

Rx COMPLIANCE REPORT

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SALES AND MARKETING COMPLIANCE

Federal prosecutors report slowdown in the filing of new fraud claims, say less egregious violations cited

Qui tam attorneys say evidence of off-label promotion is becoming harder to establish

For the better part of the past decade, pharma companies have been working to stop the steady flow of *qui tam* suits alleging drug marketing fraud in much the same fashion that engineers have been trying to “plug the hole” and stop the oil from gushing into the Gulf of Mexico. According to several federal prosecutors, these efforts are now paying off. The pace of new filings has slowed considerably, they report, and the alleged illegalities cited in new *qui tam* suits are less egregious than in years past. Notably, several prominent members of the *qui tam* bar echo this theme. “We are seeing people driving 67 in the middle lane as opposed to 92 in the fast lane,” says *qui tam* attorney **Robert M. Thomas, Jr.** “That makes our job harder.”

The bad news is that, much like the Gulf of Mexico, the well of *qui tam* suits is by no means fully plugged. Moreover, the clean-up will take years to complete, because the pipeline of cases remains badly backlogged. Worse yet, blockbuster settlements for activity in years past continue to fuel the perception among many in Congress and the mainstream media that nothing has changed. This, in turn, continues to drive increased

discussion at both the Justice Department and the OIG about ever stronger deterrents, including individual prosecutions and mandatory divestiture. ▶ *Cont. on page 2*

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DOJ spotlights investigations into reimbursement of unapproved drugs

By all accounts, allegations of off-label marketing remain the dominant theme of pharma *qui tam* suits. But this is, by no means, the only area the government is investigating. “It’s not just off-label,” says DOJ Senior Trial Counsel **Sanjay Bhambhani**.

According to Bhambhani, the cases DOJ is now actively investigating include drug pricing cases, best price cases, and nominal price/bundling cases. One case singled out by Bhambhani during ABA’s False Claims Act conference last month is the government’s best price/bundling investigation into Wyeth’s marketing of Protonix (*see related story, p. 8*).

The most novel investigational area Bhambhani addressed, however, is DOJ’s scrutiny of reimbursement for unapproved drugs. “This is a new area,” he said. “It has not received much attention, but it is something that we are closely scrutinizing and taking a good hard look at.” ▶ *Cont. on page 6*

► *Cont. from page 1*

Prosecutors report slowdown in new fraud suits, say less egregious violations being cited

Prosecutors and *qui tam* attorneys alike are quick to point out that pharma is hardly out of the woods. According to *qui tam* attorney **Brian Kenney**, who has represented relators in some of the largest pharma fraud cases, including Pfizer's \$2.3 billion Bextra settlement, even the "monstrous fines" imposed on drug companies in recent years may not have had the impact they should have on the industry. Nevertheless, while there is still "plenty of off-label activity" in the newly filed cases he is seeing, there is also "a qualitative difference" in terms of the conduct that is described, he reports.

Kenney maintains that when he started working on off-label cases ten years ago, there were sometimes entire divisions dedicated to off-label marketing. For example, a department with as many as 300 sales reps might visit nursing homes to promote an anti-psychotic drug that was only approved to treat bipolar mania or schizophrenia. "There are very few psychotic patients in nursing homes," he points out.

In addition, Kenney says it was not uncommon to find in-house training manuals discussing the criteria for how to market off-label. Likewise, he says, many of the larger companies allowed their sales departments to decide which doctors received honoraria, which was often directly tied to the number of prescriptions they wrote.

Recent allegations

Kenney says the type of egregious conduct outlined above is no longer evident. "It has taken a long time to turn the ship around and I don't think it's turned around completely," he says, "but I do think there has been a downtick in how outrageous the off-label marketing and kickbacks have been in terms of payments." In short, he says, the "river of money" flowing to physicians" has been staunched.

According to Kenney, the more recent cases appear to have a slightly different focus. For example, he says, these cases focus more heavily on issues such as falsity. "One of the factors that we find attractive in these cases is when the off-label marketing is accompanied by falsity as to the efficacy of the drug or specific falsities as to the side effects of the drug," he explains.

While some may consider these factors to be "atmospherics" that have only marginal influence, Kenney says, his firm takes these types of allegations very seriously in evaluating cases. "There is still a lot of that type of thing going on," he maintains. "There are still a lot of questions about the scientific studies that are being used and the accuracy of some of those studies."

In short, he says, the ground has shifted. "The evidence of off-label marketing is not as strong as it used to be," he says, "but we are still seeing a lot of claims."

Recent trends

In order to effectively assess the enforcement landscape, it is useful to break the industry into different segments,

says Thomas, of Thomas & Associates in Boston. In the wake of a steady stream of settlements, these companies have established sophisticated compliance programs. "Those companies tend to have more awareness of their downside risk for some of their

behaviors than device

companies or biotech companies," says Thomas, who has been involved in several major pharmaceutical *qui tam* investigations, including Pfizer's \$2.3 billion Pfizer settlement last year and Serono's \$704 million Serono settlement in 2005.

The change in the behavior among smaller companies has not been as appreciable, warns Thomas. "You still see a fair amount of wild west behavior in some of these smaller companies, particularly in the biotech and medical device sectors, where you are not necessarily going to have a whole compliance team set up that is deeply immersed in these issues," he explains.

On the whole, Thomas' overall views of the current fraud and abuse landscape largely mirror those of Kenney. He suggests the government is still largely focused on "off-label plus" cases. This means the government looks for off-label promotion, plus an aggravating factor such as kickbacks, false statements, patient harm, or serious risk to patients.

"The evidence of off-label marketing is not as strong as it used to be," says qui tam attorney Brian Kenney. "But we are still seeing a lot of claims."

