Democratic takeover of Congress likely to mean greater scrutiny of drug advertising, marketing, and communications
Incoming Democratic committee chairs ready to put spotlight on pharma

The Democratic takeover of the House and Senate will likely have a range of adverse consequences for drug advertising, marketing, and communications. “If the past is prologue, we can expect much greater oversight from Democrats who have lamented that the oversight role of Congress has gone unfulfilled under the Republicans,” says Adonis Hoffman, senior vice president and counsel of the American Association of Advertising Agencies in Washington, D.C. “First and foremost,” he says, “in the all-important House Energy and Commerce Committee, a revived chairman John Dingell (D-MI) will likely resume congressional scrutiny over a number of industries—not the least of which will be pharmaceuticals.” ▶ Cont. on page 2

National Pharma Audioconference: How the Democratic Takeover of Congress Will Impact Pharma

Please join us in two weeks for a special briefing on the sweeping impact the Democratic takeover of Congress will likely have on areas ranging from off-label promotion and continuing medical education (CME) to drug safety and DTC advertising.

Wednesday, November 29, 2006
1:00 pm - 2:30 pm (EST)
www.pharmaaudioconferences.com

Featured speakers include Adonis Hoffman, Senior V.P. & Counsel, American Association of Advertising Agencies, former Hill staffer Steven Irizarry, V.P. Government Relations, ML Strategies, Daniel Kracov, Partner and Chair, Pharmaceutical and Medical Device Practice, Arnold & Porter, and John Kamp, Executive Director, Coalition for Healthcare Communication (moderator).

See p. 3 for more details and special discount offer.
Democratic takeover of Congress likely to mean greater scrutiny of drug advertising, marketing, and communications

**In the House**

With Rep. Henry Waxman (D-CA) heading the House Energy and Commerce Health Subcommittee and Rep. Pete Stark (D-CA) in charge of the House Ways & Means Health Subcommittee, Hoffman says, the industry can expect more contentious debate on drug safety. “That alone opens the door to a host of issues, including restrictions on DTC advertising, moratoria on new medicines, and stepped-up review and enforcement by the FDA.”

Former Senate Health, Education, Labor and Pensions (HELP) Committee Counsel Steven Irizarry takes a similar view. “The pharmaceutical industry will be scrutinized much more vigorously by a greater number of congressional committees and on many more subjects than in previous years,” says Irizarry. These attacks may bring about congressional hearings in such areas as FDA oversight and Medicare Part D, he predicts. But they could easily translate into legislation, he warns.

**A friendlier Democratic party?**

Some leading Democrats, including Rep. Steny Hoyer (D-MD), have talked about adopting a more business-friendly posture, says Hoffman. If Hoyer becomes House Majority Leader, as expected, he could represent a moderating voice for less regulation, says Hoffman. But House Speaker Nancy Pelosi (D-CA) is not expected to give business an easy pass, as the stakes for 2008 become higher, he adds. “Pelosi is poised to renegotiate the way the government contracts for prescription medicines,” says Hoffman. While nobody knows how that debate will be resolved, he says, it portends big changes for the industry.

A key question, Irizarry says, is how much control a Speaker Pelosi is able – and willing – to exert on committee chairmen and their legislative agendas. Reps. John Dingell, Henry Waxman, and Pete Stark are all strong-willed and outspoken legislators who have been waiting a long time to hold the gavel, he points out.

Irizarry anticipates a number of hearings highly critical of FDA’s approach to drug safety, the Prescription Drug User Fee Act (PDUFA) -- which must be reauthorized next year -- and Medicare Part D. “Incoming Ways and Means Health Subcommittee Chairman Stark and Government Reform Chairman Waxman, in particular, have been harsh critics of the Medicare prescription drug program,” he says. “It will be interesting to see if their approach to legislation will be more temperate than their hearings.”

Another person to watch, says Irizarry, is Rep. Bart Stupak (D-MI), a tough critic of both the FDA and the pharmaceutical industry, who will likely chair the House Energy and Commerce Oversight and Investigations Subcommittee.

**In the Senate**

In the Senate, the Democrat’s thin majority promises more, rather than less, gridlock, says Hoffman. Under the chairmanship of Senator Ted Kennedy (D-MA), the Senate HELP Committee likely will address Medicare, prescription drugs, and reimbursement issues with renewed urgency. “Their long experience and entrenched positions on consumer health matters leads me to believe they will renew efforts to pressure FDA into tighter industry review,” says Hoffman. Democrats also could be more successful in attaching amendments to must-pass legislation, including appropriations measures in 2007, he adds.

