

To: Our Clients and Friends

August 27, 2010

Pharmaceuticals, Medical Devices and Biologics Regulatory and Policy Bulletin



Top News

During China Visit, FDA Commissioner's Focus Not on Heparin Investigation

FDA Commissioner Margaret Hamburg's recent trip to China focused primarily on avenues of collaboration and cooperation between the FDA and Chinese regulators rather than on the current investigation into the contamination of heparin, which has caused some to express concern that US legislators may perceive the two bodies as not trying to work effectively to determine the cause of the contamination. FDA officials have indicated that the issue was discussed, but it was not focused on during the meetings.

Industry Expresses Concern Over New Drug User Fees

The drug industry is expressing concern over the FDA's recent increase in prescription drug user fee rates, saying that the increase of approximately 10 percent is not appropriate given the backlog and failure to meet other review deadlines. Industry has indicated that it would like more accountability and adherence to performance goals if will be paying such increased fees. As the FDA discusses drug user fees and other programs as part of the Prescription Drug User Fee Act legislative proposal, some consumer, safety, and patient groups are voicing their concern that the agency is not including them in its discussions of the Act.

Official, Panel Members Criticize Glaxo's Report on Avandia Committee Meeting

An article in the *New York Times* indicates that a government official and some members of the FDA advisory panel that recently reviewed Avandia are critical of Glaxo's [letter to doctors](#) participating in the TIDE trial, intended to compare the risks of Avandia with those of competing drug Actos. Those critical of the letter say that it is [misleading](#) and could lead to harm to trial participants. The FDA is scheduled to review the drug and determine whether it may remain on the market in the coming weeks. Meanwhile, despite a new study showing that the risks of the drug are similar to its competitor Actos, prescriptions for the embattled diabetes drug have plummeted as a result of the controversy.

Administrative Conference of the United States Reconvened

The Administrative Conference of the United States was recently re-established to examine the FDA's application of pre-emption. The Conference has commissioned New York University School of Law Professor Catherine Sharkey to draft recommendations on how the agency should address such issues.

FDA to Undertake Nanotechnology Initiative

FDA officials have announced that the agency plans to undertake its first nanotechnology initiative in 2011, which is slated to receive more than \$7 million in its fiscal 2011 budget request. The agency has indicated that the initiative will focus on expanding collaborative opportunities, training staff and conducting research on evaluating nanomaterial safety and potency. Industry has expressed its general support for the program, but has also expressed concern that the agency is moving too slowly and lacks sufficient resources to properly undertake the initiative, even with the new funding.

Judge Blocks Federal Funding of Stem Cell Research; Justice Department to Appeal

U.S. District Judge Royce Lamberth issued a [ruling this week](#) that found that [federal government funding could not be applied to research](#) involving human embryonic stem cells. The ruling was based on a 1996 law banning the use of government funding related to the destruction of human embryos. The judge issued a preliminary injunction that will [prevent NIH from funding stem cell research](#) as set forth in [new guidelines promulgated](#) by the Obama administration. The Justice Department has indicated that it [will appeal the ruling](#). Colorado Rep. Diana DeGette, has indicated that some Representatives may consider reintroducing legislation on the issue following the ruling.

Administration Releases Plan to Provide Funding for Small Companies Developing Public Health Emergency Products

Reports are indicating that the Obama administration may ask for Congressional authorization for an independent strategic investment fund that will provide funding to small companies who are developing products intended to be used in response to public health emergencies, including bioterror attacks and pandemic flu outbreaks. The plan would establish an "Independent Strategic Investment Firm For Innovation in Medical Countermeasures" as a 501(c)(3) non-profit corporation.

Device Makers Express General Support for ISO Audit Report program, But Request More Detail

The device industry has indicated that it is generally supportive of the FDA's plan for accepting voluntary international audit reports as a means for possibly delaying an FDA inspection, but it has also indicated that more details will be needed before many firms decide to participate in the program. Comments on the plan have included that the plan, as drafted, does not clearly state what information needs to be included in a report, that it is unclear what kind of review timelines would exist for the reports, and that the plan may not include sufficient incentives to encourage participation.

Agency News

A district court has ruled that CMS cannot disregard the fact that a device has received 510(k) clearance from the FDA when making a determination about whether to pay for that device. The ruling places pressure on CMS to justify why it did not cover products that obtained 510(k) clearance.

An FDA advisory panel voted 8-6 to [approve the use of Cymbalta](#) for certain chronic pain conditions, including lower back pain.

The FDA has proposed [revoking its approval](#) of Shire PLC's drug ProAmatine following the [company's failure to conduct](#) post-marketing studies on the drug.

