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RX COMPLIANCE REPORT

EXCLUSIVELY DEVOTED TO PHARMACEUTICAL SALES AND MARKETING COMPLIANCE

Government's off-label case against Stryker-Biotech unravels at trial; 13 felony counts reduced to single misdemeanor plea

Defense reveals DOJ failed to interview surgeons allegedly duped by Stryker Biotech

Last month, federal prosecutors walked into federal court with 13 felony charges against Stryker Biotech Corporation and six against its former national sales director and two former regional managers. The Justice Department alleged an illegal off-label promotion scheme designed to enrich both the company and the individual defendants. The case was expected to last two months and the government planned to call 74 witnesses. But before the government had finished direct examination of its first witness the case that it had spent several years constructing had essentially collapsed in the face of a vigorous defense by Stryker Biotech's defense team.

On January 18, the trial that had started in a packed courtroom just a week earlier quietly ended when federal prosecutors dismissed all charges against the three individuals and settled for a single misdemeanor plea and a fine of $15 million from Stryker Biotech, a fraction of the total sales at issue. "It was a remarkable turn of events in a case that has been going on since 2008," says **Joshua Levy**, a partner with Ropes & Gray, which represented Stryker Biotech, a subsidiary of Stryker Corporation.

In many respects, the prosecution of Stryker Biotech represents the first *bona fide* off-label case against a pharmaceutical or medical device company to go to trial since the government's enforcement initiative in those two sectors started in earnest roughly a decade ago.

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Janssen settles wide-ranging Texas off-label suit for $158 million

Last month, Janssen agreed to pay $158 million to settle claims brought by the state of Texas in 2004 that it fraudulently marketed its antipsychotic drug Risperdal over a period of 12 years. Johnson & Johnson and its subsidiary, Janssen, agreed to the settlement halfway through a four-week trial. The lawsuit brought by the Texas Attorney General, which sought $579 million in damages, alleged a wide-ranging and systemic off-label scheme that started even before the drug was approved in 1994.

While the settlement falls short of initial expectations, it marks the first time Janssen has agreed to resolve any claims related to Risperdal. It also represents the largest Texas Medicaid fraud settlement in history. "It is the biggest Texas Medicaid fraud settlement by almost a factor of two," says plaintiff's attorney **Thomas Melsheimer**.

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DOJ's off-label case against Stryker-Biotech unravels at trial; 13 felony counts reduced to single misdemeanor plea

The stakes could hardly have been any higher for Stryker Biotech and the three individual defendants. The company faced mandatory exclusion from federal healthcare programs if convicted and the individual defendants faced exclusion, as well as potentially lengthy prison sentences.

"The core of the government's allegations centered on alleged off-label promotion and the concealment of adverse events," says WilmerHale's **Brent Gurney**, who represented David Ard, one of the regional managers. "The government tried to turn it into a fraud case," he says, "but that square would not fit in that circle."

"The mistake they made in this case was not bad tactics," says Gurney. "It was a case that never should have been brought."

Prosecutors say company misled surgeons

The government alleged that Stryker Biotech had deliberately misled surgeons and put patients at risk by marketing an unapproved mixture of two separate products – OP-1 and Calstrux – used to generate human bone growth. "That mixture was never studied clinically," Assistant U.S. Attorney Susan Winkler told the jury in her opening statement. "They did not know if it worked. They did not know if it was safe, and they marketed it to doctors anyway."

Winkler promised to provide evidence that the defendants knew that promoting the mixture of OP-1 and Calstrux to doctors was illegal. "That mixture was not approved by the FDA," she said. "It's the patients who were put at risk by that sort of promotion," she charged, "the patients who don't know they're guinea pigs for this unapproved mixture of OP-1 and Calstrux."

"In short," said Winkler, "the evidence is going to be that these three men and the corporation knew that doctors had been misled into thinking this product was all OP-1, that they didn't even realize in many cases that Calstrux was involved, and that they would convince doctors to buy it on that basis."

The evidence would also show that the defendants sought to put hundreds of thousands of dollars in their pockets through the scheme, she said.

Defense turns surgeons on the government

The government specifically identified seven surgeons in its indictment who, it charged, had been deliberately misled by Stryker Biotech's sales team. But in the sharpest blow to the government's case, Ropes & Gray's **Brien O'Connor** revealed during his opening argument that federal prosecutors had failed to speak with any of the surgeons. "The indictment specifically identifies only seven surgeons: Drs. H, P, C, D, M, I, and R," O'Connor told the jury. And then he dropped the bomb. "Incredibly," he told the jury, "the prosecutors and their hefty core of investigative agents never interviewed even one of these supposed victim surgeons. They never spoke with them. They never even tried to speak with them."

> *"Incredibly," Ropes & Gray's Brien O'Connor told the jury, "the prosecutors and their hefty core of investigative agents never interviewed even one of these supposed victim surgeons."*

Then O'Connor dropped the second bomb. "They may not have talked to the surgeons, but we did," he told the jury. "And because of that, you're going to get to hear the surgeons' side of the story."

See extended excerpt, next page.

The next blow to the government came when the government's first witness testified that doctors mixed the two products in question, because that is consistent with medical practice, not because they had been influenced by Stryker Biotech sales reps.

Shortly thereafter, the government agreed to dismiss all charges against the individuals and settle the case against the company with a single misdemeanor count of misbranding a medical device.

A week later, DOJ dropped all charges against the remaining defendant, Mark Philip, who was president of the company from 2004 to 2008.

US Attorney cites "strategic error"

Shortly after the charges against Philip were dropped, U.S. Attorney Carmen Ortiz issued a statement regarding the outcome of the case. Ortiz correctly pointed to the "unparalleled" success the U.S. Attorney's Office in Boston has achieved in

combating fraud in the healthcare sector over the past decade, with recoveries during that time amounting to more than $10 billion.

