

To: Our Clients and Friends

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Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin



Top News

Device Industry Calls for Closer Coordination Between FDA, CMS

Members of the device industry are calling for closer coordination between FDA and CMS related to the competitive bidding process. Stakeholders have said that the two agencies sometimes send mixed messages, due to their different approaches to devices, and particularly for sophisticated therapy products for home use, with CMS focused on pricing and the FDA focused on support services and safety issues, including labeling and training. Members of industry have indicated that they hope that new FDA guidelines on home-use devices will ensure that suppliers ensure that training and support are provided as part of their bids.

FDA Weighs New Approach to Regulation of DTC Genetic Tests

In the wake of a recent GAO report finding that direct-to-consumer genetic tests are providing inaccurate results to the public, the FDA has indicated that it is considering an approach to regulating the tests that would increase oversight without creating heavy reporting burdens on individual companies. The agency's potential approach, as currently envisioned, would not require the developers of certain diagnostics to submit data on their individual diagnostics, if a manufacturer had previously provided information on the overall indication of the diagnostic to the FDA.

Pharmacies Calling for Removal of Reimportation Amendment from Food Safety Bill

Pharmacies are ramping up their efforts to encourage lawmakers to remove an amendment to the food safety legislation, offered by senator Byron Dorgan, that would allow for the reimportation of drugs from Canada and Mexico into the United States. Pharmacies are stating that the safety of such drugs cannot be ensured and that the use of reimportation means that individuals would not be consulting with a pharmacist at the time that they obtain the drug. Some are speculating that the amendment, which Dorgan also attempted to introduce in the health reform legislation, could prevent the passage of the overall bill, and are thus encouraging its removal.

Agency News

CMS has issued a [final rule](#) that many expect will cause a [sharp decrease in the use of anemia drugs](#) such as Epogen.

The FDA has granted [priority review status](#) to Merck KGaA's cladribine multiple sclerosis drug. The agency has also granted priority review status to Amgen's drug Prolia.

An FDA official has stated that the agency is considering using a tiered, or risk-based, approach to increased monitoring of laboratory developed tests. The approach would evaluate diagnostics differently based on the potential for adverse events associated with an inaccurate product.

The FDA has indicated that office and division leadership will remain largely unchanged when the Office of Oncology Drug Products becomes the Office of Hematology and Oncology Products next year. The change in the division will result in the addition of a Division of Hematology Oncology Toxicology, which is to be led by John Leighton, currently associate director of the Office of New Drugs' pharmacology/toxicology staff.

The Institute of Medicine committee charged with recommending reforms to FDA's 510(k) clearance program has indicated that the remainder of its efforts will occur behind closed doors.

The FDA has received a citizen petition asking the agency to issue a statement that there is insufficient evidence to state that the new formulation of OxyContin is less addictive and more abuse-resistant.

Publications

The FDA and the Federal Communications Commission have published a [Joint Statement on Wireless Medical Devices](#).

The FDA has published [Medical Device Safety Tips for Air or Electric Dermatome Instruments](#).

A new study, published in the *Archives of Otolaryngology - Head & Neck Surgery*, has found that the use of zinc nasal gel products may cause patients to [lose their sense of smell](#).

Approvals

The FDA has approved Daiichi Sankyo Inc.'s blood pressure drug Tribenzor.

The FDA has approved the sale of Perrigo Co.'s said over-the-counter allergy treatment Cetirizine.

The FDA has approved Orthovita, Inc.'s facility to process collagen used in Vitagel, a product used to control bleeding during surgery.

An FDA panel has recommended approval for Medtronic Inc.'s spine surgery device Amplify.

The FDA has approved Endologix, Inc.'s PowerFit Aortic Extensions stent.

An FDA panel has voted to [recommend approval](#) for AstraZeneca's Brilinta blood thinner drug.

The FDA has [approved](#) Cuvposa (glycopyrrolate) Oral Solution.

The FDA has granted 510(k) clearance to Kent Medical Devices for the KMD-Mark1.

The FDA has granted 510(k) clearance to Calibra Medical for its Finesse insulin patch-pen.

Recalls, Warnings, and Notifications

The FDA has announced that federal agents have [seized \\$346,954.43 worth](#) of FastSize Extender devices and FastSize EQM Erectile Quality Monitor devices, as well as component parts used in the manufacture of those items, on the grounds that they are misbranded and adulterated.

