I. INTRODUCTION

This is the fifth annual article that examines agency behavior, court decisions and legislative or other developments that affect manufacturers of pharmaceuticals, medical devices and biotechnology products (Manufacturers).

As far as continuing trends are concerned, given yet more enhancements to the False Claims Act (FCA) as part of the Patient Protection and Affordable Care Act (PPACA) discussed below, it is clear that the management of effective compliance programs should continue to be a major corporate goal for all manufacturers. Since the government has started targeting individuals as well as companies, as we predicted would happen in earlier articles, compliance may become a more personal concern to many managers. In addition, the enforcement trends by various federal agencies involving Manufacturers appear to be increasing across the spectrum of Manufacturers' activities.

The Food and Drug Administration's (FDA's) approval and clearance processes are expected to become harder to navigate. In addition to FDA being likely to maintain the flow of warning letters and other enforcement actions, the agency has noted that it may take action against individuals as well. The government's focus seems to be directed at changing the behavior of individuals. The Federal Trade Commission (FTC) and Securities and Exchange Commission (SEC) are unlikely to experience significant change regarding their regulation of Manufacturers. The FTC, as it has for many years, continues to try to prevent “reverse” payments to generic drug manufacturers by Innovator Manufacturers to diminish generic drug competition, and proposed legislation is before Congress. SEC still appears focused on the Foreign Corporate Practices Act with respect to enforcement against pharmaceutical manufacturers. As we forecast last year, shareholder suits have become fewer, and federal preemption of state law now is focused on a group of fairly narrow issues.

II. FDA ENFORCEMENT ACTIVITY

A. Overview of Agency Activities

Last year we reported on a major development in which the U.S. Supreme Court limited FDA's authority to preempt state liability laws involving drug-related issues. This decision followed an earlier decision concerning devices that affirmed FDA's authority to preempt state laws when pre-market approval devices were involved in the dispute. During 2009-2010, there has not been a similar fundamental question regarding FDA's enforcement jurisdiction, but there have been developments in the discussion of FDA's authority to preempt state laws involving drugs, which are discussed further in the products liability section below.

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There continue to be major changes in how FDA conducts its business. Last year we reported that FDA planned to increase the transparency of its operations, activities, processes and decision making. In 2009-2010, the agency made great strides in meeting that objective. Phase I, completion of which was announced on January 15, 2010, consists of a Web-based resource called FDA Basics, providing information about the agency and how it works.¹ The agency announced Phase III of the Transparency Initiative on March 12, 2010, which followed a number of public meetings with the regulated industries and which involved a request for comments on how the agency can improve training and education. The principles suggested by FDA include:

- Training and education for regulated industry about the FDA regulatory process in general and/or about specific new requirements;
- The guidance development process;
- Maintaining open channels of communication with industry routinely and during crises and
- Providing useful and timely answers to industry questions about specific regulatory issues.²

On May 19, 2010, the Transparency Task Force released the Phase II Transparency Report which contained 21 draft proposals about expanding the disclosure of information by FDA, on maintaining confidentiality for trade secrets, and securing individually identifiable patient information.³ The agency accepted comments through July 20, 2010. The report cited herein can be used to access the various documents and details about the 21 proposals.

While the Transparency Initiative for the public is not yet fully up and running, it is an issue manufacturers need to monitor, particularly to ensure the accuracy of reports of any drug and device problems identified by the agency. FDA noted that some adverse events might be reported prior to evaluation, and this is a matter about which industry should be concerned.

The agency used much of the latter part of 2009 to plan the Transparency Initiative. It issued a number of transparency-related regulatory initiatives, and meanwhile continued to develop new initiatives related to certain regulated product lines, as well as undertaking enforcement across the board. In late December 2009, FDA issued a proposed rule for increased transparency related to the use of information in clinical trials by expanding the informed consent provisions related to such trials.⁴ In January 2010 FDA initiated a plan to offer Web-based videos about the agency’s tasks, and planned to initiate on-line forums where the public may question senior officials about its responsibilities.⁵ In April 2010, the Center for Devices and Radiological Health (CDRH) added to its transparency program a range of topics providing information about CDRH processes and decisions.⁶ In March the agency published a proposed rule concerning direct-to-consumer advertising on television and radio in which it proposed standards for the disclosure of side effects and contraindications in a clear, conspicuous and neutral manner.⁷

² http://www.fda.gov/InternationalPrograms/InternationalCommunications/ucm207906.htm
³ http://www.fda.gov/AboutFDA/Transparency/PublicDisclosures/default.htm
⁵ http://fdatransparencyblog.fda.gov/2010/01/12/fda-launches-webbased-resource-to-make-information-about-the-agency-more-easily-available/
⁶ http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHTransparency/default.htm
In addition to its use of warning letters about good manufacturing processes, misleading claims and post-marketing issues that do not require a recall, all discussed below, the agency has added some new approaches that involve sharing information and advocating change without (yet) following rule making. In February 2010 the agency issued its “White Paper: Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging,” reflecting its concern about the amount of radiation patients received from computed tomography (CT) scans, nuclear medicine studies and fluoroscopy. CDRH proposed three broad initiatives:

1. Promote safe use of medical imaging devices;
2. Support informed clinical decision making and
3. Increase patient awareness;

These initiatives include, but are not limited to, manufacturers adopting equipment standards such that patients’ treatment would be appropriately justified and their doses optimized, working with the Centers for Medicare and Medicaid Services (CMS) to ensure accreditation standards included appropriate requirements and other approaches to ensuring the delivery of appropriate doses to patients.8 In March the agency held a two-day meeting with industry to discuss appropriate approaches. In April CDRH announced a Home Care Initiative concerning the use of medical devices in the home. Because CDRH is concerned that many marketed medical devices are not appropriate for use in the home environment, it is establishing a website for use by consumers and industry to identify issues and proposing the development of Guidance Documents and other information to address the problem.9 Also in April, CDRH announced the “Infusion Pump Improvement Initiative” to:

- Establish additional requirements for infusion pump manufacturers;
- Proactively facilitate device improvements and
- Increase user awareness.

The initiative included requiring additional information in pre-market submissions, a suggestion that manufacturers conduct additional assessments of new and marketed products, and other actions.10 In June 2010, the agency launched a post-marketing drug safety evaluation website in which it will be providing information about post-market safety evaluations, either 18 months after approval or after 10,000 patients have used a drug, whichever comes later.11 These new initiatives suggest the agency is taking a more proactive approach to solving perceived problems, without waiting for product recalls to initiate change.

In addition to the proposed cooperation with CMS noted above, FDA and the National Institutes of Health (NIH) have developed an initiative designed to accelerate the process from scientific breakthrough to the availability of new, innovative medical therapies for patients. The initiative involves two interrelated scientific disciplines: translational science, the shaping of basic scientific discoveries into treatments, and regulatory science, the development and use of new tools, stan-

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10 http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDeviceandSupplies/InfusionPumps/ucm202501.htm
Interagency cooperation, which we have noted in prior years with certain cooperative activities between FDA and the Federal Trade Commission (FTC), clearly is on the increase.

1. FDA Enforcement

FDA appears to have increased its direct enforcement activities in 2009-2010 compared with its level of activity in 2008-2009.

In the context of the delivery of product to market, FDA enforcement post-product approval or clearance may be thought of as starting with ensuring that the manufacture of the product meets regulatory standards. During the year under review, FDA issued warning letters concerning the failure of both drug and device companies to meet good manufacturing process requirements. For example, in August 2009, a warning letter was issued to Hospira, Inc., concerning failures related to AC power cords provided with infusion pumps. While the company had made adverse event reports to FDA, the inspection found that the company had not determined whether additional corrective or preventive action was needed, particularly as it was still providing the old power cords as replacement parts.

In February 2010 FDA issued a warning letter to Guidewire Technologies, Inc., resulting from an inadequate response to an inspection conducted in January 2010. The letter identified three failures. One was the failure to establish procedures to ensure that each production run, lot or batch of finished product meets acceptance criteria by conducting designated sterilization testing. The second was failure to ensure that when the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures. The letter noted that no validation data was available, and no product bioburden testing had been undertaken since 2006. Third was failure to conduct quality audits in accordance with established procedures to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system. Indeed, the letter noted that the Internal Audit standard operating procedure (SOP) requires annual internal audits; however, an internal audit had not been conducted on any quality system since October 2006. Not following one's own SOPs generally guarantees a negative reaction from the agency. No close-out date is recorded as of this writing. It is frequently difficult to determine the timing of a company’s response to an FDA warning letter, probably because most manufacturers respond immediately by making appropriate changes.

A warning letter sent to Philips Healthcare, Inc., identified failures to evaluate complaints properly and to comply with the medical device reporting requirements, but noted that the company’s responses to the observations were adequate. On the other hand, a problem in regard to maintaining adequate procedures for implementing corrective and preventive actions required a follow-up inspection. This follow up was required because, while the company fixed the problem for the product identified, it did not look to see if the problem could be “endemic to other

device models.”15 This approach by the agency should put manufacturers on notice to look broadly at their corrective action programs.

Warning letters are not only issued for domestic operations, but also resulting from inspections of facilities that import products into the United States. A warning letter to Baxter in January 2010 concerned a Belgium operation where the agency identified a recurrent clogging of filters without neither appropriate steps being taken to evaluate the effect on the product nor correction of the problem. Moreover, the firm failed to follow its written procedures for initiating exception reports and investigations. FDA noted the deficiencies were indicative of the quality control unit not fulfilling its responsibilities. The agency acknowledged the receipt of two written responses to the inspection report, but stated that these were insufficiently detailed for FDA to assess the quality of the corrective actions taken. The agency required a response within 15 days, which is common with most of these warning letters.16 It is important that companies’ responses to inspection reports are such that the agency can determine the problem is solved.

In May 2010 FDA issued a warning letter to an Italian company which stated it had reviewed the firm’s responses to a December 2009 inspection and noted that the company did not take sufficient corrective actions. The identified problems included microbiological contamination of drug products that were intended to be sterile. There was considerable discussion of various approaches taken by the company to assess sterility testing, which FDA found inadequate. FDA was sufficiently concerned that it stated in the letter that until all corrections have been completed and FDA has confirmed corrections of the violations and its compliance with Current Good Manufacturing Practices (cGMP), it may withhold approval of any new applications or supplements listing the company as a drug product manufacturer. It may also refuse admission of manufactured articles into the United States.

The time it takes to resolve some of these issues can be substantial, as demonstrated by a Stryker Corporation news release in March 2010, stating that it had resolved a warning letter that had been issued in 2007. Stryker noted that FDA had re-inspected the plant in 2009, all the issues had been cleared, and the warning letter was lifted in October 2009.17

In December 2009, the agency issued a warning letter to MW Laboratories Inc. resulting from an inspection in December 2008 and following actions by the company and FDA, during which FDA determined that the firm is manufacturing over-the-counter (OTC) drug products. The letter identified 11 products that are unapproved new drugs because the labeling makes it clear they are intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease, or to affect the structure or function of the body of man. Some of the products are subject to final monographs established under the OTC Drug Review, but even those products are found to be misbranded because they do not bear indications, directions and warnings required by the final monographs. The letter detailed an exhaustive review of each of the 11 products. Evidently, MW Laboratories had agreed to withdraw from the market eight of the 11 products. However, FDA noted that as late as December 2, 2009, the website was still promoting those products. The warning letter

required prompt action to correct the violations without which the agency noted it could seize the products and enjoin production and marketing. The agency noted other sanctions it could impose. It seems likely that the company has heeded the FDA warnings as its website is now unavailable.

The agency has been increasingly active in warning companies about their marketing claims and other promotional activities when they appear to go beyond the product label. Later in this article we discuss the penalties associated with promoting off-label use. These warning letters relate to expansive claims of various kinds made by both device and pharmaceutical manufacturers. A small selection of these letters includes a September 2009 letter to Baxter Healthcare Corporation stating that the Isolex device is a Class III device and does not have an approved application for premarket approval or an approved application for an investigational device exemption (IDE). The agency also stated that the package insert was false and misleading. In addition, the warning letter covered a significant number of other failures to comply with a range of FDA requirements. In a follow-up press release, Baxter stated that it was working with FDA to resolve the issues.

In April 2010 the agency sent a warning letter to St. Jude Medical, Inc., stating that as a result of an inspection in July 2009, and after reviewing the firm’s website, the agency determined the company is promoting and marketing an ablation system for the treatment of arterial fibrillation in violation of the Federal Food, Drug and Cosmetic Act (FDCA). The label of the cleared system stated the intended use of the device was for ablation of cardiac tissue during cardiac surgery. FDA also had approved an IDE application for the clinical study of a new indication for the treatment of arterial fibrillation. In a letter, the agency noted that the website made claims that the agency considered promotion of the devices for the treatment of arterial fibrillation, consequently the promotion violated the approved label since a product under an IDE cannot be promoted before FDA has approved the device for commercial distribution. During the inspection the agency also found lunch kit materials that included sales representative slides for use with physicians that unlawfully promoted these uses. Distribution of these kits prior to approval, if any, of the IDE would result in a violation of the statute.

