

To: Our Clients and Friends

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Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin



Top News

FDA 510(k) Workgroup Identifies Areas for Change

Members of the FDA's internal workgroup charged with reviewing the 510(k) clearance process have identified ten areas that could require administrative, regulatory or legislative changes, including the De Novo process, incorporation of new technology, postmarket data collection, third-party review, indication definitions, evidence, standards, product bundling, device modifications and the use of predicates. The agency has stated that, now that it has completed this review, it plans to begin formulating an action plan and implement preliminary elements of that plan in September. FDA device center chief Jeffrey Shuren said the FDA evaluation and the study currently being undertaken by the Institute of Medicine are not intended to be mutually exclusive, and stated that he hopes that IOM members would provide input to the agency on its final recommendations.

Obama Continues Push for Health Reform, House Budget Committee May Begin Work on Reconciliation Bill on Monday

As President Obama [continues to push](#) for the final passage of healthcare reform, he is facing renewed opposition from the [U.S. Chamber of Commerce](#), which plans to spend between \$4 million and \$10 million on a campaign to encourage lawmakers to oppose the bill. The President has been traveling in an effort to [rally publish support](#) for the bill, and recent remarks have [emphasized efforts](#) to [curb waste and fraud](#) in government health programs. The Obama administration has also [critiqued insurance companies](#) regarding recent premium increases.

Sources have indicated that the House Budget Committee may be slated to start work on the reconciliation legislation on Monday. On Thursday, the Congressional Budget Office released an [estimate of the direct spending and revenue effects](#) of H.R. 3590. In addition, [procedural concerns](#) remain regarding the [reconciliation process](#), including whether the President would be required to sign the Senate bill into law before it could be changed through reconciliation.

Hamburg Says FDA Not Ready for Drug Reimportation

FDA Commissioner Dr. Peggy Hamburg told a Senate appropriations subcommittee on Tuesday that the agency is not prepared to support prescription drug reimportation due to fears about potential safety issues.

Supreme Court to Hear Vaccine Case

The Supreme Court has agreed to hear a case concerning the liability of drugmakers for health problems related to vaccines. The appeal involves parents in Pittsburgh who want to sue Wyeth over the serious side effects their daughter allegedly suffered as a result of the company's diphtheria, tetanus, and pertussis vaccine. The Third Circuit previously ruled against the parents, finding that federal law does not allow suits against drugmakers for injuries that were 'unavoidable' if the vaccine was made properly. The Obama administration asked the Supreme Court to hear the case and to uphold the 3rd Circuit ruling.

House Committee Turns to Drug Safety Issues

On Wednesday, the House Energy and Commerce Committee turned its attention to improving the safety of drugs made abroad, with Chairman Henry A. Waxman (D-CA) saying that the FDA needs to expand its international reach. FDA deputy commissioner Joshua M. Sharfstein emphasized the increase in pharmaceuticals being manufactured abroad and in the percentage of active pharmaceutical ingredients that are being acquired from foreign sources and called for the FDA to have increased authority to crack down on safety hazards from imported drugs when they reach the U.S. market.

Sharfstein also announced that the agency plans to release a new guidance establishing a standard for unique identification for prescription drug packages to help identify the location and authenticity of specific drug packages and distinguish them from counterfeits. Committee members have stated that they hope to move forward this year on 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.

Congress May Consider Reinspection Fees

Federal budget pressures, coupled with a need to increase the FDA's international presence, may result in Congress passing a new drugmaker user fee to cover the costs of reinspections. A reinspection fee is included in the FDA Food Safety Modernization Act, which was passed by the Senate Health, Education, Labor and Pensions (HELP) Committee and currently awaits a full Senate vote. Although that fee is not aimed at drugmakers, industry fears that it could open the door for reinspection fees for all FDA-regulated facilities.

Hamburg Indicates Need for Additional User Fees

FDA Commissioner Margaret Hamburg told a Senate appropriations subcommittee that an increase of \$101 million in funding — \$51 million of which would come from two new user fees — is needed to finance the agency's Protecting Patients Initiative.

Industry, FDA Staff Hope New Standard Will Give Better Roadmap for Devices

Device makers and FDA staff are hoping that new standard HE-75 from the Association for the Advancement of Medical Instrumentation will give firms a better roadmap for designing user-friendly devices that are less prone to human error.

