By **Al Scott, CFE**

Emerging health care fraud: Schemes go beyond Medicare, Medicaid fraud

Part 1 of 2

In part 1 of 2 parts, Al Scott, CFE, principal for NSD Bio Group LLC in Philadelphia, Pa., describes lesser-known but emerging health care frauds, including schemes involving fraudulent treatments, cures and devices, and crimes involving the manufacture, sale or distribution of unapproved FDA-regulated products. In part 2, he describes Chinese emerging enforcement approaches. The opinions expressed in this column aren't necessarily those of the ACFE, executives or employees. — ed.

In January of 2012, the critically acclaimed television show, "60 Minutes," featured a segment, "Stem Cell Fraud," which included an exposé on an Alabama doctor, Dan Ecklund, who's under investigation for fraud. His U.S. medical license was revoked in 2005, but that didn't keep him from starting a company in Ecuador to peddle stem cell treatments online as a fraudulent cure-all for incurable diseases.

This investigative piece followed a 2010 segment about fraud in the regenerative medicine sector. In that investigation, Lawrence Stowe and Frank Morales promised miracles from a $125,000 stem cell therapy for patients suffering from multiple sclerosis (MS), Parkinson's, ALS and other diseases. That story launched a U.S. federal investigation, which led to an allegation that Stowe and Morales procured $1.5 million via stem cell fraud. (See http://tinyurl.com/8fjtkge.)

As a result of the "60 Minutes" show, Stowe surrendered to authorities. Morales was already in jail on an indictment for a cross-border scheme to use stem cells as a bogus cure for cancer, MS and other incurable diseases.

In October of 2011, the U.S. Department of Justice (DOJ), via the efforts of the Food and Drug Administration (FDA) Office of Criminal Investigations (OCI), charged Ralph Conti, M.D, a Las Vegas pediatrician, with participating in a scheme to defraud investors and chronically ill patients of large amounts of money through the use of experimental stem cell implant procedures that wouldn't benefit patients and weren't approved by the FDA. (See http://tinyurl.com/8wqmjth.)

Conti was charged in a superseding indictment with conspiracy to commit mail and wire fraud and criminal forfeiture. Also named was his partner, Alfred T. Sapse, of Las Vegas, who had been previously indicted in the same case.

Under direction from Sapse, Conti would implant portions of placental tissue into patients' abdomens for the treatment of their diseases. They allegedly targeted extremely sick patients with false claims and misrepresentations. They would say that they obtained the placental tissue for the procedures only from Caesarian section births, which ostensibly reduce the risk of infection. The dynamic duo also would tell patients that their "proprietary" procedure was especially effective for patients with multiple sclerosis, cerebral palsy and retinitis pigmentosa

© Richard Wozniak/iStockphoto

— a disease of the retina, which can cause blindness.

Several of their approximately 34 patients became infected from the procedures. In February 2007, Sapse moved to Mexico, where he directed another physician to implant placental tissue in approximately 100 patients until May 2010.

In December 2011, Richard Bohner, an officer for Norian Corporation — a wholly owned subsidiary of Synthes Inc. based in West Chester, Pa. — was sentenced to eight months in prison for one misdemeanor count of shipping adulterated and misbranded

medical devices in interstate commerce. Bohner was the last of four executives to be sentenced in the case. His former colleagues were each sentenced from five to nine months in prison. The defendants approved clinical trials using bone void fillers (Norian XR and Norian SRS) to treat vertebral compression fractures of the spine (VCFs) — a painful condition commonly suffered by elderly patients. Despite known and serious safety concerns and a warning on the label that the products weren't intended for that use, Synthes didn't stop the illegal testing until after a third patient had died on the operating table during one of these surgeries. Three of the four executives also lied to the FDA during an investigation.

From May 2002 until fall of 2004, Norian conspired with others, including Synthes and the former executives, to conduct unauthorized clinical trials of Synthes' medical devices. These surgeries were performed despite a warning on Norian XR's FDA-cleared label prohibiting this use and in the face of serious medical concerns about the safety of the devices when used in the spine.

