VOL. X, ISSUE 15/DECEMBER 2, 2011

RX COMPLIANCE REPORT

EXCLUSIVELY DEVOTED TO PHARMACEUTICAL SALES AND MARKETING COMPLIANCE

Merck agrees to pay $950 million to settle civil and criminal investigations into the marketing and promotion of Vioxx

The Justice Department announced last week that Merck has agreed to pay $950 million to resolve criminal charges and civil claims related to the promotion and marketing of the painkiller Vioxx. Under the terms of the agreement, Merck will plead guilty to violating the Food Drug and Cosmetic Act (FDCA) by misbranding Vioxx and pay a $321 million criminal fine. The company will also enter into a $628 million civil settlement to resolve off-label allegations and charges that it made false statements about Vioxx's cardiovascular safety. The settlement and plea conclude a long-running investigation into the promotion of Vioxx, which was withdrawn from the marketplace in September 2004.

Merck's criminal plea relates to its misbranding of Vioxx by promoting the drug for the treatment of rheumatoid arthritis. The company eventually sought and gained an additional indication for Vioxx for the treatment of rheumatoid arthritis, but did not secure FDA approval for this indication until April of 2002. As a result, the Justice Department charged Merck with promoting Vioxx for rheumatoid arthritis absent any FDA-approved indication for that purpose. Worse yet, DOJ says this took place both before and after Merck received a Warning Letter from the FDA in September 2001 that specifically cited the off-label promotion of Vioxx for rheumatoid arthritis.

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Three former synthes executives sentenced to prison

Three former Synthes executives were each sentenced to prison last week for charges related to illegal clinical trials of a medical device without the authorization of the FDA. Thomas Higgins, who was president of Synthes North America when the clinical trials were conducted, and Michael Huggins, who was president of Synthes Spine Division during that period, were each sentenced to nine months in prison. John Walsh, director of regulatory and clinical affairs, was sentenced to five months.

"This is not a case of an executive who failed to prevent crimes being committed on his watch only because he was so consumed by other responsibilities," the government argued in its pre-sentencing memorandum for Huggins, the highest ranking of the four defendants. "Not only was this defendant aware of the rogue clinical trials, but he authorized and participated in them."

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Merck agrees to pay $950 million to settle civil and criminal investigations into the promotion of Vioxx

Under the terms of its plea agreement, Merck will plead guilty to a misdemeanor for its illegal promotional activity and pay a $321 million criminal fine.

The parallel civil settlement covers a broader range of illegal conduct by Merck. The settlement resolves allegations that Merck representatives made inaccurate, unsupported, or misleading statements about Vioxx's cardiovascular safety in order to increase sales of the drug that resulted in payments by the federal government. It also resolves allegations that Merck made false statements to state Medicaid agencies about the cardiovascular safety of Vioxx, and that those agencies relied on Merck's false claims in making payment decisions about the drug.

Like the criminal plea, the civil settlement also recovers damages for false claims caused by Merck's unlawful promotion of Vioxx for rheumatoid arthritis. Of the total $628 million civil settlement, roughly $426 million will be recovered by the United States, and almost $202 million will be distributed to the participating Medicaid states.

"In 2004, the FBI initiated a seven year investigation that showed Merck's inaccurate, misleading and inconsistent claims regarding the safety of Vioxx was a criminal act which compromised the safety of patients," said Richard DesLauriers, Special Agent in Charge of the FBI in Boston. "Today's criminal plea and nearly billion dollar settlement demonstrates why the Boston Division of the FBI and its law enforcement partners are national leaders in the effort to prevent health care fraud."

The Vioxx approval process

In November of 1998, Merck submitted a new drug application (NDA) for approval of Vioxx to treat osteoarthritis, management of pain, and the treatment of primary dysmenorrheal. The FDA approved Vioxx for those uses in May 1999 and approved a label at the same time.

According to the government, from May of 1999 through April 2002, the unapproved or off-label uses of Vioxx included the treatment of the signs and symptoms of rheumatoid arthritis.

In 1999, Merck initiated a clinical trial, known as Gastrointestinal Outcomes Research (VIGOR), designed to determine whether Vioxx was safer for the gastrointestinal tract than traditional pain relievers. The VIGOR trial was a prospective, randomized, double-blind comparison of 50 mg of Vioxx and 1000 mg of naproxen in over 8,000 patients with rheumatoid arthritis. The findings of the VIGOR study were made public by Merck and provided to the FDA in March 2000.

