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RX COMPLIANCE REPORT

EXCLUSIVELY DEVOTED TO PHARMACEUTICAL SALES AND MARKETING COMPLIANCE

Proliferation of state consumer protection actions aimed at pharma companies threatens long-standing regulatory practices

For years, pharmaceutical manufacturers and the FDA have engaged in constructive dialogue about a range of regulatory matters. However, an upsurge in a new brand of state consumer protection actions aimed at drug companies threatens this constructive dialogue, says former DOJ attorney, **Stephen Brody**, a partner with O'Melveny & Myers in Washington, D.C. The problem, he says, is that while negotiating a regulatory matter with the FDA used to conclude the matter, today it leaves it on the table as potential fodder for increasingly aggressive state consumer protection actions.

This is hardly a theoretical threat. In June, South Carolina won a $327 million judgment against Ortho-McNeil-Janssen in connection with the company's promotion of the antipsychotic drug Risperdal. The basis of that suit was a warning letter that Janssen received in 2004. That follows a similar case in Louisiana last year that resulted in a $257 million verdict.

That is, by no means, the end of the story. Janssen now faces a potential $1 billion liability in connection with its marketing of Risperdal in Texas, where trial is slated for November. That is a broader and more complex case than the South Carolina or Louisiana suits, but part of it is based on an FDA warning letter. Moreover, this new trend already extends well beyond Risperdal.

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OIG unexpectedly drops bid to exclude Forest CEO Howard Solomon

On Friday, the HHS Office of Inspector General (OIG) unexpectedly dropped its effort to exclude Forest Laboratories CEO, Howard Solomon. The reasons for the OIG's decision are unclear, since the agency does not comment on exclusions. But the move certainly qualifies as a surprise.

The prosecution and potential exclusion of pharmaceutical executives has been the focus of considerable attention over the past year, largely the result of a series of public comments by government officials, including long-time OIG Chief Counsel, Lew Morris. Last year, Morris started publicly discussing the OIG's plans to use its exclusion authority more affirmatively as a means of deterrence. "We are going to hold executives personally accountable for what happened on their watch," he said. The OIG's tougher stance was also reflected in the release of guidance last October that outlined how the agency planned to use its permissive exclusion authority.

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Proliferation of state consumer protection actions threatens long-standing regulatory practices

Brody first raised the specter of this troubling pattern prior to the South Carolina verdict based on his involvement in a similar case brought by West Virginia in 2004. In that case, West Virginia Attorney General, Darrell McGraw, filed suit against Janssen based on FDA regulatory activity that took place in the fall of 2003.

In that instance, the agency required a class-wide warning regarding diabetes for atypical antipsychotics. In response, Janssen sent out the new package insert and also noted a published body of peer-reviewed epidemiological evidence – eight studies in all – that suggested Risperdal does not have an elevated risk compared to some of the other atypical antipsychotics on the market.

Janssen's letter eventually found its way to DDMAC, notes Brody, and six months later the agency sent the company a warning letter. In July 2004, Janssen sent a correction letter to doctors across the country and in October 2004 the FDA said the matter was concluded. But then West Virginia decided to sue in state court, claiming that the original communication that went to doctors was false and misleading, because DDMAC had so indicated in its warning letter. In its suit, West Virginia demanded $5,000 for each letter that went to West Virginia physicians.

The judgment against Janssen in West Virginia was eventually overturned on appeal by the West Virginia Supreme Court, notes Brody. Unfortunately, he says, it was not overturned on any of the grounds that would have been helpful as precedent, but rather because the trial judge made an issue preclusion ruling that indicated the court was not in a position to second guess the FDA about whether Janssen's claim was false and misleading.

South Carolina's $327 million judgment against Janssen has since raised the profile of this issue rather dramatically. By no means, however, is the troubling scenario outlined by Brody limited to Janssen's Risperdal. "There have been similar claims all across the country relating not only to Risperdal but Duragesic, Zyprexa, and other drugs," he says. "They have been used in the Vioxx litigation. They have been used all over the country."

FDA juristiction

Brody points out that prescription drug advertising has long been part of the FDA's jurisdiction. "The FDA has standards," he says. In fact, there are 20 different definitions of areas where an advertisement is misleading, he points out, as well as 13 others where it may be misleading. For example, FDA's oversight addresses misrepresentations of statistical significance and failure to disclose variations in results.

"We not only have standards," says Brody, "we have discretion with the FDA in terms of enforcement." The FDA engages in dialogue with pharmaceutical manufacturers when it believes there is a violation, he explains, and it has a range of options based on the seriousness of perceived violation.

While negotiating a regulatory matter with the FDA used to conclude the matter, today it leaves it on the table as potential fodder for state consumer protection actions, says Melveney & Myers' Stephen Brody.

In general, Brody points to a division of authority over prescription drug advertising that is shared by the FDA and the FTC, with the FTC largely deferring to the FDA's expertise on prescription drugs. "It is not quite this simple," he says. But the framework is generally understood.

"Little FTC Acts"

The increasing number of cases now being brought by states against pharma companies constitutes a serious problem, in part, says Brody, because every state in the country has some form of a consumer protection statute. Many of them are modeled after the FTC Act. In fact, says Brody, some are so close in design that they are known as "Little FTC Acts." In 29 states, he points out, courts or statutes have explicitly indicated that when seeking to determine whether a claim is false or misleading, it is important to look to the FTC's guidance.

Unfortunately, the FTC's guidance in this regard comes in the form of 23 words as opposed to the FDA's 23 factors or its discussion of statistically significant results noted above, says Brody.