Thomas says it is not uncommon to have a relator describe an off-label marketing scheme that lacks this additional component. “In terms of whether it is going to be something we invest in and ask the government to invest in,” he says, “it has to have some additional factors—the off-label plus piece.”

“The quality of the evidence that we have and whether we can get a prosecutor’s attention is obviously a big issue,” he adds. “If it’s a borderline off-label case, that is going to be a tough sell.”

Compendia issues

According to Thomas, compendia issues, which are present in all off-label cases, remain a paramount consideration. When a drug is approved for a certain use, it often may have efficacy for other uses that are not approved, he notes. However, reimbursement for these off-label uses depends on whether there is support for these uses in research compendia, such as Drugdex.

“What we are seeing in a lot of our off-label cases,” he says, “is that before or even during the period that the matter is under investigation, companies are continuing to do research and pay doctors to do clinical studies and write papers that will show – or hope to show – efficacy for some of these unapproved uses.”

According to Thomas, it takes the sting out of an prosecution to take off-label activity to a prosecutor and have them turn to the compendia and say, ‘Yes, it’s unapproved, but the vanguard or research seems to show that it is efficacious’.”

In other words, if patients really need the drug, it creates a “no harm, no foul” situation even if the FDA has not given it the stamp of approval, he says.

In short, he says, the relationship between the research community and these databases are having a major impact on how off-label cases are brought.

“One might be more trusting of this situation if he or she could be assured that the compendia were providing neutral and objective data,” says Thomas. But many of the submissions to the compendia come from sources that are being funded by the drug companies themselves, he says.

According to Thomas, this has a doubly pernicious effect. “It means the government may be paying for more uses of the drugs than it should, but also that a level of ambiguity has been inserted into the analysis of potential off-label prosecutions,” he says. “It’s a serious problem in both respects.”

The evolution of off-label cases

According to **Sara Bloom**, an Assistant U.S. Attorney in the U.S. Attorney’s Office in Boston who has played a leading role in several major drug marketing investigations, off-label cases are now becoming “less simple” in some respects. Bloom says Pfizer’s record-setting \$2.3 billion off-label settlement can be viewed as something of a paradigm in this regard. “If you look at the conduct that is included in the Pfizer settlement,” she says, “you can see the past, present, and maybe a little bit of the future in the variety of the conduct.”

“You still see a fair amount of wild west behavior in some of these smaller companies,” says qui tam attorney Robert Thomas, Jr.

The past. The theory behind the landmark Neurontin settlement, the government’s first major off-label case six years ago, was the straightforward proposition that a drug that is approved for one indication cannot be promoted for other uses.

In the case of Neurontin, there was very little confusion that the drug was not approved for anything other than secondary use in epilepsy, says Bloom, who was speaking on her own behalf. “There was no confusing those diagnoses. It was a different set of doctors. It was clearly a different set of uses.”

The present. In contrast to the Neurontin settlement, last year’s Bextra settlement includes more nuanced behavior, says Bloom. For example, the government alleges that the drug was promoted for dosages for which it was not approved.

Likewise, the government alleges that while Bextra was approved for chronic pain and arthritis pain, it was also promoted for acute pain, she notes.

The first time prosecutors looked at these allegations the feeling was that it was “too close,” says Bloom. “But several billion dollars later,” she says, “it turns out the FDA was very clear about what it meant by arthritis pain versus acute pain.”

In short, she says, considerations such as dosages and promoting for the side effects of a product rather than its approved use are now considered legitimate areas of investigation.

The future. Bloom says the Pfizer settlement also includes allegations that are likely to be “growth areas for healthcare fraud.” One specific area she highlights is comparative claims. Bloom says there is an inevitable tension between the purpose of a sales call, namely to explain why a certain product works better than a competitor product – “Why would they be there if they were not trying to do that?” – and the underlying regulations.

Sales reps are not *permitted* to do that unless they have two double-blind placebo-controlled head-to-head studies, says Bloom. Rarely do they have this, she says, and rarely do they cover the entire universe of claims they want to make even if they do have some of it.

Deterrent penalties

As off-label cases have developed and grown larger, the concept of what it takes to preclude prohibited activity from being considered “a cost of doing business” is continually being reevaluated by the government, says Bloom. Within both DOJ and the OIG there is “serious thought” about what type of remedy might be required to prevent future violations, she says.

“It is not easy to prove felony Food and Drug Cosmetic Act violations against a lot of individuals at these companies,” says Bloom. “But there are a lot of other remedies out there.” She says there is considerable discussion about whether, and to what extent, the government will use the Responsible Corporate Official Doctrine, which says that anyone in a position of responsibility can be liable under the government’s misdemeanor authority even if they lack specific knowledge of the violations in question.

Other potential remedies could include divestiture of specific products or giving up generic exclusivity in order for the OIG to waive its permissive exclusion authority, says Bloom. “That is an ongoing dialogue,” she says.

Kickback cases persist

In addition to continued off-label allegations, Kenney also points to a considerable number of kickback cases. “Some U.S. Attorney’s Offices, at least in my experience, are much more open to bringing kickback claims as a basis for a False Claims Act,” he says.

“I think you are going to see a lot more kickback theories,” he adds, “not only straight-up payments, but kickbacks disguised in the form of rebates.”

A defense perspective of off-label promotion

Veteran attorney **Stephen Immelt** of Hogan Lovells in Washington, D.C. points out that off-label prescribing is an integral part of the practice of medicine. This is especially the case in certain areas such as oncology, he says.

“Oncologists tell us that the best and current standard of care often does not track the FDA approval process,” says Immelt. If oncologists were forced to wait for that process to unfold, it would have a deleterious impact on patients, he maintains.

