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RX COMPLIANCE REPORT

EXCLUSIVELY DEVOTED TO PHARMACEUTICAL SALES AND MARKETING COMPLIANCE

Pfizer faces $142 million in damages for promoting unapproved uses of Neurontin under first successful use of RICO statute against pharma

Late last month, a federal jury found that Pfizer violated anti-racketeering laws in promoting its anti-seizure drug, Neurontin, for unapproved uses and ordered Pfizer to pay $142 million in damages. More important than the monetary penalties in this case is the fact that attorney **Tom Greene**, who spearheaded the underlying landmark off-label case involving Neurontin, and class action attorneys from Hagens Berman were able to secure a jury verdict using the federal Racketeer Influenced and Corrupt Organizations Act (RICO). This is the first time a pharmaceutical company has been found guilty in a case citing the RICO statute, according to Hagens Beman's **Tom Sobol**. "The jury found that Pfizer engaged in a racketeering conspiracy over a 10-year period," said Sobol. "That bodes well for future cases."

That appears to be true, not only for use of the RICO statute in other third-party payor suits regarding other drugs, but for the remaining third-party payor suits regarding Neurontin. That is because District Court Judge, Patti Saris, indicated in a pre-trial order last November that the Court would issue special jury instructions that the findings in this case would have a preclusive effect on subsequent litigation.

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IN THIS ISSUE

Pfizer, BIO cite need for formal rulemaking to regulate Internet promotion and social media

FDA should not try to fit the square peg of Internet and social media communications into the round hole of the agency's existing rules developed for conventional media," Pfizer told the FDA in response to the agency's request for comments on Internet promotion and social media. But neither should it attempt to regulate this area solely through the use of voluntary guidance.

The FDA should fashion new rules in this area in the form of binding, legally enforceable regulations established through the formal rulemaking process, rather than through guidance, which can only provide an "interpretive gloss" on those rules, veteran attorney **Geoffrey Levitt** argued on behalf of Pfizer.

Pfizer's position was echoed by the Biotechnology Industry Organization (BIO), which represents 1,200 biotech companies.

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Pfizer faces $142 million damages for promoting unapproved uses of Neurontin

As a result, says Greene, Judge Saris will likely make findings, which could have preclusive impact on future third-party payor suits that Pfizer is facing regarding Neurontin.

In other words, now that the March 25 jury verdict has established liability, similar third-party payors must only prove damages. Pfizer has already indicated it will appeal the decision.

Moreover, the Court has yet to assess damages under California's Unfair Competition Law, Business and Professions Code Section 17200, the other statute used by paintiffs in this case. Greene tells *Rx Compliance Report* that Judge Saris has yet to enter her decision in this regard.

Genesis of the case

The third-party payor suits regarding Neurontin were filed in the wake of the $430 million off-label Neurontin settlement in 2004. Those cases were transferred to Judge Saris' Court and a multi-district litigation (MDL) was created that included all third-party payor suits regarding Neurontin.

Kaiser claimed it was forced to pay $90 million more than it should have for Neurontin. According to the lawsuit, filed in 2004 in U.S. District Court in Boston, Pfizer promoted the drug as a treatment for a variety of conditions including pain, migraines, and bipolar disorder even though clinical evidence showed the medication was not effective in treating these conditions.

Initially, the third-party payor cases failed to gain much traction. The plaintiffs moved for class certification for a consumer class. But the Court denied it. Then they moved for a third-party payor class. But the Court denied that, too.

Finally, the Court indicated there would be a trial for one third-party payor, namely Kaiser.

Six plaintiffs' firms formed a steering committee. Greene's firm, which had spent years working on the underlying off-label case against Pfizer, was enlisted to spearhead that effort, which included more than 40 depositions. Greene's firm also engaged a number of expert witnesses.

After deliberating for two days, the jury found that Pfizer violated the federal RICO statute and California's Unfair Competition Law.

Outside experts weigh in

According to Greene, who has now been pursuing Pfizer over Neurontin for almost 14 years, beginning with a former employee's whistleblower suit, plaintiffs were able substantiate Kaiser's claim that it was misled into believing that Neurontin was effective for various off-label treatments with the help of outside experts who reviewed Pfizer's internal research reports about the drug's efficacy to treat migraines, bipolar disorder, neuropathic pain, and doses over a certain threshold.

Greene says outside experts, including former FDA Commissioner, David Kessler, and Kay Dickerson, a Johns Hopkins epidemiologist, used Pfizer's own internal data to demonstrate that the company had delayed, and sometimes misrepresented, the data. The jury foreman was quoted after the trial as calling Dickerson "the lynchpin."

In short, Greene says, the company's own studies showed that Neurontin was no more effective than a placebo in treating those conditions. However, Pfizer never told doctors or patients about the findings, he maintains.

The third-party payor suits regarding Neurontin were filed in the wake of the $430 million off-label Neurontin settlement.

Pfizer reportedly argued that Kaiser physicians continue to recommend the drug for the various off-label uses that were challenged and pointed out that no doctors testified that they would have acted any differently.

Warner-Lambert developed and marketed Neurontin for several years before Pfizer acquired the company in 2000. Four years later, when the company pled guilty and agreed to pay $430 million to resolve off-label marketing allegations, the Department of Justice claimed in a sentencing memorandum that Warner-Lambert's marketing increased off-label sales from 15 percent of all Neurontin prescriptions in 1994 to 94 percent of the drug's $2.12 billion sales in 2002.

NOTE: Pfizer did not respond to a request for comment, but the company has publicly stated that it plans to vigorously appeal the verdict in this case.

Off-label promotion

FDA weighs in on Allergan's off-label challenge

In a detailed rebuttal to a legal challenge to its off-label marketing restrictions, the FDA told the U.S. District Court for the District of Columbia March 29 that the remedies sought by Allergan would effectively weaken the Food Drug and Cosmetic Act (FDCA).

