Last year, when the first “Your Business in Court” appeared in Update, we concluded the “overriding theme to be derived from this review of cases, settlements, and standards is the need for pharmaceutical, medical device, and biologics companies to have aggressive corporate compliance plans that establish a culture of compliance throughout the panoply of activities undertaken by those companies.” While most biologics companies are too new to have faced enforcement actions, this is a good time for companies to adopt preventive programs.

The past year has added more of an imperative that companies establish effective compliance plans—and enforce them. Not only has government agency enforcement continued at a high level, but also more private actors are attempting to enforce the False Claims Act (FCA), to ride on the shirttails of government enforcement to obtain additional sums for themselves, or to pursue their own private actions.

Fraud and Abuse and the FCA

In 2005, there were fewer large multimillion-dollar settlements involving major FCA cases, but the number of cases involving pharmaceutical or medical device companies continues at a high level.

In a settlement with Caremark involving AdvancePCS, the government alleged that AdvancePCS, a pharmaceutical benefits manager (PBM), contracted to provide PBM services and 1) solicited administrative fees from pharmaceutical companies to include their products on its formulary; 2) charged fees for various products and services related to its formularies and business considerably higher than the value of those products and services; 3) conspired to receive rebates not disclosed by the manufacturers, thereby raising the manufacturer’s Medicaid best price; and 4) made payments to customers in the form of signing bonuses that were unrelated to any costs incurred by the customers. The government argued that these improper payments violated the Anti-Kickback Statute and resulted in the filing of false claims. Caremark paid $137,500,000 in penalties and agreed to a corporate integrity agreement (CIA).

In King Pharmaceuticals, the government alleged that King calculated the average manufacturer’s price (AMP) inappropriately and included improper customers in the calculation, thereby generating false records. These actions resulted in improper Medicaid best prices and lower rebates than required by the Medicaid Rebate Statute. King settled by paying penalties of $73 million to the federal government, and $51 million to various states that had supplementary state rebate programs. The company also entered into a CIA.

The final case involves Serono Laboratories, Inc.’s guilty plea, which resulted in its exclusion from Medicare for five years and payment of $567,065,000, with $305 million paid to the federal government and $262 million to participating states. The government stated that Serono introduced devices that used software for which premarket approval had not been given by the Food and Drug Administration (FDA), provided the devices free to physicians, and gave physicians free trips and other payments in violation of the Anti-Kickback Statute. The company paid rebates to pharmacies that recommended or arranged for the use of its growth hormone.
Serostim®. These activities resulted in Serono knowingly causing the submission of false claims.

The government moved on to the medical device industry when the Department of Justice sent subpoenas to DePuy Orthopedics, BioMed, Stryker, Smith & Nephew, and Zimmer for any consulting and service contracts that those companies had entered into with orthopedic surgeons.® The New York Times reported six-figure consulting agreement payments to a physician working for a state institution who used a particular company’s product.® Late in 2005, the government started issuing subpoenas to orthopedic surgeons.® We expect significant discussions among the government, medical device companies, and their contracting physicians during the next couple of years.

**SEC Issues**

Last year, Bristol-Myers Squibb Co. paid monetary penalties under an SEC settlement because of a program that resulted in excessive sales to wholesalers ahead of demand, resulting in an improper recognition of revenue. In August 2005, the Securities and Exchange Commission (SEC) filed a civil fraud action against current and former executive officers of the company. Income. The proposed remedy is a permanent injunction from engaging in such acts, disgorgement, and interest and civil penalties. It is important for company executives to recognize that the SEC does not limit its enforcement to activities against the companies, as the following cases also illustrate.