Ortiz noted that Stryker Biotech was ordered to pay a $15 million fine in connection with the misbranding misdemeanor. "However," she said, "unfavorable pretrial rulings, combined with a strategic error in preparing for trial, led to the dismissal of charges against the individual defendants in the Stryker case." Ortiz called it "a difficult decision" that was warranted by a "complex confluence of factors."

"At the end of the day," she said, "doing justice meant dismissing the charges, rather than subjecting these individuals to a protracted trial where the government could not put its most effective case before the jury."

Insurmountable problems

According to the defense team, the government faced several significant problems from the outset. The first, says Levy, is the fact that surgeons are highly-skilled individuals who make their own decisions about how they use medical devices in complex spine and trauma surgeries. "The government claims they were victimized," he says, "but never spoke to them."

In addition, the government's core allegation was that Stryker Biotech had not only misled the surgeons about the attributes of the two products, but also about the adverse events associated with the use of those products. In other words, the government claimed the products were not only unproven, but dangerous. But as O'Connor and Gurney demonstrated at the outset of the trial, the number of adverse events totaled 63 out of 10,000 uses – or less than one percent. Moreover, many of the adverse events were relatively minor conditions, such as fevers or infections that were quickly remedied. "I think we effectively defused the notion that the products were not safe," says Levy.

According to the defense team, another problem with the government's case was its characterization of the relationship between Stryker Biotech's sales force and the physicians who would potentially use the products in question. Gurney says that relationship is paramount for the company's long-term success. "The company is interested in a long-

Lead counsel opens and closes

Below is an excerpt of the opening argument of lead counsel, Brien O'Connor, that helped close the trial:

The indictment specifically identifies only seven surgeons: Drs. H, P, C, D, M, I, and R. Now, you would think that before bringing these very serious criminal charges bringing us all together, the prosecutors would have taken the time to interview these seven surgeon victims, right? They would have wanted to confirm that the supposed victims were actually victimized, right?

Well, apparently not. Incredibly, before hauling these defendants into court on criminal charges, the prosecutors and their hefty core of investigative agents never interviewed even one of these supposed victim surgeons. They never spoke with them. They never even tried to speak with them. They took two years before this indictment to investigate. They could have taken longer. There was no deadline to meet.

They had the awesome power to subpoena to the grand jury any person, including surgeons anywhere in the country. They had the time to compel dozens of people to testify before the grand jury, but not these surgeons. They had the time to pore over millions of pages of emails and other documents and cherry-pick -- the ones Ms. Winkler had in her hand – a handful of emails, isolate them and present them in the most negative possible light. But apparently, they had no time to ask the surgeon victims: "Were you tricked?"

Ladies and gentlemen, they may not have talked to the surgeons, but we did. And because of that, you're going to get to hear the surgeons' side of the story. Let's stop and think about this for a second. The defendants in this criminal fraud case who, as the Court will tell you, have no burden to do anything at all and are entitled to just look the prosecutors in the eye and say, "Prove it," are the ones who will bring the supposed victims of this fraud here to testify.

Why will that testimony be important? Well, because these surgeons, whose full identities you're going to have, and who are going to take that witness stand will tell you three things: The defendants did not lie to them; the defendants did not deceive them; the defendants did not defraud them in any way.

term relationship with surgeons," he explains. "This isn't a quick hit business." In short, he says, the notion that the company would deliberately attempt to trick sophisticated physicians into using a product by concealing important facts is "absurd."

In addition, says Gurney, there are many bone void fillers on the market. "It is almost a commodity," he says, "so the idea that a surgeon would be confused about the two products or how they should be used is also absurd."

Finally, Levy points out that the products in question were approved under a humanitarian device exemption that precluded the company from making a profit. While the restriction was not necessarily a hard cap, he says, this further undermined the notion that the company was primarily interested in maximizing short-term sales.

Genesis of the case

One seeming advantage the government had was the fact that four Stryker sales reps had earlier pled guilty to felony misbranding charges in connection with the two products. The problem for the government, says Levy, was the fact that the company itself had fired those individuals for forging documents. Because of the humanitarian exempt status of the products, institutional review boards (IRB) had to sign off on the use of these products, he explains. The sales reps who later pled guilty had forged signatures associated with that process.

Ironically, the company not only turned them in, says Levy, it also made four written voluntary reports about the incident to the FDA. Prosecutors subsequently requested the company's internal statements, he says, and then used them to start building a criminal case against Stryker Biotech.

"They pled guilty to felony misbranding with intent to deceive," he says, "but they cut a deal with the government and were set to testify pursuant to personal cooperation agreements with the government at trial."

A landmark case

The case against Stryker Biotech is especially noteworthy in that it joined two of the government's major prosecutorial initiatives. The Justice Department has made violations of the Food Drug and Cosmetic Act (FDCA) a top priority for close to a decade. More recently, DOJ has repeatedly stated its intent to prosecute individuals along with companies.

The case against Stryker Biotech was brought by the Healthcare Fraud Unit in the U.S. Attorney's Office in Boston, which has played a central role in prosecuting drug and device companies over the past decade. This includes many of the largest corporate off-label cases, such as Pfizer's $2.3 billion off-label settlement in 2009. It also includes most of the high-profile cases against individuals, dating back to the prosecution of several TAP employees in 2001 and the prosecution of several Serono employees in 2005. In both instances, the individuals were tried separately from the company and, in both instances, the individuals were acquitted.

"The mistake they made in this case was not bad tactics," says WilmerHale's Brent Gurney. "It was a case that never should have been brought."

More recently, it included the high-profile prosecution of former GSK attorney, Lauren Stevens. That case came to an abrupt conclusion when the judge threw the case out of court at the conclusion of the government's evidence.