Allergan is seeking permanent injunctive relief against the FDA, alleging that the FDCA unconstitutionally restricts a drug sponsor's speech regarding unapproved uses of an approved product in violation the First Amendment. Narrowly, say experts, this case involves Allergan's concern that FDA may take enforcement action with respect to its communications regarding unapproved uses for Botox. More broadly, it represents a fundamental challenge to FDA's authority to require manufacturers to show that a drug is safe and effective for each of its uses before the manufacturer promotes the product for such use.

According to the agency, the FDA regulations at issue in this case are an integral part of the regulatory system that, for the past half century, has protected the public by requiring manufacturers to demonstrate the safety and efficacy of drugs for their intended uses before marketing them for those uses. "Without the challenged regulations," the FDA argued, "manufacturers would be free to engage in virtually unlimited promotion of off-label uses of approved drugs, subject only to after-the-fact enforcement actions for misbranding."

The FDA maintains that Allergan overstates the regulatory limitations on manufacturer speech regarding off-label uses and, at the same time, gravely understates the impact of its own constitutional challenge on the new drug approval process and the public health. "The Act and its implementing regulations strike a careful balance with respect to information relating to off-label uses, preventing manufacturers from promoting drugs for off-label uses while allowing dissemination of truthful, non-promotional information regarding health and safety risks associated with those uses," the agency argues. "That balance is a constitutional one, both on its face and as applied in this case."

According to the FDA, Allergan's statutory challenges to FDA's regulations are equally misconceived. "The regulations that Allergan is challenging have been in effect for many decades," says the agency. "They have been applied by FDA and the courts on countless occasions, without any suggestion that they are at odds with the Act… This unbroken record of administrative, judicial, and legislative acceptance confirms that the regulations, far from conflicting with the Act, are an appropriate and indeed vital complement to it."

On the other side of the constitutional balance, says the FDA, Allergan's overarching theme is that FDA has adopted a "draconian" regime that "suppress[es] virtually all off-label speech" by manufacturers. "The draconian scenarios offered by Allergan have no basis in reality, and their hypothetical nature confirms the absence of a ripe constitutional controversy here," the FDA contends.

According to the agency, the regulatory provisions at issue in this case cast a narrower net, one that reaches efforts by manufacturers to promote unapproved uses but leaves room for non-promotional dissemination of health and safety information.

FDA's Temple weighs in

To support its contention, the FDA submitted a supplemental declaration by FDA's Robert Temple, who cites significant adverse events that have resulted from off-label uses of approved drugs. Temple notes that Allergan proposes that it be allowed to promote off-label uses that are "medically accepted," and that it defines "medically accepted" drugs to include drugs that are listed in medical compendia. Such a proposal would endanger the public health, he argues.

"What is perhaps most troubling about Allergan's proposal," said Temple, "is that it would, in large measure, move us back to the days before 1962 when drugs were labeled and promoted without the support of any controlled trial data, when there was no standard at all for evidence of effectiveness, and when a large proportion of the drugs marketed and the uses to which they were put lacked valid evidentiary support.".

The FDA also submitted a declaration by Michael Wilkes, a professor of medicine at the University of California at Davis, offering a physician's perspective on the potential harm of allowing off-label promotion. ■

FDA's proposed rule for DTC advertising is ambiguous, say experts

On March 29, the FDA published a proposed rule to amend its direct-to-consumer (DTC) regulations to require that prescription drug advertisements present information about side effects and contraindications in a "clear, conspicuous, and neutral manner."

Current regulations require the disclosure of major side effects and contraindications (commonly known as the "major statement") in either the audio or audio and visual parts of an advertisement and that they be presented in a comparable manner to any statements regarding the drug's efficacy, Hyman Phelps attorneys **Carrie Martin** and **Dara Katcher Levy**, point out. With the passage of the FDAAA, Section 502(n) of the FDCA now requires that the major statement in television and radio advertisements to consumers be presented in a "clear, conspicuous, and neutral manner," they note.

According to Martin and Levy, the agency believes that these proposed guidelines are consistent with the draft guidance it issued in May 2009 about the presentation of risk information. "Unfortunately," they say, "both the draft guidance and the proposed regulations fail to clearly articulate what type of language will be clear, conspicuous, and neutral to consumers."

According to DTC expert **Robert Erhlich**, the real issue is whether DDMAC will be stricter in what is acceptable. "They could interpret any of the four requirements to make it harder to do broadcast ads," he says. In other words, any ad on television now could be found in violation depending on what is meant by each of the four requirements, he explains.

In short, says Erhlich, FDA's new proposed rule could be much ado about nothing or big news depending on how DDMAC acts.

For more on this issue, see http://www.fdalawblog.net/ and http://www.dtcperspectives.com/index.php.

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Pfizer, BIO cite need for formal rulemaking to regulate Internet promotion and social media

"It is the experience of BIO's members that guidance on this topic—particularly guidance that is written in terms of 'enforcement discretion'—is simply not adequate to provide pathways for regulated entities to engage in conduct that, while perhaps satisfying FDA, may be questioned in court by the many non-FDA parties, both public and private, who now seek to enforce the Food Drug, and Cosmetic Act directly or indirectly," said BIO's Deputy General Counsel for Healthcare **Sandra Dennis**.

According to Levitt, the case for formal rulemaking is fourfold:

1. Because of the First Amendment values involved in FDA regulation of Internet and social media communications, rulemaking is the appropriate procedural mechanism for FDA to invoke in this area;

2. The public health would benefit from rulemaking because rulemaking results in legal norms that are binding and therefore enforceable through regulatory action;

3. The lack of a clear regulatory framework for manufacturer participation in new media will proliferate the largely unregulated conversations currently taking place online; and

4. The new requirements that FDA establishes through rulemaking should recognize the specific user expectations that exist in the Internet and social media contexts, and should not assume that the techniques FDA has developed to assure that conventional promotion is truthful and non-misleading are necessary to achieve that same objective in the new media context.