"This is a huge problem," says Brody. While there can be legitimate grounds to complain about the way the FDA or the FTC looks at certain regulatory issues, at least there is guidance, he says, and where FDA's regulation of prescription drug marketing is concerned there is also a dialogue. "Unfortunately," says Brody, "you now have state consumer protection laws, which are typically designed for pyramid schemes or telemarketing, being applied aggressively in the area of prescription drug marketing, particularly by state AGs."

In some cases, state AGs bring these actions on their own, notes Brody. But often they are brought by private plaintiffs' lawyers acting as special deputy AGs suing in the name of state AGs. In fact, he says, some plaintiff attorneys routinely lobby state AGs to allow their firm or a consortium of other plaintiffs' firms to file a suit in the name of the state AG in order to be able to bring an aggregate claim without having to meet class certification requirements. Worse yet, he says, they sometimes seek to bring a claim under a consumer protection statute that provides for civil penalties without the need even to show that anyone was damaged.

No standards for juries

Another complicating factor, says Brody, is the lack of standards for courts or juries to evaluate these claims. "That's a big problem," he says, "when you think about twelve lay jurors deciding whether a scientific opinion about what a body of published peer-reviewed epidemiological evidence suggests about the comparative incidence of a disease in different products as opposed to experts at the FDA."

"An enormous complication"

According to Brody, this new brand of state litigation interferes with the relationship manufacturers have with federal regulators. When a manufacturer receives a warning letter from the FDA, which is something happening with increasing frequency, it engages in a dialogue with the agency, he explains.

In fact, he notes, the FDA Regulatory Procedure Manual specifically states that warning letters are informal and advisory and are designed to allow DDMAC to go to negotiate a satisfactory resolution with the company in question. "Needless to say, if negotiating with the FDA is going to potentially lead to millions – or even billions – of dollars in civil penalties, it is a real problem," he says.

In short, he says, it takes the FTC's Memorandum of Understanding and the deference the FTC traditionally gives to the FDA and its expertise in the area of prescription drugs and adds "an enormous complication" that interferes with longstanding regulatory practices.

No easy answer

Unfortunately, says Brody, there is no easy answer to this growing problem. There are, however, some potential steps that would help. For example, he says, Congress could step in and instruct state courts that the Food Drug and Cosmetic Act (FDCA) and FDA's enforcement efforts in this area preempt state law. This would keep the states out of certain areas, he says.

This is particularly true after *Wyeth vs. Levine*, says Brody. In fact, he says, it is difficult to overstate how often judges indicate that *Wyeth* means there is no preemption. That requires stepping back and discussing the history of *Buckman* and other relevant decisions, he says. But that is a complex argument that often does not resonate with the court.

State consumer protection laws typically designed for pyramid schemes or telemarketing are now being applied aggressively in the area of drug marketing, says Steven Brody.

Wyeth was a failure to warn case where the company argued a preemption defense, based on the fact that the FDA mandates what goes into the label and the package insert, notes Brody. The Supreme Court determined that is not an affirmative defense if there is a state law duty to warn.

Buckman suggests there is no private right of action to enforce FDA regulations, notes Brody. In short, if a company does something to violate one of the standards in the FDCA, that does not create a right of action. "That is preempted," he says. "The FDA has jurisdiction there."

"They are very different cases that are difficult for many judges to understand," says Brody. This can make it difficult to explain to courts where a plaintiff or a state AG may be entering a preempted area, he says.

At this point, says Brody, anything that elevates the profile of this problem, which is like a hammer being held over the head of manufacturers, would be useful. Congressional action would be very helpful, he says, as would some affirmative guidance or affirmative statement by the FDA. "Active *amicus* participation in many of these cases by the FDA would also be extremely useful," he adds.

According to Brody, the alternative is very unattractive, which is a scenario where pharma companies refuse to send a correction letter or do anything that any state AG or private plaintiff's lawyer could attempt to use as evidence to suggest that the company agrees they have done something false and misleading. "Do we really want to have manufacturers arguing with the FDA every time the agency comes out with a warning letter?" he says.

"There have been state consumer protection actions across the country relating not only to Risperdal but Duragesic, Zyprexa, and other drugs," says Stephen Brody.

At present, says Brody, the emerging status quo is in conflict with the notion that companies should be able to negotiate regulatory matters with federal regulators without fear of retribution by state courts. "It is a real problem, because even if you win companies spend millions of dollars defending these cases," he says.

With a more aggressive DDMAC, a more aggressive FDA, and very aggressive state AGs who see the opportunity to bring money into cash-strapped state coffers, the problem is only going to get worse, Brody predicts. ■

■ **Stephen Brody**, Partner, O'Melveny & Myers, Washington, DC, sbrody@omm.com

Note: Last week, the Massachusetts AG announced it is suing Janssen for illegally marketing Risperdal. The lawsuit alleges that Janssen promoted the drug to treat elderly dementia and a number of uses for children and adolescents when these uses had not been shown to be safe and effective and had not been approved by the FDA.

GSK implements next phase of new incentive compensation program for U.S. sales reps

GlaxoSmithKline announced last month that it has implemented the next phase of its new incentive compensation program for its U.S. sales reps with the introduction of a new performance evaluation methodology and process.

In July of 2010, GSK announced that bonuses for U.S. sales reps who work directly with HCPs and other customers would no longer be based on individual achievement of sales targets. Instead, incentive compensation would be based primarily on the service that sales reps deliver to customers and determined, in part, by customer feedback and adherence to the company's emphasis on transparency, integrity, respect and patient-focus.

Implementing the new initiative has proven to be no easy task, however. "Since first announcing its plans to radically change its sales incentive compensation system, GSK has conducted extensive research to define how best to obtain robust, ongoing, unbiased assessments of the effectiveness of its sales professionals in meeting customer needs," the company said in a statement. "This effort," said GSK, "is part of a wider evolution" to align the company's sales and marketing programs with societal and customer expectations."

