

To: Our Clients and Friends

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Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin



Top News

Device Industry Pushes for Preemption on Payment Reporting

Representatives of the device industry have indicated that they support the new federal mandate requiring disclosure of payments to physicians, but are pushing for federal preemption, so as to ensure only one set of regulations govern such reporting.

FDA Cracking Down on Annual Device Registrations

The FDA indicated that it will begin cracking down on medical devicemakers that haven't submitted their annual establishment registration and device listing information for the past two years. The agency sent warning [letters](#) to five companies that had not registered their facilities as of the Oct. 1 to Dec. 31, 2008, registration period.

Reports Indicate Staggering Economy Affects Innovation for Drugs, Devices

Although the health sector is generally considered to be somewhat safeguarded against changes to the economic climate, reports are indicating that the economic climate over the part year could cause a hampering effect on innovation in the U.S. medical device and pharmaceutical industry, which have suffered through numerous layoffs throughout, as well as a general decrease in available capital and funding opportunities, particularly for smaller companies. In addition, reports are indicating that research and development in the industry has shifted away from more risky projects.

Industry Urges Change to Device Malfunction Reporting Requirements

As industry officials contemplate whether to lessen requirements on manufacturers to report device malfunctions, some in the industry are urging Congress to scrap parts of the program and lessen the burdens on device manufacturers, particularly in light of the fact that many of the reports were not being adequately reviewed. However, consumer advocates are urging for a continuation of the requirements, and citing recent leadership changes as evidence of a new focus that could result in the agency's increased ability to review the reports.

Consumer Groups, Industry Share Views about PDUFA Reauthorization

At the FDA's public meeting surrounding the Prescription Drug User Fee Act reauthorization, consumer groups and industry shared their views of what should be part of the reauthorization. While consumer groups pushed for a host of reforms, including requiring agency pre-review of direct-to-consumer drug advertising, mandating studies on off-label use and prioritizing actions related to comparative effectiveness research, industry members advocated against using the user fee law as a vehicle for policy reforms.

Industry: System for Resolving Patent Disputes a Potential Obstacle to Biosimilars

As the pharmaceutical industry waits for FDA to implement an approval pathway for biosimilars, some stakeholders are focusing on the new law's process for resolving patent disputes and fearing that the law's requirement that innovators and biosimilars applicants begin resolving patent issues eight years before the biosimilar becomes eligible for approval might result in longer approval decisions and both sides finding ways to game the system.

Proposed Bill in House Would Double Medicare Fraud Penalties

Under the Medicare Fraud Enforcement and Prevention Act, proposed in the House of Representatives this week, prison sentences and monetary penalties for Medicare-fraud related crimes are doubled. The bill also creates a new crime -- illegal distribution of a patient's Medicare or Medicaid identification or billing information -- which would carry a three year maximum sentence.

Georgia Insurance Commissioner Refuses to Create High Risk Insurance Pool

The insurance commissioner of Georgia has indicated that he will not create a state pool for high-risk insurance plans, despite a federal request to do so. Reports are indicating that his decision marks a new front in certain states' resistance to the new federal health care law.

New Jersey Seniors May Face Higher Drug Costs

Some are expressing concern that the New Jersey Gov. Chris Christie's proposed budget, which will require that senior citizens enrolled in a subsidized prescription drug program pay higher deductibles and copays, will result in some no longer being able to afford their medications.

AMIC Predicts Imaging Devices Will Move to Hospitals

The Access to Medical Imaging Coalition (AMIC) is predicting that the new health law's tax on imaging equipment and its estimated utilization rate will result in more expensive imaging equipment, including equipment for MRI and CT scans, being pushed from providers' offices to hospitals. AMIC predicts that this will make it more difficult for patients in rural areas and inner cities to access these services.

Nanotech Researchers Want More Funding for Safety Initiatives

Nanotechnology researchers and stakeholders are calling for increased expenditures on health and safety initiatives as part of future nanotechnology research under the National Nanotechnology Institute (NNI).

Pharmacies Push to Allow Pharmacists to Administer Flu Vaccine

Drugstore chains, including CVS/Caremark Corp. and Walgreens are pushing regulators to allow pharmacists to provide an array of vaccines. The number of seasonal flu vaccines administered by pharmacists this flu season increased 36 percent. Doctors and nurse practitioners are fighting against allowing pharmacists to administer more vaccines.

Coalition Files Suit to Force FDA Action on Animal Testing

A coalition of alternative drug evaluation procedure proponents and animal rights advocates filed a lawsuit last week to force the FDA to act on a two-year old petition by the group, calling for the agency to encourage non-animal testing methods as a means of evaluating drugs during their development.

Publications

The FDA has [published](#) "Questions and Answers for Healthcare Professionals and the Public: Use an Approved Pancreatic Enzyme Product."

A US research study has found people with DNA deletions on chromosome 16 are at higher risk of developing epilepsy compared with those lacking the genetic variant. The study also found that the missing DNA in patients with epilepsy covers seven genes.

