PUBLISHED WEEKLY VOLUME 31 NUMBER 1 MONDAY JANUARY 2, 2017

CORPORATE CRIME REPORTER

PIETRAGALLO PARTNER PAMELA COYLE BRECHT ON MEDICARE PART D FALSE CLAIMS

In 2014, the federal government reported that government auditors had recovered only $10 million of an estimated $1.9 billion in annual improper payments in the Medicare Part D prescription drug benefit program.

One reason for the low recovery rate? Insufficient investigative resources.

But help is on the way.

Conscientious employees inside the Part D program -- at insurance companies, pharmacies and pharmacy benefit managers -- are learning about the False Claims Act.

And that means an increased rate of recovery in the years to come.

Pamela Coyle Brecht is a partner at Pietragallo, Gordon, Alfano, Bosick & Raspanti in Philadelphia.

Her focus -- pharmacy benefit managers. The big three are -- Express Scripts, CVS Caremark, and United Health.

In a pathbreaking case, Brecht represents industry insider Anthony Spay who alleged that one of the big three pharmacy benefit managers – CVS Caremark – engaged in a nationwide scheme to defraud the Part D program. Spay survived a motion to dismiss, but Caremark was granted summary judgment. The case is now on appeal to the Third Circuit.

Spay is one of the first whistleblowers to allege Part D fraud against a pharmacy benefit manager.

The Spay case was filed in 2009. Spay's company was hired to audit the Part D claims processed by Caremark on behalf of Medical Card System, a Puerto Rican health insurance company.

After a 2007 merger, CVS and Caremark have served as a Part D Sponsor, pharmacy benefit manager, and retail pharmacy in the Part D program.

In the course of his company's audit, Spay alleged that he found that Caremark was improperly adjudicating and submitting claims for prescriptions that were not allowed under the Part D Program.

Spay alleged that Caremark improperly dispensed gender-specific drugs to the opposite gender, failed to apply "maximum allowable cost" pricing to prescription drugs, billed for drugs with expired and obsolete National Drug Code identifiers, billed for prescriptions that contained false physician identifiers, dispensed prescription drugs without prior authorization, and billed for quantities of supplies of drugs that exceeded approved limits.

Spay also alleged that these practices were part of CVS Caremark's nationwide practice.

Brecht says that the pharmacy benefit managers are the key players in the Part D program.

"Most people don't realize that the central player in the Part D program is the pharmacy benefit manager," Brecht *told Corporate Crime Reporter* in an interview last week.

Who are the actors in the Part D program?

"You have the sponsor -- the insurance company. The insurance company contracts with the pharmacy benefit manager -- which actually provides the pharmacy benefit service. That benefit includes not just the pill, but those bundles of services that go with it. Someone has to dispense the pill, but also make sure that the medical care is being taken care of -- that the person has a prescription, that the drug is proper for this person, that there is no gender contraindications, that it is not going to interact with other drugs they are taking, that they didn't get the same prescription filled at another pharmacy yesterday. All those services are handled through the pharmacy benefit manager. The pharmacy benefit manager contracts with the pharmacies on behalf of the sponsors -- the insurance companies."

"CMS has looked into Part D at the pharmacy level. There have been some newsworthy cases of the government conducting stings at pharmacies to prevent Part D drugs from ending up on the black market. There was some attention being paid to that level of fraud. But little attention is paid to the pharmacy benefit managers."

(See **BRECHT**, page three)

IN THIS ISSUE

PIETRAGALLO PARTNER
PAMELA COYLE BRECHT ON
MEDICARE PART D FALSE CLAIMS 1

REDFLEX GETS NON PROSECUTION
AGREEMENT IN TRAFFIC CAMERA BRIBE CASE 3

TEVA UNIT PLEADS GUILTY PARENT
GETS PROSECUTION DEFERRED TO PAY
$520 MILLION TO RESOLVE FCPA CHARGES 4

HALF OF MULTINATIONALS FAILING TO PREVENT
THIRD PARTY BRIBERY AND CORRUPTION 5

TELECOM COMPANIES PAY $30 MILLION
TO END LIFELINE FRAUD CASE 6

PACKAGED SEAFOOD EXEC TO PLEAD
GUILTY TO PRICE-FIXING CONSPIRACY 6

ODEBRECHT AND BRASKEM TO PLEAD GUILTY
TO MASSIVE BRIBERY SCHEME AND PAY RECORD $3.5 BILLION 7

VOLKSWAGEN TO RECALL 83,000 VEHICLES 9

COMPANY SETTLES CHARGES IN WHISTLEBLOWER RETALIATION CASE 10

MORGAN STANLEY TO PAY $7.5 MILLION TO SETTLE SEC CHARGES 11

NEUSTAR SETTLES SEC WHISTLEBLOWER CHARGES 11

FOREST LABS TO PAY $38 MILLION TO SETTLE FALSE CLAIMS CASE 12

DEUTSCHE BANK TO PAY $37 MILLION TO SETTLE FRAUD CHARGES 12

BUMBLE BEE EXECUTIVE PLEADS GUILTY 13

INTERVIEW WITH PAMELA COYLE BRECHT,
PARTNER, PIETRAGALLO, PHILADELPHIA, PENNSYLVANIA 13

Corporate Crime Reporter is published by Corporate Crime Reporter, Inc., 48 times a year. ISSN Number: 0897-4101. Principal Editorial Offices: 1209 National Press Building., Washington, D.C. 20045. Telephone: (202) 468-8868. Editor: Russell Mokhiber. Subscription Information: $795 per year in U.S. and Canada. $995 Elsewhere (Air Mail Delivered). Payable in advance in U.S. currency. Make checks payable to: Corporate Crime Reporter, P.O. Box 18384, Washington, D.C. 20036. Copyright by Corporate Crime Reporter Inc. ALL RIGHTS RESERVED. REPRODUCTION IN ANY FORM WHATSOEVER IS FORBIDDEN

(**BRECHT**, from page one)

Why aren't the whistleblowers coming out of these PBM companies?

"There are only a few major PBMs and people value their jobs. You don't want to be knocked out of the marketplace. Our whistleblower happened to have his own business where he actually audited PBMs. Because they are so powerful, there really aren't any PBM sponsors who can take on the PBMs. It's a powerful player in the Part D program. You and I don't know what cases are currently under seal."

Do you sense that we will be hearing more about these cases?

"I do because there has been a lot of focus on drug prices. One of the issues that we had in our CVS Caremark case was whether a Part D sponsor has to provide a negotiated price. And the question became -- what is that price? A sponsor has an obligation to pass on negotiated prices to the beneficiaries. In Medicaid the government is entitled to the best price. Perhaps that will be coming into Part D -- I don't know. But there is a lot of focus on prescription drug prices right now."

"Who would know whether the patient is getting the negotiated price? Only if you know what the contract says and also what is the price charged by the pharmacy would you know whether the patient is getting the negotiated price."

