Your Business in Court — 2006

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I. INTRODUCTION

In the authors’ past annual reviews of “Your Business in Court,” they concluded that 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.”1 This requirement has become still more important.

Not only has government agency enforcement remained at a high level, but private actors continue to find innovative ways to pursue claims against pharmaceutical and medical device companies, as the authors demonstrate below. And while the activities of certain government agencies may be constrained, such as the Federal Trade Commission (FTC) with respect to patent litigation settlements, private class action suits are generating settlements on the same issue with shareholders and other plaintiffs, such as States’ Attorneys General. Effective compliance plans should institute policies affecting all the aspects of a company’s business discussed in this article, from product design and manufacture through marketing and sales to post-market surveillance.

II. FRAUD AND ABUSE AND THE FCA

The 2006 review of the False Claims Act (FCA) will begin with the year’s most significant legislative development—the reaction from State legislatures to the Deficit Reduction Act of 2005 (DRA). The authors follow that update with discussions of the year’s significant trials, settlements, and FCA jurisdictional rulings concerning pharmaceutical and medical device companies. They include in their discussion of significant settlements a special mention of the year’s most important medical device case. They conclude the FCA portion of the review with a financial analysis of the Department of Justice (DOJ) civil fraud recoveries, in a section they call “The Numbers.”

A. Legislation

The DRA provided the biggest policy news in 2006. President Bush signed the DRA into law on February 8, 2006. Pharmaceutical and medical device manufac-

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turers will want to focus on section 6031 of the DRA. Section 6031 encourages state legislatures to enact false claims statutes at least as effective as the federal FCA. The provision rewards States which do by increasing their share of Medicaid recoveries by 10 percent.

The DRA State incentive met with mixed results in the first year. Of the 12 states which have passed false claims statutes, only five qualified for the increased recovery share. The Department of Health & Human Services (HHS), in consultation with DOJ, determined that Hawaii, Illinois, Massachusetts, Tennessee and Virginia qualified because their statutes were at least as effective as the federal FCA. In contrast, statutes enacted by California, Florida, Indiana, Louisiana, Michigan, Nevada and Texas did not qualify. HHS cited the scope of liability, the length of the statute of limitations, the amount of the civil penalty, the breadth of the state’s right to intervene, and the size of the relator’s share as grounds for rejecting state requests to partake in the DRA financial incentive.

The DRA, Section 6032, also requires companies that directly receive $5,000,000 from Medicaid agencies, or that contract with a Medicaid managed care organization that receives $5,000,000 to educate its employees, agents, contractors and vendors about the Federal and state false claims acts. Furthermore, if a manufacturer is a contractor to an entity that receives $5,000,000 in Medicaid funds, it must furnish such education to the designated people.

B. Significant Trials

Though not involving pharmaceutical and device manufacturers directly, the following case demonstrates the power of the FCA.2 State law enforcement officials in Illinois did not have to rely on the DRA incentive to pursue false claims jointly with U.S. Attorney Patrick Fitzgerald in Chicago. On October 30, 2006, a federal jury found that Amerigroup—a managed care company which contracts with state governments to insure indigents—violated the federal FCA when it discouraged pregnant women from enrolling in its Chicago-area health plan. On March 14, 2007, the federal court levied more than $190 million in civil penalties against Amerigroup and the affiliate. The jury had determined that each of the 18,130 enrollment forms that Amerigroup submitted to the Illinois Department of Public Aid during a three-year period was a false claim and subject to penalties. U.S. District Court Judge Leinenweber assessed a penalty of $10,500 for each false claim, resulting in civil penalties of $190,365,000. The jury had awarded $48 million in damages in its October verdict on the value of the false claims. By law, that amount had to be increased to $144 million. Judge Leinenweber said the companies’ actions “constituted a several-years-long, institution-wide goal to fleece defendants’ pockets at the expense of the government, the Medicaid system and the avoided pregnant women” and others with expensive health conditions. Jeffrey L. McWaters, Amerigroup’s chairman and chief executive officer, promised to appeal after the March 2007 sentencing. He claimed that the State of Illinois knew of and approved the company’s actions.

C. Significant Settlements

Schering-Plough brought a closely watched investigation to an end on August 29, 2006, when it agreed pay a total of $435 million to resolve allegations of il-

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2 31 U.S.C. § 3729 et seq.
legal off-label marketing, illegal remuneration to physicians (both in connection with and independent of the alleged off-label marketing), and the misreporting of Schering’s best price to the government in connection with its drugs Temodar, Intron A, Claritin RediTabs, and K-Dur.3

The details set forth in the settlement agreement provided helpful guidance to other pharmaceutical companies in their quest to avoid government scrutiny. The government alleged that Schering targeted off-label sales in its marketing plans, trained sales reps to sell off-label, and re-enforced off-label sales objectives during manager “ride-alongs,” district meetings, teleconferences, and sales meetings. Training practices included the provision of scientific articles and abstracts to sales reps for their meetings with physicians even though the articles were stamped “for your information only.” Management allegedly also required the sales force to adopt off-label sales goals, evaluated and compensated the sales force based the achievement of sales in unapproved uses, and provided the sales force with budgets for advisory boards, speakers, entertainment and preceptorships in off-label areas. In a reminder of the enduring power of the written word, one sales rep commented that their work would be done “at noon on Monday” if they did not sell cancer drugs for unapproved uses.

Finally, the settlement presents a case study on the importance of managing government relationships. The government contends that Schering responded in bad faith to a letter from the Food and Drug Administrations’s (FDA’s) Division of Drug Marketing, Advertising and Communications (DDMAC). The DDMAC letter advised Schering that FDA had become aware of off-label promotional conduct by Schering at trade meeting conference booth in Chicago. FDA later concluded that Schering’s letter in response falsely characterized the promotional activity as an isolated incident and falsely assured the government that the conduct would not be repeated. The government also believed that Schering took inadequate remedial action when it disseminated an email notice to its sales representatives about the event which the government deemed ineffective. The government’s perception of this series of events undoubtedly clouded the investigation and settlement negotiations which ensued.

On October 26, 2006, InterMune, Inc, a Brisbane, CA, biopharmaceutical company, entered into a Deferred Prosecution Agreement (DPA) with the United States.4 Under the agreement, InterMune accepted responsibility for criminal conduct by one or more former employees and agreed to pay approximately $40 million to resolve its criminal and civil liabilities.

InterMune did not contest that one or more former employees instructed members of its sales force and a specialty pharmacy to promote a drug called Actimmune for an off-label use. FDA had approved the drug for two diseases which affect very small patient populations. In October 2002, InterMune began a Phase III clinical trial to study the efficacy of the drug with respect to a third disease, called idiopathic pulmonary fibrosis (IPF). IPF is a debilitating, fatal lung disease for which there is no FDA-approved treatment and which afflicts approximately 83,000 Americans. The Phase III trial was designed to study whether Actimmune extended the “time to disease progression” or death. In early August 2002, InterMune personnel received data from the clinical trial showing that the trial failed to achieve statistical significance on the primary endpoint or any secondary endpoint, including overall

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survival. InterMune discussed the data with FDA representatives during an informal conference call later that month. An FDA representative acknowledged an optimistic trend on overall survival during the call. The FDA representative cautioned, however, that the company would likely have to engage in further rigorous clinical testing before FDA would approve the drug because the data had failed to achieve statistical significance in the primary endpoint.

The following day, InterMune publicly announced the results of the trial. The press release bore the headline, “InterMune Announces Phase III Data Demonstrating Survival Benefit of Actimmune in IPF,” with a subheading, “Reduces Mortality by 70 percent in Patients with Mild to Moderate Disease.” In the release, InterMune’s then-President and CEO characterized the clinical trial as indicating that “Actimmune is the only available treatment demonstrated to have clinical benefit in IPF, with improved survival data in two controlled clinical trials.” The chair of an independent committee that had monitored the safety and efficacy of the Phase III trial wrote to InterMune in early September 2002. He expressed his “serious concerns” with the press release. The chair believed that the press release provided a “serious misrepresentation of results obtained from exploratory data subgroup analyses.”

Notwithstanding the reservations expressed by both FDA and the independent committee, InterMune embarked on a campaign to promote the use of Actimmune to address IPF. A specialty pharmacy which distributed Actimmune disseminated a promotional fax regarding IPF to more than 2,000 pulmonologists. The same pharmacy distributed a patient letter by mail to Actimmune patients, which included the August 2002 press release. InterMune sales representatives, at the direction of management, called on pulmonologists, ostensibly to discuss another pulmonary drug that InterMune had acquired, when their primary purpose was to promote Actimmune and its application to IPF patient populations. InterMune derived the majority of its revenues from Actimmune during this period.

The success enjoyed by InterMune’s former senior management was short-lived. The great majority ended their employment at the company by 2004, when InterMune sought outside legal counsel. The DPA requires ongoing and complete cooperation by the company, and does not protect former employees.

The government’s FCA suit against pharmacy benefits manager Medco Health Solutions, Inc. arguably ended with a “split decision” in May 2006 after a seven-year war. The proceedings began in May 1996 when two pharmacists formerly employed by Medco at its Las Vegas, Nevada, pharmacy facility filed the first of three separate qui tam actions against the company in the Eastern District of Pennsylvania. The government intervened in the actions in 2003, and added as a defendant a former Medco vice president and general manager, Diane Collins. The government alleged that Medco had submitted false claims for mail order prescription drug services it provided to federal employees. The government claimed that Medco destroyed valid prescriptions to avoid late penalties; switched patients’ prescriptions without their consent to earn undisclosed rebates from drug makers; and billed patients for drugs they never ordered. The government also claimed that Medco had solicited and accepted payments from drug makers to favor their drugs on Medco’s formulary. While the settlement agreement required Medco to adopt a robust, five-year Corporate Integrity Agreement and to pay a $155 million fine, it did not require either the company or Collins to admit to wrongdoing.

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D. Jurisdiction

There were a number of important rulings in 2006 regarding jurisdiction and the right of a *qui tam* relator to bring an action on behalf of the government.

An oral argument before the Supreme Court in December 2006 yielded an opinion in March 2007 that will be of interest to both corporations and *qui tam* relators. 6 The Court in *Rockwell* limited federal-court jurisdiction over FCA proceedings through strict application of the “original source” requirement of the statute. Under the Court’s ruling, the “original source” requirement precludes actions by *qui tam* relators after public disclosure of fraud through the media unless the relator is an “original source” of the allegations proven at trial.

Section 3730(e)(4) of the FCA sets forth the “original source” requirement. Subsection (A) of the provision eliminates federal-court jurisdiction over an action which is based upon the “public disclosure of allegations or transactions … from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.” Subsection (B) defines “original source” as “an individual who has direct and independent knowledge of the information on which the allegations are based ….” That phrase—“information on which the allegations are based”—framed the Supreme Court’s “original source” analysis in *Rockwell*. The Court determined that final allegations, as opposed to allegations stated in an initial complaint, resolved the question of who is an “original source.” Justice Scalia, writing for the Court, opined: “The statute speaks not of the allegations in the ‘original complaint’ (or even the allegations in the ‘complaint’), but of the relator’s ‘allegations’ *simpliciter*."

As applied to the relator in *Rockwell*, James Stone, this required examination of the allegations as amended by the final pretrial order and the false claims ultimately found by the jury. On this score, Stone fell short. He had left Rockwell before the facts proven at trial had occurred. He had merely predicted the contract performance failures at issue, but did not know of their existence when his employment terminated. He did not know that Rockwell would fail to address the problem. And he did not know about the subsequent false statements Rockwell would make to the government. In short, “Stone’s prediction [of the failure to perform the contract did] not qualify as ‘direct and independent knowledge’ of the [alleged] defect” charged and proven at trial.

In reaching its decision, the Court brushed aside the government’s concern that a focus on amended “allegations” at the time of trial would likely drive a wedge between *qui tam* relators and the government. In cases where the government joins a *qui tam* action, the Solicitor General advised, the government often seeks to narrow its theories of liability as trial approaches. This practice, the government warned, might eliminate jurisdiction as to the relator. The Court was unmoved, stating: “[E]ven if this policy concern were valid, it would not induce us to determine jurisdiction on the basis of whether the relator is an original source of information underlying allegations that he no longer makes.”