In January, GSK eliminated the use of individual sales goals as part of the incentive compensation for sales reps who work directly with HCPs. Going forward, sales reps who work directly with HCPs will be compensated with "a competitive mix of salary and bonus."

In place of individual sales targets, three primary factors will be evaluated to assess performance and determine bonuses:

- selling competency,
- customer evaluations, and
- the overall performance of their business unit.

GSK's original announcement last summer drew praise from industry critics, who continue to take a "wait and see" approach as the company implements its novel compensation initiative. ■

▸ *Cont. from page 1*

OIG unexpectedly drops bid to exclude Forest CEO Howard Solomon

On April 12, Solomon learned that the OIG was considering excluding him from doing business with federal healthcare programs. But on Friday, the company announced the OIG had decided not to exclude him under section 1128(b)(15) of the Social Security Act, its permissive exclusion authority.

"Based on a review of the information in our file and consideration of the information that your attorneys provided to us, both in writing and during an in-person meeting, we have decided to close this case," the OIG wrote Solomon on August 5. "We anticipate no further action related to this matter."

The 83 year-old Solomon was chief executive at Forest when it entered into a $313 million settlement and pled guilty to obstructing the FDA, distributing an unapproved new drug, and distributing a misbranded drug last year. That made Forest a "sanctioned entity" and subjected Solomon to potential exclusion.

Every indication was that it was only a matter of time before the OIG exercised its permissive exclusion of a senior pharmaceutical executive. When the government's case against former GSK attorney, Lauren Stevens, was thrown out in May, the immediate focus of the government's deterrent efforts aimed at senior pharmaceutical executives seemed to shift even more heavily to the OIG's pending exclusion of Solomon. But then the OIG decided not to pull the trigger.

While Solomon did not represent the OIG's first attempt to exclude a senior pharmaceutical executive, he would have been the first such executive excluded solely by virtue of his position, as well as the most prominent. KV Pharmaceutical CEO, Marc Hermelin, who was barred from doing business with federal healthcare programs, later pled guilty to felony misbranding charges. Likewise, the exclusion of three senior executives of Purdue Pharma in 2007 followed misdemeanor pleas. In other words, Solomon would have represented the first permissive exclusion of a senior pharmaceutical executive who was not personally charged with any wrongdoing.

"We are gratified by the HHS-OIG's determination that an exclusion of Mr. Solomon is unwarranted," said Forest's Kenneth Goodman.

A measure of intrigue

The decision to drop the exclusion of Solomon also included a measure of intrigue. Hours before Forest made its announcement on Friday the Icahn Group announced that the Delaware Chancery Court had ordered Forest Labs to release documents relating to the pending OIG action to exclude Solomon.

The backdrop here is that the Icahn Group is seeking to have four nominees elected to the ten-person Board of Directors of Forest Labs at its 2011 annual meeting of stockholders next week. "Among the information released," the Icahn Group announced in a press release, "is a letter from Forest Labs' counsel to the OIG which indicates that the OIG had initially contemplated bringing an exclusion proceeding against not only Howard Solomon but *eight* top executives of Forest."

Howard Solomon would have represented the first permissive exclusion of a pharmaceutical executive who was not personally charged with any wrongdoing.

The Icahn Group claims that Forest was made aware of this possibility on or prior to September 2010, but that minutes of a Board meeting held on April 5, 2011, indicate the Board was not informed about the OIG's potential action until that meeting. "This is symptomatic of larger governance problems at Forest Labs," charged the Icahn Group.

Forest responds

Forest responded with its own press release charging that Icahn's decision to publicize the Delaware litigation was "a sideshow and an effort to advance his self-serving agenda in his proxy contest."

"The documents to which he refers demonstrate what Forest has said all along," said the Forest release, "that Mr. Solomon has never been accused of any wrongdoing; that the potential exclusion is based solely on his 'association with' Forest; and that HHS-OIG is considering embarking on an unprecedented and unjustified action."

Any connection between this activity and the timing of the OIG's decision is speculative. ■

SEC whistleblower law

House bill would encourage SEC whistleblowers to use company programs first

By Joshua Horn

One of the more controversial rules to come out of the SEC since Dodd-Frank was the rules implementing its whistleblower program. Under the rules as adopted by the SEC, a whistleblower does not have to report internally before approaching the SEC. This was the most charged aspect of the final rule and was opposed by two SEC commissioners. In addition, many business groups opposed this provision of the rules because they felt, among other things, that dispensing with an internal report would effectively defeat compliance programs that companies spend a lot of time and money to develop and implement. Conversely, the plaintiffs' bar welcomed this rule because they believed that many compliance programs were ineffectual.

On July 12, four House Republicans introduced legislation known as the Whistleblower Improvement Act to overturn this controversial aspect of the SEC's whistleblower rules. Under this proposed legislation, in order to be eligible to collect the whistleblower bounty, the reporting employee would be required to first report this information to his or her employer before reporting to the SEC. This proposed legislation does not, however, require internal reporting on those cases where there is evidence the purported misconduct was committed by or had the complicit involvement of management's highest levels or evidence of bad faith on the employer's part.

This House bill also seeks to restrict the recovery of whistleblower bounties by those who are culpable for wrongdoing. Finally, this proposed legislation imposes a burden on the SEC to advise a company that it possesses information from a whistleblower and that the SEC is conducting an investigation of the alleged behavior before conducting an enforcement proceeding. By receiving this information, a company could potentially remediate the reported problem without having to be submitted to an enforcement proceeding.

Undoubtedly, the advocates on both sides of the debate will make their voices known with respect to this proposed change to the SEC's whistleblower rules. The proposed legislation can be seen as attempting to strike a middle ground between a whistleblower never having to internally report before going to the SEC and always having to first internally report. Whether this legislation gains any traction remains to be seen.

