

To: Our Clients and Friends

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Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin



Top News

Work Continues on Health Bill

Senate [Democrats](#) are facing continued [challenges](#), including [stalling tactics](#) and other pressing business, as they seek to reach the [60 votes](#) necessary to pass [health care](#) legislation. [President Obama met with Senate Democrats](#) on Tuesday to [urge them](#) to pass the bill. In order for Majority Leader Reid to meet the December 22 or 23 deadline that aides floated last week, he would need to lock in 60 votes and begin bringing the debate to a close within days.

The Senate [voted down](#) an [amendment](#) designed to facilitate the importation of cheaper prescription drugs from Canada and Western Europe. Democratic Senators said Wednesday they've been told the pharmaceutical industry will contribute [billions of dollars more](#) than it had previously promised, and that the money will be used to close a gap in Medicare drug coverage.

Senator Evan Bayh (D-IN) has filed an amendment that would delay the implementation of and expand exemptions for the excise tax that medical device manufacturers would pay under health reform legislation. The Senate health reform bill currently includes a device tax designed to raise \$20 billion over 10 years, assessed by a company's market share, with an exemption for manufacturers with less than \$5 million in annual U.S. sales. Bayh's amendment would exempt up to \$100 million in sales and tax half of annual sales revenue between \$100 and \$150 million.

A Washington Post/ABC News Poll has found that [public support](#) for the bill is waning, and that more than half of those polled believe that the bill would lead to higher costs for themselves and a higher overall cost of national health care system.

Maryland Insurance Commissioner to Move to FDA

Maryland Insurance Commissioner Ralph S. Tyler, has announced that he is stepping down early next year to become [general counsel](#) at the FDA.

32 Arrested on Charges of Medicare Fraud

U.S. officials have stated that the government is expanding its [investigations of Medicare fraud](#) and that 32 have been arrested on charges that they submitted \$61 million in phony Medicare claims.

Sanofi-Aventis Recalls 800,000 Doses of H1N1 Vaccine

Sanofi-Aventis has announced that it is [recalling 800,000 doses](#) of its swine flu vaccine for [infants and children](#) due to a [loss of strength](#) since they were shipped. Officials have emphasized that the recall is not due to any safety concerns with the vaccine.

FDA Expands Presence Outside U.S. with Opening of Mexico City Post

The FDA has announced the opening of a [Mexico City post](#). Staff assigned to the Mexico City post will work with their counterparts in the Mexican government to harmonize regulations and guidance standards and to work on other collaborative initiatives.

FDA Official Rescinds Order Permitting Agency Reviewers to Miss Deadlines, but Concerns About Experience Remain

The FDA's top drug reviewer has rescinded a 2007 order allowing reviewers to miss deadlines for assessing new pharmaceuticals in light of recent hiring in the agency. However, Office of New Drugs Director John Jenkins also acknowledged that lack of experience among new hires could pose hurdles to the agency's ability to meet its goal of reviewing 90 percent of new drug applications within the time frame mandated by the Prescription Drug User Fee Act.

Jenkins has also stated that he supports the public release of FDA "complete response" letters as part of the agency's transparency initiative, as this might lead to sponsors submitting more complete applications from the outset.

Harkin Shuffles Office, Committee Staff

Senate health committee Chair Tom Harkin (D-IA) is reshuffling staff in both his personal office and at the committee level, bringing in former aide and American Cancer Society Cancer Action Network President Dan Smith as committee staff director and tapping Pam Smith, his personal office's legislative director, to serve as the committee's deputy staff director.

Proposed DTC Rule on Horizon

A proposed rule on direct-to-consumer prescription drug advertising that is currently slated for release next year could give FDA more leeway to regulate ads, according to industry sources. The proposed rule would require that a product's side effects and contraindications in DTC television and radio ads be presented in a "clear, conspicuous and neutral manner."

Senate Committee Approves Bill for Domestic Production of Medical Isotope

The Senate Energy and Natural Resources Committee approved by voice vote a bill that would authorize and encourage domestic production of low-enriched uranium for use by domestic molybdenum-99 producers, in an effort to encourage domestic production of the substance, which is used in diagnostic medical procedures. The House passed the bill 400 to 17 in November.

Approvals

The FDA has approved the first [generic versions of Aricept](#) (donepezil hydrochloride) orally disintegrating tablets.

The FDA has approved Chelsea Therapeutics International Ltd.'s request to enroll 24 more patients in a study evaluating Droxidopa's (L-dihydroxyphenylserine) effectiveness in treating symptomatic neurogenic orthostatic hypotension.

The FDA has granted 501(k) clearance to Dilon Diagnostics for its GammaLoc lesion localization system.

