

Rx COMPLIANCE REPORT

EXCLUSIVELY DEVOTED TO PHARMACEUTICAL
SALES AND MARKETING COMPLIANCE

Lilly's \$62 million Zyprexa settlement imposes sweeping new mandates by state Attorneys General

Veteran attorneys say state Attorneys General now filling the void left by FDA

Last week, thirty-three state Attorneys General announced a record \$62 million settlement with Eli Lilly to resolve allegations surrounding the alleged improper marketing of the antipsychotic drug Zyprexa. While the settlement represents the largest ever multi-state consumer protection-based pharmaceutical action, it is widely believed to be merely a run-up to a record-breaking \$1 billion settlement with the federal government to resolve similar issues.

The most significant aspect of last week's settlement has nothing to do with the dollars, according to several experts. Rather, it lies in the numerous prescriptive mandates that dictate how Lilly will market Zyprexa going forward. In fact, experts say the sweeping mandates imposed by the state AGs reach into the bowels of Lilly's business operations in a largely unprecedented fashion. Specifically, the requirements relate to the company's promotional practices, dissemination of medical information, funding of continuing medical education (CME) and grants related to Zyprexa, as well as continued disclosure of Zyprexa clinical trials and their results. ▶ *Cont. on page 2*

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MedPAC drafts broad disclosure requirements as Senate works on revisions to the Sunshine Act

Senators Charles Grassley (R-IA) and Herb Kohl (D-IA) are said to be working on a revised version of the Physician Payments Sunshine Act to be introduced early next year. Meanwhile, the latest draft version of recommendations for a drug and device disclosure law being drafted by the Medicare Payment Advisory Commission (MedPAC) includes a broad range of items that go well beyond payments to physicians. The draft also includes a relatively low \$100 reporting threshold and what a MedPAC analyst described as "a partial preemption requirement." The MedPAC analyst also suggested that "public reporting" of free drug samples should be considered.

It does not take a conspiracy theorist to suggest that these two developments offer a potentially troublesome combination for the drug and device industries. ▶ *Cont. on page 6*

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Lilly's \$62 million Zyprexa settlement imposes sweeping new mandates by state AGs

Because of the vague guidance often provided by the FDA regarding drug marketing, companies will have little choice but to look at this settlement to help steer their activity, says **Meredith Manning**, a partner with Hogan and Hartson in Washington, D.C.

For years, she says, the industry has complained that FDA offers only general principles as guidance, leaving many details vague or unanswered. "Now, the state AGs are essentially filling the void," says Manning, a former FDA attorney and a former Assistant U.S. attorney.

According to Manning, federal settlements typically establish the requisite compliance practices and standard operating procedures companies must employ only in a broad fashion. For example, she says, there is not much in the federal pharma settlements, to date, that dictates how companies should make specific decisions, such as who in the company can respond to unsolicited requests, how much a speaker can earn, and whether they can provide recommendations for speakers for CME events. "All those sticky little details are left to the company under the federal settlements," she says.

The Lilly settlement unveiled last week stands in sharp contrast to that pattern, says Manning. "It is really a very interesting shift away from the feds to the states," she says. "It is fairly stunning."

Veteran attorney **Arnie Friede**, of McDermott Will and Emery's Washington, D.C. office, takes a similar view. "As in the Merck settlement of the Vioxx matter with the State AGs, the Lilly settlement on Zyprexa is further evidence that the State AGs have insinuated themselves as the new cop on the beat in implementing and enforcing requirements that have historically been in FDA's bailiwick." Like Manning, he says the mandates imposed by the settlement are considerable.

Genesis of the case

According to Illinois Attorney General Lisa Madigan, who spearheaded the investigation along with Idaho Attorney General Steve Carter, Lilly aggressively promoted Zyprexa for unapproved uses. "The company's deceptive marketing practices were illegal and highly dangerous, and unfairly targeted

doctors serving extremely vulnerable populations, including children and elderly patients with dementia," Madigan said last week. "This settlement will protect patients by banning marketing campaigns aimed at promoting this drug for unapproved uses and prohibiting false or misleading statements about the drug's benefits."

In a complaint filed along with the settlement agreement, Madigan alleges that Eli Lilly engaged in unfair and deceptive practices when it marketed Zyprexa for off-label uses.

The two-year investigation focused on Lilly's aggressive Zyprexa marketing campaign, which involved allegedly illegal promotions of off-label uses to doctors. Specifically, state AGs allege that as part of its "Viva Zyprexa!" campaign, the company encouraged doctors to prescribe Zyprexa for pediatric uses, for treating symptoms rather than diagnosed conditions, and for elderly patients with dementia.