The SEC brought enforcement proceedings against former executives of Transkaryotic Therapies, Inc. (TKT) who had misrepresented that clinical trials for its drug, Replagal®, were a success when FDA had been giving the company negative commentary for a period of at least two years prior to TKT’s disclosure that the drug was not successful, after which disclosure its stock price plunged. The SEC alleges that TKT and the former Chief Executive Officer (CEO) knew, but failed to disclose, material negative information about the FDA-required clinical trials. The CEO had sold shares of stock and avoided losses of over $1,600,000 during this time period.® The SEC also has taken action against a former chief operating officer of aaiPharma Inc. for fraudulent sales transactions designed to inflate the company’s reported sales revenue.®

A number of 2005 cases related to companies not disclosing negative information from FDA regarding product approvals. The SEC filed enforcement proceedings against Biopure Corporation and its three top executives because FDA had placed a clinical hold barring Bio Pure from conducting clinical trials of a synthetic blood product in trauma settings, which the company concealed while making public statements about plans to obtain approval for trauma uses of the synthetic blood product. Similarly, the company misrepresented FDA’s position about use of the drug in orthopedic surgery, describing negative communications as “good news.” During this period, the company raised over $35 million dollars from investors. Requested penalties include a permanent injunction, civil money penalty, and an order barring the defendants from serving as officers or directors of any publicly traded company.®

This case demonstrates the growing cooperation between FDA and the SEC. Historically, FDA has limited public disclosures as a result of trade secrets rules governing its relationships with companies. In the past, companies had to disclose before investors had any information. It is conceivable that FDA could begin disclosing to the public, but, in the interim, it seems likely that companies that misrepresent FDA’s position may find themselves dealing with the SEC as a result of FDA disclosures to the SEC. This change in FDA behavior means companies will have significantly less flexibility in how and when they disclose FDA approval problems to their investors.

The SEC has at least one reported case a year dealing with violations of the Foreign Corrupt Practices Act. In 2005, a company established a Chinese joint venture company. The company routinely paid a percentage of the sales to the hospitals, doctors, and laboratory employees who controlled the purchasing decisions in the Chinese state-owned hospitals. Because the U.S. company management immediately took appropriate remedial measures when it learned of the payments, the SEC’s remedies were relatively mild, including outside oversight of the compliance program initiated by the company. If the consultant’s report requires company action, it shall advise the Commission staff of steps taken. The total penalty payment was a little over $2.75 million.®

The SEC also took action in two high-profile cases. First, a final judgment was entered against HealthSouth Corporation requiring a civil penalty of $100 million and retention of consultants to review its corporate governance practices and accounting controls. HealthSouth also had to appoint a company Inspector General to implement training programs for certain officers and employees to prevent future violations of securities laws, and to continue its cooperation with ongoing government investigations.®

In the second case, the SEC alleged that Elan Corporation, PLC misled investors by failing to disclose material
information over a number of years. Elan sold partial royalty rights to some of its products and sold off all the drug product lines, but reported these transactions as product revenue on its income statement. It engaged in a joint venture program, but did not disclose that the licensure fees paid by the partners were funded by money provided by Elan. Finally, Elan facilitated an artificial sale of certain joint venture securities that enabled it to conceal liquidity issues with respect to both the subsidiary’s debt, which Elan had guaranteed, and the company’s debt. The SEC’s request for relief is a permanent injunction, and a $15 million penalty to be added to a disgorgement fund established for the benefit of the victims. In 2004, Elan’s stock price fell from $64 to $16.

There continues to be significant private litigation in cases dealing with claims of securities fraud. In one case involving sales of diabetic testing supplies, the plaintiff alleges the company artificially inflated the market price of its stock by misrepresenting sales, revenues, and accounts receivable, and by issuing false press releases. The current status of the case relates to approval of a class action. In another case, a group of investors sued the manufacturer and distributor of products used to improve or correct vision in patients with cataracts, refractive conditions, and glaucoma. Prior to FDA approval of the product, FDA inspected the plant and found significant objectionable conditions. The company allegedly did not notify investors of the FDA inspection, its findings, or the company’s response. Subsequent to a second inspection, FDA issued another warning letter, which also allegedly was not disclosed by the plaintiffs until some months later. The company’s motion to dismiss was denied.

**FTC Issues**

The Federal Trade Commission (FTC) pursued a number of enforcement actions in 2005, including intervening in agreements to delay market entry of generic drugs, consent agreements in mergers of drug companies, and settlements with companies concerning FTC charges, including false advertising and enforcement of alleged violations of an FTC order. The FTC also issued a report commenting on mail order pharmacies.

