health care professionals.

Warner-Lambert (now owned by Pfizer) paid more than \$430 million to settle criminal and civil liabilities related to paying physicians to promote Neurontin for off-label use. After the settlement, private insurers began suing Warner-Lambert, and Dr. Longmire was named as an individual defendant in a suit filed by Blue Cross and Blue Shield of Alabama (BCBS). BCBS alleged that Dr. Longmire encouraged physicians to prescribe Neurontin more frequently than they otherwise would have, costing BCBS millions of dollars in improper reimbursements. The case is still pending.

Conclusion

The increasing number of criminal and civil investigations by the government against individual physicians, company executives and other health care providers for the marketing of drugs and devices off-label are a warning that these individuals should be wary of their marketing activities. Caution is especially warranted when the physician or other health care provider engages in a financial relationship with the drug or device company whose product the physician or health care provider advocates for off-label use.

Further, in discussions concerning off-label use, these individuals should ensure that all statements regarding off-label usage are accurate and supported by published data. When physicians begin to promote the drugs or devices they are using, the lines get blurred and both consumers and the government may begin to wonder: is the physician's decision to promote and/or use the drug or device for an off-label use influenced by promising medical results, or rather the promise of a new, highly-lucrative income as a guest speaker? Physicians and other health care providers who are not cautious in their off-label promotional activities risk being perceived as putting their own greed ahead of the welfare of their patients. Worse, they risk becoming the subject of a government investigation, or the defendant in a civil action.

For more information, please contact Kevin E. Raphael at (215) 320-6200 or via e-mail at KER@PIETRAGALLO.com, or Shannon L. Voll at (412) 263-2000 or via e-mail at SLV@PIETRAGALLO.com.

ACFE Greater Chicago Chapter Upcoming Events - 2008

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| July 21
<i>Monday</i> | Chicago Chapter Evening Meeting & Networking Reception
Presented by: Todd Glud,
Guidance Software- Prof. Service Div.
Location: Rock Bottom Brewery
Chicago, IL
4:00 PM Registration & Networking
4:30 PM Program |
| August 11
<i>Monday</i> | Chicago Chapter Luncheon and Workshop
Topic: Value of Handwriting Analysis
in Fraud Investigations
Presented by: Warren Spencer,
Location: 111 S. Wacker Drive,
Jackson Park Room
11:30 AM Registration
1:00 - 3:00 PM Program |
| Sept. 11-12
<i>Thur-Fri</i> | National ACFE Training Workshop
"Mortgage Fraud"
Location: AMA Executive Conference
Center
Chicago, IL |
| Oct. 13
<i>Monday</i> | Chicago Chapter Luncheon and Workshop
"Investigative Intuition"
Presented by Dan Draz, Corp
Investigations, TansUnion
Location: 111 S. Wacker Drive,
Jackson Park Room
11:30 AM Registration
1:00 - 3:00 PM Program |
| Dec. 9
<i>Tuesday</i> | Chicago Chapter Annual Holiday Luncheon
Location: Maggiano's Banquets
Chicago, IL |