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RX COMPLIANCE REPORT

EXCLUSIVELY DEVOTED TO PHARMACEUTICAL SALES AND MARKETING COMPLIANCE

DOJ's Deputy Fraud chief outlines "bottom-up" approach to building pharma fraud cases

New approach puts initial focus of investigations on physicians and individual employees, says DOJ's Kirk Ogrosky

The criminal division at the Department of Justice is now building cases against drug companies by targeting individual employees and physicians and working cases from the "bottom-up" rather than initially focusing on the companies that may ultimately be the subject of an investigation, says **Kirk Ogrosky**, deputy chief of DOJ's fraud section. "The government has learned a great deal about how to handle these cases," he says, "and it's a lot easier to focus on individual physicians and individual employees and build a case from the bottom-up."

"I look at the individuals like a pyramid," Ogrosky told attendees at American Conference Institute's sales and marketing conference in New York on April 21. "There is someone at the top directing the bad conduct," he says, "but I want to know how high up the pyramid goes in the corporation, who else is involved, and how that pyramid stacks up at the bottom."

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Vermont legislature passes sweeping gift ban

On May 8, the Vermont legislature passed the most stringent gift ban in the country. If, as expected, the legislation is signed into law by the Governor, Vermont will become the third state, in addition to Minnesota and Massachusetts, to enact an outright ban on gifts to physicians. In addition, the proposed law would require disclosure of permitted marketing activities and eliminate the trade secrets provision in the state's existing disclosure law.

According to several observers, enactment of the new law would likely accelerate the reduction of drug marketing in Vermont, which appears to be reflected in the state's most recent drug marketing disclosure report, released last month. In fact, the Vermont Attorney General's report shows a 30 percent decline in drug marketing expenditures in the state over the past five years. "We don't know if this reflects largely financial decisions by the industry or a mere desire to avoid public scrutiny," said Vermont Attorney General William Sorrell.

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DOJ's Deputy Fraud chief outlines "bottom-up" approach to building pharma fraud cases

According to Ogrosky, it is both "easier" and "more productive" to start at the bottom of the pyramid and build cases through cooperation and plea agreements. "Quite frankly, if I sit in my office and start cutting subpoenas to corporations, I get bogged down," he says. It is more productive, he says, to have FBI agents develop evidence by interviewing doctors and individual employees.

Ultimately, he says, it is important to understand the "inner workings" of a company when attempting to bring a case against it, including how the company's business units are interacting. Ogrosky says that includes creating a lot of charts and graphs, along with the FBI, that outline the managers in charge of particular regions of the country and those in charge of marketing particular products.

However, that is a very time-consuming process that involves gathering a lot of documents and issuing a lot of subpoenas, he says. "If I reverse it and approach a case from trying to get information from the physicians," he says, "I can get my cases faster."

Targeting physicians

When looking at physicians from a criminal perspective, Ogrosky says, he begins by downloading all the prescribing data he can attain. When questioned, he says, physicians will uniformly maintain they simply prescribed the drugs for purposes advanced by sales reps. However, physicians who initially claim their prescribing practices were not influenced by marketing efforts tend to tell another story once they are indicted, he adds.

According to Ogrosky, examination of internal documents that include the rate of prescribing and the volume of prescriptions makes it fairly easy to determine which physicians were misled by marketing tactics, which physicians saw a therapeutic benefit, and which physicians were "just writing everybody."

Needless to say, DOJ is most concerned about the physicians "at the top end that are just writing scripts to everybody," says Ogrosky. "That is where we would end up in a criminal investigation," he says, "targeting those physicians, in particular."

Increasing criminal prosecutions

DOJ has been steadily increasing its criminal prosecutions in recent years, reports Ogrosky. In fact, he points out, both the number of cases and the number of defendants have increased roughly 20 percent in each of the last two years. "We see a trend going up and it is really a result of the way we are attacking healthcare fraud," he says.

While pharma cases typically take longer to investigate, says Ogrosky, the criminal division is trying to execute its investigations "quicker" and "more actively." In the past, he says, FBI and HHS agents would typically pitch the criminal division regarding cases it had been working on. Today, by contrast, criminal prosecutors are actively working with these agents to identify targets.

"It's a lot easier to focus on individual physicians and individual employees and build a case from the bottom-up," says DOJ criminal chief Kirk Ogrosky.

Former DOJ attorneys say this philosophy is consistent with Ogrosky's background as part of DOJ's south Florida task force, which racked up numerous convictions against medical equipment companies, infusion providers, and others. "The Ogrosky model is to look current, look quick, and get convictons," says one former DOJ attorney.

In addition, Ogrosky says, he is now encouraging prosecutors to close cases that have been lingering, because they do not have a good deterrent effect. "We need a temporal relationship between the crime and the punishment to get a good deterrent effect," he explains.

"I want to close the old cases and focus on what is happening now," he says, "and the way that we have been organizing that is to look at the current claims data."

According to Ogrosky, this means asking: "Where are we spending our money? How are we spending our money? What sort of diagnostic testing? What sort of devices? Where is the federal money going?

