

To: Our Clients and Friends

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Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin



Top News

Health Reform Stalls in House, Senate

The win by Republican [Scott Brown](#) of a seat in the Massachusetts Senate has Democrats struggling to find [alternative options](#) for passing the health care bill. Among the options being considered are offering a [more scaled-back](#) measure, using the budget reconciliation process, or reaching out to Republicans, such as [Olympia Snowe](#), in an attempt to gain their support.

White House Chief of Staff Rahm Emanuel has outlined that the [scaled-back version](#) of the legislation may primarily address [insurance reform](#) and a Medicaid expansion. The fate of the medical device tax in a scaled-back version is unclear, but experts predict that such industry fees could still be employed to help cover costs. Snowe has stated that she supports a pared-down version of the bill that focuses on insurance market reforms.

On Thursday, [House Speaker Nancy Pelosi](#) announced that the House [lacks enough support](#) to pass the Senate's version of the bill, one of the alternatives initially under consideration. Reports are predicting that, if the budget reconciliation process were used to pass health reform, House Democrats likely would have to accept the Senate's more insurance-friendly reforms.

Some consumer groups and patient advocates, however, are urging against scaled-back reforms, calling for passage of [a comprehensive bill](#). BIO has announced that it is continuing to fight to preserve the 12 year exclusivity period for innovator biologics, a provision in both the House and Senate bills.

FDA Releases 2010 Goals, Names Device Director

The FDA has named Jeffrey Shuren as permanent device center director and released its list of strategic priorities for 2010. Priority areas for CDRH include implementing a total product life cycle approach, enhancing transparency and communication, strengthening the CRDH workforce, and fostering innovation to better meet public health needs. In addition, the FDA has identified several other objectives for 2010, including making changes to the 510(k) and PMA pre-market programs, harmonizing international inspection activities by 2011 and creating unique device identification by 2013.

FDA Moves for Dismissal of Allergan Suit

The FDA has argued for dismissal of Allergan's lawsuit regarding whether the agency should allow companies to provide doctors with dosing information on off-label uses of its drug Botox. The agency argues that its drug approval system is constitutional and that its "Good Reprint Guidance" allows companies to provide certain information regarding off-label uses of Botox.

Industry Urges REMS Changes

Industry groups, including the Pharmaceutical Research and Manufacturers of America and the Biotechnology Industry Organization Industry, are urging the FDA to revise its draft guidance on Risk Evaluation and Mitigation Strategies to ensure that manufacturers of drugs and biologics are not held accountable for the actions of third parties and to further explain how it will determine whether a REMS is necessary and how it will be assessed. Kaiser Permanente has urged the FDA to give health care providers and the public a key role in the REMS development process. Deborah Henderson, director of CDER's Office of Executive Programs, has stated that the FDA will increasingly ask its advisory committees for input on ensuring drugs are used safely.

Survey Finds Increase in Orphan-Drug Designations

A survey by Tufts University found that the number of treatments that received orphan-drug designation from the FDA more than doubled since 2000, increasing from 208 products between 2000 and 2002 to 425 between 2006 and 2008.

California State Legislature Introduces Single Payer Health Legislation

Democrats in California revived a bill Thursday that would create a [single-payer, universal health care system in the state](#).

India Imposes New Rules on Trial Investigators

The Medical Council of India (MCI) has imposed new rules on the relationships between physicians and drug- and devicemakers, banning industry gifts and establishing ethical rules for clinical trials.

Publications

The FDA has updated its listings of [current](#) and [resolved](#) drug shortages.

The Agency for Healthcare Research and Quality (AHRQ) has written a draft report stating that tests like HeartScape Technologies' Prime ECG and Premier Heart's 3DMP show potential but that insufficient information remains on whether these and other ECG-based signal analysis technologies have any impact on diagnostic decision-making or patient outcomes. The report calls for more research on the technologies.

The FDA's Pediatric Review Committee has published a report finding that the FDA needs to update its guidance on submitting pediatric drug assessments and ensure staff reduces errors in granting waivers for them.

The MHRA has published a public consultation document stating its [plan](#) to make counterfeiting a specific criminal offence with a maximum sentence of 12 years.

Saudi Arabia has issued a draft guidance indicating that drugmakers wishing to make products in Saudi Arabia should submit a site master file to the Saudi Food and Drug Authority with the names, dosage forms and product licenses of all drugs manufactured at a plant.

Approvals

Thoratec has announced that the FDA has approved its HeartMate II heart pump.

Lupin Ltd has announced that it has received FDA approval to continue operations at its Mandideep manufacturing plant.

