

To: Our Clients and Friends

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Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin



Top News

House Panel Prioritizes Bill for More FDA Oversight of Imports

Lawmakers from the House Energy and Commerce health subcommittee have stated that they hope to move forward this year on the Globalization Act, legislation that would increase foreign facility inspections for FDA-regulated products and add new user fees in an effort to ensure the safety of medical goods entering the country. FDA Principal Deputy Commissioner Joshua Sharfstein has stated that the administration does not yet have an official position on the bill, but that the FDA supports some of the elements in the legislation.

House Leadership Preparing Health Reform Reconciliation Package

The House Budget Committee approved yesterday a shell sidecar bill in a 21-16 vote, setting in motion the health reform reconciliation process that could lead to a floor vote in the House by Friday or this weekend. Democratic leaders are continuing efforts to secure the 216 votes needed for passage, with White House [officials](#) and [Democratic leaders](#) expressing [optimism](#) that the votes will materialize. The House Rules Committee is expected to unveil the actual package of health reform fixes on its Web site Tuesday or Wednesday, and could take up the package as early as late Wednesday. The House is expected to take up the legislation this Friday or Saturday.

AdvaMed, the Medical Device Manufacturers Association, and the National Venture Capital Association have sent a letter to the White House requesting that the President cap the device excise tax included in his healthcare proposal so it will not cost more than \$20 billion over a 10-year period.

FDA Wants Greater REMS Role, Plans to Issue Drug Identifier Guidance

FDA Principal Deputy Commissioner Joshua Sharfstein indicated to the House Energy and Commerce Health Subcommittee in a March 10 hearing that the agency would like Congress to provide it with a larger role in writing Risk Evaluation and Mitigation Strategies. During the hearing, Sharfstein also indicated that the FDA is preparing to release guidance on a process for providing unique numbers to identify each unit of prescription drugs.

Hamburg Speaks before House, Senate on FDA Budget

In House and Senate hearings on the FDA's budget proposal, FDA Commissioner Margaret Hamburg stated that the agency supports user fees for the generic drug industry. She also defended the agency's plans to limit the use of certain animal antibiotics and its opposition to a drug reimportation proposal. At the Senate budget hearing, Hamburg also indicated that, while the agency has a solid technical capability for nanotechnology, it currently lacks the necessary infrastructure to pursue nanotechnology initiatives.

FDA Creates Division of Medical Imaging Products

The FDA has indicated that it plans to realign several of its offices and create a new Division of Medical Imaging Products in the face of congressional criticism and a broader effort to ensure the safety of medical imaging products following recent over-exposures to radiation. The move is part of a drug center reorganization slated to take effect March 15. As part of the realignment, rheumatology products will be relocated into a newly named Division of Pulmonary, Allergy, and Rheumatology Products and out of the Division of Anesthesia, Analgesia, and Rheumatology Products.

FDA Considering Ways to More Quickly Inform Industry

FDA device center director Jeffrey Shuren has stated that the agency is exploring ways to inform industry of changes to its regulatory expectations more quickly than through guidance documents or standards development, and that the center is trying to determine when and how to update manufacturers on revisions to standards for getting a new product to market.

Stakeholders, Congress Prepare for Post-Passage Health Reform Efforts

The Obama administration, Democratic lawmakers and health reform stakeholders are preparing themselves for post-reform implementation activities in anticipation of the passage of health care reform, with health reform advocates and stakeholders launching Enroll America, a nonprofit cooperative effort to ensure that the millions of newly eligible Americans enroll in health care plans if health care reform passes.

Venture Capital Investors Urge FDA to Increase Efforts on Novel Technologies

The National Venture Capital Association is calling on the FDA to focus its efforts on novel technologies and increase the number of experienced reviewers on staff to review innovative products. The group is advocating for the agency to establish a predictable regulatory pathway for novel technologies, structure the device clearance process based on risk, and ensure consistent expertise on review panels.