The FTC has intervened in several mergers. For example, the FTC entered a consent agreement with DaVita, Inc., related to DaVita’s acquisition of Gambro Healthcare, Inc. wherein DaVita was required to divest many of its dialysis clinics in markets across the United States to another company prior to acquiring Gambro Healthcare.

The FTC also intervened in Novartis AG’s acquisition of Eon Labs. The FTC approved the proposed acquisition conditioned on Novartis’ divestiture of three drugs to Amide Pharmaceuticals, Inc. and on Novartis providing Amide with these drugs until Amide obtained FDA approval to manufacture the drugs.

FTC enforcement has been concerned with false statements and other fraudulent conduct. For example, the FTC successfully shut down a prescription drug scam perpetrated by MyFree-Medicine.com where the Internet company sent consumers applications for free prescription drugs through patient assistance programs, but charged the consumers who received the forms almost $200. The FTC argued, and a U.S. district court agreed, that MyFree-Medicine.com’s statements were deceptive.

In another example, an individual paid the FTC $485,000 to settle charges of making false product claims and sending illegal spam email about the anti-aging effects of human growth hormone herbal supplements. The settlement provided for a suspended judgment of $5.9 million—the estimated amount of consumer injury caused by the spam messages. The FTC imposed recordkeeping requirements for the purpose of continuing to monitor the defendant’s compliance with the settlement.

The FTC developed “Operation Big Fat Lie” and entered settlements with several companies to settle allegations of false or deceptive statements in connection with marketing weight loss products. These settlements carried with them cash payments by the defendants to the FTC; in one, the defendants paid $4.5 million. The FTC also filed an amended complaint against CHK Trading Corporation alleging deceptive advertising involving Hamelin Cellulite Cream and Hamelin Breast Cream.

In the largest monetary settlement in any FTC healthcare fraud case, Great American Products, Inc. and Physician’s Choice, Inc. paid $20 million to settle FTC claims that the companies made deceptive claims about various pills, sprays, and dietary supplements that the companies manufactured and marketed by falsely claiming that the products would provide anti-aging benefits and increase human growth hormone levels.

**Products Liability**

In 2005, the plaintiff’s bar pursued products liability claims about pharmaceuticals and medical devices. Enactment of the Class Action Fairness Act (CAFA) in February 2005 resulted in an increase in the filing of large class
actions in the beginning of the year. CAFA, coupled with FDA efforts to preempt state tort claims, highlighted a number of events favorable to industry.

Federal Jurisdiction
CAFA provides litigants with greater access to the federal courts, prevents “forum shopping” by plaintiffs, protects the rights of individual class members in settlements, and reduces the attorneys’ fees recoverable by plaintiffs’ counsel. CAFA attempts to shift significant class action litigation from state to federal courts.

Preemption
Federal preemption arguments were made with more force in 2005 as a result of the Third Circuit Court of Appeals decision in Horn v. Thoratec Corporation. This decision—strengthened by an FDA amicus brief supporting express preemption—was followed in several decisions involving PMA-approved medical devices. Efforts to extend this reasoning to claims against pharmaceuticals have not been as successful. While FDA submitted an amicus brief in Motus v. Pfizer, Inc. supporting federal conflicts preemption in a pharmaceutical case, the court refused to give deference to FDA’s interpretation of its own regulations. Recently, a federal court addressed Pfizer’s argument that duty to warn claims brought against it for suicide deaths allegedly caused by its antidepressant drug, Zoloft were preempted. The court rejected application of Horn and refused to accept Pfizer’s argument that FDA’s position in Motus should be controlling.

New Federal Labeling Requirements
In January 2006, FDA issued a final rule amending its regulations governing the content and format of labeling for pharmaceuticals. FDA formally adopted the view that compliance with FDA labeling requirements preempts state law claims against pharmaceutical manufacturers that seek to impose additional or different requirements. While courts are not required to accept FDA’s position, the new regulations provide manufacturers with strong support for the contention that FDA’s approval of their drug labels preempts state law tort claims that seek to impose liability for failure to provide different or additional warnings.