According to the state AGs, Zyprexa, which the FDA approved for treating schizophrenia and bipolar disorders, causes dangerous side effects, including weight gain, hyperglycemia, diabetes, cardiovascular complications, an increased risk of mortality in elderly patients with dementia and other severe conditions.

According to Hogan & Hartson's Meredith Manning, the settlement will likely have a profound impact not only on Lilly's practices with respect to Zyprexa but those of the entire industry.

Numerous mandates

As a result of the investigation, Lilly has agreed to significantly change how it markets Zyprexa.

The agreement mandates that for a six-year time period, Eli Lilly will:

Promotional activities

- Not make any false, misleading or deceptive claims regarding Zyprexa;
- Not promote Zyprexa using selected symptoms of the FDA-approved diagnoses unless certain disclosures are made regarding the approved diagnoses;

Dissemination of medical information

- Require its medical staff, rather than its marketing staff, to have ultimate responsibility for developing and approving the medical content for all medical letters and medical references regarding Zyprexa, including those that may describe off-label information. This information shall not be distributed unless certain criteria are met;
- Provide specific, accurate, objective and scientifically balanced responses to unsolicited requests for off-label information from a health care provider regarding Zyprexa;
- Require its medical staff to be responsible for the identification, selection, approval and dissemination of article reprints containing more than an incidental reference to off-label information regarding Zyprexa, and that such information not be referred to or used in a promotional manner;

Continuing medical education and grants

- Disclose information about grants, including continued medical education on its Web site (www.lillygrantoffice.com), for at least two years and maintain the information for five years;
- Not use grants to promote Zyprexa, or condition CME funding on Eli Lilly's approval of speakers or program content;
- Contractually require continuing medical education providers to disclose Eli Lilly's financial support of their programs and any financial relationship with faculty and speakers;

Payments to consultants and speakers

- Provide each signatory Attorney General a list of health care provider promotional speakers and consultants who were paid more than \$100 for promotional speaking and/or consulting by Eli Lilly;

Product samples

- Only provide product samples of Zyprexa to a health care provider whose clinical practice is consistent with the product's current labeling; and

Clinical research

- Register clinical trials and submit results as

required by federal law; register Zyprexa Eli-Lilly sponsored Phase II, III and IV clinical trials beginning after July 1, 2005; and post on a publicly accessible Web site all Eli-Lilly sponsored Phase II, III and IV clinical trials completed after July 1, 2004.

Sweeping restrictions

Several industry experts who reviewed the mandates imposed by the settlement say they are fairly sweeping.

For example:

Unsolicited requests. According to Manning, one of the more notable requirements in the settlement deals with responding to unsolicited requests. For example, the settlement requires that if Lilly elects to respond to a request from a physician's office, that response must come from a medical person. "If a sales rep responds orally," she says, "there is a specific paragraph that limits what the rep can say. That is quite granular."

Moreover, the settlement indicates that non-medical personnel may not respond in writing, she points out. That means reps cannot carry scripts or slide presentations approved by the company to respond to a question, she explains.

Reprints. The settlement also includes a section on reprints, which says that reprints containing off-label information may only be disseminated by medical personnel. According to Manning, that goes beyond the FDA's existing policy in this area.

Another former Assistant U.S. Attorney takes a similar view. She says the settlement appears to address reprints in a somewhat "conflicted fashion."

The Lilly settlement on Zyprexa is further evidence that the State AGs have insinuated themselves as the new cop on the beat in implementing and enforcing requirements that have historically been in FDA's bailiwick, says veteran attorney Arnie Friede.

On one hand, the settlement is designed to be consistent with FDA requirements, she says. But it appears to be “much stricter” than the Food and Drug Administration Modernization Act provisions that relate to this area, she adds. The settlement not only bans sales rep involvement in reprint dissemination, she says, but it also requires that any exception must be requested by the president of Eli Lilly, US and that notice be given to the states. “To me, that is very close to a prior restraint of admittedly truthful information,” she says. “If I were a company, I would find that a little troubling.”

Friede agrees it is significant that the state AGs establish a regime for off-label dissemination, which is at variance with what had been permitted by the Washington Legal Foundation (WLF) case. The historic practice for many companies has been to allow sales personnel to disseminate off-label reprints without discussing them, he says.

According to Friede, this settlement effectively says that when anyone other than the medical department sends out a reprint, it is promotional. “That really goes beyond what Judge Lamberth held in the WLF case,” he maintains.

Continuing medical education. According to Friede, the settlement appears to “prejudge” some of the policies about which the American Accreditation Council (ACCME) recently sought comment. For example, the settlement says that Lilly may not suggest topics for CME programs. According to Friede, that was one of the key issues that the North American Association of Medical Education and Communication Companies (NAAMEEC) and other CME provider organizations recently weighed in on as part of ACCME’s call-for-comment. To date, however, the ACCME has not said that companies are prohibited from suggesting topics, he points out.

