

To: Our Clients and Friends

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Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin



Top News

Industry Reps: FDA Interacting Less with Industry

In their comments regarding ways in which the FDA can improve its openness to industry, industry representatives commented that they have noticed a trend of the FDA being more reluctant to interact with them. Comments included that the agency should respond more quickly to industry input on important issues, keep industry apprised of plans to issue or revise guidance documents, provide more notice about upcoming meetings, and post messages more clearly on its website. Industry groups also encouraged the agency to make better use of available, industry-sponsored educational programs. In addition, some members of the industry called on the FDA to clarify its criteria on product recalls.

FDA Launches Radiological Health Transparency Website

The FDA has launched a new [website](#) that will allow individuals to track how the agency has regulated a catheter or a computed tomography (CT) scanner, including the approval process, reports of errors or adverse events, and recall notices. The website was launched as part of the FDA's [transparency](#) initiative and comes at a time when the agency is increasingly focusing on problems with excessive medical radiation.

Improving REMS to Be Focus of PDUFA

Reports are indicating that, in the next round of PDUFA negotiations, a major focus will be on improving the implementation of the REMS program. Stakeholders, at an April 12 public meeting, expressed that they would like the PDUFA V to work out the kinks in how the safety program is implemented. They also expressed that they would like the FDA to issue a uniform guidance to help the agency streamline the review process, and to involve pharmacists and health professionals sooner in the process if they anticipate a REMS. Stakeholders also called for a uniform and transparent way to express their opinions on a REMS so that the agency can make a decision based on all available data.

FDA May Implement More Strict Approval for RT Devices

The FDA is indicating that it may implement a more [strict approval process](#) for certain radiation therapy (RT) devices as a result of faulty design or misuse. The agency is also set to hold a public meeting to gather input on potential new safeguards and possible changes in premarket device testing

Industry Calls for Information about Role of Post-Market Safety Office

The pharmaceutical industry is urging the FDA to clarify the role of its post-market safety office as part of the upcoming user fee reauthorization. In light of the recent controversy surrounding Avandia, industry is pushing for better coordination between the various offices within the agency.

FDA Plans to Hold Corporate Officers Accountable for FDCA Violations

Although FDA Commissioner Margaret Hamburg indicated that the agency plans to increase the use of misdemeanor prosecutions of corporate officers to hold them accountable for violations of the Food, Drug and Cosmetic Act (FDCA), the extent to which the agency will aggressively pursue such actions remains unclear. Commissioner Hamburg has indicated that the agency has drafted guidelines for the selection of appropriate cases, and that these guidelines are still under internal review. The agency has indicated that it plans to make the final guidelines public.

FDA to Regulate At-Home Devices

The *Wall Street Journal* is reporting that the FDA has indicated that it plans to launch an initiative to increase its oversight over medical devices used at home by patients, including devices such as infusion pumps, kidney dialysis machines, and respiratory-support devices. As part of this initiative, the agency plans to create guidelines for manufacturers for the creation of devices specifically intended for home use.

FDA May Regulate Tanning Beds as Class II or III Devices

At a March 25 hearing to discuss a recent report by the International Agency for Research on Cancer, part of the World Health Organization, the panel urged the agency to make tanning beds [Class II or III devices](#). The report, covering X-rays and other devices that emit radiation, reclassified tanning beds into the highest cancer risk category -- carcinogenic to humans. The panel also recommended that the FDA require more prominent warning labels for tanning beds.

White House Officially Nominates Berwick as CMS Administrator

On Monday, President Obama [officially nominated](#) Dr. Donald [Berwick](#) to be Administrator of the Centers for Medicare and Medicaid Services, Department of Health and Human Services (CMS).

FDA Compliance Officer: Negotiate Quality Agreements with Wholesalers

At a recent conference, an FDA compliance officer encouraged manufacturers to negotiate quality agreements with wholesalers to ensure safe storage of their products and noted that manufacturers who neglect to do so may risk recalls.

MGMA Advises Members to Comply with Provision Requiring List of Alternative Facilities

The Medical Group Management Association (MGMA) is advising its members to make a good faith effort to comply with Section 6003 of the new health reform law, which requires physicians providing MRI, CT or PET scans to create a list of alternative facilities. Although the law set forth an effective date of January 1, 2010, debate exists among health lawyers and stakeholders as to whether the law could be enforced prior to the issuance of regulations by the Secretary of HHS.

Publications

The FDA has published a [transcript](#) of the statement of Charles J. Ganley, M.D., Director of the Office of Drug Evaluation IV, before the Senate Caucus on International Narcotics Control on April 13, 2010.

The FDA has published its online summary listing of March 2010 [Drug Safety Labeling Changes](#).

The FDA has published a [guidance](#) entitled "Tobacco Health Document Submission."

A report by Express Scripts Inc. found that prices for brand name drugs increased by 9.1%, and those for specialty drugs by 11.5%, in 2009.