With respect to drug safety, Irizarry believes Kennedy may refrain from introducing a new, more austere bill out of concern that he might alienate his chief cosponsor, current Senate HELP Committee Chairman Mike Enzi (R-WY). According to Irizarry, however, Kennedy might not have to. “Even under a GOP-controlled Congress, PDUFA IV was expected to be contentious and a
magnet for all kinds of drug-related amendments,” he explains.

These amendments, Irizarry says, could include other drug safety measures not addressed in the Enzi-Kennedy bill, as well as legislation addressing DTC advertising, off-label promotion, and continuing medical education (CME).

While leadership of the Senate Finance Committee will move from Senator Chuck Grassley (R-IA) to Max Baucus (D-MT), the committee’s examination of off-label use and CME may continue, says Irizarry (see related story, p. 7). “The investigation was launched jointly by Grassley and Baucus,” he says, “and the latter may continue to pursue this issue in the spirit of bipartisan cooperation.”

**An eye toward 2008**

In the lead-up to the 2008 presidential elections, Hoffman says, it is reasonable to expect a lot of talk about the impact of media on consumer behavior. “The notion that media drive more consumption of things that may not be good for consumers—from junk food to costly prescription drugs—is likely to find its way into the debate,” he explains.

“With the first open presidential election in years looming in 2008, Democratic control of Congress will be characterized by high-level debates on popular social and economic issues,” Hoffman concludes. “In the pharmaceutical category, that leaves a lot of room for grandstanding.”

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**Steven Irizarry**, Vice President Government Relations, ML Strategies, SEIrizarrymlstrategies.com

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**Two weeks away!**

*National Pharma Audioconferences: How the Democratic Takeover of Congress Will Impact Pharma*

*Wednesday, November 29, 2006   1:00 p.m. – 2:30 p.m.*

www.audioconferences.com

1:05 p.m. — **The New Congressional Landscape** - John F. Kamp, J.D., Ph.D. (Moderator)

1:15 p.m. — **Big Pharma and the New Democratic Congress** - Adonis Hoffman, Esq.

- Strengths, weaknesses, opportunities and threats for the industry
- Balancing business and consumer interests
- Threats facing Direct-to-Consumer advertising

1:30 p.m. — **The Likely Impact on Drug Safety and FDA Reform** - Daniel A. Kracov, Esq.

- The prospects for PDUFA and potential for FDA drug safety legislative “reform”
- Likely areas of Congressional oversight and investigations
- Prospects for clinical trial registry and database legislation

1:45 p.m. — **Off-label promotion and CME Under the Spotlight** - Steven E. Irizarry, Esq.

- The potential impact on off-label promotion
- Possible scenarios for continuing medical education

2:00 p.m. — Moderators Comments and Panel Discussion

2:10 p.m. — Questions and Comments

2:30 p.m. — Audioconference Adjournment

**Special discount offer!** Please visit www.pharmaaudioconferences.com or call 800/684-4549 for special discount offer when registering for this audioconference and the December 13, 2006 audioconference – The InterMune Off-label Settlement and the Rise of Deferred Prosecution Agreements (see back page for details).
District Court Judge Patti Saris dealt the industry a major blow this month when she denied the companies’ motion to dismiss a nationwide class action lawsuit alleging they defrauded consumers by illegally inflating the costs of prescription drugs. The ruling against nearly two dozen pharma companies cleared the way for trial to begin in Boston.

“This decision means one thing to big pharma,” says qui tam advocate Patrick Burns. “Settle every Average Wholesale Price case they can, as fast as they can, before the court decides the case for them.” With this decision, Burns predicts $3 billion in federal False Claims Act recoveries from the pharmaceutical industry this year. “I think this will be a landmark decision,” says Burns. “The dominoes are going to tumble pretty fast now,” adds Burns.

“The core argument put forth by the pharmaceutical industry has been effectively gutted,” he argues.

Right behind these class action lawsuits, in the same court, is a series of large False Claims Act cases with essentially the same set of facts, reports Burns.

“A reckoning is about to be felt,” warns Burns, communications director for Taxpayers Against Fraud in Washington, D.C., “and big pharma is going to have to pay the piper in terms of triple damages, statutory fines, and criminal penalties.

