

To: Our Clients and Friends

February 2, 2010

Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin



Top News

President Releases 2011 Budget

President Obama has released his fiscal year [2011 budget](#). As part of this budget, the FDA has requested \$4.03 billion, a 23 percent increase over the agency's current budget. The FDA has outlined [four major initiatives](#) in its budget request: an additional \$318.3 million for Transforming Food Safety, an additional \$100.8 million to support the safety of drugs, devices and vaccines as part of the Protecting Patients Initiative, an additional \$25 million for the Advancement of Regulatory Science, and an additional \$215 million to implement the to implement the Family Smoking Prevention and Tobacco Control Act. The FDA has also indicated that one of its priorities will be to demand that the drug industry take more responsibility for quality control throughout the production cycle. The budget request also includes \$4 million for a new medical device registry that would link unique device identifiers to electronic health data.

CDRH Publishes Strategic Priorities for 2010

CDRH has published its [2010 Strategic Priorities](#). The four major identified priorities of CDRH include: fully implementing a total product life cycle approach, enhancing communication and transparency, strengthening the workforce and workplace, and facilitating innovation and addressing unmet public health needs. Within these priorities, CDRH has set forth a timeline, in which it states that it intends to begin implementation of the recommendations of the 510(k) Working Group by September 30, 2010. Director Jeffrey Shuren has indicated that he plans to review public comments from a meeting this month and the findings of an internal review, to be completed this summer, before making any proposals. In its notice announcing this month's meeting on the 510(k) process, the FDA stated that it is seeking comments pertaining to four areas: predicate devices; new technologies and scientific evidence; practices for managing the high volume of 510(k) submissions; and post-market surveillance.

CDRH has also announced that it intends to launch a "Unique Device Identification" (UDI) system by Sept. 30, 2013.

Gates Foundation to Donate \$10B to Vaccine Research

Bill and Melinda Gates have announced that the Gates Foundation will donate [ten billion dollars](#) over the next decade to support the research, development, and delivery of [vaccines to developing countries](#).

FDA Moves Radiological Devices Branch to OIVD

FDA Commissioner Margaret Hamburg has signed orders to officially move the Radiological Devices Branch to the Office of In Vitro Diagnostic Device Evaluation and Safety, a result of long-term discrepancies between how in vitro and in vivo diagnostics have been regulated by FDA. OIVD will now house four product divisions - the division of chemistry and toxicology devices; immunology and hematology devices; microbiology devices; and radiological devices.

FDA and Health Orgs to Study Effects of Drugs During Pregnancy

The FDA has announced that it will partner with various health organizations to fund research as part of the Medication Exposure in Pregnancy Risk Evaluation Program, which will study the effects of prescription drug use during pregnancy.

FDA and NIH to Begin Bioequivalence Study

NIH and FDA are expected to begin a study on bioequivalence for generic and brand epilepsy drugs by next year, which some anticipate may change the way the FDA and healthcare providers perceive bioequivalence. The study is slated to monitor the effects of switching between branded drugs and generic drugs.

NIH to Record Radiation from CT Scans

NIH has announced that it will begin recording how much radiation patients receive from CT scans and other procedures.

Philippines to Again Call for Reduction in Drug Prices

The Philippines plans to announce that it will again ask drugmakers to [reduce prices of certain drugs](#) to help reduce healthcare costs.

FDA Struggles with Conflicts of Interest on Advisory Panels

FDA's Office of New Drugs Director John Jenkins has stated that the agency may revisit its conflict of interest policies due to difficulties it is currently facing in filling slots on its pharmaceutical advisory panels. Although financial conflict policies are central to the debate, consumer groups are advocating for the agency to loosen its policies on intellectual conflicts as well.

FDA Struggles with Interoperability of Medical Devices

At a recent FDA workshop on medical device interoperability issues, the FDA, device makers and other stakeholders indicated that they are struggling to find an ideal way to regulate interoperable medical systems, particularly as technology, including the iPhone, advances in ways that devicemakers may not currently anticipate. Some suggested that a separate classification scheme might be necessary.

FDA Enforcement Letters on Marketing Campaigns Doubled in 2009

An FDA official has stated that the agency sent 41 enforcement letters in 2009 related to questionable drug-marketing campaigns, almost twice as many as it issued in 2008.

Nonprofit to Fund FDA Vaccine Research

The FDA has announced that it will receive [\\$480,000 from nonprofit](#) PATH to assist in the development of an improved vaccine against pneumococcal disease in poor countries.

Pain Drug Researcher Pleads Guilty to Falsifying Data

Former pain drug researcher Scott Reuben, has agreed to plead guilty to one count of healthcare fraud for fabricating patient data in trials of painkillers, including Vioxx and Celebrex.

Publications

CDRH has published its strategic [priorities](#) for 2010.

Cephalon has published a listing of its physician payments under a Corporate Integrity Agreement. The disclosure covers a year-long period and states that Cephalon paid 937 physicians for consulting and speaking services during 2009, with its top-paid doctor earning \$149,900.

CDRH has published a [draft](#) guidance on preclinical and clinical studies to support investigational device exemptions and PMA applications. The guidance is the first in 16 years on heart valves.

Approvals

The FDA has [approved](#) the ProGEL™ Pleural Air Leak Sealant - P010047.

The FDA has approved a combination of lapatinib (Tykerb) and letrozole (Femara) to treat hormone-positive and HER2-positive advanced breast cancer in postmenopausal women.

Allergan has announced that it has received approval for Juvederm XC, a new version of its Juvederm dermal filler.

