

To: Our Clients and Friends

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Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin



Top News

White House Releases Health Care Proposal for Summit

The [President](#) released his [proposal](#) for health care reform [yesterday](#), touting it as a starting point for the [bipartisan](#) health care [summit](#) on Thursday. The President's [proposal](#) aims to [bridge the gap](#) between the health reform bills passed by the House and the Senate and includes [provisions](#) targeting [insurance rate increases](#). The plan also increases fees on brand name pharmaceuticals by \$10 billion. In addition, the plan calls for the creation of an approval pathway for biosimilars but does not provide details regarding the level of data exclusivity for innovator biologics. The plan also includes a \$20 billion excise tax on the device industry, similar to a provision passed by the House last November. The proposal indicates that the tax would start in 2013, but does not include a tax rate.

Republicans [responded](#) to the plan by saying that it is a mere echo of the bills already in existence, suggesting that the [summit](#) may be [more likely](#) to produce a face-off between the parties than a deal. Democrats have stated that they believe that, even without Republican support, they could [advance the package](#) through the budget reconciliation process, which would require only 51 votes. A top AARP official has predicted that, even in the absence of health reform, Congress will push this year for lowered prescription drug costs.

Stakeholders Call for Clarity on 510(k) Process

Stakeholders, at a meeting with the FDA on the agency's 510(k) process, asked the agency to clarify its "unofficial policies" that are hampering the 510(k) review process currently in use by the agency. Devicemakers also asked the agency for guidance on substantial equivalence topics such as the appropriateness of multiple predicates in a 510(k) submission and approval of minor modifications of a device's indications for use. In addition, some stakeholders suggested that the agency shift the regulatory framework away from a predicate device-centric mentality and toward a more risk-based approach, or to bolster the de novo device review process for Class II devices.

The FDA called for the meeting in order to obtain industry input as it evaluates potential changes to its 510(k) process. One of the issues being considered by the agency is the extent to which the agency should consider new information about the risk-benefit profile of a marketed device during the premarket review of a similar device. The FDA is also considering changing how predicate devices are selected for 510(k) submissions and beefing up its post-market authorities for 510(k)-cleared products.

FDA Generic Drug Decisions Delayed Due to Backlog

Industry analysts are reporting that American consumers wait nearly a year longer on average for FDA approval of new generic drugs than they did in 2005 due to a current backlog of applications at the FDA. It is estimated that the delay costs Americans and the federal government hundreds of millions of dollars annually. FDA Commissioner Margaret Hamburg has said that the agency hopes to see generic user fees enacted this year to reduce the backlog.

Grassley Continues to Prod FDA on Foreign Drug Inspections

Sen. Charles Grassley (R-IA) is continuing to prod the FDA regarding its progress on initiatives tied to its foreign drug inspection program, and has stated that he is considering a legislative press on the issue. According to a Senate Aide, the Senator is weighing reintroducing legislation that would expand FDA's authority to inspect foreign manufacturers and importers and allow it to share confidential information with foreign governments.

FDA: REMS Guidance May See Further Delays

Kathleen Frost, CDER's associate director for regulatory affairs has cautioned that the FDA's guidance on Risk Evaluation and Mitigation Strategy, which has been under construction by the agency for more than a year, could see further delays before it is finalized, as the same CDER staff charged with reviewing proposed REMS are charged with drafting the guidance.

FDA to Place Increased Focus on Financial Disclosures

FDA spokeswoman Ayse Yeaton has stated that, as part of a recent change to the FDA's Compliance Program Guideline Manual, FDA inspectors will verify that clinical investigators initially disclosed information about personal financial interests, along with those of his or her spouse and dependent children, and that the FDA will step up its efforts to verify such disclosures during site inspections.

Swine Flu to Be Added to Seasonal Flu Vaccine

An FDA advisory committee has determined that the 2010-2011 seasonal influenza vaccine will include protection against swine flu. Even with the CDC's announcement that the swine flu is no longer widespread in any state, disease experts are unwilling to discount the possibility that the country may experience another wave of the flu.

FTC Criticizes Pharma Cooperation with Investigations

Richard Feinstein, director of FTC's Bureau of Competition, stated at a recent conference that the FTC is growing frustrated with the difficulties it is facing with exacting the cooperation and compliance of pharmaceutical companies with FTC probes, saying that the agency has faced difficulties in getting some companies to comply with compulsory process requests, civil investigative demands, and subpoenas.

Eucomed Calls for Increased Harmonization of Device Regulations

Eucomed, representing the device industry in Europe, is calling on the European Commission (EC) to increase global harmonization of device regulations and make the process mandatory rather than voluntary. The group noted that the EU receives the most innovative medical technologies two years ahead of the U.S. and 10 years earlier than Japan.

Ireland Cuts Drug Prices

Ireland slashed the prices of 300 branded multisource medicines, including Zofran and Casodex, by around 40 percent at the start of the month, and there are strong indications that more cutbacks are to follow.

Publications

The FDA has published an article in the *New England Journal of Medicine* defending its decision to approve diabetes drug Victoza, despite the warning by some that the drug may cause a rare type of thyroid cancer.

A [retrospective analysis](#) published in the *Journal of the National Cancer Institute* reviews the more than 50 new indications for the use of oncology and hematology drugs and biologics between July 2005, when the office began reviewing marketing applications, and the end of 2007. The journal article is available at <http://jnci.oxfordjournals.org>.

The FDA has published a listing of [January 2010 labeling changes](#) for drug products.