The FDA is [warning physicians and patients](#) that the intravenous antibiotic [Cubicin](#) can cause life-threatening eosinophilic pneumonia.

The FDA has notified healthcare professionals and patients that it is [reviewing reports of adverse effects](#) from Evamist.

The FDA has sent a warning letter to Sanofi Pasteur's for violations of manufacturing procedures at its production plant in Marcy l'Etoile, France.

The FDA has cited an Abbott Pharmaceuticals plant in a Form 483 for failing to assure that it generates proper analytical data or performs a complete medical assessment to support its conclusions for complaint investigation.

The FDA has issued a warning letter to Piezosurgery for its complaint-handling and medical device reporting (MDR) procedures.

The FDA has issued a warning letter to Aveva Drug Delivery for GMP violations related to manufacturing of its transdermal patches.

International News

The *Wall Street Journal* is reporting that the manufacturers of CT scanners are watching closely China's preparations to spend \$125 billion on an expansion of its hospitals and clinics.

Merck & Co. and China's Sinopharm Group Co. have announced that they may enter into a partnership to market vaccines and drugs in the country.

Business News

The *Wall Street Journal* has reported Sanofi-Aventis SA is seeking a temporary restraining order to prevent Sandoz from selling a generic version of its drug Lovenox. The company is also [suing the FDA](#) over its approval of the generic. The company, which is [considering a bid for US biotechnology firm Genzyme](#) recently announced that its [second quarter profit was \\$3.2 billion](#).

Michigan's State Attorney General has announced that it has reached a settlement with Johnson & Johnson subsidiary Ortho-McNeil-Janssen Pharmaceuticals, Inc., under which Ortho will pay \$584,000 to settle claims by the state that it illegally promoted the drug Topamax.

GlaxoSmithKline PLC has stated that it erred when it created a paid supplement for the journal *Urology* last year, which included information about the drug Avodart reducing the risk of prostate cancer. The drug had not yet been approved for that kind of treatment.

St. Jude Medical Inc. has stated that it is filing a lawsuit against Volcano Corp., alleging that Volcano infringed upon its patents.

Cephalon Inc. has filed a citizen petition to the FDA, asking the agency to withdraw its approval of Watson Pharmaceuticals Inc.'s application to market a generic version of Cephalon's pain drug Fentora.

Ireland-based Covidien has reported a profit for its most recent quarter of \$364 million, an increase of almost 30 percent from the prior-year quarter.

Reports are indicating that the state of California is pressuring Bristol-Myers Squibb to reduce the cost of its AIDS medication Reyataz.

Roche Holding AG's Genentech unit has announced that it will [purchase the rights](#) to an experimental medicine being developed by NovImmune SA.

Novartis AG has announced that it [plans to give away up to 250,000 bottles](#) of its new liquid children's medicine, Triaminic Fever Reducer Pain Reliever, in an attempt to lure parents frustrated by the recent recalls of Tylenol's competing product.

Reports are indicating that Merck has agreed to pay [\\$4.85 billion](#) to settle claims filed by the families of 3,468 users of its drug Vioxx who died of heart attacks or strokes.

Eli Lilly & Co. has [lost its bid](#) to block generic sales of the cancer medicine Gemzar after November of this year.

The Senate Appropriations Committee has passed its financial services spending bill, containing a provision that would prevent brand-name and generic drug makers from reaching deals to delay generic drug marketing.

Devicemakers are criticizing recent proposals by the FDA Transparency Task Force to disclose information about PMA and 510(k) submissions prior to the approval or clearance of the devices, stating that the proposal could result in the agency revealing trade secrets.

Regulatory Notices

FDA Extends Comment Period for Proposed Neurological Device Regulations

The FDA has announced that it is reopening until September 7, 2010, the comment period for the proposed rule and guidance published in the Federal Register of April 5, 2010 (75 FR 17093). The document proposed to amend certain neurological and physical medicine device regulations to establish special controls for these class II devices and to exempt some of these devices from premarket notification requirements. More information is available at <http://edocket.access.gpo.gov/2010/2010-18405.htm> and <http://edocket.access.gpo.gov/2010/2010-18406.htm>.

Public Meetings

Radiological Devices Panel of the Medical Devices Advisory Committee to Meet

The FDA has announced that the Radiological Devices Panel of the Medical Devices Advisory Committee will meet on September 24, 2010, from 8 a.m. to 6 p.m. in Gaithersburg, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-18416.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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