While the *Rockwell* opinion restricts the definition of “original source,” the Court left the jurisdictional door open for relators with imperfect information about a false claim so long as it rises to the level of actual knowledge. The Court noted that “a *qui tam* relator’s misunderstanding of why a concealed defect occurred would normally be immaterial so long as he knew the defect actually existed.”

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7 Id.
Finally, the Court left intact the $4.2 million judgment and award in favor of the government despite the finding that the FCA barred jurisdiction over the relator's claims. The Court reasoned that dismissal of the relator did not bar the government from proceeding because the government had an independent right to initiate an action.

The Seventh Circuit addressed a related jurisdictional question. In Gear, an emergency room physician brought a FCA suit against two corporations that provided physicians to hospital emergency rooms. The relator alleged that the defendants billed Medicare for physician services that he and other residents had rendered during their residency hours. The Seventh Circuit affirmed a district court order granting summary judgment in favor of the defendants on the ground that the “public disclosure bar” applied. The Court noted that the plaintiff had filed suit after DOJ and HHS-OIG announced their audit program of billings for physicians at teaching hospitals (the so-called “PATH” audits). Indeed, the plaintiff had served as an editor of a magazine published by the American College of Emergency Physicians when it featured an article about this enforcement initiative before he filed suit. The Court did not credit an affidavit the plaintiff filed by which he asserted that he had an independent and personal basis of knowledge of billing errors in his residency program. The Court characterized the affidavit as “self-serving” and ruled it “insufficient” in the wake of the substantial public record of the billing errors. Finally, the Court noted that the plaintiff had failed to “voluntarily provide[] the information to the Government before filing [the] action” as required by the “original source” provisions of the FCA.

Shortly before the oral arguments in Rockwell, the Supreme Court denied certiorari in Catholic Healthcare. The petition sought to resolve a split in the circuits on the question whether a Freedom of Information Act (FOIA) production amounts to a “public disclosure” under the FCA. The FCA's “public disclosure” provisions deprive a court of jurisdiction over a relator's claim if the allegations are based on specified “public disclosure[s],” including disclosures made in an “administrative … report.” The Ninth Circuit ruled that the production of documents pursuant to a FOIA request was a ministerial act which did not amount to a government “report.” The Ninth Circuit acknowledged that its opinion conflicted with that of the Third Circuit in Mistick. In Mistick, a 2-1 majority opinion authored by Justice (then-judge) Alito, ruled that a FOIA response was a “public disclosure” which operated to bar a relator's claims because the production of records was a “report” in the common meaning of that term. This apparent split may well result in forum shopping to the extent that venue lies in a jurisdiction friendly to qui tam relators.

E. Devices

There was very little public information about this year's most pertinent medical device False Claims matter, which suggests that the case may not have been as strong as the government first thought. Minneapolis-based Medtronic, Inc. entered into a Settlement Agreement with the government on July 18, 2006, to resolve two qui tam actions filed against it in the Western District of Tennessee. The first-filed qui

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11 United States ex rel. Haight et al. v. Catholic Healthcare West et al., 445 F.3d 1147, 1153 (9th Cir. 2006).
12 United States ex rel. Mistick PBT v. Housing Authority, 186 F.3d 376, 383 (3d Cir. 1999).
13 USA, et al v. Zdeblick, et al., Western District of Tennessee (Memphis), Civil No. 03-cv-02979-BBD.
tam action remains under seal. The disposition of the second-filed qui tam action is discussed below.

In describing the government's position, the Settlement Agreement uses the term “the United States contends,” as opposed to “the United States alleges,” which suggests that the government did not intervene in either action. The settlement agreement enumerates the government's contentions as follows: Medtronic's spinal-implant division, Medtronic Sofamor Danek USA (MSD), 1) paid physicians to attend medical education events, think tanks, VIP/MVP events, and meetings at resort locations, 2) provided services and payments to physicians through MSD's Healthcare Services and eBusiness Departments (formerly called the Physician Provider Services or PPS department), and 3) paid physicians pursuant to consulting, royalty, fellowship and research agreements. The government further contends that “certain” of the payments, services, and remuneration were improper, and resulted in the submission of false and fraudulent claims. Medtronic, for its part, denies any wrongdoing, and contends that none of the payments, services and remuneration were illegal or improper or resulted in any false or fraudulent claims. The negotiated release covers only Medtronic and its current employees, and includes a five-year Corporate Integrity Agreement.

The payment terms under the agreement have changed since the parties initially settled the matter. Medtronic originally agreed to place $40 million in escrow subject to dismissal of the two qui tam actions and the exhaustion of all appeals. Through three written modifications, the parties have amended these terms to permit Medtronic to retain the monies until the qui tam actions are finally dismissed subject to an agreement by Medtronic to pay interest at the rate of 5.25 percent. The district court dismissed the second-filed qui tam action (and presumably the first-filed, which remained under seal), but the relator has since appealed to the Sixth Circuit.

F. The Numbers

The Department of Justice (DOJ) announced on November 21, 2006, that the federal Treasury reclaimed $3.1 billion in civil fraud settlements and judgments during the Fiscal Year (FY) ending September 30. Of the $3.1 billion, $1.3 billion stemmed from lawsuits initiated by whistleblowers, $1.8 billion from actions commenced by the government. By industry, 72 percent of the recoveries came from healthcare, 20 percent from defense, and 8 percent from other categories. The $2.2 billion in healthcare settlements included approximately $1.2 billion in qui tam recoveries. Of the total figure, $920 million stemmed from Tenet Healthcare Corporation settlement and $565 million from The Boeing Company settlement (not qui tam). In short, the two largest FY 2006 civil fraud settlements comprised nearly half of the year’s total.

III. THE FEDERAL TRADE COMMISSION

During 2006, the Federal Trade Commission (FTC) continued to be active in reviewing proposed mergers, became increasingly concerned about patent litigation settlements being used by brand name pharmaceutical manufacturers to inhibit consumer access to generic drugs and vigorously pursued companies making false
or misleading statements about dietary products, particularly those making weight loss claims.

The FTC reviews of mergers ranged from the largest of acquisitions, such as Boston Scientific’s acquisition of Guidant Corporation, to small transactions not even subject to the Hart-Scott-Rodino notice requirements, such as Hologic’s acquisition of Fischer. These reviews covered major consolidations in the device manufacturing industry, a significant consolidation by a user of devices that could have interesting implications for the marketing of dialysis equipment, and a number of pharmaceutical company consolidations, primarily involving generic drug products.

The authors start their discussion of examples of FTC reviews of device company merger activity with Boston Scientific’s (Boston) $27 billion acquisition of Guidant Corporation (Guidant). The settlement order\footnote{14} required Boston to divest Guidant’s drug eluding stents with rapid exchange delivery system, its percutaneous transluminal coronary angioplasty balloon catheters and coronary guide wires, and all associated patents to Abbott Laboratories (Abbott). In accepting this divestiture, Abbott had to relinquish its voting rights to an equity position it owned in Boston immediately, and to divest that equity position within 30 months. These divestitures were required because Guidant was the only potential competitor to Boston and Johnson & Johnson (J&J) in the relevant stent business, and the catheter market was highly concentrated. Furthermore, Guidant, Medtronic and St. Jude account for more than 98 percent of the implantable cardioverter defibrillator (ICD) market, and Boston had a right to purchase Cameron Health, Inc., a potential entrant into the ICD market. Consequently, Boston had to agree to limits on its access to Cameron’s information, and its right to control Cameron. Boston had to divest its equity interest in Cameron if it did not purchase Cameron within eighteen months unless it decides to purchase Cameron during the option period, which it can only do after giving prior notice to the FTC, and in the meantime had to vote its Cameron shares in the same proportions as other shareholders voted their shares. In approving this transaction with conditions, the FTC examined not only the existing market shares of the various products held by the different companies in deciding its divestiture and other requirements, but also at the potential for future dominance in the relevant markets.

An interesting contrast in the breadth of review is the FTC’s treatment of Fresenius AG’s acquisition of Renal Care Group\footnote{15} (RCG). In this case, the FTC appears to have examined the consumer (particularly health plan) market, but not the supplier market. Both Fresenius and RCG provide outpatient dialysis through clinics they own and operate or manage. Subsequent to this merger, Fresenius will be the largest provider of outpatient dialysis services in the United States. The FTC focused on the importance to consumers of having choices about where to obtain dialysis services and, in consequence, required Fresenius to sell ninety-one outpatient dialysis clinics and RCG’s joint venture equity interest in twelve clinics to National Renal Institutes, Inc. (NRI) Fresenius was required to obtain the agreement of physicians and lessors of the clinics to continue to provide services under the management of NRI, and for NRI to be able to hire appropriate employees.

\footnote{14} “Decision and Order,” In the matter of Boston Scientific Corporation, a corporation and Guidant Corporation, a corporation; File No. 061-0046, Docket No. C-4164, Decision and Order, July 1, 2006.

\footnote{15} “Decision and Order,” In the matter of Fresenius AG; File No. 051-0154, Docket No. C-4159, June 30, 2006.
related to these divested clinics. The Consent Agreement also put other restrictions in place to ensure that the divested assets would continue to be viable businesses during their transfer to NRI. Of interest in this transaction is that the FTC appears not to have examined the purchasing power that Fresenius might be able to exercise with respect to the acquisition of equipment and supplies as a result of its acquisition of RCG. RCG, with a per-merger sales volume about one-third that of Fresenius before the merger, had been the third largest provider of outpatient dialysis services. After the merger, Fresenius became the dominant provider of dialysis services in the United States. This dominance suggests that Fresenius might be in a position to exercise substantial market power with respect to the pricing of products it needs to purchase to provide dialysis services. The authors find it of interest that the FTC did not appear to have contemplated this aspect of the transaction in its analysis.

It was in the device arena that the FTC decided to challenge a 2005 merger between Hologic, Inc. and Fischer Imaging Corporation that had not been reportable under the Hart-Scott-Rodino Premerger Notification Act as it was valued less than the almost $57 million filing threshold. Hologic paid $32 million to acquire Fischer’s assets, including its stereotactic breast biopsy systems (SBBS) business, in which market Fischer was virtually Hologic’s sole competitor. The merger would have given Hologic a virtual monopoly of the market for Prone SBBS, a diagnostic intervention that permits physicians to undertake precise, minimally invasive breast biopsies using X-ray guidance. The FTC’s analysis of Hologic’s market position and patent ownership determined there were significant regulatory and market barriers for a competing Prone SBBS product to enter the U.S. market. Consequently, the FTC required Hologic to divest to Siemens the SBBS-related assets it acquired from Fischer, while it permitted Hologic to retain a license to use Fischer’s Prone SBBS patents so it can continue to compete in the U.S. market.

Turning to pharmaceutical mergers in 2006, the FTC’s review of J&J’s acquisition of Pfizer Inc.’s consumer healthcare products—often called over-the-counter (OTC) products—for over sixteen and a half billion dollars, led the FTC to require J&J and Pfizer to sell Pfizer’s Zantac H-2 blocker business, that relieves heartburn, to Boehringer Ingleheim Pharmaceuticals, Inc. (Boehringer) and Pfizer’s Hydrocortisone anti-itch business, Pfizer’s Unisom night time sleep aid business, and J&J’s Balmex diaper rash treatment business to Chattem, Inc. In all four product areas, without divestiture, J&J would have provided from about 50 percent to over 70 percent or more of the products in the relevant markets. The FTC also required that J&J and Pfizer turn over all relevant research and development, intellectual property and customer supply contracts for the divested assets to Boehringer and Chattem, respectively, and to ensure that key personnel would be in a position to be employed by the acquiring companies. The FTC’s goal was to ensure the transfer of such assets was accomplished in a manner that enables the acquirors to be viable competitors for the J&J and Pfizer products that continue to be sold after the merger was effected.