Friede says the guiding principle in this area is that companies must not bias the content. But he maintains that as long as companies are not telling speakers what to say or how to say it, this should be permitted. “Why should it all be left to guesswork?” he asks.

Worse yet, says Friede, it is not clear that the prohibition on suggestion of topics included in the settlement actually exists. What it says, he explains, is that there is a prohibition on suggesting topics consistent with the ACCME guidelines.

“Conceivably, what that means is that, unless and until, the ACCME adopts that specific pro-

Lilly settlement demonstrates broad scope of state consumer protection statutes, says former federal prosecutor

According to a former Assistant U.S. Attorney, the Lilly settlement is further evidence (as the Cephalon settlement was a week earlier) of an increased prosecutorial focus on publishing and consulting agreements as well as other relationships with health care professionals. “That is going to be the new hot button,” she predicts.

It is also clear that pharma settlements will continue to be “additive” in nature, she says. “The government is going to layer on additional protections that it believes are appropriate.”

The Lilly settlement is noteworthy for several other reasons, she says. Unlike most pharma settlements, she points out, it is a separate settlement of consumer protection issues. As a result, it is “very limited in what it does and does not do,” she says. For example, it does not address any liability Lilly might have for either the state portion of Medicaid violations in areas such as off-label marketing or other claims typically found in this type of settlement.

“Typically, the federal government leads the investigation and settlement process,” she adds. “In this case, the consumer protection piece was settled first, which likely portends more aggressive involvement by the states.”

Like several other experts who reviewed the settlement, the former prosecutor says the most notable feature is the level of specificity regarding what Lilly can and cannot do with respect to sales and marketing and medical information. “The specificity of the conduct that is prohibited and the involvement in the actual internal processes of how Lilly conducts its business is unprecedented,” she says.

The reason, she says, is that no comparable federal statute would allow the government to “reach into the actual operations of a corporation” regarding its internal practices. “No federal consumer protection statute is this broad,” she explains. “The states have more power because of their statutory schemes, which permit this type of activity.”

hibition it is not part of the settlement agreement,” says Friede. “But that is very ambiguous.”

Conversely, while the ACCME proposed an outright ban on commercial support, the state AGs did not include such a ban in the settlement. “They are saying you can support CME providing you do it in a certain way,” he explains.

Here too, the state AGs appear to be “prejudging” the ACCME, says Friede. “If the state AGs thought that commercially-supported CME was inherently biased, why didn’t they force Lilly to give it up entirely?” he asks.

The former federal prosecutor agrees that the CME provisions included in the settlement appear to be somewhat inconsistent with general practice in this area. “The settlement is supposed to be consistent with ACCME guidelines,” she says. “But ACCME’s guidelines, even as amended, do not prohibit companies from suggesting topics or speakers from an accredited provider.”

Off-label information. Apart from the apparent inconsistencies, the settlement presents even more fundamental problems, says the former federal prosecutor. CME programs, by their nature, are supposed to include the newest information, she points out. Because it is new information, a lot of the information that will actually be of interest will be off-label, she explains. However, Lilly’s agreement would not permit it to use a provider if they are “promoting” off-label, she says. Moreover, she adds, the definition of promotion is very broad.

“This would appear to not allow the company to support a speaker talking about interesting new clinical results no matter how scientifically valid they may be,” she says.

It also appears to prohibit meta-analyses, which has limitations, but is clearly a part of scientific discourse, she argues. “That is potentially problematic from the perspective of having useful valid information provided to the clinical community.”

Samples. The settlement makes it clear that state AGs believe companies often use sampling as a way of promoting drugs for off-label uses, says Friede. “For example, if a drug is not approved for use in children, what explanation other than off-label promotion is there, they argue, for distributing samples to pediatricians.”

According to Friede, the state AGs have effectively created a *per se* rule that prohibits

sampling to physicians whose practices do not fall within the scope of the product’s intended uses. “Whether this is the beginning of a more general wholesale attack on sampling is not entirely clear,” he says, “but the practice has been criticized on numerous other grounds.”

Participating states

The thirty-two states participating in the agreement are Alabama, Arizona, California, Delaware, Florida, Hawaii, Illinois, Indiana, Iowa, Kansas, Maine, Maryland, Massachusetts, Michigan, Missouri, Nebraska, Nevada, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Vermont, Washington and Wisconsin, as well as the District of Columbia.

The company previously disclosed these state investigations, which were brought under those states’ various consumer protection laws, in May 2007, in a quarterly filing with the U.S. Securities and Exchange Commission.