The FDA has indicated that it will be increasing its review of online social media, even absent a firm policy regarding such online tools. In a recent letter to Novartis, the agency stated that the company did not provide adequate risk information in a Facebook widget for a drug; the company subsequently removed the application. Industry is critical of the agency using warning letters absent a firm policy to govern the use of such social media.

Reports are indicating that the FDA plans to enter into contracts in the coming weeks to launch comparative effectiveness research initiatives. The initiatives will aggregate and assess data on certain products and evaluate patient populations and other issues.

An FDA panel voted to recommend [against approving](#) Jazz Pharmaceuticals Inc's drug candidate Rekinla because the drug's benefits were not proven to outweigh its risks of abuse or overdose.

The FDA has announced that it intends to establish a new council to address and modernize the agency's toxicology and risk assessments of certain products.

The FDA has indicated that it will study Novartis Parkinson's disease treatment to determine if it contributes to an increased risk of heart attacks or strokes.

A group of economists is criticizing the FDA and CBO's position on pay-for-delay settlements, saying that a ban on them may actually delay the introduction of generics and not lead to the intended savings for the federal government.

Joel Ario will join the HHS Office of Consumer Information and Insurance Oversight on August 30 as deputy director of the office of health insurance exchanges.

The FDA has indicated that it plans to accept International Conference on Harmonisation standards for bulk density and tapped density of powders as part of an ongoing effort to reduce the paperwork required of drugmakers.

Publications

The FDA has published a [guidance for small business entities](#) entitled "Organ Specific Warnings: Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Use--Small Entity Compliance Guide."

The journal *Proceedings of the National Academy of Sciences* (PNAS) has [published an article](#) discussing that researchers have discovered murine leukemia viruses (MLV) related gene sequences in blood samples collected from patients diagnosed with chronic fatigue syndrome (CFS).

The AARP [has released a report](#) finding that the retail prices of 217 most popular brand-name drugs increased on by 8.3 percent during 2009.

A recent poll by Consumer Reports found that 69 percent of adults are concerned that pharmaceutical companies have too much influence over their physicians' prescribing practices.

Global Industry Analysts has published a survey estimating that protein drug sales will be worth more than \$158bn by 2015.

Approvals

The FDA has granted priority review status to Bristol-Myers Squibb Co.'s cancer drug ipilimumab. The FDA will also conduct a priority review for Glaxo's systemic lupus treatment Benlysta.

The FDA has granted orphan drug designation status to Acceleron Pharma, Inc. for its Duchenne Muscular Dystrophy drug candidate ACE-031.

The FDA has cleared Alexion Pharmaceuticals Inc.'s Rhode Island manufacturing facility for Soliris.

The National Institute for Health and Clinical Excellence has approved the drug Multaq for treatment of atrial fibrillation.

Recalls, Warnings, and Notifications

The FDA has issued a [notification to healthcare professionals](#) that it is evaluating clinical trial data that suggest patients taking Stalevo may be at an [increased risk for cardiovascular events](#).

The FDA has filed an injunction against a Broomfield Regenerative Sciences clinic to stop the clinic from injecting an individual's cultured stem cells into his or her joints as a treatment to alleviate pain.

Ikaria, Inc. is notifying healthcare professionals of a [Class I Recall](#) of the INOMAX (nitric oxide) Drug-Delivery System.

The FDA has issued a warning to Johnson & Johnson's DePuy Orthopaedics, Inc. unit that it is illegally marketing two of its products.

Octapharma USA is voluntarily recalling 31 lots of immune globulin G (IgG) intravenous (human) 5% liquid preparation based on increased reports of thromboembolic events.

The FDA has issued a [warning](#) for the foot tanning device known as the Tootsie Tanner.

International News

The Chinese Ministry of Commerce has approved Novartis AG's plan to acquire Alcon, Inc.

Japanese regulators have the use of Hospira Inc.'s drug Precedex in patients for more than 24 hours.

An Australian court has ruled that Baxter International Inc.'s Australian unit must pay [A\\$4.9 million](#) (\$4.3 million) in fines for attempting to stifle competition in the country.

The National Institute for Health and Clinical Excellence [has determined that the use of Avastin](#) in colorectal cancer patients is not cost-effective.

The European Medicines Agency has issued a [guidance](#) on the use of electronic data in drug clinical studies that provides that sites should retain copies of trial data before transferring it to the sponsor.

Business News

Lilly announced that it [ceased two clinical trials](#) for an [experimental Alzheimer's drug](#) after patients receiving the drugs showed worse cognitive functioning and less ability to perform daily tasks than patients receiving a placebo.

Baxter International, Inc. is facing a new challenge from a lawsuit seeking documents relating to the contamination of heparin in 2008; the lawsuit claims that the documents could provide information on the source of the contaminated drug from China.