According to Immelt, this issue of patient harm versus patient benefit is paramount from a defense perspective. “It has always been true,” he says, “but I think it is even more true today as more off-label cases have been brought that from a defense perspective the issue of patient harm versus patient benefit is the first issue we always think about.”

“The issue of whether physicians have been misled in any serious way is the second thing we think about,” says Immelt.

The third factor, from the defense perspective, he says, is whether the FDA has been misled in any material way.

The gatekeeper theory

Immelt expressed concern about new cases advancing what he calls the “gatekeeper theory.” Rather than focusing on individual false claims, these cases look at the FDA as the gatekeeper. “We are seeing cases in the device area asserting that the FDA was misled about whether to clear a device,” he explains. “From that premise, they argue that every use of that device over the last ten years is invalid.”

In short, says Immelt, cases are moving “further upstream” away from the claims submission process, where considerable attention has been expended for some time, to what transpired in the approval process. He sees many legal hurdles for relators pursuing these upstream cases, but they also can create significant risks and exposures for the companies, he cautions.

Lengthy investigations persist

One thing that has not changed in recent years is the length of time most pharma *qui tam* suits take to settle. According to **David Haron**, who heads the *Qui Tam* Practice at Frank, Haron, Weiner & Navarro in Troy, MI, off-label cases are especially time-consuming for several reasons. First, he says, they are nationwide cases covering billion dollar drugs produced by multiple-billion dollar multi-national companies with sometimes millions of claims all over the country that have to be assembled, sampled, and evaluated.

In addition, he says, witnesses must be interviewed and conclusions reached while the case is still under seal. Moreover, he points out, acquisitions often occur during the evolution of a case.

In the recent Topomax investigation, Haron says, his team of attorneys reviewed and assembled additional evidence as the case proceeded. The massive amount of information and claims and the numerous individual Medicaid State agencies that were involved further complicated the investigation, he says.

Moreover, Haron says, there were hundreds of physicians targeted nationwide by 150 or more employed sales reps, which meant many potential witnesses and individual schemes. In fact, he says, sales reps would receive a bonus if they detailed every doctor in their assigned zip codes.

Further complicating this case was the fact that a grand jury was convened as part of a criminal investigation. "That always delays a case, because of the more intense burden of proof in criminal cases and length of time to establish evidence of criminal intent," he explains. ■

Grassley queries 16 major drug companies on compliance program development

Last month, Senator Charles Grassley (R-IA) queried 16 major pharma companies about the development of their compliance programs, including educating employees on the False Claims Act (FCA) and whistleblower provisions.

While pharma companies are technically exempt from the compliance obligations included under the Deficit Reduction Act, Grassley says, any "respectable" compliance program should include a relevant sample of all federal laws designed to combat fraud and abuse in the Medicare and Medicaid programs.

Here are the eight specific questions posed by Grassley in a sample to Boehringer, which was one of the companies queried, even though it has not been the subject of a major settlement:

- 1) What changes have taken place at Boehringer with regard to notifying employees about the FCA? Please provide examples of current policies, educational materials, and/or any other documents that Boehringer distributes to its employees that describe the FCA.
- 2) What materials are provided to employees to educate them on FCA whistleblower protections, specifically resources on the filing of claims or where employees can seek additional information? Please provide the relevant materials and literature distributed to employees.
- 3) Please describe Boehringer's process for handling whistleblower allegations. Have there been any changes to the program since its inception?
- 4) Since the implementation of Boehringer's compliance program, how many allegations has Boehringer received each year? Please describe any quantitative and qualitative differences in the allegations, complaints or reports Boehringer has received since establishment of the program.
- 5) Of the claims received, how many were resolved in favor of the claimant and how many were resolved in favor of the company?
- 6) What measures do you have in place to ensure fair treatment to those filing complaints?
- 7) Of employees who have filed complaints, have any complained of unfair treatment and/or retaliation after the filing of the complaint?
- 8) What modifications, if any, has Boehringer made to its compliance program in light of the passage of FERA, which extends whistleblower protections to contractors and agents?

► *Cont. from page 1*

DOJ spotlights reimbursement of unapproved drugs

The unapproved drugs the Justice Department is now investigating are distinct from the off-label promotion cases DOJ has been working on for the past decade, Bhambhani explains.

According to Bhambhani, these are typically drugs with active ingredients that were on the market prior to 1962 when a drug could come on the market with only FDA approval for safety, he explains. After 1962, Congress changed the law to require approval of safety and efficacy. “That left a big question about what to do with all of these drugs that were on the market before 1962,” he says.

To remedy this issue, the FDA contracted with the National Academy of Sciences to establish the Drug Efficacy Study Implementation (DESI) program to review the efficacy of all of the drugs that were on the market prior to 1962.

For drugs found to be ineffective, the FDA issues a notice designating them as such, says Bhambhani. That, in turn, triggers a provision in the Medicaid statute prohibiting payment by Medicare and Medicaid.

Targeting DESI-ineffective drugs

According to Bhambhani, DOJ has learned that many companies continue to seek reimbursement even after they receive notice that a particular drug is ineffective. “What these companies will do is continue to code the drug as DESI effective when, in fact, it is DESI ineffective,” he says. “That is a false statement that leads to continued payment for reimbursement for these drugs.”

“This is not just limited to a few drugs,” says Bhambhani. “There are thousands of drugs like that on the market.” According to Bhambhani, DOJ is now coordinating closely with both the Centers for Medicare and Medicaid (CMS) and the FDA to determine to full scope of the problem. “CMS and FDA are onto the issue,” he says.

Bhambhani pointed out that a settlement with Schwarz Pharma was recently reached involving precisely this issue (*see story, this page*).