If this proposed legislation becomes law, it could ultimately place a greater burden on a whistleblower to determine whether he or she must first internally report or can go right to the SEC. Under this proposed approach, the whistleblower has to make the right decision or else forgo the whistleblower bounty. By the same token, company's need to always make certain that they have adequate programs that promote a culture of compliance and encourage internal reporting regardless if a whistleblower must first internally report before approaching the SEC.■

"The proposed legislation can be seen as striking a middle ground," says Joshua Horn of Fox Rothschild.

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False Claims Act Update

Rx Compliance Report will publish a False Claims Act Update featuring several veteran attorneys from Morgan Lewis. The update will include:

- Recent U.S. Supreme Court and Federal Court decisions involving FCA procedural and substantive challenges
- Recent settlements and the impact of FCA investigations and settlements on criminal and administrative actions
- Defense strategies to effectively challenge FCA investigations and litigation proceedings
- Compliance strategies to mitigate risk

Social media

How to navigate the emerging social media terrain absent FDA guidance: Part II

"What social media is mainly about are communities of people who are seeking to have conversations among themselves," says **Glenn Byrd**, who has headed up the Advertising and Promotions team at MedImmune since 2007. The statistics make it very clear that people want to hear from their peers, says Byrd, who used to lead the promotional enforcement team at the FDA Center for Biologics. "They do not want to be talked at." Rather, he says, they are seeking information around their health so they can have informed communications with their doctors or seek information themselves.

Byrd says this is where companies need to be, because this is where the people are and this is where companies will have an impact if they are able to communicate or participate in a way that results in meaningful dialogue.

The amazing reach of social media

The reach of this new media is nothing short of "amazing," says Byrd. For example, he points out that there are over two billion daily views on YouTube, which is currently the top search engine.

Byrd also cites these statistics (from Razorfish Health):

- **89 million adults** in the United States use social media for health-related purposes.
- **152 million people** use Facebook in the United States, while 600 million use it worldwide.
- **175 million** people use Twitter worldwide.
- **25 billion** tweets were sent on Twitter in 2010.

Moreover, it just keeps growing, says Byrd. For example:

- **30 billion** pieces of content (e.g., links, photos, notes) are shared on Facebook each month (Source: Royal Pingdom)
- There are **200 million** views of YouTube ***via mobile*** per day (Source: Google)
- **20 hours of video** are uploaded to YouTube every minute – the equivalent of Hollywood releasing 86,000 new films every week! (www.medicalbillingandcoding.org)
- **1/3 of the U.S. population** views/uses YouTube (www.medicalbillingandcoding.org)
- **100 million** new accounts added on Twitter in 2010 (Source: Royal Pingdom)
- **$3.08 billion** will be spent to advertise on social networking sites in 2011, ***a 55 percent increase*** over 2010 (Source: eMarketer)
- **65%** of U.S. adults use social media and say they have received a positive benefit as a result (Source: Harris Interactive)

"What social media is mainly about are communities of people who are seeking to have conversations among themselves," says MedImmune's Glenn Byrd.

Byrd says the key statistics above are the 200 million views in YouTube through mobile channels and the fact that one-third of the U.S. population uses YouTube. "I think that you will see an explosion in mobile applications from regulated industry this year," he says. That will present a real challenge for pharma, he says, because companies will have to learn how to evaluate the content they are producing digitally. In other words, he says, companies will have to determine if it functions on a hand-held device the same way it was intended to on a computer screen.

Another very telling statistic, says Byrd, is that more than $3.8 billion will be spent to advertise on social networking sites in 2011, which marks a 55 percent increase over 2010.

"Industry is going there," he says. "They are not waiting for FDA guidance, although there are some real challenges in that regard."

Who is using social media?

According to Byrd, the demographics of social media users are also changing rapidly. For example:

- College-aged kids (18-24) made up the fastest growing segment of users on Facebook in 2010. (AllFacebook.com)
- During the average 20-minute period in 2010, there were: 1,587,000 wall posts, 2,716,000 photos uploaded and 10,208,000 comments posted. (AllFacebook.com)
- Since April 2010, Twitter has gained 40 million users and a 62% increase in mobile use of the platform (Source: ClickZ)
- The average American Internet user watches 30 minutes of video online per day, a 40% increase over 2009 (comScore)
- The change in social media use among Baby Boomers 55-64 rose from 9% in Dec. 2008 to 43% in Dec. 2010 (Marketingcharts.com via David Erickson)

Byrd points out that the industry is not only targeting its messages to college-age audiences, even though that is the fastest-growing segment in Facebook. He notes that 43 percent of Baby Boomers were using social media by the end of last year compared to only nine percent two years earlier. "It is not just particular segments of the market where this is happening," he says. "It is across the whole market."

How is social media being used?

According to Byrd, there are a variety of ways industry is taking advantage of social media. Some companies are actually brand marketing, he says, while others are utilizing these tools for market research. "You can get a lot of information from people through market research using social media as opposed to going out and doing focus groups," he explains. "You can also get new ideas related to your product."

Byrd says much of the "community building" that is taking place is centered around unbranded communications in chronic disease areas, such as diabetes or rheumatoid arthritis.

Competitive intelligence is another way that companies are utilizing these tools, including monitoring corporate reputation, says Byrd. "It is not just about the marketing departments," he says. "It is also about Corporate Affairs departments and what they are trying to achieve utilizing these tools."

The point to remember, says Byrd, is that all of these tools have the potential to be regulated, because advertising and promotion includes all activities used by the sponsor or license holder to create an interest in their product. The FDA's view, he explains, is that if a sponsor provides content, proofs, comments, pays for or otherwise influences a product-related presentation that means it is regulated and considered promotional.