With respect to warning letters to pharmaceutical companies, the selection identifies four types of promotional activity reviewed by FDA for which it identified problems. In April 2010 the agency notified GlaxoSmithKline (GSK) that the agency’s Division of Drug Marketing, Advertising and Communications (DDMAC) had reviewed a professional slim jim with a pull-out tab for Altabax that had been submitted by GSK to the agency. FDA stated that the slim jim is false or misleading because it broadens the indication of Altabax, makes unsubstantiated superiority claims and omits and minimizes important risk information. The agency identified various statements and graphs that implied Altabax is effective for a broader range of conditions than covered by the approved label. FDA was also critical of the superiority claims because of lack of appropriate studies. The slim jim also omitted the warning and precaution information of the approved label. FDA not only required GSK to cease dissemination of the materials, but sent corrective information to anyone to whom those materials may have been distributed.

http://www.reuters.com/article/latestCrisis/idUSN20440861
http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/UCM211596.htm
http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/UCM210240.htm
In an untitled letter to Novartis Vaccines and Diagnostics, Inc., the Office of Compliance and Biologics Quality (OCBQ) discussed its review of an audio news release for Menveo. OCBQ found that the audio news release presents the efficacy claims in a slow and deliberate manner that is understandable in terms of the pacing and articulation. However, OCBQ states the risk information is presented in a fast and inarticulate manner, at a pace that does not allow the audience to hear and process it and understand the risks. OCBQ also was concerned about whether the risk information was even presented with the audio news release because the news release said the audio was 60 seconds, but the total play time including the risk information was 119 seconds.23 Also in May 2010 FDA issued a warning letter after reviewing an ISTA Pharmaceuticals professional sales aide for XIBROM. DDMAC reviewed the sales advertisement and determined it presented unsubstantiated superiority claims, broadened the indications, overstates efficacy, omits and minimizes important risk information, makes misleading patient preference claims and omits other material facts. For example, DDMAC asserted that the sales aide used a study showing the product should be used for pain inflammation only after cataract surgery to add inappropriate claims that it was useful for any ocular pain or inflammation. The approved claim is presented in very small type compared to the broad claims. DDMAC viewed the assorted overstatements of efficacy, omission of risk information and other misleading statements to be sufficiently significant to issue a warning letter.24

On or before July 2010 DDMAC reviewed a DTC patient starter kit related to extended release tablets (Intuniv) produced by Shire Development, Inc. In this untitled letter, the package included a waiting room brochure, brochure holder and appearance guide, all of which DDMAC reviewed and determined that they impliedly overstated the efficacy of the drug and misstated various measurers of behavioral problems. The risk information does not include all of the warnings and precautions from the product insert nor do various aspects of this package relate the risk information to the particular claims being made. Shire was asked to immediately cease dissemination of these promotional materials.25

Related to these concerns, FDA launched a “bad ad program” designed to educate healthcare providers about their role in ensuring that prescription drug advertising and promotion is truthful and not misleading. The bad ad program is a DDMAC educational effort. In Phase I, DDMAC would engage healthcare providers at selected medical conventions in partnership with specific medical societies to distribute educational materials. Phases II and III will expand FDA’s collaborative efforts and update the educational materials developed for Phase I. This is part of FDA’s proactive program to mitigate problems regarding the sale of drugs, particularly in an age of OTC and DTC advertising.26

FDA issued numbers of warning letters to companies that they were not complying with the various reporting requirements for adverse events related to their medical devices or drugs. In December 2009 FDA issued a warning letter to Micromed Technology, Inc., alleging it had failed to make reports regarding adverse events involving a DeBakey VAD child heart assist device approved under the humanitarian device exemption earlier in 2009. The letter stated that there was a

24 http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/UCM204321.htm
26 http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/UCM211611.htm
failure to report an adverse event within 90 days despite Micromed’s participation in a registry and failure to implement written Medical Device Reporting (MDR) procedures for internal systems to provide timely and effective identification, communication and evaluation of events subject to a reporting requirement.27 As an example of a similar reporting issue on the pharmaceutical side of the ledger, FDA issued a warning letter to Pfizer, Inc., in May 2010 reviewing the company’s compliance with the postmarketing Adverse Drug Experience (ADE) reporting requirements of the FDCA. The warning letter gave various examples of problems identified by the inspectors and stated that the company’s subsequent response was inadequate. The letter states that the company’s rationale for failure to submit these reports included a lack of file tracking control as well as inadequate training in use of the system. FDA pointed out that Pfizer had been informed previously that the Agency had identified similar problems and the company’s corrective actions, including training, had been showed to be ineffective. The letter went on to state that other adverse events reports had been late or downgraded to non-serious without reasonable justification. The warning letter identified other failures to comply with the adverse drug reporting requirements.28

In an alternative route to trying to ensure postmarket safety and efficacy of products, FDA reviews information and provides information to the public about potential adverse events. For example, in March 2010 FDA issued a drug safety communication concerning high-dose Zolcor (Simvastatin) and an increased risk of muscle injury. The communication stated that muscle injury is a known side effect of all statin medications. The release goes on to discuss the action that should be taken by healthcare professionals as well as patients, noting that the muscle injury is a rare adverse event reported with all statins but both providers and patients should review the ongoing signs or symptoms to be aware of the potential for an adverse event.29 Similarly, in June 2010, FDA issued a drug safety communication concerning the appropriate use of long-acting inhaled asthma medications called Long-Acting Beta Agonists (LABAs). FDA noted that there are new recommendations for the LABA drug labels. In February 2010, the agency announced it was requiring manufacturers to revise the drug labels because of a risk of severe exacerbation of asthma symptoms, leading to hospitalizations, in pediatric and adult patients, as well as death in some patients. The new recommendations put significant restrictions on the use of LABAs. FDA states that it believes that the benefits of LABA use in improving asthma symptoms when used according to the new label outweigh their risks of increasing severe asthma exacerbations and deaths.30 The agency updated a February 2010 posting in June to note that it is requiring a risk evaluation and management strategy (REMS) and class labeling changes for all LABAs. The REMS require a revised medication guide written specifically for patients and a plan to educate health professionals about the appropriate use of LABAs.31

In a similar approach involving devices in April 2010, FDA issued a warning to users about faulty components in 14 external defibrillator models made by a number of manufacturers. FDA noted that there are some 280,000 external defibrillators

27 http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/UCM195995.htm
28 http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/UCM215405.htm
30 http://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm108111.htm
used worldwide in a wide variety of settings. FDA noted certain components specifically, and that the company manufacturing the faulty components had recalled two of four components and had developed modified software, though FDA’s review of the updated software indicated that all the software defects had not been identified and corrected. FDA recommended using alternative defibrillators when available and arranging for the repair or replacement of the affected models. However, if alternative defibrillators are not immediately available, FDA recommends continuing to use the affected devices if needed, because they may still deliver necessary therapy. FDA states that the potential benefits of using available external defibrillators outweigh the risks of not using any of the affected external defibrillators because of the risk of device failure. Once again, the agency is undertaking a risk analysis, and concluded that if a defibrillator was needed, and no alternative was available, it was better to use the potentially faulty defibrillator than none at all. Obviously this risk evaluation led to the conclusion not to require the manufacturer to engage in a full-scale recall but to continue to modify the software as rapidly as possible to resolve the problem.32

Product recalls are one of the most aggressive actions FDA can ask manufacturers to undertake.

The Food and Drug Administration reported more than 1,742 [drug] recalls last year, skyrocketing from 426 in 2008, according to the Gold Sheet, a trade publication on drug quality that analyzes FDA data. One company, drug repackager Advantage Dose, accounted for more than 1,000 of those recalls. Even excluding Advantage Dose, which has shut down, recalls jumped 50 percent last year.

“We’ve seen a trend where the last four years are among the top five for the most number of drug recalls since we began tallying recalls in 1988,” said Bowman Cox, Managing Editor of the Gold Sheet.33

Similarly, the number of medical device recalls is increasing. “Last year, the FDA said it recalled nearly 2,500 medical devices due to potential safety defects—about twice as many as the year before…”34 In fact, FDA does not have the authority to mandate either a drug or device recall. However, because it can impose more drastic sanctions, most companies respond to an FDA request to issue a recall.

The LIFEPAK 15 monitor/defibrillator manufactured by Physio-Control, Inc., a subsidiary of Medtronic, was recalled in March 2010 because there is a potential for the device to unexpectedly experience a series of alternative power problems, each of which may make the device inoperable.35 Examples of medical device recalls include the Physio-Control LIFEPAK 20 and LIFEPAK 20e external defibrillators/monitors recalled on May 27 because of failures on the power supply assembly which can result in an inability to deliver defibrillation therapy.36 FDA noted that nearly 43,000 devices were distributed worldwide and used by trained medical personnel

32 http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/UCM209874.htm
36 http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/UCM217933.htm
in hospital and clinic settings. FDA noted that the affected power supplies will be updated and customers are advised to keep the defibrillators in service and follow recommended daily Operator Checklist steps while service updates are scheduled. Even though this was a Class I recall, it appears that recall was intended to get attention, since the product is not actually being taken out of treatment settings.

In March 2010, FDA issued a copy of the Medicine Company's press release concerning its announcement that it is voluntarily expanding the recall of Cleviprax injectable emulsion to four additional identified lots, and FDA instructed anyone with affected lots to arrange for its return. The problem causing the recall was visible particulate matter primarily made up of sub-visible inert stainless steel particles that could theoretically reduce blood flow in capillaries, cause damage to some tissues and initiate acute or chronic inflammatory reactions.37

Another device recall with a Class I level of concern involved a May 2010 recall on specified lots of GE “Aisy” and “Advance anesthesia systems.” The control board wiring harnesses have a defect that can cause a machine to unexpectedly shut down, terminating ventilation, anesthetic delivery and potentially patient monitoring. In its notice, FDA encouraged professionals to report adverse events related to the use of these products to FDA’s MedWatch Safety Information and Adverse Event Reporting Program.38 Also, in May 2010 FDA notified healthcare professionals not to use certain intravenous medications manufactured by Claris. These involve intravenous bags in which foreign floating matter was identified. Because foreign matter should not be present in a sterile injectable product, Claris initiated a recall of all lots of these products.39 Hospira initiated a voluntary recall of severable injectable products because the containers may contain particulate matter primarily made up of some visible inert stainless steel particles.40 There seems to be a more general problem with the manufacturing process since Hospira also undertook a product recall because of stainless steel particles in certain lots of propofol and lycosin, noted in a product recall in October 2009.41 This is an expanded recall, not identified in a March 2010 recall.42 The company stated that anyone with existing inventory should stop the use and distribution, quarantine the product immediately and arrange for the return of the products.43 An interesting recall with no known particular health effects of the compound eventually causing a problem was the McNeil and FDA recall of Tylenol arthritis pain caplets for which consumers reported an unusual odor associated with nausea, stomach pain, vomiting and diarrhea. This odor is believed to result from the breakdown of a chemical used to treat wooden palettes to transport and store the packaging materials. The recall asked consumers to stop using the product and contact McNeil for instructions on refunds and replacements.44

As we move to the more vigorous enforcement arenas, an interesting new approach taken by FDA in November 2009 was the issuance of warning letters to 22

37 http://www.fda.gov/Safety/Recalls/UCM204997.htm
40 http://www.fda.gov/safety/medwatch/safetyinformation/safetyalertsforhumanmedicalproducts/ucm215033.htm
42 Supra, note 40.
43 Supra, note 40.
website operators intended to curb illegal sales of unapproved or misbranded drugs to U.S. consumers. None of the websites are for pharmacies in the United States or Canada. The agency noted that in many cases the Internet service providers and the name registries may have grounds to terminate the websites and suspend the use of the Web names. This action was taken as a result of coordination among international agencies called the International Internet Week of Action. It involves cooperation of the national health and law enforcement agencies of 24 participating countries, the International Criminal Police Organization and the World Health Organization’s International Medical Products Anti-Counterfeiting Task Force. The activities include seizure of shipments of pharmaceutical products moving through certain international mail facilities and express courier hubs.45

In June 2010, after several months of working with Beckman Coulter, Inc., FDA sent a warning letter that it was marketing the AccuTnl on the Access Immunoassay System in the United States, without market clearance or approval, in violation of the FDCA. The device has been sold without premarket approval or an IDE. Moreover, the company did not notify the agency of its intent to introduce the device into commercial distribution as required by section 510(k) of the FDCA.46 The FDA announced Beckman Coulter had undertaken a Class II recall of this test,47 and Beckman Coulter continues to work with FDA to establish a pathway to market clearance status for use of the test in the United States.

Finally, as an example of the ultimate enforcement action FDA can take, it instructed U.S. Marshals to seize $39,000 worth of products labeled as cyanide antidote kits from Keystone Pharmaceuticals in Laguna Hills, California. FDA had sent a warning letter to Keystone’s contract manufacturer, and had twice verbally warned Keystone not to distribute the unapproved drugs. The agency stated the kits were misbranded because their labeling did not contain adequate directions for use and they were manufactured under conditions not in compliance with current good manufacturing practice.48 FDA advised purchasers to return product to the manufacturer. In another seizure, U.S.Marshals seized more than $346,000 worth of Fast Size Extender devices and Fast Size EQM Erectile Quality Monitor devices for which various healthcare claims were made and which were not approved or cleared for marketing by FDA, and were manufactured under conditions that did not meet current good manufacturing practices. During an inspection, the inspectors noted deviations from the cGMP regulations as well as the fact that the devices were not listed with FDA, and the firm failed or refused to furnish materials or information regarding the devices in accordance with federal regulations.49

In an interesting new development, FDA sent a letter to Pathway Genomics Corporation which markets a personal genetic health report based on a home-use saliva collection kit. The report evidently indicates customary and personal genetic health results for more than 70 health conditions. FDA sent an untitled letter to Pathway stating that it does not appear to have FDA clearance or approval, and if it believes it does not need it, it should provide FDA with a basis for that determination.50 Since Pathway was about to enter into an agreement with Walgreens to sell the Pathway kit in its stores, this letter from FDA was an interesting “shot across the

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45 http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/UCM191330.htm
47 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres.cfm?id=89075
48 http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/UCM220001.htm
50 http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/UCM211866.htm
bow.” Pathway and Walgreens agreed that Walgreens would not continue developing the sales program. In June 2010 FDA sent untitled letters to five corporations concerning genetic testing using alleged OTC products, and in July FDA sent similar letters to 14 more companies. The genetic testing initiative appears to be one that FDA will be pursuing for some time to come. In July the U.S. Government Accountability Office (GAO) released a report titled “Direct Consumer Genetic Tests: Misleading Test Results are Further Complicated by Deceptive Marketing and Other Questionable Practices.” FDA undertook investigative reporting with regard to four DTC testing companies and found unpredictable results.