FDA's Warning Letter

On September 17, 2001, the FDA sent Merck a Warning Letter regarding the company's improper promotional practices in connection with its marketing practices of Vioxx. The Warning Letter stated, among other things, that Merck was promoting Vioxx for unapproved uses, including rheumatoid arthritis.

DOJ says that both before and after the receipt of a Warning Letter in September 2001, Merck sales reps promoted Vioxx for the unapproved treatment of rheumatoid arthritis.

Specifically, the FDA's Warning Letter stated:

> "Your [Merck's] audio conferences are misleading because they promote Vioxx for unapproved uses. For example, in your June 21, 2000, conference, you claim that in your VIGOR study "… the Vioxx 50 milligrams a day and the Naprosyn, a gram a day, were absolutely equally effective in terms of treating the patients with rheumatoid arthritis." Your claim is misleading because it suggests that Vioxx is effective for the treatment of rheumatoid arthritis when this has not been demonstrated."

DOJ cites call notes

DOJ maintains that both before and after receipt of the September 17, 2001, Warning Letter, Merck sales reps promoted Vioxx for the treatment of rheumatoid arthritis without any FDA- approved indication for that purpose. According to the Criminal Information, Merck sales reps recorded numerous instances of this in their call notes, including the following:

- March 20, 2000 – Representative A recorded as an "accomplishment" that he was able to "gain agreement on use of Vioxx for Ra [rheumatoid arthritis]" with Physician 1.

- March 24, 2000 – Representative B noted as a "strategy" with Physician 2 that he would "Continue to push Vioxx past Celebrex. Build on story RA pa[tient] given 12.5 mg Vioxx."

- September 5, 2000 – Representative C noted as a "next call strategy" that she urged that Physician 3 "use [Vioxx] first line in OA and RA pts."

- September 15, 2000 – Representative D noted as an "accomplishment" in his interaction with Physician 4 that he had an "in depth talk on RA and OA and how Vioxx helps during a lunch tutorial."

- October 16, 2000 –Representative E noted as a "strategy" with Physician 5 that he would "reinforce efficacy of Vioxx vs Celebrex for RA and pain."

- June 27, 2001 — Representative F noted as an "accomplishment" that "v[ioxx] is eff[ective] in ra" in conversation with Physician 6.

- June 28, 2001 – Representative G noted as an "accomplishment" that she had "discussed" with Physician 7 "additional uses/benefits of V[ioxx]" which included rheumatoid arthritis.

- September 25, 2001 – Representative H noted as an "accomplishment" in a conversation with Physician 8 that he had "discussed Vioxx excellent efficacy and off-label use in RA."

- November 15, 2001 – Representative I noted as a "strategy" for his interaction with Physician 9 that he would "gain agreement that Vioxx can be used for RA."

The government also charged that from 2000 through September 30, 2004, "Merck promoted the cardiovascular safety of Vioxx with certain statements by representatives and promotional speakers in written materials that were inaccurate, misleading, and inconsistent with the approved labeling for the drug, in violation of the FDCA."

In addition, the government charged that from April 2000 through September 30, 2004, when Merck withdrew Vioxx from the market, "Merck made false representations concerning the safety of Vioxx to state Medicaid agencies on which state Medicaid agencies relied to their detriment in making formulary and prior authorization decisions."

In addition to the off-label promotion of Vioxx, DOJ says Merck made false representations regarding the safety of Vioxx to state Medicaid agencies

The settlement points out that certain states have filed civil actions against Merck that are now consolidated in *In re VIOXX Products Liability Litigation, MDL No. 1657,* a federal multi-district litigation venued in the United States District Court for the Eastern District of Louisiana that allege that Merck caused false claims for Vioxx to be submitted to the Medicaid program. The state civil actions allege other, non-Medicaid claims and are not subject to last week's agreement.

As part of the settlement, Merck also agreed to enter into an expansive corporate integrity agreement that will strengthen the system of reviews and oversight procedures already imposed on the company.

Why no scalps?

A now familiar mantra was adopted by many in the mainstream media that, once again, no individuals were held liable for Merck's conduct. "It's just a cost of doing business until a pharmaceutical executive does a perp walk," Erik Gordon, a pharmaceutical analyst and clinical assistant professor at the Ross School of Business at the University of Michigan. told *The New York Times*..

However, Merck points out that as part of the plea agreement, the government acknowledged that there was no basis for a finding of high-level management participation in the violation. The government also recognized Merck's full cooperation with its investigation.