Plaintiffs weigh in
The suit, led by attorney Steve Berman, managing partner of Seattle-based Hagens Berman Sobol Shapiro, targets the companies’ practice of allegedly inflating the Average Wholesale Price (AWP) they reported for certain drugs. In turn, Medicare, Medicaid, and third-party payers reimburse pharmacies and physicians for drugs they provide based on the AWP. Individual patients’ out-of-pocket costs also are determined on this basis.

“This was the last big hurdle we faced before trial,” says Berman. He says Judge Saris’ ruling “roundly rejects” the defendants’ assertions that, while the data was termed “average wholesale price,” Congress and others responsible for setting reimbursements inherently understood the figures were not accurate, and had little reflection on the actual average wholesale price, but rather was a benchmark used for negotiation purposes.

According to Judge Saris, “determining the plain language meaning of the regulatory and statutory term ‘average wholesale price’ is a straightforward exercise that begins with the dictionary.” She cited Webster’s Third New International Dictionary of the English Language for the words “average,” “wholesale,” and “price.”

“In essence, the court found that average wholesale price means just that: the average price at which wholesalers sell drugs to their customers, and not a fictitious figure made up by defendants to game the system,” says Berman.

Earlier this year, the plaintiffs reached a $70 million settlement with GlaxoSmithKline on behalf of consumers and third-party purchasers, removing them from this litigation.

First Data Bank
Hagens Berman also recently announced a settlement with First Data Bank (FDB), a primary publisher of the AWP list for pharmaceutical products. In that settlement, FDB will adjust the Wholesale Acquisition Cost to AWP mark-up on 95 percent of pharmaceuticals sold in the United States. Savings to the government from the settlement are estimated to reach $4 billion in 2007 alone. If the settlement is approved, $3.3 billion will go to third-party payers and approximately $400 million to the uninsured. FDB has also agreed to stop publishing the AWP list for pharmaceutical products after a two-year notice period.

See the next issue of Rx Compliance Report for more on the FDB settlement.
Medco’s final $155 million settlement with the U.S. Attorney’s Office for the Eastern District of Pennsylvania and the Department of Justice, announced October 23 marks the conclusion of one of the most hard-fought, protracted, and extensively litigated whistleblower lawsuits in False Claims Act history. Proponents say the final settlement makes major improvements in the way PBMs operate. Detractors question the notion of regulating the PBM industry through judicial decree.

The matter had been scheduled for a lengthy jury trial before mediation efforts proved successful. “The novelty, complexity, and magnitude of this multi-faceted litigation demanded a vast expenditure of both public and private resources in order to reach a settlement,” says Marc Raspanti, co-counsel for the whistleblowers. He says the settlement will fundamentally alter the way PBMs contract and deal with both the federal government and state governments.

According to Alison Duncan, co-counsel for the whistleblowers, the Medco case represents “the most comprehensive, blueprint litigation” for the PBM industry. “Settlement of this case established new ground rules for a critical component of the United States healthcare system,” says Duncan, a partner with Porter, Wright, Morris & Arthur in Washington, D.C.

However, defense counsel Bill Sarraile counters that False Claims Act litigation is an inadequate way to mandate PBM transparency. “There is no doubt that transparency in PBM operations is an important public policy issue,” says Sarraile, “but it does not make sense to define such complicated public policy issues in False Claims Act cases.” Rather, he says, the government should take the time to develop a standard, through notice and comment, before lawsuits are filed. “We have to stop this tendency to regulate through False Claims Act litigation,” he argues.

Raspanti maintains that all PBMs have “awakened” as a result of this litigation and have moved forward to include greater transparency in the manner and method in which they interact with both federal and state governments.

A daunting investigation
By all accounts, the scope of the investigation was daunting. Before reaching a mediated settlement, more than nine million pages of documents, complex and extensive computer data, and thousands of pages of motions, replies, and sur-replies had been exchanged among the parties, according to plaintiff’s counsel. In addition, the depositions of more than 20 experts and more than 100 fact witnesses were taken throughout the country.

The highly protracted nature of the case is reflected in the enormous court docket, say Raspanti, a founding partner with Miller, Alfano & Raspanti in Philadelphia, which includes hundreds of docket entries and detailed written opinions by the late Senior Judge Clarence Newcomer, as well as numerous opinions by Magistrate Judge Peter Scuderi on myriad discovery disputes between the parties during the heated litigation.

A seven-year investigation
The first qui tam lawsuit in the consolidated settlement was filed by two former Medco pharmacists, Walter Gauger and George Bradford Hunt, on May 6, 1999, in the Eastern District of Pennsylvania under both the federal and several states’ False Claims Acts. Gauger and Hunt were employed by Medco for nearly two decades and worked at its largest automated mail order facility in Las Vegas, Nevada. In their qui tam suit, the two relators alleged that, since 1993, Medco defrauded...
the federal government, as well as state governments, of hundreds of millions of dollars using a variety of false and fraudulent schemes.