Hinchey Reintroduces Drug Safety Bill

Rep. Maurice Hinchey (D-NY) has reintroduced a sweeping FDA bill that would establish a new center for post-market safety, remove the direct link between user fees and FDA drug reviews, and reverse a U.S. Supreme Court decision barring tort suits against many medical devices.

Support for Antibiotic Bill May Be Growing

Support may be growing for a bill that would ban antibiotic use in animals, with some believing that the House Energy and Commerce Committee could hold hearings on such legislation later this year. Stakeholders are indicating that they might solicit assistance from Danish experts to help explain the impact of a European ban on growth promotion uses of the pharmaceuticals, and they say that data regarding the ban has been misrepresented by industry and opponents of the prohibition. The FDA has not expressed a formal opinion on such legislation, but chief Margaret Hamburg has indicated a desire to crack down on the use of antibiotics for growth promotion purposes instead of a strict ban.

Patient Advocacy Groups Express Support for Rare Diseases Initiative

Patient advocacy groups are expressing their support for the FDA's creation of the position of associate director for rare diseases. The Director will lead an initiative to ensure collaboration in the development of scientific and regulatory innovations that will facilitate the development, review, and approval of rare disease treatments. The FDA has chosen Anne Pariser as the acting associate director.

Judges Rule that Thimerosal Not a Cause of Autism

Three judges in separate test cases ruled Friday that thimerosal, a preservative containing mercury, does not cause autism. The rulings in the cases are the second step in the Omnibus Autism Proceeding begun in 2002 in the United States Court of Federal Claims, which combined the cases of 5,000 families with autistic children seeking compensation from the federal vaccine injury fund. Although the rulings do not end the dispute, as appeals are available, experts believe that the appeals court will uphold the decision.

Companies Find Draft Pandemic Guidance Overly Burdensome

GSK, Genentech, BIO and PDA have stated that it is "unnecessarily burdensome" for pandemic production plans to conform to parts of 21 CFR and have urged the FDA to revise its draft guidance. The companies also commented that the FDA's recommendation that test batches of products should be manufactured under conditions detailed in a company's plan is problematic because producing test batches could be expensive, lead to product shortages, and inadvertently compromise GMP.

Publications

The UK Independent published an article finding that the National Institute for Clinical Excellence (NICE) is denying thousands of cancer patients access to costly drugs under end-of-life spending criteria.

Australia has enacted an amendment to its 2002 medical devices regulations that will require all in vitro diagnostic (IVD) devices to undergo a risk-based level of review before they can be marketed in Australia beginning July 1.

Devicemakers, in comments to the FDA, have asked the agency to reconsider its apparent rejection of a "one-click" policy for presenting device safety information in some online messages, saying that they should be allowed to use links and rollover features, where there are space constraints, to lead users to additional information.

The FDA has published a final rule requiring makers of OTC acne drug products that contain benzoyl peroxide, resorcinol, resorcinol monoacetate, salicylic acid or sulfur to revise warnings and directions on the product's labeling to meet content and format requirements of 21 CFR 201.66 by March 4, 2015.

A study published in the March 16 Annals of Internal Medicine found a benefit from using proton-pump inhibitors with antiplatelet drug clopidogrel over using clopidogrel alone, a finding that could lessen the impact of the FDA's November 2009 warning against concurrent use of the drugs.

Approvals

GlaxoSmithKline has announced that the European Commission has granted marketing approval for Revolade.

An FDA panel of neurological experts voted 7-5 to recommend approval for Medtronic's Deep Brain Stimulation implant.

Recalls, Warnings, and Notifications

Boston Scientific has stated that it is recalling all lines of its implantable cardioverter defibrillators and cardiac resynchronization therapy defibrillators because the firm made manufacturing process changes without proper FDA approval.

The FDA has issued a warning to doctors and patients about [counterfeit surgical mesh](#) being illegally marketed under the C.R. Bard brand name.

The FDA has added a [boxed warning](#) to the anti-blood clotting drug Plavix (clopidogrel), [alerting patients](#) and health care professionals that the drug can be less effective in people who cannot metabolize the drug to convert it to its active form.