Moreover, the conduct in question is a decade old, which hardly makes it a ripe candidate for the type of recidivist behavior the government says it is targeting through individual prosecutions. ■

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Three Synthes executives sentenced to prison

A fourth former Synthes executive, Richard Bohner, senior vice president of operations, will be sentenced at a later date, because his attorney fell ill in court. All four previously pleaded guilty to one misdemeanor count of shipping adulterated and misbranded Norian XR in interstate commerce.

Last year, Synthes' subsidiary, Norian, pleaded guilty to a single felony, conspiring to impede FDA functions, along with 110 misdemeanor counts of shipping a mislabeled product. Synthes pleaded guilty to the shipping misdemeanor.

In short, the government argued that the Synthes executives sought to bypass the lengthy FDA approval process for the company's bone cement product by devising a scheme to train select surgeons in the off-label use of the product and then have those findings published.

The individual defendants, by virtue of their respective positions, were "responsible corporate officers" at various times during the events described in the indictment. As a result, all four were prosecuted under the Park Doctrine, which typically involves senior corporate officers being held responsible for things that happened under their watch, but often without their clear knowledge.

In this case, however, the judge determined that the defendants actually planned and executed the scheme in question. In addition to a scathing verbal indictment, he accepted the prosecution's recommendation to go above the zero-to six-month range included in the sentencing guidelines.

A vigorous prosecution

For its part, the prosecution vigorously argued that the four former executives were anything but negligent bystanders. "For his own selfish ends," prosecutors argued in his pre-sentencing memorandum, "Huggins approved and participated in the illegal clinical trials of SRS and XR, with the result that elderly and frail patients who were entitled to the hospital and FDA safeguards that attend a legal clinical trial, did not receive them."

"After the third patient died on the operating table, Huggins could have insisted that Synthes recall the devices, inform the FDA, and tell the surgeons who had attended the 'test market' training the truth," they added, "but he did not."

Huggins had another opportunity "to make a clean breast of it" during an FDA inspection in May through July 2004, say the prosecutors. "But instead he lied to cover up his leading role in the fraud."

Defense counsel point to "progression"

Former DOJ attorney, **Laurence Freedman**, says the government's decision to seek a sentence above the guidelines, and its success in getting the Court to impose it, is very significant. "I expect this will be a common tactic," says Freedman, a partner with Patton Boggs in Washington, D.C.

Former federal prosecutor, **Christopher Hall**, takes a similar view. "We can now see a progression in the government's approach to 'responsible corporate officer' pleas and sentencings," says Hall, a partner with Saul Ewing in Philadelphia.

"We can now see a progression in the government's approach to 'responsible corporate officer' pleas and sentencings," says Saul Ewing's Christopher Hall.

In 2007, he notes, the government agreed to probation for the officers at Purdue Pharma who held a responsible relation to a promotional program that illegally promoted an addictive drug that resulted in patient deaths.

"Now, in 2010 and 2011 in the Synthes/Norian matter, the government refused to give any assurance of probation to officers who had a responsible relation to a promotional program involving a medical device, which the Court found had caused patient deaths," says Hall. This trend toward insisting on jail raises the stakes for all senior drug and device executives, regardless of their personal involvement with a bad result, he says.

Regardless of how one views the government's aggressive use of the responsible corporate officer doctrine, this case underlines the importance of negotiating the sentence (or the parameters for the sentence) as much as possible in advance, says Hall.

According to Hall, the qualifying words "as much as possible" reflect the fact that the government did not give defense counsel many choices in this case, and, even if given the opportunity to revisit the plea/no plea decision, the defendants would likely make the same difficult choice they did.

Calls for probation fall short

Defense counsel for the defendants took somewhat different approaches in arguing for probation rather than incarceration. For example, Adam Hoffinger of Morrison Foerster in Washington, D.C., who represented Higgins, pointed out that incarceration for a misdemeanor conviction of the FDCA under the responsible corporate officer doctrine is very rare. In fact, he said, the only such case is that of Mark Hermelin, the former President and CEO of KV Pharmaceuticals, who received a seventeen-day sentence after he pled guilty as a responsible corporate officer to two misdemeanor counts involving the misbranding of morphine tablets produced by his company.

Hoffinger pointed out, however, that Hermelin was the CEO and Chairman of the Board of Directors of KV and owned or controlled voting rights for significant amounts of KV's stock. Moreover, he said, his company had a history of significant compliance problems during his tenure. For example, in 1995, it had pled guilty to misdemeanor drug misbranding violations and failure to notify the FDA about those problems, precisely the same conduct to which Hermelin and his company pled guilty in 2009.