“I think this whole explanation is a demonstration of the wonders of the False Claims Act,” Assistant U.S. Attorney **Sara Bloom** observed. “I don’t think we ever would have figured this out but for the miracle of a relator.” ■

Schwarz Pharma’s \$22 million settlement for reimbursement of unapproved drugs likely the first of many similar cases

Schwarz Pharma recently agreed to pay the government \$22 million to resolve False Claims Act allegations that the company failed to advise the Centers for Medicare and Medicaid Services (CMS) that two unapproved products did not qualify for coverage under federal healthcare programs.

What the Department of Justice does not point out is that the complaint against Schwarz Pharma cites nearly 20 individual companies. “It’s got some company,” says **Marcella Auerbach** of Nolan & Auerbach, who represented the relator in the Schwarz case.

“We have a real problem in this country of the permeation of unapproved drugs,” says Auerbach.

“People assume that because they get drugs from a pharmacy that they are automatically FDA approved,” she says. “This case represents another signal that that is not the case.”

In fact, she says, there are many unapproved drugs, but enforcement has been lagging. “We believe this is a signal that the FDA is going to increase enforcement,” she says.

“This is not just limited to a few drugs,” DOJ’s Sanjay Bhambhani said about unapproved drugs. “There are literally thousands of drugs like that on the market.”

The case against Schwarz

Schwarz, which is now a subsidiary of Belgium-based UCB S.A., is alleged to have submitted false quarterly reports to the government related to a pair of drugs, Deponit and Hyoscyamine Sulfate Extended Release (Hyoscyamine Sulfate ER).

Deponit is a nitroglycerin skin patch that has been used to prevent angina. Hyoscyamine

Sulfate ER is an antispasmodic medication that has been used to treat various stomach, intestinal, and urinary tract disorders that involve cramps, colic, or other painful muscle contractions. While the active ingredients in Deponit and Hyoscyamine Sulfate ER had been in products on the market for many years, the FDA made determinations in 1997 and 1999 that resulted in the drugs being ineligible for reimbursement by government healthcare programs such as Medicaid.

DOJ alleges that Schwarz misrepresented the regulatory status of both drugs and failed to advise CMS that these unapproved drugs did not qualify for coverage under federal health care programs. As a result, the government contends, Schwarz knowingly caused false claims to be submitted for Deponit and Hyoscyamine Sulfate ER. Ultimately, neither Deponit nor Hyoscyamine Sulfate ER ever received full regulatory approval for safety and effectiveness, and neither product is currently on the market.

The settlement resolves allegations against Schwarz in two separate multi-defendant whistleblower actions under *U.S. ex rel. Constance Conrad v. Schwarz Pharma, et al* and *U.S. ex rel. James Conrad v. Schwarz Pharma et al*. The federal share of the settlement is roughly \$12 million and the state Medicaid share is roughly \$10 million. The two whistleblowers will receive a total of \$1.8 million from the federal share and additional amounts from the state share.

DOJ's Sara Bloom says the government's investigation of reimbursement for unapproved drugs is "a demonstration of the wonders of the False Claims Act."

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Top DOJ attorney joins Patton Boggs

Former high-ranking Justice Department fraud prosecutor **John S. "Jay" Darden** recently joined Patton Boggs where he will play a key role in the Litigation Department's healthcare fraud and abuse and white-collar crime practices.

Before joining the firm, Darden was Assistant Chief of the Fraud Section of the Criminal Division at DOJ where he supervised the investigation and prosecution of healthcare fraud and anti-kickback violations in multiple districts across the country. He was the lead prosecutor in one of the largest Foreign Corrupt Practices Act dispositions in the history of the statute. Darden can be reached at: JDarden@PattonBoggs.com or 202-457-6427.

Nominal price investigations

Wyeth's Motion to Dismiss Protonix suit denied

Transcript from hearing on Protonix suit signals hotly contested case for Wyeth

In May of 2009, the federal government and 16 states joined two *qui tam* suits alleging that Wyeth Pharmaceuticals violated the Medicaid Drug Rebate program in its marketing of Protonix Oral and Protonix IV, which belong to a class of drugs known as proton pump inhibitors. The government alleges that Wyeth evaded paying hundreds of millions in rebates to state Medicaid programs through a bundling scheme. The government and 16 states intervened shortly after Wyeth disclosed the sealed case in a SEC filing in May of 2009.

In a more recent development that received scant attention, the federal judge overseeing the case, Judge Douglas Woodlock, denied Wyeth's Motion to Dismiss on February 24. Subsequently, 17 additional non-*qui tam* states filed a Motion for Leave to intervene against Wyeth.

A bench ruling

Notably, the government won the Motion to Dismiss in a ruling from the bench that included sometimes sharp commentary from Judge Woodlock (*see excerpt, next page*). The 112-page transcript of the hearing, strongly challenged Wyeth's purported defenses. "I read the Agreement in terms of what is it that Congress was trying to do in the rebate, that is the fundamental language here, and Congress was trying to ensure that they always got the best deal possible," said Woodcock. "And your marketing people, based on the allegations, were thinking this through and said, 'This is our way to get this market. And not only that; we get this market for the after-hospital sales, spillover sales.'"

"Nobody ever hired me to be a businessman," the Judge continued, "but I am reading this the muckety-mucks at Wyeth were thinking this through and said, 'As a marketing strategy, this is a good one, and it involves the use of discounts at the hospital level.' The question is whether or not they can pass through the eye of a needle on this. But it seems to me that I have to look at the actual dimensions of the camel that is trying to do that."

"This case is a big deal," one veteran defense counsel observed after reading the transcript. "The judge seems willing to effectively read the DRA bundling rules back in time. This is a huge threat."

"Nobody should have walked out of that courtroom without realizing that Wyeth, now Pfizer, has a real problem on its hands," says one attorney familiar with the case.

