

To: Our Clients and Friends

January 19, 2010

Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin



Top News

Push for Final Health Bill Continues

Democrats have announced that they hope to reach a final resolution on health care this week, even as Tuesday's special election to fill the Massachusetts Senate seat formerly held by Edward Kennedy threatens the Democrats' filibuster-proof majority in the Senate.

Democrats are considering alternative options should they lose their 60th vote in the Senate, including asking House Democrats to approve the Senate version of the bill and sending it directly to President Obama for his signature.

Some lawmakers are also continuing to push for the exemption of smaller device companies from the proposed \$2 billion annual device tax. In addition, on Thursday, a group of House Democrats urged their leaders Jan. 14 to keep certain provisions of the House bill that assist Medicare patients with cost-sharing, reduce out-of-pocket costs, and allow CMS to create a new Part D program.

Reports are predicting that the health care reform bill will establish an approval pathway for biosimilars, but people familiar with the legislation say it could be several years before that pathway is truly available for use.

In addition, reports are circulating of a deal being floated under which generics would offer up money to help close the Part D doughnut hole and in exchange would get the health reform bill's biogenerics exclusivity for innovator companies lowered to 10 years, with an additional 6 months exclusivity available for pediatrics and new indications. BIO, PhRMA and the Massachusetts Biotechnology Council (MBC) continue to press Congress to maintain the 12-year exclusivity period for biologics.

FDA Launches First Phase of Transparency Initiative

The FDA has unveiled the first phase of its Transparency Initiative, which is designed to explain agency operations, how it makes decisions, and the drug approval process. The second part of the initiative, slated to occur in February, will involve the FDA providing guidance on how far FDA might go in releasing information currently withheld from the public, including complete response letters, withdrawn applications and other similar material.

FDA Considers PMA Changes

The FDA, industry, and others are debating which reforms are necessary to PMA study standards following recent critical reviews. Acting FDA device chief Jeffrey Shuren has stated that the agency will employ tougher standards for pre-market clinical trials and that it plans to release draft guidance on clinical trial design and on gender-related trial design issues. The FDA has announced that it also will revise internal standard operating procedures for device review staff.

FDA to Draft Guide on Threshold for RF Exposure

Researchers, engineers, biologists and physicians gathered in Gaithersburg, Maryland, last week to help the FDA better understand the thermal hazards of radiofrequency exposure in humans. The FDA has stated that the IEEE International Committee on Electromagnetic Safety intends to use the meeting's outcomes as a guide for the next revision of an IEEE standard on safe levels for human exposure to radio frequency electromagnetic fields.

Industry Comments on REMS Draft Guidance

The Pharmaceutical Research and Manufacturers of America have provided comments to the FDA's draft guidance on requirements for Risk Evaluation and Mitigation Strategies, saying that the agency should focus on sponsors' activities and not the behavior of third parties. Kaiser Permanente has called for the agency to open up the process for developing REMS to include elements to assure safe use. The Generic Pharmaceutical Association has called a REMS exemption to allow generic firms that want to develop ANDAs for products in closed distribution systems to obtain samples from the brand sponsors.

Postmarket Industry Studies to be Future Challenge for Sentinel

Center for Drug Evaluation and Research Director Janet Woodcock has stated that the FDA has not yet decided whether or how drug firms could tap into its upcoming [Sentinel](#) electronic drug safety surveillance system to conduct postmarket studies required by the agency, but that the agency would address that problem when they come to it. The Sentinel database will be created under a four-year, \$72 million contract between the FDA and Harvard Pilgrim Health Care Inc.

Questions Abound Regarding Flu Vaccine

As fears about the H1N1 virus continues to lessen, a top World Health Organization official [dismissed](#) statements that the agency exaggerated the threat posed by the virus due to influence from the pharmaceutical industry. The EFPIA's European Vaccine Manufacturers (EVM) group has reiterated that its members did not hype up the threat of the H1N1 pandemic to boost vaccine sales.

Sen. Charles E. Grassley (R-IA) sent a letter to HHS Secretary Kathleen Sebelius, FDA Commissioner Margaret A. Hamburg, and CDC Director Thomas R. Frieden on Tuesday questioning the government's future plans for the vaccine, including whether the government has plans to check the potency of the vaccine over the longer-term as [demand lessens](#).