Eleven states with strong state False Claims Act statutes that closely mirror the federal law and the District of Columbia also brought suit against Medco.

**Interim settlement**

In April 2004, Medco agreed to pay 20 states a total of almost $30 million to settle numerous claims, including those raised in the qui tam complaint. At the time of its settlement with the states, Medco also agreed with the federal government to a consent order requiring permanent, wide-sweeping changes to its business practices. “The enterprise-wide change required by the consent order instilled transparency into Medco’s business practices,” says Duncan, “and the consent order has served as a model for change throughout the entire PBM industry.”

**Powell v. Express Scripts**

The Medco settlement is not the only notable development in this area, according to Sarraile. Last month, he reports, trustees of the United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund filed a class action complaint on behalf of similarly situated self-funded prescription drug plans against Express Scripts, its subsidiary National Prescription Administrators, and 25 “John Doe” pharmaceutical manufacturers.

According to Sarraile, the plaintiffs allege that Express Scripts secretly exercises its discretionary control and authority over prescription drug pricing to enrich itself through the creation of “pricing spreads.” These pricing spreads result, in part, from arrangements under which pharmaceutical manufacturers, allegedly, pay the PBM “kickbacks” — in the form of rebates, discounts and other “soft dollars” — in exchange for favored positions on the PBM’s formulary or in its drug-switching program.

“Plaintiffs claim that Express Scripts’ failure to disclose or pass through these alleged secret payments from pharmaceutical companies constitute a breach of the PBM’s fiduciary duty to the health plans,” says Sarraile. “Plaintiffs also allege that the 25 ‘John Doe’ pharmaceutical manufacturers knowingly aided, abetted, and participated in Express Scripts’ breach of fiduciary duty.”

“While the naming of these John Doe pharmaceutical manufacturers may simply be a ploy by plaintiffs to gain additional leverage against Express Scripts,” says Sarraile, “plaintiffs may ultimately decide to amend their complaint and begin naming specific defendant manufacturers.”

According to **Paul Kalb**, Chair of Sidley Austin’s Health Care Practice Group, the new developments in litigation against Medco and Express Scripts suggest that, absent substantial transparency concerning all of the relationships between PBMs and manufacturers, PBMs face exposure to claims that they unlawfully acted in a self-interested manner, contrary to the paramount interests of health plans and patients.

“Indeed,” says Kalb, “manufacturers may also face potential liability for aiding and abetting such actions as plaintiffs’ counsel begin to allege that manufacturers are somehow responsible for the communications PBMs make or do not make to their plan sponsors.”

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Medco, Express Scripts, and Other Recent PBM Cases: Implications for Manufacturers?

**Friday, November 17, 2006**

12:00 p.m. – 1:30 p.m. (EST)

Sidley Austin will be hosting an audio teleconference regarding these recent cases and their impact on the industry on Friday, November 17, from 12:00-1:30 p.m. (EST). Please e-mail dcevents@sidley.com or call 202-736-8565 to participate in this program.

**Note:** Replay information will be available by calling the number above.

**Paul Kalb, M.D.**, heads Sidley’s national Health Care Group and represents drug and device manufacturers in government enforcement actions.

**Bill Sarraile**, is a senior partner in the firm’s Washington, D.C. office where he regularly analyzes PBM contracts and evaluates PBM transparency issues.
Despite the guidance that is out there, sales and marketing still play a significant role in how [drug] companies are distributing educational grants,” Dan Donovan, senior investigative counsel on the Senate Finance Committee, told education professionals at the AMA’s 17th Annual Conference of the National Task Force on CME Provider/Industry Collaboration in Baltimore October 18.

According to Donavan, the committee’s ongoing investigation of the CME grant-making process, which has rattled the industry, is a work in progress. The first round of letters to pharma companies sent in 2005 was followed by a second round last spring. Donovan says the responses received by the committee indicate that, by and large, most companies are adhering to the appropriate grant-making guidelines such as the OIG compliance guidance and the PhRMA Code on Interactions with Healthcare Professionals.

The challenge, he says, is to “drill down and understand what is written on paper versus what happens in practice.” The first round of letters were general, says Donovan, as the committee sought to understand in greater detail how companies approach grant-making. The second round addressed specific areas that required further examination.