Warnings and Notifications

The FDA has posted a listing of drug products with [safety labeling changes](#) to the Boxed Warning, Contraindications, Warnings, Precautions, Adverse Reactions, or Patient Package Insert/Medication Guide sections.

The FDA has warned Abbott Laboratories that one of their Swedish plants is in violation of manufacturing practices.

Novartis and Endo Pharmaceuticals have revised the prescribing information for pain drug Voltaren to warn of hepatic risks such as liver failure.

Procter & Gamble have announced that they are conducting a voluntary recall of three lots of Vicks Sinex nasal spray after finding the bacteria *Burkholderia cepacia* in a small amount of product.

Division of Psychiatry Products Director Thomas Laughren has stated that the FDA likely will move metabolic information to the warning section in labeling for all atypical antipsychotics.

Publications

MHRA has published a guidance that allows devicemakers seeking to amend a marketing authorization in the UK to group a series of minor amendments in the same application. The guidance states that changes should be related and meaningful to be reviewed simultaneously but that applicants need not group them if there are advantages in making separate submissions for each of the nonconsequential changes.

CDRH has stated that it is investigating more than 250 reports of patients receiving excessive radiation from imaging machines manufactured by GE Healthcare and Toshiba and has released [recommendations](#) to reduce the risk of overexposure.

The Global Harmonization Task Force has published a discussion paper calling for the use of unique codes in a globally accepted format when developing a global unique device identification system. Comments on the paper are due March 31, 2010.

CMS to Cover HIV Screening Tests for Certain Medicare Patients

CMS has announced that it will cover standard laboratory and rapid HIV screening tests for certain Medicare patients.

CMS Revises Carotid Artery Stenting Policy

CMS has revised its carotid artery stenting policy and has stated that new embolic protection devices used in conjunction with carotid stents are covered by Medicare, but that the stenting procedure cannot be covered without the use of a protection device.

FDA Advisory Panel Recommends Against Approving Tarceva

An FDA advisory panel has [recommended against](#) approving Tarceva for use in patients with advanced lung cancer.

Judge Dismisses Lawsuits Against Pfizer and Teva

A New York judge [has dismissed](#) at least 23 lawsuits against Pfizer Inc.'s Wyeth and Pharmacia & Upjohn units and Teva Pharmaceutical Industries Ltd. by women alleging that the companies' menopause drugs caused their breast cancer.

Pfizer Asks Judge to Order Removal of Prempro Video from Internet

Pfizer Inc. has asked a judge to [order the removal](#) of an Internet video about its menopause medicines, saying that the video is both misleading and aimed at swaying jurors in future trials.

Missouri Governor Supports Proposal for Biotech Incentive Fund

Missouri Governor Jay Nixon has stated his support for a proposal to direct tens of millions of tax dollars generated by biotechnology companies to a special state fund which would give incentives to new or expanding biotechnology entrepreneurs.

EC Conducts Surprise Pharma Inspections

European Commission officials have been conducting surprise inspections at certain pharmaceutical companies as part of their recent clampdown on anticompetitive practices. H Lundbeck and Teva Pharmaceutical Industries have confirmed that they were among the companies inspected.

Scientists Find Certain Artificial Cells May Lead to Better Drug Delivery

A team of scientists from the University of California have found that using artificial red blood cells that mimic certain characteristics could allow for better nanotech drug delivery.

NIOSH Chief Discusses Upcoming Issues

NIOSH chief John has stated that some of the upcoming issues for NIOSH in the year ahead include support for extramural research, work on H1N1, nanotechnology, the relationship between workplace exposures and genetic traits, flu respirator needs, and challenges posed by demographic transitions in the workforce.

Cellular Dynamics Launches Human Heart Cells Derived from iPS Cells

Cellular Dynamics International has announced that it is launching its iCell Cardiomyocytes, human heart cells developed from induced pluripotent stem cells.

AdvaMed Announces Plan to Form IVD Association

AdvaMed has announced that it plans to form an association that will focus exclusively on in vitro diagnostics.

Steris' MedWatch Highlights Need for Communication

Daniel Owczarski, a device analyst at Avondale Partners who covers Steris, has stated that the recent MedWatch about Steris' System 1 (SS1) processor used to sterilize devices was not expected by the company.

Teva and Abbott Reach Generic TriCor Agreement

Abbott Laboratories and Teva Pharmaceuticals USA have reached a licensing agreement that would allow Teva to begin selling a generic version of Abbott's TriCor as early as 2011.

Approval of Novartis' Everolimus Could Mean mTOR Inhibitor Class REMS

The likely approval of Novartis' everolimus for prevention of kidney transplant rejection could bring with it safety labeling updates and Risk Evaluation and Mitigation Strategies for all drugs in the mTOR inhibitor class.