Craig Margolis of Vinson & Elkins in Washington, D.C., who represented Walsh, noted the case of Hermelin, but also made a First Amendment argument, citing the Supreme Court's recent decision in *Sorrell*. He said that decision provides additional grounds to contest the government's attempt to punish Walsh's approval of the company's Technique Guide and CD-ROM, which included depictions of what he called "a concededly off-label use" of Norian XR. Both represent "quintessential commercial speech" under *Sorrell*, he argued. ■

The complete briefs can be found here:

http://media.philly.com/documents/PreSentMemo-Huggins-11-15-11.pdf

http://media.philly.com/documents/PreSentMemo+-+Higgins+-+11-15-11.pdf

http://media.philly.com/documents/PreSentMemo-Walsh-11-15-11-main.pdf

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Scientific speech and First Amendment at issue in appeal of former InterMune CEO

Another case to watch involving a pharmaceutical executive is the appeal of W. Scott Harkonen, the former president and CEO of InterMune, who stands convicted of wire fraud for issuing a press release announcing that the preliminary results of a clinical study "demonstrated" that the drug Actimmune prolonged survival for patients with interstitial pulmonary fibrosis (IPF), a rare and fatal lung disease.

The indictment charged Harkonen with one count of wire fraud and one count of misbranding. The jury convicted on the wire fraud count and acquitted on the misbranding count. The district court denied Harkonen's motions for judgment of acquittal and a new trial, and sentenced him to probation.

Harkonen's attorneys maintain that in prosecuting this case, the government crossed a line into criminalizing scientific opinions that it never has been permitted to cross. "More than a century ago, the Supreme Court held that the federal fraud statutes do not permit the government to prosecute individuals for expressing scientific opinions about which reasonable minds can differ," attorneys from Sidley Austin argued on Harkonen's behalf in a recent brief to the Court.

PhRMA weighs in

According to an amicus brief developed by attorneys from Arnold & Porter on behalf of PhRMA, the trial court's approach also violated the First Amendment. "A person may not be convicted for fraud based upon speech about scientific matters unless the level of scientific consensus is such that no reasonable expert could find the defendant's statement to be true," argued the trade group.

PhRMA says the trial court's contrary approach risks branding a minority view on any controversial scientific subject as a fraudulent one, thereby chilling scientific speech on uncertain issues and impeding discovery and innovation in the pharmaceutical sector.

In fact, said PhRMA, "the Government's avowed purpose for this case, to send a message that 'will be noted in the executive suites and board rooms of drug companies across the United States,' U.S. Sentencing Mem. at 23 (dkt. 287), only confirms this chilling effect."

Guest commentary

FDA's Recent Proposal to Marry Provider Education under a REMS and CME

By Ellen Y. Chung, Anne R. Mutashi, and Nancy M. Parsons, Associates, Pharmaceutical and Biotechnology Practice Group, Hogan Lovells US LLP

Following years of False Claims Act litigation, OIG guidance, and Congressional scrutiny, the pharmaceutical industry is by now very familiar with the principle that accredited medical education programs must be free from control by commercial interests, both in terms of content and speaker selection. It is also well understood that medical education grants should not be positioned as a promotional tool or tracked in a manner that would permit a return on investment (ROI) analysis for prescriber attendees. A recent twist in this well-ingrained doctrine is the Food and Drug Administration's (FDA's) mandate that pharmaceutical companies with certain products subject to a Risk Evaluation and Mitigation Strategy (REMS) fund, help develop, and track accredited, independent continuing education (CE).

In February 2009, FDA notified all manufacturers of long-acting and extended release opioids that a class REMS will be required to ensure that the benefits of the drug class outweigh the risks. Because healthcare professionals are in the best position to ensure the safe and effective use of long-acting opiods, FDA considered education to be a key REMS component and one that could be provided to healthcare professionals for free by accredited CE providers as an incentive to healthcare professionals, who are accustomed to CE programming, to educate themselves.

Industry mandated education

Under REMS, the agency has previously viewed industry-mandated education for prescribers as promotional labeling because the companies have controlled the content and delivery. Except when attendance is required in order to receive access to a drug, prescriber participation has been tepid, and FDA has struggled with methods to assure that safety messages have been received by prescribers. FDA's new REMS/CE construct is designed to address these issues by offering prescribers CE credit to incentivize their participation and giving the agency more control over the messaging.