"The key to the Part D program? The insurance company sponsors have to make certain promises to the government. For every drug dispensed, the insurance company sponsor has to submit what is called a PDE -- prescription drug event. And that data has to be true, accurate and complete to the best of the sponsor's ability."

"But there is another set of promises made by the pharmacy benefit managers. They help create the PDE claims. They have to certify that they are true, accurate and complete. And the cost of Medicare drugs is part of the PDE. In exchange for getting the money, the major players are supposed to submit true, accurate and complete information to the government."

"There haven't been many challenges to the truth of those PDE claims. Unless you can see what the pharmacy is dispensing and can compare it to the PDE submitted to the government, you wouldn't know whether those are true, accurate and complete."

"That's why there are very few Part D False Claims Act cases that deal with the sponsor or the PBM. There are more cases brought against pharmacy fraud -- that controlled substances are being dispensed without a prescription -- that kind of thing. It's easier to know about that."

There is a lot of fraud and little enforcement?

"Correct. There is not very much transparency at the PBM area at all. And you have to remember that Part D came into existence January 1, 2006. It takes a long time for a False Claims Act case to percolate out from under seal and then get to the motion to dismiss stage."

(For the complete Interview with Pamela Brecht, see page 13.)

REDFLEX GETS NON PROSECUTION AGREEMENT IN TRAFFIC CAMERA BRIBE CASE

Redflex Traffic Systems Inc., a Phoenix-based automated safety company, was granted a non prosecution agreement in connection with a Chicago bribery case.

Redflex Traffic Systems is wholly owned by Redflex Holdings Group of Melbourne, Australia, which owns and operates a network of digital speed and red-light cameras worldwide.

The company installs cameras that automatically record and ticket drivers who run red lights.

Its former CEO was convicted as part of the probes into bribes paid to elected officials to procure or expand Redflex's contracts with Chicago and Columbus.

The investigations also resulted in the convictions of a Chicago official and a Columbus lobbyist. John Bills, a former Chicago assistant transportation commissioner, was convicted of accepting cash and benefits from Redflex in exchange for expanding the company's business with Chicago.

The lobbyist, John Raphael, pled guilty to extorting cash from Redflex to pass on to elected officials in Ohio in an effort to obtain red-light camera contracts.

Redflex was represented by Scott Lassar, David Hoffman and Geeta Malhotra of Sidley & Austin in

Chicago.

Since the inception of the U.S. investigations, Redflex has initiated substantial additions and changes to its compliance program, policies and procedures. The company agreed in the non-prosecution agreement to revise and address any deficiencies in its compliance code, policies and procedures regarding compliance with applicable anti-bribery and anti-corruption laws. Redflex agreed to adopt new policies to ensure that it maintains a rigorous anti-bribery and anti-corruption compliance code, and to install procedures designed to detect and deter violations of such laws.

During the term of the agreement, Redflex must prepare at least four follow-up reports and periodically submit them to Department of Justice.

If the Department determines that Redflex has violated any provision of the non-prosecution agreement, Redflex shall be subject to prosecution for any applicable violation of U.S. law, including perjury and obstruction of justice.

The Justice Department said that the agreement was reached in part due to Redflex's extensive and thorough cooperation over recent years – including cooperation with the successful prosecutions of several individuals, including a high-ranking city of Chicago official and Redflex's prior Chief Executive Officer.

Among the company's obligations under the agreement, which shall continue for two years, Redflex will pay restitution and compensatory damages to the City of Chicago, the amount of which will be determined either by a final judgment or a settlement agreement in Chicago's pending civil lawsuit against Redflex.

Redflex will also pay restitution of $100,000 to the City of Columbus, Ohio.

TEVA UNIT PLEADS GUILTY PARENT GETS PROSECUTION DEFERRED TO PAY $520 MILLION TO RESOLVE FCPA CHARGES

Teva Pharmaceutical Industries Ltd. (Teva), the world's largest manufacturer of generic pharmaceutical products, entered in a deferred prosecution agreement and its wholly-owned Russian subsidiary, Teva LLC (Teva Russia), plead guilty and in connection with schemes involving the bribery of government officials in Russia, Ukraine and Mexico in violation of the Foreign Corrupt Practices Act (FCPA).

Teva will pay $520 million to resolve the charges.

Teva was represented by Martin Weinstein of Willkie Farr & Gallagher and Mark Filip of Kirkland & Ellis in Washington, D.C.

"Teva and its subsidiaries paid millions of dollars in bribes to government officials in various countries, and intentionally failed to implement a system of internal controls that would prevent bribery," said Assistant Attorney General Leslie Caldwell. "Companies that compete fairly, ethically and honestly deserve a level playing field, and we will continue to prosecute those who undermine that goal."

The Department of Justice alleged that Teva executives and Teva Russia employees paid bribes to a high-ranking Russian government official intending to influence the official to use his authority to increase sales of Teva's multiple sclerosis drug, Copaxone, in annual drug purchase auctions held by the Russian Ministry of Health.

The corrupt arrangement occurred at the same time that the Russian government was seeking to reduce the amount spent on costly foreign pharmaceutical products, such as Copaxone.

Between 2010 and at least 2012, pursuant to an agreement with a repackaging and distribution company owned by the Russian government official, Teva earned more than $200 million in profits on Copaxone sales to the Russian government.

The Russian official earned approximately $65 million in corrupt profits through inflated profit margins granted to the official's company.

Teva also admitted to paying bribes to a senior government official within the Ukrainian Ministry of Health to influence the Ukrainian government's

approval of Teva drug registrations, which were necessary for the company to market and sell its products in the country.

Between 2001 and 2011, Teva engaged the official as the company's "registration consultant," paid him a monthly fee and provided him with travel and other things of value totaling approximately $200,000.

In exchange, the official used his official position and influence within the Ukrainian government to influence the registration in Ukraine of Teva pharmaceutical products, including Copaxone and insulins.

Teva admitted that it failed to implement an adequate system of internal accounting controls and failed to enforce the controls it had in place at its Mexican subsidiary, which allowed bribes to be paid by the subsidiary to doctors employed by the Mexican government. Teva admitted that its Mexican subsidiary had been bribing these doctors to prescribe Copaxone since at least 2005.

Teva executives in Israel responsible for the development of the company's anti-corruption compliance program in 2009 had been aware of the bribes paid to government doctors in Mexico.

Nevertheless, Teva executives approved policies and procedures that they knew were not sufficient to meet the risks posed by Teva's business and were not adequate to prevent or detect payments to foreign officials.

Teva also admitted that its executives put in place managers to oversee the compliance function who were unable or unwilling to enforce the anti-corruption policies that had been put in place.

Teva entered into a deferred prosecution agreement (DPA) in connection with a criminal information, filed today in the Southern District of Florida, charging the company with one count of conspiracy to violate the anti-bribery provisions of the FCPA and one count of failing to implement adequate internal controls.