The Learned Intermediary Doctrine
One court recently addressed the learned intermediary doctrine in the context of post-sale duty to warn cases. Stanger v. Smith & Nephew, Inc. involved various claims brought against the manufacturer of a tibial insert by a patient who was injured when the device underwent gamma sterilization and subsequent oxidation. The manufacturer became aware of this potential problem after the device was implanted in the patient, but the surgeon contended that he did not know of the problem. The court held that the learned intermediary doctrine did not apply in a medical device case such as this, where the physician does not have “knowledge of the dangers involved in placing this particular tibial insert into [the] plaintiff.” The Stanger decision highlights the importance of timely notification to medical professionals of newly-discovered dangers.

Few courts have addressed the direct-to-consumer (DTC) advertising exception to the learned intermediary doctrine since the groundbreaking Perez decision in 1999 where the court recognized an exception to the doctrine when manufacturers market their drugs or devices directly to consumers. Two recent New Jersey cases have helped define the limits of the Perez exception and arguably have placed reasonable limitations on the DTC exception to the learned intermediary doctrine.

In February 2006, the Superior Court of New Jersey rejected an effort to expand the Perez exception. In Banner, a patient and her husband sued the manufacturer of the acne drug, Accutane, after she became pregnant while taking the drug and their child was born severely disabled. Plaintiffs asserted a products liability action against the manufacturer for, among other things, failing to warn her directly that the drug should not be taken by women who are pregnant or who may become pregnant. Plaintiffs contended that the manufacturer had marketed the drug directly to patients by placing informational brochures about Accutane in physicians’ offices.

The court stated the simple act of placing informational brochures about a drug in a physician’s office “cannot fairly be equated with a course of mass advertising or be deemed direct-to-consumer advertising so as to remove the predicates of the learned intermediary doctrine.” In December 2005, a New Jersey federal court noted that the Perez court “did not explain whether … a failure to show actual influence from direct advertising would serve to circumvent the newly-articulated exception to the learned intermediary doctrine or whether it would merely defeat causation.” The court further stated, “[r]egardless, it is clear that a plaintiff who has never seen any advertising cannot be harmed by flaws in that advertising.”
FDA and Equitable Remedies

Two recent court decisions have upheld FDA’s right to obtain restitution from prescription drug manufacturers who violate the FDCA. In 2002, FDA sought restitution from Lane Labs-USA, Inc. for allegedly misbranding health products. In October 2005, the Third Circuit found that there was no statutory limitation on the broad grant by the FDCA to the courts to “restrain violations” and ruled that FDA’s failure to use restitution as a remedy does not in any way limit the court’s right to exercise its powers. In February 2006, the Court of Appeals for the Tenth Circuit similarly ruled that FDA is entitled to disgorgement of profits for FDCA violations.

These decisions provide legal precedent for FDA’s right to seek and obtain equitable relief in cases where the facts are challenging for the manufacturer. It is hoped that FDA will seek disgorgement and other equitable remedies only from manufacturers who violate the FDCA when the alleged violations are egregious.

Conclusion

The government has maintained a high level of activity prosecuting marketing programs that it can allege successfully violate the Anti-Kickback Statute or Stark II, which then can be used to invoke the FCA and very significant penalties so that companies are inclined to settle. Marketing schemes that industry participants think are reasonable are not necessarily viewed as such by the government. Many medical device companies take the position that their industry is different from the pharmaceutical industry because it depends on physicians for creating new and improved devices. While that may be true, arrangements that appear to pay participating physicians significantly more than fair market value for their participation are likely to be viewed askance by the government.

The SEC is becoming more aggressive—with FDA’s assistance—in pursuing securities fraud claims when products are aggressively positioned for investor purposes prior to FDA approval. Even if FDA’s labeling provisions are not violated, or the product is not marketed before receiving FDA approval, companies need to be careful about the position they espouse with respect to a product’s development and its expected price on stocks. Forward-looking statements need to be examined with care. In addition, the FTC appears to be taking a harder look at false advertising and other actions of companies within its jurisdiction.