Note: One senior executive from a major pharmaceutical company reports an estimated 6,800 hours have been devoted to responding to the committee’s inquiry.

Educational grants are increasing by large percentages, according to Donovan, and many recipient groups depend on this funding. That, he says, leads to questions about whether the level of financing compromises the independence of medical specialty groups, patient advocacy groups, and others. “When we see that, that leads to further inquiries,” he says.

Small payments under scrutiny

Even small payments given by pharma companies to CME providers are attracting the attention of federal investigators. According to Donovan, the committee initially had some difficulty defining an educational grant. “We had to drill down and open it up to just payments, to get down to the $100 level,” he reports.

The committee’s review, he says, indicates some sales forces are “doling out so-called educational grants in $100 increments.” In certain regions, he says, these payments were under the control of sales and marketing. “That raises additional questions in our mind about exactly what the intent is behind some of these educational grants,” says Donovan.

Broad jurisdiction

“Sometimes people think we are over-stepping our bounds,” says Donovan, “but our jurisdiction is extremely broad.”

“We work with everyone,” says Donovan. “We take all comers.” Unfortunately, he says, it is often “a one-way street.” The committee accumulates but rarely provides information until it takes formal action because of Senate confidentiality rules.

“Most frequently, we hear from whistleblowers,” says Donovan. “We have whistleblowers coming in on a daily, if not hourly, basis,” he reports. “My phone, e-mail system, and voice box is constantly full.”

“We also hear from the competition,” says the senior investigator. Companies frequently report their competition is using tactics and approaches that do not conform with applicable guidelines.

Donovan pointed out he was not in a position to telegraph the committee’s next move, but he did seek to reassure both professional educators and drug companies. “We are not out to kill continuing medical education,” he says. “That is not going to happen.” ■

Dan Donovan, Senior Investigative Counsel, Senate Finance Committee, Washington, DC, Dan_Donovan@Finance-Rep.Senate.gov
**Former FDA official blasts Stanford’s ban on gifts to physicians**

“When a patient gets a prescription from her doctor, she shouldn’t have to worry that the drug was selected because of a pharmaceutical company’s marketing skills,” *The Los Angeles Times* recently opined. That’s why Stanford University Medical Center’s announcement that no longer will allow physicians to accept gifts from pharmaceutical sales reps is “so refreshing,” contend the editors (see editorial, this page).

Former FDA Associate Commissioner for External Relations **Peter Pitts** takes a decidedly opposing view. In fact, he argues the editorial is “the worst kind of holier-than-thou pronouncement—ill informed, full of unintended consequences, and bombastic.”

“The philosophy behind the policy is that interaction with drug industry representatives is inherently bad,” says Pitts, now director of the Center for Medicine in the Public Interest, “and that any interaction with industry representatives taints a doctor’s ability to make an appropriate medical decision.”

Ironically, the editors maintain that doctors need more information on new medicines and therapies and appropriate prescribing patterns, notes Pitts. The question, he says, is where are doctors getting this information? The answer is from pharmaceutical sales reps. “That is not to say that pharmaceutical detail personnel should not do a better job educating,” he adds. The research, he concedes, shows that over the years pharmaceutical reps have become more oriented toward sales than education.

Nevertheless, says Pitts, that does not mean sales reps do not provide a valuable service. “It certainly does not mean, and there is no research whatsoever to show, that doctors visited by detail forces inappropriately prescribe,” he adds.

In short, says Pitts, the Stanford initiative is a “publicity stunt” that will decrease the quality of care for patients. “I propose that we do a double-blind study of doctors who see pharmaceutical reps and doctors who don’t,” he concludes, “and you show me, based on their patient records, who provides better care.”

**LA Times: Stanford sets pace for curbing pharma’s influence on doctors**

*Here is an excerpt from the Los Angeles Times recent editorial on Stanford’s gift ban:*

The relationship between pharmaceutical companies and physicians—their protestations to the contrary—is uncomfortably close. The drug industry doles out $21 billion a year in marketing (90 percent directed at physicians), far more than it spends on consumer advertising. And it’s often money well spent; studies have shown that even small gifts increase doctors’ sense of obligation to pharmaceutical makers, especially free drug samples that clearly sway decisions to stick with expensive medicines that often aren’t any more effective than cheaper competitors.

The drug industry says such bans, which also have been enacted in the last two years by Yale University and the University of Pennsylvania, will make it more difficult for doctors to interact with and learn from sales representatives. This is true. But so what? Drug reps typically keep physicians up to speed on pharmaceutical pipelines and medical research, something research shows doctors don’t do enough on their own. But physicians, who control patients’ lives with their decisions, must be held to the highest ethical standards possible to ensure that those decisions are based on the best empirical knowledge, not personal gain or social proximity.