Teva will pay a total criminal penalty of $283,177,348.

Teva also agreed to continue to cooperate with the department's investigation, enhance its compliance program, implement rigorous internal controls and retain an independent corporate compliance monitor for a term of three years.

Teva Russia has signed a plea agreement in which it has agreed to plead guilty to a one-count criminal information, also filed today in the Southern District of Florida, charging the company with conspiring to violate the anti-bribery provisions of the FCPA.

The case was assigned to U.S. District Judge Kathleen M. Williams of the Southern District of Florida and Teva Russia's initial court appearance has been scheduled for January 12, 2017.

The U.S. Securities and Exchange Commission (SEC) filed a cease and desist order against Teva, whereby the company agreed to pay approximately $236 million in disgorgement to the SEC, including prejudgment interest.

The combined total amount of U.S. criminal and regulatory penalties to be paid by Teva is nearly $520 million.

While Teva did not timely voluntarily self-disclose the conduct, it did cooperate with the department's investigation after the SEC served it with a subpoena.

Teva received a 20 percent discount off the low end of the U.S. Sentencing Guidelines fine range because of its substantial cooperation and remediation.

The company, however, did not receive full cooperation credit because of issues that resulted in delays to the early stages of the Fraud Section's investigation, including vastly overbroad assertions of attorney-client privilege and not producing documents on a timely basis in response to certain Fraud Section document requests.

Because many of the company's compliance enhancements were more recent, and therefore have not been tested, the deferred prosecution agreement imposes an independent compliance monitor for a term of three years.

HALF OF MULTINATIONALS FAILING TO PREVENT THIRD PARTY BRIBERY AND CORRUPTION

Nearly half (49%) of multinationals are failing to carry out basic bribery and corruption checks on third party contractors before starting to work with them, according to a new report from global law firm Hogan Lovells.

The report found that 47% of respondents are failing to carry out desktop due diligence, 44% don't ask third parties to complete a questionnaire, and the same proportion fail to conduct face to face interviews with third parties.

The results follow interviews with 604 chief compliance officers, heads of legal, and equivalent, based in the UK, U.S., Asia, France and Germany, at many of the world's largest multinational companies in four sectors – energy, minerals and resources, life sciences and healthcare, transport (including automotive and aviation), and technology, media and telecommunications.

"As companies expand overseas, there are good reasons to engage third parties – local know-how, connections to potential customers, and familiarity with the bureaucratic hurdles," said Crispin Rapinet, Global Head of Investigations, White Collar and Fraud at Hogan Lovells. "But it's a fine line to balance the commercial advantages against the risk that third parties pose to your organization, when they are acting in your name."

"If you don't have the right checks in place your company can be held liable if your third party bribes for your benefit. Regulators and enforcement agencies are sharpening their focus and corporates are increasingly facing enforcement actions such as criminal exposure for individuals and the company, and reputational damage."

TELECOM COMPANIES PAY $30 MILLION TO END LIFELINE FRAUD CASE

Three U.S.-based subsidiaries of the Japanese conglomerate KDDI will pay $30 million to settle charges that they defrauded a government program established to help low-income Americans.

The settlement resolves an action brought by Nelson J. Gomez, a whistleblower, under the False Claims Act.

Gomez was represented by Willens & Scarvalone.

The defendants are California-based telecom company Total Call Mobile, Inc., its parent company KDDI America, Inc., and sister company Locus Telecommunications.

In the lawsuit, Gomez claims that Total Call Mobile defrauded the FCC's "Lifeline" program that offers discounted mobile phone services to eligible low-income consumers.

A Lifeline provider, such as Total Call Mobile, may receive reimbursement from the FCC's Universal Service Fund for each Lifeline subscriber enrolled, but the provider is obligated to ensure that the subscriber qualifies under program rules aimed at preventing fraud.

Total Call Mobile falsely certified compliance with these program rules and received reimbursement for tens of thousands of ineligible consumers – reimbursement to which the company was not entitled under the law.

With the $30 million payment from defendants, Gomez's lawsuit is the largest recovery to the Government ever in a False Claims Act lawsuit involving one of the FCC's Universal Service Fund programs.

Resolution of the lawsuit also requires Total Call Mobile to be excluded from further participation in the Lifeline program, and resolves an FCC administrative action against the company.

Gomez expressed his appreciation for the efforts of the government's lawyers and investigators to stop the defendants' misconduct and recover millions for the taxpayers.

PACKAGED SEAFOOD EXEC TO PLEAD GUILTY TO PRICE-FIXING CONSPIRACY

The current senior vice president of trade marketing of a leading packaged seafood company will plead guilty for his role in a conspiracy to fix the prices of packaged seafood such as canned tuna sold in the United States.

Kenneth Worsham and his co-conspirators agreed to fix the prices of packaged seafood from as early as 2011 until about 2013.

In addition to his guilty plea, which is subject to court approval, Worsham has agreed to pay a criminal fine and cooperate with the division's ongoing investigation.

According to the charge, Worsham and his co-conspirators discussed the prices of packaged seafood sold in the United States and agreed to fix the prices of those products.

The defendant and his co-conspirators negotiated prices and issued price announcements for packaged seafood in accordance with the agreements they reached.

ODEBRECHT AND BRASKEM TO PLEAD GUILTY TO MASSIVE BRIBERY SCHEME AND PAY RECORD $3.5 BILLION

Odebrecht S.A. (Odebrecht), a global construction conglomerate based in Brazil, and Braskem S.A. (Braskem), a Brazilian petrochemical company, pled guilty and will pay a combined total penalty of at least $3.5 billion to resolve charges with authorities in the United States, Brazil and Switzerland arising out of their schemes to pay hundreds of millions of dollars in bribes to government officials around the world.

Odebrecht was represented by William Burk, Richard Smith and Eric Lyttle of Quinn Emanuel in Washington, D.C.

Braskem was represented by Joan Meyer and John Rowley of Baker & McKenzie and John Darden and Robert Luskin of Paul Hastings in Washington DC.

"Odebrecht and Braskem used a hidden but fully functioning Odebrecht business unit – a 'Department of Bribery,' so to speak – that systematically paid hundreds of millions of dollars to corrupt government officials in countries on three continents," said Deputy Assistant Attorney General Sung-Hee Suh. "Such brazen wrongdoing calls for a strong response from law enforcement, and through a strong effort with our colleagues in Brazil and Switzerland, we have seen just that. I hope that today's action will serve as a model for future efforts."

Odebrecht pled guilty to a one-count criminal information charging the company with conspiracy to violate the anti-bribery provisions of the Foreign Corrupt Practices Act (FCPA).

The Justice Department said that Odebrecht agreed that the appropriate criminal fine is $4.5 billion, subject to further analysis of the company's ability to pay the total global penalties.