FDA Panel Finds GE MRI Gadolinium Contrast Agents Have Higher Side Effect Risk

At a December meeting, the Cardiovascular and Renal Drugs and Drug Safety and Risk Management Advisory Committees determined that GE's Omniscan and Mallinkrodt's OptiMARK have a greater risk of a rare but crippling and life-threatening disease called nephrogenic systemic fibrosis than other gadolinium agents in higher-risk patients.

Regulatory Notices

FDA to Accept Comments on Draft Guidances from ICH

The FDA is announcing the availability of a draft guidance entitled "Addendum to ICH S6: Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals S6(R1)." The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). Although the FDA is accepting comments on the guidance at any time, comments must be submitted by February 1, 2010, to ensure consideration of the comments before the FDA begins work on the final version of the guidance. More information is available at <http://edocket.access.gpo.gov/2009/E9-29991.htm>.

The FDA is announcing the availability of a draft guidance entitled "Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 11: Capillary Electrophoresis General Chapter." The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). Although the FDA is accepting comments on the guidance at any time, comments must be submitted by February 16, 2010, to ensure consideration of the comments before the FDA begins work on the final version of the guidance. More information is available at <http://edocket.access.gpo.gov/2009/E9-29990.htm>.

The FDA is announcing the availability of a draft guidance entitled "Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 12: Analytical Sieving General Chapter." The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). Although the FDA is accepting comments on the guidance at any time, comments must be submitted by February 16, 2010, to ensure consideration of the comments before the FDA begins work on the final version of the guidance. More information is available at <http://edocket.access.gpo.gov/2009/E9-29988.htm>.

CDC Extends Comment Period for Proposed Rulemaking on Total Inward Leakage Requirements for Respirators

The Centers for Disease Control and Prevention is extending to March 29, 2010, the comment period for the notice of proposed rulemaking by the National Institute for Occupational Safety and Health (NIOSH) of CDC, entitled "Total Inward Leakage Requirements for Respirators," published in the Federal Register on Friday, October 30, 2009 (74 FR 56141). In the notice of proposed rulemaking, CDC requested comments by December 29, 2009. The Agency is taking this action in response to requests for an extension to allow interested parties additional time to submit comments. More information is available at <http://edocket.access.gpo.gov/2009/E9-29959.htm>.

Public Meetings

FDA Announces Meeting of Oncologic Drugs Advisory Committee

The FDA has announced that the Oncologic Drugs Advisory Committee will meet on February 10, 2010, from 8 a.m. to 5 p.m. in Gaithersburg, Maryland. The Committee will consider Cell Therapeutics' pixantrone dimaleate for recurring,

aggressive non-Hodgkin's lymphoma and ChemGenex's omacetaxine mepesuccinate for chronic myeloid leukemia with the Bcr-Abl T3151 mutation. More information is available at <http://edocket.access.gpo.gov/2009/E9-29989.htm>.

FDA Announces Meeting Regarding CDRH Strategies

The FDA is announcing a public meeting entitled "Incorporation of New Science Into Regulatory Decisionmaking Within the Center for Devices and Radiological Health." The purpose of the public meeting is to identify strategies and means for incorporating new science into the regulatory decisionmaking process within the agency's Center for Devices and Radiological Health (CDRH). The meeting will be held on February 9, 2010, from 8 a.m. to 5 p.m. in Gaithersburg, Maryland. Persons interested in attending the meeting must register by 5 p.m. on February 3, 2010. More information is available at <http://edocket.access.gpo.gov/2009/E9-30114.htm>.

FDA Announces Public Workshop on Clinical Trial Requirements

The FDA Florida District, in co-sponsorship with The Society of Clinical Research Associates, Inc. (SoCRA), is announcing a public workshop entitled "FDA Clinical Trial Requirements, Regulations, Compliance and GCP." This 2-day public workshop is intended to provide information about FDA clinical trial requirements to the regulated industry. The workshop will be held on Wednesday, March 3, 2010, from 8 a.m. to 5 p.m., and Thursday, March 4, 2010, from 8 a.m. to 4:35 p.m. in Orlando, Florida. More information is available at <http://edocket.access.gpo.gov/2009/E9-30017.htm>.

FDA to Hold Public Workshops on Orphan Drugs

The FDA has announced that it will hold an orphan drug workshop series, to provide an opportunity for academics, biotechnology companies and larger pharmaceutical firms to spend two days in creation of applications for orphan status designation. More information is available at <http://www.fda.gov/downloads/ForIndustry/DevelopingProductsforRareDiseasesConditions/UCM189586.pdf>.

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](#).

If you have any questions regarding any of these issues, please contact:

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