The FDA has approved Novo Nordisk's Victoza (liraglutide), but the drug will require a "black box" warning about thyroid C-cell tumors observed in pre-clinical rodent studies, a REMS consisting of a Medication Guide and communication plan, and significant post-marketing studies.

Recalls, Warnings, and Notifications

The FDA has issued an order [permanently debarring](#) Brian Ullom from providing services in any capacity to a person that has an approved or pending drug product application.

The FDA has issued a warning letter to Baxter International Inc. regarding its facility in Belgium where it makes Gammagard.

The FDA is notifying healthcare professionals of a [Class I recall](#) of Hettich Centrifuges with 2050 and 2076 plastic rotors, used in combination with the Mikro 12-24, Mikro 20, Haematokrit 20 and Haematokrit 24 bench top plastic centrifuges. The recall was initiated because the plastic centrifuge rotor may crack, break apart and be forcefully ejected through the plastic centrifuge housing at a high rate of speed.

The FDA and Edwards Lifesciences are notifying healthcare professionals of a [Class I recall](#) of the Aquarius Hemodialysis System due to reports of clinically significant fluid imbalance and the potential for users to repeatedly override the fluid imbalance alarm.

Lilly and the FDA are notifying healthcare professionals of [changes to the Prescribing Information](#) for Zyprexa related to its indication for use in [adolescents](#) (ages 13-17) for treatment of schizophrenia and bipolar I disorder.

The FDA is notifying healthcare professionals and patients about a rare, but serious, [complication](#) in the liver known as non-cirrhotic portal hypertension in patients using Videx or Videx EC (didanosine).

CRS Medical Diagnostics has received a Form 483 with several design control-related observations.

Business News

Drugmakers AstraZeneca PLC, Bristol-Myers Squibb Co. and Eli Lilly & Co.'s revenues rose about 10 percent in the fourth quarter of 2009, mainly due to sales of drugs for heart disease, depression and other mental illnesses, according to an AP report.

GlaxoSmithKline Plc has announced that its Stiefel dermatology unit [will promote](#) Amgen Inc.'s Enbrel [etanercept] psoriasis treatment to US dermatologists.

A federal judge has ruled that Merck & Co., Pfizer Inc. and seven other drugmakers [overcharged](#) New York City and 42 New York counties for medicines.

The Wall Street Journal has reported that major biotechnology firms are facing problems developing new drugs that are similar to those currently being faced by pharmaceutical companies.

Novartis AG has reached a settlement agreement under which it will pay \$185 million to resolve a criminal investigation that the company promoted its epilepsy drug Trileptal [oxcarbazepine] off-label in violation of the US Food, Drug, and Cosmetic Act. The company has stated that it is also being investigated for off-label marketing allegations involving five other drugs.

Theravance Inc. has stated that the FDA has indicated that further clinical studies might be required to win marketing approval for its infection drug candidate Vibativ.

The Supreme Court of Canada has ruled that companies prevailing in Canadian patent suits [can't collect](#) for competitor's profits or future losses.

Boston Scientific has announced that it has reached an [agreement](#) with a unit of Johnson & Johnson under which it will pay \$1.725 billion to settle a dispute over patents for coronary stents.

Spectrum Pharmaceuticals Inc. has announced that it has received \$16 million to develop its bladder cancer drug apaziquone.

Cephalon has announced that it plans to [purchase](#) Swiss-based drug company Mepha AG for an estimated \$590 million.

A Pennsylvania judge has [reduced from \\$75 million to \\$5.6 million](#) a damages award to a woman who claimed Pfizer's menopause drug caused her cancer.

Reports are circulating that GSK will announce plans to cut 4,000 jobs, mainly in its R&D division.

A Pennsylvania judge has ruled against dismissal of a case brought against GlaxoSmithKline by Roxane Laboratories alleging that GSK filed a series of false citizen petitions in an effort to attempt to delay generic competition for its drug Flonase.

Teva Pharmaceutical Industries and AstraZeneca have reached an agreement regarding patent infringement involving Nexium, under which Teva may market a generic version of the treatment in May 2014.

Combination product firms are calling for the FDA to simplify its proposed adverse event reporting requirements when multiple manufacturers are involved.

Public Meetings

Endocrinologic and Metabolic Drugs Advisory Committee Meeting Cancelled

The FDA has announced that the meeting of the Endocrinologic and Metabolic Drugs Advisory Committee scheduled for February 24, 2010, has been [cancelled](#).

Pulmonary-Allergy Drugs Advisory Committee to Meet

The FDA has announced that the Pulmonary-Allergy Drugs Advisory Committee will meet on March 9, 2010, from 8 a.m. to 5 p.m. in Silver Spring, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-2054.htm>. The Committee is also scheduled to meet on March 10 and 11, 2010, from 8 a.m. to 5 p.m. in Silver Spring, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-2097.htm>.

Risk Communication Advisory Committee to Meet

The FDA has announced that the Risk Communication Advisory Committee will meet on February 25, 2010, from 8 a.m. to 5 p.m. and February 26, 2010, from 8 a.m. to 2 p.m. in Silver Spring, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-2053.htm>.

FDA to Host Public Workshop

The Food and Drug Administration (FDA) is announcing a public workshop entitled "Workshop on Pediatric Neurological and Neurocognitive Assessments for Cardiovascular Devices." The purpose of the public workshop is to solicit information from clinicians, academia, professional societies, other government agencies, and industry on various neurological and neurocognitive assessments for pediatric patients implanted with cardiovascular devices. The workshop will be held on March 25, 2010, from 8 a.m. to 5 p.m. in Silver Spring, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-2110.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

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