The FDA has issued a warning letter to MicroMed Cardiovascular regarding whether a death related to the DeBakey VAD Child Device occurred and was not reported.

The FDA has issued a letter to endoscope manufacturers stating that devicemakers must remove all statements indicating their endoscopes may be reprocessed with the SS1, which is no longer cleared for marketing. Instead, the labels should specify reprocessing with legally marketed sterilizing systems.

The FDA has indicated that it discovered several manufacturing problems at Amylin Pharmaceuticals' facility in West Chester, Ohio, during a December inspection.

Business News

AstraZeneca Plc has stated that it is [partnering with Torrent Pharmaceuticals Ltd.](#) to market 18 of Torrent's medicines in nine emerging economies. This will be AstraZeneca's first generic-drug partnership.

Allergan Inc.'s [gastric band](#) may become the first such device cleared by US regulators to be sold to children as young as 14 and may result in up to 2 million new customers.

Azur Pharma Ltd. has announced that it will buy chronic-pain drug Prialt from Elan Pharmaceuticals.

Caraco Pharmaceutical Laboratories Ltd. has announced that it has launched a generic version of Sanofi-Aventis' cancer treatment Eloxatin.

Pfizer Inc. has stated that [two studies](#) of its cancer drug Sutent failed to halt the progression of advanced breast tumors.

The New York Times is reporting that Medicis Pharmaceutical has introduced a [new marketing campaign](#), which places its anti-wrinkle injection Dysport head to head with Allergan's Botox.

Merck has announced that researchers will continue a study of its cholesterol drug Vytorin, following a determination that data indicate the drug is safe and effective.

The Wall Street Journal is reporting that the FDA is currently considering whether to end its practice of approving medical devices based on third-party reviews.

Teva Pharmaceutical Industries Ltd. has [filed suit](#) against Mylan Inc. to prevent it from selling copies of the LoSeasonique and Seasonique birth-control.

Drugmakers may be required to disclose information on their financial relationships with pharmacy benefit managers if an expanded version of Sen. Chuck Grassley's (R-Iowa) transparency legislation is passed.

The FDA has asked Protalix BioTherapeutics for additional product validation data for its Gaucher's disease drug taliglucerase alfa NDA before the agency can set an action date.

Heparin manufacturers, including Baxter, have indicated that they are having trouble getting their product past a new test established after the contamination scandal, and that this is resulting in a nationwide shortage of heparin.

Sorin Group, a developer of devices for heart rhythm disorders, has agreed to pay \$10 million to settle an inquiry by the U.S. Department of Justice into the sales and marketing practices of its division, Ela Medical, and former sales employees.

FDA reviewers have expressed uncertainty regarding clinical significance of a study demonstrating the effectiveness of pirfenidone to treat lung scarring.

AdvaMed's new chairman, Jim Mazzo, has stated that regulatory roadblocks in China, including its country-of-origin registration requirement and its reluctance to accept a variety of foreign clinical data, are the most important international marketing issue facing U.S. device manufacturers.

Companies and researchers developing cell-based and tissue engineering therapies have formed a lobbying group, the Alliance for Regenerative Medicine, to improve the federal policy environment surrounding their efforts.

Covidien has agreed to remove certain statements from promotional materials for its surgical sutures following arbitration with Johnson & Johnson/Ethicon.

The FDA has asked for additional data supporting the clinical utility of MannKind's inhalable insulin candidate Afrezza.

Regulatory Notices

FDA Seeks Comments on Smokeless Tobacco Rotational Warning Plans

The FDA is seeking public comments on the collection of information pertaining to the submission of smokeless tobacco rotational warning plans under the Comprehensive Smokeless Tobacco Health Education Act of 1986, as amended by the Family Smoking Prevention and Tobacco Control Act. Comments are due by May 17, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-5654.htm>.

Public Meetings

FDA Announces Public Meeting

The FDA is announcing a public meeting on the Prescription Drug User Fee Act (PDUFA) on April 12, 2010, from 9 a.m. to 5 p.m. in Rockville, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-5664.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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