"What we are finding," he says, "is that if we are able to hit the federal spending, that translates over into a lot private claims, too, so we get a transfer into private fraud."

A flood of new *qui tam* suits

DOJ's criminal division is not the only federal agency experiencing heavy traffic. **Margaret Hutchinson**, Assistant U.S. Attorney, Eastern District of Pennsylvania, reports "no slow down whatsoever" in terms of the number of *qui tam* suits being filed against drug companies. In fact, she says, as expected, Lilly's $1.4 billion Zyprexa settlement prompted a sharp spike in these suits. "Every time we announce a case like that," she reports, "we are flooded with new *qui tams*."

While many of these relators lack the requisite information necessary to file a civil action and prove falsity, she says, her office also continues to receive many "troubling new allegations."

Increased state coordination

In addition to cases filed under the federal False Claims Act, companies can expect to see a state claim for every state they do business in that has a False Claims Act, says former federal prosecutor **Christopher Hall**, now a partner with Saul Ewing in Philadelphia.

State Medicaid Fraud Control Units now review *qui tam* actions using a coordinating committee to determine which states will take the lead, notes Hall. "That committee is a formidable body," he says.

Hall also points out that, unlike DOJ, states can issue a press release based on a subpoena. Instead of having a quiet period while the case is under seal, he warns, if a state Attorney General takes an interest in a company, there is going to be a press release before any grand jury work has been started. "It is very fast moving and unfair," he says, "but but there is no need to cry about it, because it is not going to do any good."

Putting the pieces together

Ogrosky points out that the criminal division monitors, but does not get involved, in the majority of *qui tam* cases. That said, if *qui tams* are repeatedly filed against the same companies, his office begins to get "different pictures from different areas within the business" that may begin to establish a pattern. "You may have a disgruntled employee who may not have sufficient information to bring a *qui tam*, but who may provide sufficient information to help with some other issue that we have been looking at," he explains. "You put all the pieces together."

Veteran prosecutor outlines major fraud themes

Margaret Hutchinson, a veteran Assistant U.S. Attorney in the Eastern District of Pennsylvania, told attendees at American Conference Institute's sales and marketing conference in New York last month that her caseload continues to be driven almost exclusively by *qui tam* suits brought under the False Claims Act. Each time she outlines the most common schemes, she says, "a relator will present a whole new set of allegations."

That said, Hutchinson says, drug and device fraud can be broken down into several major themes.

Fraud on the FDA

The first theme outlined by Hutchinson is "fraud on the FDA," which addresses various frauds that may have been perpetrated against the agency.

For example, she says:

- What do companies do to get their drug or device approved?
- What was the process that was taken to get that approval?
- What kind of research was done to support it?
- Were there problems in that process?
- Were there problems in the research that would not have supported the results that were being submitted?
- What kind of testing was done?
- What kind of results were captured?

"More importantly," she adds, "what results were *not* captured?"

Those are areas her office is now looking at, she reports, as relators who are part of the company's process to put together drug applications come forward. "They see that there were things omitted," she says. "They see that things were not completed that should have been."

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The rise of "pre-relators"

According to Hutchinson, many recent allegations come from "pre-relators," namely people concerned about a potentially fraudulent activity who have yet to file a *qui tam* suit. "We encourage them, with their counsel, to come forward and talk to us about it before they have even filed a *qui tam* case," she says. Often times, they may be wrong, she adds. But almost without fail, she says, the first thing "pre-relators" talk about are the steps they took within the company to have the behavior in question addressed.

Hutchinson says that makes it crucial for companies to revisit their complaint policies. That is where companies will find people who, if they are heard and their concerns are addressed, will not become relators, she maintains. ■

See the next issue of *Rx Compliance Report* for ten steps Hutchinson, Ogrosky, and Hall say companies should take to reduce their exposure.

Government joins Best Price case against Wyeth

The United States and 16 states this week joined two *qui tam* suits against Wyeth, alleging violations of the Medicaid Drug Rebate program. The government says Wyeth avoided paying hundreds of millions in rebates to state Medicaid programs for Protonix Oral and Protonix IV, which belong to a class of drugs known as proton pump inhibitors (PPI), through a complex bundling scheme.

"Our complaint charges that Wyeth created the Protonix bundle so they could increase their market share at the expense of the Medicaid program," said Tony West, Assistant Attorney General for DOJ's Civil Division. "By offering massive discounts to hospitals, but then hiding that information from the Medicaid program, we believe Wyeth caused Medicaid programs throughout the country to pay much more for these drugs than they should have.

"This is going to be a big case," predicts a *qui tam* attorney. "The states are taking it seriously. DOJ is taking it seriously. It has been thoroughly investigated and you have a criminal grand jury."

The next issue of *Rx Compliance Report* will examine this case in detail.

An equally important question in terms of fraud on the FDA, says Hutchinson, is, "What was done to keep it approved?" One issue that has been included in some fraud resolutions, she points out, is whether the company complied with directives from the FDA, such as a warning letter to pull an advertisement.

Scrutiny of online advertising

According to Hutchinson, another important and "fascinating" frontier that is likely to receive considerable scrutiny from federal prosecutors is online advertising. "I think we are going to be going there in the future," she predicts.