Odebrecht also settled with the Ministerio Publico Federal in Brazil and the Office of the Attorney General in Switzerland.

Under the plea agreement, the United States will credit the amount that Odebrecht pays to Brazil and Switzerland over the full term of their respective agreements, with the United States and Switzerland receiving 10 percent each of the principal of the total criminal fine and Brazil receiving the remaining 80 percent.

The fine is subject to an inability to pay analysis to be completed by the Department of Justice and Brazilian authorities on or before March 31, 2017, because Odebrecht has represented it is only able to pay approximately $2.6 billion over the course of the respective agreements.

Sentencing has been scheduled for April 17, 2017.

Braskem separately pled guilty to a one-count criminal information charging it with conspiracy to violate the anti-bribery provisions of the FCPA.

Braskem will pay a total criminal penalty of $632 million.

Sentencing has not yet been scheduled.

Braskem also settled with the U.S. Securities and Exchange Commission (SEC), the Ministerio Publico Federal in Brazil and the Office of the Attorney General in Switzerland.

Under the terms of its resolution with the SEC, Braskem agreed to a total of $325 million in disgorgement of profits.

Braskem will pay Brazilian authorities 70 percent of the total criminal penalty and agreed to pay the Swiss authorities 15 percent.

The department has agreed to credit the criminal penalties paid to Brazilian and Swiss authorities as part of its agreement with the company.

The United States will receive $94.8 million, an amount equal to 15 percent of the total criminal fines paid by Braskem.

Under their respective plea agreements, Odebrecht and Braskem are required to continue their cooperation with law enforcement, including in connection with the investigations and prosecutions of individuals responsible for the criminal conduct.

Odebrecht and Braskem also agreed to adopt enhanced compliance procedures and to retain independent compliance monitors for three years.

With a combined total of at least $3.5 billion, today's resolutions with Odebrecht and Braskem are the largest-ever global foreign bribery resolution.

Odebrecht engaged in a massive and unparalleled bribery and bid-rigging scheme for more than a decade, beginning as early as 2001.

During that time, Odebrecht paid approximately $788 million in bribes to government officials, their

representatives and political parties in a number of countries in order to win business in those countries.

The criminal conduct was directed by the highest levels of the company, with the bribes paid through a complex network of shell companies, off-book transactions and off-shore bank accounts.

Odebrecht and its co-conspirators created and funded an elaborate, secret financial structure within the company that operated to account for and disburse bribe payments to foreign government officials and political parties.

By 2006, the development and operation of this secret financial structure had evolved such that Odebrecht established the "Division of Structured Operations," which effectively functioned as a stand-alone bribe department within Odebrecht and its related entities.

Until approximately 2009, the head of the Division of Structured Operations reported to the highest levels within Odebrecht, including to obtain authorization to approve bribe payments.

After 2009, this responsibility was delegated to certain company business leaders in Brazil and the other jurisdictions.

To conceal its activities, the Division of Structured Operations utilized an entirely separate and off-book communications system, which allowed members of the Division of Structured Operations to communicate with one another and with outside financial operators and other co-conspirators about the bribes via secure emails and instant messages, using codenames and passwords.

The Division of Structured Operations managed the "shadow" budget for the Odebrecht bribery operation via a separate computer system that was used to request and process bribe payments as well as to generate and populate spreadsheets that tracked and internally accounted for the shadow budget.

These funds for the company's sophisticated bribery operation were generated by the Odebrecht Finance Department through a variety of methods, as well as by certain Odebrecht subsidiaries, including Braskem.

The funds were then funneled by the Division of Structured Operations to a series of off-shore entities that were not included on Odebrecht's balance sheet as related entities.

The Division of Structured Operations then directed the disbursement of the funds from the off-shore entities to the bribe recipient, through the use of wire transfers through one or more of the off-shore entities, as well as through cash payments both inside and outside Brazil, which were sometimes delivered using packages or suitcases left at predetermined locations.

Odebrecht, its employees and agents took a number of steps while in the United States to further the scheme.

For instance, in 2014 and 2015, while located in Miami, two Odebrecht employees engaged in conduct related to certain projects in furtherance of the scheme, including meetings with other co-conspirators to plan actions to be taken in connection with the Division of Structured Operations, the movement of criminal proceeds and other criminal conduct. In addition, some of the off-shore entities used by the Division of Structured Operations to hold and disburse unrecorded funds were established, owned and/or operated by individuals located in the United States. In all, this conduct resulted in corrupt payments and/or profits totaling approximately $3.336 billion.

Braskem also admitted to engaging in a wide-ranging bribery scheme and acknowledged the pervasiveness of its conduct.

Between 2006 and 2014, Braskem paid approximately $250 million into Odebrecht's secret, off-book bribe payment system.

Using the Odebrecht system, Braskem authorized the payment of bribes to politicians and political parties in Brazil, as well as to an official at Petróleo Brasileiro S.A. – Petrobras (Petrobras), the state-controlled oil company of Brazil.

In exchange, Braskem received various benefits, including: preferential rates from Petrobras for the purchase of raw materials used by the company; contracts with Petrobras; and favorable legislation and government programs that reduced the company's tax liabilities in Brazil. This conduct resulted in corrupt payments and/or profits totaling approximately $465 million.

The Department of Justice said it reached these resolutions with Odebrecht and Braskem based on a number of factors, including – the failure to voluntarily disclose the conduct that triggered the investigation, the nature and seriousness of the offense, which spanned many years, involved the highest levels of the companies, occurred in

multiple countries and involved sophisticated schemes to bribe high-level government officials, the lack of an effective compliance and ethics program at the time of the conduct, and credit for each company's respective cooperation.

The companies also engaged in remedial measures, including terminating and disciplining individuals who participated in the misconduct, adopting heightened controls and anti-corruption compliance protocols and significantly increasing the resources devoted to compliance.

The criminal penalty for Odebrecht reflects a 25 percent reduction off the bottom of the U.S. Sentencing Guidelines fine range because of Odebrecht's full cooperation with the government's investigation, while the criminal penalty for Braskem reflects a 15 percent reduction off the bottom of the U.S. Sentencing Guidelines as a result of its partial cooperation.

VOLKSWAGEN TO RECALL 83,000 VEHICLES

Automakers Volkswagen AG, Audi AG, Porsche AG and related entities (collectively referred to as Volkswagen), will recall 83,000 model year 2009 through 2016 3.0 liter diesel vehicles sold or leased in the U.S. that are alleged to be equipped with "defeat devices" to cheat emissions tests, in violation of the Clean Air Act and California law.

For the older vehicles, Volkswagen is required to offer to buy back the vehicles or terminate leases, and must also offer an emissions modification to substantially reduce emissions if one is proposed by Volkswagen and approved by regulators. For the newer vehicles, if Volkswagen demonstrates it can make the vehicles compliant with the certified exhaust emission standards, it will have to fix the vehicles and will not be required to buy the vehicles back. Volkswagen is also required to spend $225 million to fund projects that will reduce emissions of nitrogen oxide (NOx).