**B. FDA Caselaw**

In a case involving an issue of first impression, the Ninth Circuit Court of Appeals determined that a plaintiff’s allegation of a Lanham Act violation, where FDA had affirmatively not acted on various complaints the plaintiff had previously made with respect to a competitive marketing of a device, was precluded by the statutory provision prohibiting private enforcement of the Food, Drug and Cosmetic Act. In this case, PhotoMedex, a direct competitor of Ra Medical Systems, Inc., alleged that “Ra Medical engaged in misleading advertising in violation of the Lanham Act by representing its dermatological laser product had been approved by FDA.” Ra Medical had obtained a licensing agreement to sell a third company’s laser and did not submit a 510(k) application for the device, taking the position that it was substantially equivalent to the device that it had licensed. The court pointed out that PhotoMedex had complained to FDA on various occasions that the product had been promoted without 510(k) clearance, but FDA never reached such a conclusion. At one point FDA inspected the manufacturing plant, specifically discussing the clearance issue with the competitor, but took no further action. The court took the view that FDA had the opportunity to take enforcement action against Ra Medical but never opted to do so. Indeed, because the licensed product had clearance, and the manufacturer took the position that its product was substantially equivalent to the already approved device, the mere fact that FDA had not affirmatively approved the device did not mean it did not have clearance under the approval of its predecessor. Consequently, under these facts, PhotoMedex was not permitted to circumvent FDA’s exclusive enforcement authority by attempting to impose a Lanham Act theory.

In an enforcement action regarding an unapproved biofrequency device, trial testimony revealed the defendant, James Folsom, had sold to distributors and to retail customers over $8 million of devices. The devices were manufactured in a location which the defendant failed to register as a device manufacturing establishment. The defendant used false names when selling the device and used various means to conduct his business in an effort to avoid detection by FDA. The devices were marketed for investigational purposes with the intent of deceiving consumers into the false belief that the defendant had an IDE from FDA. This was a criminal case developed by the FDA Office of Criminal Investigations and prosecuted by the

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51 http://www.huffingtonpost.com/2010/05/13/walgreens-will-not-stock_n_574538.html
52 http://www.genomeweb.com/dxpgx/fda-warns-dtc-genomics-firms-genetic-tests-are-not-ldts-may-need-clearance-or-ap
54 http://www.gao.gov/products/GAO-10-847T
55 Ibid.
56 Ibid.
United States Attorney’s Office. The defendant was convicted on 26 felony counts relating to the sale of the unapproved medical device. In February 2010, the U.S. Attorney announced that Folsom was sentenced to serve 51 months in custody and a $250,000 fine following his conviction on the 26 felony counts and a commission of offenses while on pretrial release. The court also ordered the destruction of more than 450 devices seized by the government during the execution of a search warrant at a self-storage unit used by the defendant.

Cases involving preemption and similar matters are discussed under the products liability section of this article.

III. FRAUD, ABUSE AND THE FCA

Legislative, agency and enforcement developments in 2010 will shape your business in court for years to come. Congress passed and the President signed amendments to the FCA and the Anti-Kickback Act (AKA) that will affect all pharmaceutical and medical device manufacturers, and amendments to the Exchange Act of 1934 that will affect all publicly traded life science companies, especially those that promote their products internationally. On the regulatory front, FDA breathed new life into the Responsible Corporate Officer (RCO) doctrine, requiring in-house and outside counsel to consider how best to “Park-proof” senior executives. On the enforcement front, we saw a valiant First Amendment fight fade and a new prosecution trend emerge based on cGMP violations. This combination of initiatives raises new risks for pharmaceutical and medical device manufacturers, and will require ever-increasing vigilance by persons with legal, compliance, audit, supervisory or governance responsibilities. We end with a recommendation for how best to address these new risks. An amendment to the corporate culpability provisions of the U.S. Sentencing Guidelines which took effect on November 1, 2010, encourages companies to vest the individual with operational responsibility for compliance and ethics with “direct reporting obligations” to the company’s board. The ability and requirement to report directly to a board will likely prompt individuals responsible for the report to develop more robust internal compliance processes, which, in turn, will have the collateral effect of reducing risk.

A. Legislative Action

Legislative action in 2010 will drive government enforcement proceedings in court for years to come. The Patient Protection and Affordable Care Act (PPACA)—signed into law by President Obama on March 23, 2010—expanded the reach of both the FCA and the AKA. Just a few months later, Congress included whistleblower provisions in the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank) legislation. These new statutes combine to fortify the government’s already powerful array of weapons to combat fraud and abuse.

1. The False Claims Act

PPACA expanded the reach of the FCA in two significant ways: it narrowed the “public disclosure” bar to FCA claims, and effectively reversed judicial precedent that had limited the definition of a “false” claim.


58 Title 31, United States Code, Sections 3729 et seq.
a. PPACA Constricts “Public Disclosure” Bar to Whistleblower Actions

Section 3730(e)(4) of the FCA precludes qui tam relators from bringing actions based on “publicly disclosed” allegations or transactions. The provision goes on to define what is meant by “public disclosure,” and, as a result, the effect of this bar depends completely on the scope of those words. Justice Scalia recently complained about the “really terrible text” of the definition during oral argument in *Graham County Soil & Water Conservation District v. United States ex rel. Wilson* (U.S., No. 08304, Nov. 30, 2009). The language did not make clear whether disclosures of fraud made in and during state-level “administrative” reports, hearings, audits or investigations represented “public disclosures” of fraud that barred qui tam actions, or whether instead the bar applied only to prior federal administrative proceedings. Justice Scalia asked the whistleblower’s attorney in Graham County what ruling the Court had to adopt to prompt Congress to go back and fix the text—ruminating out loud that the Court should find for the state water district and against the relator—to propel Congress to act.

On March 30, 2010, the Court ruled as Justice Scalia had wanted, and in the process limited the universe of eligible qui tam relators. The Graham County opinion interpreted the reference to “administrative” reports to include state and local proceedings as well as federal sources. This definition precluded the relator’s claim because she had filed her suit in the wake of a state audit report.

In what surely represents one of the shortest lived opinions ever written, Congress preempted the Court’s ruling seven days before it was handed down. Congress included provisions in PPACA that explicitly defined the term “public disclosure” in a way that limited the scope of the FCA’s “public disclosure” bar. Under a new section 3730(e)(4), only public disclosure of allegations or transactions in “federal” proceedings or in “federal” reports, hearings, audits and investigations could bar a whistleblower action. State audit reports and proceedings no longer presented a hurdle.

Congress further expanded the reach of the FCA by also modifying the “original source” provisions of the “public disclosure” bar. An “original source” can bring a claim even after a “public disclosure” if the original source meets certain criteria. Under the old provisions, the original source had to have “direct and independent knowledge of the information” and had to voluntarily provide the information to the government before filing the claim. The new provisions drop the requirement of


60 New section 3730(e)(4) provides as follows:

(A) The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed—

(i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;

(ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or

(iii) 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.

(B) For purposes of this paragraph, “original source” means an individual who either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.
“direct” knowledge, and in its place require only that the independent information “materially adds” to the public information. This modification opens the door for private auditors and investigators to collect, analyze, package and submit public information, and still qualify as an “original source” if they offer material assistance to the government.

Yet a third amendment to the “public disclosure” bar shifts the balance of power between the judiciary and the U.S. Department of Justice (DOJ) with respect to who enforces the bar. The old provision created a jurisdictional bar to claims brought after “public disclosures.” As a procedural matter, defendants could file a motion to dismiss for want of jurisdiction, but the courts decided the question. The new provision deletes the jurisdictional bar and instead directs courts to dismiss actions that follow public disclosures unless DOJ objects—putting the prosecutor in the driver’s seat.

b. PPACA Expands the Reach of the FCA

Until now, pharmaceutical and medical device companies could defend an FCA allegation on the ground that a claim for payment was literally true—that the items or services for which the government had been billed were actually provided. PPACA amended the AKA to add a new subsection (g) to 42 U.S.C. 1320a-7b. The new subsection provides that a claim that includes items or services resulting from a violation of the AKA now constitutes a false or fraudulent claim for the purposes of the FCA. In other words, if a pharmaceutical or device manufacturer offers or pays remuneration to healthcare provider A to induce a referral in violation of the AKA, and healthcare provider A then provides bona fide medical services either to hospital B or patient C and thereby directly or indirectly causes the submission of a claim for reimbursement under Medicare or Medicaid or some other federal healthcare program, that claim will violate the FCA and the pharmaceutical or medical device manufacturer that paid the remuneration will stand liable.

2. PPACA Dilutes the Intent Requirement for Liability under the AKA

PPACA also amended the AKA to lower the scienter requirement enunciated by the Ninth Circuit in its landmark Hanlester Network opinion. The amendment adds a new subsection (h) to 42 U.S.C. 1320a-7b that attempts to clarify the intent element. While the statute continues to require the government to prove that a defendant acted “knowingly and willfully” with respect to an offer or payment of remuneration, the amendment provides that a person need not have actual knowledge of the AKA or specific intent to violate the act. We note the apparent conflict between these two standards, and trust that the courts will have much to say about the application of the new intent element. As a practical matter, however, this amendment will only embolden the government to pursue AKA prosecutions.

B. Dodd-Frank Legislation

Just four months after enacting PPACA, President Obama signed the Dodd-Frank Wall Street Reform and Consumer Protection Act (the Dodd-Frank legislation or act) on July 21, 2010. While the act focuses on reforming the financial services industry, section 922 creates a whistleblower program that will profoundly

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61 Hanlester Network v. Shalala, 51 F.3d 1390 (9th Cir. 1995).
impact the compliance programs of all publicly traded companies (and privately held companies that the SEC regulates). The program requires the commission to pay an award to whistleblowers who voluntarily provide original information about violations of the federal securities laws. When the whistleblower’s information leads to a successful judicial or administrative action, the commission must award not less than 10 percent and not more than 30 percent of any monetary sanction exceeding $1,000,000.

The universe of potential whistleblowers under the Dodd-Frank legislation is vast. The statute defines eligible whistleblowers by excluding a limited group and leaving open the possibility of a claim—including an anonymous claim—from all other sources. The only persons who may not seek an award are regulators, law enforcement personnel, auditors and anyone convicted of a crime in connection with the matter. The statute fortifies this initiative by including anti-retaliation provisions, and gives federal district courts original jurisdiction despite any binding arbitration provisions that may apply. The whistleblower protection provisions also require the SEC to guard the identity of anonymous whistleblowers to the extent possible.

The SEC issued proposed rules implementing the whistleblower provisions on November 3, 2010, and solicited public comments by December 17, 2010. The proposed rules encourage whistleblowers to use internal company reporting processes, but still encourage tips, complaints and referrals (TCRs) regardless of whether a company has a robust compliance program. They even reward whistleblowers who are employed as corporate compliance professionals if their entity does not disclose information to the commission within a reasonable time or proceeds in bad faith. The “take-away headline” for this new program is that companies will feel more pressure to self-disclose than ever before.

Pharmaceutical and medical device manufacturers will want to pay special attention to the impact that the new whistleblower provisions will have on the accounting provisions of the Exchange Act, which were designed to operate in tandem with the anti-bribery provisions of the Foreign Corrupt Practices Act (FCPA). The accounting provisions require corporations to (a) make and keep books and records that accurately and fairly reflect the transactions of the corporation and (b) devise and maintain an adequate system of internal accounting controls. These three statutory schemes—the FCPA, the accounting provisions of the Exchange Act and the whistleblower provisions of the Dodd-Frank legislation—will operate together to induce employees of publicly traded companies to provide original information about potential FCPA violations directly to the SEC, possibly at the expense of internal reporting channels hosted by corporate compliance programs. Corporate compliance officers will have to work harder than ever before to train and educate their workforces, and to enlist their cooperation in reporting suspect conduct internally first.

62 H.R. 4173, section 922 amends the Exchange Act of 1934 to add new section 21F, which sets forth the whistleblower program.
63 Section 922(c)(2).
64 Section 922(b)(1) and (2).
66 Proposed 17 C.R.F. §§ 240.21F-4(b)(5)-(7), 240.21F-9.
C. FDA's New Enforcement Agenda

FDA gave notice to the pharma and medical device industries in March 2010 that the agency would use the RCO doctrine to enforce compliance with healthcare program fraud and abuse regulations. By letter to Senator Grassley dated March 4, 2010, FDA Commissioner Dr. Margaret Hamburg announced that her Office of Criminal Investigations (OCI) would use the doctrine in “appropriate” cases to “hold responsible corporate officials accountable” through misdemeanor prosecutions. Dr. Hamburg also advised Congress that FDA would measure the efficacy of its enforcement effort in part by tracking the number of RCO prosecutions it brings.

This initiative does not come as a surprise. FDA has locked horns with several former pharmaceutical executives in recent years to establish its authority to exclude executives convicted under the RCO doctrine from participating in federal healthcare programs for career-ending periods of time. These twin policies—increasing the number of RCO prosecutions and excluding executives—represent the dawn of a new era in FDA compliance enforcement.

FDA (at the urging of Congress) embarked on this course because it has determined that large fines and detailed Corporate Integrity Agreements (CIAs) have not sufficiently deterred illegal promotional activities in the life sciences industry. Attorneys representing corporations and senior executives will want to assess whether their current compliance processes meet the governance obligations required by the RCO doctrine, and the possible collateral consequences that may follow if they do not.