"There is a new focus on how accurate your online advertising is," says Hutchinson, including what portion of the disclaimers included in DTC advertising must be included as part of any online advertising. "Those can be an interesting area for potential for problems in the future," she warns.

Fraud on the doctor and patient

The second theme – "fraud on the doctor or patient"—is "equally compelling to prosecutors," she says. Fraud on the patient can result if what the doctor receives from the company amounts to a kickback that influences the doctor's selection of a particular drug or device, she explains.

According to Hutchinson, fraud on the doctor can occur if a sales rep visits a doctor's office and does *not* divulge information about the product, does not give the doctor the known or potential bad side effects, or does *not* address the conditions for which the product was approved.

"That is fraud on the patient and/or fraud on the doctor," she says. "I think that is an area we are going to see more and more involvement by our friends at the state level," she predicts.

Fraud on the payors

Finally, says Hutchinson, there is the potential for "fraud on the payors," namely the federal program paying for the drug or device. DOJ's civil division is responsible for protecting the federal fisc, she points out, and that includes federally funded healthcare programs. In short, she says, prosecutors will attempt to determine whether federal healthcare dollars should be paying for the drug or device and what was done to get that particular payment made?

SEC disclosures show that off-label, antikickback, Best Price cases continue to dominate enforcement landscape, reports Saul Ewing

More than 50 active drug and device cases are reported at both the state and federal level, says veteran attorney

According to former federal prosecutor **Christopher Hall**, a comprehensive examination of recent disclosures by drug and device companies to the Securities and Exchange Commission (SEC) shows that off-label, antikickback and Best Price cases continue to dominate the enforcement landscape

In all, the data shows more than 50 active investigations in these sectors underway at U.S. Attorneys' Offices around the country, along with approximately two dozen similar investigations at Main Justice. The increased level of activity among state Attorneys General Offices is also reflected in the SEC disclosures. In fact, says Hall, the number of active cases in state agencies now rivals the number of active investigations in U.S. Attorney Offices (*see table, this page*).

In short, says Hall, drug and device companies have to fight on two and sometimes three fronts. "On the government side, its not always a happy marriage, though many times it is," he says.

The bottom-line, he says, is that companies have to anticipate multiple scenarios to protect their respective interests.

These findings were derived from the latest quarterly review conducted by Hall's firm, Saul Ewing, of over 2,000 securities filings made by publicly-traded drug and device manufacturers. While closely held companies do not file these disclosures, says Hall, the information serves as a useful proxy and a valuable guidepost to smaller companies as well.The survey reports all disclosed pre-indictment investigations. Saul Ewing then sorts the information to reveal the most active enforcement agencies and their most current focus.

This data, along with supporting information collected by his firm, are used by drug and device companies to develop annual risk assessments. Companies also use it as background prior to responding to government subpoenas. In addition, securities attorneys use the information to inform their disclosure judgments.

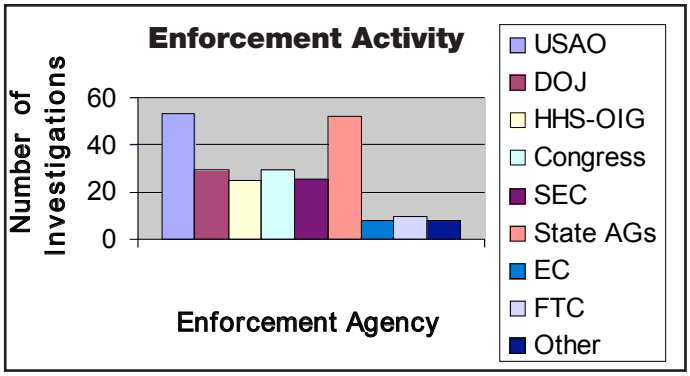
Here is a rundown of the aggregate data compiled by Saul Ewing for the first quarter of 2009:

Enforcement activity: The agencies

The increased level of activity among state Attorneys General Offices is reflected in the SEC disclosures.

As noted above, the data show more than 50 disclosures regarding active drug and device investigations in U.S. Attorney's Offices, as well as a similar number of investigations by state Attorneys General. In addition, Main Justice has roughly two dozen investigations underway. The HHS Office of Inspector General works "hand-in-hand" with the U.S. Attorney's Offices and Main Justice, notes Hall. Several Congressional inquiries are also underway, he adds.

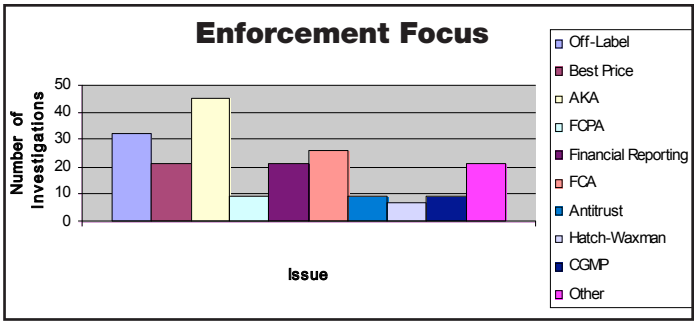
In addition to the increased level of activity in the states, says Hall, the data reflects an uptick in European Community (EC) investigations, as drug and device companies become more global in their reach.