Fundamental principles of compliant promotion

Needless to say, there has been considerable discussion about a lack of guidance for social media, says Byrd. "But we also need to recognize that there is guidance," he says. The most recent guidance is the risk presentation guidance, he notes. "In the absence of anything from the FDA at this point, taking the fundamental regulatory requirements and then applying the existing guidance gives us a good starting point," he says.

"I think that you will see an explosion in mobile applications from regulated industry this year," says Glenn Byrd.

"We know that we have to be truthful and non-misleading," says Byrd. "We know that we have to communicate balanced information of risks and benefits." However, the third part of that equation is sometimes forgotten, he warns. "You must give all of the information or at least enough of the information for people to be able to understand whether that product is appropriate for them or whether or not it is something doctors should prescribe to their patients," he says. "Those are the material facts."

How to present risk information

Another important area is "help-seeking" and disease awareness, says Byrd. Namely, he points to the need to separate unbranded and branded communications. "That is very important and the FDA has already done a nice job of laying out how you should think about it and how you can execute that kind of communication separately," he says.

Enforcement actions, while not guidance *per se*, also offer insight to how the FDA is thinking about content, says Byrd. In terms of presenting risk information, he says, the evidence that can be gathered through the enforcement actions is very well articulated, he explains. "You have to provide risk information or the FDA will take action."

"Those are all important things to look at," he says.

The limits of FDA guidance

In terms of any guidance the FDA eventually introduces, Byrd says, it is important to recognize the reach and breadth of social media. "Will a guidance really address all of that and tell you exactly what you need to know?" he says. "I think it won't."

In fact, he points out, the FDA has indicated that it will focus on six key areas, so whatever the agency releases initially will only be a small part of a very large picture. "I think it is unreasonable to expect that guidance is the answer," he says.

This is especially true in light of the way guidance will be issued, says Byrd. "It comes out as draft," he points out. "You have a comment period. There is a potential for that guidance to change. There is a long iterative process even when the guidance does come out before things will be final."

Increasing collaboration

According to Byrd, there has been notable collaboration between industry and the providers of electronic media and social platforms. For example, Google Health and YouTube recently brought in a number of companies and asked them what they needed in order to operate in this space.

Byrd says these companies recognize that there is a lot of revenue they can tap into in terms of corporate-financed communications. "I think they are listening," he says. "They are providing functionality that caters to some of the unique needs that our regulated industry has, compared to what they might do for regular consumer products."

What are the challenges?

Needless to say, there is no shortage of challenges the industry will confront in this area, says Byrd, including the different tools and sharing features, such as Facebook and Twitter. There is also the challenge companies face in terms of the limited number of characters they are afforded in certain media, he add.

Search results are another challenging area, says Byrd. "You have search engines that generate content based on a hierarchy of all kinds of different things, some of which you can program into your actual content yourself," he says. Something the FDA is probably not going to regulate – at least in the near future – is the technology that underlies the actual search result, he says.

The colored or shaded bar at the top of a Google search reveals paid content, he says, but the rest of the material on that page is typically related to the proprietary technology of the provider.

"You have hidden links," says Byrd. "You have pop-up windows." With YouTube, people view "watch pages," he says. "When you click on a video it takes you to a page that is a watch page," he explains. "That page does not only have the video you selected on it, it has a lot of other stuff that you may or may not have control over."

"How does FDA regulate that?" he says. "How do you account for that kind of situation when you are going through a promotional review process if it is a brand or aided communication in your company?"

Companies must base their social media decisions on many different factors, says Glenn Byrd, much of it having to do with their risk tolerance.

Part of the challenge, says Byrd, remains the absence of any direction from FDA in terms of specific questions, such as where responsibility lies in terms of communication about a product if it is a company communication versus someone sharing or commenting about it. But the area and functionality that requires attention is how it really works, he says.

Byrd says he has encountered some brand initiatives where there has been desire to put forth content. But once you get through the promotional process, the challenge is to critically look at how every specific function works. "It is very difficult," he says. "You have to look carefully at those sharing pieces."

There could be an oversight in some cases, says Byrd, where all the content was approved on a Facebook page, for example, but the sharing feature was overlooked. "You have to look at each piece,"

he says, "and you have to ask critical questions of your brand teams and your agencies."

Sometimes, the medium may simply not be appropriate, says Byrd. For example, he points to Twitter. "What can you really do in 140 characters?" he says. "Should you be trying to do product specific and non-reminder type communications in Twitter?

"I would suggest it is almost impossible to do," he says. "I think we have to make the critical decisions both about whether to be in this space and then what tools are useful and appropriate to use in this space."

What are we to do?

Ultimately, companies must base their decisions on many different factors, says Byrd, much of it having to do with their risk tolerance. "I think we also have to look internally within each of our own organizations and find out, what is our risk tolerance," he says.

When he was at the FDA, Byrd says, it was easy to discern which companies consistently "pushed the envelope" and which ones played it very conservatively. "That did not direct enforcement in any way," he says. "That is just representative of the reality within industry. Some companies just take more risks than others and you have to evaluate your corporate position."

Byrd says this is especially true today with so many companies operating under corporate integrity agreements and other actions that go beyond FDA regulation. "There is a lot less risk tolerance," he says.

In short, Byrd says, companies must first determine what they are trying to achieve. "Are you trying to just educate an audience?" he says. "Or are you trying to educate an audience about a product and then translate that into marketing efforts?"

Alterntively, companies may just be out there listening, says Byrd. They may just want to hear what audiences and communities are saying.