The Agency for Healthcare Research and Quality has issued a draft report, entitled "*Comparative Evaluation of Radiation Treatments for Clinically Localized Prostate Cancer*." The report focuses on evidence of the benefits and harms of radiation therapy for localized prostate cancer compared to no treatment or no initial treatment, and the benefits and harms of different forms of radiation therapy.

The Agency for Healthcare Research and Quality has published its National Healthcare Disparities Report, in which it found that disparities among racial, ethnic and socioeconomic groups in health care are worsening over time and exist in all aspects of health care, including effectiveness, patient safety and timeliness. It also found that lack of health insurance is a key contributor to the problem.

The National Quality Forum has issued a report on "*National Voluntary Consensus Standards for Public Reporting of Patient Safety Event Information*," which recommended that state agencies, CMS and other organizations reporting patient safety information use validated, standard definitions of adverse events and vet the data to improve the quality and usefulness of patient safety reports.

International News

The European Federation of Pharmaceutical Industries and Associations (EFPIA) has announced that its 2-D data matrix anti-counterfeiting pilot project, launched last year in Sweden, was a success and that it hopes to convince others about the benefits of such an approach.

The Medicines and Healthcare products Regulatory Agency (MHRA) has issued a draft guidance stating that makers of CE-Marked cardiac ablation catheters (CACs) should have procedures in place for the ongoing postmarket review of their products.

To address cyberthreats to implantable devices, the FDA is working with the International Electrotechnical Commission and the International Organization for Standardization to develop a new international standard. The standard is expected by year's end.

Merck Chairman Karl-Ludwig Kley has stated that the German government's proposed changes to the nation's drug-pricing system will hurt efforts to bring drugs to market by requiring drugmakers to prove a new drug has a superior cost-benefit ratio compared with existing treatments.

Approvals

The FDA has approved Lannett Co.'s generic version of GlaxoSmithKline's Zofran.

Steris has received FDA clearance for its Steris System 1E (SS1E) next-generation, liquid chemical sterilizing system.

Recalls, Warnings, and Notifications

The FDA has issued a [warning letter](#) to Slate Pharmaceuticals for misleading sales aid, web pages, and video materials.

The FDA sent letters to four companies for [false](#) and misleading [advertisements](#), [emails](#), and a [webpage](#) regarding their drugs.

Hospira Inc. received a [warning letter](#) from the FDA regarding manufacturing defects at two of its plants.

The FDA is seeking an [injunction](#) against Franck's Compounding Lab of Ocala, Fla., to prevent the company from introducing adulterated, misbranded, and unsafe animal drugs into interstate commerce.

The FDA ceased enrollment in ongoing device studies reviewed by the Genetics & IVF Institute institutional review board (IRB) because of continuing review, expedited review, and record-keeping failures.

French company Poly Implant Prothese (PIP) has suspended its operations and is recalling its silicone gel breast implants after French drug and medical device regulatory authority, AFSSAPS, issued a medical device alert to healthcare

professionals based on reports of an increased number of ruptures with PIP implants and an investigation of the company's manufacturing site.

Business News

The *Wall Street Journal* is reporting that the FDA is considering halting a clinical trial studying the safety of the drug Avandia.

Oracle Corp. has indicated that it will [purchase](#) Phase Forward Inc. for approximately \$685 million, in an effort to add clinical-trial software and services that help drug companies develop products and ensure safety.

3M Co. has filed a lawsuit against Andover Healthcare Inc. alleging that the company's CoFlex 2 system appropriates trade dress, copyrighted packaging, and copyrighted instructions.

The Mississippi Supreme Court has revived a 2008 lawsuit against Bayer that alleged that the company inflated drug prices and drove up the state's Medicaid spending.

AP is reporting that healthcare reform trimmed Eli Lilly's first quarter 2010 profits by 5 percent due to the company's retiree prescription drug coverage. The company has indicated that it expects Medicaid-related rebates to further contribute to shrinking profits.

Hospira Inc. has indicated that it reached a deal to purchase specialty drugmaker Javelin Pharmaceuticals Inc. for \$145 million in cash.

Elan Corp. indicated that it may separate Elan Drug Technologies, its drug delivery business, from its main business, and create separate publicly listed companies.

Novartis AG announced that its generic drug division Sandoz bought Oriel Therapeutics.

Mylan Inc. announced that it has begun selling additional doses of the generic form of Novartis AG's antipsychotic drug Clozaril.

Two cardiologists in Minneapolis have asked a judge to reject the \$296 million plea agreement that would settle a case involving a defect in a heart defibrillator made by the Guidant division of Boston Scientific Corp.

Apotex chairman Barry Sherman has stated that the recent letter posted to the FDA site summarizes routine inspection findings dating back two years, and that the company expects that all issues will be formally resolved within months.

Opening statements in the [trial over the use of large vials of the anesthetic propofol](#) in endoscopy centers throughout southern Nevada began Monday. The plaintiff in the trial, who is suing Teva Parenteral Medicines and Baxter Healthcare Corporation for \$10 million for product liability and negligence, alleges that the use of large-sized bottles of the anesthetic encouraged the centers to use one vial on several individuals and led to his contracting hepatitis C.