The focus of investigations

The next area examined by Saul Ewing is the focus of these investigations. To nobody's surprise, says Hall, the two areas receiving the most government scrutiny are off-label promotion and kickback violations, roughly 32 and 46, respectively. The data also confirm a continued focus on Best Price cases, he adds, with more than 20 such cases reported.

The number of Foreign Corrupt Practice Act (FCPA) cases does not figure as prominently in terms of the *number* of investigations, says Hall. "But the number of investigations does not necessarily reflect the potential dollar volume of those investigations," he points out.



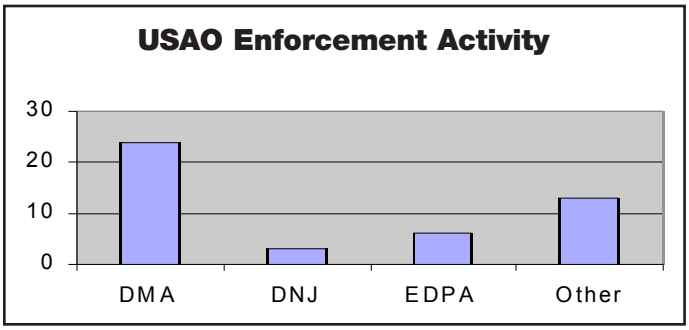
USAO Enforcement activity

In terms of the U.S. Attorneys' Offices conducting these investigations, the District of Massachusetts remains "far and away" the most active, Hall reports, with roughly two dozen open investigations. The Eastern District of Pennsylvania placed second, with approximately half that number. "That is largely a function of the reputation of those offices for investigating cases in these areas by *qui tam* relators," he explains.

In addition to the increased level of activity in the states, the data reflect an uptick in European Community investigations.

The raw number of cases does not necessarily reflect the dollar volume of those cases, Hall points out. For example, he says, there are some very sizable cases coming out of the Eastern District of Pennsylvania that may speak louder than the raw number of cases alone.

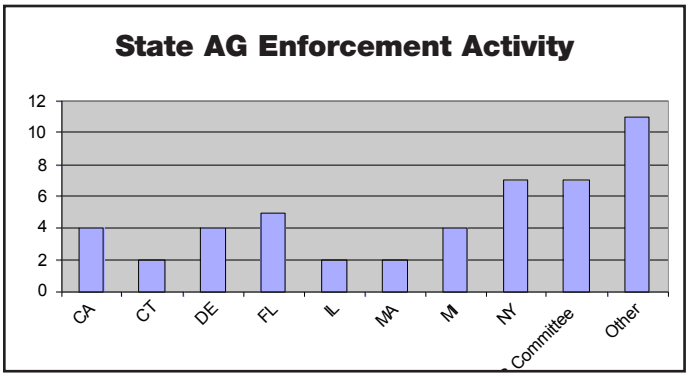
Several cases were reported in the District of New Jersey, he says, along with several cases scattered in various offices around the country.



State AG Enforcement activity

The New York Attorney General is the most active state agency, Hall reports, with seven drug and device investigations underway, followed by Florida with five.

According to Hall, the Illinois Attorney General is another very active office, which collaborates with the U.S. Attorney's Office in the Northern District of Illinois. The Massachusetts and Delaware Attorneys General are also very active, he adds.



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Guest commentary

The Growing Role of Economic Analysis in Off-Label Promotion Cases

By Paul E. Greenberg and Tamar Sisitsky, Analysis Group, Inc.

In an increasing number of government investigations, the central allegation is that a pharmaceutical manufacturer promoted one of its products off-label. Many of these investigations have resulted in hundreds of millions of dollars in payouts by drug companies.

The sheer number of these investigations and magnitude of settlements, as well as the complex regulatory, scientific and business environment in which prescription drug sales occur, suggest a key role for economic analysis.

Newly announced U.S. Food and Drug Administration regulations that permit pharmaceutical companies to distribute copies of medical journal articles describing unapproved drug uses are likely to add further to this complexity.

In some investigations, the focus has been the disease or medical condition for which a drug was allegedly promoted, while in other investigations, the target population has been of primary interest (e.g., pediatric, elderly).

At times, the leading concern has been the alleged promotion of off-label patterns of treatment (e.g., initial versus subsequent line of therapy, acute versus chronic use of the drug), while in other instances off-label promotion of higher-than-indicated doses has invited close scrutiny.

In still other matters, the government's primary focus has been the promotion of a beneficial property of a drug that is alleged to help its manufacturer establish a more competitive footing compared with alternative interventions (e.g., breast cancer prevention property, equivalent or more favorable safety profile relative to comparator products).

Even if off-label promotion by drug manufacturers is not permitted, a physician can prescribe a medication for a non-approved use if it is medically appropriate. In practice, physicians often choose to prescribe medications for unapproved uses for a variety of reasons.

Off-label prescribing is common when there is substantial unmet need—for example, when treating painful conditions, cancer and mental illness—and the physician has tried other available on-label therapies. In such instances, resolving patient symptoms may be best achieved with off-label prescribing.