Defense counsel weighs in

"I give them credit for doing the right thing in this case, even in the middle of the trial," says Gurney. "To their credit, they dismissed it." But the lesson, he says, is that the case never should have been brought in the first place. "The whole case arose out of alleged off-label promotion where the government thinks the rules are 'black and white' when they are not," he says. "Then they jacked it up into a fraud case, which was inappropriate, and this was the result."

Most off-label cases brought by the government never get tested in court, Gurney points out, because companies cannot afford the risk of being excluded. Public companies facing criminal charges are in an especially difficult position, says Gurney. "There is enormous pressure to avoid trial at all costs," he says. As a result, most of these cases end up in resolutions that are never tested in a court room. "Here a case got tested," he says, "and all four wheels flew off the car shortly after the test began."

A "sensational" outcome

"What Brien O'Connor and his team at Ropes accomplished is nothing short of sensational," says former federal prosecutor, **Christopher Hall**. According to Hall, the Ropes & Gray team did an exceptional job of researching the elements of the government's fraud theory and then investigating the facts and evidence. "They out-investigated the government," he says.

From there, he says, O'Connor pulled together a cohesive opening argument to present to the jury. "It had every element of any opening statement in any regulatory case, regardless of industry, that you would want," says Hall. "He touched every single base."

"What Brien O'Connor and his team at Ropes accomplished is nothing short of sensational," says former federal prosecutor, Christopher Hall.

Hall gives equally high marks to the rest of the defense team, which also included Robert Ullmann of Nutter McClennen & Fish and Frank Libby, Jr. of Libby Hoopes, who represented the other two individual defendants, William Heppner and Jeffrey Whitaker, respectively. Stephen Huggard of Edwards Wildman represented Mark Philip.

"They all worked very seamlessly together," he says. "It was a very effective joint defense group."

According to Hall, considerable resources were afforded to the defense team, which was another important factor in the outcome. "If the company had not funded and indemnified the individuals as it did, they would not have been able to put the government to the test the way they did," he explains.

Hall says that underscores the importance of indemnification provisions and bylaws. ■

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Smith & Nephew reaches $22 million FCPA settlement

Earlier this month, UK-based medical device maker Smith & Nephew Inc. agreed to pay $22.2 million to settle Foreign Corrupt Practices Act (FCPA) offenses committed by its U.S. and German subsidiaries. The agreement recognizes Smith & Nephew's cooperation with DOJ's investigation and the remedial efforts and compliance improvements undertaken by the company. As part of the agreement, Smith & Nephew will pay a $16.8 million penalty. The company is also required to implement rigorous internal controls and retain a compliance monitor for 18 months. In a related matter, Smith & Nephew reached a settlement with the SEC and agreed to pay $5.4 million in disgorgement of profits, including pre-judgment interest.

A ten-year scheme

According to DOJ's criminal information, Smith & Nephew, through certain executives, employees and affiliates, agreed to sell products at full list price to a Greek distributor based in Athens, and then pay the amount of the distributor discount to an off-shore shell company controlled by the distributor. These off-the-books funds were then used by the distributor to pay cash incentives and other things of value to publicly-employed Greek HCPs to induce the purchase of Smith & Nephew products.

In total, from 1998 to 2008, Smith & Nephew, its affiliates and employees authorized the payment of approximately $9.4 million to the distributor's shell companies, some or all of which was passed on to physicians to corruptly induce them to purchase Smith & Nephew medical devices.

In April last year, J&J paid $70 million to resolve bribery charges related to payments in Greece, Poland, and Romania. DOJ has stated that J&J's cooperation played an important role in identifying improper practices in the life sciences industry.

The Smith & Nephew settlement will be examined in detail in an upcoming issue. ■

Off-label promotion

The lessons of Genentech's $20 million Rituxan settlement

Perhaps the most striking feature of the demise of the government's criminal case against Stryker Biotech and four of its former executives last month was the lack of attention it received. That was not the only long-running case to be concluded without much fanfare, however. A month earlier, Genentech settled a *qui tam* suit by former employee, John Underwood, for $20 million, along with an agreement to pay his legal fees. That would appear to be a modest result for a case that included a six-year criminal investigation and some seven million documents.

Underwood, who was a senior hospital systems specialist for Genentech from 1986 through 2005, originally filed suit in 2003. DOJ initiated a criminal investigation in 2003, but disbanded the grand jury in 2008 without an indictment.

Relator successfully taps DOJ's investigative findings

The Rituxan settlement is the latest off-label case brought to a successful conclusion by a whistleblower absent intervention by DOJ. Last year, Tom Greene, who spearheaded the landmark Neurontin case, successfully concluded a $20 million off-label settlement with Pfizer over its marketing of Detrol. That marked the first non-intervened off-label settlement since Neurontin in 2004.

But whereas Greene's firm was forced to build the Detrol case against Pfizer entirely on its own, Underwood was the beneficiary of court rulings that enabled him to amend his complaint with information derived from the government's five-year criminal investigation.

In June 2010, after the government declined to intervene, Underwood sought to amend his complaint to add new allegations that drew on information the Justice Department had obtained during its six-year investigation.

Genentech objected to the relator's use of any discovery to amend his complaint. The Court interpreted that to mean that Genentech objected to discovery from the company and concluded that it would be too difficult to distinguish discovery from the company from discovery from any other source.

In short, requiring the relator to establish the "genealogy" of all seven million documents he obtained from DOJ would likely make it impossible for him to proceed, the judge concluded.

The larger point is that Genentech mounted a vigorous defense and skirmished with the relator repeatedly over both discovery and substantive issues.