The [National Institutes of Health](#) has issued a proposal to [expand its definition of human embryonic stem cells](#), a move which would enable researchers to begin a clinical test of the use of embryonic stem cells to treat macular degeneration.

A Millman study financed by GlaxoSmithKline has found that patients take fewer cancer drugs when insurance plans make them pay more for expensive oral medications.

Approvals

The FDA has [approved](#) Rituxan (rituximab) to treat certain patients with chronic lymphocytic leukemia.

The FDA has approved Syneron Medical's eMatrix heat-based system to smooth facial wrinkles.

The FDA has approved Novartis AG's meningitis vaccine Menveo for use in teenagers and adults.

The FDA has approved Gilead Sciences Inc's lung infection [antibiotic](#) Cayston.

The FDA has approved Medtronic's Physio-Control division to resume the distribution of its external defibrillators.

Recalls, Warnings, and Notifications

FDA notified healthcare professionals and consumers that, due to [safety concerns](#), FDA is requiring a risk management strategy ([REMS](#)) and class-labeling changes for all [Long Acting Beta Agonists](#). REMS will require a revised Medication Guide [written specifically for patients](#), and a plan to educate healthcare professionals about the appropriate use of LABAs.

The FDA has announced that it is requiring that the drug deferiasirox include a [black box warning](#) about potentially fatal renal, hepatic, and gastrointestinal damage.

Confidential government reports obtained by the [New York Times](#) recommend the [removal](#) of the drug Avandia from the market due the drug's [associated risks](#) of heart attack and heart failure. The Senate has issued a report saying that GlaxoSmithKline, the maker of the drug, knew of the potential risks. Another report linked the drug to 83,000 heart attacks between 1999 and 2007.

The FDA is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) [permanently debarring](#) Patrick J. Lais from providing services in any capacity to a person that has an approved or pending drug product application.

The FDA is issuing a [warning to consumers](#) not to use ear candles because they can cause serious injuries, even when used according to the manufacturer's directions.

Repros Therapeutics has submitted a revised indication to investigate Androxal oral tablets as a low-testosterone treatment for hypogonadal men.

Business News

The FDA has stated that drugmakers may have to wait longer than usual for FDA decisions on their products as the agency catches up after being shut down for several days by heavy snow.

An article in the Wall Street Journal discusses the lack of patent protection and enforcement in India, and the effect it is having on the generic drug industry in the country, including India's compliance with WTO rules on intellectual property.

Hologic Inc. stated that it has reached a settlement with a division of Johnson & Johnson concerning the patents on biopsy devices used to test for breast cancer, under which Hologic will pay \$12.5 million and the Johnson & Johnson division will pay royalties to Hologic on sales of its Mammotome MR system.

Basilea Holding AG is accusing Johnson & Johnson, its development partner for the MRSA drug ceftobiprole, of breaching their licensing agreement and giving Basilea full rights for the drug after it was rejected by European regulators.

Pfizer is facing a [national class-action lawsuit](#) in Canada for allegations that the company failed to warn consumers about the risks of its epilepsy drug Neurontin.

Transcept Pharmaceuticals Inc. has announced that the FDA has agreed to review its revised application for Intermezzo.

Sandoz, a generics subsidiary of drugmaker Novartis, will pay \$3.5 million to settle allegations that sales of a drug deemed ineffective by the FDA continued to be billed to Medicaid and the military's Tricare program.

A state court jury in Pennsylvania has found Pfizer liable for [\\$9.45 million](#) for failure to warn a woman of the risks of taking its drug Prempro. The woman later developed breast cancer. The amount includes \$6 million in punitive damages.

The first trial over whether AstraZeneca [properly disclosed the risks](#) of its diabetes drug [Seroquel](#) has begun in a New Jersey court.

Adam Sims, commercial director at Aesica, has stated that the company is looking to acquire manufacturing assets in the US to expand its client base in the country.

Eli Lilly, Merck & Co and Pfizer have announced that they will be combining resources to form the Asian Cancer Research Group (ACRG), a non-profit company which aims to accelerate research into lung and gastric cancers in Asia.

AdvaMed and the Medical Device Manufacturers Association urged CMS to provide better payment incentives for device companies to develop and deploy innovative technologies at the fiscal 2011 New Technology Town Hall held at CMS headquarters.

Regulatory Notices

FDA Seeks Comments on Proposed Information Collections

The FDA is announcing an opportunity for public comment on the Experimental Study of Graphic Cigarette Warning Labels that is being conducted in support of [the graphic label statement provision](#) of the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act). Comments are due by April 23 2010.

FDA Seeks Comments on Environmental Impact of Amending OTC Monographs

The FDA is requesting data and information regarding the potential environmental impact of [amending over-the-counter \(OTC\) drug monographs](#) to include certain active ingredients not previously marketed in the United States or marketed in the United States under approved applications after the OTC drug review began in 1972. Information is due by May 24, 2010.

Public Meetings

House Hearing on Medical Radiation Scheduled for Friday

The Subcommittee on Health of the House Energy and Commerce Committee will hold a hearing on medical radiation on Friday. The hearing, originally scheduled for Feb. 10, was postponed because of snowstorms in Washington, D.C. Subcommittee chairman Rep. Frank Pallone Jr., D-N.J., will preside over the hearing, which will tackle radiation-related problems, including increasing exposure to radiation and errors in the use of radiation in imaging and therapy.

CDC Advisory Committee to Meet

The CDC's Advisory Committee on Immunization Practices is scheduled to meet in Atlanta on Feb. 25, 2010, to determine whether a trio of vaccines to treat meningitis eventually should be recommended routinely for infants and toddlers less than two years of age.

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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