Eleven other states (Louisiana, Mississippi, Montana, New Mexico, Pennsylvania, South Carolina, Utah, West Virginia, Connecticut, Arkansas and Idaho) have filed lawsuits over Zyprexa and are not covered by this agreement.

In March, Lilly entered into a \$15 million settlement with the State of Alaska, which concluded an ongoing trial involving various issues surrounding Zyprexa. In addition, since 2005, Lilly has settled approximately 31,000 individual product liability lawsuits alleging that certain adverse events are associated with Zyprexa. ■

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According to Friede, the state AGs have effectively created a per se rule that prohibits sampling to physicians whose practices do not fall within the scope of the product’s intended uses.

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MedPAC drafts broad disclosure requirements as Senate works on Sunshine Act revisions

Congressional staff have already made it abundantly clear to pharma that it faces a tough fight when Congress returns next year when the Democrats enjoy what are widely expected to be wider margins in both the House and Senate.

In any case, if the industry's critics are looking to propose a tough disclosure law, the chances are they will find it in the final recommendations tabled by MedPAC, an influential Congressional advisory committee.

MedPAC commissioners will vote on the draft proposal early next month, well ahead of the Congressional debate expected to take place some time next year.

Last week, MedPAC analyst Ariel Winter presented the Commission with draft recommendations for a public disclosure law based on MedPAC's June report and the discussion that ensued at last month's meeting (see *Rx Compliance Report, October 2, 2008*). While there are potential pros and cons to such a law, Winter told the commissioners, "there is a growing consensus that the benefits of a national reporting system outweigh the disadvantages."

A sweeping proposal

Winter proposed that the national reporting system should apply to "a broad set of manufacturers and recipients of payment." Drug and device companies would have to report their financial relationships regardless of the company's size, he said. Subsidiaries should be included, he added, to prevent companies from paying physicians through a subsidiary to evade reporting requirements.

DRAFT MEDPAC RECOMMENDATION:

Congress should require all manufacturers of drugs, biologicals, medical devices, and medical supplies, and their subsidiaries, to report to the Secretary their financial relationships with physicians and other prescribers, hospitals, medical schools, organizations that sponsor continuing medical education, patient organizations, and professional organizations.

While discussion of disclosure took place under the rubric of disclosure of payments to physicians, Winter proposed disclosure of payments to a broad group of recipients including hospitals, professional organizations, and continuing medical education providers.

He suggested that disclosure should include the following:

- Physicians and other prescribers such as physicians assistants and nurse practitioners;
- Hospitals and medical schools (because academic medical centers receive significant industry support for research and education);
- Professional organizations and patient advocacy groups (because they frequently receive grants from manufacturers for research, fellowships, and public education);
- Organizations that sponsor continuing medical education.

MedPAC analyst Ariel Winter proposed disclosure of payments to a broad group of recipients including hospitals, professional organizations, and continuing medical education providers.

Continuing medical education

Winter noted the concerns expressed by some commissioners during the September meeting about including continuing medical education (CME). However, he said it was retained because commercial support accounts for an increasingly large share of the total CME dollars, roughly one-half in 2006. "There are concerns that the support may result in a disproportionate focus by CME programs on drugs and devices," he said.

Winter noted that accredited CME organizations are required to disclose industry support to participants in their programs. However, this information is not available to the general public, he pointed out. "Including these organizations in a

public reporting system would enable researchers and others to track industry support of CME,” he suggested.

Cost implications “uncertain”

According to Winter, there will be some administrative costs for the government to implement and enforce a reporting law. However, it is difficult to estimate these costs precisely. Likewise, the Medicare spending implications are indeterminate, he added.

Winter told the commissioners the current

MedPAC’s Winter proposed “a partial preemption provision,” which is likely to face opposition from the industry.

proposal would have no impact on beneficiaries and providers, although physicians with large financial arrangements may be scrutinized. Hospitals, medical centers and health plans should benefit from information on physicians’ financial ties, he said.

Moreover, if a federal system replaces multiple state laws, this should reduce manufacturers’ compliance costs, he maintained.

A \$100 threshold

Winter proposed that manufacturers report payments if the total annual value of payments to a recipient exceed \$100 (annually adjusted for inflation). Once this threshold is reached, all payments or transfers of value to a recipient would have to be disclosed, he said. “We think this strikes a balance between reducing the reporting burden and maximizing public transparency,” Winter said.