Levitt said that Pfizer concurs with both PhRMA, regarding the need for timely guidance to facilitate the provision of important health information, and BIO, that FDA could supplement its ultimate regulations with guidance as technological and other developments warrant.

BIO weighs in

BIO maintains that rulemaking is warranted in light of the advances in technology and changes in the access, frequency and methods by which consumers and healthcare providers obtain information from the Internet and via social media regarding their health and available treatments.

Dennis points out that the body of available data on physician and consumer perceptions of medical product communications has been expanded recently, as FDA, expert bodies, industry, and other entities have focused on risk communications. These data can help to inform new regulatory approaches to providing product information in an effective manner, she maintains.

Pfizer's Geoffrey Levitt told FDA that what is needed are "clear enforceable, evidence-based regulatory requirements that reflect real-world user expectations."

In addition, she says, there have also been significant developments in the law relating to commercial speech and exchange of scientific/medical information by manufacturers that should be carefully considered as the agency addresses medical product promotion and communications in this context.

The impact of FDA's warning letters

Citing a recent survey, Dennis points out that FDA's 14 warning letters regarding sponsored links last year resulted in a considerable decline in company sponsored link advertising and Internet user exposure to this information (*see box, next page*). Testimony at FDA's November hearing suggests the types of advertisements that have replaced those sponsored links are less informative, she adds.

BIO also notes, anecdotally, that use of Internet search engines to seek disease-specific information appears to lead to many links for products that are less highly regulated than FDA-approved drugs and biologics, such as herbal remedies. "Such restrictions on promotion of FDA-approved products could result in an imbalance of information on the Internet, leaving users that are actively seeking information with comparatively less exposure to information that has the credibility and reliability of

FDA-approved labeling," said Dennis.

Manufacturers remain absent

According to Levitt, manufacturers have remained "largely absent" from the many conversations taking place in social media concerning FDA-regulated medical products. A recent Pfizer review of social media communications relating to 22 prescription drugs over 30 days reveals substantial interest in and conversation about prescription drugs across a wide variety of social media platforms, he reports. A straight-line projection would yield an annual total of over 1.4 million conversations about these 22 products alone, he said.

In addition, said Levitt, a recent Internet search of eight Pfizer prescription drug products using the search engine Google found that only 22 percent of the first-page results and linking sites were regulated by FDA. Of the unregulated content:

- 33% were international pharmacy sites
- 32% were unregulated drug information sites
- 14% were "spam" sites or links
- 11% were user-generated sites, including blogs and forums
- 2% were plaintiffs' attorneys sites
- 1% were non-sale international sites.

Levitt points out that in *Wyeth v. Levine* the Supreme Court recognized that manufacturers have "superior access to information about their drugs," as well as access to extensive information about many non-product-specific health-related topics. Nevertheless, he said, manufacturers have limited their participation in online activities because of the lack of clear regulatory standards. As a consequence, he told FDA, most online information about FDA-regulated products is provided by sources not regulated by FDA, and is of highly variable quality.

Levitt argues that absent a comprehensive new set of regulatory standards for product communications through the Internet and in the social media setting, the conversations taking place in these media will remain largely unregulated. ■

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Survey shows total sponsored link exposure plummeted in wake of FDA warning letters

According to a study by comScore, sponsored link exposures to U.S. Internet users declined more than 50 percent immediately after the FDA issued 14 warning letters in March 2009 regarding the exclusion of fair balance language in sponsored link advertising.

An analysis of exposure to branded URLs within comScore's data revealed substantial declines immediately following the letters, says comScore. Sponsored link exposures dropped 59 percent from 10.5 million during the week ending March 29 to 4.3 million during the week ending April 5. Moreover, declines in sponsored link exposures not only occurred in the weeks immediately following the letters, but continued over the next several months, plummeting 84 percent overall from March to June.

Vanity and unbranded link exposures also experienced a decline, on average, across brands during the same period, although these methods were not under scrutiny in the FDA letters.

Unbranded sites, which give additional information on the condition and treatment but do not directly promote the brand drug, declined 35 percent between March and June to slightly more than one million exposures.

Vanity URLs, which make no mention of a specific brand while generically describing a health condition but then redirect to the brand or drug's website, declined 11 percent in June to 3.2 million average exposures versus March.

NEXT WEEK!

THE FDA WEIGHS IN ON SOCIAL MEDIA

Next week's issue of *Rx Compiance Report* will include an update on social media from FDA's Jean-Ah Kang, Special Assistant to the Director, DDMAC, Ele Ibarra-Pratt, Chief, Advertising and Promotional Labeling Branch, CBER, and Glenn Byrd, former Chief of the Advertising and Promotional Labeling Branch, CBER.

OIG Chief Counsel ratchets up the volume on use of the "responsible corporate officer" doctrine

Leading prosecutor says "magnitude of harm" is a poor surrogate for prior notice

> "In case after case, the government says companies that illegally market drugs and devices for unapproved uses are endangering the health, and in some cases the lives, of patients. But the people punished for that corporate wrongdoing have almost always been relatively low-level executives. But that is now changing."
>
> *Nightly Business Report*, PBS, March 19, 2010

"One of the things that we are turning our attention to now is trying to find ways to hold corporate officials responsible for the misconduct of their subordinates," HHS ffice of Inspector General (OIG) Chief Counsel **Lew Morris** told a PBS interviewer last month.

"A corporation is just a corporate fiction," said Morris. "It's a piece of paper. It is run by people." According to Morris, responsible corporate officials are the ones who should be exercising control over their subordinates. "If they have the opportunity to prevent problems and fail to do so, we want them out of that company," he said.