Government charges of manufacturer wrongdoing with respect to off-label promotion can include civil false claims as well as criminal violations.

From an economic perspective, these legal theories generally translate into two types of damages: (1) government loss, based on the claim that federal and state health care programs (e.g., Medicare and Medicaid) sustained elevated reimbursements as a result of the conduct at issue; and (2) corporate gain, where the damages are based on the gain that resulted from the wrongful conduct.

The sheer number of off-label investigations and magnitude of settlements, in such a complex regulatory, scientific and business environment, suggest a key role for economic analysis.

In instances where liability can be established, a central economic issue under both legal theories involves separating out off-label sales due to off-label promotion from those that would have occurred anyway even in the absence of the conduct at issue.

This often requires analysis of numerous confounding factors in the marketplace which, taken together, may have contributed substantially to the observed level of off-label prescribing.

But before any causation analysis can be implemented, it is necessary to distinguish on- versus off-label sales. Doing so requires careful attention to the available data.

In many therapeutic classes, there exist detailed surveys of physicians' prescribing habits. This includes widely cited data sources such as NDTI (IMS) and PDDA (Verispan), which collect information on the primary medical reason for recommending a specific drug during a patient encounter. Such data sources can provide some insight concerning the range of drug uses.

While these off-the-shelf sources are often relied upon in government investigations to assess the rate of off-label prescribing, at times they may be inadequate, because they do not take full account of the patient's medical history. Instead, they focus solely on stated clinical considerations the day the drug was recommended.

For chronic diseases with many associated symptoms, on any given day, treatment may be characterized as primarily intending to address either the patient's most disconcerting symptom(s) on that particular day, or the underlying chronic illness giving rise to that specific complaint.

But whereas the first characterization could well translate into a determination that the drug was used for off-label purposes, the second designation could result in on-label classification of the drug's use.

The importance of data analysis

Such ambiguity can be settled with attention to the patient's full medical profile, which can be accomplished using several different approaches.

One strategy, where such data are available, is to rely on company surveys specifically designed to assess on- versus off-label use over time.

Another approach is to examine administrative claims data (e.g., Medicaid, Medicare, private payer), which capture patient encounters with the healthcare system that trigger insurance claims for the payer. These data contain patient medical histories, including disease and drug use patterns.

By bringing to bear a rich longitudinal perspective, these data make it possible to go beyond the limits of market research like NDTI and PDDA. Instead, analysis of actual patient health care use over time allows for more informed classification of on- versus off-label use.

The next critical step in an economic analysis of the conduct at issue is to determine what portion of off-label sales is attributable to improper promotion as opposed to confounding factors.

Other drivers of off-label prescribing could include unmet need for the conditions in question, emerging scientific information about the drug, changing reimbursement rules, label changes in other countries for the drug under investigation, and label changes in the U.S. of therapeutically equivalent drugs.

The next critical step in an economic analysis of the conduct at issue is to determine what portion of off-label sales is attributable to improper promotion as opposed to confounding factors.

Here, economists draw upon a number of techniques, from yardstick approaches to more elaborate statistical methods. A yardstick approach can be useful in establishing levels of off-label sales for the period in question by identifying a benchmark time period or a comparison set of similar products in the same therapeutic class.

The goal with both yardstick measures is to develop an estimate of the background rate of off-label prescribing that would have occurred in the absence of the conduct at issue in the investigation.

Alternatively, more sophisticated statistical analysis, such as regression modeling, may be helpful to accomplish the same objective where no such yardstick measure exists.

Using these methods, it is possible to estimate sales stemming from off-label promotion, a key input into the estimation of damages in connection with both criminal and civil charges. ■

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Internet marketing and social media

Veteran attorney outlines FDA-related legal issues to consider with Internet promotion and social media

It is important for drug and device companies to understand what they are not permitted to do in the emerging area of social media, says veteran attorney **Alan Minsk**, an expert in this area. But it is equally important for them to understand what they *can* do, he says.

According to Minsk, who heads the Food and Drug Practice Team at Arnall Golden Gregory, LLP, the ground rules in this area are somewhat fluid due to the lack of specific FDA guidance on Internet promotion and social media. As a result, he says, regulatory affairs personnel and counsel should seek to minimize the risk associated with this emerging media even if they cannot always eliminate it.

Clearly, says Minsk, the Internet has empowered consumers to find information on their own. Moreover, companies are increasingly looking to the Internet and social media to deliver a better return-on-investment (ROI), especially as the ROI from direct-to-consumer advertising is called into question and thousands of sales reps are eliminated.

In short, he says, market research suggests patients are seeking to educate themselves, rather than solely relying on physicians.

Here are several key facts to consider:

- One-third of U.S. physicians are reported to use social media to create, consume or share medical content.
- Approximately 90 percent of consumers report they trust on-line user-generated health content.
- The number of adults who use the Internet to research health information has grown annually since 2000 to more than 145 million recorded in the last year.
- The number of consumers searching for pharmaceutical information online has increased to 95 million, up 16 percent from 2007.
- The number of U.S. adults who looked to the Internet for health information was greater than the number who asked their doctors for information.