A “comprehensive” list of relationships

Winter proposed “a comprehensive list” of relationships that would be covered by the new law, including the following:

- Gifts
- Food
- Entertainment
- Honoraria
- Research
- Funding for education and conferences
- Consulting fees
- Investment interests
- Product royalties

MedPAC’s Draft Recommendations: Public Reporting of Physicians’ Financial Relationships

Advantages of national database on physician-industry relationships

- Could discourage inappropriate financial arrangements
- Media/researchers could shed light on relationships
- Payers and plans could examine whether industry ties affect physicians’ practice patterns
- Academic medical centers could verify financial interests of researchers
- Hospitals could check whether physicians involved in purchasing decisions have financial ties

Costs and limitations of national database on physician-industry relationships

- Compliance costs for manufacturers
- Administrative costs for government
- Might discourage beneficial arrangements
- Would not eliminate conflicts of interest
- Information may be of limited use to patients

Reporting system would apply to broad set of manufacturers and recipients

- Manufacturers of drugs, biologicals, devices, and supplies:
- Include small and large companies
- Include subsidiaries

Recipients of payments:

- Physicians and other prescribers
- Hospitals and medical schools
- Professional and patient advocacy organizations
- Organizations that sponsor CME

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“We propose that the companies should report the value, type, and date of each payment and the name, specialty, Medical billing number, if applicable, and address of each recipient,” he added. “The billing number is important for linking the payment information to claims data.”

Discounts and rebates excluded

According to Winter, discounts and rebates were excluded from this list because this information is considered “very proprietary” and public reporting of this information could make it difficult for purchasers to negotiate price reductions.

Samples remain contentious issue

Free drug samples for patients were also excluded based on the commissioners’ comments at the last meeting, said Winter. However, he noted that while

MedPAC’s Winter said the government should have the authority to assess civil penalties on manufacturers for non-compliance.

federal law requires companies to internally track the drug samples they distribute, including details about the drugs and recipients, this information is not reported to the government. “One idea to think about is whether this information should be publicly reported so that researchers could

examine the impact of samples on prescribing patterns and overall drug costs,” he told the Commission.

New product development

According to Winter, MedPAC is seeking to strike a balance for the reporting of payments related to new product development by proposing that companies be allowed to delay reporting of payments related to clinical trials until the trial is registered on the NIH website. Registration of the clinical trials is currently required for Phase II and Phase III trials, he noted. “We are trying to balance a trade-off between allowing manufacturers to protect sensitive information and the goal of the public transparency,” he explained.

Winter also proposed that companies be permitted to delay reporting of other payments related to development of a new product until the

Threshold for payments that should be reported:

- Manufacturers should report payments if total annual value of payments to a recipient exceeds \$100
- Adjust threshold annual based on inflation

Types of relationships to report

- Gifts, food, entertainment, *honoraria*, research, funding for education and conferences, consulting fees, investment interests, product royalties
- Exclude discounts, rebates, free samples for patient use
- Companies should report:
 - Value, type, date of each payment
 - Name, specialty, Medicare billing number (if applicable), and address of each recipient

Guidelines for reporting payments related to new product development

- Trade-off between protective sensitive information and public transparency
- May delay reporting of payments related to clinical trials until trial is registered on NIH website
- May delay reporting of other payments related to development of new product until FDA approval, but no later than 2 years after payment made

Federal reporting law should preempt equally or less stringent state laws

- Strike balance between state autonomy and advantages of national system
- Preempt state laws that collect data on same types of financial relationships and recipients as federal law

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product is approved by the FDA but no later than two years after a payment is made. “This would ensure that payments related to their products that are never approved by the FDA are eventually disclosed,” he explained.

“A partial preemption requirement”

Winter proposed that a Federal reporting law should preempt equal or less stringent state laws. In this regard, he said, MedPAC is trying to strike a balance between state autonomy and the advantages of a national uniform system. Under this scenario, he said, state laws that collect data on the same types of financial relationships and recipients as the federal law would be preempted. However, states would be allowed to collect information on other categories of payments and recipients such as samples.

In response to questions from the Commission, he described this more accurately as “a partial preemption requirement.”

Civil penalties proposed

According to Winter, the government should have the authority to assess civil penalties on manufacturers for non-compliance. “The law should require manufacturers to investigate and correct any errors in a timely way that are reported to them by recipients,” he said. The information should be reported annually, he added.

In addition, companies should be allowed to report additional clarifying information about a payment, said Winter. For example, he said, they may wish to explain that a payment was made for training other physicians in the proper use of an implantable device.

Implementation issues

Winter suggested that Congress should allow the Secretary of HHS to choose which agency should administer a reporting law. The possibilities, he said, are the FDA (because it regulates drugs and devices), CMS (because it pays for a significant number of drugs and devices), or the OIG (because it has the responsibility for investigating financial relationships that may violate the anti-kickback statute).