"We have been talking to some companies, even as we speak, about executives within their current power structure," Morris continued. "We would like to know what responsibility they had when the misconduct took place, what opportunities did they have to stop the problem, and why they didn't affirmatively step in and prevent the abuse of our program."

In the wake of the successful prosecution of senior Purdue Pharma executives under the responsible corporate officer doctrine last year, Morris' remarks do not represent a new enforcement policy. Rather, it is an emphatic assertion that the Purdue case was anything but a one-time affair.

Morris' remarks came in a two-part interview with PBS that aired March 18 and March 19. In the first segment, Morris suggested the OIG might require a company facing repeated violations to divest itself of the drug or device under investigation in order to avoid exclusion (*see Rx Compliance Report, March 31, 2010*).

A "very harsh tool"

Healthcare industry lawyer and former prosecutor **David Douglas** calls that harsh. "You are the executive in charge," he says. "You are responsible. The question is whether the captain should then be executed for a mistake made in the boiler room."

Brent Gurney, a former federal prosecutor and a partner with WilmerHale in Washington, D.C., describes the government's use of the so-called strict liability doctrine in similar terms. He says a strict liability misdemeanor under the Food Drug and Cosmetic Act (FDCA), together with the "responsible relation" doctrine announced in the *Dotterweich* and *Park* cases, creates "a very harsh tool" for prosecutors and regulators. Gurney says the case of Purdue Pharma, in which he represented the company, points to the need for some meaningful restrictions to control prosecutors' discretion in bringing charges that are essentially impossible to defend.

"A corporation is just a corporate fiction," said HHS OIG Chief Counsel Lew Morris. "It's a piece of paper. It is run by people."

A historic anomoly

Gurney points out that the government's love affair with the responsible corporate officer doctrine is something of a historical anomaly. This doctrine has traditionally has been used sparingly, he says. In fact, in the last fifty years, there have been only a handful of reported decisions in which the government charged a corporate executive with a misdemeanor FDCA violation based solely on the executive's "responsible relation" to the violation.

According to Gurney, most of the cases brought against executives under the misdemeanor provision were based on the executive's own personal conduct, not just the executive's position. "Of those cases that do seem to be 'responsible relation' cases, the overwhelming majority involve an individual defendant who was, in fact, on notice of the conduct giving rise to the violation," he says.

For example, in *Park*, the company had been notified repeatedly by the FDA that there were infestation problems in its warehouses, and the defendant-president had personally received notice of at least one failed inspection. Gurney points out that lawyers for the government in the *Park* case represented to the Supreme Court that the government "will not ordinarily recommend prosecution unless [the responsible corporate officer], after becoming aware of possible violations… has failed to correct them or… to prevent further violations."

"Magnitude of Harm" as a surrogate for prior notice

In the Purdue case, says Gurney, the government insisted that company executives plead to misdemeanor charges, but not because they were directly involved in any alleged improprieties or because they knew of any improprieties and failed to take corrective action. Instead, he says, the rationale seemed to be that criminal liability was appropriate simply because, in the judgment of the government, the magnitude of the harm caused by the underlying violations was so great.

According to Gurney, there are many reasons to be concerned about the government viewing "magnitude of harm" as a surrogate for knowledge or prior notice in making criminal charging decisions. First, he says, from a practical perspective, such a policy might make it intolerably risky to be a pharmaceutical executive. "Even assuming that all prosecutors are well meaning and reasonable, the pharmaceutical business is and always will have catastrophes where products do not work or are not used as anticipated," he says. "To make magnitude of harm an independent ground for seeking criminal charges when something goes wrong is to subject every manager and executive in the industry to potential criminal liability, and liability for events that are entirely outside of his or her control."

Second, he argues, it is precisely in those cases in which an unanticipated problem has arisen and caused widespread harm that imposing criminal liability upon a few individuals is least appropriate. "It is in these cases that the stain of a prosecution is most severe, because the public, quite reasonably, continues to associate criminal prosecutions with allegations of fault," he explains.

Third, says Gurney, from the standpoint of basic fairness, it is simply preferable to have prior notice or something approaching culpability as a guidepost for prosecutorial discretion. "Unlike knowledge or prior notice, 'magnitude of harm' is largely in the eye of the beholder and is not easily susceptible of proof," he maintains. "Allowing magnitude of harm to justify criminal charges is tantamount to requiring no justifications at all, and converting the FDCA misdemeanor into an all-purpose conviction tool, effective in whatever circumstances the prosecutor needs it."

Under these circumstances, says Gurney, the prosecutor is effectively given the power both to enforce the law and to say what it is, because the burden is so low, and "misbranding" and "adulteration" are so broadly defined.

Finally, he says, it will often be the case that the "harm" is not truly traceable to the alleged violative conduct, but that will not hinder any prosecution because the government does not actually have to prove that link in court.

"Allowing magnitude of harm to justify criminal charges is tantamount to requiring no justification at all and converting the FDCA misdemeanor into an all-purpose conviction tool," warns WilmerHale's Brent Gurney.

"A real danger"

In part because of the breadth of the FDCA's prohibitions, says Gurney, there is a real danger that unrestrained, the FDCA misdemeanor will merely become a lever that allows prosecutors to obtain convictions or extract pleas in vindication of suspicions.