"Those are questions that have to be asked," says Byrd. "Those questions will help direct you to the appropriate tool." ■

■ **Glenn Byrd**, Senior Director, Regulatory Affairs, MedImmune, Gaithersburg, MD, byrdg@medimmune.com

Social media and the regulated environment

How is social media used?

- Brand marketing
- Market research/insights
- New product ideas
- Community building
- Information dissemination
- Product improvement
- Competitive intelligence
- Gauge brand sentiment
- Reputation monitoring

What are the challenges?

Electronic media have *unique functionality*

- Hypertext links
- Search engines
  - Keyword searches
  - Heirarchy of search results
  - Paid sponsors
  - Organic search results
  - Metadata
- Pop-up windows; hidden links/functions
- "Watch pages"
- "Sharing" apps
- Mobile access

What are we to do?

We need to base our decisions on many factors:

- What is your risk tolerance?
- What do you want to achieve with internet and/or social media tools?
- Brand focused communications?
- Corporate focused communications?
- Disease only communications?
- Listen to your various audiences?

Practical advice

Ensure that your organization has appropriate processes in place for reviewing all materials from an ad/promo perspective before issuance/going live – including social media and internet based tools

Stick to the fundamentals

- Is content truthful and non-misleading?
- Is there a fair balance between benefit and risk?
- Have you communicated the material facts?
- Have you clearly separated product from disease awareness information?

Source: Glenn Byrd, MedImmune

Social media

Is Big Pharma a Social Media Nin-compoop?

By Peter Pitts

Just back from the ePharma West conference where he delivered a keynote address on the future of social media, Peter Pitts offers these useful observations:

Healthcare social media has precious few rules. But there's only one Golden Rule – *transparency*. 100 percent transparency. 100 percent of the time. You can't airbrush social media.

Social media for regulated industry is a wonderful green field of opportunity. But to maximize the opportunity, we must accommodate the reality of a messier world. Social media, almost by definition, is messy – and the regulatory framework (or lack thereof) is equally so. And it's not likely to get much better. Get used to it.

Embracing social media means embracing regulatory ambiguity. And that's a paradigm shift for an industry that has (in a post-Vioxx world) been going in precisely the opposite direction.
Social media (and its game-changing opportunities) demands a move away from the cautious tactics of the Vioxx Populi towards a better understanding of the digital Vox Populi. And that means more than sponsored Google links and branded Facebook pages with the interactivity turned off.

It means mixing it up with real people in real time. And when it comes to FaceBook, it means – *turn the interactivity on!*

It's not going to be easy, or risk-free, or inexpensive. And whatever social media "marketing models" companies build will have to be elastic – just like the media environment in which they are designed to operate.

Benjamin Franklin once said: "Every problem is an opportunity in disguise." While Facebook strategies and approaches have to be reexamined, Mr. Zukerberg's medical mandate provides pharmaceutical marketers with an excellent opportunity to finally acknowledge and embrace the full capabilities of two-way social communication writ large.

FaceBook's changes represent an opportunity for regulated industry to learn, understand and embrace the three key tenets of Pharmaceutical Marketing 3.0:

1. The Rise of the "Face of Pharma"

For the past 20 years, the overwhelming majority of pharmaceutical marketing budgets were dedicated to promoting specific products. Now, due to both a less robust drug development pipeline and an increase in the rates of patent expiry, the next era of pharma marketing will put the company – and it's corporate reputation – front and center.

When you think about it, its a perfect match for social media where transparency is the most urgent, non-negotiable and magnificent mantra.
Not third party groups, not KOLs (although these traditional avatars have their place) – but the company speaking on behalf of itself and its products. What a concept!

2. The Role of Social Media in the Era of Post-Patent Medicine

I believe that the blockbuster era of the pharmaceutical industry will be replaced by the Era of Post-Patent Medicine. To compete in an era of generics and biosimilars, Pharma companies will need not only a robust portfolio of lower cost medications, but an army of brand loyalists. Communications programs, supported by social media must be one tool. Why? Because it's where the people are.

3. Social Media Can Help Increase Patient Education and Prescription Compliance

You know the numbers. It's estimated that Pharma loses $30 billion a year in patient non-compliance. True two-way social media has the potential to serve as a new and puissant health education platform by helping to keep patients informed of the dangers of non-compliance ***by earning their trust through transparent dialogue.*** And that's twice as true when it's mobile-based.

As another conference presenter, Dr. James Fowler, of the University of California at San Diego opined, "Pharma must realize their own network power."Amen.

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Regulatory compliance

Promotional agencies invest in regulatory compliance to minimize client risk and increase efficiencies

An increasing number of promotional agencies are investing in regulatory compliance testing to minimize risk for their clients and increase efficiencies by shortening review cycles. This trend is best illustrated by the recent announcement of the nation's first patient relationship marketing (PRM) agency credentialed in regulatory compliance for Internet Promotion and Social Media through a new online certificate program taught by former FDA officials. The program was developed by the Center for Communication Compliance (CCC) and co-marketed by the non-profit association WOMMA (Word of Mouth Marketing Association).

Michael Misocky, a former FDA official and CCC Advisory Board member, says the course was developed in anticipation of the FDA's social media guidance and based on existing regulations and recent enforcement actions.

This includes how to use links, answer unsolicited requests, promote within space limitations, and correct online misinformation, in the absence of FDA guidance, as well as regulatory considerations for marketing tools, such as Facebook Share, search engine optimization, and unbranded websites.

According to Misocky, this type of testing and credentialing will likely factor favorably in a federal investigation because it demonstrates a company's good-faith commitment to doing everything possible to maximize compliance.

A recent survey of regulatory professionals quantified the significant drain on the resources of drug and device companies that results from the lack of adequate education among promotional agencies.