Underwood initially alleged that Genentech's scheme began in 2000 and continued until at least December 2002. His second amended complaint extended the conspiracy's duration to 2005. Notably, the total sales of Rituxan rose sharply during this period, from $263 million in 1999 to more than $1.8 billion in 2005. Both complaints charged that Genentech pressured its sales team to illegally to market off-label uses for Rituxan prescriptions, and paid illegal kickbacks, such as tropical vacations or honoraria, to induce and reward physicians who prescribed Rituxan off-label.

One lesson of the Rituxan settlement may be that not every big investigation results in a big settlement.

Lessons of the settlement

One lesson of the Rituxan settlement may be that not every big case results in a big settlement. But while the Rituxan settlement may be evidence of pharma's willingness to "push back" against *qui tam* suits it also highlights the willingness of relators to litigate cases where the government has declined to intervene.

In the next issue of *Rx Compliance Report*, several prominent *qui tam* attorneys explain why they expect non-intervened cases to play a more prominent role going forward.

Genentech was represented in this matter by Paul Kalb, John Gallo, Kimberly Dunne, Michelle Goodman, and Scott Stein of Sidley Austin and Robert Welsh and Catherine of Recker of Welsh & Recker. ■

▸ *Cont. from page 1*

Janssen settles Texas' off-label case for $158 million

The lawsuit was originally filed by a former Pennsylvania state investigator named Allen Jones, who uncovered the program. Texas Attorney General, Greg Abbott, joined the suit two years later.

Janssen says the settlement resolves all claims brought by the state in 2004 for alleged Medicaid overpayment from 1994 to 2008. It also follows reports that J&J has reached a tentative $1 billion deal with the U.S. Attorneys' Office in Philadelphia to resolve a long-running federal investigation into the marketing of Risperdal.

Meanwhile, additional Risperdal suits have been filed in Arkansas, Massachusetts, Montana, New Mexico, Texas, and Utah. California, and New York are considering similar actions.

Two Risperdal cases went to trial in Louisiana and South Carolina last year resulting in judgments of $257 million and $327 million, respectively. However, both of those cases are now under appeal.

A challenging case

According to Melsheimer, managing principal of Fish & Richardson's Dallas office, who acted as lead counsel for Jones, it is important to understand both the complexities of the Texas Risperdal case and how it differs from the cases in Louisiana and South Carolina.

One of the potential challenges facing the plaintiffs in Texas is the conservative nature of the Texas Supreme Court. "The Texas Supreme Court is famously challenging for plaintiff's cases," says Melsheimer, "and not just the Supreme Court, but most of the appellate courts."

"Obviously, this is not your typical plaintiff's case, and you can make an argument that as a law enforcement type case the Supreme Court might take a different view," he adds. But that was nonetheless a consideration, he says.

Another problem with the Texas Medicaid statute, says Melsheimer, is that there have not been any appellate cases interpreting the statute. "There has never been an appeal of the Medicaid fraud act case in Texas," he explains. "That's good in one sense, because it means there is no bad law. But it's bad in the sense that there is no good law."

Melsheimer says both trial judges and the parties would have been on their own in terms of trying to figure out how broad the statute is intended to be. "We certainly took that into consideration," he says.

According to Melsheimer, it is also important to differentiate the Texas Risperdal case from the Risperdal cases that went to trial in Louisiana and South Carolina last year. "Those are different cases that were, in some ways, quite a bit easier, because of both the statutes involved, as well as some of the evidentiary rulings," he says. "Those cases were much less challenging cases than the case we had down in Austin."

In short, Melsheimer says it is difficult to compare the three cases. "Our case was much broader," he explains. "It involved broad off-label promotion. Their case was much narrower and had some big proof advantages that our case did not have."

Lead counsel Tom Melsheimer, said Janssen illegally promoted Risperdal for use in children even though the FDA had explicitly told them that they could not do so.

The Louisiana and South Carolina cases were based on a Dear Doctor letter that J&J sent out that was later deemed by the FDA to be false and misleading. That letter made certain representations about Risperdal being safer with regard to certain side effects, including diabetes, than its competitor Zyprexa. "It turns out that that ended up being a true statement," says Melsheimer. Later, the FDA's warning label for Zyprexa was stronger regarding diabetes than the warning label of the other antipsychotics, including Risperdal, says Melsheimer.

However, the courts in those cases did not allow any evidence regarding subsequent developments, says. Melsheimer. "In our case, which went all the way up to 2010, there was evidence admitted about the FDA agreeing with J&J on the Zyprexa point," he says. "Who knows how those cases would have turned out if that evidence had been admitted?"

Below is an outline of the complex case brought against Janssen by Melsheimer's firm and the Texas Attorney General:

The case against Janssen

The heart of the state's case was that Janssen led the Texas Medicaid program to believe that Risperdal was safer and more effective than older antipsychotic drugs used to treat schizophrenia that were less expensive and had been on the market for years. "Risperdal is no better, and in some ways, it is worse," Assistant Attorney General, Cynthia O'Keefe, told the jury.

"It was not a one-time event, and it was no accident," said O'Keefe. Rather, she said, Janssen's activity amounted to "the systematic looting of money" from the Texas Medicaid Program to the tune of $579 million.

O'Keefe said one of the most disturbing facts uncovered by the investigation took place in the spring of 2000 when the FDA notified Janssen of concerns about a link between Risperdal and diabetes. However, that was the very point in time that Janssen decided to "aggressively ramp up" its illegal marketing of Risperdal for children, she charged.

In terms of cost, O'Keefe said Risperdal has always been far more expensive than older drugs. In fact, she said, in 2004 a two milligram tablet of Haldol, one of those older antipsychotics, cost the Texas Medicaid program less than 10 cents while the two milligram tablets of Risperdal cost the program $4.57. "That's over 45 times more expensive," she said

O'Keefe also told the jury that once Janssen successfully executed its plan in Texas the company tried to export it nationwide by pointing to Texas as a model state to follow. Worse yet, Janssen used Texas state employees to accomplish that, she charged.