Gurney points out that modern-day pharmaceutical executives "supervise" the work of sometimes hundreds of thousands of employees and scores of corporate entities in dozens of countries. "If it ever made sense to have a criminal provision that holds executives and owners strictly criminally liable for errors and mixups and misbehaviors of their subordinates, it no longer does," he concludes. "It certainly makes no sense for the government to broaden its use of this provision." ■

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Off-label promotion

Limiting Off-Label Exposure in Speaker Programs: The Case for Live Monitoring

By Diva Duong, Heather McCollum, Mark Scallon

Speaker Program Compliance Risks

One of the most popular and effective ways to educate healthcare professionals about particular medicines is a speaker program. Although these programs offer many advantages, without proper monitoring, they may also pose significant compliance risks. Training and standard operating procedures can only offer a certain amount of protection. Moving forward, appropriate monitoring of speaker programs must include live monitoring to observe physician interactions and demonstrate corporate commitment to compliance.

Potential Compliance Issues

What are the risks associated with speaker programs?

Off-label promotion. By far the most significant compliance risk related to speaker programs is off-label promotion. Any number of situations may generate compliance issues regardless of company efforts to provide speakers with proper training and guidelines. For example, some companies allow speakers to use self-generated slides in addition to approved presentations. These speaker-generated slides may reference inappropriate off-label information. Audience participation may also lead to off-label promotion if speakers are not properly trained to respond to such inquiries. Finally, the company's own representatives may discuss unapproved uses of a drug with program attendees. Live monitoring is the only approach for identifying these off-label issues.

Inappropriate speaking venues and/or lavish meals. Luxury venues such as resorts are still being used for promotional programs, despite the fact that the PhRMA Code clearly describes these venues as inappropriate for speaker programs and other similar events. Furthermore, meals at these events may be problematic if they appear to be excessive as judged by local standards or if inappropriate parties, such as spouses, attend.

Reducing Risk Through Monitoring

Comprehensive monitoring strategies offer an opportunity to identify and reduce compliance risks associated with speaker programs, but until now, live monitoring has not always been a part of this process. The recent Pfizer settlement and resulting corporate integrity agreement (CIA) illustrate how important it is to establish monitoring procedures that immediately identify and correct serious compliance issues.

Under the terms of the CIA, Pfizer must conduct 200 live audits per year of its speaker programs as part of its effort to implement a Speaker Monitoring Program. By mandating 200 live program audits, the OIG is sending a clear signal of the importance it places on speaker monitoring programs.

In the past, most monitoring programs have relied on retrospective analysis of speaker programs using techniques such as interviews, surveys and document review. This type of periodic monitoring is a cost-effective way to address some risks such as attendee, venue, or meal risks. In addition, surveys can be used to evaluate compliance knowledge and practices of field staff and speakers, which can be extremely useful for training purposes.

Moving forward, appropriate monitoring of speaker programs must include live monitoring.

However, without the ability to observe an event firsthand, it is difficult to accurately assess whether off label promotion is occurring at these events and whether the materials are presented as intended. As monitoring programs continue to evolve, it has become clear that the ideal strategy involves a two-track process that examines both past and current programs. This allows the reviewer to identify and react to historical areas of non-compliance while simultaneously tracking current behavior.

Benefits of Live Monitoring

Live monitoring provides a unique opportunity to pick up subtle clues about possible compliance issues that may not be readily apparent during interviews or document review. Live audits offer a chance to monitor program content and conversations for possible off-label promotion. They also permit monitors to observe many of the factors related to program logistics, such as sign-in processes, meals and appropriateness of venue.

Though live monitoring is expensive, it is too important to ignore. Even at low volumes, well-communicated live monitoring programs reinforce a company's commitment to compliance. They are also the only way to identify critical off-label exposures.

Companies may choose to monitor programs using internal resources, and there are a number of ways to offset the significant travel costs associated with monitoring. Trips can be combined with other compliance/audit activities such as rep ride-alongs. In addition, regional sales managers may be used to conduct monitoring to reduce travel expenses. Another possibility is to select a third party vendor to monitor programs or to validate internal monitoring efforts conducted by regional sales managers.

Going forward

Speaker programs are an important educational and marketing tool for pharma, but without proper monitoring, these programs can generate significant compliance issues. The federal government has sent a clear message about its expectations, and companies must now adjust their practices to include a more comprehensive monitoring strategy that allows them to evaluate their speaker programs in real time. While live monitoring of speaker programs is expensive, this type of in-person review is critical to a successful monitoring program. ■

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All the news that's unfit to print

By Peter Pitts

There is "renewed optimism" that the European Union's proposed legislation on allowing drug makers to provide information to patients on prescription-only medicines will again start moving through the legislative process. The latest thinking, however, is strongly focused on the rights of patients to receive such information, rather than industry's right to disseminate it.

An interesting and important finesse – the rights of a patient to the information but no "right" for industry to provide it.

Suggested amendments emerged on March 10 from European Parliament Member Christofer Fjellner. He is reviewing the proposed legislation for the EU parliament's Committee on the Environment, Public Health and Food Safety.

For patients, Fjellner contends that information on pharmaceuticals should only be made available to patients who are actively searching for it, i.e., information should be "pulled" by the patient rather than "pushed" by industry. Fjellner believes that companies should not be allowed to make available information on prescription-only medicines on television or in newspapers or magazines. He believes the Internet is the appropriate medium for providing information to patients.

And maybe he is right—but is there really a difference? If a pharmaceutical company makes available information on a web page, why is that different than making it available in other media? And what about patients who do not have access to the Internet—what about their rights?

Fjellner's stance comes as a response to a ruling from the European Court of Justice, which concluded in April 2009 that current legislation could be applied to independent journalists. The environment committee will vote on the patient information proposals in June. After that a plenary vote of all European Members of Parliament will be held in September. It will then go to the Council of the EU for further consideration. ■

- **Peter Pitts**, PresidentCenter for Medicne in the Public Interest, New York, NY, ppitts@cmpi.com

Congressional oversight

When Congress comes calling: The unique rights and wrongs of responding to Congressional investigations

Congressional oversight veteran offers a roadmap for navigating Congressional hearings and inquiries

In recent years, pharmaceutical executives have found themselves in front of Congressional Committees answering questions about a variety of topics ranging from drug safety to drug marketing. Meanwhile, companies have devoted literally thousands of man-hours to answering questions from Senator Charles Grassley (R-IA), and others, about medical education and similar subjects. This pattern is likely to continue, says **John Sopko**, a partner with Akin Gump Strauss Hauer & Feld, LLP, in Washington, D.C., who has been involved in oversight and investigations either as a prosecutor, congressional counsel or senior advisor to the federal government for more than 30 years.