“The administrative costs of implementing a reporting system are unclear,” said Winter. according to Minnesota, the cost of collecting and posting data on a website is minimal, he reported. But Minnesota’s program does not yet have a searchable electronic database, which might increase

Other design issues

- Authority to assess civil penalties on manufacturers for non-compliance
- Require manufacturers to investigate and correct reported errors in timely fashion
- Information should be reported annually
- Allow companies to report clarifying information about payments

Implementation issues

- Allow Secretary to choose which agency to administer (options include FDA, CMS, OIG)
- Administrative costs unclear:
- According to Minnesota, cost of collecting and posting information is minimal (but no searchable electronic database)
- No data on enforcement costs
- Ask Congress to provide sufficient resources to Secretary

Source: MedPAC

the cost, he pointed out. MedPAC also lacks data on costs incurred by states to monitor and enforce compliance. In any case, he said, MedPAC should ask Congress to provide “sufficient resources” to the Secretary to administer a reporting law.

Finally, Winter said that Congress should direct the Secretary to post the information submitted by manufacturers on a public website in a format that is searchable by manufacturer; recipients’ name, Medicare billing number, if applicable, location and specialty, type of payments, and year. “The goal here is to maximize the accessibility and usability of information in the reporting system,” he explained.

In terms of spending, there would be some administrative costs for the government, he added, but the Medicare spending implications are “indeterminate.” ■

FINAL MEDPAC MEETING: NOVEMBER 6-7 IN WASHINGTON, DC

MedPAC’s final meeting will be held November 6-7, in Washington, D.C. Comments may be submitted, in advance of the meeting, to: awinter@medpac.gov

Off-label promotion

District Court rejects First Amendment argument in off-label promotion case

Late last month, a federal judge in the Eastern District of New York rejected an argument that the misbranding provisions of the Federal Food, Drug, and Cosmetic Act (FDCA), as applied to off-label promotion, violate the Free Speech Clause of the First Amendment. “While the court left open other possible statutory and factual arguments, this decision will be viewed by the government as further endorsement of the questionable ‘adequate directions for use’ misbranding theory,” says **Coleen Klasmeier**, a partner in Sidley Austin’s Washington, D.C. office. She says the case – United States v. Caronia – should serve as a caution to companies and individuals alike as they assess their promotion practices in the context of the First Amendment.

Genesis of the decision

Caronia was a pharmaceutical sales representative employed by Orphan Medical, now known as Jazz Pharmaceuticals. In July 2007, Jazz pleaded guilty to felony misbranding in connection with the off-label promotion of the drug Xyrem and agreed to pay more than \$20 million in fines. Meanwhile, the government continued to press criminal charges against individuals. Caronia was charged with promoting Xyrem for off-label uses to a physician and with introducing that physician to Peter Gleason, another physician allegedly paid by Orphan to promote Xyrem for off-label uses, notes Klasmeier. On August 8, 2008, Gleason pleaded guilty to a misdemeanor misbranding violation under the FDCA.

The Court’s decision

In refusing to dismiss the criminal charges against Caronia, says Klasmeier, the district court rejected the defendant’s First Amendment argument, employing the four-part commercial speech analysis set forth in Central Hudson v. Public Service Commission of New York. Relying on the Washington Legal Foundation (WLF) line of cases and United States v. Caputo, she says, the court concluded that: 1) the off-label speech at issue concerns lawful activity and is not inherently misleading; 2) the government has a substantial

interest in restricting off-label promotion by manufacturers; and 3) restricting off-label promotion by manufacturers directly advances a substantial government interest.

An important but limited decision

According to **Paul Kalb**, who heads Sidley Austin’s national health care practice, Coronia is an important, but limited decision for several reasons. First, he points out, it came in the context of a motion to dismiss an indictment, which is a very unfavorable context for defendants.

Second, he says, while the decision upholds the right of the government to regulate speech by sales reps, it does not address, much less fundamentally disagree with, the approach taken by the court in WLF vis-a-vis other forms of communication about off-label information by manufacturers such as the dissemination of reprints. “Indeed,” he says, “the court very much leaves open the argument that government regulation of other forms of manufacturer communication may be protected by the First Amendment because there are less restrictive means, such as counter-speech, for the government to advance its legitimate goals.”

Finally, Kalb argues that the court’s statutory analysis is flawed because “it leapt much too quickly to the conclusion that there cannot be ‘adequate directions’ for an off-label use.”

“That is not what the statute says,” he argues. “The question of ‘adequacy’ is not a legal one but rather a factual one.”

Given that Coronia is in the early stages of a criminal proceeding, says Klasmeier, some of the issues in the district court’s opinion could be addressed more fully at trial or on appeal. “As it stands, Coronia could make it more difficult for drug and device manufacturers to prevail on a First Amendment defense in off-label cases,” she concludes. ■

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Featured resource: DTC advertising

Leading House Democrat threatens business-tax deduction for DTC spending

Rep. Rahm Emanuel (D-IL) recently warned advertising industry leaders that the business-tax deduction for DTC spending could be taken away in 2009 tax legislation, reports *DTC Insights*.