New York AG Settles Regarding Drug Disposal

New York Attorney General Andrew Cuomo has announced that a settlement has been reached with five healthcare facilities that flushed pharmaceutical waste into the New York City watersheds.

US Accuses Johnson & Johnson of Kickback Scheme

The Office of the United States Attorney in Boston has filed a [complaint](#) against Johnson & Johnson accusing the company of paying [kickbacks](#) to Omnicare to increase the number of elderly patients taking the antipsychotic Risperdal and several other medications.

AAJ Hopes to See Action on FDA Preemption Bill

The American Association for Justice has stated that it is continuing to monitor a bill that would allow state courts to hear lawsuits involving FDA-approved medical devices and tort reform pilot projects in health care legislation.

Supreme Court's Refusal to Review Case May Limit Patent Protection

Industry experts are concerned that the U.S. Supreme Court's refusal to hear Boston Scientific's appeal in a long-running cardiac device patent infringement case with St. Jude Medical will allow device companies to export products made in the U.S. that are capable of performing a patented method outside the U.S. without infringing the U.S. patent.

Appeals Court Decision May Indicate Trend Against Preemption for Generic Drug Labeling

The U.S. Court of Appeals for the Fifth Circuit ruled that product liability lawsuits related to labeling are not preempted by federal regulations, the second federal appeals court to make such a ruling. Some are concerned that the rulings may indicate a trend against favoring federal preemption for generic-drug makers.

Philippines Asks for Further Price Reductions for Medicines

The Philippine Department of Health has asked that drug companies reduce by half the prices of the "top-selling and most expensive" medicines with few generic rivals. Sanofi-Aventis has already [announced](#) that it will cut the prices of some of its drugs in Southeast Asia to tap rising rates of diseases including diabetes and cancer in the region.

Device Companies Send Supplies to Haiti

Device companies have mobilized to send emergency medical supplies to Haiti in the wake of the catastrophic earthquake that hit the country Jan. 12.

EU Probes Pharmaceutical Companies on Generic Delays

The European Commission has issued [questionnaires](#) to pharmaceutical companies, including AstraZeneca Plc, GlaxoSmithKline Plc, Sanofi-Aventis SA, regarding details of agreements that may have slowed the sale of generic medicines. The questionnaires are part of the probe by the Commission into strategies employed by drugmakers to prevent generics from entering the market.

EU Council Outlines Streamlined Patent System

The European Council has approved an outline for a streamlined EU patent system that would include a specialized court. The European Commission estimates that the new system would save companies operating in Europe as much as \$415 million annually.

UK Early Access Scheme Likely But Without Funding

The proposed UK Early Access Scheme may allow patients early access to certain new medicines prior to formal approval; however, the UK government has announced that it will not provide funding for drugs used under the program.

Publications

The FDA has published a [letter](#) from FDA Commissioner Margaret A. Hamburg to America's health care professionals thanking them for their efforts during the 2009 H1N1 influenza outbreak and providing information on safety monitoring of the 2009 H1N1 vaccines.

The CMS Office of the Actuary released a memo last week finding that savings from Medicare cuts will not finance wider coverage and extend the life of the Medicare trust fund. It also states that reducing payments to Part A providers based on productivity gains will not likely be sustained on a permanent annual basis.

The GAO has issued a report finding that the prices of a growing number of prescription medications have increased in recent years due to several factors, including consolidation in the drug industry. Lawmakers and other stakeholders are seizing on the report in the hopes of erasing some of the pharmaceutical industry's lobbying victories on health care reform.

A study published in the Annals of Internal Medicine has found that doctors are increasingly prescribing oxycodone, morphine and other opioid painkillers for back pain, arthritis and headaches, leading to potentially fatal overdoses.

A study published in the Annals of Internal Medicine finding that individuals using spoons to measure doses of liquid medication frequently give improper doses recommends that the FDA revise its draft guidance encouraging all liquid medications to include a dosing device that does not significantly surpass the size of the maximum recommended dose and to clearly label measurements on the dosing apparatus.

A federally sponsored study, whose findings were recently published in the Journal of the American Medical Association, found that although biomedical research funding in the U.S. outpaced the economy from 2003 through 2007, the funding was not large or steady enough to ensure investments in "high- risk/high-reward" projects.

A report by GBI research estimates that global vaccine revenues will reach \$52bn in 2016.