In fact, the drug and device sectors should brace for numerous Congressional inquiries on a variety of fronts, warns Sopko. "A lot of people and a lot of companies are going to receive letters this year," he told listeners at a recent webinar hosted by the Washington Legal Foundation. Many will fall short of a formal hearing, but only if handled properly.

According to Sopko, it is important for drug and device companies to understand the unique character of Congressional investigations, because they are as serious as, if not more serious than, investigations by the Department of Justice or the Securities and Exchange Commission. Moreover, they are one of the fastest-growing, most important, and least understood areas of the law, says Sopko, who was Chief Counsel for Oversight and Investigations for the House Committee on Energy and Commerce for the 110th Congress, where his purview included FDA investigations.

In short, Sopko predicts that 2010 is going to be an extremely busy time for Congressional oversight. After spending unprecedented sums of money the last two years, he says, it is a safe bet that Congress will "come back with a vengeance" doing something that will not cost money, namely oversight.

Here is Sopko's blueprint for how to respond to Congressional inquiries, based on his many years in the trenches:

How does it all start?

According to Sopko, Congressional investigations usually begin with a letter or a telephone call asking the target of the investigation to answer a volume of questions and provide a volume of information in a very short time period. "The first rule of thumb when you get one of these letters or one of these phone calls is take it seriously," he says. "I have seen a lot of companies and a lot of individuals—both on the Hill and in private practice—who didn't take it seriously and it caused drastic problems."

Congressional hearings are one of the fastest growing, most important, and least understood areas of the law, says Akin Gump's John Sopko.

Your first question: Why us?

Usually the first question that is asked, says Sopko, is, "Why us?" The answer to that question is critical, he says, because it will guide the response to the inquiry.

In a civil or criminal litigation, the target of the investigation usually knows how they got there, says Sopko. "You don't always know how you got there in a Congressional investigation," he says.

According to Sopko, the genesis of a Congressional investigation is often the convergence of several factors, many of which are not fully understood at first blush. The media, constituent demands, and corporate demands can each play a role in triggering a Congressional investigation, he explains. So too can politics and the interests of individual members, or any combination of the above, he adds.

Sopko points out that unlike grand juries, search warrants, law suits, and indictments, there is practically no legal threshold to starting a Congressional investigation. No probable cause or reasonable suspicion is necessary, he explains. Moreover, no notice to the company is required before the investigation is made public.

In short, he says, it is completely up to the discretion of the committee chair when the investigation begins and who the subject of the investigation will be.

Your second question: Who are these people?

Any committee can conduct an oversight hearing, says Sopko, but few do. "Even fewer really know how to do it well," he adds. Among the committee chairs who posses that skill, he says, are Rep. Henry Waxman (D-CA), who heads the Committee on Energy and Commerce, [who also happens to be a vociferous critic of pharma].

When it comes to Congressional investigations, however, nobody takes a back seat to Senator Charles Grassley (R-IA), says Sopko. "If there is anybody who really knows how to do Congressional oversight and who has a long record and history of doing Congressional oversight," he says, "it is Senator Grassley."

Sopko says Grassley has developed the extraordinary ability to conduct almost all of his investigations in the press, despite the fact that, as a member of the minority, he has no committee to hold hearings. "He has been extremely effective," he says. "His staff knows how to do investigations and knows how to deal with the press."

Note: While not singled out by Sopko, Grassley's point man on investigations into the pharmaceutical industry, Paul Thacker, has recently drawn some attention (*see box, p. x*).

Needless to say, all the oversight committee chairs are Democrats, but what is not always immediately evident, says Sopko, is that they are all to the left of the Democratic party and not usually known as corporate friends.

In the Senate, the Permanent Subcommittee on Investigations has long been the main oversight body. While that tradition continues, says Sopko, a number of other committees and subcommittees have recently become very active in this area.

One committee that few people focus on until they get a request letter is the Senate Aging Committee headed by Senator Kohl (D-IL). The Senate Aging Committee has historically not been very active, says Sopko. However, under Kohl's leadership and particularly under the staff direction of former investigative reporter, Jack Mitchell, and former federal prosecutor, Kristine Blackwood, who are leading those investigations, the committee has started to fill the vacuum in the healthcare arena, among other areas, says Sopko. "That is a committee to watch if you have not already gotten a request letter from it," he says.

Your third question: Can they do this?

The next question after receiving a a letter or a phone call, says Sopko, is often, "Can they do this?" For a variety of reasons, he says. the likely answer to that question is going to be, "Yes."

In short, he says, as long as Congress can demonstrate some legitimate legislative function, it can conduct the investigation. Moreover, the courts have historically held that Congress has extraordinary powers to probe. "The power to probe has few limits," he says.

In practice, says Sopko, it is extraordinarily rare to succeed in arguing that Congress lacks the authority to conduct a particular investigation. Accordingly, he says, a company is safe to assume that any investigative request that it receives from Congress is valid and should promptly make plans to respond.

"If there is anybody who really knows how to do Congressional oversight and who has a long record and history of doing Congressional oversight," says John Sopko, "it is Senator Charles Grassley."

Your fourth question: What rules govern this process?

That leads to the next question, says Sopko, which is, "Are there any rules?"

"Actually, there are a lot of rules," he says. But those rules depend on which committee sent the request. The House and Senate have their own rules on investigations. In addition, each committee adopts its own rules and often individual subcommittees will adopt special rules, as well.