Stanford’s decision also is further proof that voluntary drug industry guidelines aren’t working, as if that is a surprise. After threats from Congress to crack down on industry swag, manufacturers agreed in 2002 to limit gifts to those of “modest value.”

Still, companies continue to spend millions flying physicians to winter conferences in Hawaii and throwing lavish parties. Meanwhile, sanctions against doctors who accept forbidden costly gifts are rare. Considering the supply isn’t likely to stop anytime soon, hospitals should follow Stanford’s lead and cut the demand with similar bans.

This won’t be cheap. Stanford estimates that making up for all those “free” lunches and drug samples could cost the medical center millions. But when it comes to patient safety, and the fundamental importance of trusting your doctor for impartial information, it’s money well spent.

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**Peter Pitts**, Director, Center for Medicine in the Public Interest, New York, ppitts@cmpi.org
**False Claims Act**

*Defense counsel explains do's and don’ts for handling potential whistleblowers*

“The False Claims Act is the government’s number one civil fraud fighting authority,” says health care attorney Jesse Witten, a partner in the litigation group at Ropes and Gray and a member of the firm’s healthcare group. “To a large degree,” he says, “it is whistleblowers who are setting the government’s fraud enforcement agenda, as government prosecutors readily [admit].”

Roughly 400 federal *qui tam* actions are filed each year, notes Witten, who has extensive experience in helping clients handle suspected or potential whistleblowers and in defending *qui tam* lawsuits. Roughly 270 of those cases are filed against the health care industry (276 in 2004 and 270 in 2005). In addition, he adds, there are the numerous lawsuits filed under state *qui tam* statutes and sometimes others under municipal and county *qui tam* statutes. However, there are no statistics on such state or municipal litigation, Witten points out.

**DRA likely to expand trend**

“This trend is going to continue,” Witten says flatly. One reason, he says, is the recently passed Deficit Reduction Act (DRA), which requires companies with more than $5 million in annual Medicaid revenue to include detailed information about False Claims Act and *qui tam* provisions in their employee handbooks.

According to Witten, there is some question about whether the DRA’s disclosure requirement mandates actual training or only to include that information in the employee handbook. “I think the correct reading of the literal language is the latter,” he says.

“The statute does not require [companies] to walk around with a giant ‘Kick Me’ sign on their back,” says Witten. Nevertheless, he maintains, that is essentially the effect.

The DRA also gives states financial incentives to enact their own *qui tam* provisions, notes Witten. Specifically, under the statute, in a Medicaid settlement in which the federal government took the lead, the state’s share of the recovery will be greater if the state has its own False Claims Act statute and *qui tam* provisions, he explains.

**Understanding whistleblowers**

“Anyone can file a *qui tam* law suit,” warns Witten, including employees, former employees, CEOs, board members, competitors, customers, suppliers, consultants, and total strangers. The only exception, he says, is if there has been a prior public disclosure of the allegations of fraud, the relator must have direct and independent knowledge of what they are alleging.

Conversely, if there has been no public disclosure, anybody can file a *qui tam* lawsuit against anybody else. “There are plenty of data miners out there who have done just that,” Witten points out.

Editor’s note: Perhaps the best example of so-called data miners is Jim Breen and his colleagues at VenaCare, a small infusion company located in Florida, that started filing drug pricing *qui tam* lawsuits beginning in the early 1990s. This month, a U.S. District Court dealt a major blow to pharma companies seeking to have many of these cases dismissed (see related story, p. 4).

Companies cannot prevent lawsuits from so-called data miners, says Witten, except to operate the business as ethically as possible. That said, he points out that most *qui tam* lawsuits are filed by current or former employees motivated by a variety of factors.

Some of these relators are genuinely frustrated by regulatory non-compliance and a perceived lack of adequate response on the part of the company. For this group, says Witten, an effective compliance program and appropriate feedback can be effective.

Others sue because they want to get rich, are seeking revenge, or are motivated by a personal vendetta, says Witten.
Creating documentation
The overall objective in dealing with potential whistleblowers, Witten maintains, should be to channel those employees into the company’s compliance program, which leads to appropriate corrective action.

Sometimes, however, employees are intent on filing a qui tam suit for their own personal motivations, says Witten. In these cases, the best companies can likely hope for, he says, is to “smoke out the employee’s concerns” and create a record that demonstrates the company investigated and addressed the concerns of that employee.