The role of private citizens in bringing qui tam suits, and their role and that of companies and state and local govern-
ments increasingly pursuing claims against corporations creates new risks. Companies’ activities are coming under ever-greater scrutiny from all sources.

These issues can be best addressed by having integrated compliance plans that result in comprehensive oversight of a company’s activities in FDA’s regulatory sphere, in the payor coverage, payment and pricing issues, and in marketing programs and postmarketing surveillance. Companies should discuss the legitimacy of arrangements being promoted internally with outside counsel who can look at government enforcement across the board by the U.S. Attorney and the Office of Inspector General in order to test the level of risk a particular marketing program may generate.

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2 Id. at 7-8.
3 31 U.S.C. § 3729 et seq.
4 42 U.S.C. § 1320a-7b(b).
7 Settlement agreement with the U.S. Attorney dated October 14, 2005 and a plea agreement, letter dated October 13, 2005 between the U.S. Justice Department and Henry J. DePippo, Esquire, Nixon Peabody LLP.
8 MDCA Extra Medical Devices (Sept. 26, 2005) DePippo—Litigation, United States; see also Subpoenas Seek Data on Orthopedics Makers’ Ties to Surgeons, N.Y. TIMES, Mar. 31, 2005, at C12.


FTC Accepts Settlement to Remedy DaVita’s Acquisition of Rival Outpatient Dialysis Provider Gambro, 2005 WL 2436937 (F.T.C.) (Oct. 4, 2005).

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FTC Targets Bogus Anti-Aging Claims for Pills, Sprays Promising Human Growth Hormone Benefits, 2005 WLNR 9212036 (June 9, 2005).


376 F.3d 163 (3d Cir. 2004).

See McMullen v. Medtronic, Inc., No. 2:03-CV-00005-LJM-WG, 2004 WL 2538642, at *1 (S.D. Ind. Sept. 16, 2004), aff’d, 421 F.3d 482 (7th Cir. 2005), cert. denied, No. 05-682, 2006 WL 5121556 (U.S. Mar. 6, 2005); Baker v. St. Jude Med., S.C., Inc., 178 S.W.3d 127, 134 (Tex. App. Hous. 1st Dist. 2005); but see Goodlin v. Medtronic, Inc., 167 F.3d 1367, 1375-80 (11th Cir. 1999) (finding that PMA process does not impose specific requirements on manufacturer of medical devices and, therefore, MDA does not preempt state law tort claims based on defects in class III devices); Oja v. Howmedica, Inc., 111 F.3d 782, 789 (10th Cir. 1997) (holding failure-to-warn claim was not subject to preemption under MDA); see also Cusek v. Medtronic, Inc., 405 F.3d 421, 423 (6th Cir. 2005), cert. denied sub nom, Kinsley v. Medtronic, Inc., 126 S. Ct. 420 (2005) (upholding trial court’s denial of motion to amend to add claims for post-sale duty to warn and to recall because they would impose state requirements different from or in addition to PMA application and supplement process).

Motus v. Pfizer, Inc., 127 F. Supp. 2d 1085, 1087 (C.D. Cal. 2000); but see Medtronic, Inc. v. Lohr, 518 U.S. 470, 495-96 (1996) (ruling that FDA “is uniquely qualified to determine whether a particular form of state law ‘stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,’ . . . and, therefore, whether it should be pre-empted”) (citations omitted).


See Medtronic v. Lohr, 518 U.S. at 495-96; Horn, 376 F.3d at 170-71 (giving substantial deference to FDA’s amicus curiae position that the PMA approval process should be given preemptive effect).


Id. at 984.


Id. at *6.

Id.


Id.

United States v. Lane Labs-USA, Inc., 427 F.3d 219 (3d Cir. 2005).


See United States v. Utah Med. Prods., Inc., 404 F. Supp. 2d 1315 (D. Utah 2005) (refusing to grant FDA’s request for equitable relief in the form of injunction where FDA manufacturing practices regulations found vague and were manufactured in substantial compliance over lengthy period of time).