Review of the still pending Purdue Frederick exclusion proceedings provides insight into how FDA’s new RCO doctrine policy may play out. In the criminal proceedings that preceded this long-running exclusion action, Three Purdue officers were sentenced in 2007 to three years’ probation, a $5,000 fine and a $25 special assessment. They also disgorged $34.5 million collectively, and had paid those monies—which represented the bonuses Purdue had paid to them—to the Virginia Medicaid Fraud Control Unit. Purdue funded these payments pursuant to previously existing board resolutions which bound the company to indemnify officers.

The Department of Health and Human Services (HHS) Office of Inspector General (IG) notified the Purdue executives after they were sentenced that the IG would exclude them from all federal healthcare programs for a period of 20 years—17 years above a presumptive three-year term that applied. Each defendant appealed, first to an administrative law judge, and then to the HHS Department Appeals Board (DAB). During the course of this process, the exclusions were reduced to 12 years, in part by voluntary reconsideration by the IG, and in part by order of the DAB.

The executives appealed the DAB’s ruling to the U.S. District Court for the District of Columbia on the ground that the IG lacks the authority to exclude them based on their RCO convictions. The District Court affirmed the DAB by Memorandum Opinion dated December 13, 2010, from which the officers have since appealed to the United States Court of Appeals for the District of Columbia Circuit. A motion for oral argument is pending as of the date of this article.

A brief review of the facts of the criminal case provides context for the issues at stake. The officers signed an Agreed Statement of Fact as part of their plea agreements. The Agreed Statement of Facts described a scheme by which “certain
Purdue supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications … over a period of five-and-a-half years.”71 The Agreed Statement of Facts also defined a responsible corporate officer as an individual “who had responsibility and authority either to prevent in the first instance or to promptly correct certain conduct resulting in the misbranding of a drug introduced or delivered for introduction into interstate commerce.”72 Although the executives did “not agree that they had personal knowledge of all of the matters set forth in” the Agreed Statement of Facts, they acknowledged that they “were responsible corporate officers of Purdue” and that “the Court may accept these facts … as part of the factual basis supporting the guilty pleas.”73

On appeal to the District Court, the executives opposed their debarment on the ground that the two permissive exclusion triggers on which the IG relied do not apply. The IG excluded the executives based on their conviction of a misdemeanor “relating to” fraud and “relating to” the unlawful distribution of a controlled substance. The executives asserted that their RCO misdemeanor convictions did not “relate to” fraud or the distribution of a controlled substance because their convictions involved no bad intent and no bad conduct by them. They were convicted on strict liability grounds by dint of their positions alone. Finally, assuming for the sake of argument that an RCO misdemeanor conviction could “relate to” bad conduct by others, the executives asserted that their strict liability convictions on the record of their case do not establish the presence of aggravating factors that warranted exclusion for periods of time longer than the presumptive three-year term. The record in their case, they argued, did not establish that the improper marketing by Purdue employees influenced prescribing physicians or harmed any person or healthcare program. The $34.5 million disgorgement payments they made to the Virginia MFCU Program Fund (for which Purdue indemnified them) did not stem from any losses suffered by the Virginia Medicaid program.

The government’s response in the Purdue appeal to the District Court serves as a clear signal to the industry. The government intends to exclude individuals who fail to act in the face of a duty if the inaction “relates to” any acts referred to in the exclusion statute. In the Purdue case, the executives’ guilty pleas “related to” and arose from their failure to prevent or to promptly correct the company’s misbranding of OxyContin and its unlawful distribution of a misbranded drug. Aggravating factors applied, moreover, because the acts resulting in the conviction caused or reasonably could have been expected to cause a financial loss of $5,000 or more to a government program and were committed over a period of one year or more. The government has pointed to the $34.5 million the executives had disgorged and to $160 million the company had paid in restitution to support the IG’s conclusion that the executives’ omissions had caused a financial loss significantly more than $5,000. The executives had acknowledged, moreover, in the Agreed Statement of Facts, that Purdue employees had engaged in the scheme to misbrand OxyContin over a period of five years, far in excess of the one-year threshold for an enhanced sentence. Finally, the government relied in substantial part on the degree of deference the courts afford to agencies vested by Congress with regulatory responsibilities. The District Court’s affirmance of the DAB’s ruling will, for the time being, embolden FDA in its new focus on RCO doctrine prosecutions. The latest round in this long-running skirmish provides executives in the pharma and medical device industries an even greater incentive to give high priority to their obligation to detect and immediately respond to information regarding possible misbranding or adulteration of the products they sell.

71 Id. at ¶ 20.
72 Id. at ¶ 11.
73 Id. at ¶ 46.
D. FDA Court Actions Break New Ground

The past year brought a string of large pharmaceutical and medical device settlements in actions brought by the DOJ, FDA and HHS-OIG. We feature four court proceedings that, either individually or in combination, broke new legal ground.

1. A Valiant First Amendment Fight Fades—For Now

On October 1, 2009, Botox manufacturer Allergan filed a complaint in the United States District Court for the District of Columbia by which it sought to establish the right of pharmaceutical manufacturers under the First Amendment to transmit truthful and non-misleading information to physicians regarding the safe and effective use of FDA-approved drugs for off-label indications. Allergan argued that (a) FDA had defined the term “labeling” too broadly in its regulations and had far exceeded the definition of “labeling” set forth in the FDCA, and (b) the FDCA prohibited only “false or misleading” labeling, not truthful, non-misleading information about off-label uses.

This valiant and eagerly watched effort to establish the boundaries of free speech came to an abrupt end on September 1, 2010, when DOJ announced a settlement of a parallel civil and criminal investigation of Allergan's promotional practices. The resolution included an agreement by Allergan to withdraw its complaint for injunctive relief, to plead guilty to a misdemeanor violation of the FDCA stemming from its misbranding of Botox for headache, pain, spasticity and juvenile cerebral palsy, to pay $600 million in fines, forfeiture and penalties, and to enter into a CIA. The $600 million financial penalty was composed of a criminal fine and forfeiture totaling $375 million and a civil settlement with the federal government and the states in the amount of $225 million. The civil settlement resolved three lawsuits filed by qui tam relators under the FCA in the Northern District of Georgia.

While Allergan lost this battle, the legal theories which it advanced in the action it brought for injunctive relief resonate. Perhaps, on a future day with slightly different facts, another manufacturer will succeed.

2. The Rise of Enforcement Actions Based on cGMP Violations

The other significant development we saw in court during the past year was a rise in cGMP enforcement actions and a gradual increase over time in the penalties the government sought and obtained.

a. The FDA Recalls Baxter Infusion Pumps

Infusion manufacturers have struggled to correct software defects, user interface problems and mechanical and electrical failures for years. These and related problems prompted FDA to seize a number of pumps manufactured by Baxter Healthcare Corp. (Baxter) in 2005, and led to a consent decree between the company and the government the following year. Under the agreement, FDA prohibited new sales of the affected Baxter infusion pumps unless Baxter corrected the software defects and met certain other conditions.
sales until the company corrected the problems, but permitted Baxter to continue to service pumps already in use. The problems continued to persist, however, and Baxter acknowledged on April 8, 2010, that it would not complete a new round of corrections until 2013.

FDA refused to accept that schedule, and, on April 30, 2010, ordered the company to recall and destroy all the infusion pumps at issue. FDA also ordered the company to provide refunds to customers or replace pumps at no cost. FDA noted at that time—without attributing the data to any one manufacturer—that it had received more than 56,000 reports of adverse events associated with the use of infusion pumps over the past five years. Those events included serious injuries and more than 500 deaths, again not attributed to Baxter.

FDA’s announcement of the Baxter recall did not address the question whether Baxter will forfeit a $20 million penal bond it had posted in connection with the 2006 consent decree. The agency also made no mention of an ongoing investigation, suggesting that Baxter’s executives do not face the risk of RCO liability for a failure to correct problems promptly. As the reader will see below, this resolution of the infusion pump problem has begun to look relatively fair.

b. Genzyme Plant Shuttered

FDA appears to have taken a much harder line with pharmaceutical manufacturers in connection with cGMP failures. On May 24, 2010, Genzyme Corp. entered into a consent decree by which it resolved a longstanding FDA inspection of its Allston, Massachusetts, plant. The regulatory action began with a plant inspection in September 2008, then progressed to a warning letter in February 2009, then escalated to a Form 483 list of observations in November 2009, and then concluded with the May 2010 consent decree. The observations in the Form 483 focused on the company’s quality procedures for responding to foreign particles that had found their way into the company’s products during the manufacturing process. Under the terms of the agreement, Genzyme will correct manufacturing quality violations at the plant and disgorge $175 million in profits from the sale of four products made there. The company also agreed to adhere to a strict timetable to bring the plant in line with quality requirements, and to pay additional fines if it fails. The decree was agreed to by Genzyme, its Chief Executive Officer, its Senior Vice President for Manufacturing Sciences and Technical Operations and its Senior Vice President for Global Product Quality. These executives have a substantial incentive to ensure that the remediation effort succeeds in light of FDA’s recent emphasis on RCO prosecutions.

c. GSK Subsidiary Charged with Felony Violation

In what may represent an upward trend, FDA extracted even harsher terms later this year in connection with cGMP violations by another pharmaceutical manufacturer. On October 26, 2010, the government reached an agreement with GlaxoSmithKline PLC (GSK) to settle a long-running investigation of a plant in Cidra, Puerto Rico, that had been run by an indirect subsidiary named SB Pharmco Puerto Rico, Inc. (SB Pharmco). Under the agreement, SB Pharmco agreed to plead guilty to a felony violation of the FDCA based on its failure to abide by cGMP standards and its introduction of adulterated drugs into interstate commerce with intent to defraud and mislead. The resolution included a criminal fine and forfeiture

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totaling $150 million and the settlement of a *qui tam* action filed in the District of Massachusetts under the FCA and related state claims for $600 million. In sum, we have seen in the span of a year a progression in FDA’s response to cGMP violations, from recall (Baxter) to plant shut down (Genzyme) to felony conviction and substantial financial penalty. Compliance officers will want to assess the strength of their Quality Systems in the year ahead.

### E. U.S. Sentencing Guidelines Amendment

We close this section with a final recommendation that stems from an amendment to the U.S. Sentencing Guidelines that took effect on November 1, 2010. The amendment adds a safe harbor to the Culpability Score provisions of the Guidelines that apply to convicted corporations. The amendment encourages companies to vest the individual with operational responsibility for compliance and ethics with “direct reporting obligations” to the board or an appropriate subgroup of the board, such as the audit committee. The application note that accompanies the amendment defines “direct reporting obligations” as “express authority to communicate personally to the governing authority or appropriate subgroup thereof (A) promptly on any matter involving criminal conduct or potential criminal conduct and (B) no less than annually on the implementation and effectiveness of the compliance and ethics program.”

The Sentencing Commission has encouraged companies to adopt this provision to decrease the odds of a systemic compliance failure. The creation of this direct reporting line, however, has ramifications for the RCO doctrine as well. The obligation to report directly and annually to the board, if granted to a qualified compliance professional, will drive the compliance officer to develop processes to support the report. These processes, in turn, should both detect problems at an early stage to permit their correction and deter their formation in the first instance. These processes will also reinforce the duty of other, senior executives to prevent and to correct promptly any illegal distribution of misbranded or adulterated drugs or medical devices, and hopefully tip the balance of aggravating and mitigating factors away from prosecution.

### IV. Federal Trade Commission

In *King Drug Co. of Florence, Inc., et al v. Cephalon, Inc., et al*., which was a consolidated case involving FTC as a plaintiff, antitrust complaints had been filed concerning reverse payment settlements involving the drug Provigil. The agreements were between Cephalon, Inc., and several generic drug makers. The plaintiffs generally alleged that these agreements constitute an unlawful restraint of trade. The plaintiffs included four subcategories: direct purchasers, endpayers class action, the Apotex litigation and the FTC litigation. Defendants had moved to dismiss the complaints in their entirety, focusing the bulk of their argument on the applicability of the scope of the patent and asserting that the settlement agreements do not go outside the scope of the patent because they do not include products beyond that scope and provide generic market entries three years prior to the end of the

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79 U.S. SENTENCING GUIDELINES MANUAL, § 8C2.5, app n. 11.
80 King Drug Company of Florence, Inc. vs. Cephalon, Inc., et al., U.S.D.C. E.D.P.A., cv 2:06-cv-01797-msg. Memorandum and Order that Defendant’s Motions to Dismiss were Granted in Part and Denied in Part.
Among many arguments raised by the plaintiffs, FTC had asked the court to make a ruling that these reverse payment contracts were *per se* illegal. While the Sixth Circuit Court of Appeals found a reverse payment settlement to be a *per se* illegal restraint of trade in violation of the Sherman Act in 2003, subsequently the Second, Eleventh and Federal Circuits have adopted a “scope of the patent test.” The Fifth Circuit Court reviewed the decisions of each of the other jurisdictions. After its review, the Eastern District determined it would apply “a framework which examines whether any of the agreements in question exceeds the exclusionary patent rights granted to Cephalon.”

The court assessed that the exclusionary patent rights afforded to Cephalon under a patent term extension right had to be taken into account. Because the plaintiffs had alleged Cephalon had misrepresented material facts to the patent office, which purported misrepresentation was known by the generic drug companies, the court pointed out that limiting the analysis to the scope of the patent framework would exclude consideration of these allegations. The court also noted that a rule about reverse payment agreements as *per se* anti-competitive would ignore a longstanding preference on the law favoring settlements. The court reviewed the plaintiff’s allegations and found that the scope of the patent test was too limiting under the facts of this case, and that plaintiffs proposed a plausible cause of action. The judge issued his decision on March 29, 2010. FTC’s attempt to prevent reverse payments continues.

However, the generic companies are fighting back with an interest order by a magistrate judge in Washington, D.C. on July 15, 2010, to approve a request that FTC answer interrogatories in *FTC v. Bisaro*.

In this case Watson Pharmaceuticals accuses FTC of attempting to force the manufacturer to give up its marketing exclusivity of Modanifil in a joint venture with Apotex. Watson seeks the discovery to see if FTC subpoena was issued for an improper purpose.