According to Sopko, it is important for companies to know those rules. "They are not your normal rules," he warns. "These are not the federal rules of evidence, the federal rules of civil procedure, or the federal rules of criminal procedure that your counsel may be used to." Rather, he says, they are arcane rules, all of which are subject to the chairman of the committee.

"Equally important to understanding what committee or subcommittee you are dealing with and what is motivating the investigation is to know the members and staff and how they interpret the rules," he adds, "because that is what you are going to have to deal with if Congress comes calling."

Do Congressional committees have subpoena power?

According to Sopko, both chambers of Congress have the power to issue subpoenas to require the production of documents and/or the attendance of witnesses. In fact, subpoenas issued by committees operate with the same authority as if they were issued by the entire House of Congress, he says. Moreover, the courts have ruled that Congress' subpoena authority is very broad.

Nevertheless, he says, committees usually do not begin investigations with subpoenas. "They start with sending a letter and they ratchet it up," he says. "If they don't get much response, they will try to get your attention."

For a number of legal and public relations reasons, says Sopko, targets of Congressional investigations—or even persons who have to provide records or other evidence—should work with committee staff to avoid the issuance of a subpoena. The exception to this rule, he says, is when a "friendly subpoena" is necessary to protect certain rights from litigation.

According to Sopko, one of the problems with subpoenas is that it allows the committee to get "three bites at the press apple." They get one bite when they vote to issue the subpoena, he says, another bite when the subpoena is served, and a third bite when the company responds.

Moreover, Congress faces no obstacles in issuing a subpoena, says Sopko. "If Congress comes calling with a subpoena, rest assured, they will get served" because the U.S. Marshall Service views a subpoena from Congress "as an order from God." Moreover, he adds, the Supreme Court has long recognized Congress' power to hold a witness in contempt, as inherent to its legislative authority.

Do privileges apply?

Another frequent question that arises, says Sopko, is whether privileges apply. He says it is important for all parties, especially corporations, to remember that the federal rules of evidence do *not* apply. "What is unique about Congressional oversight in this area of the law is that the Congressional committee is basically the prosecutor, judge and jury," he says. "They will be asking for the information and then they will make the determination on whether your privilege applies."

Nevertheless, committees *are* bound by certain constitutional privileges, he points out. For example, the right to invoke the Fifth Amendment protection against self-incrimination in response to a question is recognized by the courts, he says, although committees will usually require witnesses to invoke that right in person and in public.

According to Sopko, while the law is not completely settled on the availability of common law privileges—such as attorney-client, work-product, and deliberative-process—in the context of congressional investigations, most committees will determine if a privilege applies on a case-by-case basis where the need for the information is weighed against the potential harm caused to the client by its production.

The Senate Aging Committee is a committee to watch if you have not already received a request letter from it, warns John Sopko.

Congress is a very public body by nature and by definition, says Sopko. "That is a double-edged sword," he says, "and it cuts both ways to you the client, as well as the Congress."

Congressional committees will respect valid and properly-asserted claims of privilege, he says. But they will require negotiations and agreement on the nature of those privileges, he explains. They will also likely require a log to track what is being withheld, he adds.

Sopko says it is also important to remember that the security of material may cause comfort problems for some companies, because it is less stringent than what they are accustomed to. At the same time, he says, neither members or their staff are anxious to be seen as publicly damaging a company.

Should we schedule meetings with committee members and their staff?

Whether it makes sense for companies to schedule meetings with committee members and their staff depends on a number of factors, says Sopko. "It all depends on you, what your story is, and who you are dealing with," he explains.

Meeting with committee members and staff can be helpful in certain circumstances, he says, especially if the company believes there are facts that are not adequately being reported or readily available to members or staff. However, all contact with the committee and its staff should be conducted by counsel or with counsel present to ensure a proper legal buffer between the client and the committee, he cautions.

"It cannot be overemphasized that an investigative committee is unique and not comparable to the operations of a legislative committee," says Sopko. "They think differently. Their mindset is completely different."

"I have to keep reminding clients, these people are not your friends," he says. "They approach this matter differently. They are trying to score points. They are trying to get to the truth of an investigative matter, not negotiate a piece of legislation."

What if you are called for an interview?

According to Sopko, most interviews are informal and conducted by attorneys serving as committee staff. However, some can be formal, such as a deposition where testimony is on the record and transcribed by a court reporter. In fact, some committees have deposition authority (where testimony is on the record) and many use it frequently, he says.

In these instances, says Sopko, committees will issue an actual deposition notice pursuant to rules. Companies should always inquire whether the proceeding is being recorded, he cautions.

It is also important to remember that no matter how informal it may appear, what you say can come back to hurt you, warns Sopko. "It is an official investigation," he says. "You have to be truthful and you have to give them what they ask for after negotiations."

While many issues surrounding an interview are negotiable, witnesses should be aware that what they say can be used against the company at a hearing, or if it is released, possibly in litigation. As a result, counsel should take care to ensure that the record of an interview is as clear and as balanced as possible.

Companies should also remember that there is a symbiotic relationship between Congress, the press, and the plaintiff's bar, says Sopko. "Don't be too surprised that what you say to a Congressional committee may end up in the press or in the hands of a plaintiff's counsel," he cautions. Even when staff conducts the interview in private, the substance of the proceeding can be leaked, he points out.

Remember! There are serious consequences

It is important to remember that all interactions with a Congressional committee are conducted pursuant to an official government investigation, says Sopko. In responding to Congressional investigative requests, or subpoenas, individuals and companies alike should be aware that a number of federal criminal provisions apply. In fact, he says, federal perjury, obstruction of justice, and false statements provisions apply not only to statements and records produced during the course of a hearing or deposition, but also to informal telephone calls with counsel.