The FTC took similar action with respect to a number of mergers proposed for generic pharmaceuticals, the largest of which was Teva Pharmaceutical Industry

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Ltd.’s (Teva) nearly $7.5 billion acquisition of IVAX Corporation. The FTC determined that after consummation of the merger Teva would have had 15 generic pharmaceutical products in which it would have had major market shares. The Herfindahl-Hirschman Index (HHI) post acquisition for these products would have ranged from approximately 4,000 points to 10,000 points. Markets in which the HHI is between 1,000 and 1,800 points are considered moderately concentrated, and those in which the HHI exceeds 1,800 points are considered concentrated. Transactions that increase the HHI by more than 100 points in concentrated markets presumptively raise antitrust concerns for the DOJ and the FTC. Four of the 15 products were divested to Barr Pharmaceuticals, Inc. (Barr) and the remainder to Par Pharmaceutical Companies, Inc. (Par). The FTC approved Barr and Par as acquirors based on their respective product lines and experience in the generic drug industry. The FTC determined that these companies could maintain the acquired products’ competitive status, and acted to ensure an effective transition of the products to the acquirers by establishing many conditions for the transfer of know-how and personnel. Moreover, the FTC required Teva to supply the acquiring companies with the drugs until those companies received their FDA approvals. In addition, the FTC appointed an overseer to ensure Teva and IVAX complied with the terms of the Consent Order.

In a transaction involving cosmetic botulinum toxins, the FTC required divestiture before allowing Botox marketeer Allergan, Inc. to merge with the Inamed Corporation in an over $3 billion acquisition. This was a case where only one product was on the market, Allergan’s Botox, but Inamed was developing a competing product under license. The FTC required Allergan to divest the rights to develop and distribute Reloxin. The potential competitor of Botox being developed by Inamed, which is in Phase III clinical trials and is best positioned to next enter the market in competition with Botox. Inamed had obtained the development and distribution rights to Reloxin from Ipsen, Ltd., a United Kingdom (UK)-based manufacturer, and the Decision and Order required the return of these rights to Ipsen. The FTC also imposed conditions similar to those discussed in the previous case in order to ensure the viability of the program being taken on by Ipsen.

During 2006 there was a significant increase in the rate of consolidation of generic drug companies, so the FTC reviewed a number of other cases, of which we will mention only two. These cases, generally were similar to the Teva acquisition of IVAX, though on a smaller scale. They include Watson Pharmaceutical, Inc.’s nearly $2 billion acquisition of Andrx Corporation in which divestitures were made to Teva as well as two smaller companies. It is interesting to see that the FTC will require divestiture to large companies if it believes that will ensure the viability of the product involved. In Barr’s acquisition of Pliva d.d for $2.5 billion, the FTC

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20 “Analysis of Agreement Containing Consent Orders to Aid Public Comment,” In the matter of Teva Pharmaceutical Industries, Ltd. and Ivax Corporation, File No. 0510214, Docket No. C-4155.
required the divestiture of three drugs for which the markets had limited competition or, in one case, in which Barr and Pliva were the only companies planning to enter a market. In these cases the FTC imposed conditions similar to those discussed above to ensure continued vitality of the divested products.

An arena in which the FTC has tried to be increasingly active has been in opposing patent litigation settlements between generic pharmaceutical manufacturers and branded pharmaceuticals, under which the settlement postpones the entry of the generic drug for a number of years in exchange for payment by the brand-name manufacturer. Clearly, these arrangements result from brand-name manufacturers being able to maintain sufficient profitability after making the payments to the generics, while the generics receive a bottom-line pre-tax payment that compensates them adequately for the loss of profits resulting from not bringing the generic to market. Consequently, these transactions result in increased drug prices compared to the generic price on entry into the market. The FTC testified before the U.S. Senate’s Special Committee on Aging to discuss this issue, as well as brand-name manufacturers’ use of the 180-day marketing exclusivity for generic drug first-filers. Brand name manufacturers pursue at least two strategies. One is to develop their own generic version, file first, and thereby preempt entry for 180 days by other generic manufacturers. The second is to use a patent settlement agreement to require the settling generic manufacturer to use its 180 days exclusivity to block entry by other generic manufacturers. In addition to bringing this issue to the attention of Congress, the FTC filed amicus briefs taking a case to the U.S. Supreme Court in an unsuccessful effort to persuade the courts to prevent these so-called “reverse payments.” In a more current case, patients and payors have challenged an agreement between AstraZeneca Pharmaceuticals LP (AstraZeneca) and Barr that alleges excessive prices were paid for the breast cancer treatment Tamoxafin Citrate because AstraZeneca paid Barr $57 million to abandon its successful challenge of AstraZeneca’s Tamoxafin patent. Also, Barr is alleged to have agreed to use its 180 days of market exclusivity under Hatch-Waxman Drug Patent Law to block market entry by other generic companies according to the suit. The plaintiffs have been unsuccessful to date. Since this case involves a different set of players, having various aggrieved consumers and purchasers seeking redress, it will be interesting to see if the Supreme Court grants certiorari.

Because of these court decisions, the FTC has founds its hands tied as it attempted to limit these transactions which increased in frequency significantly in 2006. In early 2006, the FTC was unable to oppose a settlement between Teva and Wyeth to market a generic version of Wyeth’s anti-depressant Effexor. Similarly, Barr and Cephalon agreed to a patent litigation settlement involving two drugs. One concerned Actiq, for which Cephalon had issued Barr a license by FDA order in 2004, and for which it granted a supplemental license under the settlement. The other Provigil, for which Cephalon granted Barr a non-exclusive royalty-bearing right to market and sell the drug after October 2011, which could be extended to April 2012 if Cephalon obtains a pediatric exception for the product. While the Actiq agreement permitted Barr into the market within a year of the settlement, the Modafinil agreement did not allow Barr

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28 “Barr/Cephalon settle patent disputes relating to Actiq and Provigil,” Drug Delivery Insight Medical Devices, 2/7/06).
into the market until 2011 at the earliest, unless another generic version of Provigil enters the market. It is possible that, if the Supreme Court does not decide to hear arguments on this issue, Congress will act with respect to these reverse payments since they increase the cost of Medicare Part D, as well as other aspects of the Medicare program, and Congressman Henry Waxman has an interest in these matters, having been given leave to file an *amicus* brief in the Schering-Plough case.\(^{29}\)

In an exception to this pattern, but under a special set of facts, the FTC was able to ensure entry of a generic birth control pill to the market. Warner Chilcott Holdings Co. III, Ltd. (Warner Chilcott) had entered into an agreement with Barr as a result of patent litigation that permitted Barr to introduce a generic version of Warner Chilcott’s Ovcon birth control pill. Under that agreement, Warner Chilcott paid Barr $20 million not to introduce the generic version for five years, and Barr agreed to supply Ovcon to Warner Chilcott if requested. While the case was pending, Warner Chilcott developed a strategy to convert consumers to a chewable pill, so that there would not be a branded product against which the generic could compete. Upon learning of this strategy, the FTC filed for a preliminary injunction to require Warner Chilcott to continue to manufacture the branded version. Warner Chilcott settled by waiving the exclusionary period for Barr.\(^{30}\)

The FTC had a considerable number of enforcement actions in 2006 in the arena of deceptive or false advertising. As in 2005, the FTC has dealt with ranges of products, including weight loss products, various purported cures for diseases, and pain relief products.

Examples of the weight-loss cases include a $3 million settlement with Basic Research, LLC\(^{31}\) in which the company made the payment on behalf of a number of defendants including itself, for various gels that claimed to “melt away fat where they were applied,” and pills that would cause weight loss of more than 20 pounds. Advertisements ran on television and in magazines. In addition to the penalty, the FTC prohibited the marketers from making unsubstantiated claims about products without having competent and reliable scientific evidence and from making misrepresentations concerning products. This type of settlement is fairly typical of these arrangements as future violations of such settlements can result in penalties of $11,000 for each event. In a similar case,\(^{32}\) the defendants had to pay restitution of more than $22 million in total, with the FTC managing up to $12.5 million as a result of the settlement, the balance being required under other litigation. There were other requirements of the settlement, including a five-year monitoring period.

One case involved dietary supplements being offered to treat sexual dysfunction, fatigue and improve night vision.\(^{33}\) In addition to making unsubstantiated claims about the effectiveness of the products, the marketing scheme did not disclose to consumers the full obligation to which they were committing and, as a result, derived revenue from unauthorized use of consumer’s credit card accounts. This

\(^{31}\) In the matter of Basic Research, LLC, File No. 002-3300, Docket No. 9318, FTC, 2006 FTC LEXIS 34, (June 19, 2006).
\(^{32}\) FTC v Robert Chinery, Jr., Tracy A. Chinery and RTC Research and Development, LLC, Civ. Action 05-34 60 (GEB), (USDC, NJ); 2006 U.S. Dist. Lexis 94941; (Dec. 21, 2006).
case has been stayed pending outcome of a related criminal case. There were a number of similar cases settled during 2006 that traded on consumers’ desire for easy weight-loss solutions.

In another case concerning products claiming to cure disease, Window Rock had been selling products purporting to prevent various serious health conditions including osteoporosis, obesity, diabetes, Alzheimer’s, cancer and cardiovascular disease as well as making weight-loss claims. Window Rock not only was permanently restrained and enjoined from using endorsements or product names or making any representation about health benefits of any products, but had to withdraw all advertising that was still in progress, had to make it clear that any advertisement was a paid advertisement, and had to make a settlement payment to the FTC of over $10 million within 60 days as part of a potential $160 million payment of equitable monetary relief. Window Rock also had to ensure that its distributors ceased to provide products unless they complied with the terms of the Order which included statements about the effectiveness of the product.

In addition to these examples of FTC action against dietary supplements associated with false claims, in examples of actions against other types of products, the FTC brought actions against a Florida business which purported to sell height-enhancing pills for children, a seller making illegal sales of contact lenses over the internet because the company did not verify consumers’ prescriptions, and the sellers of an ionized bracelet which purported to provide immediate significant or complete pain relief, and for which no scientific tests proved their claims. In the last case, the Court found that this was a device, there were no appropriate studies conducted, and the claims were materially misleading. Defendants had to disgorge all of their profits to provide refunds to purchasers.

IV. THE SECURITIES AND EXCHANGE COMMISSION

The Securities and Exchange Commission (SEC) penalizes healthcare companies for failure to disclose all material negative information, or for making material misrepresentations of fact, in documents provided to the SEC as part of its reporting requirements, such as 10Qs, thus misleading investors and shareholders. The SEC also takes action against insider trading, where people with special knowledge about the status of a company’s products purchase or sell shares of stock before the general public is given the same information.

In 2006, the SEC brought to conclusion a case we reported in 2005 involving allegations that Bristol-Myers-Squibb (BMS) overstated its sales and earnings in order to create a false appearance that the company had met or exceeded financial protections set by the company’s officers, as well as earnings projections established

by Wall Street securities analysts. BMS had inflated its earnings by distribution channel stuffing in violation of generally accepted accounting principles. In June 2006, the SEC announced that $750 million would be distributed to the shareholders of BMS injured by the scheme. The fund included $150 million in penalties and disgorgement imposed by the SEC and two $300 million funds, one created by settlement of a related shareholder derivative class action suit and one paid under a deferred prosecution agreement with the U.S. Attorney’s office in New Jersey.40

Insider trading continues to be a major issue either because of the failure or success of a clinical trial in which an insider trades his or her shares before public disclosure of the event. In another case we reported initially last year,41 the SEC concluded its enforcement by penalizing the general counsel of Biopure Corporation more than $3 million in disgorgement, penalties and interest and prohibiting him from being an officer or director of a publicly traded company for five years.42 The general counsel had traded his shares at market price immediately on learning that a patient in a clinical trial had contracted a rare and often fatal brain disease. In a related case, the former vice chairman of the board of directors of Biopure, who was also the senior technology officer, agreed to a $40,000 fine and an injunction for his role in concealing Biopure’s negative information on its potential blood product.43

In this case, FDA had given continuous negative information to Biopure about its product, including placing a clinical hold barring it from conducting clinical trials. Despite these FDA actions, Biopure continued to make public statements about its expected use of the product. In another insider trading case, a wife induced her husband, the chairman and chief executive of a publicly-traded company, to tell her about the failure of a clinical trial, which information she imparted to her brother, apparently as part of an ongoing scheme.44 These, and other similar cases, demonstrate that employees, their spouses and others in privity with such persons who take advantage of insider information may be subject to significant repayment requirements and potential exclusion from working for public companies.