At first glance, this would appear to be an unlikely marriage. Under the REMS statute, the drug sponsor proposes REMS content – including provider training programs in some REMS – and then negotiates the final program with the agency. As a consequence, a REMS inherently involves industry's input on the content of prescriber training and often involves documentation of prescriber participation. However, FDA and the Accreditation Council for Continuing Medical Education (ACCME) are currently contemplating a REMS for long-acting and extended release opioids that they believe will sidestep these potential conflicts. Based on prescriber input, FDA is considering a REMS framework that would allow prescribers to receive CME credit for opioid REMS training funded, created in part, and tracked by industry.

"Under REMS, the agency has previously viewed industry-mandated education for prescribers as promotional labeling because the companies have controlled the content and delivery."

Since May 2011, FDA has been in close communications with ACCME to discuss the feasibility of using accredited CE providers to train healthcare professionals under the required REMS. To address the fact that sponsors would be involved, ACCME revised the FAQs to its Standards for Commercial Support in May 2011. Although recognizing that "[t]he opioid REMS juxtaposes pharmaceutical companies, FDA, and accredited CME in a way that has not occurred before," ACCME clarifies that CME activities conducted under the REMS must still comply the Standards for Commercial Support and remain independent and free from the control of commercial interests.

ACCME takes the position that FDA will control content development, using some information provided by manufacturers, and that accredited CE providers will control the specific materials (e.g., slides, webinars) to implement this content. With FDA acting as the gatekeeper for proposed REMS content from industry, ACCME and the agency believe that the standards upholding independence of CE content will not be compromised.

Thus, guided by submissions from industry, FDA developed a draft Blueprint that outlines the core messages that should be conveyed to healthcare professionals and requested comments by December 7, 2011. See 76 Fed. Reg. 68766 (Nov. 7, 2011). After the Blueprint is finalized and approved as part of the class REMS, accredited providers "can develop accredited CE in the manner they choose."

"With FDA acting as the gatekeeper for proposed REMS content from industry, ACCME and the agency believe that the standards upholding independence of CE will not be compromised."

It remains to be seen whether FDA's proffer for a REMS-CME convergence is isolated because of the national platform against drug abuse (e.g., the Prevention Drug Abuse Prevention Plan released by the White House Office of National Drug Control Policy earlier this year calls for major action in continuing education on substance abuse for healthcare professionals) or whether this construct will be challenged on other grounds (e.g., whether FDA can mandate that industry fund CE to promote FDA messaging), but the willingness of ACCME and FDA to find a compromise may indicate a new approach for continuing education. ■

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What's ahead in *Rx Compliance Report*

Here are some of the items that will be featured in upcoming issues of *Rx Compliance Report*:

OIG Enforcement Update

OIG Senior Counsel Mary Riordan provides an update on OIG activity, including the agency's new Work Plan, and offers predictions and recommendations for the year ahead.

FDA DDMAC Update

DDMAC Director Tom Abrams offers updates on guidance, voluntary compliance, and enforcement. Also, Deloitte's Larry Spears weighs in on the mounting regulatory challenges confronting the industry.

Fair Market Value Update

A four-part update on Fair Market Value methodologies to include: International FMV, Growing Trends and Methodology Approaches, FMV and the Emerging Company, and Operationalizing FMV.

What's ahead in *Disclosure Update*

The next issue of *Disclosure Update for Drug and Device Companies* will report on the upcoming Senate Aging Committee hearing on the Sunshine Act, along with these items:

Industry experts weigh in on best practices

Industry professionals weigh in on best practices for aggregate spend from project management to training and branding.

Transparency and Disclosure Reporting Benchmarks: Beyond the Waiting Game

Polaris experts Lauren Mormile and Chuck Bell suggest steps to ramp up for the Sunshine Act regardless of when guidance emerges.

Sunshine Act

CMS sends draft Sunshine Act regulations to OMB

Senate Aging Committee schedules hearing on Sunshine Act implementation

The Centers for Medicare and Medicaid Services (CMS) has sent draft regulations for the Sunshine Act to the Office of Management and Budget (OMB), according to the OMB website. OMB review is required before federal agencies can issue proposed rules, which is why this signaled progress for drug and device companies that have been clamoring for guidance since the statutory deadline for the rule came and went on October 1.

Unfortunately, while OMB registration of the draft regulations is a positive development, it is no guarantee that the end is near. According to former Acting HHS General Counsel, **James Stansel**, it would be a mistake to put too much stock in what OMB's database says about when they received the regulations. The regulations could have been sent over informally before they actually showed up on the website, he points out, although in this case that is unlikely. It is also possible that HHS sent OMB incomplete regulations, he says.