Risperdal: A $34 billion drug

Melsheimer told the jury the "simple motivation" behind Janssen's conduct was "greed." Over the course of 17 years, he said, Janssen sold $34 billion worth of Risperdal at a profit margin of sometimes nearly 97 percent. "At times, the company sold $350,000 worth of Risperdal every hour," he said.

According to Melsheimer, Janssen's illegal scheme had four main components. First, he said, the company made false statements about Risperdal being better than the older less expensive medications, in part, by funding and manipulating treatment guidelines. Melsheimer said that included a scheme to pay Texas officials to promote Risperdal for Janssen's own benefit at the expense of their duties to the state of Texas.

Second, he said, Janssen illegally promoted Risperdal for use in children even though the FDA had explicitly told them that they could not do that.

Third, he said, Janssen made false claims that Risperdal was safer than the older less expensive medications, including minimizing serious side effects such as hormonal side effects and diabetes.

Lastly, he said, Janssen made false claims that Risperdal was more cost-effective than the older less expensive medications.

Melsheimer argued that some of the jury's work was already done, because in 2004 the FDA made Janssen send a Dear Doctor letter to over 600,000 healthcare professionals, including 18,000 in Texas, stating that an FDA warning letter had concluded that Janssen had omitted material information about Risperdal, minimized potentially fatal safety risks, and made misleading claims suggesting superior safety.

Janssen's internal marketing plans show the company wanted to "create the perception" that Risperdal represented "the new gold standard in drug therapy," said prosecutors.

"But the FDA was not the only group that thought Janssen had given out false and misleading information," said Melsheimer. "It turns out Johnson & Johnson executives thought so, too," he said, pointing to an e-mail from Dr. Scott Reines, an executive vice president with J&J's research division in April of 2004, that read: "They never consulted the team or anyone in PRD. No competent person would have let it go out. It's really a black mark for J&J."

In his report analyzing Janssen's marketing activities, veteran attorney, **Arnie Friede**, who served as an expert witness for the prosecution, also zeroed in on Reines e-mails. "To their credit," said Friede, "there were individuals within Janssen who were seriously troubled by the company's Dear Healthcare Provider letter and the entire course of events that led to its issuance." Unfortunately, he added, Reines' e-mails also "speaks volumes about "the character of the underlying behavior and the flagrant misrepresentations" it contained (*see sidebar. p. 11*).

Making Risperdal "the new gold standard"

Melsheimer told the jury that Janssen's internal marketing plans show the company's strategy was to "create the perception" that Risperdal represented "the new gold standard in drug therapy." Notably, he said, this was the strategy as early as 1993, before the FDA had even approved the drug.

In its final approval, he said, the FDA told Janssen that it would consider any advertisement or promotional labeling for Risperdal false, misleading or lacking fair balance if it stated that Risperdal is superior to Haldol or any other marketed antipsychotic with regard to safety or effectiveness.

Nevertheless, eight months after the drug was approved in the fall of 1994, Janssen's stated objective to make Risperdal "the new gold standard for antipsychotic therapy" had not changed, he said. In just the first eight months that Risperdal was on the market, he told the jury, the drug quickly established itself as the market leader, accounting for 20 percent of the entire company sales.

But what nobody knew in 1993, said Melsheimer, was that Janssen's plan to claim that Risperdal was superior was only a small piece of the company's overall plan to turn Risperdal into a blockbuster.

The problem Janssen faced was twofold, he said. First, Risperdal is designed to treat schizophrenia, which only affects about 1 percent of the adult population, he said. Second, the drug was very expensive. "It was 45 times more expensive than the older drugs," he told the jury. "So how in the world do you turn that drug into a blockbuster under those circumstances?"

Making Risperdal a blockbuster

The first step in making Risperdal a blockbuster, said Melsheimer, was a strategic reimbursement plan, which Janssen created in September of 1992, a year before Risperdal was approved. Melsheimer,said Janssen's internal documents concluded that 60 to 80 percent of all schizophrenia treatments are paid for by Medicaid. "They knew that in order to turn this drug into a blockbuster, they had to find a way to get Medicaid to pay for it," he argued.

According to Melsheimer, one of Janssen's first initiatives was to develop treatment guidelines that would favor Risperdal over older drugs and competitor drugs. Treatment guidelines or algorithms can be a good idea, he said. "But in this case, Janssen ended up creating, funding, and implementing treatment guidelines that favored its own drug."

This included hiring three doctors to draft treatment guidelines, which Janssen referred to as the Risperdal treatment guidelines. Publicly, however, they were called the expert consensus guidelines or the Tri-University Guidelines, because the doctors involved were from three universities.

Melsheimer told the jury that during the drafting process of these guidelines, Janssen had input into the questions that were to be asked the way the guidelines would be framed, and how they could be best used to help market the drug.

After these guidelines were developed, Melsheimer said, the three doctors that Janssen had hired formed their own company called EKS. Janssen then paid the company $600,000 to travel around the country promoting these guidelines, seemingly as an independent third party, he said.

"One of the reasons Janssen committed substantial funding for TMAP was to develop a treatment guideline for schizophrenia that positioned atypicals as first line agents," read an internal Janssen e-mail.

When these guidelines were actually published, he said, Risperdal was the only new antipsychotic listed by name. "That wasn't an accident," he told the jury, "and it wasn't the result of some great scientific breakthrough."

To substantiate his charge, he pointed to a 1996 presentation by the reimbursement team within Janssen, which listed as one of their major accomplishments the Tri-University Schizophrenia Treatment Guidelines. "The reimbursement team are not scientists," he said. "They are people in charge of getting the drug paid for" and "they took credit for them as a marketing and reimbursement tool, not as a medical breakthrough."