FDA to Test New Recall Template

The FDA has announced that it will test a new standardized template to quickly and clearly communicate risk to consumers during the next big recall. The template includes a facts box, a headline with the product's name, the risks cited and the geographic scope of the recall.

Device Industry Seeks Definition of "New Science" from FDA

Stakeholders in the device industry are calling for the FDA to more clearly define what it considers "new science" when deciding how to incorporate emerging data into product reviews and post-market surveillance, cautioning that not all such data is scientifically credible.

CMS to Extend Bid Review Times for DME

CMS has indicated that it will extend review times for competitively bid durable medical equipment to deal with an expansion of the program in the second round of bids. CMS has also indicated that it plans to promulgate regulations on the second round of bids this summer and issue a final rule by fall, which will include product categories and education requirements.

Justice Department Investigating Ablation Devices

The Wall Street Journal has reported that the Justice Department is investigating whether devices approved by the FDA for ablation are being marketed by manufacturers for off-label treatments, including atrial fibrillation.

D.C. Appeals Court Finds ANDA Exclusivity Protected From Patent Delisting

The U.S. Court of Appeals for the District of Columbia has found that Teva was entitled to marketing exclusivity for its generic version of Merck's hypertension drugs Cozaar (losartan) and Hyzaar (losartan and hydrochlorothiazide), in a decision that means that generic manufacturers will no longer be stripped of marketing exclusivity if a brand name company delists a patent in FDA's Orange Book.

Massachusetts AG Joins Risperdal Suit

Massachusetts Attorney General Martha Coakley's office has joined a federal lawsuit alleging that Johnson & Johnson paid tens of millions of dollars in kickbacks to Omnicare in an attempt to get its drugs, and particularly its antipsychotic Risperdal, prescribed in nursing homes.

Montana Governor Asks CMS to Allow State to Import Drugs from Canada

Montana Gov. Brian Schweitzer is reportedly asking CMS to allow the state to import pharmaceuticals from Canada, in an effort to save an estimated \$40 million in expenses on Medicaid and other related programs.

Public Citizen Calls for FDA to Fire Official, Pull Three Drugs from Shelves

Public Citizen has sent a letter to the FDA requesting that the agency fire drug center director Janet Woodcock and pull the diabetes drug Avandia, the painkiller propoxyphene, and the diet drug sibutramine from the shelves.

Publications

The FDA has [updated](#) its listing of current drug shortages.

The FDA has published a listing of [February 2010 510\(k\) Clearances](#).

The FDA has published a listing of [February 2010 Drug Safety Labeling Changes](#).

The FDA has published an update to its [Pediatric Exclusivity Statistics](#).

The FDA has published a [Q&A](#) on Hydroquinone Studies Under The National Toxicology Program (NTP).

The FDA has published a [guidance](#) on S9 Nonclinical Evaluation for Anticancer Pharmaceuticals.

The FDA has published a [determination](#) that 15 drug products were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

The FDA has published a [guidance](#) for drugmakers designed to make it more straightforward for vaccine makers to use cell culture methods, and accelerate production.

The EU's revised Medical Device Directives (MDD), and the accompanying national legislation, take effect this month.

The FDA and the European Medicines Agency (EMA) have stated that they will allow sponsors to send a copy of the same orphan drug designation annual report to each agency.

Approvals

The FDA has [approved](#) Botox to treat spasticity in the flexor muscles of the elbow, wrist, and fingers in adults.

ImmunoGen, Inc. has announced that the FDA and European regulators have granted orphan drug status to the company's potential cancer drug IMG901.

Cell Therapeutics has announced that the FDA has cleared a manufacturing facility in Nerviano, Italy for its experimental cancer drug pixantrone.

The FDA's panel of lung experts voted in favor of approval for InterMune Inc.'s experimental drug pirfenidone.

Cytokinetics Inc. has announced that regulators have granted 'orphan drug' status to its potential ALS treatment.

The FDA has granted clearance to Haupt Pharma for its Italian antibiotics production facility.

The FDA has granted orphan drug designation status to Bayer HealthCare's powdered form of lung infection medicine ciprofloxacin.

The FDA has approved Sun Pharmaceutical Industries' generic version of Eloxatin.