An [analysis](#) by the Institute of Medicine has found that 40% of Phase III clinical trials conducted by the Clinical Trials Cooperative Group Program, a unit of the National Cancer Institute, end up being terminated because of inefficiency and lack of funding.

The American Society of Clinical Oncology has indicated that it is drafting a letter to the FDA citing concerns that the society was excluded from the agency's development of a classwide risk evaluation and mitigation strategy (REMS) for Amgen's three erythropoiesis-stimulating agents (ESAs) that took effect March 24.

Changes to International Regulations

A new rule requires devicemakers to get approval from the Federal Institute for Drugs and Medical Devices (BfArM) and an ethics committee before beginning clinical trials in Germany.

A new Brazilian regulation requires that all local and foreign device companies that are registering or reregistering a product undergo an on-site audit before entering the market. The regulation sets a deadline of May 24 for good manufacturing practice inspections of facilities seeking to register or reregister in Brazil.

Approvals

The FDA has [approved](#) Pancreaze Delayed Release Capsules, a pancreatic enzyme product (PEP).

The FDA has approved Generic drugmaker Akorn Inc.'s version of painkiller Dilaudid-HP.

Boston Scientific has announced that it has [received clearance](#) from regulators to [resume shipment of two models](#) of its heart defibrillators, the Cognis cardiac resynchronization therapy defibrillator (CRT-D) and the Teligin implantable cardioverter defibrillator (ICD).

The FDA has granted FDA fast-track status to Genta's gastric cancer treatment tasetaxel and Allon Therapeutics' neuroprotective drug davunetide.

The FDA has granted tentative approval for Synthon Pharmaceuticals' ANDA for a generic version of Novartis' once-daily hypertension drug Exforge.

Recalls, Warnings, and Notifications

The FDA has announced that, in accordance with longstanding U.S. obligations under the Montreal Protocol on Substances that Deplete the Ozone Layer, [seven metered-dose inhalers](#) (MDI) used to treat asthma and chronic obstructive pulmonary disease (COPD) will be [gradually removed from the U.S. marketplace](#).

The FDA has issued a second [warning letter](#) to Apotex for [significant violations](#) of the Current Good Manufacturing Practice (CGMP) regulations, including charred particles in a diabetes drug; contamination of an antihistamine, and drug cross-contamination that resulted from inadequate cleaning of manufacturing equipment.

Ranbaxy Laboratories Ltd. has instituted a voluntary recall of two lots of its oral antibiotic for ear, nose, and throat infections in children in the US.

The FDA sent Keith Pierce, who conducted a Ketek trial at the Michigan Institute of Medicine, a Notice of Initiation of Disqualification Proceeding and Opportunity to Explain letter March 17, claiming he submitted false information to the sponsor.

Bisco has received five observations related to medical device reports (MDRs), employee training and corrective and preventive action during an inspection of its Schaumburg, Ill., plant.

Business News

David Hood, former head of the Louisiana Department of Health and Hospitals, stated at trial this week that managers of Louisiana's state-sponsored health plan [would not have covered Vioxx](#) if they were aware that the drug posed a heart-attack risk. Louisiana is currently seeking to recover refunds of up to \$20 million for the drug.

Orexigen Therapeutics Inc. has indicated that it [miscalculated data from a study](#) of its obesity drug candidate Contrave, which made the drug appear more effective than it was. The company revised its data to state that 64.9 percent of the patients who took Contrave lost at least 5 percent of their body weight after 56 weeks (rather than 75.8 percent that was reported in July), and 39.4 percent lost at least 10 percent of their body weight (rather than 48.2 percent that was reported in July). The company stated that the revised data meet FDA standards for demonstrating weight loss.

Catalyst Pharmaceutical Partners Inc. has announced that the National Institute on Drug Abuse will cover \$10 million for a midstage clinical trial of CPP-109 [vigabatrin], intended to help treat cocaine addiction. Catalyst will pay \$2.8 million for the trial.

Mersana Therapeutics has announced that it licensed an experimental cancer drug to Teva Pharmaceutical Industries Ltd., in a deal that could be worth more than \$334 million.

Penwest Pharmaceutical Co. and Endo Pharmaceuticals Holdings Inc. have indicated that they have reached a settlement with Teva Pharmaceutical, under which the company may begin selling a generic version of Opana ER beginning Sept. 15, 2012.

Perrigo Co. has announced that it has reached a settlement regarding patent litigation between the company and Graceway Pharmaceuticals. Under the settlement, Perrigo will sell an authorized generic version of Graceway's Aldara cream starting in a few weeks.

The *Wall Street Journal* is reporting that Genzyme Corp. will appoint Ralph Whitworth as board director in the near future rather than wait until the autumn.

US Renal Care, Inc. has announced that it plans to purchase Dialysis Corp. of America for about \$112 million.

[Bloomberg News](#) is reporting that the competition between Teva Pharmaceutical Industries Ltd. and Bayer AG over women's health products is increasing, with Teva indicating that it aims to increase its annual revenue in that area to \$1 billion as early as 2012.

Aveo Pharmaceuticals announced that it received \$5 million from Biogen Idec Inc. as a part of a partnership arrangement surrounding the selection of an antibody drug candidate for development.