Melsheimer also pointed to an investor relations plan that discussed the guidelines being published in 1996. "They knew back in 1996 when they were talking to potential investors… that this treatment guideline was going to position Risperdal as superior, which, of course, was the exact thing the FDA told them they could not do," he said.

The Texas Medication Algorithm Project

According to Melsheimer, Janssen's overriding objective was to generate "a perception of superiority." To accomplish that, soon after the guidelines were initially adopted, Janssen went back to Texas and contributed money to get the Texas Medication Algorithm Project (TMAP) implemented throughout the state. "All told," he said, "Janssen and its charitable arm, the Robert Wood Johnson Foundation, contributed over $3 million to [TMAP]."

Melsheimer told the jury that shortly after Janssen began making these contributions (along with other drug companies that were coming out with their own newer expensive drugs) the treatment guidelines were changed by Texas officials, placing older less expensive drugs further down on the list and making the newer more expensive drugs the first choice. "So a drug that was 45 times more expensive was now going to be the first choice," he said. "In other words, they got TMAP, this Texas program, to make the exact same claim that the FDA had told them back in 93 they couldn't make."

Attempting to leave little doubt about Janssen's motive, Melsheimer pointed to an e-mail from a Janssen executive in 2001 that stated: "One of the reasons Janssen committed substantial funding for TMAP was to develop a treatment guideline for schizophrenia that positioned atypicals as first line agents."

Meanwhile, he said, treatment guidelines developed by the *American Psychiatric Association, the Journal of Psychiatry*, the Veterans Administration, and others, listed older and less-expensive drugs as the first line of treatment.

Purchasing public officials

According to Melsheimer, Janssen's scheme did not stop with getting TMAP implemented throughout Texas. In order to beat their competitors that also had new drugs, he said, Janssen needed the help of certain Texas officials, including Dr. Steven Shon, the medical director for the Texas Department of Mental Health, who had considerable influence over mental illness treatment in the state.

Melsheimer told the jury that Janssen proceeded to make a series of illegal payments to Shon that effectively turned him into a salesman for Risperdal. "They even had the man sign a consulting agreement in which he said that he had no obligations that would interfere with his obligations to Janssen," he said. "All the while, he was an employee of the State of Texas subject to their ethical rules."

One of the presentations Shon made in October of 1997 was an all-day meeting to brief the companies which had contributed to TMAP on how things were going, said Melsheimer. "Well, it turns out for Janssen, things were going pretty well," he said. In fact, he said, the percentage of patients in mental health clinics with schizophrenia who had been prescribed Risperdal was 68 percent.

In 2000 alone, he said, Janssen paid Shon to spend almost half his time as a Texas employee on the road for Janssen selling Risperdal. This was designed to get other states to buy in to the program they had implemented in Texas, he said. By 2001, Janssen's revenue for Risperdal was $1.8 billion.

To back up that claim, he pointed to an internal e-mail about the importance of Shon that read: "Note: Dr. Shon can and is influencing not only the $50 million atypical in Texas, but likewise in many other states. WE WILL NOT LET LILLY OR PFIZER PREVAIL WITH OUR MOST IMPORTANT PUBLIC SECTOR THOUGHT LEADER."

Melsheimer told the jury that Janssen made a series of illegal payments to Dr. Steven Shon, the medical director for the Texas Department of Mental Health, that effectively turned him into a salesman for Risperdal.

Melsheimer said Janssen also paid three other physicians, in excess of $250,000 to fly around the country at the company's expense to support the company's claims of Risperdal's superiority.

Targeting adolescents

Melsheimer told the jury that in order to fully realize its ambitions for Risperdal, Janssen needed to expand the market beyond schizophrenia and a major target was adolescents.

The backdrop, he reminded the jury, was that they had been told by the FDA when the drug was approved in 1993 that safety and effectiveness in children had not been established. "Despite this clear statement that they couldn't promote it for pediatric use," he said, "Janssen planned to promote Risperdal for use in small children from the very beginning."

Targeting adolescents was not just an abstract idea, said Melsheimer. Rather, he said, the company had very specific medical tools. For example, one of their early marketing plans cited the need for an oral solution to be used with children who it is widely known do not like pills.

Melsheimer said the same marketing plan addressed market expansion by seeding the literature with favorable statements about Risperdal. "These weren't going to be articles that just popped up in a random journal by an academic or a doctor," he said. "Janssen had an extensive seeding and publication plan."

To help them seed the literature with favorable studies about Risperdal, he said, Janssen hired a firm called Excerpta Medica. "The goal of these articles was not to advance scientific learning," he said. "It was to advance Risperdal." Here he cited an internal e-mail stating: "Although we like to think we develop these manuscripts for scientific purposes, the real value is when a sales rep can reference them, show them and present them."

One Texas child psychologist was prepared to testify that from 1994 to 2003 a Janssen sales rep called on her 94 times.

"The seeds that Janssen planted bore very much fruit," said Melsheimer. By 2001, he told the jury, children accounted for one quarter of all Risperdal prescriptions. In fact, he said, Janssen employees decided that it was so successful they need to have a standalone business plan for adolescents.

According to Melsheimer, one month later in July of 2001, Janssen prepared another business plan for children with the stated goal of remaining the gold standard in the child and adolescent market." The end result, he said, was that fully half the market for Risperdal was for children under 13, while five percent was for children under the age of six.

As early as 1994, Janssen pushed Risperdal for use in children in Texas and elsewhere, said Melsheimer. In fact, one Medicaid provider, a child psychiatrist named Valerie Robinson, was scheduled to testify that between 1994 and 2003 a Janssen sales rep called on her 94 times. ■

Veteran attorney cites intent to promote off-label "at every level"

One component of the state's case against Janssen was a 106-page report created by former Pfizer attorney, **Arnie Friede**, who examined company documents and FDA letters and concluded that Janssen repeatedly disregarded agency warnings not to market Risperdal beyond its initial approved use for psychotic disorders including schizophrenia.