Abaxis Inc. has received marketing approval from the FDA for its C-Reactive Protein (CRP) assay.

The FDA has tentatively approved Teva Pharmaceutical Industries Ltd.'s generic version of Novartis' breast cancer drug Femara [letrozole].

Recalls, Warnings, and Notifications

The FDA has [notified healthcare professionals](#) that its review of additional data indicates an increased risk of heart attack and stroke in patients with a history of cardiovascular disease using sibutramine. Based on the serious nature of the review findings, FDA requested and the manufacturer agreed to add a new contraindication to the sibutramine drug label.

The FDA has issued a warning [letter](#) to Crothall Healthcare for several good manufacturing practice (GMP) violations.

The FDA has issued a warning [letter](#) to Symmetry Medical for failure to conduct audits of its quality system.

Business News

Merck has announced that it will not seek FDA approval for its HIV drug vicriviroc due to failure to meet goals in late-stage studies.

Public Citizen has urged the FDA to [recall](#) Forest Laboratories' drug Savella.

[GlaxoSmithKline Chief Executive Andrew Witty](#) has announced that the company plans to become more involved in developing treatments for diseases, such as malaria, that are more common in the developing world. Witty announced that the company plans to adopt not-for-profit pricing on its potential malaria vaccine, reveal previously confidential data on thousands of potential anti-malaria compounds, and spend \$8 million to fund a research lab for malaria treatments.

Medical device maker Vascular Solutions Inc. stated that it has received \$3.5 million from Marine Polymer Technologies following a court ruling that Marine Polymer employees made false statements about Vascular Solutions products.

Johnson & Johnson has announced that it has completed its \$785 million purchase of Acclarent Inc.

Johnson and Johnson's Cordis unit has [filed a lawsuit against Boston Scientific Corp.](#) claiming its Promus drug-coated stent infringes upon three of Cordis' patents.

Genzyme Corp. has announced that that FDA is scheduled to make a decision on its Pompe disease drug Lumizyme [alglucosidase alfa] by June 17.

Forbes is reporting that Pfizer and Teva Pharmaceutical Industries Ltd. are both battling to acquire German generic-drugmaker Ratiopharm.

Pfizer has announced that it is [seeking partnerships and acquisitions](#) with Chinese drugmakers and increasing its Asian sales force in an effort to tap into the Chinese market.

GenVec has announced that it has reached an [agreement with Novartis](#) to license its early-stage work aimed at reversing hearing loss.

Ipsen SA has announced that it has reached an agreement under which it will pay [\\$85 million](#) to purchase a 20 percent stake in Inspiration Pharmaceuticals Inc.

VMG Global has pleaded guilty to selling "dietary supplements" that had been spiked with steroids, according to an article in the [New York Times](#).

Amphastar Pharmaceuticals Inc. has stated that it will [appeal the FDA's rejection of its complaint](#) that Janet Woodcock, director of FDA's Center for Drug Evaluation and Research, had a conflict of interest and should not have been allowed to participate in the deliberations over Amphastar's application to make generic heparin.

The FDA has declined to use different criteria in evaluating generic versions of Reckitt Benckiser Group's Mucinex, according to an article in the Wall Street Journal.

US CMO Catalent has announced its purchase of Harro Hofiger Omnidose filling unit.

Ranbaxy Laboratories has announced its acquisition of India-based Biovel Lifesciences.

Centocor Ortho Biotech has again filed suit against Abbott Laboratories for patent infringement on Centocor's Humira.

Depomed has stated that it plans to file a special protocol assessment for a second Phase III trial of its drug Serada by February.

The FDA's Cardiovascular and Renal Drugs Advisory Committee voted against approving Forest Laboratories' Bystolic (nebivolol) for chronic heart failure, but suggested the drug could be approved for this added indication if the drug maker conducts a non-inferiority trial against other beta-blockers.

Twelve major drug developers have joined the Coalition Against Major Diseases (CAMD) to develop quantitative disease progression models for Alzheimer's Disease and Parkinson's Disease and identify biomarkers that can identify patient populations most likely to benefit from new therapies.

Regulatory Notices

FDA Publishes Draft Guidances

The FDA is announcing the availability of the draft guidance document entitled "Heart Valves -- Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications." This draft guidance document describes FDA's recommendations about investigational device exemption and premarket approval applications for heart valves. Comments must be submitted by April 20, 2010, to ensure that the agency considers them before it begins work on the final version of the guidance. More information is available at <http://edocket.access.gpo.gov/2010/2010-990.htm>.

The FDA is announcing the availability of a guidance entitled "M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals." The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). More information is available at <http://edocket.access.gpo.gov/2010/2010-1027.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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