Before the marketing program began, pilot studies demonstrated that the bone cement reacted chemically with human blood in a test tube to cause blood clots. The research also showed that such cement-caused clots became lodged in the lungs of pigs. The company ignored this knowledge and proceeded to market the product for VCFs without any FDA-required testing. It took a third patient dying on the operating table before Norian stopped marketing the product. After the death of this patient in January 2004, Norian and Synthes didn't recall Norian XR from the market, which would have required them to disclose details of the three deaths to the FDA. Instead, they compounded their crimes by carrying out a cover-up in which they made false statements to the FDA during an official inspection in May and June 2004. (See "Anger from survivor of Synthes victim," by David Sell, July 31, The Philadelphia Inquirer, http://tinyurl.com/9tgqan8.)

These cases represent a small sample of many investigations pursued by the OCI, a special unit that conducts and coordinates criminal investigations. OCI special agents employ customary federal law enforcement methods and techniques in the investigation of suspected criminal violations of the False Claims Act, Federal Food, Drug, and Cosmetic Act; the Federal Anti-Tampering Act and other related federal statutes.

OCI investigations concentrate on significant violations of these laws, with a priority on conduct that may present a danger to the public health. Criminal investigations of health care fraud have increased significantly over the past three calendar years: 7.5 percent from 2009 to 2010 (43 to 50 cases), and an aggressive 120 percent from 2010 to 2011 (50 to 110 cases). (See U.S. FDA Strategic Priorities Document 2011-2015, http://tinyurl.com/8ngycp4.)

The number of criminal convictions over five quarters in calendar years 2010 and 2011 are shown in the graph on page 62. (These are the available statistics at time of publication of this issue of *Fraud Magazine*.)

Increasing bandwidth of health care fraud

When most people read or hear of health care fraud, they immediately think of Medicaid or Medicare fraud because of the huge losses that make the headlines.

However, we can also concentrate on other types of emerging health care fraud. Here are some of the most egregious examples:

- Schemes involving fraudulent treatments, cures and devices.
- Internet-facilitated criminal violations involving FDA-regulated products.
- Illegal importation of FDA-regulated products.
- Crimes involving the manufacture, sale or distribution of unapproved FDA-regulated products.

In this column, we'll describe some of the recent Big Pharma and biotech violations and the emerging enforcement strategies in the U.S.

Emerging health care fraud enforcement strategies in the U.S.

The U.S. federal government, in recent years, has indicted a number of pharma and biotech companies — and in limited cases, their executives — on a host of violations of U.S. laws administered through the FDA, Securities Exchange Commission (SEC) and Department of Justice (DOJ). For far too long, executives who promote drugs and medical technologies — including regenerative medicine therapies using false and misleading information — have remained hidden behind the corporate veil.

Continuing aggressive and intensive efforts to investigate and prosecute C-level officials to the full extent of the law will prove, one can surmise, to be both an effective deterrent to future similar crimes and a more efficient allocation of limited resources over time.

I'll run through a few recent common violations by some big-name pharmaceutical companies:

- Novartis, for marketing a number of pharmaceutical products for uses not approved by the FDA, including the epileptic drug Trileptal ($422.5 million, September 2010). (See http://tinyurl.com/8byyu24.)

- AstraZeneca, for illegally marketing the anti-psychotic drug, Seroquel, to physicians who don't typically treat schizophrenia or bipolar disorder ($520 million, April 2010). (See http://tinyurl.com/37wd7ye.)
- Abbott Laboratories, B. Braun Medical Inc., Roxane Laboratories Inc. and Dey, Inc. for reporting false and inflated prices for numerous pharmaceutical products to federal healthcare programs relying on those reported prices to set payment rates ($701 million, December 2010). (See http://tinyurl.com/29ascjr; http://tinyurl.com/25zgy6n.)
- Novo Nordisk, for unlawfully promoting the recombinant biologic drug, NovoSeven, for other uses than treating hemophilia ($25 million, June 2011). (See http://tinyurl.com/42krl5f.)
- Guidant LLC, for inflating cost of replacement pacemakers and defibrillators to federal health care programs ($9.25 million, September 2011). (See http://tinyurl.com/3kruks7.)
- Abbott Laboratories, for the unlawful targeted marketing of the anti-seizure drug, Depakote, to elderly dementia patients in nursing homes and marketing Depakote to treat schizophrenia, even after its clinical trials failed to demonstrate relevant effectiveness ($1.5 billion, May 2012). (See http://tinyurl.com/bpgm7rd.)
- GlaxoSmithKline, for improperly promoting the antidepressant Paxil for children, despite trials that raised concerns about suicide; improperly promoting antidepressant Wellbutrin SR to treat obesity and ADHD; not reporting safety data about the diabetes drug, Avandia, and its accompanying cardiovascular risks; and improperly promoting the asthma drug, Advair, contrary to FDA guidance ($3 billion, July 2012). (See http://tinyurl.com/87myfva.)