FTC continues its ongoing campaign to stop false and deceptive efficacy claims relating to healthcare supplements. In July 2010, FTC issued a press release that it planned to file a complaint and stipulated final judgment and order against Iovate Health Sciences USA and two affiliated Canadian companies alleging they deceptively advertised their supplements in television advertisements, on Internet websites and in national magazines. The advertisements purported to show doctors claiming that certain supplements were clinically proven to treat colds or flu, other common allergies and hay fever. The FTC complaint alleges the claims are unsubstantiated. The companies also have advertisements with deceptive claims about their weight-loss supplements. Iovate may not make healthcare or weight-loss claims unless it can demonstrate the healthcare claims are approved by FDA and the weight-loss claims are supported by at least two adequate well-controlled human clinical studies. Iovate has agreed to pay $5.5 million that will be used for refunds to consumers who purchased certain designated products.

In a 2009 press release, FTC announced it had asked DOJ to file a suit in which the government charges three companies and two individuals with making advertis-
ing claims for phantom weight-loss pills that violated a 2006 FTC order barring them from making health or weight-loss claims without a reasonable basis. The commission seeks to stop the defendants from making their claims and to make them pay civil penalties. The claims involved statements that the products would allow you to eat all you want and still lose weight. In 2006, the commission ordered Basic Research LLC to pay $3 million on behalf of six companies and three principals including the two named in this complaint. Violations of FTC orders can carry a civil penalty of up to $16,000 per violation. The complaint asks for civil money penalties, a penalty injunction, rescission or reformation of contracts, restitution, refund monies paid, disgorgement of ill-gotten gains and other equitable relief.

V. SECURITIES AND EXCHANGE COMMISSION AND RELATED SUITS

In a most interesting decision, the Supreme Court of the United States decided in April 2010 that investors could pursue their claim. The Supreme Court noted in the syllabus that a securities fraud complaint is timely if filed no more than “two years after discovery of facts constituting the violation” or five years after the violation. The District Court dismissed the complaint as untimely because the plaintiffs should have been alerted to the possibility of Merck’s misrepresentations prior to November 2001, more than two years before the complaint was filed, and they had failed to undertake a reasonably diligent investigation at the time. Among the relevant circumstances were (1) a study comparing Vioxx with the painkiller Naproxen and showing adverse cardiovascular results of Vioxx, which Merck suggested might be due to the absence of a benefit by Naproxen rather than the harm caused by Vioxx; (2) an FDA warning letter released to the public on September 21, 2001, saying that Merck’s Vioxx marketing with regard to the cardiovascular results was “false, lacking in fair vows or otherwise misleading” and (3) pleadings filed in products liability actions in September and October of 2001 alleging Merck had concealed information about Vioxx and had intentionally downplayed its risks. The Third Circuit reversed, holding that the pre-November 2001 events did not suggest that Merck acted with scienter, an element of the section 10(b) violation, and consequently did not commence running of the limitations period.

The Court conducted an extensive discussion that the facts which tend to show a totally false or misleading statement (or a material admission) have to include the fact of scienter. In order for a section 10(b) violation to occur, the relation of actual falsity and statement of mind is more context-specific than simply facts that tend to show a materially false or misleading statement was made. For instance, the Court said an incorrect prediction about a firm’s future earnings, by itself, does not automatically show whether the speaker deliberately lied or made an innocent error. Discovery of additional scienter-related facts may be required. While the five-year bar is absolute, the two-year limitation requires that the plaintiffs had to have discovered the facts, particularly facts related to scienter. The Court carefully analyzed the various facts presented in the syllabus and determined a Merck-funded Vioxx study demonstrated an increase in the likelihood of heart attacks for those given Vioxx than those given a different painkiller or no painkiller at all. In November 2004, the Wall Street Journal published an article stating “internal

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86 Merck & Co. v. Richard Reynolds, et al. cv 08-905 dealing with the timeliness of a complaint filed by investors alleging securities fraud under § 10(b) of the Securities and Exchange Act of 1934.
87 Id. at ¶1.
Merck emails and marketing materials show that the company fought forcefully for years to keep safety concerns from destroying the drug’s commercial prospects. In the majority of opinion, the Court concluded that the limitations period in section 1658(b)(1) begins to run once a plaintiff did discover or a reasonably diligent plaintiff would have “discover[ed] the facts constituting the violation”—whichever comes first. In determining the time at which “discovery” of those “facts” occurred, terms such as “inquiring notice” and “storm warnings” may be useful to the extent that they identify a time when the facts would have prompted a reasonably diligent plaintiff to begin investigating; but, the limitations period does not begin to run until the plaintiff thereafter discovers or a reasonably diligent plaintiff would have discovered “the facts constituting the violation,” including scienter—irrespective of whether the actual plaintiff undertook a reasonably diligent investigation. In analyzing the various facts, the Supreme Court held that there was not sufficiently specific information to establish scienter. This decision appears to give investors a better opportunity to complain if corporations deliberately conceal negative information about their products.

In an ongoing enforcement action involving Biopure Corporation in which the commission had filed enforcement action against the company in 2005 related to its failure to disclose negative information from FDA regarding its synthetic blood product Hemopure, the former head of regulatory affairs had avoided participating in an ongoing civil case on the basis he was suffering from colon cancer. That turned out to be untrue. The commission announced in October 2009 that he was sentenced to three years’ incarceration, three years of supervised relief, a $50,000 fine and a $100 mandatory assessment. Obviously, this was an egregious case, but the SEC, along with other government agencies, appears to be beginning to go after individual corporate officials.

A. Foreign Corrupt Practices Act Enforcement

While there has been relatively little activity reported this year, the government has made it clear that it intends to ramp up enforcement of the Foreign Corrupt Practices Act (FCPA), particularly with regard to pharmaceutical companies. In prior articles in this series, we have reported on settlements made by medical device companies and on reports by both medical device and pharmaceutical companies that they were under investigation under the FCPA.

It has been reported that the government has made its intentions clear:

The opening declaration came from Assistant Attorney General Lanny Breuer in a speech last November, when he pointedly said: “Pharmaceutical companies must ensure that they are dealing honestly and fairly with patients, healthcare providers, private insurers and government programs.” If they don’t, he advised, the Justice Department will be “vigilant” in holding companies and individuals who break the law accountable, particularly for violations under the Foreign Corrupt Practices Act.

VI. PRODUCTS LIABILITY

A. Judicial Reaction to Wyeth v. Levine

In one of the big blockbuster decisions of 2009, *Wyeth v. Levine*91, the Supreme Court addressed the question of whether state law failure-to-warn claims are preempted where FDA has approved the warning in question. The Court ruled that the plaintiff’s state law failure-to-warn claims were not preempted by FDA’s approval of the Phenergan labeling. The Court reasoned that it was not impossible for Wyeth to comply with both federal and state requirements “absent clear evidence that the FDA would not have approved a change to Phenergan’s label.”92 The Court further reasoned that the jury’s verdict on plaintiff’s failure-to-warn claim does not interfere with “Congress’s purpose to entrust an expert agency to make drug labeling decisions that strike a balance between competing objectives.”93

While the Supreme Court rejected the preemption defense based on the specific regulatory history of Phenergan, it did not eliminate the preemption defense in all failure-to-warn cases. The Court characterization of the preemption argument it rejected is illustrative: “Once the FDA has approved a drug’s label, a state-law verdict may not deem the label inadequate, regardless of whether there is any evidence that the FDA has considered the stronger warning at issue.”94 In framing the relevant inquiry this way, the Court recognized that preemption may apply in cases where FDA specifically considered the proposed stronger warning and decided that it was not appropriate.

Since *Levine*, numerous federal courts have been faced with the issue of whether state law failure-to-warn claims are preempted. These cases, a few of which are discussed below, illustrate the scope of implied conflict preemption in post-*Levine*.

So far, manufacturers have largely come out on the losing end.

- **Cases Originally Decided Before Levine.** Before the Supreme Court decided *Levine*, several lower courts had ruled that failure-to-warn claims involving selective serotonin uptake inhibitors (SSRIs) were preempted because FDA had considered a warning that SSRIs increased the risk of suicide and found it scientifically unsupported.95 In one of those cases, *Colacicco*, the plaintiffs filed a petition for certiorari to the Supreme Court seeking appeal of the Third Circuit’s preemption ruling. After *Levine*, the Supreme Court granted certiorari, vacated the judgment and remanded the case to the Court of Appeals for the Third Circuit for further consideration in light of *Levine*.96 The Court of Appeals in turn returned the case to the district court for development of the factual record in light of the *Levine* standard. Other appellate courts similarly vacated preemption rulings and remanded cases to the district courts for further proceedings.97

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93 *Id.* at 1204.
94 *Id.* at 1199.
97 *Dobbs v. Wyeth Pharmaceuticals*, 606 F.3d 1269 (10th Cir. 2010); *Miller v. SmithKline Beecham Corp.*, 2010 WL 2180615 (10th Cir. June 2, 2010).
Mason v. Smithkline Beecham Corp. Mason involved claims by the parents of a 23-year-old woman who committed suicide after taking Paxil, an SSRI. They alleged that the manufacturers were negligent in failing to warn that the drug carried an increased risk of suicide, especially in young adults. The manufacturer contended that the claims were preempted and the district court agreed, awarding the manufacturer summary judgment before the Levine decision was issued. The parents appealed and in February 2010, the Court of Appeals for the Seventh Circuit addressed the preemption issue.

In discussing the Levine standard, the court first stated that the decision “restored the preemption landscape to its pre-2001 form.” It is important to point out that this is not what the Supreme Court held. The court in Mason further explained that “[a]lthough the Court found that preemption did not exist in Levine, it held that there could be preemption if the manufacturer met the stringent standard of proving that there was clear evidence the FDA would have rejected the proposed change in the drug’s label.”

The court examined the regulatory record of Paxil and concluded that, as with Phenergan, that record did not contain “clear evidence that the FDA would have rejected a label change warning about the risk of suicide by young adults” before the plaintiffs’ daughter’s suicide. The court found unconvincing the manufacturer’s contentions that: 1) FDA had repeatedly refused to approve a labeling change for Prozac, another SSRI, that would have included a suicide warning; 2) it submitted all available data on Paxil and suicide prior to the suicide in this case and 3) FDA had been thoroughly reviewing available data about the connection between SSRI and suicide and did not require a suicide warning.

Hayes v. Smithkline Beecham Corp. In Hayes, a husband and wife asserted failure-to-warn claims against the manufacturer of Paxil after their child developed a heart defect allegedly as a result of the woman taking Paxil during her pregnancy. In December 2009, after Levine, the district court considered the manufacturer’s motion for summary judgment on preemption grounds. In order to satisfy the Levine standard, the manufacturer contended that there is “clear evidence” that “FDA would not have approved a stronger warning based on the animal data.” According to the manufacturer, FDA “required this language [that the animal studies revealed no evidence of teratogenic effects] in Paxil’s labeling as a condition for approval.” The court rejected the manufacturer’s argument, ruling that as in Levine, the manufacturer failed to identify any “evidence that it attempted to strengthen the label’s warnings about Paxil and pregnancy prior to September 2005.” The court, therefore, reasoned that there was

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98 Mason v. Smithkline Beecham Corp., 596 F.3d 387 (7th Cir. 2010).
99 Id. at 390.
100 Id. at 391.
101 Id. at 395-96.
103 Hayes, 2009 WL 4912178, at *4.
104 Id.
105 Id.
106 Id.
not clear evidence that FDA would have rejected the proposed stronger warning.107

- **Aaron v. Wyeth.** Aaron is another SSRI suicide case.108 A man's estate sued the manufacturer of Effexor in the district court for the Western District of Pennsylvania alleging that the decedent committed suicide as a result of taking Effexor. The plaintiff alleged that Effexor did not contain adequate warnings about the risk of suicide. After Levine, the manufacturer moved for summary judgment on grounds that it was impossible to comply with both federal labeling laws and state law tort duties because there was clear evidence that FDA: “(1) drafted its own warnings; (2) required the entire class of modern antidepressants to carry these warnings and (3) repeatedly rejected efforts to implement different or additional warnings.”109

The court denied the motion. The court ruled that impossibility preemption is a “demanding defense,” and it cannot conclude that it “would have been impossible for Wyeth to place a warning on its Effexor other than the warnings in place at the time the antidepressant was prescribed for Aaron.”110 The court reasoned that “[t]hough the FDA disagreed with certain changes to the Effexor labeling proposed by Wyeth, Wyeth did not press its position, it instead acquiesced to the requests made by the FDA.”111 The court further reasoned that Wyeth subsequently agreed to include the class labeling for all SSRIs in the Effexor labeling.112

Unfortunately, the court’s ruling appears to limit preemption one step further than Levine as the Western District of Pennsylvania requires a manufacturer not only to show that FDA rejected the proposed stronger warning but also that the manufacturer pressed that warning in the face of FDA’s rejection.

