FDA Regulatory and Compliance Monthly Recap

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KEY FINDINGS

Pacira secures expanded marketing for painkiller medication as FDA agrees to settle lawsuit, revoke warning letter

The pharmaceutical industry won in its latest bid for more leeway to promote drugs for unapproved uses, as the Food and Drug Administration agreed to allow Pacira expanded marketing for its painkiller drug. The FDA settled a suit in which Pacira alleged the agency had overstepped its bounds by preventing some off-label marketing.

The FDA and Pacira came to terms in a battle over the regulatory agency's authority to stymie Pacira's right to market the painkiller Exparel — the latest in a round of industry complaints that the agency oversteps its limits when preventing drugs from being promoted for unapproved uses. The suit, which was filed in the U.S. District Court for the Southern District of New York, follows a successful suit brought against the agency by Amarin for the right to promote its Vascepa product for some off-label uses.

As part of the settlement, the agency decided to revoke its September 2014 warning letter alleging that Pacira promoted the drug for unapproved uses and overstated its effectiveness. The agency previously removed the letter from its website after it began discussing possible resolutions with Pacira.

The regulatory authority also agreed to allow Pacira to promote Exparel for use after an expanded number of surgeries, instead of exclusively after the removal of bunions and hemorrhoids. The drugmaker is also allowed to tell clinicians that the drug can relieve pain for up to 72 hours, extending the 24-hour limit the FDA imposed on the drug when it was approved in 2011.

While Pacira chalked up the decision to the FDA's realization that "an unfortunate mistake had been made," the FDA said the revised label was based on scientific research previously submitted as part of the original

marketing application. This was a marked difference from the language the agency used in the warning letter, in which it said the violations were "extremely concerning from a public health perspective."

Pacira had also accused the FDA of infringing its free speech rights — a hotly debated issue since 2012, when a federal appeals court overturned a criminal conviction of a sales rep for promoting off-label sales on the basis that his speech was protected since the information conveyed was truthful and nonmisleading. Pacira reportedly didn't need to push the free speech issue since the FDA agreed to revise the label, permitting more widespread marketing. Several pharmaceutical industry groups, including the Medical Information Working Group and PhRMA, supported Pacira.

At this time, it's not clear whether the Department of Justice is still probing Exparel marketing. The agency subpoenaed Pacira in April requesting documents, but declined to comment following the FDA settlement.

DOJ recoveries reach $3.5 billion in FY2015 as qui tam lawsuits continue to grow

For the fourth year in a row, the Department of Justice achieved more than $3.5 billion in settlements and judgments related to fraud and false claims, bringing the total secured from the False Claims Act to $26.4 billion since 2009. The pharmaceutical industry continues to contribute to DOJ recoveries, particularly due to kickback allegations.

In fiscal year 2015, the Department of Justice brought in more than $3.5 billion in settlements and judgments from civil cases related to fraud and false claims — marking the fourth consecutive year the department surpassed $3.5 billion in cases under the False Claims Act. Since January 2009, the DOJ has secured $26.4 billion from the FCA, which Principal Deputy Assistant Attorney General Benjamin C. Mizer, head of the Justice Department's Civil Division, calls the government's "most effective civil tool" to uncover fraud.

The health care industry, particularly the pharmaceutical segment, was a big contributor to this year's total. The health care industry contributed $1.9 billion to the total, reflecting federal losses only. Since January 2009, the DOJ has recovered $16.5 billion in health care fraud, representing more than half the amount recovered since the 1986 amendments to the FCA. The DOJ attributed the successful recoveries to the Obama administration's emphasis on battling health care fraud. Claims in the health care industry related to improper care, paying kickbacks to health care providers or overcharging for goods and services provided by Medicare, Medicaid and other federal health care programs.

The pharmaceutical industry contributed $96 million in settlements and judgments. Daiichi Sankyo agreed to pay $39 million to settle allegations of paying kickbacks to physicians to persuade them to prescribe its drugs. AstraZeneca paid $26.7 million and Cephalon paid $4.3 million to resolve allegations of underpaying rebates owned under the Medicaid Drug Rebate Program. They also agreed to pay an extra $23 million to state Medicaid programs for their losses. In another settlement, PharMerica agreed to pay $9.25 million over allegations that it solicited and received kickbacks from Abbott Laboratories for promoting Depakote to nursing home patients.