In 2006, there were two interesting procedural matters involving interagency issues. As the authors mentioned last year,45 FDA seems to be more willing to provide information to the SEC than was the case historically, though it still seems reluctant to disclose to the public because of trade secret protection reasons. A corporation attempted to serve subpoenas on FDA in connection with the corporation’s defense of an SEC civil enforcement action where FDA was not a party to the litigation.46 Here the court agreed that the fact that the SEC was a party did not make FDA a party. One government agency being subject to subpoena does not make another government agency so subject. FDA did not have to respond to the Corporation’s subpoenas. FDA had provided documents to the SEC through its regulations permitting inter-agency disclosure and, unlike the Corporation, the SEC had complied with FDA’s regulations to obtain testimony from FDA employees. Moreover,

the documents given to the SEC by FDA had been provided to the Corporation. However, in a subsequent case where FDA was an interested party, a third party defendant did have the right to compel production of documents in accordance with the FDA's Toughy regulations. This result, which was contrary to that in the previous case, resulted from an intervening decision from the U.S. Court of Appeals for the District of Columbia determining that a government agency is a “person” within the meaning or Rules of Civil Procedure 45 and thus subject to third party subpoenas.

Finally, there was a case involving alleged payments of kickbacks in exchange for business in violation of the Foreign Corrupt Practices Act. The SEC subpoenaed St. Jude Medical (St. Jude) in its investigation of the UN Oil for Food Program. In a United Nations report released in October 2006, an Austrian Subsidiary of St. Jude was listed as paying nearly $650,000 in kickbacks to secure a business deal with the Iraqi government. The company had more than $9.5 million in Iraqi contracts for heart valves and other medical equipment. St. Jude states it is investigating the allegations and will inform the SEC when it is completed.

V. PRODUCT LIABILITY

In 2006, civil litigation against pharmaceutical and medical device manufacturers related to product liability was very active. Highly publicized recalls and voluntary withdrawals of prescription drugs and medical devices, as well as ongoing investigations by federal and state governments, precipitated litigation and decisional law in product liability actions, state consumer fraud actions, fraud actions by State Attorney Generals and securities litigation by disappointed shareholders. These cases are significant — not necessarily for any particular holding emerging from them — but because, as a whole, they demonstrate how the litigation and risk management landscape has changed for prescription drug and medical device manufacturers. The most significant cases in 2006 involve a number of different drugs and devices (some better known than others) on these substantive issues: federal class actions, federal preemption of state tort claims and the continued applicability of the learned intermediary doctrine. This section focuses most of its attention on developments in these areas.

- **Class Actions.** Courts have issued a number of class certification rulings as well as substantive decisions in 2006. These cases span a wide range of actions related to products — from securities litigation to state consumer fraud act claims — and illustrate the breadth of litigation that pharmaceutical and device manufacturers face.

- **FDCA Preemption.** In the preamble to its new regulations, FDA formally announced its position that the FDCA and FDA regulations preempt state tort claims against the manufacturers of a drug or device that received FDA approval and is labeled pursuant to that approval. Courts have issued rulings

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49 Medical Device Maker St. Jude gets subpoena in oil-for-food program probe. ASSOCIATED PRESS, (Mar. 17, 2006).
that vary widely on the deference to be given to FDA’s preemption policy and its effect on state tort claims.

• *Buckman Preemption.* Courts have also examined the reach of the U.S. Supreme Court’s decision in *Buckman v. Plaintiffs’ Legal Committee* to fraud exceptions contained in state statutes that immunize pharmaceutical and medical device manufacturers from product liability suits. The resulting decisions have important implications for manufacturers defending actions in a state with that type of statute.

• *MDA Preemption.* Courts have also issued a number of interesting decisions concerning the preemptive effect of the MDA on state tort claims against the manufacturers of PMA-approved medical devices.

• *Learned Intermediary Doctrine.* As always, the learned intermediary defense and its applicability to state tort claims remains a hotly-debated issue. This section will also discuss the 2006 developments in this area.

### A. Developing Trends in Class Action Claims Against Pharmaceutical Manufacturers

Class actions remain a popular vehicle for plaintiffs’ attorneys to sue drug and medical device manufacturers. The types of class actions being brought speak to the fallout from several of the highly publicized recalls that took place over the last few years and the resolve of plaintiffs’ attorneys to find new methods and new theories to hold manufacturers financially responsible for their clients’ alleged injuries. In 2006, courts addressed a number of issues related to the viability of class actions against drug and device manufacturers.

#### 1. Securities Litigation

Securities litigation against pharmaceutical, medical device and biotechnology companies increased in 2006. This litigation is brought by a manufacturer’s shareholders to recover for the allegedly inflated price they paid for their stock or for the decline of their stock after the disclosure of information about the company’s drug or device. These securities cases typically follow on the heels of product liability actions involving the same drug or device. However, these securities actions have been met with justifiable skepticism by the courts.

In April 2007, a federal district court judge in New Jersey dismissed all of the plaintiffs’ claims in a securities class action brought by Merck shareholders. The investors alleged that Merck failed to disclose the cardiovascular risks associated with Vioxx. Because those disclosures were not made, the price of Merck’s stock was allegedly inflated when the investors purchased it. The investors asserted claims under the Securities Exchange Act and the Securities Act of 1933.

Merck moved to dismiss the claims on the grounds that they were barred by applicable statute of limitations. The court agreed. The court reasoned that the plaintiffs were on notice of their claims when *The New York Times* published an article in which a Merck doctor admitted that the company knew of the cardiovascular risks of Vioxx. Because that article was published more than two years

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51 *Id.* at 11 & 17.
before the investors brought their lawsuit, the court held that their claims were barred by the statute of limitations.

Earlier in 2006, a federal district court in New York similarly dismissed a securities class action brought against GlaxoSmithKline (GSK). In *In re GlaxoSmithKline PLC Securities Litigation*, a class of shareholders alleged that GSK violated section 10(b) of the Securities Exchange Act of 1934 by making false and misleading statements about the withdrawal effects of its drug Paxil and the validity and duration of its patent for Paxil. The plaintiffs alleged that those misleading statements caused them to purchase GSK’s stock at an inflated price and subsequently caused the value of their stock to decrease.

The manufacturer moved to dismiss the claims, and the court granted the motion. The court ruled that the plaintiffs did not bring their claims within the statute of limitations contained in Sarbanes-Oxley for Securities Exchange Act claims — the shorter of five years from the occurrence or two years from the time plaintiff had actual or inquiry notice of the claim. The court reasoned that the plaintiffs were on notice of the claims because they, themselves, alleged that the revelation of these facts caused their stock to decrease more than two years prior to the institution of their action.

The court further ruled that to the extent plaintiffs’ claims were based on FCA allegations made against GSK, those allegations failed to state a claim upon which relief could be granted. The court explained that plaintiffs never alleged that GSK made any misrepresentation.

2. Class Certification of Products Liability Litigation

There has been a continuing attempt by plaintiffs’ counsel to obtain class certification of medical products liability actions despite the clear trend of court to dismiss them. There have been two significant class certification decisions in 2006 and early 2007.

First, in *Blain v. SmithKline Beecham Corporation (SmithKline)*, the district court for the Eastern District of Pennsylvania was faced with a motion for nationwide class certification of all persons whose minor children committed or attempted to commit suicide while using Paxil. The plaintiffs alleged that: 1) Paxil can cause suicidality in pediatric patients; 2) the manufacturer knew or should have known that Paxil could cause suicidality in pediatric patients; and 3) the manufacturer failed to adequately warn patients of those risks.

The court ruled that the requirements of Fed. R. Civ. P. 23 were not satisfied and, accordingly, denied the plaintiffs’ motion for class certification:

- Commonality. The court ruled that the requirement of commonality was satisfied because the plaintiffs established that there was one question of fact — whether the manufacturer had general knowledge of the risks of suicidality in pediatric patients. The court found commonality to be satisfied even though the issue of whether Paxil caused suicidality in each of the children “depends

53 *Id.* at 1.
54 *Id.* at 8.
55 *Id.* at 11.
56 *Id.* at 11.
58 Blain, 2007 WL 178564, at 5.
upon a number of individualistic factors, such as: the patient’s diagnosis; the dosage taken; the duration of treatment; the patient’s age and physical characteristics; the patient’s family, mental and medical histories and whether the patient previously suffered from suicidality."

- Typicality. The court ruled that plaintiffs failed to meet the typicality requirement. The court explained that there were numerous factual and legal differences among the other class members. For example, the court explained that even the two class representatives had different family situations and medical histories prior to taking Paxil. The court also explained that these children and their parents’ alleged different exposure to Paxil advertisements and the package insert. These differences were too “marked” for the typicality requirement to be satisfied. The court also ruled that “[a]ny similarity in legal theories among the named plaintiffs and the proposed class of plaintiffs is eclipsed by the individualistic defenses SmithKline can raise to each plaintiff’s claim.” The court explained that “[w]here the defendant can raise unique defenses to each plaintiff’s claim, typicality may not exist if the defenses could threaten to become the focus of the litigation.” Id. at 8.

- Adequacy of Representation. The court ruled that plaintiffs also failed to meet the adequacy of representation requirement. The court pointed to the same factual and legal differences that precluded a finding of typicality. Because of these differences, the class representatives had “divergent interests”, which precluded them from adequately representing other class members.

- Rule 23(b)(3). The court ruled that, in addition to not satisfying the requirements of Rule 23(a), the plaintiff failed to satisfy the predominance requirement in Rule 23(b)(3). According to the court, the common questions of law or fact did not predominate over questions affecting only the individual members. The court reasoned that “[i]ndividual issues in [drug product liability] cases invariably overwhelm common ones. This case is no different.” The court explained that specific questions of causation unique to each plaintiff precluded a finding of predominance. The court cited In Re Paxil Litigation, which ruled that “[i]ndividual questions of fact regarding causation nevertheless subvert any benefits to be gained through a class action proceeding. Whether, and to what extent, Paxil causes discontinuation symptoms varies from patient to patient. Not only do individual physiologies affect the causation issues, but so too do the underlying illnesses and medical history of each individual plaintiff.”

- Rule 23(c)(4). Plaintiffs attempted to circumvent the predominance requirement of Rule 23(b)(3) by seeking certification under Rule 23(c)(4). The court rejected plaintiffs’ contention that Rule 23(c)(4)(a) may serve as a basis to certify a class regardless of whether the claim as whole satisfied Rule 23(b)(3)’s predominance requirement.

89 Id. at 4.
90 Id. at 6.
91 Id.
92 Id. at 8.
93 Id.
95 Id. at 9.
The second ruling of interest was issued in November 2006. In *In re Vioxx Products Liability Litigation*, the district court overseeing the multidistrict Vioxx products liability litigation denied plaintiffs’ class certification motion. In maintaining that class certification is proper, the plaintiffs contended that New Jersey substantive law should be applied to all plaintiffs’ injuries and deaths. The court disagreed, ruling that the substantive law of each plaintiff’s home jurisdiction applied to the plaintiff’s claims. The court reasoned that because each plaintiff ingested Vioxx in the state where he or she resides, each home jurisdiction has a “stronger interest in deterring foreign corporations from personally injuring its citizens and ensuring that its citizens are compensated than New Jersey does in deterring its corporate citizens’ wrongdoing.” The court further ruled that “application of the laws of fifty-one jurisdictions to the claims of the proposed class creates problems for the typicality, adequacy, predominance, and superiority requirements of Rule 23.”

- Typicality. After considering the plaintiffs’ allegations, the court ruled that the proposed nationwide class did not satisfy the typicality requirement for class certification. The court reasoned that “This case involves a vast number of persons who took different dosages of [Vioxx], at different times, and possibly took [Vioxx] concomitantly with other prescription drugs.”

- Adequacy of Representation. The court also ruled that the class representatives were not adequate representatives of the class. The court explained that because of the legal differences among the class members’ claims, the class representatives have “no incentive to pursue the claims of the other class members.”

- Predominance. The court further ruled that common questions of law and fact did not predominate over questions affecting individual class members.

3. **State Consumer Fraud Statutes**

State consumer fraud statutes have provided plaintiffs with another legal theory to pursue against pharmaceutical manufacturers. Because many of these state consumer fraud statutes contain treble damages and attorneys’ fees provisions, claims for violating these statutes are often asserted in class actions.