However, other seasoned observers at the hearing point out that Judge Woodlock suggested he is reluctant to decide complex cases at the Motion to Dismiss phase – a view that many other trial judges share – and that he is interested in input from experts and fact witnesses before issuing any rulings on liability.

A significant case

The Protonix case is notable for a variety of reasons. The first is that most cases of this magnitude never reach the Motion to Dismiss phase. In fact, almost all of the major pharma cases to date have been settled while the case was still under seal. Even in the case of Merck's \$671 million nominal pricing settlement two years ago, which is similar

to the theory in this case, there was an intervention notice but no complaint was filed. Likewise, neither TAP nor Serono nor any of the more recent blockbuster settlements such as Lilly or Pfizer went beyond the seal stage.

The typical pattern in large pharma cases is for a combination intervention/dismissal/settlement to be rolled into what amounts to one transaction. By contrast, this case is now actively being litigated with deadlines for pre-trial litigation in place.

One factor worth noting is that many federal courts are pushing to have these cases resolved more rapidly. The Protonix case is likely part of that trend.

It also likely suggests that Wyeth strongly disagrees with the government's theory in the case.

"Nobody should have walked out of that courtroom without realizing that Wyeth, now Pfizer, has a real problem on its hands," says one attorney familiar with the case.

During the hearing, Judge Woodlock indicated that a written opinion would be forthcoming. If that opinion includes the more critical portions of his commentary from the bench, it will presumably be a public blow to Wyeth, now Pfizer.

Competing tensions

The Protonix case is complicated by a variety of factors. Wyeth has known for years that a criminal grand jury has been convened, according to the company's own SEC filings.

One tension facing Wyeth was to keep it under seal, resolve it, or convince DOJ not to intervene. But those objectives were in conflict with a separate tension that requires companies to disclose investigations to shareholders.

In this instance, there was yet a third set of tensions, namely the impending acquisition by Pfizer and the degree to which the Protonix litigation may have been factored into the value of that transaction.

The underlying theory

At the ABA's False Claims Act conference last month in Washington D.C., DOJ Senior Trial Counsel **Sanjay Bhambhani** pointed to best price/bundling cases under active investigation at the Justice Department. "We are actively involved in the litigation right now with Wyeth," he noted.

"What we are focusing on are pricing arrangements where the nominal price is actually tied to a purchase [requirement]," said Bhambhani, in outlining the government's position in public filings. "That's what we had in Merck and that's what we have in Wyeth." The government's \$671 million settlement with Merck in 2007 was also a nominal price/bundling case, he noted. While

"What we are focusing on are pricing arrangements where the nominal price is actually tied to a purchase requirement says DOJ's Sanjay Bhambhani."

Bhambhani was not speaking officially on the Justice Department's behalf, he worked on the Merck case and is involved in the Wyeth matter, as well.

Excerpt from the Protonix hearing

Below is an excerpt of the Motion to Dismiss hearing. The dialogue is between Judge Woodlock and WilmerHale's Stephen Jonas:

THE COURT: What is the significance if the case proceeds?

MR. JONAS: Well, obviously the case involves the filing of Best Price reports.

THE COURT: Is it a statute-of-limitations issue? Is that what you are saying?

MR. JONAS: No. It is that the Government is bringing a False Claims Act case, suggesting that those Best Price reports based on a reading of the Rebate Agreement were erroneous and connected to the PPAs, the Protonix Performance Agreements that Wyeth entered into with these hospitals.

The Government has known about the PPAs and these allegations since 2002 and continued to receive the Best Price reports, which are the subject now of a False Claims Act claim for years thereafter without objection.

THE COURT: So what? I put it bluntly. So what?

MR. JONAS: With respect to the Motion to Dismiss, it is not an issue here.

THE COURT: With respect to anything, is it an issue?

MR. JONAS: Well, because we think that the Government -- there may be defenses based on whether the Government can rely on what it claims were false Best Price reports, knowing these allegations and knowing the way that the company reviewed the Protonix Performance Agreements in their Rebate Agreement.

THE COURT: It does not make any sense to me. Is there any case law out there that suggests--

The nominal price exception is an exception to the Best Price reporting requirement, notes Bhambhani. “What manufacturers have done is bundle nominally priced goods with not nominally priced goods and the effective prices in those bundled arrangements, according to us, are no longer nominal,” he explains.

According to Bhambhani, the effect of these marketing schemes is to deny the Medicaid program the same low prices that are widely available around the country. The core purpose of the Medicaid statute is that the Medicaid program should get the benefit of the lower prices. “The bottom line is a manufacturer has to properly report its best price,” he says.

“That is the core of our bundling theory in Wyeth,” says Bhambhani. It was also at the heart of the government’s case against Merck, he says.

A defense perspective

Veteran defense counsel **Stephen Immelt** takes a decidedly different view of these cases. “While it is easy to say that this is intended to get the government the best price, the way the statute

works in practice is about as complicated as designing a rocket ship,” he maintains.

According to Immelt, these cases typically involve “many transactions over many years” that were structured to meet the requirements of the nominal price provision. Immelt

“The way the statute works in practice is about as complicated as designing a rocket ship,” says veteran defense counsel Stephen Immelt of Hogan Lovells.

maintains that in many cases there was not any tie-in as described by the government. “It is a matter of getting under the hood and figuring out what was actually happening, especially the details of and what the actual arrangements were with hospitals,” he says.

Notably, each of the major fraud cases that Pfizer has been forced to defend in recent years deal with problems they “acquired” through the purchase of other companies. ■

This dialogue ensued later in the hearing:

MR. JONAS: If the case proceeds, there is a question concerning the company’s intent that the Government would have to show, and we think it might be relevant, your Honor, that these issues were raised as early as 2002. No one ever notified Wyeth. Wyeth continued to file Best Price reports for four years thereafter.