### B. Viability of Preemption Defense in Generic Drug Cases

Following Levine, the question remained whether failure-to-warn claims against manufacturers of generic drugs are preempted. The majority of courts confronted with that issue have ruled that the Levine decision applies with equal force to generic drugs and that failure-to-warn claims are not preempted absent evidence that FDA would have rejected the proposed stronger warning.113 Not all courts agree, however, creating a split of authority that may be resolved by the U.S. Supreme Court this coming year.114

The majority position is exemplified by the Court of Appeals for the Eighth Circuit’s decision in Mensing v. Wyeth, Inc.115 In that case, the plaintiff developed a condition called tardive dyskinesia after taking the generic form of Reglan to treat

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107 Id. See also In re Preempro, Products Liab. Litig., 586 F.3d 547 (8th Cir. 2009).
109 Aaron, 2010 WL 653984, at *4.
110 Id. at *6. See also Forst v. Smithkline Beecham Corp., 639 F. Supp. 2d 948, 953-954 (E.D. Wis. 2009).
111 Id.
112 Id.
115 588 F.3d 603 (8th Cir. 2009).
her diabetic gastroparesis. The plaintiff sued the manufacturers of both Regland and the generic drug, alleging failure to warn against the generic manufacturers and fraud and negligent misrepresentation against the named brand manufacturer. All of the generic manufacturers contended (some through motions to dismiss and some through motions for summary judgment) that the failure-to-warn claims were preempted. The manufacturers contended that there is a fundamental difference between labeling requirements of prescription drug manufacturers and labeling requirements of generic drug manufacturers. The manufacturers reasoned that federal law requires generic drugs to contain the same labeling as the name brand drug and the failure-to-warn claims would conflict with that federal law by requiring generic manufacturers to deviate from the name brand drug label. The district court agreed and granted the motions.

The Court of Appeals disagreed and reversed the district court.\textsuperscript{116} The court examined Congressional intent and concluded that if Congress thought that state law tort claims interfered with its objectives, it would have enacted an express preemption provision.\textsuperscript{117} The court rejected the generic manufacturers’ impossibility preemption argument based on the contention that they may not deviate from the name brand label. The court reasoned that generic manufacturers had the same ability to propose labeling changes to FDA through the changes being effected (CBE) process.\textsuperscript{118} The court further reasoned that they “need not decide whether generic manufacturers may unilaterally enhance a label warning through the CBE procedure because the generic defendants could have at least proposed a label change that the FDA could receive and impose uniformly on all [generic] manufacturers if approved.”\textsuperscript{119}

In addition, the court ruled that the generic manufactures “could have suggested that the FDA send out a warning letter to health care professionals.”\textsuperscript{120} The court explained that even though the manufacturer has no federal law obligation to take such a step, the “question before the court is whether generic defendants can both fulfill a state law duty to warn and comply with the FDCA.”\textsuperscript{121} The court ruled that, under the Levine standard, the manufacturers could not show that FDA would have not approved the proposed stronger tardive dyskinesia warning.\textsuperscript{122}

The court recognized that the plaintiff’s state law failure-to-warn claims against generic drug manufacturers could still be preempted if they “would obstruct the purposes and objectives of federal law.”\textsuperscript{123} The generic manufacturers contended that requiring them to propose changes to the name brand drug label “would necessitate expensive clinical studies, thwarting the goal of the Hatch-Waxman Amendments to bring low cost generic drugs to market quickly.”\textsuperscript{124} The court rejected this argument ruling that the scientific substantiation need not come from manufacturer-conducted clinical trials but could come from published studies or other sources.\textsuperscript{125} Accordingly, the court ruled that the state law obligation the plaintiff sought to impose did not obstruct the purposes and objectives of the Hatch-Waxman Amendments. The court reasoned that the state law obligation actually reinforced the “FDCA’s

\textsuperscript{116} Mensing, 588 F.3d at 607-11.
\textsuperscript{117} Id. at 607.
\textsuperscript{118} Id. at 608.
\textsuperscript{119} Id.
\textsuperscript{120} Id. at 610.
\textsuperscript{121} Id.
\textsuperscript{122} Id.
\textsuperscript{123} Id. at 611.
\textsuperscript{124} Id.
\textsuperscript{125} Id.
premise that manufacturers, not the FDA, bear primary responsibility for their
drug labeling at all times.\textsuperscript{126} In \textit{Gaeta v. Perrigo Pharmaceutical Co.},
the district court for the Northern District of California reached the opposite conclusion.\textsuperscript{127} That case involved
failure-to-warn claims against the generic drug manufacturers of ibuprofen. The
generic manufacturers moved for summary judgment raising the same preemption
arguments as the defendants in \textit{Mensing}. The court granted that motion before
the Supreme Court issued the Levine decision.\textsuperscript{128} The plaintiffs filed a motion for
reconsideration after Levine.\textsuperscript{129} The court denied the motion. The court reasoned that the Levine court “did not face the question of whether the CBE regulation allowed generic drug manu-
facturers to make changes to their labels without prior FDA approval.”\textsuperscript{130} The court
ruled that the generic manufacturers’ argument was different than the argument
advanced by Wyeth in the Levine case.\textsuperscript{131} Unlike the argument in Levine, the generic
manufacturers contended that FDA regulations require their labeling “to conform
exactly to the approved labeling for the listed drug, making it impossible for generic
drug manufacturers to make unilateral changes to their labels.”\textsuperscript{132} Because the court
did not address that issue, the court concluded that its ruling did not conflict with
the Levine holding.\textsuperscript{133}

The issue of whether federal law preempts state law claims involving generic
drugs is currently before the United States Supreme Court as the manufacturer in
\textit{Mensing} filed a petition for certiorari. In May 2010, the court asked the United
States Solicitor General to file an amicus brief setting forth the government’s
position on whether federal law preempts state law failure-to-warn claims against
generic drug manufacturers.\textsuperscript{134} In November 2010, the United States filed an amicus
curiae brief setting forth the government’s position that the Court of Appeals for
the Eighth Circuit correctly ruled the plaintiffs’ claims were not preempted and that
the Supreme Court should not grant certiorari.\textsuperscript{135} In December 2010, the Supreme
Court granted the petition for certiorari.

\textbf{C. Alleged Parallel Claims Post-Riegel}

In 2008, the United States Supreme Court narrowed the scope of state law tort
claims that could be maintained against the manufacturer of a Class III PMA ap-
proved medical device. In \textit{Riegel v. Medtronic, Inc.}, the Court ruled that state law
tort claims against the manufacturers of PMA-approved devices are preempted
when they seek to impose on manufacturers requirements that are additional to
or different than FDA’s PMA approval. The Court recognized that tort claims will
not be preempted if they seek to impose obligations on manufacturers of PMA-
approved devices that are parallel to FDA’s PMA approval requirements. Since

\begin{itemize}
\item \textsuperscript{126} \textit{Id.} at 612.
\item \textsuperscript{127} \textit{See Gaeta,} 672 F. Supp. 2d at 1022.
\item \textsuperscript{128} \textit{Id.} at 1018.
\item \textsuperscript{129} \textit{Id.}
\item \textsuperscript{130} \textit{Id.} at 1021.
\item \textsuperscript{131} \textit{Id.}
\item \textsuperscript{132} \textit{Id.}
\item \textsuperscript{133} \textit{Id.}
\item \textsuperscript{134} \textit{See} http://www.supremecourt.gov/Search.aspx?FileName=/docketfiles/09-993.htm (last visited
Jan. 24, 2011). Note, a panel of the Sixth Circuit Court of Appeals also asked FDA to explain its posi-
tion on whether state law claims involving generic drugs are preempted.
\item \textsuperscript{135} \textit{See} http://www.justice.gov/osg/briefs/2010/2pet/6invit/2009-0993.pet.ami.inv.pdf (last visited
\end{itemize}
at that time, plaintiffs have tried to avoid preemption by characterizing their claims as parallel claims.

Most of the decisions issued over the past year have rejected plaintiffs’ creative attempts to characterize their state law tort claims as parallel claims under Riegel and ruled those claims preempted.136 Those courts have offered varying explanations for why the plaintiffs’ claims are not parallel claims137:

- The plaintiff’s claim was actually a disguised claim to impose additional or different requirements on the device manufacturer.138 In Williams v. Cyberonics, Inc., for example, the plaintiff alleged that the defendant’s device was manufactured defectively and sought to have the jury infer that the device, therefore, must have deviated from FDA requirements. The district court rejected plaintiffs’ characterization of their claim and ruled that the claims were preempted under Riegel. The Court of Appeals for the Third Circuit affirmed, ruling that plaintiffs’ “success on appellants’ breach of warranty claims would require them to show that the… device was unsafe or ineffective despite the PMA process, thereby interfering with the requirements already established by the MDA.”139

- The plaintiff pleaded insufficient facts to establish a parallel claim.140

- The alleged parallel claim is too “vague and open-ended” and allowing such claims would practically lead to the imposition of different or additional requirements.141

- The plaintiff’s claims are grounded in allegations of fraud-on-the-FDA, which as explained in more detail below are preempted under the United States Supreme Court’s decision in Buckman v. Plaintiffs’ Legal Committee.142

- A failure to recall claim is not a parallel claim because a recall is a voluntary remedial action and not required under the FDCA.143

Adulteration claims are non-parallel preempted claims because such claims constitute improper private enforcement of the FDCA.144

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138 Williams, 2010 WL 2982839 at *1-2.

139 Id. at * 1.


Several courts, however, have found plaintiffs’ claims against medical device manufacturers to be legitimate parallel claims that are not expressly preempted by the MDA. Phillips v. Stryker Corporation provides an example of the type of parallel claims that are not preempted. In that case, the plaintiff alleged that he experienced pain after receiving a hip implant allegedly manufactured by the defendant. He asserted state law claims against the manufacturer for strict liability, negligence and breach of warranty. The manufacturer moved to dismiss those claims on preemption grounds.

The court denied that motion. First, the court examined “whether the federal government has established requirements applicable to the medical device at issue.” The court agreed with the manufacturer that FDA established requirements applicable to its hip implant, such as fatigue and corrosion testing.

Second, the court considered whether the plaintiff’s claim is “based upon [state] requirements with respect to the device that are ‘different from, or in addition to’ to the federal [requirements], and that relate to safety and effectiveness.” The court concluded that the plaintiff’s claims alleged that the manufacturer failed “to comply with FDA regulations in manufacturing the Trident System” in that it

1. violated 21 C.F.R. § 820.20(b)(2) by “fail[ing] to provide adequate resources, including trained personnel, for management, performance of work and assessment activities, including internal quality audits ...” and

2. violated 21 C.F.R. § 820.70(e) by “fail[ing] to establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be anticipated to have an adverse effect on product quality.”

The court reasoned that because the plaintiff’s state law claims were based on violations of these federal requirements, they were parallel claims and “survive preemption under the second step of the Riegel analysis.”

In Howard v. Sulzer Orthopedics, Inc., the Court of Appeals for the Sixth Circuit similarly ruled that a plaintiff’s claims against the manufacturer of a knee prosthesis were non-preempted parallel claims. The court reasoned that the federal good manufacturing practice rule can be deemed a federal requirement for purposes of express preemption under the MDA. In that case, the court ruled that the plaintiff’s state law claims sought to impose obligations on the manufacturer that were parallel to the GMP rule. Not all courts confronted with this issue have agreed that the GMP rule constitutes a federal requirement.

In July 2010, the district court for the District of New Jersey ruled that breach of express warranty claims were not preempted because they rested on “voluntary

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147 Id.
148 Id. at *6.
149 Id. at *7.
150 Id.
152 Id.
statements relating to approved uses, or on voluntary statements about off-label uses that were outside the safe harbor.” The court reasoned that plaintiffs are not imposing any different or additional requirements on the manufacturer where they are seeking to impose liability based on those voluntary warranties.

D. Buckman Preemption Is Alive and Well

In the wake of Levine, it is important for manufacturers to remember that while implied conflict preemption may be more difficult to establish, so-called Buckman preemption remains a viable defense to claims based on allegations of fraud-on-the-FDA. In Buckman v. Plaintiffs’ Legal Committee, the U.S. Supreme Court ruled that fraud-on-the-FDA claims are preempted.

The case of Lofton v. McNeil Consumer & Specialty Pharmaceuticals is illustrative. In Lofton, a man’s estate sued the manufacturers of Motrin alleging that the drug caused the decedent to develop a viral rash and die. The estate asserted claims against the manufacturer for design defect, marketing defect, breach of express and implied warranties, negligence and violation of the Texas Deceptive Trade Practices Act. The manufacturer moved for summary judgment on numerous grounds, including that under Texas law, Motrin’s labeling was presumed to be adequate because it was approved by FDA and there was no evidence to rebut that presumption. The plaintiff contended that the statute recognized an exception to that presumption where the manufacturer perpetrated a fraud-on-the-FDA and that this exception applied. In response, the manufacturer contended that this exception was preempted in accordance with Buckman.

The court agreed, recognizing that the overwhelming majority of courts confronted with similar immunity statutes containing fraud-on-the-FDA exceptions have held the exceptions to be preempted under the Supreme Court’s ruling in Buckman. Most courts follow the pro-preemption reasoning of the Sixth Circuit Court of Appeals in Garcia v. Wyeth-Ayerst Laboratories, Inc. instead of the anti-preemption reasoning of the Second Circuit Court of Appeals in Desiano v. Warner-Lambert & Co. Two other courts within the Fifth Circuit—Lofton’s jurisdiction—had disagreed and found no preemption.

The court in Lofton agreed with the majority ruling that the fraud-on-the-FDA exception is preempted and the FDA-approved Motrin labeling was entitled to a rebuttable presumption. The court ruled that “[u]nlike the other courts in this district, this court determines that the rationale of Garcia is persuasive and that extending the holding of Buckman to fraud-on-the-FDA exceptions is warranted.” The court reasoned that “the concerns in Buckman hold true not only where a plaintiff brings a fraud-on-the-FDA claim but also where it seeks to show an exception to the presumption here.” Because the record contained no evidence to rebut the presumption, the court awarded the manufacturers summary judgment.

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156 Cornett, 414 N.J. Super. at 405, 998 A.2d at 567.
157 Id.
158 682 F. Supp. 2d 662 (N.D. Tex. 2010).
159 Lofton, 682 F. Supp. 2d at 665.
160 Id. at 675.
161 See id.
163 Lofton, 682 F. Supp. 2d at 675.
164 Id. at 675-76.
As explained above, courts have also ruled that state law tort claims against manufacturers of PMA-approved medical devices based on fraud-on-the-FDA allegations are preempted under *Buckman*.