Here is an excerpt of an October 2 item from DTC Insights:

Rep. Emanuel's comments are seen as an important indicator of how a Democratic-controlled House could step up the pressure on DTC under a new administration in 2009.

In a September meeting with the Government Affairs Committee of the American Association of Advertising Agencies, Rep. Emanuel was said to present two options for the pharmaceutical industry in new tax legislation: retain the tax credit for research and development spending, or keep the business expense deduction for DTC advertising – but not both. “He said this without any tinge of satire, so you have to accept him at his word,” said one advertising industry advocate familiar with the meeting. (Note that an average pharmaceutical company spends roughly 10 times more on R&D efforts every year than is actually spent on consumer promotion.)

Pharmacy

Walgreen & Company pays \$10 million to settle novel Medicaid fraud suit

Earlier this month, Walgreen & Co. agreed to pay the United States and four states nearly \$10 million to resolve allegations of falsely billing Medicaid, the U.S. Justice Department announced. This is the third time that Walgreens is paying a multi-million dollar settlement to settle Medicaid fraud allegations. However, the case involves a novel fraud theory involving dual-eligible Medicaid patients.

The United States initiated the investigation in response to a lawsuit brought by pharmacists Daniel Bieurance and Neil Thompson. According to their False Claims Act lawsuits, the two Walgreen pharmacists brought evidence to the government that in 1999, Walgreen's started a billing system for its pharmacies that was designed to defraud

Rep. Emanuel sits on the House's Ways and Means Committee, which controls and writes all tax legislation, and he also chairs the House's Democratic caucus.

The idea of “taxing” DTC advertising has been around for many years, most notably in a bill sponsored in each Congress by Rep. Pete Stark (D-Calif.), the second ranking Democrat on the Ways and Means Committee and chairman of its health subcommittee. Stark's proposal has not gained traction in the past.

If the Ways and Means Committee were to move toward a change in the tax status of DTC, the industry would argue that such a move is unconstitutional. “The motivation, it can be clearly argued, is not sound tax policy, but the motivation is to suppress speech,” said Jim Davidson, a Washington-based attorney with the firm Polsinelli. “When you use the tax code to suppress speech that is a violation of the First Amendment.” ■

For more information about DTC Perspectives, including its upcoming annual meeting in Livingston, N.J. October 29-30, visit: www.dtcperspectives.com

Medicaid on prescription charges. This was allegedly done in relation to dual-eligible customers — those legitimately on Medicaid who also maintained their private health insurance coverage. The insurance coverages required Walgreen to charge the insurance company a smaller amount for prescriptions, and a limited co-pay from the customer. When a person is allowed Medicaid coverage, the government always obtains an assignment of the person's rights under their private health insurance coverage. The government essentially takes over the citizen's rights under the coverage. This includes the common right to pay a smaller amount for co-pay on prescriptions.

The \$9.9 Million settlement reached covers over-billings by Walgreen in the states of Minnesota, Massachusetts, Michigan and Florida. ■

Less than two weeks away!

The Ninth Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum

October 27-29, 2008 • Washington, DC
www.pharmacongress.com

Here are the breakout sessions for the upcoming Pharmaceutical Regulatory and Best Practices Forum, the premiere pharma compliance conference, which takes place in less than two weeks in Washington, D.C.

To view the complete agenda, including the preconference program and plenary sessions, visit www.pharmacongress.com.

Tuesday, October 28, 2008

MORNING TRACK SESSIONS:

Morning Track I: Sales and Marketing Compliance Update

9:30 a.m.

Sales & Marketing Compliance Lessons from Recent Developments: Recent settlements, CIAs; Compliance Challenges in Implementing the Revised PhRMA Code; FDA Draft Guidance on Off-Label Dissemination; AAAMC Report on Industry Funding of Medical Education; Access Issues and Industry Responses; and Sunshine Act and State Transparency Laws

10:30 a.m.

State Laws: Assessing Challenges, What's Ahead: State Reporting Implementation Challenges - Dealing with Incomplete Data; Specific Challenges Requiring Legal Interpretation; Tracking Total Spend; Effectiveness of State Reporting Requirements in Changing Company Practices; and Future Areas of State Focus

Morning Track II: Research, Development and Clinical Trials Compliance Update

9:30 a.m.

Current Compliance Challenges

10:00 a.m.

Assessing Future Regulatory and Compliance Developments: Complying Clinical Trial Reporting Obligations

10:30 a.m.

GAP Analysis: How we Get to Where we Want to be—Managing GCP Inspections Pre-Approval

11:00 a.m.