THE COURT: I do not want to spend too much time on this, but the conundrum for me is the defense of blaming the victim. The Governments, it seems to me, have the right to conduct their investigation, and, in fact, I suspect that there would be a different argument – if they had pulled the plug early – raised by the defendant.

But I am not aware of any law on false claims – put to one side it is common law misrepresentation itself – that makes this anything other than the defendants said that they were badly treated because they let this string out for a period of time. The defendant got the benefit of the money for that period of time.

Unless there is some legal issue that is presented, I simply do not understand it. Maybe a statute of limitations, maybe something like that, but I really have some difficulty understanding that, except my own concern that the Government’s approach took longer than it should have as a kind of management issue but not as a legal issue.

Later in the hearing, the Judge remarked:

THE COURT: I think the Government has adequately set forth the False Claims Act set of charges. I am of the view that a fair reading, even without getting to the amendment in 2007, would treat this marketing activity and strategy and initiative by Wyeth as coming within the bundled-sale provisions.

I recognize that arguments can be made about allocation, although I am of the view that the Government’s treatment of allocation, once one gets into the bundled-sale area, is the proper one, and I am of the view that even formulary can be viewed as a form of performance contingency.

DTC advertising

Consumer groups and advertising coalition offer competing views of FDA's draft DTC guidelines

Proving that DTC advertising remains controversial, consumer and industry groups recently gave FDA's DDMAC strong, divergent advice in response to its rulemaking notice on how to implement the new DTC standards mandated by the Food and Drug Amendments Act of 2007 (FDAAA). The rulemaking notice sought guidance on implementing the terms "clear, conspicuous and neutral." Consumer groups urged FDA to use these terms to create broad, new regulatory standards limiting DTC advertising, while media and industry commentators urged FDA to worry as much about "over deterring" and under warning consumers.

Stronger measures urged

The National Legislative Association on Prescription Drug Prices (NLARx) joined Community Catalyst's Prescription Access Litigation and 21 other consumer, senior, patient safety groups, and small insurers in comments endorsing "groundbreaking" new guidelines for DTC advertising in comments filed on June 25.

The consumer groups endorse the use of "simple every day terms" and a ban on distracting sounds or images as means to help prevent consumers from being misled by televised drug ads. They also endorse new proposed FDA standards to spell out drug risks and present them more slowly and prominently in broadcast advertisements, which are currently subject to laxer rules than print ads.

"State legislators have many concerns about drug company television advertising," says NLARx Executive Director **Sharon Treat**. "TV ads tend to gloss over the true risks of drugs, glamorize pharmaceutical responses when alternative medical interventions may be safer and more effective, and present scientific information in a confusing way."

The consumer groups maintain that states' efforts of state legislators to address concerns about potential health risks and the financial costs of increased drug spending, which they attribute to televised DTC advertising, are often stymied. "Drug companies are quick to bury, downplay, and mask the risks of drugs they advertise on TV with visual tricks, speed-talking, and scientific jargon," charges

Wells Wilkinson, director of Community Catalyst's Prescription Access Litigation Project.

In several areas the consumer groups urged the agency to go further in its rulemaking. For example, they agree that drug risks above a certain frequency should be quantified in commercials. Likewise, citing consumer protection rules from the Federal Trade Commission, their comments recommend that the FDA require companies to tailor risk information to the consumer who might have the most difficulty understanding an ad – a "least informed viewer" standard – rather than the "reasonable consumer" standard used by FDA in the past.

The consumer groups also maintain that the FDA should also ensure that ads are more "neutral," by addressing what they call the "widely held myths" that FDA approves all televised ads, and that the government only lets drugs that are "really safe" be advertised on television. The groups propose that until Congress funds FDA's program to review all televised ads, a disclaimer that "FDA has not approved this ad" should be required.

"Drug companies are quick to bury, downplay, and mask the risks of drugs they advertise on TV with visual tricks, speed-talking, and scientific jargon," charges consumer advocate Wells Wilkinson.

Advertising Coalition spotlights neutrality

By contrast, the Advertising Coalition focused its comments primarily on the so-called "neutrality" criterion. Writing on behalf of the Coalition, veteran attorney **Arnie Friede** says that a DTC television or radio advertisement that overemphasizes risks is as potentially misleading as one that overemphasizes benefits. "It does no one any good needlessly to

frighten consumers away from using the advertised product with a major statement that effectively amounts to a skull and crossbones warning,” he says. “While a major statement should admittedly not under warn about risk, it should likewise not over deter beneficial use of the product.”

This concept that the major statement of risk should neither under warn nor over deter can be called “NUNO” for short, says the Coalition. The NUNO principal – neither under warn nor over deter – should be acknowledged by FDA to be the operative standard for evaluating the “neutrality” of a major statement of risk even though it is admittedly somewhat qualitative, it argues.

“While self-styled consumer groups seek to restrict consumer information, the Advertising Coalition thinks informed consumers have more robust conversations with their doctors and take the better care of themselves and their families,” says **John Kamp** of the Coalition for Healthcare Communication, a co-sponsor of the ad industry comment.

Kamp predicts that DTC will remain a battleground for pro and anti-DTC forces this year and next both at FDA and on Capitol Hill. “This session, expect Congressional Democrats, especially in the House Commerce Committee chaired by Henry Waxman, to hold hearings and openly criticize DTC at every opportunity,” he says. ■

Elan announces \$203 million tentative deal to settle fraud allegations for Zonegran

Elan Corporation announced last week that it has reached an agreement in principle with the U.S. Attorney’s Office for the District of Massachusetts with respect to the previously disclosed Justice Department investigation of sales and marketing practices for Zonegran, an antiepileptic prescription medicine that Elan divested in 2004.