"Janssen's intention to market Risperdal for an array of 'mood' and 'anxiety' symptoms beyond those associated merely with the manifestations of psychotic disorders in schizophrenic patients is evident as far back as the 1994 Marketing Plan for the drug that was prepared in 1993 before its actual launch," said Friede, who also worked at the FDA.

"We see false and misleading representations, and an intent to promote Risperdal off-label, at every level of marketing, including, but not limited to, business plans, sales training materials, and on the ground," wrote Friede. "When you see consistent evidence of this kind, it proves that what started off as a concept in a business plan was broadly communicated by Janssen to doctors day-in and day-out over the course of many years."

A "systemic and pervasive" course of action

Friede wrote, and later testified, that Janssen repeatedly disregarded the drug's label. For example, he states that while the FDA was insisting that Janssen add specific warnings to its labeling advising about the serious adverse metabolic effects from Risperdal, the company was "blatantly telling its sales force to continue 'business as usual' and to perpetuate what FDA believed was a false and misleading message about the risk of diabetes from the drug, both monadically and comparatively."

According to Friede, a variety of material that he reviewed, including call notes from Texas field sales representatives, and Field Conference Reports, likewise evidence "a systematic and pervasive" course of conduct by Janssen.

"Collectively," he said, "the Texas call notes, that reflect the relatively contemporaneous memorialization by Texas sales representatives of key aspects of then-just-concluded detailing discussions with doctors in Texas, amount to some of the best evidence of illegality of Janssen's behavior in this regard." ■

Whistleblowers

Facilitating Disclosure and Prohibiting Retaliation: Perspective of a *Qui Tam* Plaintiffs' Counsel

In the last ten years, there is no question the pharmaceutical industry has gotten a lot cleaner," says *qui tam* attorney **Shelley Slade**, who has been a member of the Washington, D.C. law firm Vogel, Slade & Goldstein, LLP since 2000. "But I can tell you based on the calls I am getting every week that there are still units and divisions within your companies that are operating using plans that assume a wrongful mode of conduct, whether it is kickbacks, off-label promotion or nationwide billing policies."

According to Slade, who is currently lead counsel in nine pharma *qui tam* cases, it is important to understand the factors that drive potential whistleblowers. At the recent Pharmaceutical Regulatory and Compliance Congress in Washington, D.C., Slade shared the insights she has gleaned from the numerous *qui tam* cases she has handled, along with several dozen cases involving the pharmaceutical industry that she has rejected.

Research on whistleblowers

To put her observations in context, Slade reviewed some of the major research findings regarding whistleblowers:

Observers of corporate wrongdoing rarely report it to anyone. According to Slade, who in 1998 and 1999 was the Senior Counsel for Health Care Fraud in the Civil Division of the Department of Justice, observers of corporate wrongdoing rarely report it to anyone. "If you delve into the research, you will find that most individuals who witness wrongdoing don't identify it as such," she says. "Of the remainder, most stay mum."

For example, she says, during the corporate accounting frauds that led to enactment of the Sarbanes-Oxley Act, knowledgeable employees rarely spoke out about wrongdoing because of a "compelling norm of silence among employees."

Those who do decide to blow the whistle are more inclined to report internally than externally. According to Slade, the research also shows that those who decide not to stay mum and recognize the wrongdoing are predisposed to report internally.

What that means, she says, is that compliance professionals have a "head start" on enforcement authorities and the *qui tam* bar. "You just have to tap into that predisposition," she says.

Nearly every observer of perceived wrongdoing who reports it to someone outside the organization has reported it first within the organization. Lastly, she says, whistleblowers almost always report wrongdoing internally before the report it externally.

Trends in pharmaceutical *qui tam* matters

According to Slade, at least two of the following three elements are typically present when a *qui tam* suit is filed:

Wrongful practice is part of corporate business plan. Slade says the primary factor that leads whistleblowers to report externally is that the wrongful factor they are complaining about is part of a corporate business plan.

According to qui tam attorney Shelly Slade, most individuals who witness wrongdoing do not identify it as such, while most of the remainder, "stay mum."

Relator did not report to Compliance Office. The second factor cited by Slade is that the relator did not report to the Compliance Office. "That's not to say they didn't report to someone," she says, "just not to Compliance."

Relator humiliated as a result of wrongful practice or reporting thereof. Notably, Slade says, almost all of her clients or would be clients were humiliated in some fashion inside their company as a result of their attempt to report wrongful conduct. "Sometimes it is because of their participation in it at the direction of managers," she says. "But most often it is because of some effort they made to question the conduct or to report it to a supervisor."

FACTOR 1: WRONGFUL PRACTICE IS PART OF CORPORATE BUSINESS PLAN

According to Slade, the schemes that law enforcement is interested in and that *qui tam* attorneys are attracted to are those that are part of a business plan. "This is the elephant in the room and what makes many of your jobs so difficult," she says.

When a potential whistleblower realizes the activity in question is part of a business plan, they realize that it is going to be very hard for the Compliance Office to take that on, she says. "They recognize that if they report it they are more likely to be retaliated against than to see any sort of remediation of the wrongful conduct," she explains.

Slade says they also realize that their immediate supervisor has no discretion to change the plan and/or the corporate sales forecasts and budgets that are dependent on continuation of illegal practice.

FACTOR 2: RELATOR DID NOT REPORT TO COMPLIANCE OFFICE

According to Slade, the second factor is related to the first factor. For almost all of her clients, she says, compliance was not on their radar screen. "It was a box on the organizational chart," she says.