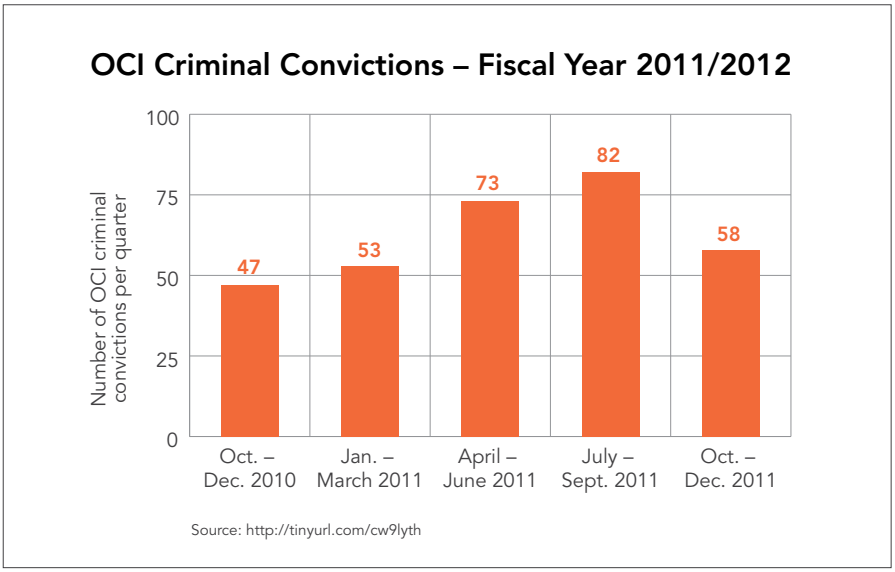

Figure 1

These violations, which some companies committed multiple times, are particularly egregious and unconscionable on two points: 1) They show hyper-aggressive sales and marketing strategies taking precedence over medical decision-making, thus violating basic tenets of health care and ethics — particularly when specifically aimed at older patients with dementia or diminishing mental capacities and 2) They tacitly acknowledge that many companies in the pharmaceutical industry have hoodwinked Congress and the U.S. public for decades about the true, actual cost of bringing a drug to market.[1]

In spite of ubiquitous "patients-first" mission statements and glossy marketing advertisements from the pharmaceutical industry, these violations are even more galling considering the delayed access to cheaper generic drugs (an estimated $3.5 billion in higher drug costs to consumers and taxpayers per year) from the "Pay-for-Delay" settlements brought to light by the FTC.[2]

Against this backdrop of health and safety concerns from tainted, intentional misbranding of medicines, threats continue to consumers' health from fraudulent practices within the health care system. In recent years, pharmaceutical fraud cases have constituted a significant part of the efforts of the DOJ's Civil Division, together with U.S. Attorneys throughout the country, in combating health care fraud.

The Health Care Fraud and Abuse Control Program (HCFAC), under the joint direction of the attorney general and the secretary of the Department of Health and Human Services, acting through its inspector general, has intensified efforts to coordinate federal, state and local law enforcement activities.