In *Hughes v. Boston Scientific Corp.*, for example, a federal district court ruled that a plaintiff’s state law tort claim was preempted under *Buckman*. The court reasoned that the plaintiff’s claims were fraud-on-the-FDA claims because they alleged that the manufacturer made negligent misrepresentations to FDA in connection with post-marketing reporting. The court agreed with the manufacturer’s contention that “couching one’s claim to focus on the basis of the FDA’s decision (i.e. the information provided to the FDA by the manufacturer) as opposed to the decision itself (i.e. the approval of the design, manufacturing process, labeling, etc.) is nothing but an attempt to allow each of the 50 states to usurp the role of the FDA and call into question the regulatory process in place.”

Similarly, in *Wheeler v. DePuy Spine, Inc.*, a federal district court ruled that a plaintiff’s state law tort claims against the manufacturer of a PMA-approved medical device were preempted fraud-on-the-FDA claims. Those claims were based on allegations that the manufacturer did not accurately disclose adverse event reports to FDA. The court awarded the manufacturer summary judgment.

Although, the *Levine* decision limits the scope of federal preemption, manufacturers should remember that *Buckman* preemption remains a strong defense to claims based on fraud-on-the-FDA allegations.

**E. Learned Intermediary Doctrine**

The learned intermediary remains one of manufacturers’ strongest defenses to state law tort claims. This doctrine provides that a prescription drug manufacturer fulfills its obligation to warn of the potential adverse reactions associated with its drug if it warns physicians—or the learned intermediaries—of those risks. Several decisions during the past year reinforce the continued viability of this defense and the factual circumstances in which that defense applies.

Although the majority of jurisdictions have already addressed and adopted the learned intermediary doctrine, the Colorado Court of Appeals recently became the first Colorado appellate court to adopt the learned intermediary doctrine. In *O’Connell v. Biomet, Inc.*, the plaintiff was permanently injured when his radial nerve was pierced during the installation of an external elbow fixator to help heal his fractured elbow. After settling claims against the physician, the plaintiff asserted negligence, strict liability, failure to warn, design defect and breach of implied warranty claims against the manufacturer. The manufacturer moved for summary judgment on the failure-to-warn claim, and the district court granted that motion. The Court of Appeals affirmed, ruling that “we are persuaded that the learned intermediary doctrine should apply to failure-to-warn claims in the context of

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166 *Hughes*, 669 F. Supp. 2d at 712.
167 *Id.*
a medical device installed operatively when it is available only to physicians and obtained by prescription, and the doctor is in a position to reduce the risks of harm in accordance with the instructions or warnings.”173 The court noted that the learned intermediary doctrine has been recognized by courts in other jurisdictions and in the Restatement (Third) of Torts: Products Liability § 6(d).174 The court ruled that “[b]ecause it was the responsibility of [plaintiff’s] physician as a learned intermediary to assess the risks and benefits of surgically applying the fixator to [plaintiff’s] arm, defendants’ duty was to warn and provide adequate instructions to [the physician].”175

In March 2010, the Court of Appeals for the Eleventh Circuit was faced with the issue of whether under Georgia law the learned intermediary doctrine barred a plaintiff’s claims for design defect, failure to warn, negligence and breach of warranty.176 Dietz v. Smithkline Beecham Corp., like the preemption cases discussed above, involved allegations that an SSRI, Paxil, caused the plaintiff’s husband to commit suicide. The plaintiff alleged that under Georgia law, the manufacturer was liable because it manufactured “a defective and unreasonably dangerous product,” made misrepresentations in marketing the drug, was negligent and breached its warranty.177 The manufacturer moved for summary judgment on the grounds that the learned intermediary doctrine barred the claims. The district court granted the motion. The Court of Appeals affirmed. The court’s ruling illustrates that often the lines between the learned intermediary doctrine and lack of causation become intertwined. The court bypassed the typical inquiry into whether the manufacturer adequately warned the physician about the risk at issue and ruled that the plaintiff “cannot demonstrate that [the manufacturer’s] alleged failure to warn [Dietz’s doctor] about increased suicide risks associated with Paxil proximately caused Dietz to commit suicide.”178 The court reasoned that the decedent’s physician “explicit[ly]” testified that even if he had been provided with the most up-to-date warnings and research, he still would have prescribed Paxil to treat the decedent’s depression.179 Where, on the other hand, genuine issues of material fact exist as to whether the prescribing physician would have prescribed a drug and whether the prescribing physician would have prescribed the drug had a different warning been provided, summary judgment is not warranted on learned intermediary grounds.180

Manufacturers also scored learned intermediary doctrine wins in two recent Pennsylvania decisions—Cochran v. Wyeth, Inc. and Owens v. Wyeth, Inc.181 Cochran was a fen-phen case in which the plaintiff alleged that the drugs caused her to develop primary pulmonary hypertension (PPH). The plaintiff, however, did not contest the adequacy of the drugs’ PPH warning. She alleged instead that the drugs’ warnings about valvular heart disease were inadequate even though she did not suffer from valvular heart disease.

The district court awarded the manufacturer summary judgment on the grounds that the learned intermediary doctrine barred the claims since there is no dispute that the manufacturer adequately warned the physician of the risk of the adverse reaction that plaintiff suffered—PPH. The Pennsylvania Superior Court affirmed

173 Id. at *3.
174 Id.
175 Id. at *4.
176 Dietz, 598 F.3d at 815.
177 Id. at 814.
178 Id. at 816.
179 Id.
180 See In re Levaquin Prods. Liab. Litig., No. 08-1943, 2010 WL 2975415, at *8-10.
the district court, but based its ruling on proximate cause grounds. The court ruled that under plaintiff’s theory there was no proximate cause because “the relationship between the legal wrong (the failure to disclose the risk of VHD) and the injury (PPH) is not directly correlative and is too remote for proximate causation.”

A recent Tenth Circuit Court of Appeals’ decision suggests a possible limitation on the learned intermediary doctrine. In Van Dyke v. United States, the court ruled that not only do physicians have a duty to warn but in certain circumstances, nurses may often have a duty to warn patients of a drug’s risks. The court ruled that a Veterans Affairs’ nurse who fielded patients’ calls acted as an intermediary and had a duty to warn a patient about Paxil’s risk of suicidality to the extent she knew. Although the issue of the learned intermediary doctrine was not before the court, plaintiffs may use this decision to argue that if a nurse has a duty to warn patients, a manufacturer’s duty to warn should extend not only to prescribing physicians but also to nurses.

F. Application of Iqbal/Twombly

One of the leading stories at this time last year was the United States Supreme Court’s decision in Ashcroft v. Iqbal—ruling that the rigorous pleading standard recognized in Bell Atlantic v. Twombly applies to all civil actions, not just securities actions. During the past year, numerous federal courts in prescription drug/medical device cases have applied the Iqbal/Twombly standard to dismiss loosely pled complaints that failed to allege specific facts to support plaintiffs’ claims. Courts have dismissed different types of claims for different reasons. A few examples are discussed below.

- Courts have dismissed alleged parallel claims because of: (a) failure to plead specific facts; (b) excessive reliance on “information and belief” allegations; and (c) formulaic allegations.
- Courts have dismissed claims for failure to plead facts to establish product identification.
- Courts have dismissed claims for failure to plead proximate cause.

The Iqbal/Twombly pleading standard provides manufacturers with an excellent first line of defense to strict liability claims in federal court (and state courts that...
have adopted the *Iqbal/Twombly* standard). This standard bars attempts by plaintiffs to haul manufacturers into federal court without a factual basis to establish the elements of a cognizable cause of action.

**G. Off-Label Cases**

During the past year, several courts have addressed manufacturers’ challenges to plaintiffs’ claims based on allegations of off-label promotion—i.e., that a manufacturer promoted a drug for uses other than those uses approved by FDA. The following cases show that courts have rejected most of plaintiffs’ attempts to impose expansive liability against manufacturers for off-label promotion:

*In re Yasmin and Yaz Marketing, Sales Pracs. and Prod. Liab. Litig.* involved claims by plaintiffs Philadelphia Firefighters Union Local No. 22 Health and Welfare Fund and American Federation of State, County and Municipal Employees, District Council 47 Health and Welfare Fund against the manufacturers of an oral contraceptive, Yaz. Plaintiffs are welfare benefit plans that pay for prescription drugs for their participants (and their families). Plaintiffs allege that, although Yaz was only FDA approved for the treatment of PMDD in women using oral contraceptives and the treatment of moderate acne in women using oral contraceptives, the manufacturer “improperly promoted ‘as safe and effective for unapproved off-label uses lacking scientific support, including PMS, acne, anxiety, tension, irritability, moodiness, fatigue, headaches, and muscle aches.’” As a result of this alleged overpromotion, the plans contended that the drug was overpromoted and overpriced.

The plaintiffs sought to recover the monies they paid for prescriptions of Yaz for off-label uses. They asserted claims against the manufacturer for federal Racketeer Influenced and Corrupt Organizations (RICO) statute and common law claims for negligence, fraud and misrepresentation, and unjust enrichment.

The manufacturer filed a motion to dismiss the plaintiffs’ RICO claims for failure to state a claim upon which relief may be granted. The district court granted the motion. The court explained that the federal RICO statute requires proof that the defendant’s alleged conduct was both the “but for” and proximate cause of the plaintiff’s injury. The court further explained that under controlling case law “proximate cause is determined by examining whether a direct relationship exists between the injury asserted and the injurious conduct alleged.”

The court looked to a decision by the Seventh Circuit Court of appeals involving RICO claims against a tobacco manufacturer. In that case, the court ruled that the alleged injury was too indirect because 1) the statements in question were directed to the public in general and 2) the insurers were not seeking to recover monies paid the wrongdoers but instead were seeking to recover monies paid to physicians and hospitals that treated smokers.

In addressing the manufacturer’s alleged statements, the court ruled that it “is inclined to agree with other district courts that have found direct proximate cause lacking in cases of this nature.” The court reasoned that there were too many “steps”
between the manufacturer’s alleged conduct and the plaintiffs’ alleged injury of paying too much for Yaz prescriptions. Those steps include “patient preference, the independent judgment of the prescribing physician, and the reimbursement decision rendered by the third party payor and its benefits manager.”

The court rejected the plaintiffs’ alternative proximate cause argument that rested on the foreseeability of their alleged injury. Plaintiffs contended that proximate cause existed because “victims like the plaintiff funds were not merely foreseeable, but were the intended and inevitable targets of defendants’ schemes.” The court ruled that it “will not stray from the direct relationship test by considering issues of foreseeability and intent.” In doing so, the court reiterated that “the remoteness of the injury and the speculative nature of any potential damages analysis prevent Plaintiffs from meeting the direct causal relationship requirement and proximate cause is therefore lacking.”

Carson v. DePuy Spine, Inc. is another positive decision for manufacturers confronted with off-label claims. In that case, the plaintiff asserted negligence per se claims against the manufacturer alleging, among other things, that the manufacturer of an artificial spinal disc promoted the disc for off-label uses. The district court granted the manufacturer’s motion for summary judgment.

On appeal, the Court of Appeals for the Ninth Circuit affirmed. The court began by recognizing that the FDCA “expressly protects off-label use” and the United States Supreme Court “has emphasized that off-label use by medical professionals is not merely legitimate but important in the practice of medicine.” While manufacturers may not promote a drug for off-label uses, “a manufacturer is not liable merely because it sells a device with knowledge that the prescribing doctor intends an off-label use.”

With respect to the plaintiff’s claims, the court ruled that plaintiff failed to come forward with evidence sufficient to create a genuine issue of material fact as to the elements of its negligence per se claim, which required proof that: 1) the defendant violated a statute or regulation; 2) the violation caused the plaintiff’s injury; 3) the injury resulted from the kind of occurrence the statute or regulation was designed to prevent; and 4) the plaintiff was a member of the class of persons the statute or regulation was intended to protect. In particular the court ruled that there was no violation of federal law because there was no record evidence that the manufacturer “illegally promoted an off-label use of the [spinal disc], that [the plaintiff’s physician] was influenced by such promotion, or that the off-label use of the disk caused [the plaintiff’s] injury.”

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194 Id.
195 Id.
196 Id. at *8.
197 Id.
198 Id.
201 Id. See also Central Reg’l Employees Benefit Fund, No. 09-3418, 2009 WL 3245485, at *4 (D. N.J. Oct. 7, 2009) (“it is well-established that off-label marketing of an approved drug is not inherently fraudulent”); In re Zyprexa Prod. Liab. Litig., No. 04-MD-1596, 07-CV-645, (E.D.N.Y. Dec. 1, 2009) (allegations that Zyprexa prescriptions for off-label use were “not medically necessary” were not sufficient to survive summary judgment were record contained evidence that patience benefited from off-label uses of the drug).
202 Id.
203 Id.
Manufacturers scored another off-label victory in *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action (Schering II)*. That case involved claims by various benefit funds that Schering-Plough improperly engaged in a scheme to promote and sell various drugs—Intron-A, PEG-Intron, Rebetrol and Temodar—for off-label use. The plaintiffs asserted federal and state RICO claims, a claim under the New Jersey Consumer Fraud Act and various common law causes of action. In early 2009, the district court for the District of New Jersey dismissed the plaintiffs’ complaint for lack of standing but afforded them an opportunity to amend.

Plaintiffs’ amended the complaint and in the summer of 2010, the court considered whether the amended allegations satisfied the standing requirement. The court ruled that plaintiffs still lack standing. The court explained that in order to have standing under Article III of the Constitution, a plaintiff must establish three elements: 1) an injury in fact; 2) “the injury has to be fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court”; and 3) it is likely that the injury will be addressed by a favorable decision. A plaintiff must also satisfy standing under the federal RICO standard—an injury to business or property as result of racketeering activity.