The Intersection of the False Claims Act and FDA's Authority over Clinical Trials

11:30 a.m.

FDA and Duke University's Clinical Trials Initiative

Morning Track III: The "411" on Government Price Reporting: What Every Compliance Professional Needs to Know

9:30 a.m.

Current Compliance Challenges - Developing a Robust Compliance Framework for Price Reporting Using the OIG's Seven Elements

10:00 a.m.

Assessing Future Regulatory and Compliance Developments—An Assessment of the Current Landscape and Future Legislative Changes Medicaid, Medicare, and VA Price Reporting Obligations

11:00 a.m.

A Primer on Service Fee Payments and Fair Market Value for Government Price Reporting

Cont. on next page

11:30 a.m.
Practical Case Study: A Compliance Professional's Playbook on Conducting a Pricing Assessment

Morning Track IV: Relationships with Healthcare Professionals Compliance Update

9:30 a.m.
Emerging (Regulatory and Prosecutorial) Focus on Physicians

10:15 a.m.
Orthopedics Panel: Learning from the Implementation to Comply with Settlement Requirements

11:00 a.m.
Facilitated Dialogue: Managing and Preparing for More Change: A Survey/ Interactive Discussion on Gaps and Best Practices Regarding: Fair Market Value; CEO/Other Certification; Training: Reps, Speakers, Others; and Monitoring

Morning Track V: Emerging Compliance Challenges

9:30 a.m.
Executive Liability: Beyond the Park Doctrine

10:10 a.m.
Relationships between Pharmaceutical Companies and Research Publications

10:45 a.m.
Maintaining Compliance in a Changing World

11:15 a.m.
The Implementation of Fair Market Value: What Can We Learn From Recent Enforcement Actions?

Morning Track VI: Interactive International Case Studies Covering a Range of Topics to Include: Distribution Channel Challenges; Third Party Oversight (Including Use of HCPs as Third Parties, and Anti-bribery and Anti-corruption Considerations); Organization of International Congresses and Conferences for

HCP Attendance; and Management of Allegations and Investigations

AFTERNOON TRACK SESSIONS:

Track I: Pharmacovigilance and Drug Safety Compliance Update

1:15 p.m.
Current Compliance Challenges

1:45 p.m.
Assessing Future Regulatory and Compliance Developments

2:15 p.m.
GAP Analysis: How we Get to Where we Want to Be

2:45 p.m.
REMS

3:15 p.m.
Sentinel Program

Afternoon Track II: Working with Third Parties, Vendors and Strategic Partners

1:15 p.m.
Current Compliance Challenges Involved in Working With Third Parties - What Things Should We Worry About?

1:45 p.m.
Due Diligence Monitoring and Auditing of Third Party Vendors

2:45 p.m.
Robust Agreements and Vendor Training: When, Where and How

Afternoon Track III: Creating an Environment for Productive Post-Settlement Interactions with the Government: CIAs, DOJ Monitors and Disclosures

1:15 p.m.
The Government Perspective

2:30 p.m.
The Industry Perspective

Cont. on back page

Afternoon Track IV: FCPA Compliance Update

1:15 p.m.

Overview of the FCPA: Scope, Key Definitions, Exceptions and Affirmative Defenses, Books and Record Keeping Requirements, and Interaction with Anti-bribery Laws in Other Countries

1:45 p.m.

Current Trends in Enforcement/Recent Cases: Industry Sweeps, Including Pharma and Medical Device Industries, Increased Extra-territorial Reach, Increased Collaboration Between DOJ and SEC, Imposition of Independent Monitors, Increased Focus on Fines, etc. for Individuals, not Just Companies, Discussion of Recent Enforcement Actions - Pleas, Sanctions Imposed, etc.

2:15 p.m.

Implementing an Effective Anti-Corruption Compliance Program - Lessons Learned

2:45 p.m.

Issues in Conducting FCPA Investigations Outside the US and How to Deal with Them: Data Protection/Privacy Laws in Non-US Jurisdictions; Privilege Issues in Multi-national Investigations, Collecting, Reviewing and Retrieving Electronic and Hard-copy Documents; Issues in Interviewing Witnesses Outside the US, and Dealing with the DOJ and SEC while Conducting an Investigation

3:15 p.m.

The Importance of FCPA Due Diligence in International Mergers, Acquisitions and Joint Venture

Afternoon Track V: Interactive Domestic Case Studies Covering a Range of Sales & Marketing "Hot" Topics such as: Speaker Management Issues; In-Office Interactions; Conflicts of Interest with Customers; Firewall Issues Related to Marketing/Medical Vendors; and PhRMA Code Issues Pre-and Post-implementation.



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