- 76% of respondents cited that three or more days per month would be saved if materials were prepared by professionals with a certified understanding of regulatory compliance. This can cost a brand $200,000 or more, say experts.
- 77% of respondents expressed concern that agency programs and materials could be sources of trouble during litigation.
- 91% said they would be reassured if they worked with vendors certified in regulatory compliance.

According to industry veteran, **Wayne Pines**, agencies providing communication services in advertising/promotion, promotional medical education, and public relations are recognizing the importance of demonstrating proficiency of regulatory compliance fundamentals through certification. "Compliance with government regulatory requirements and voluntary codes is both complex and challenging," says Pines, who chairs the CCC Advisory Board. "Testing is essential to ensure that companies understand the rules the government enforces."

Omnicom, Weber: Two largest companies to invest

Siren Interactive is one agency that recently made a financial investment in certification testing to validate the firm's regulatory competence in both digital media and off-line tactics directed to patients. "Our mastery over regulatory compliance requirements is critical to ensure that patients receive fairly balanced, objective information about products and diseases," says Siren President **Wendy White.** "Compliance savvy also helps to reduce unnecessary rewrites because we submit materials that are prepared with the FDA regulations in mind."

Testing and credentialing will likely factor favorably in a federal investigation because it demonstrates a company's good-faith commitment to compliance, says industry veteran, Michael Misocky.

Siren, which is also certified in PRM, joins a select roster of companies that CCC has tested that are dedicated to maintaining high compliance standards. IPG agency Weber Shandwick became the first agency to certify its entire staff in public relations. It is currently certifying its European staff in Spain, Italy, France, Germany and the UK.

International Meetings & Science, a division of WPP, is the first agency to be fully certified in promotional medical education. Recently, Omnicom/DAS announced its commitment as a holding company to train and certify its healthcare agencies in all disciplines through CCC.

"Clients expect agencies to share the responsibility for developing communications with a thorough understanding of the complex regulatory environment around the world," explains **Tom Harrison**, Chairman and CEO of DAS, a division of Omnicom Group Inc. "Our overall aim is to be the first of the holding companies to achieve training and certification for all of our relevant communications agencies. This will demonstrate to our clients, and to the industry at large, that regulatory compliance continues to be one of the highest priorities for our agencies."

"In today's complex regulatory climate, we view this training and competency certification as a critical investment in our clients and staff," said **Laura Schoen**, president of Weber Shandwick's global healthcare practice. "By credentialing our entire U.S. and European healthcare practice, we have taken steps to ensure that all team members are fluent in the most current regulatory policy."

Benefits of testing

According to CCC president and founder, **Ilyssa Levins**, experience shows that when testing is added to a regulatory compliance curriculum, more employees are motivated to access available training. "Testing makes employees more accountable to fulfilling their coursework obligations," she says. It also increases mastery over the information provided in the training, she adds, because it forces the student to pay more attention to the subject matter.

See sample questions, next page.

Levins says that by combining accountability with learning intensity, testing also helps employees become more motivated to learn. "Employees increase the impact of their learning process by reviewing and revising their mistakes," she explains. "This develops the learners' capacity for self-assessment so that they can become reflective, which is a critical step toward behavioral change."

Levins says testing helps determine what employees already know, and to what degree. Supervisors can inform employees about their current progress in order to help each person set goals for improvement. They can also implement spot training where necessary, she adds.

CCC quantifies the scores and number of attempts needed to pass a test for each employee, along with a list of questions the person got wrong, says Levins. If desired, she says, an aggregate report can be provided to indicate questions that were missed across the department or company. This can inform the need for spot training, which CCC can provide through its modular content approach.

Outsourcing increases

Another trend related to promotional agencies and compliance that Levins points to is the increase in private outsourcing training and testing programs. Corporate integrity agreements mandate education of personnel at external promotional agencies working a certain number of hours on the company's business, she points out. However, monitoring those educational requirements can be time consuming given the often large number of agencies contracted to execute drug or device promotion. In some cases, there are several thousand agency employees undergoing education at any one time. Given the high employee turnover rate at many promotional agencies, keeping track of their compliance education status can be labor intensive, draining company resources, says Levins.

Center for Communicatons Compliance President Ilyssa Levins says testing helps determine what employees know already and to what degree.

"It is typically more efficient to outsource the monitoring of agency personnel to determine whether vendors have completed their required regulatory compliance education training," says Levins. CCC's tracking capabilities monitor promotional agency regulatory compliance training participation online, she says. Companies then receive detailed reports for short-term updates and long-term record-keeping in a cost-effective and timely manner, including names of individual staff by brand assignment.

For more information about CCC, contact Ilyssa Levins at ilevins@communicationcompliance.com or 212/361-9868, or visit: www.communicationcompliance.com.

Sample questions:

Below are sample questions from the certificate program for Internet Promotion and Social Media. Ask your promotional agencies-of-record working on your behalf if they know the answers.

Which of the following statements are in accordance with recent FDA enforcement actions regarding online promotion

A. In FDA's view, the fact that there is limited space for risk information in an online promotional context where product claims are made is not an acceptable rationale for omitting risks

B. In FDA's view, if space is limited in an online context, a company should refrain from making a claim about a product and instead use only the product name without any suggestion of an approved use

C. When a company submits Web site content to DDMAC for pre-approval, the click-through content should also be submitted

D. In promotion to the consumer, the company should present the information in consumer-friendly terms

E. All of the above

F. Only B and C are true

G. Only A and D are true

The FDA's Risk Communication draft guidance urges that fair balance be addressed in which of the following ways in social media: (select the best answer)

A. The Package Insert must be scrolled at the start of an online video

B. The Package Insert must be scrolled at the end of an online video

C. The Package Insert must be scrolled at both the start and at the end of an online video

D. The risk information must be integrated along with the benefits throughout the online video

E. All of the above

F. None of the above

Which of the following statements are true about using quality of life claims in online promotion: (select the 2 best answers)