The FDA has [approved](#) Debiopharm Group and Watson Pharmaceuticals' six-month dose of Trelstar for prostate cancer patients.

The FDA has approved Boston Scientific's Express LD Iliac Premounted Stent System for the treatment of iliac artery disease.

Recalls, Warnings, and Notifications

Cangene, Baxter and FDA have notified healthcare professionals that [cases of intravascular hemolysis \(IVH\)](#) and its complications, including fatalities, have been reported in patients treated for immune thrombocytopenic purpura (ITP) with WinRho SDF.

The FDA [has updated the information available](#) on the Class I recall of Cardiac Science Corporation's Powerheart, Cardiovive, NK, and Responder Automated External Defibrillators (AEDs).

The FDA is [notifying healthcare professionals and patients](#) that, at this point, the data that the FDA has reviewed have not shown a clear connection between bisphosphonate use and a risk of [atypical subtrochanteric femur fractures](#). The FDA recommends that healthcare professionals follow the recommendations in the drug label when prescribing oral bisphosphonates. The FDA has also stated that patients should continue taking oral bisphosphonates unless told by their healthcare professional to stop. Patients should talk to their healthcare professional if they develop new hip or thigh pain or have any concerns with their medications.

The FDA is notifying healthcare professionals of the [Class 1 recall](#) of Torflex Transseptal Guiding Sheath, a medical device used to pass heart catheters from the right to the left side of the heart.

The FDA is notifying healthcare professionals of the [Class 1 recall](#) of the AB5000 Circulatory Support System, a product that supplies power to disposable blood pumps used to support the left and/or right sides of the heart. The computer may shut down (stop pumping) without an alarm and this defect may cause serious injuries or death.

The FDA is notifying healthcare professionals of the [Class I recall](#) of UniCel DxC Synchron Clinical System – Ion Selective Electrode (ISE) Flow Cell. These systems are computer-controlled clinical chemistry analyzers used to determine different types of blood chemistries and other chemistries from blood samples collected from an individual. There may be

excessive build-up of protein, bacteria, and sample tube additives in the instrument's ion selective electrode flow cell which may cause incorrect sodium results.

A unit of Johnson & Johnson has warned doctors that an artificial hip implant appears to have a [high early failure rate](#) in some patients.

The FDA has stated that a study comparing Medtronic's deep brain stimulation system Activa PC to an inactive device has found that patients with epilepsy who were treated with the company's device did not experience a greater reduction in seizure activity.

Abbott Molecular's Des Plaines, Ill., facility has received six observations related to its hepatitis B virus (HBV) in vitro diagnostic. Abbott doesn't have complete procedures to accept or reject finished device production runs, lots or batches, and its out-of-specification products weren't adequately controlled, according to a Form 483 that stems from a June inspection.

The FDA has asked the Orthopedic and Rehabilitation Devices Panel to reconsider the 510(k) clearance of ReGen Biologics' Menaflex collagen scaffold.

Cardiac Science is providing customers with a new software update after the FDA told the company in a Feb. 5 warning letter that its previous update would not prevent failures of its Powerheart automated external defibrillators.

The FDA has warned Xian Libang Pharmaceutical for its quality control unit's failure to detect that an employee had manipulated testing data on incoming raw materials.

Business News

The UK's Prescription Medicines Code of Practice Authority has issued a preliminary ruling that AstraZeneca failed to accurately reveal the side effects of antipsychotic drug Seroquel in an advertisement to doctors.

Medtronic has stated that federal prosecutors are investigating the company's relationship with cardiologists at a hospital in Massachusetts.

Plaintiffs in a class action antitrust lawsuit against Pfizer are asking the U.S. District Court for the District of New Jersey to review company documents, saying that the documents may evidence that the company wrongfully tried to delay generic competition for its epilepsy drug Neurontin.

[Bloomberg News](#) reported that the acquisition price of OSI Pharmaceuticals Inc.' will likely increase due to its status as one of the few US biotechnology companies with income from an approved cancer.

Nabi Pharmaceuticals has announced that it closed an option and license agreement for the smoking vaccine candidate NicVax with GlaxoSmithKline.

ISTA Pharmaceuticals Inc. has announced that the FDA will make a regulatory decision on the once-daily eye inflammation treatment XiDay by Oct. 16.