This approach will have several positive affects, says Witten. First, if properly documented it may convince the government not to intervene in the case. In addition, a record to this effect shared by a potential whistleblower with a qui tam attorney could – and in some cases should – persuade the qui tam attorney not to take the case, he argues.

Finally, says Witten, at the summary judgment stage or at trial, this type of documentation can provide a defense by demonstrating an attempt on the part of the company to investigate the employee’s concerns and take appropriate actions.

Effective reporting and certification
According to Witten, an effective compliance program should require employees to report regulatory violations internally. “That is an important part of the compliance program that is sometimes [missing],” he says. Employees should be encouraged or directed to report concerns to their supervisor or the compliance officer, says Witten. “They should be cautioned that a failure to report a regulatory violation of which they are aware can lead to their own disciplinary action,” he adds. However, they should also be assured that good faith internal reports will not lead to retaliation against them.

Witten says all these policies should be included in an employee handbook or in the compliance program materials.

Some companies also require a subgroup of employees to certify annually they are aware of no compliance concerns or state what those compliance concerns may be, says Witten.

If companies take this approach, he says, the certification should not be phrased in a leading way. For example, it should not say, “I hereby certify there are no compliance issues.” Rather, it should be open-ended and written to encourage the employee to state any compliance concerns.

When companies do encounter an employee who has complained about a regulatory issue, it is important to take several steps, says Witten. The first is to get a complete account from the employee about the issue that concerns them. “Document that interview,” says Witten. Two people should conduct the interview, he adds, to avoid having it deteriorate into a “he-said, she-said” situation. “You will be in much better shape if there were two witnesses who can attest to what was said,” he explains.

If the interview is conducted by an attorney, says Witten, it is important to remind the employee the conversation is covered by the attorney-client privilege and the employee is not authorized to disclose the content of that communication -- because it is privileged -- or any documents the employee produces to anyone outside the company.

Witten points out that when investigating or interviewing an employee in a union setting, different rules may apply. In short, union employees may enjoy certain collective bargaining or other rights.

“A balancing act”
According to Witten, companies face “a balancing act” in this area. “The process has to be transparent to the employee,” he says, “but not too transparent.” In other words, he explains, employees must see the company is making a good faith effort to investigate. But that does not mean the company has to reveal all known facts to the employee.

How much transparency is appropriate and to what degree the company should include the employee in the investigation and/or the remedial action depends on a variety of factors, says Witten. In short, some employees will prove far more helpful than others, he says.

Employees must be informed of the ultimate resolution, says Witten. “How you provide that information to the employee is going to vary from one situation to another,” he says. In some cases, companies may wish to let the employee read the final report. In other cases, an oral report may be
more appropriate. “One way or another,” he says, “the employee needs to see that something was done and that it was done in good faith.”

**Reassignment as an option**

Sometimes, reassigning an employee from one position to another is appropriate, says Witten. Potential whistleblowers are sometimes misfits, he says. Dealing with them requires flexibility, he argues, sometimes more than is required by the human resources department. “Sometimes a little flexibility can go a long way [in deterring] someone who might otherwise be a whistleblower,” says Witten.

Reassignment can be a good option when the employee is uncomfortable with the regulatory issue but is willing to accept that the company’s position on the issue is reasonable. However, he adds that reassignment must be executed carefully or it could be viewed as retaliation.

Needless to say, retaliation must be avoided, says Witten. There are numerous state and federal laws that protect employees against retaliation for having raised regulatory concerns internally. The broadest laws in this area are state laws, which vary from state to state, he notes. However, the False Claims Act also prohibits retaliation against an employee who was “acting in furtherance of a False Claims Act investigation or litigation.” There are many other federal laws that also protect whistleblowers in different contexts, he adds.

**Departing employees and severance agreements**

According to Witten, exit interviews are one of the most valuable tools in dealing with departing employees because these employees are often more willing than current employees to speak their minds. “They will often say things more bluntly,” he explains.

Again, he says, companies should use two interviewers, and document what the employee says and the actions taken in response to what the employee reports. Severance agreements with departing employees are sometimes appropriate, says Witten. “These agreements usually have broad general releases,” he says. However, the courts are divided over whether these releases cover *qui tam* actions. “Some courts say, ‘Yes.’ Some courts say, ‘No.’ And some courts say, ‘Maybe.’”