The [WiCell Research Institute](#) has asked the National Institutes of Health to approve four embryonic stem cell lines, including one known as H9, for approval under President Obama's new stem cell policy.

Pozen, Inc. has announced that has reached a settlement in its patent dispute with Teva Pharmaceuticals Industries Ltd. over the generic version of its migraine treatment Treximet.

Roche Holding AG announced that its first-quarter revenue rose 6 percent as doctors prescribed more of its tumor medicines Avastin, Rituxan, and Herceptin. The drugmaker also indicated that it would ask the FDA to approve its [experimental cancer drug](#) T-DM1 this year.

The WHO convened a panel earlier this week to review the global response to the H1N1 influenza pandemic last flu season and has set an agenda for a year-long study of how the pandemic was managed. [Some critics accuse the U.N. health agency of having exaggerated the severity and dangers of the disease.](#)

Canadian press is reporting that debate over generic drug reform is heating up in Ontario, as drug stores in the region are calling for aggressive patient outreach to stop the government's plan to ban professional allowances paid by generic drug companies to pharmacies. Meanwhile, labor organizations and organizations representing senior citizens are coming out in support of reform, which would cut drug costs in the region. The ban is expected to have the greatest impact on independent rural pharmacies.

A federal judge has ruled that Sanofi-Aventis SA and Bristol-Myers Squibb Co. can pursue [more than \\$442 million](#) in damages from Apotex Inc. for its sales of a generic version of the blood-thinner Plavix in 2006. The judge found that the PTO had already upheld the patent for Plavix, as had a US court.

Pfizer, Inc. has announced that it is partnering with Stemgent Inc. to make new reagents available for non-human experimentation in cell and stem-cell based research in fields including neuroscience, cancer, and metabolic diseases.

Impax Laboratories, Inc. has announced that it has revised its agreement with Pfizer, Inc. and will now co-promote Pfizer's medicine Lyrica.

Celgene Corp. and Agios Pharmaceuticals have announced that they will collaborate on potential cancer treatments. The collaboration will secure for Agios \$130 million upfront and a potential long-term revenue stream in exchange for giving Celgene the exclusive option to develop any drugs resulting from its cancer metabolism research platform for an undisclosed period of time.

Shares of Santarus fell 34 percent Thursday after the company stated that a federal judge found five of the company's patents on its acid reflux drug were invalid. The company said it plans to appeal the decision.

Sanofi-Aventis has announced that it will shift the focus of its French manufacturing operations to vaccine and biotech drugs.

As some patients taking Genzyme's drug Cerezyme [contemplate switching](#) to other treatments, including experimental ones, due to the high costs associated with the drug and recent shortages of the drug, the company has stated that the cost of the drug was necessary to recoup its investment and to continue research.

Ethex, a subsidiary of KV Pharmaceutical, has stated that it will plead guilty to two felony counts of failing to file field alert reports for out-of-specification dextroamphetamine and propafenone tablets and pay \$25.8 million in fines and restitution to resolve a Justice Department investigation.

Regulatory Notices

FDA Issues Final Rule on Use of Ozone-Depleting Substances

The FDA, after consultation with the Environmental Protection Agency (EPA), is amending FDA's regulation on the use of ozone-depleting substances (ODSs) in self-pressurized containers to remove the essential-use designations for flunisolide, triamcinolone, metaproterenol, pirbuterol, albuterol and ipratropium in combination, cromolyn, and nedocromil used in oral pressurized metered-dose inhalers (MDIs). The FDA has concluded that there are no substantial technical barriers to formulating flunisolide, triamcinolone, metaproterenol, pirbuterol, albuterol and ipratropium in combination, cromolyn, and nedocromil as products that do not release ODSs, and therefore they will no longer be essential uses of ODSs as of the effective dates of this rule. MDIs for these active moieties containing an ODS may not be marketed after the relevant effective date. More information is available at <http://edocket.access.gpo.gov/2010/2010-8467.htm>.

FDA Determines Regulatory Review Period for Afinitor, Savella

The FDA has determined that the applicable regulatory review period for AFINITOR is 4,486 days. Anyone with knowledge that any of the dates as published are incorrect may submit written or electronic comments and ask for a redetermination by June 14, 2010. Furthermore, any interested person may petition the FDA for a determination regarding

whether the applicant for extension acted with due diligence during the regulatory review period by October 12, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-8443.htm>.

The FDA has determined that the applicable regulatory review period for SAVELLA is 2,571 days. Anyone with knowledge that any of the dates as published are incorrect may submit written or electronic comments and ask for a redetermination by June 14, 2010. Furthermore, any interested person may petition the FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by October 12, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-8518.htm>.

FDA Submits Proposed Collection of Information

The FDA has announced that it has submitted to OMB for review and clearance a proposed collection of information regarding the export of medical devices and foreign letters of approval. Comments on the collection of information are due by May 17, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-8572.htm>.

More Information

Archived issues of the Bryan Cave Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin and other FDA news bulletins are available at www.bryancave.com on the [FDA Practice Bulletins web page](#).

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