The partial settlement does not resolve any pending claims for civil penalties, nor does it address any potential criminal liability.

The settlement also does not resolve any consumer claims, claims by the Federal Trade Commission or claims by individual owners or lessees who may have asserted claims in the ongoing multidistrict litigation.

The state of California has secured a separate resolution for the 3.0 liter violations that addresses issues specific to vehicles and consumers in California.

The affected older vehicles (referred to as "generation 1" vehicles) are the 2009 through 2012 Volkswagen Touareg and Audi Q7 diesel models.

The affected newer vehicles (referred to as "generation 2" vehicles) are the 2013-2016 Volkswagen Touareg diesels, 2013 through 2015 Audi Q7 diesels, 2013 through 2016 Porsche Cayenne diesels and 2014 through 2016 Audi A6 quattro, A7 quattro, A8, A8L and Q5 diesel models.

"The settlement marks another significant step in holding Volkswagen accountable for cheating Americans out of the promise of cleaner air by selling vehicles equipped with defeat devices," said Assistant Attorney General John C. Cruden. "This consent decree provides a remedy for every affected vehicle which will be removed from the road or meet enforceable standards that will reduce emissions, and will also require VW to provide additional funding to address the harmful impacts to human health and the environment from VW's violations."

According to the civil complaint against Volkswagen filed by the Justice Department on behalf of EPA on Jan. 4, 2016, and amended on Oct. 7, 2016, Volkswagen allegedly equipped its 3.0 liter diesel vehicles with illegal software that detects when the car is being tested for compliance with EPA or California emissions standards and turns on required emissions controls only during that testing process.

During normal driving conditions, the software renders these emissions control systems inoperative or reduces their effectiveness, resulting in increased emissions. This is known as a defeat device.

By using a defeat device, these cars meet emissions standards in the laboratory, but emit up to nine times or more above the EPA-compliant levels for NOx during normal on-road driving conditions.

The Clean Air Act requires manufacturers to certify to EPA that vehicles will meet federal emissions standards. Vehicles with defeat devices cannot be certified.

Because Volkswagen cannot modify the affected 2009 through 2012 Volkswagen Touareg

and Audi Q7 generation 1 diesel vehicles to meet EPA-certified exhaust emissions standards, the settlement requires Volkswagen to offer owners of generation 1 vehicles the option to have the company buy back the car and to offer lessees a lease cancellation at no cost.

If a plan is proposed by Volkswagen and approved by EPA and CARB to substantially reduce emissions from the generation 1 vehicles, Volkswagen will also have to offer that as an option for consumers.

For the generation 2 vehicles, Volkswagen will recall and fix these vehicles so they meet their certified exhaust emissions standards, after the technical solution is approved by regulators. If after extensive testing the solution does not perform as expected and is not approved, Volkswagen must offer to buy back the vehicles.

In that case, the company can also seek approval of an emissions modification plan to substantially reduce emissions and, if approved, can offer that as an additional option for generation 2 vehicles.

Under the terms of the settlement, Volkswagen must achieve an overall recall rate of at least 85 percent for each of the generation 1 and generation 2 vehicles recall programs or pay additional sums into the mitigation trust fund.

The buyback and lease termination program for generation 1 vehicles will begin within 30 days following court approval of the settlement. Vehicle modifications will become available to eligible owners and lessees once the modifications are approved by regulators.

The settlement requires Volkswagen to pay $225 million to fund projects across the country that will reduce emissions of NOx where the 3.0 liter vehicles were, are or will be operated.

This funding is intended to fully mitigate the past and future NOx emissions from the 3.0 liter vehicles.

That money will be placed in the same mitigation trust to be established under the partial settlement for the 2L vehicles.

This $225 million is in addition to the $2.7 billion that Volkswagen is required to pay into that trust under the prior settlement.

The mitigation trust will be administered by an independent trustee. Beneficiaries, which may include states, Puerto Rico, the District of Columbia and Indian tribes, may obtain funds for designated NOx reduction projects upon application to the trustee.

The emissions reduction program will help reduce NOx pollution that contributes to the formation of harmful smog and soot, exposure to which is linked to a number of respiratory- and cardiovascular-related health effects as well as premature death.

Children, older adults, people who are active outdoors (including outdoor workers) and people with heart or lung disease are particularly at risk for health effects related to smog or soot exposure. NO2 formed by NOx emissions can aggravate respiratory diseases, particularly asthma, and may also contribute to asthma development in children.

COMPANY SETTLES CHARGES IN WHISTLEBLOWER RETALIATION CASE

An oil-and-gas company has agreed to settle charges that it used illegal separation agreements and retaliated against a whistleblower who expressed concerns internally about how its reserves were being calculated.

A Securities and Exchange Commission (SEC) order found that Oklahoma City-based SandRidge Energy conducted multiple reviews of its separation agreements after a new whistleblower protection rule became effective in August 2011, yet continued to regularly use restrictive language that prohibited outgoing employees from participating in any government investigation or disclosing information potentially harmful or embarrassing to the company.

The SEC's order further finds that SandRidge fired an internal whistleblower who kept raising concerns about the process used by SandRidge to calculate its publicly reported oil-and-gas reserves.

The employee had been offered a promotion, which was turned down. Just months later, senior management concluded the employee was disruptive and could be replaced with someone "who could do the work without creating all the internal strife." The company had conducted no substantial investigation of the whistleblower's concerns and only initiated an internal audit that was never completed. The employee's separation agreement also contained the company's prohibitive language that violated the whistleblower protection

rule.

"Ignoring a rule that protects communications between outgoing employees and the SEC, SandRidge flatly prohibited such contact in their separation agreements and at the same time retaliated against an employee who raised concerns about the company to its management," said Shamoil T. Shipchandler, Director of the SEC's Fort Worth Regional Office.

Without admitting or denying the SEC's findings, SandRidge agreed to pay a penalty of $1.4 million, subject to the company's bankruptcy plan.

MORGAN STANLEY TO PAY $7.5 MILLION TO SETTLE SEC CHARGES

Morgan Stanley will pay $7.5 million to settle charges it used trades involving customer cash to lower the firm's borrowing costs in violation of the Securities and Exchange Commission's Customer Protection Rule.

The Customer Protection Rule is intended to safeguard customers' cash and securities so that they can be promptly returned should the broker-dealer fail.

The SEC order finds that from March 2013 to May 2015, Morgan Stanley's U.S. broker-dealer used transactions with an affiliate to reduce the amount it was required to deposit in its customer reserve account.

According to the order, the transactions violated the Customer Protection Rule, which prohibits broker-dealers from using affiliates to reduce their customer reserve account deposit requirements.