"One client of mine compared the noise coming from compliance to that of a mouse that tried to squeak under the roar of a jet engine," she says. "The jet engine were the managers with whom they interacted day in and day out."

These individuals typically had some compliance training, such as online training and a presentation at a national sales meeting, says Slade. But this "noise" was simply overwhelmed by the "noise" from their managers telling them the do things that were unethical and/or illegal, she says.

Due to a lack of familiarity with compliance, potential whistleblowers also had a lack of trust in the process, Slade reports. For example, one client said that when compliance officers would come to his office of 25 people, they failed to communicate with the entire department. "They would be the suits and they would talk to other suits," the relator recounted, "They would have lunch with the managers, but they would not meet in private with the 'foot soldiers' who are the rank in file."

Naturally, she says, these individuals viewed the compliance officers as aligned with management.

According to Slade, one of the key takeaway messages from all of this is that compliance officers should try to get out in the field to meet individually or in small groups with the "foot soldiers" so that people in the field view compliance officers as a person with a face. "If they know your first name, it is a lot easier to call somebody and run an issue by them in that situation," she explains.

Another potential problem is a lack of trust in the process, says Slade. For example, she says, one relator told her that he initially tried to report wrongdoing to Compliance through an employment counsel he had hired, because he wanted to remain anonymous. Unfortunately, the compliance officer, who reported directly to the individual who was carrying out the alleged scheme, told the employment counsel that the anonymity of the potential whistleblower could not be guaranteed. That led the individual to file suit.

Slade says that while potential whistleblowers will most often not take their concerns to Compliance, they often can't resist saying something to their supervisor.

Slade says that another client learned that a colleague of his had reported through what was believed to be an anonymous online reporting mechanism. "He was very strident and very firm in voicing his concerns, going into all the details online," she says. Two days later, he lost his job, she reports. "That sent a pretty powerful message to my client."

According to Slade, while it may sound counterintuitive, potential relators will most often *not* take their concerns directly to the Compliance Office. On the other hand, they often can't resist saying something to their supervisor, because they see this person day in and day out. Ironically, she says, that person is often somebody who is invested in the fraud, which makes that person defensive.

FACTOR 3: RELATOR HUMILIATED

Slade says the third factor, the humiliation of a potential whistleblower, is so prevalent among her clients that it is difficult to overstate. For example,

one of her clients raised concerns five or six times over a period of two years about relatively minor misconduct. "Each time," she says, "he was shot down and humiliated in a meeting by the same manager two levels above him." At the end of the second year, he was denied a merit-based pay raise, which he had always received. "The explanation was illogical," she says. "It made no sense."

A few months later, she says, he zeroed in on fairly significant high-dollar healthcare fraud. "This time, he was not going to raise it internally," she says. "That's when he called us."

Sometimes the humiliation occurs when a person follows directions or participates in the wrongful conduct, says Slade. Often, they get an ethical violation or a bad performance evaluation. "That can also lead to reporting externally," she says.

Practical steps

Slade says the first step that should be taken to enhance internal reporting is for managers to be trained not only to follow the law but to treat those who voice concerns and to encourage that with respect and dignity.

Second, she says, compliance officers should have real and apparent authority to remedy misconduct. "Ideally, they should report to the Board," she adds.

Third, Slade says, every Compliance Office should have a good story to publicize about a case in which an employee reported wrongdoing. Ideally, she says, the person who reported the wrongdoing should get promoted while the immediate supervisor who directed them to engage in the illegal conduct should get fired and their boss should get demoted. In addition, she adds, the company should self-disclose the activity and repay the overpayment.

"If you have a story like that and you can publicize it within your organization, that will go a long way towards encouraging people to come forward internally," she maintains.

In addition, she says, managers who encourage whistle blowing should be rewarded, while those who don't should be penalized.

Needless to say, says Slade, business models that depend on a violation of the law for their success should be eliminated. "As long as a corporation treats False Claims Act fines and penalties as just a cost of doing business," she says, "whistleblowers are going to continue to report externally rather than internally." ■

■ **Shelley Slade**, Partner, Slade & Vogel, Washington, DC, sslade@vsg-law.com

Focusing on new hires pays compliance dividends, says defense counsel

One of the best ways for compliance officers to uncover wrongful conduct is to interview new hires, as well as employees who recently assumed a new posistion within the company, says **Michael Koon**, a partner with Shook Hardy & Bacon in Kansas City. Koon bases this advice on research that shows that a significant majority of whistleblowers fall into this category,

Specifically, Koon cites research conducted by Aaron Kesselheim, MD, a research associate in the Department of Health Policy and Management at Harvard School of Public Health, that found that 22 of the 26 whistleblowers in pharma *qui tam* settlements (beginning with the TAP case in 2001 and ending with Eli Lilly's Zyprexa case in 2009) were industry "insiders." Moreover, fully 16 of the 22 "insiders" encountered the "troubling behavior" they eventually reported as part of career change.

Kesselheim found that these 16 relators were either new hires, existing employees who had recently assumed new responsibilities, or people who were part of a company that had been formed as result of a merger or an acquisition. "That was how they found out about something that they previously had not been involved in," says Koon. "All of a sudden people were seeing things that they had not seen before."

In all but a handful of instances, notes Koon, the industry "insiders" who became whistleblowers said they first reported the activity to supervisors, filed internal complaints, or both. "Over 90 percent of the 'insiders' reported internally before they became whistleblowers," he says, "and it didn't work."

The obvious take away from this information, says Koon, is that pharma companies should approach new hires in their first or second month to ask them if they are receiving the support they need from a compliance standpoint and if there are any issues they have encountered that are confusing. ■

■ **Michael Koon**, Partner, Shook Hardy & Bacon, Kansas City, mkook@shb.com

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