Minsk says drug and device companies must consider a host of both FDA-related issues and non-FDA-related issues when operating in this venue.

Here are some of the FDA-related issues that must be considered:

Pre-approval discussions. According to Minsk, companies must strike a balance between education and promotion. Needless to say, companies are not allowed to promote an investigational product as safe and effective, he says. Yet, the same regulation indicates that FDA does not want to restrict scientific exchange of information. "There is a fine line between education and promotion," he explains.

In short, he says, the challenge in this area is how to communicate scientific disease state-related information without appearing to suggest that an investigational product is safe and effective.

Off-label communications. The FDA recently finalized its guidance on good reprint practices regarding the proactive dissemination of off-label information in certain cases and under specific conditions, notes Minsk. The focus of the guidance, in part, he points out, is on truthful and balanced medical or scientific information and full disclosure, rather than product promotion. In fact, he says, FDA even stated in the guidance that if information dissemination starts turning into product promotion, the agency reserves the right to take enforcement action against companies.

Veteran attorney Alan Minsk says companies are increasingly looking to the Internet and social media to deliver a better return-on-investment, especially as thousands of sales reps are eliminated.

The same considerations apply to Internet promotion and social media, says Minsk. "In any type of promotional venue, you have to be careful about disseminating off-label information and recognize the legal risks and consequences," he warns.

False or misleading information. Minsk says companies must tell a complete story and not omit or minimize risk information, overstate safety or efficacy, or broaden the indication, which are common themes in terms of FDA enforcement. All of these risks are present, including enforcement action against unlawful promotion in these venues, when using social media or Internet promotion. "It is important to understand that FDA has not issued any written guidance on Internet promotion, social media, or similar forums," he says, "which makes in-house legal and regulatory wary of such promotion."

Minsk points out that FDA considered issuing written guidance on Internet promotion and even held public meetings on the issue years ago. However, that guidance never occured. He says it is hard to imagine that the agency could have anticipated the notion of social media when it was considering guidance for Internet promotion, much less the onslaught of YouTube, Sermo WebMD, or other third-party websites. "I think to some extent they were correct that they could not keep up with the technological advances," he observes.

A more cynical view might hold that any guidance released by the agency would be challenged on a First Amendment basis as a restriction on commercial free speech, says Minsk. "Whatever the reasons were, FDA decided not to issue any guidance," he says.

At the end of the day, says Minsk, the agency opted to apply the various standards and conditions that apply to any promotion or marketing of products (such as labeling requirements) to Internet promotion, blogs, chat rooms, and the like. Clearly, this includes truthful, substantiated, on-label, and balanced information, he says.

Issues raised by third party vendors

According to Minsk, however, it is important for marketing personnel and third-party vendors to understand that social media is new territory. Additional concern arises when companies use a third party to convey information through websites, brochures, and other promotional forums. "When you can control the dissemination of the message and know the FDA's rules, it might give you more comfort from a regulatory perspective than when you lose control of the message or how it is going to be used," he explains. "Your name is still on that video or that message."

Chat rooms, News Groups, Social Networking Sites, and Blogs

According to Minsk, companies value social media for a variety of reasons. For example, it enables the exchange of information between patients and physicians, he says. It also helps make complex science more understandable to non-scientists and non-physicians, he adds. In short, social media may allow companies to go straight to the consumer with user-friendly language the average person will understand regarding the disease state and how the medicine or treatment may help them. This can be accomplished through testimonials, endorsements, patients talking to patients, and doctors talking directly to patients online, he says.

Moreover, says Minsk, manufacturers can publicly associate themselves with disease states, generate goodwill with patients and physicians, raise awareness about a product, and obtain feedback information about consumer needs and concerns.

"There is a fine line between education and promotion," warns Minsk.

In addition, social media can enable companies to hear, in real time, what people are thinking, says Minsk. Companies can use these media to gather market research, he says, including where people are located geographically, what people think about the disease that is the subject of the company's research or business, and what they think about a particular product. That type of "real time return on investment" is not likely to be available from a television or radio ad, he points out. "There is value from a market research standpoint," he says. "It is an immediate research and message targeting tool because you can do more with less."

"There is a certain comfort level that people feel," says Minsk, "that they can empower themselves." The concern from a legal and regulatory perspective, he says, among other things, is that it creates "a real time issue" of enforcing

regulatory compliance, as well as a loss of control that could result in a legal quagmire.

Why some companies do not sponsor or moderate chat rooms or news groups

According to Minsk, while social media may provide valuable information and serve a useful role in expanding communications, there are a number of legal and regulatory concerns that companies should consider with social media.

For example:

1. Concern about product liability.

From a product liability standpoint, says Minsk, there is always the potential that companies will associate themselves with a particular website or chat room and that a doctor or patient will report using a drug or device for an off-label use. If a doctor subsequently prescribes a drug or device for an off-label use that causes patient harm, he says, the company could potentially be sued under the rationale that the company tried to assume the benefits of the exposure without assuming the risks, he cautions.