*Adamson v. Ortho-McNeil Pharmaceuticals, Incorporated* involved a class action against the manufacturer of Ortho Tri-Cyclen, an oral contraceptive, for intentionally misrepresenting and concealing that its product and another oral contraceptive, TriNessa, are identical drugs. The named plaintiff alleged that the manufacturer violated the New Jersey Consumer Fraud Act (CFA). The manufacturer moved to dismiss the claim on the grounds that plaintiff’s allegations failed to state a claim under the statute.

The court ruled that “[t]o state a claim under the CFA, an advertisement must have “the capacity to mislead the average consumer.” The court explained that “actionable statements cannot be ‘mere puffery.’” The court ruled that the manufacturer had had no duty to “inform the public that TriNessa and Ortho Tri-Cyclen

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67 *Id.* at 456.
68 *Id.*
69 *Id.* at 459.
70 *Id.* at 460 (citing *In re Baycol Prods. Litig.*, 218 F.R.D. 197, 205 (D. Minn. 2003)).
71 *Id.*
73 *Id.* at 501.
are identical.”74 The court further ruled that none of the following statements made by the manufacturer were actionable under the CFA:

- TriNessa is “therapeutically equivalent to Ortho Tri-Cyclen;”
- “Isn’t it great to find the one that’s right for you?”
- “Myth: All birth control pills are the same. Fact: Not all birth control pills contain the same type of hormones”
- “The progestin in some birth control pills may cause unpleasant effects.”75

A decision with a different result may be distinguished readily from Blaine since that case included allegations of particular physical injuries involving alleged breaches of many applicable state tort laws, and this case involves a third-party payor alleging economic loss.

In this second decision involving a class action under the New Jersey CFA, International Union of Operating Engineers Local #68 Welfare Fund v. Merck & Company, Inc., a union, as a third-party payor sponsoring a healthcare benefits plan, brought a class action against Merck.76 The union alleged that Merck violated the New Jersey CFA by misrepresenting the safety of Vioxx and concealing information relating to its cardiovascular risks.77

The union filed a motion for class certification on behalf of itself and all third-party payors who paid for Vioxx. The trial judge granted the motion and the appellate division of the New Jersey Superior Court affirmed.78 At the outset, the court noted that its decision did not rest on the merits of the plaintiffs’ New Jersey CFA claims. The court ruled that “class certification should generally not be denied based on the complaint’s merits.”79 The court explained that “[t]he question is not whether plaintiff can prevail on its claims, but whether the prosecution and defense of these claims are best addressed on a class-wide basis.”80 The court, therefore, assumed that the plaintiffs could state a claim against Merck under the NJCFA.

The court rejected Merck’s argument that class certification was improper because each plaintiff “would have to establish that Merck’s alleged misrepresentations and omissions caused individual doctors to prescribe Vioxx and individual P&T Committees to include Vioxx on health plan formularies.”81 The court ruled that each class member did not need to prove that it specifically relied upon Merck’s representations and omissions. The court ruled that the plaintiff only needs to prove that its ascertainable loss was “attributable to conduct made unlawful by the [Act]. It is not necessary that the wrongful conduct be the sole cause of the loss, but merely that it be a cause.”82 The court further stated that “[a]lthough the causal chain appears somewhat elongated, we cannot say that the alleged fraud was not a cause of the third-party payors’ loss.”83

The court also ruled that while the amount of money each class member lost may differ, “plaintiff can prove ascertainable loss by classwide expert opinion.” According to the court, “[i]ndividual variations in the amount of ascertainable loss would not render a class action inferior to individual lawsuits because common questions of liability and the fact of ascertainable loss predominate.”84

74 Id. at 504.
75 Id. at 502-503.
77 Id. at 280-281, 894 A.2d at 1139.
78 Id.
79 Id. at 284, 894 A.2d at 1141.
80 Id.
81 Id. at 288, 894 A.2d at 1143.
82 Id. at 289, 894 A.2d at 1144.
83 Id. at 289-90, 894 A.2d at 1144.
84 Id. at 291, 894 A.2d at 1145.
Finally, the court ruled that the New Jersey CFA would apply to all claims nationwide. The court reasoned that "New Jersey's interests in this litigation, in our opinion, far outweigh the interests of all other states." The court stated that the differences between state consumer fraud laws "do not represent competing or conflicting resolutions of a particular policy issue. Rather, [the laws] reflect a legislative determination to attack the same evil."

4. Class Action Fairness Act

The Class Action Fairness Act (CAFA), which 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. The Act generally provides that:

- federal district courts have subject matter jurisdiction over any diversity (interstate) class action in which the matter in controversy exceeds $5 million, exclusive of interest and costs.
- defendants may remove class actions filed in state courts to federal courts.
- district courts may refuse to exercise jurisdiction under certain circumstances.

CAFA also attempts to shift significant class action litigation from state to federal courts. In doing so, the Act represents a positive development for pharmaceutical and medical device manufacturers.

First, the Advisory Committee on Civil Rules tasked The Federal Judicial Center (FJC) to conduct a long-term study of the impact CAFA has on federal court resources. The FJC recently issued an interim report detailing its findings to date. The report states that the number of class actions filed in federal court from January to June 2006 have increased 46 percent compared to July to December 2001. The court found that, in the sixteen months since CAFA was enacted, there was similarly a "substantial increase in class action activity based on diversity of citizenship jurisdiction." The report, however, concludes that the number of personal injury class actions has not increased since CAFA. The number of personal injury class actions "reached their lowest level in the study period in January-June 2006." Only 41 cases were filed or removed, which was down from 66 in January to June 2005. The report attributes these low numbers to strict limits on class certification in federal courts.

Second, in 2006, courts addressed CAFA in two noteworthy areas: 1) the burden of proving exceptions to the Act; and 2) the possible legislative extension of the Act.

a. Burden of Proving Exceptions to the CAFA

Several federal courts have addressed the issue of who bears the burden of proving an exception to the CAFA. The majority of courts to address the issue have ruled that a plaintiff challenging federal jurisdiction bears the burden of proving an exception to the Act.
exception to the CAFA. These courts point to the Senate Judiciary Committee’s statement that

[I]t is the intent of the Committee that the named plaintiff(s) should bear the burden of demonstrating that a case should be remanded to state court (e.g., the burden of demonstrating that more than two-thirds of the proposed class members are citizens of the forum state).

A number of other federal courts have disagreed and placed the burden of proving an exception to the CAFA on the defendant. These courts have reasoned that placing the burden on the defendant is consistent with the CAFA’s goal of establishing federal jurisdiction over class claims.

b. Proposed Expansion of CAFA

One court has recommended that Congress expand the CAFA to apply to national multi-district litigation (MDL), non-Rule 23, aggregate actions. The court explained that “As use of the class action device to aggregate claims has become more difficult, MDL consolidation has increased in importance as a means of achieving final, global resolution of mass national disputes.” The court reasoned that “Much the same concerns which animated CAFA’s preference for a single, federal forum apply to national MDL aggregate actions.”

B. New Federal Labeling Requirements

In January 2006, FDA issued a final rule amending its regulations governing the content and format of labeling for pharmaceuticals. In the preamble to the new regulations, 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. The Preemption Preamble, as some have called it, formalized the position that FDA has been advocating in amicus curiae briefs. The text of the final rule unequivocally states, “FDA believes that under existing preemption principles, FDA approval of labeling under the act, whether it be in the old or new format, preempts conflicting or contrary State law.” FDA takes the position that the FDCA establishes both a “floor” and a “ceiling” — not simply a floor as the plaintiff’s bar has contended. In support of its position, FDA states:

89 Serrano v. 180 Connect, Inc., 478 F.3d 1018, 1024 (9th Cir. 2007); Frazier v. Pioneer Americas LLC, 455 F.3d 542, 546 (5th Cir. 2006); Hart v. FedEx Ground Package Sys., 457 F.3d 675, 679 (7th Cir. 2006); Evans v. Walter Indus., Inc., 449 F.3d 1139 11th Cir. 2006); Martin v. Lafon Nursing Facility of the Holy Family, Inc., No. 06-5108 2007 WL 162813 (E.D. La. Jan. 18, 2007).
90 S. Rep. No. 109-114, at 43 (2005); Hart, 457 F.3d at 681; Frazier, 455 F.3d at 545 n.5; Evans, 449 F.3d at 1163.
93 Id. at 543.
94 Id.
FDA is the expert Federal public health agency charged by Congress with ensuring that drugs are safe and effective, and that their labeling adequately informs users of the risks and benefits of the product and is truthful and not misleading.97

FDA acknowledged that its labeling regulations might not preempt all state law claims, however, stating that the agency “believes that State laws conflict with and stand as an obstacle to achievement of the full objectives and purposes of Federal law when they purport to compel a firm to include in labeling or advertising a statement that FDA has considered and found scientifically unsubstantiated.”98 The agency identified a number of corresponding claims that it believes should be preempted by its regulation of prescription drug labeling.99 FDA explained that “state-law attempts to impose additional warnings can lead to labeling that does not accurately portray a product’s risks, thereby potentially discouraging safe and effective use of approved products.”

C. Courts’ Different Treatment of the Deference Warranted by the Preemption Preamble

Before FDA announced its Preemption Preamble in January 2006, the majority of courts had ruled that the FDCA does not preempt state tort claims. Those courts reasoned that, unlike the MDA, the FDCA does not contain an express preemption clause. Since FDA issued the Preemption Preamble, drug and device manufacturers have renewed preemption challenges to plaintiffs’ state tort claims. Manufacturers maintain that courts must accept FDA’s position and dismiss state tort claims because they seek to require manufacturers to provide additional warnings beyond those approved by FDA. Federal and state courts have had mixed reactions to manufacturers’ preemption arguments.

1. Federal Courts’ Reactions

Jackson v. Pfizer, Inc. In May 2006, one district court ruled that FDA’s requirement that prescription drug manufacturers’ use verbatim the label specified by FDA did not preempt the plaintiffs’ state law failure to warn claims.100 The plaintiffs — parents of a boy who committed suicide after taking Zoloft — alleged that the anti-depressant caused their son’s suicide and that Pfizer failed to warn doctors and patients of the increased risk of suicide associated with the drug. It is important to note that, although Jackson was decided after FDA issued its Preemption Preamble, the court did not consider FDA’s policy in rendering its decision.

Colacicco v. Apotex, Inc. Judge Baylson of the Eastern District of Pennsylvania was the first judge to consider FDA’s Preemption Preamble and its effect on plaintiffs’ state law tort claims.101 In Colacicco, a man alleged that his wife committed suicide as a result of taking Paxil. The plaintiff contended that GSK, the manufacturer of Paxil, and Apotex, Inc., the manufacturer of the generic version of the drug, failed to adequately warn physicians and patients of the risk of suicide associated

97 Id. at 3934.
98 Id. at 3935.
99 Id. at 3935-36.
100 432 F.Supp.2d 964 (D. Neb. 2006).
with the drug. The defendants moved to dismiss the plaintiff’s claims on several grounds, including that they were impliedly preempted by the FDCA and FDA regulations. FDA filed an amicus brief in which it agreed with the manufacturers that plaintiff’s claims were preempted. FDA explained that it specifically considered and rejected claims that Selective Serotonin Reuptake Inhibitors (SSRIs) — such as Paxil — caused increased suicidality.

In ruling on the manufacturer’s motion, the court considered FDA amicus brief as well as the Preemption Preamble. As an initial matter, the court ruled that “FDA's position is entitled to significant deference.” The court reasoned that “the subject matter [of the FDCA] is technical; and the relevant history and background are complex and extensive,” and we find that the FDA is ‘uniquely qualified to comprehend the likely impact of state requirements.” The court explained that although FDA supported an inconsistent position prior to 2000, FDA’s position in favor of preemption has been consistent since 2000.

The court ruled that “based on deference [to FDA's position] alone, this Court would deem any state failure-to-warn claim impliedly preempted.” In addressing the plaintiffs’ claims, the court ruled that the FDCA and FDA regulations preempted plaintiff’s failure to warn claims. The court reasoned that in approving the Paxil package insert FDA had considered the risk of suicide associated with SSRIs, such as Paxil, and concluded that there was “inadequate evidence of an association between adult use of SSRIs and suicidality.” Because FDA had considered the adequacy of the suicidality warning, Plaintiff’s state law claim, which sought to impose a stronger warning, would have been an additional or different requirement to FDA regulations.