Approvals

The FDA has approved Philadelphia-based URL Pharma's for a branded version of the drug colchicine called Colcrys.

Stereotaxis Inc. has announced that it received FDA approval for the Celsius RMT ThermoCool catheter.

An FDA advisory panel has voted in favor of approving Actelion Ltd.'s Zavesca (miglustat) to treat patients with the Type C version of Niemann-Pick Disease.

The FDA has approved Roche's novel interleukin-6 inhibitor Actemra for second-line use in rheumatoid arthritis.

St. Jude Medical has received approval for its Genesis neurostimulator for chronic pain treatment from Japanese regulators.

The FDA has notified Roche that it may resume enrolling patients in a Phase III clinical trial with its drug Avastin.

Recalls, Warnings, and Notifications

The FDA has issued a Follow-Up to previous Early Communications issued in 2008 by the FDA describing a potential increase in the risk of stroke, heart attack, or death from a cardiovascular cause related to the use of tiotropium, which is marketed as Spiriva HandiHaler. The FDA has completed its review and believes the available data do not support an association between the use of Spiriva HandiHaler and an increased risk for these serious adverse events.

The FDA has posted its MedWatch December 2009 Drug Safety Labeling Changes. The Summary Page of these changes is available at <http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm194965.htm>.

Wyeth has notified healthcare professionals of changes to the Rapamune Prescribing Information regarding changes in the performance of an immunoassay used for therapeutic drug monitoring (TDM) of sirolimus.

AP is reporting that the FDA has issued enforcement letters to Eli Lilly, Bayer, Amylin Pharmaceuticals, and Cephalon for making inaccurate or incomplete statements while promoting their drugs.

The FDA has posted a warning letter issued to devicemaker Endotec for several good manufacturing practice violations, including investigation failures for a device part that fell out during surgery.

Business News

The FDA has awarded a contract to Harvard Pilgrim Health Care Inc. to develop a [pilot of the FDA's Sentinel System](#), which will use automated health care data to evaluate medical product safety.

Impax Laboratories has stated that it is the target of a lawsuit over its plans to produce a generic version of the cholesterol drug Welchol.

Diagnostic test maker Sequenom Inc. has agreed to pay \$14 million plus stock to settle a class action securities lawsuit over the mishandling of study data on a potential test for Down syndrome.

Federal prosecutors have filed fraud charges against a Massachusetts doctor, alleging that he faked research in published studies related to the use of pain drug Celebrex [celecoxib] with patients following a particular type of surgery.

Thirteen individuals were arraigned in federal court on Thursday on charges that they were connected to a \$14.5-million Medicare fraud scheme.

Covidien Plc. has stated that it is filing suit against a unit of Johnson & Johnson, claiming patent infringement from a line of ultrasonic surgical products.

Hemispherx Biopharma Inc. has announced that it has submitted new information to FDA on the drug it is developing for chronic fatigue syndrome.

The Wall Street Journal has reported that a group of investors who last year funded CoreValve Inc has rounded up \$6.5 million for heart-valve maker CardiAQ Valve Technologies Inc.

According to the San Francisco Chronicle, the biotech and medical device industries in California are selling more products and employing more people despite the recession.

Merck & Co. has announced that it has submitted data to the FDA regarding expanding the use of Gardasil to between the ages of 27 and 45.

Allergan Inc. stated that it has asked a trial judge to rule that Apotex Inc. is [infringing](#) its US patent for its antibiotic used to treat 'pink eye.'

Baxter International Inc., which recalled its blood thinner heparin, is currently facing at least 30 lawsuits in Chicago by injured people or their estates.

NIOSH is conducting a technical evaluation of a 3M respirator model that makes up a third of respirators in the national stockpile after difficulties with fit-testing prompted California to tell health care providers to halt their use of 3M's 8000 N95 respirator.

MAP has announced that the FDA will not require that it run a new effectiveness study on its migraine drug candidate Levadex [dihydroergotamine].

An FDA advisory panel has rejected a new use of Forest Laboratories' hypertension drug Bystolic (nebivolol) for patients at risk of heart failure.

Xenoport Inc. has announced that the FDA [will not require](#) that an advisory panel review the company's application for an experimental drug to ease restless legs syndrome.

A district court has denied a motion by Mylan Pharmaceuticals to dismiss a patent infringement lawsuit by Bristol-Myers Squibb (BMS) over its HIV drug Sustiva.