A plaintiff's lawyer might argue that a company has waived the learned intermediary defense, whereby the healthcare professional serves as a buffer, by going straight to the consumer, says Minsk, because the company failed to clarify that it was an off-label use.

2. Government might also hold them responsible (e.g., off-label promotion)

According to Minsk, the FDA, the Justice Department, or a state Attorney General might also hold companies responsible for disseminating off-label or false or misleading information. "Your name is associated with it," he points out. "Maybe it is your website. Maybe you sponsored another website. Maybe you put the ad on YouTube or Wikipedia."

3. Edited material might be incorrect or libelous

Companies must also be aware that edited materials might be incorrect or libelous, says Minsk. For example, a company may opt not to correct information on Wikipedia or another website because it does not want to get involved. On the other hand, failure to correct knowingly erroneous information might expose the company.

Likewise, someone might recommend one product over another on a website or a blog, says Minsk. He says that could create a situation where the other company claims that a negative comparative claim was made, directly or indirectly, and could be an apples-to-oranges comparison. The result could be a competitive challenge regarding off-label or false and/or misleading or disparaging information, he says.

4. Adverse event reporting concerns

According to Minsk, companies must always be concerned about learning of an adverse event and reporting obligations to the FDA. For example, he says, "What if it is on a third party site? What if a drug company gives a grant to sponsor the site or puts an ad on a third party site and someone complains to the company or comments on a blog that they had an adverse event?

The questions stemming from this scenario are myriad, he says.

For example:

- Do I have an obligation to report?
- How much data do I have to make an investigation and possibly report?
- Is the information credible?
- How do I know it is not my competitor complaining?
- How do I know it is not a disgruntled employee?

"In any type of promotional venue, you have to be careful about disseminating off-label information and recognize the legal risks and consequences," he warns.

According to Minsk, is almost always better to investigate the issue with the facts presented, even if minimal. There may be a question of how much iidentifiable information can be gathered and how credible that information may be. Whether the complaint will rise to the level of a regulatory obligation will depend on the review. At a minimum, he says, the company can demonstrate that it took the issue seriously, particularly if challenged.

SAFE USE OF LINKS

Minsk says companies should keep several key considerations in mind when using links:

Clicking on a link takes a viewer immediately from one site to another

According to Minsk, the government has made it very clear that if a company links directly to someone else's website and that information is violative, the agency can hold the company responsible.

Because it is difficult to monitor links into a site, a company will not likely be held responsible by the FDA for "incoming" links, but can control their "outgoing" links

Conversely, says Minsk, if another party links to a company's website and the company had no control over that, FDA is not likely to hold the company responsible. If the company learns of the linkage and has concerns about the content, it might contact the other party.

Notify users that they are leaving a company's site

From a regulatory perspective, says Minsk, companies might minimize risks by focusing on education of disease states, and less product promotion, or allow a third-party to run a site without the company's active participation.

If the company hosts a site or blog, he says, it might want to avoid providing a forum for real-time continuous discussion to minimize its risk. ■

■ **Alan Minsk**, Partner, Arnall Golden Gregory, LLP, alan.minsk@agg.com

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Vermont legislature passes sweeping gift ban

A sweeping ban

The new law would prohibit drug and device makers, as well as wholesale device distributors, from giving gifts to Vermont-licensed healthcare providers. **Nikki Reeves**, a partner with King & Spalding in Washington, D.C. who specializes in this area, says the term "gift" is defined broadly to include food, entertainment, travel, subscription, advance, service or anything else of value provided to a healthcare provider for less than fair market value.

According to Reeves, the bill also defines "healthcare provider" very broadly, to include not only physicians but also nurses, office staff, and others employed in a physician's office. In this regard, she says, the Vermont legislation is similar to the new regulations now in place in Massachusetts. The bill would also impose a civil penalty of up to $10,000 for each violation, she adds.

Under the new law, says Reeves, Vermont would continue to require manufacturers to report the value, nature, purpose and recipient information associated with any allowable expenditure. Notably, however, it would add academic institutions and professional, educational, or patient organizations serving healthcare practitioners or patients to the disclosure obligation. It would also change the reporting date from December 1 to October 1 of each year and impose an annual fee, she says.

Elimination of the trade secrets provision

In terms of disclosure, the most significant change under the new law is the elimination of the opportunity for companies to claim that payments to doctors are protected as a "trade secret." According to Sorrell, more than 80 percent of the expenditures analyzed for the most recent report were designated as such by the companies. Eliminating the trade secret provision, he says, would make the state's annual disclosure report "much more useful," because it would allow Vermont residents to determine what individual doctors are receiving from companies and for which particular drugs.

In short, says Reeves, the new law would require the Vermont Attorney General to publish information about allowable expenditures in the annual report both in aggregate form and by selected types of healthcare practitioner or by individual healthcare practitioner. It would also make all disclosed data submitted by manufacturers for the Attorney General's annual report available and searchable through an Internet website after the report is issued, she adds. Advocates of the new law

say this will allow analysts to help determine whether marketing expenditures are influencing prescribing habits.