Accordingly, the court ruled that the FDCA impliedly preempted plaintiff’s state law failure to warn claims and granted defendants’ motion to dismiss.

In re Bextra and Celebrex Marketing Sales Practices and Product Liability Litigation. The district court for the Northern District of California agreed with Judge Baylson’s decision in Colaccio. In Bextra, a class of plaintiffs alleged that they suffered cardiovascular and gastrointestinal damage as a result of taking the chronic pain relief drug, Celebrex. Plaintiffs alleged that: 1) the Celebrex package insert failed to disclose that the drug presented an increased cardiovascular risks; and 2) the manufacturer falsely advertised that Celebrex had fewer gastrointestinal problems than other pain relief drugs.

The court deferred to FDA’s Preemption Preamble stating, “The Court cannot conclude that the FDA is wrong; the FDA is the agency charged with administering the FCDA [sic] and striking a ‘somewhat delicate balance’ among its statutory objectives.” The court further reasoned that “FDA is in a better position than the court to determine whether state laws that encourage manufacturers to propose defensive labels upset the FDA’s careful balance of statutory objectives.”

In applying FDA’s Preemption Preamble to plaintiffs’ claims, the court ruled that:

102 Id. at 529.
103 Id.
104 Id.
105 Id.
106 Id. at 524.
108 Id. at 9.
109 Id.
(1) The plaintiff’s failure to warn claims based on the adequacy of Celebrex’s warning of cardiovascular risks were preempted because FDA had considered the warning and determined that there was no scientific support for requiring a heightened warning. The court reasoned that “FDA specifically considered whether Celebrex poses a greater risk of adverse cardiovascular events than other NSAIDs” and “determined that the scientific evidence does not establish that it does.”

(2) The plaintiff’s claim that Pfizer falsely claimed that Celebrex had fewer gastrointestinal side effects than other NSAIDs was not preempted. In distinguishing this claim from plaintiffs’ failure to warn claims, the court ruled that FDA has remained silent as to whether lawsuits alleging false claims in prescription drug ads are preempted. The court further reasoned that FDA did not actually review all of Pfizer’s advertisements or determine that the advertising was not misleading. Therefore, there was no conflict between plaintiffs’ claims and any FDA decision.

Perry v. Novartis Pharma Corp. Four months after Judge Baylson issued his decision in Colacicco, Judge Dalzell of the Eastern District of Pennsylvania was confronted with another drug manufacturer’s motion to dismiss failure to warn claims on preemption grounds. Perry involved failure to warn, breach of warranty and fraud claims by the parents of a girl who allegedly developed lymphoma as a result of taking Elidel to treat atopic dermatitis. Following the Eastern District of Pennsylvania’s ruling in Colacicco, Novartis, the manufacturer of Elidel, moved to dismiss the plaintiff’s claims on the same preemption grounds.

Judge Dalzell adopted a much different view of FDA’s Preemption Preamble, classifying it as an advisory opinion rather than a “binding portion of the regulations.” He stated that “the Preamble is not entitled to any special consideration in our analysis.” Judge Dalzell recognized that there are “situations in which preemption of state law claims is necessary to preserve the structure of the FDA regulatory scheme.” He ruled, however, that there is a high bar against finding preemption under the FDCA because “the FDCA provides no remedy for an injured consumer.”

He ruled that preemption is limited to “cases where the FDA has made a particular determination regarding a proposed warning.” According to Judge Dalzell, the claims in Colacicco fell into this category because the FDA had “specifically and repeatedly rejected claims that adult use of SSRIs was associated with increased suicidality.” Judge Dalzell further ruled that in the absence of a “specific FDA determination as to the sufficiency of scientific evidence to support a particular warning,” however, state law claims are not preempted.

The judge ruled that “a state law requirement to provide an additional warning would not force Novartis to choose between violating state and federal law.” The

110 Id.
112 Id. at 683.
113 Id. at 684.
114 Id.
115 Id.
116 Id.
117 Id. at 685
118 Id.
119 Id. at 687.
judge reasoned that “FDA had made no finding regarding a link between use of topical calcineurin inhibitors and increased cancer risk in children and no statute or regulation prevented Novartis from adding the warning.” The judge explained that federal law did not prohibit state law from requiring such a warning because FDA was silent as to whether such a warning was necessary.

**McNellis v. Pfizer.** Another federal district court ruled that FDA’s Preemption Preamble is not entitled to any deference because the Preamble is inconsistent with the final rule itself. In McNellis, a woman alleged that her husband committed suicide as a result of taking Zoloft. The woman alleged that Pfizer failed to warn her husband’s doctor of the risks of suicidality associated with Zoloft. Prior to FDA’s issuance of the final rule and Preamble, Pfizer moved to dismiss the woman’s state law claims on grounds that they were preempted. The court denied Pfizer’s motion. Pfizer moved to vacate the court’s ruling after FDA issued the final rule.

As an initial matter, the court ruled that FDA’s final rule does not conflict with New Jersey’s failure to warn law. The court based that ruling on its view that the final rule allowed manufacturers to add or strengthen warnings without prior FDA approval. The court then stated that “[t]he extent that the Preamble purports to forbid a manufacturer from enhancing the warning when reasonable evidence of an association of a serious hazard emerges, the Preamble is squarely contradicted by the plain language of the regulations themselves, namely 21 C.F.R. § 314.70(c)(6)(iii)(A) and 21 C.F.R. § 201.57(e).” The court ruled that the Preemption Preamble cannot be enforced to nullify FDA regulations. The court further reasoned that FDA’s position with respect to preemption has not been consistent. In reaching this result, the Court openly disagreed with the holding in Colacicco, and the court denied Pfizer’s motion to vacate its earlier ruling.

The court recognized that its ruling was at odds with other decisions on preemption. The court, therefore, granted the manufacturer’s motion to stay proceedings and allow an interlocutory appeal.

**Weiss v. Fujisawa Pharmaceutical Co.** A federal district court from Kentucky recently agreed with Perry. The court acknowledged that there are three types of deference it could apply to FDA’s Preemption Preamble: 1) the *Chevron* deference applicable when an agency is construing a statute — deference unless not founded on a “permissible” construction; 2) the deference applicable when an agency is interpreting its own regulation — deference unless the interpretation is “plainly erroneous or inconsistent”; or (3) the deference applicable to other interpretations — respect but only to the extent that the opinion has “power to persuade.” The court ruled that the preamble is not entitled to *Chevron* deference. The court ruled that the preamble would ordinarily be entitled to the deference afforded to an agency’s interpretation of its own regulations. The court, however, refused to grant the preamble that level of deference because, according to the court, FDA’s preemption position has not been consistent.

The court, therefore, applied the weakest form of deference. In doing so, the court ruled that “FDA’s position is persuasive insofar as it rejects failure-to-warn

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120 Id.
122 Id. at 6.
123 Id.
124 Id.
126 Id. at 5.
claims 1) based on conduct that allegedly occurred prior to and during the labeling approval process and 2) based on proposed warnings that FDA has specifically considered and rejected as scientifically unsubstantiated.”

2. State Courts’ Reactions

Conte v. Wyeth, Inc. A California state court agreed with the decisions in Colacicco and Bextra, ruling that FDA’s Preemption Preamble was entitled to deference and that the FDCA and federal regulations preempted the plaintiff’s state law failure to warn claims.127

Levine v. Wyeth. The Supreme Court of Vermont, however, agreed with the court in Weiss. The court ruled that the Preemption Preamble “deserves no deference.”128 The court reasoned that “[t]he regulatory framework for prescription drug labeling allows drug manufacturers to add or strengthen a warning ‘to increase the safe use of the drug product’ without prior FDA approval.”129 Accordingly, the court ruled that “it is possible for manufacturers to comply with both FDA regulations and duties imposed by state common law, and there is no ‘direct and positive conflict’ between state and federal law.”130 Wyeth recently filed a petition for certiorari with the United States Supreme Court.

As these cases demonstrate, courts are split as to the level of deference FDA’s Preemption Preamble should receive, whether the FDCA preempts state law tort claims and, if so, in what circumstances. Federal preemption remains a viable defense for prescription drug and device manufacturers confronted with state law failure to warn claims. Manufacturers are wise to stay abreast of court decisions in 2007 to monitor how and if the preemption landscape changes. In particular, litigants should monitor Wyeth’s recent petition for certiorari to see whether the Supreme Court decides to hear Wyeth’s appeal and, if so, how the Court resolves the existing split of authority.

C. The Reach of Buckman v. Plaintiffs’ Legal Committee

The United States Supreme Court’s decision in Buckman v. Plaintiffs’ Legal Committee and its progeny represent another important line of federal preemption cases that manufacturers should monitor. In 2006, there were several significant decisions interpreting Buckman and the extent of its applicability to claims against pharmaceutical and medical device manufacturers.

Buckman stands for the proposition that the FDCA and Medical Device Act (MDA) impliedly preempt state common law fraud-on-the-FDA tort claims.131 Since the Supreme Court issued its ruling in Buckman, federal courts of appeals and district courts have disagreed over the extent to which Buckman applies to various situations. One of these situations arises in lawsuits brought against prescription drug and medical device manufacturers pursuant to state immunity statutes. Some states have enacted statutes that, as a general matter, immunize pharmaceutical manufacturers from liability for a drug or device that was FDA approved as long

129 Id.
130 Id.
as the drug is labeled consistent with FDA’s approval. Some of these statutes contain exceptions that allow a plaintiff to recover compensatory and punitive damages against manufacturers if the manufacturer intentionally withheld from or misrepresented to FDA information concerning the drug. Manufacturers have challenged these statutes on the grounds that they require a plaintiff to prove that the manufacturer perpetrated a fraud on the FDA and, therefore, are preempted under Buckman.133

Until 2006, all federal courts to address the issue agreed that the fraud exception to these state statutes is preempted.134 Most notable was the ruling of the Court of Appeals for the Sixth Circuit in Garcia v. Wyeth-Ayerst Laboratories. In that case, a woman alleged that ingestion of a non-steroidal, anti-inflammatory drug caused her liver to fail. The woman asserted state failure to warn claims against the drug’s manufacturer. The State of Michigan, however, enacted a drug products liability statute that immunizes drug manufacturers from liability for damages if: 1) the drug is not defective or unreasonably dangerous; 2) the FDA approved the drug for safety and efficacy; and 3) the drug and its labeling complied with FDA’s approval at the time it left the manufacturer’s control.135 The statute provides an exception if the plaintiff could prove that the manufacturer “[i]ntentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act … , and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.”

To overcome this immunity statute, the plaintiff, herself — not the manufacturer — alleged that the statute was preempted under Buckman because it required her to prove fraud-on-the-FDA. The plaintiff contended that the offending fraud-on-the-FDA exception could not be severed from the remainder of the statute and that the entire statute must be found unconstitutional. The district court agreed that the statute’s fraud-on-the-FDA exception required proof of fraud-on-the-FDA — something that Buckman explicitly prohibited. The district court, however, ruled that the offending exception was severable under Michigan law.

On appeal, the Court of Appeals agreed, stating that “Buckman teaches that state tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims.” The court found immaterial the fact that Buckman involved state law common law fraud-on-the-FDA claims and Garcia involved a “general immunity statute with a specific exception for circumstances involving, inter alia, fraud on the FDA.” The court also agreed that the fraud exception was severable and that the manufacturer was immune from liability under the surviving portion of the statute.

132 See Mich. Comp. Laws § 600.2946(5); A.R.S. § 12-701(B).
136 Id.
137 Garcia, 385 F.3d at 965.
In October 2006, the Court of Appeals for the Second Circuit was confronted with plaintiffs’ failure to warn claims against a drug manufacturer under the same Michigan immunity statute.139 In Desiano v. Warner-Lambert & Company, it was the manufacturer who filed a motion for judgment on the pleadings on the ground that: 1) the manufacturer was immune under the Michigan statute because the drug was approved by FDA and labeled consistent with that approval; and 2) the statute’s fraud exception was preempted under Buckman. The district court agreed with the manufacturer deferring to the Sixth Circuit’s analysis of the Michigan law because Michigan was a state within the Sixth Circuit — not the Second Circuit.