One outcome of this joint venture is the FDA's Pharmaceutical Fraud Pilot Program (PFPP). The PFPP has enhanced the health care anti-fraud activities of the FDA's OCI and the Office of the General Counsel, Food and Drug Division (OGC). The OCI, with

the support of the OGC, investigates criminal violations of the Food, Drug, and Cosmetic Act (FDCA), Prescription Drug Marketing Act, False Claims Act and other related federal statutes.

The PFPP is designed to detect, prosecute and prevent pharmaceutical, biologic and medical device fraud. The PFPP focuses on fraudulent marketing schemes, application fraud, clinical trial fraud and flagrant manufacturing-related violations.

The early detection and prosecution of fraudulent conduct furthers the FDA's public health mission and helps reduce health care costs and deter future violators. The PFPP, with close cooperation and coordination with the U.S. Attorneys' Offices and other agencies, has identified in a relatively short time several alleged pharmaceutical fraud schemes (as noted above).

Civil and criminal investigations and outcomes

In FY 2011, the DOJ opened 1,110 new criminal health care fraud investigations involving 2,561 potential defendants — that's a 22 percent increase from FY 2010. Federal prosecutors had 1,873 health care fraud criminal investigations pending involving 3,118 potential defendants and filed criminal charges in 489 cases involving 1,430 defendants — a 55 percent increase from 2010. A total of 743 defendants were convicted for health care fraud crimes during FY 2011. The DOJ in FY 2011 opened 977 new civil health care fraud investigations and had 1,069 civil health care fraud matters pending at the end of the FY 2011.

Also, during FY 2011, the federal government won or negotiated approximately $2.4 billion (compared to $2.5 billion in FY 2010) in health care fraud judgments and settlements, and it attained additional administrative impositions in health care fraud cases and proceedings.

Moreover, these cases are important because they involve schemes that cost federal payers billions of dollars and affect public health. For example, the Allergan, Novartis, AstraZeneca and GSK cases cited above all arose from allegations that those pharmaceutical manufacturers marketed their drugs for uses that the FDA hadn't found to be safe or effective and thereby caused federal payers to pay for those unapproved uses. It can be argued that criminal prosecutions with guaranteed prison time might be a more effective deterrent than civil settlements, of which the latter borderlines on a travesty of justice. (See "Glaxo Agrees to Pay $3 Billion in Fraud Settlement," The New York Times, July 2, by Katie Thomas and Michael S. Schmidt, http://tinyurl.com/bore279.)

Justification for the HCFAC program is supported by the return-on-investment (ROI) on dollars spent. Since 1997, $5.1 *[sic]* is returned for every $1 spent. The three-year average (2009-2011) ROI is $7.2 *[sic]* to $1, which is $2.1 higher than the historical average.[3]

Not only does emerging health care fraud in the U.S. go beyond crimes against Medicare and Medicaid, it can also contribute directly to the rising costs of these programs. Big Pharma and biotech companies plus rogue medical personnel often prey on many of our most vulnerable citizens: trusting, ailing — and often senior — consumers. ■ FM

Part 2 in January/February: Chinese emerging enforcement approaches.

> Against this backdrop of health and safety concerns from tainted, intentional misbranding of medicines, threats continue to consumers' health from fraudulent practices within the health care system

Al Scott, CFE, is principal for NSD Bio Group LLC in Philadelphia, Pa. He also advises emerging technology start-ups. His email address is: cc532@nsdbiogroup.com.

[1]From Forbes.com: Matthew Herper, "The Truly Staggering Cost of Inventing New Drugs." Feb. 10, 2012. http://tinyurl.com/8yqqd7r; Donald W. Light, Rebecca Warburton, "Demythologizing the high costs of pharmaceutical research." BioSocieties, 2011, 1745-8552, 1-17. http://tinyurl.com/crcnkbx.

[2]Edward Wyatt, NYT News Service, "Court rebuffs generic-drug deals." Philadelphia Inquirer. July 12, 2012. Front Page. http://tinyurl.com/342ml; Federal Trade Commission: http://tinyurl.com/9vlubwj.

[3]The Department of Health and Human Services and The Department of Justice Health Care Fraud and Abuse Control Program annual reports for Fiscal Year 2010/2011.