A. If the patient's experience with a quality of life benefit is typical of that drug, the patient can discuss the benefit, but only as long as the benefit reflects his or her personal experience

B. The quality of life claim made by this patient must apply to all patients who take the drug

C. The patient's doctor can make the claim, but patients are not permitted to discuss quality of life benefits

D. A quality of life claim may be used in online promotion only if there are valid studies to support it

E. A quality of life claim may be used in online promotion only if there are at least two studies published in the past 5 years to support it

Which of the following statements constitute good knowledge and advice for a company developing a branded Web site with a chat room for patients: (select the 2 best answers)

A. A company must avoid sponsoring a chat room, as this is strictly prohibited by FDA

B. A company that hosts a patient chat room has regulatory risk, since off-label information might appear and the company could be cited for engaging in off-label promotion

C. A company should regularly monitor every chat room on sites it controls to ensure FDA compliance, as off-label information may appear

D. Off-label information may be discussed by the company in a chat room it hosts, so long as the company does not encourage or advocate off-label use of any of its products

E. A company must regularly report to the FDA all off-label information that appears in all chat rooms on sites it controls or sponsors

F. The FDA requires companies that control chat rooms about specific products to provide a transcript of the chat room to the agency so that the FDA can determine whether off-label uses are being discussed

Compliance training

Overcoming the Pitfalls of Traditional Compliance Training for Sales Professionals

By Wendy Heckelman, PhD and Christina Garofano, PhD

Since 2007, more than 30 bio-pharmaceutical companies have been fined over $13 billion for sales and marketing compliance violations. All of these companies had compliance training programs in place to meet the 2003 OIG Compliance Program Guidance for Pharmaceutical Manufacturers.[1] Yet, these training programs were not sufficient to prevent the violations and fines. *Why?* They didn't focus enough on ensuring that training changed actual behavior in the field.

Most compliance training programs are online modules that provide knowledge of compliance regulations and tell field representatives what *not to do.* This makes them unpopular with the sales organization. This training is also isolated from other from other training and development efforts (like POA meetings or ongoing coaching), so there is no reinforcement of the learning.

In contrast, adult-learning best practices tell us that in order to change behavior, you need behavioral skills training.[2] This means giving the learner examples of what they *should do*, opportunities to practice what they are learning, feedback on how they are doing, and reinforcing them for doing the right thing.[3] Not only does this help the learner remember what they learned, it also supports their ability to apply their knowledge in the real world.

In addition, if you want to change behavior you need to address the strong cultural influences that affect behavior in the organization. Is there an organizational culture of compliance or is there pressure to drive sales results at all costs? Reward and recognition practices can also reinforce the organizational culture of compliance. What explicit and implicit messages are leaders reinforcing with regard to compliance? What are field representatives rewarded for doing?

An analysis of major compliance failures found that the top cause of failures was improper conduct (36%), yet the second leading cause was a systematic culture of pressure and fear (21%).[4] To enable and reinforce behavior change, compliance training should also target the organizational culture of compliance.

Traditional compliance training, with its focus on knowledge of compliance regulations, does not teach behavioral skills. It also does little to change cultural attitudes towards compliance.

To summarize the pitfalls of traditional compliance training:

- It focuses on providing knowledge of compliance regulations and telling sales representatives what not to do.
- It is isolated from other training and development efforts.
- It does not address the organizational culture of compliance.

To overcome these pitfalls and keep your company in compliance, training should be designed to:

1. Focus on changing behavior by teaching behavioral skills. For example, train sales representatives on what they can do to sell in a compliant fashion. This means that compliance training should be as specific as possible to enable field representatives to apply what they learn to real life situations.

2. Provide opportunities for practice, feedback, and reinforcement. This can be done

by combining compliance training with other sales training that normally contains these components, e.g., POA meetings. This provides the added bonus of getting sales and compliance to work together. It also helps change negative perceptions of compliance training. Compliance can be part of the team that helps field representatives perform their role effectively in an increasingly restrictive environment.

3. Link training efforts to ongoing monitoring to sustain learning and reinforce the importance of compliance in the organization. This also helps your company voluntarily comply with the field force monitoring requirements of many recent Corporate Integrity Agreements.

4. Address cultural influences of behavior. For example, to help establish a positive culture of compliance, training should be cascaded to the entire sales organization. It can even be co-facilitated by senior leaders.

About WLH Consulting, Inc
WLH Consulting, Inc. has over 20 years of experience providing custom consulting solutions to bio-pharmaceutical clients. WLH specializes in behavioral-based learning designs that change culture in the organization and conduct in the field.

WLH developed the I GLASS Method™ for defining, training, monitoring, and reporting compliant sales excellence. The I GLASS Method™ contains custom behavioral-based training at the product level to give sales professionals the skills and confidence to drive product growth in a compliant fashion.

Contact Wendy Heckelman at 954-385-0770 or wendy@wlhconsulting.com or visit: www.wlhconsulting.com to learn more and schedule a free demonstration of the I GLASS Method™.

[1] OIG Compliance Program Guidance for Pharmaceutical Manufacturers. HHS – OIG. April 18, 2003. http://www.oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf

[2] Gagne.&Driscoll (1988). Essentials of Learning for Instruction.

[3] Ajzen, I. (1991). The Theory of Planned Behavior; Bandura, A. (1977). Social Learning Theory; Baldwin, T.T. & Ford, J.K. (1988).Transfer of Training.

[4] Compliance and Ethics Leadership Council (2006). Key Findings of Compliance Failure Analysis. Corporate Executive Board. www.celc.exexutiveboard.com

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