In a surprising ruling, the Court of Appeals for the Second Circuit ruled that it was not “absolutely bound by the Sixth Circuit’s ruling” and proceeded to analyze the issue on its own. The court disagreed with Garcia and ruled that the FDCA did not preempt the fraud exception to the Michigan statute. The court offered three reasons for its decision — all of which turn on the court’s characterization of the plaintiffs’ claim under the Michigan statute as different than the state common law fraud claim in Buckman.

• First, the Court ruled that, unlike in Buckman, the presumption against preemption applied because the plaintiff’s cause of action “cannot reasonably be characterized as a state’s attempt to police fraud against the FDA. Instead, the Court stated that the Michigan statute was designed to “rein in state-based tort liability.”140 The statute, therefore, fell “squarely within [the State’s] prerogative to ‘regulat[e] matters of health and safety’” and was “a sphere in which the presumption against preemption applies.”141

• Second, the court reiterated its view that plaintiffs’ claims were not fraud-on-the-FDA claims like those asserted in Buckman. The court reasoned that plaintiffs’ claims were “premised on traditional duties between a product manufacturer and Michigan consumers. None of them derives from, or is based on, a newly-concocted duty between a manufacturer and a federal agency.”142 In adopting this view, the Second Circuit so narrowly construes the holding in Buckman that it essentially limits it to its facts.

• Third, the court similarly ruled that “proof of fraud against the FDA is not even an element of a products liability claim like the one here brought.”143 The court ruled that the issue of fraud-on-the-FDA only arises if the manufacturer asserts the immunity statute as an affirmative defense.144

The majority of courts to address the issue have ruled that fraud exceptions to state immunity statutes are preempted under Buckman. Manufacturers contending that these fraud exceptions are preempted, however, will be confronted with the Desiano decision. 2007 is expected to bring additional rulings on this issue.

D. Developments in Medical Device Preemption

The preemptive effect of the Medical Device Amendments is well known. In Medtronic v. Lohr, the U.S. Supreme Court ruled that state tort law claims against

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140 Id. at 94.
141 Id.
142 Id. at 94-95.
143 Id. at 94-95.
144 Id.
the manufacturer of a medical device that received 510(k) clearance by FDA are not preempted.145 The majority of federal courts, however, have ruled that state tort law claims against the manufacturer of a PMA-approved medical device are preempted.146 These courts have reasoned that the PMA-approval process is so comprehensive that it constitutes a federal device-specific requirement. FDA has stated that the PMA process “is the most stringent type of device marketing application required by FDA,” and “PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s).”147 PMA approval, therefore, denotes official approval of a medical device. These courts further reasoned that state tort law claims would impose additional or different state requirements. Accordingly, those claims are preempted.

In 2006, several other federal courts agreed that the PMA process constituted a specific federal requirement and that state law claims seeking to impose additional or different obligations on manufacturers are preempted by the MDA.148 The Second Circuit joined the majority of circuits to rule that the MDA preempts state law claims against the manufacturer of a PMA-approved medical device.149 In Riegel v. Medtronic, Inc., a patient sued the manufacturer of a balloon catheter after the balloon burst during his angioplasty, allegedly causing him to develop a heart block and require coronary bypass surgery. The patient alleged various state common law causes of action against the manufacturer, including strict liability, negligence, and breach of express and implied warranties. The manufacturer moved for summary judgment, contending that the balloon catheter was a PMA-approved device and that the state law claims against it were preempted by the MDA.

The district court agreed and granted the manufacturer’s motion for summary judgment. On appeal, the Court of Appeals for the Second Circuit affirmed. The court agreed with the majority of federal circuits to address the issue, ruling that the PMA process constitutes a specific federal requirement. The court reasoned that: 1) the PMA process “requires reasonable assurance of the device’s substantive safety and effectiveness”; 2) the PMA process denotes FDA approval; 3) “although the § 510(k) process essentially froze the status quo with respect to pre-1976 devices and their substantial equivalents, the PMA process was created as an entirely new regime for devices that were not substantially equivalent to older devices; and 4) the PMA process “expressly provides the FDA with the power to require the device to take a particular form in order to be approved as safe and effective.”150 The court, thereafter, ruled that all of plaintiffs’ state common law claims — except their claim for negligent manufacture — would impose additional or different requirements and, therefore, were preempted.

In Sulzer Hip Prosthesis and Knee Prosthesis Liability Litigation, however, the Court clarified that “state tort suits that allege, as the basis of their claim, that the

146 Cupek v. Medtronic, Inc., 405 F.3d 421 (6th Cir. 2005); McMullen v. Medtronic, Inc., 421 F.3d 482 (7th Cir. 2005); Horn v. Thoratec Corp., 376 F.3d 163 (3d Cir. 2004); Martin v. Medtronic, Inc., 254 F.3d 163 (5th Cir. 2001); Brooks v. Howmedica, Inc., 273 F.3d 785 (8th Cir. 2001); Kemp v. Medtronic, Inc., 231 F.3d 216 (6th Cir. 2000); Mitchell v. Collagen Corp., 126 F.3d 902 (7th Cir. 1997).
149 Riegel v. Medtronic, Inc., 451 F.3d 104, 118 & 121 (2d Cir. 2006).
150 Id. at 118.
approved FDA requirements have not been met are not preempted.”\textsuperscript{151} In that case, the court ruled that all of the plaintiffs’ claims against a PMA approved device — except one — were preempted. The Court ruled that plaintiffs’ negligence per se claim was not preempted because it alleged that the manufacturer failed to conform with the FDA requirements established by the PMA process.

One court, however, ruled that the MDA did not preempt any of plaintiffs’ product liability claims or warranty claims against the manufacturer of implantable defibrillators.\textsuperscript{152} In \textit{Re: Medtronic, Inc., Implantable Defibrillators Litigation}, plaintiffs alleged strict liability and negligence claims against Medtronic for injuries allegedly caused by the manufacturer’s implantable cardioverter-defibrillators (ICDs).\textsuperscript{153} The ICDs contained a defective battery that discharged prematurely. Medtronic recognized the problem, developed a new battery and submitted a PMA Supplement application for the new battery. FDA approved that application.\textsuperscript{154} Medtronic, however, did not disclose to FDA or physicians the problem with the old battery until months after the new battery was approved. Plaintiffs allege, among other things, that Medtronic, therefore, violated post-marketing regulations.

Medtronic moved for summary judgment on the grounds that the MDA preempted all of plaintiffs’ state law claims. The district court denied Medtronic’s motion ruling that plaintiffs’ claims were not preempted.\textsuperscript{155} The court first ruled that the PMA process does constitute a specific federal requirement and that common law claims that “threaten to interfere” with that requirement are preempted.\textsuperscript{156} The court rejected Medtronic’s contention that PMA approval protects it from any state law claims. The court ruled that Medtronic “failed to demonstrate how plaintiffs’ state law claims would actually impose conflicting requirements upon it.” The court reasoned that:

\begin{itemize}
  \item Plaintiffs’ state law claims that Medtronic violated FDA regulations were not preempted because the claims “merely impose parallel requirements.”\textsuperscript{157}
  \item Medtronic’s alleged withholding of “critical information” from FDA while seeking approval of the PMA Supplement was significant.\textsuperscript{158}
  \item Plaintiffs’ failure to warn claim was not preempted because FDA was not aware of the existing battery’s defect at the time it was approving the new battery.\textsuperscript{159}
  \item Plaintiffs’ implied warranty claims were not preempted because those state laws are only laws of general applicability.\textsuperscript{160}
  \item Plaintiffs’ claims that Medtronic violated state consumer protection statutes were also not preempted because they were based on promotional materials, which are not addressed by the PMA.\textsuperscript{161}
\end{itemize}

While most courts do not agree with the views expressed by the court in \textit{Medtronic}, litigants should be aware of this decision, as anomalous as it may be,

\textsuperscript{151} In \textit{re Sulzer Hip Prosthesis and Knee Prosthesis Liab. Litig.}, 2006 WL 2869547, at 7.
\textsuperscript{152} In \textit{re Medtronic, Inc., Implantable Defibrillators Litig.}, 465 F. Supp. 2d 886 (D. Minn. 2006).
\textsuperscript{153} \textit{Id.} at 899-890.
\textsuperscript{154} \textit{Id.} at 889.
\textsuperscript{155} \textit{Id.} at 894-895.
\textsuperscript{156} \textit{Id.} at 894.
\textsuperscript{157} \textit{Id.} at 895.
\textsuperscript{158} \textit{Id.}
\textsuperscript{159} \textit{Id.} at 896.
\textsuperscript{160} \textit{Id.} at 897.
\textsuperscript{161} \textit{Id.} at 898.
and the reasons why the court refused to extend the preemption protections of the PMA process.

E. The Learned Intermediary Doctrine

The majority of jurisdictions recognize the learned intermediary doctrine as a defense to products liability claims. Under the learned intermediary doctrine a drug manufacturer satisfies its duty “to warn of dangers involved in use of a product … if it gives adequate warning to the physician who prescribes it.”162 If, however, “the warning to the intermediary is inadequate or misleading, the manufacturer remains liable for injuries sustained by the ultimate user.”163

1. Some Jurisdictions Do Not Recognize the Learned Intermediary Doctrine

A 2006 Wisconsin federal court ruling demonstrated that the learned intermediary doctrine is not an available defense to manufacturers in all jurisdictions.164 In Peters v. Astrazeneca, LP, a prisoner brought a product liability action against the marketer and distributor of Prilosec — a drug designed to treat stomach acid reflux disease.165 He alleged that he lost his sense of taste as a result of taking the drug. The inmate alleged that the manufacturer knew of this risk associated with the drug and failed to warn physicians. The court ruled that neither the Wisconsin Supreme court nor any other Wisconsin appellate court has adopted the doctrine.166 The court reasoned: “The Court will not create Wisconsin law without some indication that the state’s highest court would apply the doctrine if given the opportunity to do so.”167 Accordingly, the court allowed the prisoner’s claims to proceed.

2. Off-Label Promotion

One court recently ruled that “the illegal and fraudulent off-label promotion [of a drug] would appear to preclude [a manufacturer’s] reliance on the learned intermediary doctrine.”168 That case involved product liability claims by a patient who alleges to have suffered serious injuries as a result of taking Neurontin for pain management. Because the manufacturer illegally promoted Neurontin as an “off-label” drug, the court ruled that the manufacturer “failed to reasonably warn physicians … about the dangerous propensities of Neurontin as an “off-label” drug.”169 As a result, the court ruled that the learned intermediary doctrine did not bar the Plaintiff’s claim.

3. Duty of Sales Representatives

Another 2006 ruling showed that, while still a strong defense to product liability claims, the learned intermediary doctrine is not absolute.170 In Zappola v. Leibinger,

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163 McNeil v. Wyeth, 462 F.3d 364 (5th Cir. 2006).
165 Id. at 1053.
166 Id. at 1054.
167 Id.
169 Id.
a patient brought a products liability action against the manufacturer of cement used to repair cranial defects and the medical sales representatives for failing to adequately warn of the product's risk of damage to a patient's skull. The manufacturer moved for summary judgment on the grounds that the learned intermediary doctrine insulated them from liability. The court ruled that the learned intermediary doctrine was not applicable because the warning provided by the manufacturer and the sales representative was not adequate. The court reasoned the medical sales representative failed to satisfy its duty to "make sure that the product is being used according to the way it’s supposed to be used." The decision is significant because the court examined the adequacy of a manufacturer’s warning to physicians in light of express statements made by sales representatives to these physicians.

4. Direct-to-Consumer Advertising Exception

In 1999, the New Jersey Supreme Court issued its decision in Perez v. Wyeth Laboratories, Incorporated, becoming the first court to recognize a direct-to-consumer advertising exception to the learned intermediary doctrine. At the time, manufacturers were legitimately concerned that other jurisdictions would follow suit. That has not occurred, however. To the contrary, since Perez, every jurisdiction to consider a direct-to-consumer advertising exception has rejected it.