Generally speaking, OMB has 90 days from the date of submission to complete its review, says Stansel, co-head of Sidley Austin's Global Life Sciences Team, but sometimes things move more quickly and sometimes they move more slowly.

Once OMB returns the regulations to HHS, the process could be completed rather quickly, he says. But it if OMB has concerns about the proposed rule, CMS might have to revise the draft regulation. The agency might even have to resubmit it to OMB.

In short, he says, is that while appearance of the regulations on the OMB registration list is a good sign, it does not offer much certainty.

Senate hearing set for December 15

Meanwhile, the Senate Aging Committee announced today that it plans to hold a hearing on December 15 to "examine the need for the timely release of regulations" and the impacts of the delay on the industry and healthcare consumers, as well as future steps for implementing the new law.

CMS Deputy Administrator Peter Budetti will testify along with Allan Coukell, Director of Medical Programs for Pew Charitable Trusts, and David Fisher, Executive Director of the Medical Imaging and Technology Alliance.

CMS will undoubtedly be in the hot seat, because Committee Chairman Herb Kohl (D-WI), who co-authored the Sunshine Act along with Senator Charles Grassley (R-IA), has clearly become exasperated by CMS' failure to directly answer any questions about the status of the regulations.

Daniel Kracov, who chairs Arnold & Porter's FDA and Healthcare Group, says he expects to see very aggressive questioning from both Kohl and Grassley. He also points out that it is not uncommon for agencies to issue a much-awaited proposed rule on the eve of a tough hearing.

The bottom line, says Sidley Austin's James Stansel, is that there is no real guarantee when the industry will finally see Sunshine Act regulations.

Grassley and Kohl started pressing recently-departed CMS Administrator Donald Berwick about the status of the draft regulation almost immediately after the statutory deadline passed on October 1. Worse yet, CMS erroneously informed them that the draft regulations had already been sent to OMB.

Last month, they asked Berwick to explain why CMS missed the statutory deadline and how the agency planned to implement the new law. Berwick responded two weeks late and did not directly address any of the Senators' questions. Instead, he curiously referenced an executive order that permits the agency to take steps to reduce the regulatory burden on companies.

"CMS' rationale is ironic," says **Michael Bell**, president of R-Squared in Princeton, N.J., "because the lack of definitive guidance on these issues creates a far greater burden on the industry, which has been working diligently to implement solutions to comply with this new mandate."

If there is any silver lining to CMS' reply, says Bell, it is that the executive order that Berwick

referred to requires a 60-day comment period, which means the industry will have an opportunity to comment on the regulations. "This also affords affected companies additional time to prepare," he adds.

The flip side, says Bell, is that definitive guidance may not be forthcoming until sometime in early to mid-2012. This raises several questions, he says, including whether CMS will persuade Congress to amend the law and whether it will afford drug and device companies a grace period while the rule is finalized.

Despite his caveats about reading too much into registration of the Sunshine regulations at OMB, Stansel says, it is also possible that CMS will issue an interim final rule within the next few weeks.

A growing chorus

Last month, a group of odd bedfellows ranging from PhRMA and AdvaMed to the Pew Health Group and the Consumer's Union joined forces in urging HHS Secretary Kathleen Sebelius to implement the Sunshine Act as quickly as possible and to ensure that there is ample opportunity for public comment. ■

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Industry veterans join Deloitte

Two highly regarded industry veterans recently joined Deloitte & Touche. Now based in Deloitte's Philadelphia office, **Seth Whitelaw** has more than 20 years of experience in the Life Sciences and Health Care sectors, as well as corporate governance and compliance within medical devices, pharmaceutical sales, and marketing and pharmaceutical R&D.

A licensed attorney, Whitelaw most recently served as the compliance officer for GlaxoSmithKline R&D, and previous to that as legal compliance officer, Pharmaceuticals NA for SmithKline Beecham Pharmaceuticals. He also was a senior attorney and compliance coordinator for C. R. Bard, Inc., where he was responsible for implementing and managing Bard's global compliance program.

Whitelaw will leverage his significant compliance officer experience — especially in R&D — to assist Deloitte life sciences clients in developing effective risk management and compliance programs, and to address compliance elements in corporate integrity or deferred prosecution agreements. He will also assist Deloitte clients with their transparency efforts.