A Senior Thai official has stated that he is hopeful that the WTO will reach a solution regarding the production of low-cost generic drugs.

Abbott Laboratories will acquire Facet Biotech Corp for approximately [\\$722 million](#), which includes about \$272 million in Facet's projected cash and marketable securities.

Medical device maker Orthofix International NV announced the sale of its vascular business to Covidien PLC.

GlaxoSmithKline Plc has announced that it plans to [increase its earnings](#) by expanding sales in middle-income countries.

French biotechnology company Transgene SA has stated that it sold Novartis AG an [option on rights](#) to the experimental TG4010 cancer vaccine. The deal could be worth as much as \$960 million.

Generic drugmaker Watson Pharmaceuticals Inc. has stated that it will settle patent litigation with Takeda Pharmaceutical Co. Ltd. tied to Watson's version of the diabetes treatment Actos.

Covance has announced that it will provide US drug major Eli Lilly with bioproduct analytical testing services under an expansion of the firms' year-old R&D collaboration.

German pharmaceutical firm Merck KGaA has announced a proposed acquisition of Millipore, valuing the company at €5.3bn (\$7.2bn).

An article in the New York Times outlines the current [bidding war](#) that is erupting over Ratiopharm, leading generic-drug maker with headquarters in Ulm, Germany.

Invendo Medical has applied for FDA 510(k) clearance for its C20 colonoscopy system and SC20 single-use colonoscope.

Regulatory Notices

CDER Announces Continuation of Site Tours Program

The FDA Center for Drug Evaluation and Research (CDER) is announcing the continuation of the Regulatory Project Management Site Tours and Regulatory Interaction Program (the Site Tours Program). The purpose of this document is to invite pharmaceutical companies interested in participating in this program to contact CDER. Pharmaceutical companies may submit proposed agendas to the agency by May 10, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-4924.htm>.

FDA Announces Determination on Dovonex

The FDA is announcing its determination that DOVONEX (calcipotriene) Ointment, 0.005%, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for calcipotriene Ointment, 0.005%, if all other legal and regulatory requirements are met. More information is available at <http://edocket.access.gpo.gov/2010/2010-4925.htm>.

FDA Seeks Comments on Information Collections

The FDA is seeking comments on the information collection requirements for FDA regulations related to human cells, tissues, and cellular and tissue-based products (HCT[sol]Ps) involving establishment registration and listing using Form FDA 3356; eligibility determination for donors; and current good tissue practice (CGTP). Comments are due by May 10, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-5229.htm>.

The FDA is also seeking comments on the estimated reporting and recordkeeping burden associated with the Mammography Quality Standards Act requirements. Comments are due by May 10, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-5230.htm>.

FDA Seeks Comments on Transparency

The FDA is seeking comments on ways in which agency can increase transparency between FDA and regulated industry. Comments on due by April 12, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-5377.htm>.

Public Meetings

FDA Announces Public Hearing

The FDA is announcing a public hearing to obtain input on the scope and implementation of potential expanded access programs with direct-acting antiviral agents (DAAs) for the treatment of chronic hepatitis C (CHC) infection in patients with unmet medical need. This public hearing is being held to obtain comments from the public on eligibility criteria that should be used for patient enrollment in expanded access protocols involving DAAs and to elicit suggestions for designs of protocols for treatment investigational new drug applications (INDs) involving DAAs and other expanded access protocols.

The meeting will be held on April 30, 2010, from 9 a.m. to 4 p.m. in Rockville, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-5055.htm>.

Advisory Committee for Pharmaceutical Science and Clinical Pharmacology to Meet

The FDA has announced that the Advisory Committee for Pharmaceutical Science and Clinical Pharmacology will meet on April 14, 2010, from 8 a.m. to 5 p.m. in Silver Spring, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-5264.htm>.

FDA to Hold Public Workshop

The FDA, in conjunction with the CDC and NIAID, will be hosting a Public Workshop on Advancing the Development of Diagnostic Tests and Biomarkers for Tuberculosis. The workshop will be held June 7 - 8, 2010, at the National Labor College in Silver Spring, Maryland. More information is available at <http://www.fda.gov/ScienceResearch/SpecialTopics/CriticalPathInitiative/UpcomingEventsonCPI/ucm203262.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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