Not only have other jurisdictions not embraced a direct-to-consumer advertising exception to the learned intermediary doctrine, but a New Jersey court has seemingly limited the exception. In Banner v. Hoffmann-La Roche Inc., the New Jersey Superior Court rejected the plaintiffs' contention that the direct-to-consumer advertising barred application of the learned intermediary doctrine. In that case, the plaintiffs alleged that Accutane caused severe birth defects in their son. The plaintiffs alleged that the manufacturer marketed the drug directly to the patient and, in doing so, failed to provide patients with adequate warnings of the risk of birth defects. Plaintiffs specifically allege that the manufacturer engaged in the following direct-to-consumer advertising: 1) supplied doctors' offices with brochures concerning Accutane; 2) placed non-branded ads in magazines; and 3) developed a Pregnancy Prevention Program.

The court ruled that “Plaintiffs, in our view, read Perez too broadly.” The Court ruled that in recognizing a direct-to-consumer advertising exception to the learned intermediary doctrine, the New Jersey Supreme Court “rested its conclusion upon the dramatic shift that had occurred in the nature of marketing of prescription medications, from advertisements directed solely to the prescribing physicians to advertisements directed to the consuming public and intended to induce the patient to request a particular medication.” According to the New Jersey Superior Court, the court in Perez “stressed the mass nature of such advertising, involving television, radio, magazine, and newspapers.” The court ruled that the plaintiffs’ allegations of direct-to-consumer advertising—informational brochures, non-branded ads, and the Pregnancy Prevention Program—“cannot fairly be equated with a course of mass advertising or be deemed direct-to-consumer advertising so as to remove

171 Id. at 5.
172 161 N.J. 1, 19 (1999).
174 Id. at 376, 891 A.2d at 1236.
175 Id.
176 Id.
the predicates of the learned intermediary doctrine.” 177 The court, therefore, analyzed the adequacy of the manufacturer’s warning to the plaintiffs’ physician and concluded that the manufacturer adequately warned of birth defects.

The court in Colacicco — the preemption decision discussed above — refused to dismiss the plaintiff’s failure to warn claims based on the learned intermediary doctrine. The court reasoned that the learned intermediary doctrine is typically an issue for summary judgment. 178 The court explained, however, “If we reached the merits of the LID issue, any direct-to-consumer (DTC) advertising exception would likely not apply. This is because, in the eight years since Perez, the New Jersey Supreme Court case making an exception to the LID for DTC advertising, was decided, no state has joined New Jersey.” 179

5. Causation

Even if plaintiffs overcome the learned intermediary doctrine, they must prove that the manufacturers’ allegedly inadequate warning caused their injuries. A recent Texas federal court reaffirmed this causation requirement. 180 That court ruled that the plaintiff must show that “a proper warning would have changed the intermediary’s decision to prescribe the product.” 181 A plaintiff that cannot come forward with evidence that an adequate warning would have changed the physicians’ decision to prescribe the product will not survive summary judgment.

VI. OTHER CASES

As we discussed in the SEC section above, BMS had faced not only SEC and Justice Department issues, but a shareholders’ derivative suit filed in the District Court of New Jersey in 2002 after disclosure of the channel-stuffing scheme. In 2006, the shareholders won that suit and the SEC and the U.S. Attorney agreed that the entire fund that they had obtained in all the actions would be repaid to the shareholders. 182 However, these were not the only problems faced by BMS. A shareholders derivative suit brought in 2000 alleged that during the time BMS was developing a drug “Vanlev,” starting as early as 1996, BMS knew it had few benefits over existing drugs, but BMS continued to promote its sales potential. In 2000, BMS announced it was withdrawing its FDA application because the drug appeared to result in angioedema, but it would be testing lower doses where the problem did not appear to be severe. The suit contended that there were still problems at the lower doses, and the drug maker did not announce this until 2002. A settlement fund of $185 million was established by BMS to settle this suit. 183 Of greater interest in this settlement is that the shareholders required BMS to publish clinical study designs and the results of clinical trials, including adverse events, for all indications of its drugs marketed in the U.S. and overseas. 184 This is an example

177 Id. at 376-377, 891 A.2d at 1236.
178 Colacicco, 432 F. Supp. 2d at 546.
179 Id. at 547 n.30.
181 Id.
182 SEC Seeks Payoffs for Bristol Investors, NEWARK STAR LEDGER, (Mar. 24, 2006).
183 $185 million set aside for drug law suit. Class action says Bristol-Myers Squibb made false and misleading claims about a heart drug, PHILADELPHIA INQUIRER, (Jan. 24, 2006).
184 Investors force BMS to post trial data for all marketed drugs, FDA WEEK, (Jan. 27, 2006).
of efforts by stakeholders to force companies to give the public access to companies’ clinical trials’ information.

The spate of shareholder derivative class-action suits alleging breach of fiduciary duty and corporate mismanagement seems to have increased during 2006. There were many cases brought during this year. Examples include a Biopure class action suit which the court found did not “piggy-back” on the SEC investigation of Biopure discussed previously in this article. The court reviewed the plaintiff’s own investigation, which supplemented that of the SEC, and determined that the plaintiffs had a basis other than the SEC complaint alone to bring the suit. The plaintiff’s alleged that the Board, defendant officers and directors knew of the FDA’s clinical hold on the proposed trials for the product and concealed that information resulting in substantial losses for the plaintiffs once the information became public.

In a similar case, the shareholders of Dura Pharmaceuticals (Dura) brought a securities fraud class action suit based on allegations that the company misled investors about the likely approval of an asthmatic spray device by concealing the fact that FDA had been requesting additional information about the device, suggesting that it was not performing as well as the company had suggested. Eventually, FDA rejected the device because of an unacceptably high failure rate and because the drug contents were not demonstrated to be stable. The suit also alleged that Dura received a number of FDA warning letters which it did not disclose at the time of receipt. All of these events ultimately led to significant declines in the value of the stock. This case has been to the Supreme Court of the United States on various procedural issues, and is still winding its way to a conclusion. By 2006, it appeared that almost any time FDA delayed a company’s product’s entry to the marketplace by requesting additional information, the likely result was the filing of a shareholder’s suit. Moreover, when companies do settle with shareholders, it frequently leads to changes in the senior executive staff, such as in the case of Lygent Pharmaceuticals which agreed to pay over twelve million dollars to settle a shareholders’ lawsuit, and subsequently the Chairman and CEO resigned.

However, not all shareholder litigation ends in victories for the shareholders. In addition to the suit brought by Merck shareholders over the withdrawal of Vioxx discussed above, in a case involving Forest Laboratories (Forest), the shareholders alleged the company misrepresented the status of the product by making representations regarding the efficacy of certain of its prescription drug products while in possession of studies which contradicted those representations. The company experienced a number of favorable FDA decisions which led to increasing share prices, increasing sales of product and increasing share prices. At some point, Forest announced that it expected slow market growth because of the

188 NPS Pharmaceuticals Faces Fraud Charges, SALT LAKE TRIBUNE, (July 14, 2006). This involves allegations that a prospectus stated Preos was superior to the bone-density promoting drug Fosamax and subsequently FDA requested more rounds of testing and the company had to lay off half its work force and otherwise reduce expenses.
189 Suits Tidying Up, NY TIMES, (Aug. 6, 2006).
public concern about the use of certain anti-depressants that it was marketing as they affected patients, especially children.

Subsequently, FDA issued a warning regarding the use of these drugs, telling physicians to watch patients closely for heightened suicide risk, and this company’s products were listed among the anti-depressants included in the warning. The court discussed the legal issue of whether the plaintiffs had made a demand on the board of directors to bring the action in the name of the corporation. The plaintiffs alleged that making such a demand would have been futile. The New York Court thoroughly analyzed the requirements for plaintiffs to make a demand on a board before they can bring a derivative law suit, determined that the plaintiffs had not met the required standards, and dismissed the suit.

In an entirely different class of suits, governments and other entities representing large groups of potential purchasers of products have engaged in efforts which parallel those of the FTC in attempting to gain access to generic drugs earlier than would be the case if the result of settlements of patent litigation prevail. For example, the Pennsylvania Turnpike Commission spearheaded a class action lawsuit against various pharmaceutical companies based on their settlement of patent litigation regarding the drug Provogil, alleging that the Turnpike had to pay artificially inflated prices because the generic competition was excluded from the marketplace.192 In a similar case that has come to a conclusion, GSK entered into a settlement with various states’ attorneys general with regard to its settlement of patent litigation over Paxil and its generic bioequivalents that involved payment by GSK to keep the generics off the market.193 GSK agreed to pay $14 million to the states in settlement of the lawsuit, without admitting any wrongdoing. In an interesting development, seventy-eight benefit plans that had opted out of this class action settlement attempted to recover damages under the Sherman Act.194 The Court took the position the purchasers were seeking to recover for the same overcharges that have been suffered by the direct purchasers and the court held they lacked standing to assert the claims.

In a continuing saga involving Tap Pharmaceuticals regarding its sales of Lupron, for which it paid $865 million in penalties in 2001, consumers and insurers brought a lawsuit to recover overpayments.195 In this case, the settlement resulted in Tap Pharmaceuticals paying $150 million to the plaintiff class. In another case, ten lawsuits were filed by union business and health plans alleging that Sanofi Aventis and BMS ended patent litigation with Apotex over Plavix which resulting in a settlement that kept the generic off the market until at least 2011.196 In a similar case, GSK settled claims that the company overcharged for its cancer drugs. It agreed to pay out over $41 million, and the company stated that other state lawsuits pending could raise the payout to $70 million.197 So, while the FTC appears to be having

194 Blue Cross and Blue Shield of Minnesota, D.C. Minnesota, Trade Regulation Reports, No. 931, paragraph 75126.
195 In Re Lupron Marketing & Sales Practice Litigation, Case No. 01CV 1086RGS (Massachusetts District Court).
196 MSNBC Associated Press from FDLI Smartbrief of 5/26/06.
difficulty changing the patent litigation settlements, private actions may be having the result of mitigating the effectiveness of these patent litigation settlements.

Finally, on this topic, there is a multi-state agreement with King Pharmaceuticals which was based on improper reporting that resulted in reduced Medicaid rebate payments. King Pharmaceuticals also was involved in securities litigation resulting from allegations it made false statements concerning its potential revenues and profitability, particularly the merger with Jones Pharmaceutical, Inc. Mediation led to settlement of $38,250,000 based on both the Medicaid rebate pricing issue and the failure to disclose these issues in SEC filings.

There are miscellaneous cases being brought under the Lanham Act where companies dispute with one another about the advertising claims for products. In one case, Tap Pharmaceuticals accused AstraZeneca of making false claims regarding Nexium which is a competitor of Tap’s Prevacid. AstraZeneca was granted summary judgment on the issue of the use of a test in advertising, but was denied summary judgment on a claim related to television advertising.

Also in a Lanham Act case, GSK gained a preliminary injunction against Merix from making verbal and pictorial advertising claims concerning its Releev medication.

Finally, in a major antitrust case involving medical devices, a hospital class action, Spartanburg Regional Healthcare System, sued Hillenbrand Company for monopolizing the market in various hospital beds and won a verdict of $316 million.

VII. CONCLUSION

The government continues to prosecute 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 programs that industry participants think are reasonable are not necessarily viewed as such by the government. It is often a good idea to have an “outsider” review proposed marketing programs to test their potential degree of risk.

The SEC continues — with FDA’s assistance — to pursue 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. The FTC is taking a harder look at false advertising and the other actions taken by companies within its jurisdiction.

Private citizens, payors, unions and state and local governments increasingly are pursuing claims against corporations using a variety of innovative approaches.

201 GSK Consumer Healthcare U.S. App. Ct., (3 Cir.) No. 05-4566, ¶75351 Trade Regulation Reports, No. 954, June 29, 2006.
Some of these approaches work, some do not, but all involve costly legal defense. Statutory and regulatory changes have resulted in changes in how pharmaceutical and medical device product liability cases are being framed —— failure to warn and off-label use claims are the norm and not the exception. Concomitantly, manufacturers are changing the way they defend these tactics. Accordingly, 2007 promises to be another interesting year of decisions with significant implications for prescription drug and medical device manufacturers.