"The Customer Protection Rule establishes crucial safeguards for investors to ensure that their cash and securities are secure when held by a broker-dealer," said Michael J. Osnato, Chief of the SEC Enforcement Division's Complex Financial Instruments Unit. "Complex trading schemes designed to artificially reduce the amount a broker-dealer must maintain in its customer reserve account run contrary to these basic obligations."

According to the SEC's order, Morgan Stanley had its affiliate, Morgan Stanley Equity Financing Ltd., serve as a customer of its U.S. broker-dealer, a relationship that allowed the affiliate to use margin loans from the U.S. broker-dealer to finance the costs of hedging swap trades with customers.

The margin loans lowered the borrowing costs incurred to hedge these swap trades and reduced the U.S. broker-dealer's customer reserve account deposit requirements by tens to hundreds of millions of dollars per day.

The SEC order finds that Morgan Stanley's affiliated transactions violated the Customer Protection Rule and that as a result of inaccurately calculating its customer reserve account requirements, it submitted inaccurate reports to the SEC.

Morgan Stanley provided substantial cooperation during the SEC's investigation and has agreed to review its compliance with the Customer Protection Rule and to take remedial steps to improve its calculation processes. Morgan Stanley also significantly increased the amount of excess funds it maintains in its customer reserve account.

Without admitting or denying the findings, Morgan Stanley agreed to pay a $7.5 million civil penalty, to cease and desist from committing or causing any similar violations in the future, and to be censured.

NEUSTAR SETTLES SEC WHISTLEBLOWER CHARGES

Neustar will pay $180,000 to settle charges involving its severance agreements that impeded at least one former employee from communicating information to the Securities and Exchange Commission (SEC).

The SEC's order finds NeuStar violated a whistleblower protection rule in the federal securities laws by routinely entering into severance agreements that contained a broad non-disparagement clause forbidding former employees from engaging with the SEC and other regulators "in any communication that disparages, denigrates, maligns or impugns" the company. Former employees could be compelled to forfeit all but $100 of their severance pay for breaching the clause.

These severance agreements were used with at least 246 departing employees from Aug. 12, 2011 to May 21, 2015.

NeuStar, which voluntarily revised its severance agreements promptly after the SEC began investigating, consented to the SEC's cease-and-desist order without admitting or denying the findings.

The company agreed to make reasonable efforts to inform those who signed the severance

agreements that NeuStar does not prohibit former employees from communicating any concerns about potential violations of law or regulation to the SEC.

"Public companies cannot use severance agreements to impede whistleblowers from communicating with the SEC about a possible securities law violation," said Antonia Chion, Associate Director of the SEC's Enforcement Division. "NeuStar's severance agreements broadly prohibited former employees from communicating any disparaging information about the company to the SEC, and unsurprisingly at least one former NeuStar employee was chilled by such language."

FOREST LABS TO PAY $38 MILLION TO SETTLE FALSE CLAIMS CASE

Forest Laboratories, and its subsidiary, Forest Pharmaceuticals Inc., will pay $38 million to resolve allegations that they violated the False Claims Act by paying kickbacks to induce physicians to prescribe the drugs Bystolic, Savella, and Namenda.

The settlement resolves allegations that Forest violated the Anti-Kickback Statute, which prohibits the payment of remuneration to induce referrals of items or services covered by federal healthcare programs, by providing payments and meals to certain physicians in connection with speaker programs about Bystolic, Savella, or Namenda.

Federal officials alleged that the payments and meals were intended as improper inducements because Forest provided these benefits even when the programs were cancelled – and Forest provided no evidence of a bona fide reason for the cancellation – when no licensed health care professionals attended the programs, when the same attendees had attended multiple programs over a short period of time, or when the meals associated with the programs exceeded Forest's internal cost limitations.

The settlement resolves allegations filed in a lawsuit by former Forest employee Kurt Kroening, in federal court in Milwaukee, Wisconsin.

The lawsuit was filed under the qui tam, or whistleblower, provisions of the False Claims Act, which permit private individuals to sue on behalf of the government for false claims and to share in any recovery.

Kroening will receive approximately $7.8 million.

DEUTSCHE BANK TO PAY $37 MILLION TO SETTLE FRAUD CHARGES

Deutsche Bank will pay $37 million to settle charges that it misled clients about the performance of a core feature of its automated order router that primarily sent client orders to dark pools.

Deutsche Bank admitted wrongdoing.

Deutsche Bank was represented by Charles Gilman at Cahill Gordon in New York.

"Deutsche Bank claimed to be using ongoing data analysis to rank the dark pools best suited for customer orders when in reality its system failed to actually do this analysis. When broker-dealers tout their material products and methodologies, their statements must be accurate," said Andrew Ceresney, Director of the SEC's Enforcement Division.

According to charges brought by the Securities and Exchange Commission and the New York Attorney General's office, Deutsche Bank made materially misleading statements and omissions concerning the Dark Pool Ranking Model feature of one of its order routers, known as SuperX+.

The Dark Pool Ranking Model was intended to measure execution quality and liquidity of venues to which it sent orders.

Deutsche Bank used the Dark Pool Ranking Model to determine which venues would receive orders and the sequence in which Deutsche Bank would send them.

Deutsche Bank described this model in its disclosures to clients and potential clients as the "quantitative core" of SuperX+, stating that it "smartly routes and selects optimal pools of liquidity on an order by order basis."

But the SEC's order finds that due to a coding error, Deutsche Bank updated the ranking model just once during a two-year period, causing at least two dark pools to receive inflated rankings and consequently millions of orders that SuperX+ would have sent elsewhere if the system was operating the way Deutsche Bank had described.

The SEC's order also finds that Deutsche Bank manually overrode the rankings on certain occasions and manually assigned fill rates for new venues based on subjective judgment that that turned out to be inconsistent with the venues' actual performance.

BUMBLE BEE EXECUTIVE PLEADS GUILTY

The current Bumble Bee senior vice president of sales will plead guilty for his role in a conspiracy to fix the prices of packaged seafood such as canned tuna sold in the United States.

Federal officials alleged that Walter Scott Cameron and his co-conspirators agreed to fix the prices of packaged seafood from as early as 2011 until about 2013.

In addition to his guilty plea, which is subject to court approval, Cameron has agreed to pay a criminal fine and cooperate with the division's ongoing investigation.

Federal officials alleged that Cameron and his co-conspirators discussed the prices of packaged seafood sold in the United States and agreed to fix the prices of those products.

The defendant and his co-conspirators negotiated prices and issued price announcements for packaged seafood in accordance with the agreements they reached.

"The admission of guilt will raise even more concerns about the allegations in civil lawsuits that Bumble Bee, StarKist, and Chicken of the Sea–the three largest U.S. tuna brands–colluded to block sustainable tuna options from being made available to U.S. consumers." said Greenpeace campaigner David Pinsky.