If the agreement in principle is finalized, Elan expects to pay \$203.5 million as part of a comprehensive settlement for all U.S. federal and related state Medicaid claims. The company has established a reserve of \$206.3 million for this expected settlement and related costs.

As part of this agreement in principle, Elan expects to plead guilty to a misdemeanor violation of the Federal Food, Drug and Cosmetic Act.

What’s ahead in the next issue of *Disclosure Update for Drug & Device Companies*:

Here are some of the developments in the area of state disclosure requirements that will be covered in more depth in the July issue of *Disclosure Update for Drug & Device Companies*:

Massachusetts House repeals gift ban

As part of the state’s economic stimulus package, the Massachusetts state house last week passed a repeal of the state’s gift ban. Amendments to keep the gift ban law in place were defeated.

Now the bill goes to a House-Senate conference committee where the real battle will take place, says **William Mandell** of Pierce & Mandell in Boston, who has considerable experience with the Massachusetts law. He says Senate President Therese Murray will no doubt wage a vigorous fight to save the law given that she was its primary sponsor.

Connecticut enacts disclosure law

Last month, Connecticut enacted legislation requiring drug and device companies to adopt compliance programs by January 1, 2011. Drug and device companies should be alert to the issuance of proposed regulations implementing the law, says Sidley Austin’s **James Stansel**.

Vermont amends disclosure laws to require reporting of product samples

Vermont recently enacted legislation that amends the state’s existing gift ban and disclosure law. Epstein, Becker & Green’s **Wendy Goldstein** says the new law is significant in several respects.

First, it is the first state law that requires drug and device companies to report free samples. Specifically, it requires companies to report annually to the Vermont Office of the Attorney General certain information related to free samples of prescribed products provided to healthcare providers during the preceding calendar year.

Goldstein says it will likely be some time before it is clear whether passage ends the surge of states interested in enacting their own transparency laws.

Social media

Recent survey by leading consulting firm gauges industry response to lure of social media

It is a well-known fact that many drug and device companies are taking a “wait and see” approach to social media activities as the industry awaits much anticipated guidance in this area from the FDA. Nevertheless, a recent survey by Huron Consulting Group found that roughly half of the drug and device companies surveyed are utilizing some type of social media.

In order to assess the current level of activity in this area, as well as related compliance efforts, Huron developed an on-line survey covering twenty questions related to how companies are dealing with the use of social media and monitoring. Roughly 80 percent of the respondents were from pharma companies. The remaining 20 percent were evenly divided between medical device and biotech firms.

Forty percent of the individuals completing the survey were from compliance departments. One-quarter were from Sales and Marketing. Ten percent were from Legal, Clinical Research, and Information Technology, while five percent were from Manufacturing.

Here are the key findings from the survey, along with observations from Huron Managing Director Mark DeWynngaert, PhD., who has broad expertise in this area.

Does your organization currently utilize any social media technology?

Key Findings:

- Over half of companies surveyed are not currently utilizing any social media technology.
- A number of companies are waiting for the final regulations to be passed before moving forward.

According to DeWynngaert, the response rate on this question likely understates the number of companies actually involved in social media. “When you talk to people from compliance and legal, what they fail to take into account is that almost all of their market research departments are actively listening and using this space,” he explains. “The other group that is actively in this space is typically their R&D group.”

Notably, says DeWynngaert, smaller, biotechnology organizations are more progressive when it comes to the use of social media technology

Which social media outlets does your company use?

Key Findings:

- Although a majority of organizations are not utilizing social media technology, the ones that do are using a diverse set of tools including blogs, video, podcasts, and other forms.
- Pharmaceutical companies are using a combination of blogs, social networking sites and Twitter.

What this question primarily highlights, says DeWynngaert is that there is currently no single social media tool being used. This was especially true of pharma companies, he adds. Medical device companies are primarily using Wikis and company web pages. Biotech companies are mainly using blogs and websites. However, pharma companies are using a broader mix of tools, including social networking sites, and Twitter.

Over half the drug companies surveyed are not currently utilizing any social media technology.

For what purposes does your company use these sites?

Key Findings:

- The main use of social media sites is for education and disease state information, as well as patient education and communications (12%).
- New product promotion and overall company information is also an area of use (10%).

- While the pharmaceutical industry follows the general trends, medical device organizations tend to focus on education / disease states and overall company information.

Who is currently responsible for updating this information?

Key Findings:

- While the pharmaceutical industry tends to shift responsibilities to current teams, the biotechnology firms create a new position specific to this area.
- According to the survey, 28 percent of the companies responding indicated that responsibility for this area has been assigned to an existing function, such as marketing, while 12 percent have created a new position to focus exclusively on this area.

“This is not a simple undertaking and you need some specialized skill sets,” says DeWyngaert. He says that it likely requires an exclusive focus. “I believe many companies are currently under-estimating the amount of work required to do it right,” he says. That is what the 28 percent represents.”

Do you currently have a review and approval process in place for monitoring social media information?

Key Findings:

- Notably, most companies do not have a review and approval process in place for monitoring social media information.
- Companies need to determine what group is going to monitor this specific area of promotional activity.
- Again, it seems that the biotechnology firms are more aggressive in not only social media outreach, but also monitoring of the information.

According to DeWyngaert, only half of the companies engaged in social media have a review process in place.

Does your social media site allow for customer feedback/uploads?

Key Findings:

- As expected, most companies do not allow for customer feedback and uploads
- All the customer feedback/upload responses came from pharma companies.