Some are predicting that devicemakers and importers will see delays in 2010 as the FDA trains more than 1,000 staff that the agency hired last year to conduct inspections and import screenings.

Pfizer has announced that it has reached an agreement with Indian non-branded drugmaker Strides Arcolab under which Pfizer will sell more generic pharmaceuticals in the US.

The share of biologics in the Center for Drug Evaluation and Research's annual approval tally reached a new high of 24 percent in 2009.

The FDA's Office of Drug Evaluation III Director Julie Beitz has emphasized that the FDA's decision to consider Orphan Europe's drug Carbaglu does not set a precedent for the agency.

Regulatory Notices

FDA Denies Hearing Request

The FDA has published a notice that it is denying Jason Vale's request for a hearing and is issuing an order under the Federal Food, Drug, and Cosmetic Act permanently debarring Mr. Vale from providing services in any capacity to a person that has an approved or pending drug product application. More information is available at <http://edocket.access.gpo.gov/2010/2010-289.htm>.

FDA Publishes Draft Guidance for IRBs

The FDA has published a draft guidance entitled, "Guidance for IRBs, Clinical Investigators, and Sponsors: IRB Continuing Review After Clinical Investigation Approval." The guidance is available at <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM197347.pdf>. More information is available at <http://edocket.access.gpo.gov/2010/2010-426.htm>.

FDA Files Reports of 2009 Closed Meetings

The FDA has announced that it has filed with the Library of Congress the annual reports of those FDA advisory committees that held closed meetings during fiscal year 2009. More information is available at <http://edocket.access.gpo.gov/2010/2010-807.htm>.

FDA Submits Proposed Information Collections to OMB

The FDA has announced that it has submitted proposed collections of information to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. More information regarding these information collections is available at the following websites: <http://edocket.access.gpo.gov/2010/2010-790.htm>, <http://edocket.access.gpo.gov/2010/2010-791.htm>, <http://edocket.access.gpo.gov/2010/2010-792.htm>, <http://edocket.access.gpo.gov/2010/2010-793.htm>, <http://edocket.access.gpo.gov/2010/2010-794.htm>, <http://edocket.access.gpo.gov/2010/2010-795.htm>, and <http://edocket.access.gpo.gov/2010/2010-796.htm>.

Public Meetings

Public Meeting on Clinical Accuracy Requirements for Blood Glucose Meters

The FDA is announcing a public meeting entitled: Clinical Accuracy Requirements for Point of Care Blood Glucose Meters. The purpose of the public meeting is to discuss the clinical accuracy requirements of blood glucose meters and other topics related to their use in point of care settings. The meeting will be held on March 16, 2010, from 9 a.m. to 5 p.m. and on March 17, 2010, from 9 a.m. to 3:40 p.m. in Gaithersburg, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-742.htm>.

Endocrinologic and Metabolic Drugs Advisory Committee to Hold Meeting

The FDA has announced that the Endocrinologic and Metabolic Drugs Advisory Committee will meet on February 24, 2010, from 8 a.m. to 5 p.m. in Silver Spring, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-785.htm>.

Vaccine and Related Biological Products Advisory Committee to Hold Meeting

The FDA has announced that the Vaccines and Related Biological Products Advisory Committee will meet on February 22, 2010, from 8:30 a.m. to approximately 1:30 p.m. in Bethesda, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-789.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](#).

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

Mark Mansour	Partner	mark.mansour@bryancave.com	1 202 508 6019	Washington
Alan K. Parver	Partner	alan.parver@bryancave.com	1 202 508 6332	Washington
Steven Kent Stranne	Partner	steven.stranne@bryancave.com	1 202 508 6349	Washington
Megan A. Gajewski	Associate	megan.gajewski@bryancave.com	1 202 508 6302	Washington
Patrice M. Hayden	Associate	pmhayden@bryancave.com	1 202 508 6147	Washington
Emily K. Strunk	Associate	emily.strunk@bryancave.com	1 202 508 6360	Washington

This bulletin is published for the clients and friends of Bryan Cave LLP. To stop this bulletin, please reply to this email. To stop this bulletin and all future commercial e-mail from Bryan Cave LLP, please reply to: opt-out@bryancave.com and leave the message blank. Information contained herein is not to be considered as legal advice. Under the ethics rules of certain bar associations, this bulletin may be construed as an advertisement or solicitation.