Excluded items

The Vermont gift ban specifically excludes certain items from the gift prohibition, notes Reeves, including samples, medical devices provided on loan to healthcare providers for short-term trial periods for their evaluation, peer-reviewed journal articles, scholarships to medical students, residents and fellows, and rebates and discounts provided in the normal course of business.

At press time, the bill had yet to be signed into law by the Governor. The next issue of *Disclosure Update for Drug and Device Companies,* a supplement to *Rx Compliance Report,* will examine the potential impact of the Vermont law. ■

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Continuing medical education

AMA's CEJA publishes recommendations for "an ethical framework" for CME

Last week, the American Medical Association (AMA) released the 2009 Council on Judicial Affairs (CEJA) proposed recommendations to the House of Delegates on Financial Relationships with Industry in Continuing Medical Education. The report concluded that while relationships with industry can offer "enormous benefit" to doctors and patients, commercial funding for professional education can pose "significant ethical challenges to medicine's ability to focus primarily on the needs of patients and ensure quality education for physicians."

As expected, the report stops short of the draconian recommendations proposed—and ultimately defeated – by CEJA last year, which called for a complete ban on industry support of continuing medical education (CME). **Tom Sullivan**, president of Rockpointe, Inc. in Columbia, MD, says most, if not all of CEJA's recommendations can be implemented under the current Accreditation Council for Continuing Medical Education's Standards for Commercial Support.

The recommendations will be considered by the AMA's Reference Committee and the Full House of Delegates, which meets June 13-17 in Chicago.

Establishing an "ethical framework"

According to the report, "an ethical framework" to guide professional practice with respect to financial relationships in the context of CME should include the provisions below.

Physician-learners," it says, should seek out CME activities that indicate their adherence to the following guidelines:

It is ***ethically preferable*** that:

1. CME providers accept funding only from sources that have no direct financial interest in a physician's clinical recommendations; and that

2. Individuals who program, develop content for, or teach in CME activities:

   a. have no current, recent (within the preceding 12 months), or potential direct financial interest (e.g., royalties or ownership interest) in the educational subject matter; and

   b. are not currently and have not recently been (within the preceding 12 months) involved in a compensated relationship (e.g., direct employment, service on a speakers bureau, service as a consultant or expert witness) with a commercial entity that has a financial interest in the educational subject matter.

The report stops short of last year's recommendation by CEJA for a complete ban on industry support of CME.

It is ***ethically permissible*** that:

3. CME providers accept funding from industry sources if the following conditions are met:

a. the educational activity is planned by the provider based on needs identified independent of and prior to solicitation or acceptance of the funding; and

b. the use of the funding is not restricted in any way; and

c. the source of the funding is clearly disclosed; and

d. the CME provider is not overly reliant on funding from industry sources.

4. CME providers permit individuals who have *modest* financial interests in the educational subject matter to program, develop content for, or teach in CME activities if the following conditions are met:

a. the existence and magnitude of any financial interests are clearly disclosed; and

b. steps are taken to eliminate or mitigate the potential influence of those interests.

5. CME providers permit an individual who currently has a *direct, substantial, and unavoidable* financial interest in the educational subject matter (e.g., as the inventor of a new device) to program, develop content for, or teach in a CME activity *only* if the following conditions are met:

a. the individual is *demonstrably uniquely qualified* as an expert in the relevant body of knowledge or skills; and

b. participants are clearly informed about the nature and magnitude of the individual's specific financial interest in the subject matter; and

c. there is a demonstrated, compelling need for the specific CME activity in the professional community that cannot otherwise be met; and

d. steps are taken to mitigate the potential influence of the unavoidable financial interest to the greatest extent possible; and

e. every effort is made to develop a pool of qualified, independent experts as quickly as possible. CME activities that involve financial relationships which cannot be addressed through any of these mechanisms are *ethically prohibited*.

The report can be read in its entirety at: www.ama-assn.org/ama1/pub/upload/mm/475/ceja01a09.pdf

Eli Lilly offers clarification and comment

Eli Lilly recently responded to a recent story in the April 14, 2009, issue of *Rx Compliance Report* on the company's Zyprexa settlement with two clarifications and a comment.

The article states that the "Lilly state settlement requires that sales representatives themselves cannot provide samples. Rather, they must be provided through a third-party and only to doctors who have or will have on-label patient populations."

According to Lilly, this in incorrect. "Lilly sales representatives can and do provide samples to doctors and are not prohibited from doing so under either the CIA or state consent decrees," says the company. "Under the state consent decrees, sales reps may only sample Zyprexa to a 'HCP whose clinical practice is consistent with the product's current labeling'."

The article states that the "Lilly state settlement affirmatively states that companies can distribute reprints as long as they are reviewed and distributed by the medical information department and there is no involvement by the sales and marketing departments."

According to Lilly, the state consent decrees do not prohibit sales representatives from distributing reprints. Rather, they restrict sales representatives' ability to disseminate Zyprexa "Reprints Containing Off-Label Information."

Finally, the article states that a consultant's report stated there were virtually no on-label patients in the primary care physician population." It is important to note that many patients who suffer from mental illness are treated by their primary care physician, particularly in certain parts of the country, says Lilly.

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