INTERVIEW WITH PAMELA COYLE BRECHT, PARTNER, PIETRAGALLO, PHILADELPHIA, PENNSYLVANIA

In 2014, the federal government reported that government auditors had recovered only $10 million of an estimated $1.9 billion in annual improper payments in the Medicare Part D prescription drug benefit program.

One reason for the low recovery rate? Insufficient investigative resources.

But help is on the way.

Conscientious employees inside the Part D program -- at insurance companies, pharmacies and pharmacy benefit managers -- are learning about the False Claims Act.

And that means an increased rate of recovery in the years to come.

Pamela Coyle Brecht is a partner at Pietragallo, Gordon, Alfano, Bosick & Raspanti in Philadelphia.

We interviewed Brecht on December 20, 2016.

CCR: You graduated in 1991 from Temple Law School. What have you been doing since?

BRECHT: After law school, I did a one year clerkship for a Pennsylvania appellate court judge. I then worked for my father -- William Coyle -- in his law practice for about a year. It had been my childhood dream to practice with my father. He had a general litigation practice. He has since retired.

I determined after about a year of practice with my father that, to save my relationship with my father, I was going to go out on my own. I opened my own law practice. I had a general litigation practice in Philadelphia for about eight to ten years. During that time, I had four children. So, life was a little busy.

After my fourth child was born, I decided that I liked spending time with my children more than I liked working eighty hours a week at my law practice. I stayed home for about nine months. I then started working for a law school classmate as a contract lawyer. I worked for another qui tam lawyer -- Brian Kenney -- for about two or three years. I then met Marc Raspanti at a conference. I convinced Marc to give me an interview. I worked as a contract lawyer for Marc Raspanti for about seven years. I became an employee in 2013 and a partner in mid 2014.

CCR: What is your practice?

BRECHT: It's a qui tam practice. But I also do some white collar criminal defense work representing third party witnesses in government investigations. It's about 90 percent qui tam relators practice.

CCR: Is Pietragallo primarily qui tam?

BRECHT: Not at all. We are a national litigation firm. We do products liability, intellectual property. Our main office is in Pittsburgh. We have national corporate clients like Smith & Wesson and Honda.

In Philadelphia we do mostly health care work and employment work.

CCR: Is the firm primarily plaintiffs' side?

BRECHT: No it's not. It's about 50/50.

CCR: The large corporate firms don't touch qui tam, right?

BRECHT: There are some defense firms who do class actions. There are some large firms that have the one off plaintiffs qui tam case. There are corporations now that are filing qui tams against competitors. So, you may have those kinds of cases in the big firms. But predominantly you are correct. The large white collar defense firms in DC tend to

do just defense. But there are other large firms that have moved into the qui tam space.

CCR: Is your qui tam practice primarily health care?

BRECHT: My personal practice yes, but the firm does defense, food supply -- across the board.

CCR: Is the firm primarily on the plaintiffs side of the False Claims Act?

BRECHT: Yes. On occasion, if we have a long time client who has a defense matter, we might do that. But we do represent witnesses in qui tam cases who are the subjects of federal investigations -- not as direct defendants now, but as third parties or witnesses.

CCR: You also have a sub speciality -- Medicare Part D.

BRECHT: When Medicare Part D was a couple of years old, the firm had a long time client who was a pharmacy auditor. He brought a qui tam case to the firm. I spent several years studying the Part D program.

We have one of the first reported Part D cases. The opinion came out four years ago today -- December 20, 2012. It's called *Spay v. CVS Caremark*. It was the first reported case that discussed how the Part D program works. The trial court opinion was 100 pages long. It denied the defendant's motion to dismiss on all counts.

CCR: Where is that case now?

BRECHT: We made it through the motion to dismiss into discovery. There were summary judgment motions filed on both sides. That decision came down in favor of CVS Caremark and is currently on appeal. It's currently before the Third Circuit. Oral arguments were heard just last month.

CCR: Give us Part D in a nutshell.

BRECHT: Part D is a federal prescription benefit program that is available as an add on to any Medicare beneficiary to pay for outpatient prescription drug costs.

If you get Medicare, you automatically get Parts A and B. You can add on Part D to get prescription as well.

CCR: Part D and Part C -- Medicare Advantage -- are private. You have to opt in. Why would you choose one or the other or both?

BRECHT: Medicare Advantage covers your hospitalization and doctors. Part D is the add on prescription plan. Part D is a privatization of the prescription drug benefit. Private insurance companies get money in advance. With that money, they are supposed to contribute to your prescription drug benefits. They are also supposed to help control prescription drug costs by making sure the beneficiaries get negotiated prices. They are also supposed to contract with a prescription benefit manager. And the regulations set out some of the terms that contract must include. Most people don't realize that the central player in the Part D program is the pharmacy benefit manager or the PBM.

CCR: Barebones Medicare coverage without opting into Part D -- does it cover any prescription drugs?

BRECHT: It covers prescription drugs you would receive in an inpatient setting -- like in a hospital.

CCR: If I go to my family doctor and the doctor says -- you need this prescription drug.

BRECHT: That is not covered unless you have purchased Part D coverage.

CCR: When did Part D pass?

BRECHT: It passed in 2003 but became effective January 1, 2006.

CCR: Before Part D passed, there was no prescription drug coverage for outpatient care?

BRECHT: If you were on disability yes. If you were a Medicaid beneficiary, yes.

CCR: Why do you see the pharmacy benefit manager as the key playcr?

BRECHT: The pharmacy benefit manager handles every prescription that is dispensed. When you go to the pharmacy, the pharmacy takes your prescription. Each insurance company contracts with the pharmacy benefit manager to handle the exchange with the pharmacy.

CCR: Why don't they handle it themselves?

BRECHT: The pharmacy benefit industry grew up handling these claims. More people take drugs than go to the hospital.

CCR: The insurance companies were incapable of doing this themselves?

BRECHT: The PBM industry grew up before Part D. They were communicating with the pharmacies. They were communicating back to the pharmacy -- saying yes, this person has coverage, this is what their co-payment should be. The pharmacy makes a claim to the PBM and the PBM makes sure all of these pharmacies get paid.

CCR: How many Medicare patients have a prescription drug benefit?

BRECHT: About 41 million of the 57 million people on Medicare are enrolled in a Part D plan in 2016. About 60 percent are in Part D plans but about 40 percent are in what are called MA-PD

plans. These people are enrolled in Medicare Advantage Plans and elect coverage through a Medicare Advantage Part D (MAPD) plan.

CCR: How much fraud is there in the Medicare Part D program?

BRECHT: In 2011, the Centers for Medicare and Medicaid Services reported that the Part D error rate -- the amount of improper payments -- was a about 3.2 percent. That would be $1.68 billion. In 2015, CMS reported that the Part D error rate was 3.1 percent -- or $1.6 billion. Improper payments would include fraud, but other types of waste.