Witten points to several *qui tam* cases he has handled brought by whistleblowers who had signed severance agreements. In one case, the company received summary judgment on those grounds. In another case, the employee had a period of time under the age discrimination statute to exercise the right to reconsider and several weeks later filed a *qui tam* suit. Unfortunately, the company did not see any red flags until it was too late. A third employee received a severance agreement but the company failed to require, as a condition of payment, that the employee tell them about any problematic regulatory issues.

Among the most important elements to include in a severance agreement is to require that the employee represent that he or she has informed the company of all regulatory violations of which he or she is aware (see sample language, p. 12)

In the severance agreement, Witten says, companies should mention a specific meeting or a memo in which the employee disclosed regulatory concerns. “If the employee has no regulatory issues to express, that also should be a warranty and representation in the severance agreement,” he advises.

Ideally, says Witten, companies can require an employee to cooperate in a continuing investigation. However, if the departing employee demands additional money for that cooperation, the company should determine, on a case by case basis, how important the employee’s help could be, he says.

Companies should also include a provision that requires the employee to return all company property, specifically company documents. “If they return the documents, you will see what they were up to,” he says. “If they do not return the documents, it is less ideal, but can also be helpful down the road.”

According to Witten, the return of documents is especially important in the event the employee may have taken documents that might contain attorney/client communications.

Witten says another common feature of severance agreements are non-disparagement agreements.
provisions or confidentiality provisions as well as provisions in which the employee promises not to cooperate with outside investigators (e.g., unions or the media). If the employee has made complaints of regulatory noncompliance, these sorts of provisions should be carefully considered, he says, in order to avoid the risk that the company could be accused of obstruction or of paying to avoid letting the government learn of noncompliance.

In short, he says, it could lead to an accusation that there was obstruction of justice. “Read them with a cynical eye toward somebody who may accuse you of ‘paying hush money,’” he says.

Finally, says Witten, it is important to state clearly in the severance agreement that the employee must return all severance payments if any provision is breached.

Although it is impossible to know if these efforts headed off the filing of qui tam actions, some of Witten’s clients have been able to get disgruntled departing employees to disclose their allegations and the bases for their allegations. According to Witten, this afforded the companies the opportunity to investigate the allegations and resolve them promptly.

Although there is no guarantee that companies will not be sued even if they follow these precautionary steps, Whiten emphasizes, such precautions will go a long way toward insulating them from False Claims Act suits.

Jesse Witten, Partner, Ropes & Gray, Washington, DC, jesse.Witten@ropesgray.com

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**Handling Potential Whistleblowers: Language to Include in Employee Agreements**

1. **Release Of All Claims:** “Employee, for himself, his agents, attorneys, heirs, administrators, executors, assignors, assignees, and anyone acting or claiming on his or their joint or several behalf, thereby waives, releases, and forever discharges Related Parties from any and all claims, causes of action, demands, damages, costs, expenses, liabilities, grievances, or other losses, whether known or unknown, that in any way arise from, grow out of, or are related to events or to circumstances prior to [DATE].

Comment: A qui tam relator is the partial assignee of claims of the United States. See Vermont Agency of Natural Resources v. United States ex rel. Stevens, 529 U.S. 765 (2000). Including “assignors” in this list above may increase the likelihood that the releases will be construed as covering qui tam actions. But, courts have regularly found that general releases cover qui tam actions, so including the term “assignors” is not critical. Courts, however, have divided over whether public policy bars enforcement of a release of qui tam action. Expressly releasing qui tam claims could backfire and be seen as obstruction.

2. **Disclosure of Regulatory Issues:**’ “Employee hereby represents and warrants that, [during his October 17, 2006 meeting with Jane Roe] [in his October 17, 2006 memorandum to Jane Roe and John Doe] he advised Employer of all instances of regulatory violations by any Released Party of which he is aware and has provided all information in his possession.” OR “Employee hereby represents and warrants that during an exit interview, scheduled for October 17, 2006 with Jane Roe and John Doe, he will advise Employer of all instances of regulatory violation of which he is aware and, at that exit interview, will provide all information in his possession.”

3. **Cooperation:** “Employee agrees not to cooperate in any way, directly or indirectly, with any [private?] person, entity or group involved in any proceeding, inquiry, or investigation, of any kind against any of the Related Parties, except as required by law, subpoena, other compulsory process.”

4. **Effect of Employee Breach:** “If Employee breaches any of the terms of this Agreement, he shall be liable to Employer for the Settlement Amount in addition to any other remedies available to Employer in law or equity.”

Source: Ropes & Gray
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