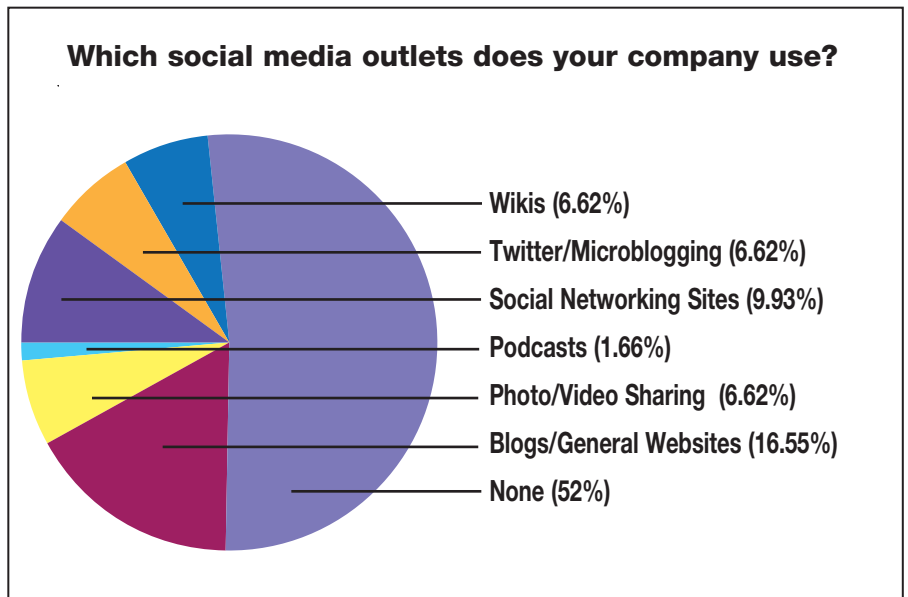
Notably, only 12 percent of the companies surveyed allow for two-way communications. “People are dabbling in this area,” says DeWyngaert. However, liability concerns lead most companies to take a highly conservative approach.

Most companies do not have a review and approval process in place for monitoring social media information.

If yes, do you have a system for monitoring the information that customers upload to your site?

Key Findings:

- For the firms that allow customers to upload information to the sites, almost none have a system in place for monitoring this information According to DeWyngaert, the survey essentially shows that for the minority of companies that do



have two-way communication, all of them monitor that communication.

Was any training given to educate employees on the use, benefits, and risks of using social media technologies?

Key Findings:

- Biotechnology firms tend to do more training overall than other firms, however, all industry organizations are low in this area.
- Very limited training given to educate employees on social media technologies.

Notably, the survey indicates that only one-third of biotech companies, one-quarter of medical device companies and only 12 percent of pharma companies offer any training.

If your company does not engage in social media technologies, why?

Key Findings:

- The reasons provided for not utilizing social media technologies range from compliance risks to lack of resources to lack of knowledge.
- Most firms are across the board as to why social media technologies are not utilized.

DeWyngaert points out that lack of knowledge was cited by 26 percent as the primary reason that social media was not utilized while 20 percent cited a lack of resources.

Meanwhile, fully 50 percent cited compliance risk. “I believe the overwhelming number one reason is that, internally, legal departments are indicating that without rules from the FDA in place yet, the risk associated with social media is too great.”

“Moreover,” he says, “if you don’t add head count, how do you manage the risk?”

Do you currently monitor/track public social media sites for non-company initiated content?

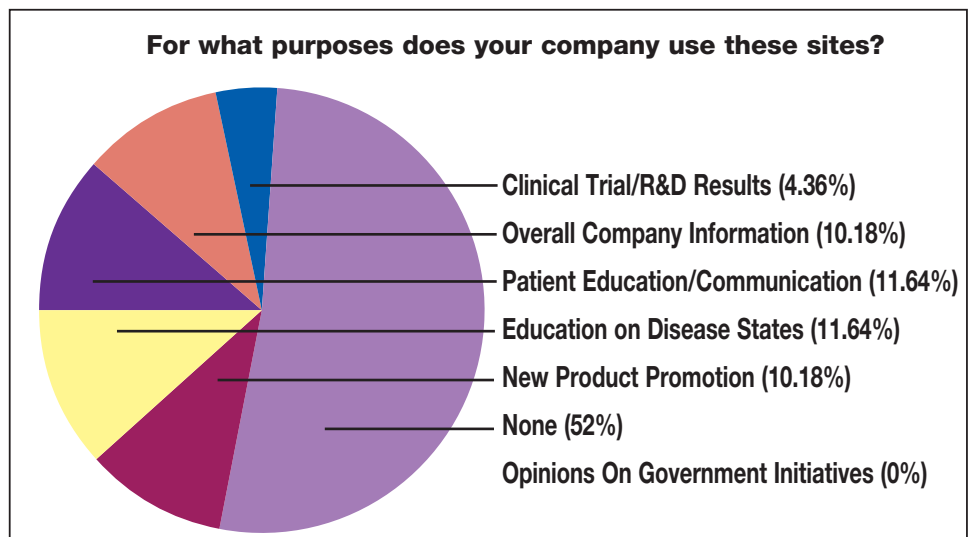
Key Findings:

- Even though this number is low, it is still higher than expected for non-company initiated content.
- Evenly split between pharmaceutical and biotechnology firms in terms of non-company initiated content.

According to the survey, only one-quarter of the respondents monitor non-company initiated content. However, DeWyngaert points out that many of them are likely overlooking the activity in this area by their market research departments. “Just because they are called market research does not mean they are not part of your company,” he says. “You possess that information.”

Biotechnology firms tend to do more training overall than other firms, however, all industry organizations are low in this area.

For more information, contact Mark DeWyngaert at mdewyngaert@huronconsultinggroup.com.



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