I don't know how much of that improper payment is straight out fraud. But there is an August 2015 GAO report where they talk about Part D auditors -- RACs. That stands for regional auditor contractor. They are supposed to data mine and determine where the improper payments to the Part D program are coming from. That is CMS' internal method of finding fraud.

In 2014, the RAC auditors recovered only $10 million of an estimated $1.9 billion in annual improper payments. The rest of that $1.9 billion was not recovered.

The recoveries through whistleblowers are much higher than these internal audits. One of the reasons is that CMS doesn't have the resources to hire enough auditors to audit all of these claims. CMS doesn't know what it doesn't know. Unless you are inside these contractors, you would have no way of knowing.

CCR: Why isn't there a lot more whistleblowing -- given the extent of the crisis?

BRECHT: There is whistleblowing going on. There are not that many Part D cases yet.

Who are the actors in the Part D program? You have the insurance company. The insurance company contracts with the pharmacy benefit manager -- which actually provides the pharmacy benefit service. That benefit includes not just the pill, but those bundles of services that go with it. Someone has to dispense the pill, but also make sure that the medical care is being taken care of -- that the person has a prescription, that the drug is proper for this person, that there is no gender contraindications, that it is not going to interact with other drugs they are taking, that they didn't get the same prescription filled at another pharmacy yesterday.

All those services are handled through the pharmacy benefit manager. The pharmacy benefit manager contracts with the pharmacies on behalf of the sponsors -- the insurance companies.

CMS has looked into Part D at the pharmacy level. There have been some newsworthy cases of the government conducting stings at pharmacies to prevent Part D drugs from ending up on the black market. There was some attention being paid to that level of fraud. But little attention is paid to the pharmacy benefit managers.

CCR: Who are the big PBM companies?

BRECHT: Express Scripts, CVS Caremark, and United Health.

CCR: Give us an example of a whistleblower PBM case.

BRECHT: Our case is on appeal, so I hesitate to speak about it in detail. But there really haven't been that many.

CCR: Why aren't the whistleblowers coming out of these PBM companies?

BRECHT: There are only a few major PBMs and people value their jobs. You don't want to be knocked out of the marketplace. Our whistleblower happened to have his own business where he actually audited PBMs. Because they are so powerful, there really aren't any PBM sponsors who can take on the PBMs. It's a powerful player in the Part D program.

You and I don't know what cases are currently under seal.

CCR: Do you sense that we will be hearing more about these cases?

BRECHT: I do because there has been a lot of focus on drug prices. One of the issues that we had in our CVS Caremark case was whether a Part D sponsor has to provide a negotiated price. And the question became -- what is that price? A sponsor has an obligation to pass on negotiated prices to the beneficiaries.

In Medicaid the government is entitled to the best price. Perhaps that will be coming into Part D -- I don't know. But there is a lot of focus on prescription drug prices right now.

Who would know whether the patient is getting the negotiated price? Only if you know what the contract says and also what is the price charged by the pharmacy would you know whether the patient is getting the negotiated price.

CCR: Doesn't the complexity of the system lead to fraud?

BRECHT: The key to the Part D program? The insurance company sponsors have to make certain

promises to the government. For every drug dispensed, the insurance company sponsor has to submit what is called a PDE -- prescription drug event. And that data has to be true, accurate and complete to the best of the sponsor's ability.

But there is another set of promises made by the pharmacy benefit managers. They help create the PDE claims. They have to certify that they are true, accurate and complete. And the cost of Medicare drugs is part of the PDE. In exchange for getting the money, the major players are supposed to submit true, accurate and complete information to the government.

There haven't been many challenges to the truth of those PDE claims. Unless you can see what the pharmacy is dispensing and can compare it to the PDE submitted to the government, you wouldn't know whether those are true, accurate and complete.

That's why there are very few Part D False Claims Act cases that deal with the sponsor or the PBM. There are more cases brought against pharmacy fraud -- that controlled substances are being dispensed without a prescription -- that kind of thing. It's easier to know about that.

CCR: There is a lot of fraud and little enforcement?

BRECHT: Correct. There is not very much transparency at the PBM area at all. And you have to remember that Part D came into existence January 1, 2006. It takes a long time for a False Claims Act to percolate out from under seal and then get to the motion to dismiss stage.

CCR: Let's talk a bit about the Spay case. Who was Anthony Spay?

BRECHT: He was a pharmacy auditor. He then started doing PMB audits for Part D plans. He's our client. He alleged that the PBMs were submitting PDE claims to CMS that had dummy or fake prescriber numbers in them.

CCR: That case is on appeal. When do you expect a decision?

BRECHT: It might be in the spring 2017.

CCR: Do you know of other similar cases against PBM?

BRECHT: I know of no others. There have been cases against PBMs. I don't know where they are in the pipeline.

CCR: Do you anticipate more such cases?

BRECHT: Yes. It took years for the average wholesale price cases in the Medicaid space to work through the system. When folks who are working at PBMs or working for sponsors and they know of things that are going on at the PBM level that are not appropriate, when those folks start speaking out, we are going to see more cases.

Under Part D, the government makes an advance per member per month payment to the Part D plan. What does the Part D plan submit to the government to get that payment? They submit a bid. The bids are very complex. Understanding whether appropriate information is being submitted in those bids is one type of conduct that could lead to Part D fraud.

The second time a payment is made is when the beneficiary comes into the pharmacy and the prescription is paid for. There is an opportunity for pharmacy fraud there.

Or if you are not providing all of the goods and services that you must provide as a sponsor, it's an opportunity for sponsor fraud -- insurance company fraud. Are you doing the drug utilization reviews? Are you checking for drug to drug interactions? OIG is looking at that now.

Once the beneficiary leaves the pharmacy, the PBM and the pharmacy have all of this data. They have to submit a PDE for every one of those claims. And when you are creating that PDE, it's another opportunity for fraud. PDEs get batched together and sent to CMS. CMS can either accept or reject them.

At the end of the year, every PDE is resubmitted to CMS during something called reconciliation. The reconciliation is when the sponsor says to the government -- I spent less than what I thought I was going to spend, and I have to pay you money back -- or I spent more than I thought I was going to spend -- and the government has to pay the money back.

CCR: Are we going to see in the new year a direct confrontation between whistleblowers and the PBM industry?

BRECHT: I don't know whether there will be a confrontation. Folks who work for PBMs are going to start to come forward as these other cases come to light. In most of the cases, whistleblowers try to work out their issues with their employers. They tend to be loyal folks. As the whistleblowers start to see the government's interest in the PBMs, as they try to right wrongs, they might start to come forward. But first there will be some publicity about actions against PBMs.

[Contact: Pamela Coyle Brecht, Pietragallo Gordon Alfano Bosick & Raspanti, 1818 Market St., Suite 3402, Philadelphia, Pennsylvania 19103. Phone 215 988 1444. Email: pcb@pietragallo.com]