The DOJ also supported its goal to use the FCA to address fraud by individuals. For example, in the health care industry, a California cardiologist agreed to pay $1 million to resolve allegations he solicited and accepted kickbacks from CareFusion for promoting the company's product and influencing recommendations for the National Quality Forum.

Qui tam suits accounted for a significant portion of the recoveries ($2.8 billion). Whistleblowers filed a total of 638 *qui tam* lawsuits in FY2015, resulting in whistleblower awards of $597 million. Since 1986,

the number of *qui tam* lawsuits has been on the rise. Since January 2009, $19.4 billion has been recovered through *qui tam* suits.

CDER Director Woodcock says agency will focus on filling vacancies, negotiating user fees in 2016

With a $1.2 billion budget in 2016, the Center for Drug Evaluation and Research will focus on filling hundreds of vacancies, renegotiating user fees and progressing on labeling initiatives.

The FDA's Center for Drug Evaluation and Research is exploring ways to negotiate three user fee arrangements, build its team and work with Congress on legislation such as the 21st Century Cures Act, following a record year for new drug approvals in 2015.

At the FDA/CMS Summit in Washington, CDER Director Janet Woodcock discussed whether the agency met its 2015 priorities and outlined its plans for the coming year. In 2015, the agency focused on reducing the backlog of abbreviated new drug applications while working with the International Conference on Harmonisation to sign new agreements to make it more inclusive, which Woodcock said should help propel negotiations for more global standards for drugs. Although new guidance on biosimilar labeling and interchangeability are still being awaited, Woodcock also said CDER was engaged in a lot of behind-the-scenes work to ensure a robust biosimilar market.

This year, the agency, armed with a $1.2 billion budget, will focus on filling its 680 vacancies while renegotiating prescription drug, generic drug and biosimilar user fees, which all expire in 2017. Additional goals for 2016 include:

- Assessing regulations on drug advertising and promotion following jurisprudence related to the First Amendment.
- Incorporating the Sentinel Network, which is focused on establishing an active surveillance system for monitoring drugs, into routine drug safety activities.
- Continuing efforts to improve drug labeling.
- Moving forward with the mutual reliance initiative with the European Medicines Agency.
- Creating and implementing a plan and training for new pregnancy/lactation labeling rules.
- Urging standards development and standardized electronic submissions.

FDA, industry stakeholders and legislators zero in on new food labeling guidelines

The food industry and the FDA are duking it out over "natural" and "healthy" labels found on food products and dietary supplements. As the agency seeks stakeholder comments on whether the term "natural" necessitates regulation, it is also facing a citizen petition on the term "healthy" and pressure to update product labeling with the introduction of the Food Labeling Modernization Act.

The FDA is allowing stakeholders in the food industry to have their say in what "natural" means when included on product labels, extending a comment period on whether the term should be defined by the regulatory body and whether guidelines should be in place to stipulate its use. To date, the FDA hasn't established formal guidelines to define the term, but has considered it to mean products produced without artificial or synthetic additives.

Initially, comments were due by Feb. 10, but the agency decided to extend the period for an extra 90 days following a request by the Natural Products Association for more time to gather input from members.

As the agency solicits input on the term "natural," it is also facing pressure to update the term "healthy."

KIND Snacks filed a citizen petition asking the FDA to redefine the term, which is currently allowed to be used only as a claim to describe foods that contain three grams or less of total fat and one gram or less of saturated fats per serving. The petition follows a warning letter by the agency saying some of KIND's snack bars failed to meet these requirements. Redefining what constitutes "healthy" food is a contentious issue among the FDA's initiatives to modernize the Nutrition Facts panel to reflect new scientific evidence.

The agency is also facing pressure to reduce what some see as confusion and misleading information on food labeling. U.S. Sens. Richard Blumenthal, D-Conn., and Edward J. Markey, D-Mass., along with Reps. Frank Pallone Jr., D-N.J., and Rosa DeLauro, D-Conn., introduced the Food Labeling Modernization Act of 2015. It would call on the Secretary of the Department of Health and Human Services to establish a standard front-of-package label that would require breaking out added sugar content as well as define terms such as "natural" and "healthy."

For more information on any of these FDA regulatory and compliance updates, please contact Scott S. Liebman at sliebman@loeb.com.

Loeb & Loeb LLP's FDA Regulatory and Compliance Practice

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