He can be reached at: swhitelaw@deloitte.com

Now based in Deloitte's Washington, D.C., office, **Larry Spears** has more than 30 years of distinguished service at the FDA. He spent the majority of his public career at the FDA's Center for Devices & Radiological Health (CDRH) Office of Compliance, where he served as compliance officer, deputy director/director of the Enforcement Division, and deputy director for Regulatory Affairs.

Spears has extensive knowledge and application of FDA compliance and enforcement programs, policy and strategy; Device Quality Systems Regulations (QSR)/Quality Systems Inspection Techniques (QSIT); medical device reporting; reports of corrections and removals; and medical device import and export regulatory requirements.

Spears will be using his insights and significant FDA experience — particularly in the medical device area — to assist Deloitte clients with developing quality and risk strategies; enhancement of highly regulated processes such as Corrective and Preventive Action (CAPA); complaint handling and medical device reporting; inspection planning and readiness; and remediation in response to enforcement such as 483s, Warning Letters, and Consent Decrees.

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Off-label information

Former FDA official says five "false assumptions" permeate debate over appropriate role of off-label information

Scott Gottlieb, MD, is a practicing physician and Resident Fellow at the American Enterprise Institute in Washington, D.C. who served in various capacities at the FDA, including senior adviser for medical technology, director of medical policy development, and, most recently, deputy commissioner for medical and scientific affairs. He also served as a senior policy adviser at the Centers for Medicare and Medicaid Services. Based on his vast experience as both a practicing physician and a policy maker, Gottlieb says, there are at least five false assumptions that permeate the current debate over the appropriate role of off-label information, especially the type of information that might be contained in a peer reviewed journal article.

First false assumption: All off-label information is somehow bad

The first false assumption that Gottlieb points to is that all off-label information is somehow bad or too preliminary to be incorporated into clinical decision-making. "That's clearly not true," he says. In fact, he says, times have changes since the early days of off-label investigations that uncovered some questionable activities, such as promotion based on marginal evidence. By contrast, he says, more recent investigations have encroached on what, he says, should be considered "very legitimate information around very legitimate uses of drugs."

In this regard, Gottlieb says, the investigation into the alleged off-label promotion of Rituxan represented "a watershed moment" for the industry. In that instance, Genentech was alleged to have distributed information and sponsored medical education around uses of Rituxan in certain forms of advanced lymphoma for which patients had few, if any, very viable alternatives.

Nevertheless, the Justice Department led an investigation into whether it was appropriate for that information to be distributed. "Clearly, in that kind of a setting that kind of information does have a public health benefit," says Gottlieb. "You are dealing with an unmet medical need where there are some rigorous studies that could guide therapy in an area where there otherwise is no available therapy."

The government ultimately dropped the off-label investigation, but it did so only after a lengthy investigation. DOJ's Criminal Division also investigated the matter from 2003, but in 2008 a grand jury concluded without the return of an indictment.

Second false assumption: Drug companies cannot be trusted to distribute off-label information

The second false assumption, says Gottlieb, is that drug companies cannot be trusted to distribute off-label information. The corollary to that assumption, he says, is that companies have nothing of value to say. "In many cases, drug companies understand these drugs better than anyone else," he contends. "After all, it is their product."

The notion that doctors cannot be trusted with off-label information is not only false, says former FDA official, Scott Gottlieb, it is alarming.

Gottlieb points out that pharma represents perhaps the only area of commerce where the provider of the service is restricted from talking to their customers, namely physicians and patients. "We need to ask hard questions about whether or not those restrictions make sense in every case," he argues.

Especially in a setting that involves biologics that are difficult to prescribe, such as Avastin, Rituxan, and Receptin, the ability of companies to interface with prescribers through peer-reviewed literature and other means, can improve public health and help guide the physicians using these products, he maintains. Gottlieb says this is especially true in areas of unmet medical need, where prescribing is often defined by the literature rather than the drug label, which is often out of date.

Third false assumption: Doctors cannot be trusted with off-label information

According to Gottlieb, the third false assumption is that doctors themselves cannot be trusted with this information. He says many of the concerns about the distribution of journal articles and sponsorship of CME more generally are centered around this concern.

Gottlieb maintains that in a situation where a learned intermediary is taking information and incorporating it into "a mosaic of information" about how to treat a patient appropriately, there simply must be a presumption that doctors themselves are not going to be unduly influenced.

Nevertheless, at the core of any argument that this information should not be more readily accessible to physicians is the assumption that they cannot be trusted. That is not only a false assumption, says Gottlieb, it is an alarming assumption that raises a host of serious concerns.