Janssen-Ortho, a Johnson & Johnson (J&J) company, has stated that it is halting Canadian sales of Zeftera, after the FDA and the EU expressed concerns about the sponsor's conduct of clinical trials.

Cadence Pharmaceuticals has indicated that it plans to resubmit its medicine Ofirmev for FDA approval within the next 30 days.

Human Genome Sciences stated that partner Novartis has rescinded an application to market in Europe the former's chronic hepatitis C drug Joulferon after the European Medicines Agency said it might ask for additional clinical data on the treatment.

Novartis has announced that it will reorganize its U.S. pharmaceutical business, effective May 1, and will eliminate nearly 400 positions mostly at U.S. headquarters.

Alkermes has announced that partner Eli Lilly and Co. filed for European approval of Bydureon. Eli Lilly and its partners have also announced that they plan to submit a response this week to the FDA's complete response letter on the drug, which requested final labeling information and a risk evaluation and mitigation strategy.

A federal court has ruled that five patents on Santarus' heartburn drug Zegerid are invalid due to obviousness, a decision which could allow for generic versions of the drug to enter the market. Santarus says it plans to appeal the decision.

A federal court has refused to allow Pfizer to release confidential source documents to the *British Journal of Ophthalmology*. The journal published a study in February 2006 finding that there was an association between the use of Viagra and a vision-loss disorder. The suit alleges that the drugmaker failed to warn about the risk of this condition.

Roche Diagnostics has announced that it is acquiring Medingo Ltd. for up to \$200 million.

WellPoint has indicated that it believes its discussions with drug manufacturers about patient outcomes have improved in the 18 months since it published technology assessment criteria focusing on that topic. The insurer has indicated that it is now looking to update its criteria to include how to submit results from comparative effectiveness research.

Regulatory Notices

FDA Amends Animal Drug Regulations

The FDA has amended the animal drug regulations to reflect a change of sponsor for a new animal drug application (NADA) from Intervet, Inc., to Teva Animal Health, Inc. More information is available at <http://edocket.access.gpo.gov/2010/2010-8945.htm>.

The FDA is amending the animal drug regulations to reflect a change of sponsor's name from Minrad, Inc. to Piramal Critical Care, Inc. More information is available at <http://edocket.access.gpo.gov/2010/2010-9045.htm>. In addition, the FDA is amending the animal drug regulations to reflect a change of sponsor's name from Parnell Laboratories (Aust) Pty. Ltd. to Parnell Technologies Pty. Ltd. and to change the sponsor's mailing address. More information is available at <http://edocket.access.gpo.gov/2010/2010-9057.htm>.

FDA Issues, Amends EUAs

The FDA is announcing an amendment to the Emergency Use Authorization (EUA) (the Authorization) for peramivir injection 200 milligrams (mg)/20 milliliter (mL) (10 mg/mL) single use vial manufactured for BioCryst Pharmaceuticals, Inc. (BioCryst) for intravenous (IV) administration in certain adult and pediatric patients issued on October 23, 2009. More information is available at <http://edocket.access.gpo.gov/2010/2010-8604.htm>.

The FDA is announcing amendments to the two Emergency Use Authorizations (EUAs) for certain products from the neuraminidase class of antivirals, zanamivir and oseltamivir phosphate, issued on April 27, 2009. On October 30, 2009, FDA amended and reissued in their entirety the Authorization letters for certain zanamivir and oseltamivir phosphate products. On November 4, 2009, FDA amended and reissued in its entirety the Authorization letter for certain zanamivir inhalation powder. The Authorization letter for certain oseltamivir phosphate products, as amended on October 30, 2009, and the Authorization letter for certain zanamivir inhalation powder, as amended on November 4, 2009, including explanations for their reissuance, are reprinted in the notice document. More information is available at <http://edocket.access.gpo.gov/2010/2010-8603.htm>.

The FDA is announcing the issuance of 10 Emergency Use Authorizations (EUAs), several of which were amended after initial issuance, for certain in vitro diagnostic devices. FDA also is announcing an amendment to the EUA for the Centers for Disease Control and Prevention (CDC) Swine Influenza Virus Real-time RT-PCR Detection Panel authorized on April 27, 2009. More information is available at <http://edocket.access.gpo.gov/2010/2010-8605.htm>.

FDA Announces Proposed Information Collection

The FDA is announcing that it has submitted a proposed information collection to OMB regarding postmarket surveillance for devices. More information is available at <http://edocket.access.gpo.gov/2010/2010-8977.htm>.

Public Meetings

Risk Communication Advisory Committee

The FDA has announced that the Risk Communication Advisory Committee will meet on May 6, 2010, from 8 a.m. to 5 p.m. and May 7, 2010, from 8 a.m. to 2 p.m. in Silver Spring, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-9056.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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