It is important for all parties, especially corporations, to remember that the federal rules of evidence do not apply to Congressional investigations, says John Sopko.

"Any statement made must, to the best of one's ability, be true and complete," he says. "I know too many people who have failed to recognize that and have faced the consequences."

What happens at the hearing?

Congressional hearings are akin to "Perry Mason meets the Ringling Brothers," says Sopko. "They are not there to gather facts at a hearing," he explains. "They already have the facts. What they are doing is putting on a show."

According to Sopko, this is when the committee presents what they have accomplished in their investigation to the public and the press. "A good hearing is like a play and like a play they are auditioning for parts," he says. "We know who the hero and the heroine are going to be in this play. It is going to be the chairman. Supporting roles are

going to the staff and to the witnesses."

"There has to be a victim in any good play," he says. "There has to be a villain. You must avoid that audition call as much as possible."

Hearing Caveat #1: A hearing room is not a courtroom

Among other important differences between a Congressional hearing and a courtroom is that a witness at the former cannot object to a line of questioning, says Sopko.

In addition, the Federal Rules of Evidence do not apply and lawyers representing the witness are not typically allowed to interject on their client's behalf or otherwise testify.

"What you say or do can and will be used against your interest," he warns. "The need for accuracy and attention to detail is essential in all matters before the committee."

Hearing Caveat #2 – Be Nice And Be Prepared

A witness may not like the questions or even the tone of a member, but visibly frustrated and difficult witnesses create further problems for themselves and their companies, says Sopko. "It s wise for a witness to be respectful to the committee members even if they are not respectful of that witness," he adds.

According to Sopko, successful preparation is essential for the success of any appearance before the committee. "It's not luck," he says. Rather, a successful appearance before a committee is the result of hours of hard work including mock sessions or "murder boards" where the witness responds to potential lines of questioning.

Considerable time must be spent not only in selecting the appropriate witness, but also in convincing the committee to let you bring that witness, he says, as well as in preparing the witness' oral and written testimony.

Why should you be concerned about a Congressional investigation?

Needless to say, says Sopko, if not handled properly, a Congressional investigation can be extremely costly to a company not only in financial terms but in terms of harm to the company's image or to the careers of company executives.

Requests for information from Congress should be handled promptly and professionally, he says. Many times a mere embarrassment can become a felony, if not taken seriously, he says.

"Watch your e-mail communications and what you say to colleagues," says Sopko. "One thing I cannot over-emphasize is watch what you say," he adds, "not only in the hearing, but watch what you say after the first letter or the first subpoena comes. Watch your e-mails."

According to Sopko, it is all too easy to face an embarrassing, if not criminal, moment, because of a thoughtless e-mail. He says companies should apply the *New York Times* test: "Would you want to see that e-mail in the *New York Times* or splashed on the Internet?

Finally, Sopko says, he tells clients to follow the sage advice of the wise former speaker of the House Tip O'Neil who is supposed to have once said, 'Don't write what you can say. Don't say what you can wink'."

Parting thoughts

As noted at the outset, Sopko predicts the 111th Congress will be extremely active in the area of oversight during its second session.

Here are four key points, he says, to keep in mind:

1. The best strategy is to avoid the investigation if at all possible.

2. Be prepared in advance. Develop a strategy to avoid becoming part of an investigation.

3. Know what is motivating the investigation and your role in it.

4. If you do your homework, hopefully Congress won't come calling. Or, if they do, they will call on someone else.

For more on this subject, see: "Trial By Ordeal: A Survival Guide For Congressional Investigations" at: http://www.wlf.org/Upload/legalstudies/contemporarylegalnote/SopkoCLN.pdf ■

"What is unique about Congressional oversight is that the Congressional committee is basically the prosecutor, judge and jury," says John Sopko.

■ **John Sopko** is a partner at Akin Gump Straus Hauer& Feld, in Washington, DC. Contact him at:: jsopko@akingump.com

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AGENDA

Pre-Conference Symposia

Monday, May 17

2:00 p.m. – 5:00 p.m.

Preconference I: International Compliance Program

Preconference II: FCPA, Antibribery and anticorruption in Asia and Middle East

Preconference III: Recent Developments in Antitrust Enforcement and Impact on IP Protection and Life Cycle Management Strategies

Day I: Tuesday, May 18, 2010

8:45 a.m. Setting the Scene: International Compliance Professional Roundtable

10:30 a.m. EFPIA Code: New Trends and Moving Forward

1:30 p.m. Keynote Comments: The Long Reach of the FCPA

2:00 p.m. Latest Developments of the European Pharma Package

2:45 p.m. Regulation and Controls from an HCP's Perspective

3:30 p.m. Roundtable Discussion of the Next Challenge in Global Pharma Compliance: Conflict of Interest, Independence of HCPs, CME and Transparency

TRACK SESSIONS

4:30 p.m. – 5:30 p.m.

Track I: Compliance Effectiveness and Adequate Procedures

Track II: Transparency

Track III: International Clinical Trial Issues

Track IV: International Compliance Hot Issues and Case Studies

Day II: Wednesday, May 19

8:00 a.m. Welcome and Overview of Day II Morning Plenary Session

8:15 a.m. Update on EU Antitrust Enforcement in the Pharmaceutical Sector

8:45 a.m. The Good, the Bad and the Ugly: Compliance Communication Challenges

TRACK SESSIONS

9:30 a.m. – 11:45 a.m.

Track I: Compliance Effectiveness and Adequate Procedures

Track II: From the Front Lines

Track III: International Clinical Trial Issues

Track IV: International Compliance Case Studies

1:15 p.m. Introduction to Closing Plenary Session

1:30 p.m. What Patients Want from Pharma

2:45 p.m. Co Chairs Closing Remarks

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May 17-18, 2010, New York, NY

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