Fourth false assumption: DOJ attorneys are the best arbiters of appropriate medical information

The fourth false assumption, says Gottlieb, is that the arbiters of what information should and should not be distributed – often Justice Department attorneys – are public health minded. In fact, he argues, prosecutorial decisions are rarely guided, first and foremost, by public health considerations.

In reality, he says, prosecutors who bring off-label cases are guided by a number of factors, including how much money they can recoup, the company in question and its past activities, and how easy it may be to bring a case. The public health considerations that go into those decisions are often low on the list, or worse yet, absent altogether, he maintains.

Fifth false assumption: The FDA approval process is efficient

According to Gottlieb, the final false assumption that underlies efforts to restrict the flow of off-label information stems from a fundamental belief that the supplemental and new drug application process is efficient and that prescribing should be defined by what is on the drug label. "This is fundamentally untrue," he says, "especially in areas of fast moving science and unmet medical need, such as cancer. Cancer is always an operative example in this regard, because the literature moves very quickly, says Gottlieb.

For example, he says, the clinical history of Avastin reveals a significant delay between the first availability of clinical data around new uses of that drug and their ultimate approval by the FDA.

In short, the FDA approval process is simply not efficient in many cases, says Gottlieb, adding that there is even a view inside FDA that the label itself does not guide clinical practice, especially in areas such as oncology. The same is true for the medical community, says Gottlieb. "You will often hear that from the oncologists," he says. "They fully recognize that the label sets a certain standard for the marketplace, but not the standard by which medicine should necessarily be practiced." The literature itself is often far ahead of the label, he explains, and by virtue of the way FDA is organized the label itself is often at least a year or two out of date. Typically, he points out, there is at least a six month review cycle that often takes closer to a year.

Prosecutors who bring off-label cases are guided by a number of factors, including how much money they can recoup, says AEI's Scott Gottlieb, but public health is rarely high on the list.

Conclusion

According to Gottlieb, the environment that needs to emerge from all these misconceptions is one that recognizes the public health consequences of both the over-promotion for unapproved uses that are not based on good evidence, as well as counter-productive restrictions that prevent the useful exchange of information.

A balance between these two extremes is possible, Gottlieb concludes, but the ability to distribute information that has gone through a peer review process and has appeared in reputable journals should clearly be the type of information that can be distributed. ■

■ **Scott Gottlieb**, Resident Fellow, American Enterprise Institute, Washington, DC, scott.gottlieb@mssm.edu

Social media

This one goes to 11

By Peter J. Pitts

By now it should be clear to regulated healthcare communicators that delaying robust entry into the world of social media due to lack of FDA guidance is an empty excuse. And, as more and more people turn to social media as their first and primary portal for healthcare information, absence from the playing field isn't only a bad business decision – it's irresponsible.

Regulated healthcare industry must participate in social media – not because of its potency as a marketing vehicle – but because it's the right thing to do. That being said, here are 11 principles that must serve as the basic substrate of regulated social media participation. (Why eleven? Because, in the immortal words of Spinal Tap's lead guitarist, Nigel Tufnel, "It's one louder.")

1. We engage in social media to help improve the lives of patients and advance the public health of our nation.

2. We will thoughtfully engage in social media while remaining in compliance with both the letter and the spirit of FDA regulations.

3. Our social media engagements will have both strong public health themes and appropriate marketing communications.

4. All social media messages and partnerships must be accurate, appropriate and transparent.

5. We believe that social media presents multiple opportunities to learn more about how our products impact the lives of patients.

6. We believe that social media engagement allows us to correct errors and misperceptions about both our company and our products.

7. We believe in using social media discover adverse drug experiences, which will then be addressed off-line.

8. We will strive to interact in a timely manner, appropriate to the general expectations of social media.

9. We believe that social media must be regularly monitored and our programs measured in real time to gauge effectiveness.

10. We respect but are not responsible for user-generated content that resides on sites we do not control.

11. We believe the path to engagement is through useful and thoughtful content and commentary.

"Regulated healthcare industry must participate in social media – not because of its potency as a marketing vehicle – but because it's the right thing to do."

One principle that runs as a red thread throughout all of these 11 principles is transparency. Real, honest transparency – not the usual translucency that "in compliance" often brings.

It's time for action. As Friedrich Engels said, "An ounce of action is worth a ton of theory. ■

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- Social Media Regulatory Issues and Compliance

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