In analyzing the plaintiffs’ amended allegations, the court noted that the plaintiffs increased their allegations of off-label promotion from the original complaint. The amended complaint alleged that “the deliberately widespread nature of Defendants’ marketing scheme supports the inference that some portion of prescriptions for the Subject Drugs paid for by the TPPs were written for off-label indications as a result of Schering’s unlawful marketing.” The court ruled that the amended complaint did not satisfy standing because the allegations, if true, did not establish an injury in fact. The court reasoned that the amended complaint does not “contain factual allegations that support Named Plaintiffs’ conclusion that they paid for off-label prescriptions written for the Subject Drugs as a result of the unlawful marketing practices described in the pleading.” The court explained that:

- “not one of the four TPPs … alleges that it overpaid for a Subject Drug in some actionable manner, meaning that the drug was worth less than what was paid due to the alleged falsity of the off-label promotional claims made by Schering.”
- “despite averring that they paid for off-label prescriptions, Named Plaintiffs fail to link their off-label purchases to the wrongdoing charged in the Amended Complaint, specifically to misrepresentations about the Subject Drugs and/or to conduct characterized as bribery.”

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204 2010 WL 2346624 (D. N.J. June 9, 2010).
205 See *Schering II*, 2010 WL 2346624, at *1.
206 2010 WL 2346624, at *1.
208 Id. at *3.
209 Id.
210 Id. at *7.
211 Id.
212 Id.
The court further reasoned that there is no causal connection between the alleged off-label promotion and the plaintiffs’ purchases of those drugs for off-label uses.\textsuperscript{213} The court reasoned that “the facts alleged in the Amended Complaint … call for the Court to speculate that Named Plaintiffs must have been injured as a result of Schering’s unlawful marketing tactics.”\textsuperscript{214} That “possibility of harm is simply not enough to establish standing.”\textsuperscript{215}

\textit{Commonwealth v. Janssen Pharmaceutica Inc.}\textsuperscript{216} illustrates the convergence of the learned intermediary doctrine and plaintiffs’ claims based on allegations of off-label promotion. The Commonwealth of Pennsylvania sued Janssen to recover reimbursements it made to pharmacies for prescriptions of Risperdal for off-label use. After asserting numerous claims initially, the Commonwealth refined its case to include claims for fraud, misrepresentation and unjust enrichment. After the Commonwealth presented its case to the jury, Janssen moved for nonsuit.\textsuperscript{217}

The court granted the motion. The court ruled that the Commonwealth of Pennsylvania is a sophisticated business entity and as such is not entitled to a rebuttable presumption of reliance—a necessary element of its fraud and misrepresentation claims.\textsuperscript{218} The court similarly rejected the Commonwealth’s contention that reliance should be presumed because Janssen created a fraud on the market theory.\textsuperscript{219} The court ruled that other Pennsylvania courts have rejected this theory because the prescription drug and securities industries are “too dissimilar” for the court to apply a rebuttable presumption.\textsuperscript{220} Absent a rebuttable presumption, the Commonwealth presented no evidence that it actually relied on any alleged misrepresentation or nondisclosure.\textsuperscript{221}

H. Class Action Developments in Drug/Device Cases

During the past year, federal courts continued to see a large number of class actions thanks to the Class Action Fairness Act. As with years past, federal courts and a few state courts continued the trend of refusing to certify the majority of class actions involving prescription drugs and medical devices. \textit{Solo v. Bausch & Lomb, Inc.}\textsuperscript{222} illustrates the problems plaintiffs have encountered in getting classes certified. In that case, the named plaintiffs sought to represent a class of all California and Pennsylvania consumers who purchased a contact lens solution, MoistureLoc, between September 1, 2004, and April 10, 2006. The plaintiffs alleged that the solution was defective by failing to prevent the growth of a certain type of fungus that causes a serious infection to the cornea.\textsuperscript{223} The plaintiffs asserted claims for statutory and common law unfair competition, California’s consumer protection statute and unjust enrichment.\textsuperscript{224}

\begin{thebibliography}{9}
\bibitem{213} Id. at *9-11.
\bibitem{214} Id. at *11.
\bibitem{215} Id.
\bibitem{218} Id.
\bibitem{219} Id.
\bibitem{220} Id.
\bibitem{221} Id.
\bibitem{223} \textit{Solo}, 2009 WL 4287706, at *1.
\bibitem{224} Id.
\end{thebibliography}
Plaintiffs moved to certify the aforementioned class and the district court for the District of South Carolina denied the motion. The court ruled that “[w]here determining membership in the class would require fact-intensive mini-trials, the class is not ascertainable, and the court should deny certification.” In refusing to certify the proposed class advanced by the plaintiffs, the court reasoned that “[i]n order to ascertain who falls within the class, the court would have to make thousands of fact-intensive inquiries.” The court explained that those individualized fact inquiries would include “whether an individual purchased MoistureLoc between September 1, 2004 and April 10, 2006, but it would also have to determine how much was purchased and at what price, whether the individual discarded the solution, when it was discarded, and how much was discarded. Moreover, the court would also have to determine whether each proposed class member ‘lack[s] full reimbursement’ for whatever quantity that individual discarded.” The court concluded, “It is abundantly clear that the administrative burdens of certification greatly outweigh any efficiencies to be gained by treating these claims as a class action.”

*In re Digitek Products Liability Litigation* is also illustrative. That case arises from the recall of Digitek, a drug used to treat heart problems, because some tablets of the drug were thicker than intended and as a result contained an increased dose. Following the recall, a wave of lawsuits were filed alleging injuries suffered by individuals who received the increased dose of Digitek and claims for economic loss. Among these lawsuits were six class actions filed in federal court, which were consolidated in a Digitek MDL in the district court for the District of West Virginia. The plaintiffs moved to certify an economic loss class consisting of:

All persons residing in the United States who purchased Digitek® pursuant to prescription, during the time period when the Recalled Digitek® was manufactured, produced, distributed, sold or otherwise supplied, who suffered economic losses, including, but not limited to, payments for Recalled Digitek®, out-of-pocket expenses for diagnostic testing, medical testing, medical visits, and/or new prescriptions, as a result of having received Recalled Digitek® …

The court denied the motion for class certification for lack of typicality and predominance of common issues over individual issues. The court reasoned that the requirement of typicality—i.e., that the representative plaintiffs’ claims be typical of and therefore advance the interests of the absent class plaintiffs—was not satisfied. Even the claims of the representative class members were not typical of each other as they asserted a wide variety of economic claims. The court further explained that the representative plaintiffs will pursue claims under the law of their respective states. In doing so, “the representatives will face benefits and obstacles not present in the home states of the class members they represent.” According to the court, this weighed against a finding of typicality.

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225 Id. at *4
226 Id.
227 Id.
228 Id. at *7.
231 Id. at *2-5.
232 Id. at *5.
233 Id. at *14-15.
234 Id. at *15.
235 Id.
236 Id.
The court also reasoned that the plaintiffs could not satisfy the requirement that issues common to all class members' claims predominate over issues affecting individual class members. The court concluded that even if it were to "confine certification to multiple, single-state class actions using only the law of the particular state certified," the common issues do not predominate. The court focused on the following individual issues:

- Each class member must prove that he or she took Digitek.
- Each class member must prove that he or she suffered economic damages and the extent of those damages, which will involve a fact-intensive investigation.
- "The vast array of individualized damages the representatives or their predecessors seek."
- "The process of sorting out those potential class members who were already fully compensated by the … refund process."
- "The nature and extent of third-party involvement in the [recall] process."

When considering a nationwide class, "using the conflicting laws of the 50 states," the individual issue predominates even more.

Two efforts to certify classes against the manufacturers of Neurontin at the state level similarly failed. In one of the cases, Clark v. Pfizer, Inc., a Pennsylvania appellate court affirmed the trial court’s decertification of a statewide class of “all other consumers who purchased the prescription drug Neurontin (or generic Gabapentin) for ‘off-label’ uses that were not approved by the Food and Drug Administration ….” In decertifying the class, the trial court reasoned that some class members benefited from off-label use of Neurontin while others did not. Such an individualized question as to which class members suffered a compensable loss predominates over common questions.

The Superior Court affirmed the decertification reasoning that the plaintiffs were not entitled to a presumption of reliance on their fraud-based claims and, therefore had to prove reliance and causation “on a class wide basis.” To meet that burden of proof, plaintiffs “would have to demonstrate doctor-by-doctor that defendants’ fraudulent misrepresentations or omissions during the off-label promotion caused the doctor to prescribe the medicine.” The court rejected plaintiffs’ contention that they could meet this burden through a statistical model. Instead, the court agreed with the trial court that such proof of reliance would involve individual inquiries that would predominate over common issues, making class certification improper.

[References and footnotes]


238 Id.

239 Id. at *17-18.

240 Id. at *18.


242 Clark, 990 A.2d at 20.

243 Id. at 23.

244 Id. at 27.

245 Id.

246 Id.
I. **State’s Use of Contingent Fee Counsel**

Over the last several years, an issue has arisen as to whether states may enter into contingent fee agreements with attorneys they hire to sue prescription drug and medical device manufacturers to recover state funds paid through their healthcare programs for off-label prescriptions. Manufacturers have challenged these arrangements on numerous grounds, including that they violate applicable state constitutions.

In 2008, the Pennsylvania Office of General Counsel entered into a contingent fee agreement with Bailey Perrin Bailey of Houston, Texas, to sue Janssen Pharmaceutica, Inc., manufacturer of Risperdal, to recover millions of dollars the Commonwealth spent through its Medicaid and Pharmaceutical Assistance Contract for the Elderly (PACE) program. Before hiring the Bailey firm, the firm had contributed money to Governor Rendell’s gubernatorial campaign.

Janssen filed a motion to disqualify the Commonwealth’s outside counsel on the grounds that the contingent fee arrangement violated the state and federal constitutions and the state Attorneys Act. In particular, Janssen contended that the arrangement violated: 1) the separation of powers clause because only the State General Assembly has the authority to authorize the use of state funds; 2) the due process clauses of both the state and federal constitutions by improperly delegating its sovereign powers to the Bailey firm; and 3) the Attorney Act by exceeding the scope of the Office of General Counsel’s authority to retain outside counsel. The trial court denied the motion, but Janssen filed a motion for extraordinary relief with the Pennsylvania Supreme Court.

The court recently affirmed the trial court’s decision ruling that Janssen lacked standing to file a motion for have the Commonwealth’s outside counsel disqualified. The court ruled that according to a Commonwealth statute, the Attorneys Act, only the “Commonwealth party” may challenge the authority of the Bailey firm to represent the “Commonwealth party.”

The California Supreme Court recently faced a similar challenge to contingent fee arrangements between private attorneys and the State Attorney General. In *Santa Clara v. Superior Court of Santa Clara*, the court ruled that these types of contingent fee arrangements may be acceptable in certain situations. The court specifically ruled that contingent-fee agreements between public entities and private attorneys “must provide: (1) that the public-entity attorneys will retain complete control over the course and conduct of the case; (2) that government attorneys retain a veto power over any decisions made by outside counsel; and (3) that a government attorney with supervisory authority must be personally involved in overseeing the litigation.”

While the past year did not contain any decisions that would likely be called “landmark” decisions as in years past, there were numerous decisions during this time period that helped flesh out some of the “landmark” decisions handed down over the last several years—i.e., *Levine, Riegel, Iqbal/Twombly, Buckman*, etc.—and reinforce the major defenses available to prescription drug and medical device manufacturers.

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248 Id.


251 Id. at *8.

252 *Santa Clara v. Superior Court of Santa Clara*, 50 Cal.4th 35, 112 Cal. Rptr. 3d 697 (Cal. 2010).

253 50 Cal.4th 35, 112 Cal. Rptr. 3d at 719-20.
VII. Conclusions

- Legislative, agency and enforcement developments in 2010 will shape your business in court for years to come. Congress passed and the President signed significant amendments to the False Claims and Anti-Kickback Acts; FDA breathed new life into the Responsible Corporate Officer (RCO) doctrine; and the DOJ brought two indictments on a new theory of criminal prosecution—adulterated product based on cGMP violations (and we see more in the pipeline). This combination of initiatives raises new risks for pharmaceutical and medical device manufacturers.
- The additional amendments to the FCA creates a likelihood of more *qui tam* whistleblower activity, more involvement by states attorneys general and more risk facing all of the Manufacturers in the industries covered by this article. Moreover, the various government agencies’ announcements about making individual executives and managers targets of criminal investigations is cautionary.
- FTC is in much the same position as we discussed last year. It is still attempting to contain reverse payments made by innovator companies to keep generic drugs off the market for some period of years.
- The SEC is looking to enforce more actively the Foreign Corrupt Practices Act, especially activities involving pharmaceutical companies.
- While there were no hallmark product liability decisions this year akin to *Wyeth v. Levine* or *Riegel v. Medtronic*, numerous cases have helped flesh out the scope of those decisions. For example, the judicial reaction to the United States’ *Wyeth v. Levine* preemption ruling garnered a great deal of interest and attention this past year. In 2009, the *Levine* court ruled that failure-to-warn claims against prescription drug manufacturers were not preempted unless FDA had considered and rejected the warning advocated by the plaintiff. This year, several courts have ruled that failure-to-warn claims, including those involving SSRIs’ alleged risk of suicidality, were not preempted under the *Levine* standard. Many had believed that failure-to-warn claims involving SSRIs had the best chance of being held preempted following *Levine*. The issue of whether *Levine* applies to failure-to-warn claims against manufacturers of generic drugs was also closely followed and will continue to be followed as the Supreme Court will address the issue to resolve a split of authority. Numerous federal courts this year have analyzed the viability of purported parallel claims against medical device manufacturers attempting to come within the preemption exception announced in *Riegel v. Medtronic*. Courts have generally not allowed plaintiffs to recast their claims as parallel claims where they seek to impose requirements on device manufacturers that are additional or different from those set forth in the device’s PMA approval.