Sanofi-Aventis SA has asked a court to block the entry of Sandoz's generic version of Sanofi's drug Lovenox, following the FDA's recent approval of the generic. Sanofi's lawsuit asks whether the FDA adequately reviewed the safety of the drug, as the heparin in the drug is sourced from companies currently involved in the 2008 heparin contamination controversy. A U.S. District judge [denied Sanofi's request](#) on Wednesday.

Medtronic has announced that it will purchase Osteotech Inc. for \$123 million.

A federal magistrate judge has recommended that the court enforce a subpoena that would require the CEO of Watson Pharmaceuticals Inc. to testify as part of an FTC investigation regarding whether a settlement for the drug Provigil wrongfully delayed generic competition.

Dr. Reddy's Laboratories Ltd. has announced that it is currently [evaluating partnership options](#) to enter Japan's generic-drug market.

Biogen Idec Inc. announced that it licensed a potential Lou Gehrig's disease treatment from Knopp Neurosciences for more than \$285 million.

Matrixx Initiatives has entered into a settlement agreement, under which it will pay up to \$35,000 to settle lawsuits following the withdrawal from the market of its Zicam product.

Impax Laboratories, Inc. has indicated that it plans to challenge MSP Singapore Co. LLC's patents on the drug Vytorin.

According to a recent report in the *Financial Times*, certain AstraZeneca documents regarding the use of selective data to increase prescriptions of the drug Seroquel may not be made available to the public under the terms of a recent \$520 million settlement the company reached with the Department of Justice and two watchdogs related to the drug.

Cumberland Pharmaceuticals Inc. announced that the FDA has extended its review of Acetadote.

Reports are indicating that Stryker Corp. is in advanced talks to purchase [Boston Scientific Corp.'s pain-management device unit](#) for approximately \$1.5 billion.

Reports are indicating that Bayer AG has reached an agreement under which it will pay at [least \\$60 million](#) to settle lawsuits regarding its drug Trasyolol.

Johnson & Johnson has announced that it is [creating a new organizational approach to quality controls](#) that will include a single framework for its drug, medical device and consumer health care divisions. The new structure will be overseen by the current corporate vice president responsible for supply chain operations, and chief quality officers will be appointed for each of the above three divisions.

A Philadelphia jury has concluded that Pfizer Inc.'s menopause drug Prempro [was not the factual cause of cancer](#) in two women, and Pfizer did not therefore have to pay damages relating to their illnesses.

A Manhattan district court judge has [dismissed a lawsuit against AstraZeneca](#) Plc, in which Verus Pharmaceuticals Inc. alleged that the company sought to limit competition when it backed out of a deal with Verus and aligned with its competitor Map Pharmaceuticals Inc.

Roche plans to announce that it has entered [into an agreement](#) with Aileron Therapeutics under which it will pay \$25 million now and up to \$1.1 billion later for the development of stapled peptide technology.

Roche Group has announced that it will purchase medical scanning company Biolumigen Inc. for \$100 million.

Roche Holding AG and biopharmaceutical firm Aileron Therapeutics has announced that they have formed a partnership worth up to \$1.1 billion for Aileron to produce a new class of drugs to treat conditions such as inflammation and metabolic ailments. Roche Holding also recently won its bid to [block the sale of generic versions](#) of its drug Boniva in the U.S.

The *Wall Street Journal* is reporting that Merck and the Gates Foundation have agreed to give \$60 million to Botswana for an HIV treatment and care program.

Pfizer has announced that its Sutent [cancer treatment failed](#) in a large-scale study to improve overall survival in patients with a certain type of lung cancer.

Neuralstem has submitted an application to the FDA to conduct an early-stage trial of a stem cell treatment for spinal cord injuries.

Regulatory Notices

FDA Seeks Comments on IRB Recordkeeping Requirements

The FDA is seeking comments on the recordkeeping requirements for institutional review boards (IRBs). Comments are due by October 18, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-20273.htm>.

FDA Issues Safety/Effectiveness Determination for Diastat

The FDA has issued a determination that DIASTAT (diazepam rectal gel) (DIASTAT), 5 milligrams (mg)/milliliter (mL), 10 mg/2 mL, 15 mg/3 mL, and 20 mg/4 mL, was not withdrawn from sale for reasons of safety or effectiveness. More information is available at <http://edocket.access.gpo.gov/2010/2010-20327.htm>.

FDA Extends Comment Period for Input on Oversight of LDTs

The FDA has announced that it is reopening until September 15, 2010, the comment period for the notice that published in the Federal Register of Thursday, June 17, 2010 (75 FR 34463), in which the agency requested input and comments from interested stakeholders on the FDA's oversight of laboratory developed tests (LDTs). More information is available at <http://edocket.access.gpo.gov/2010/2010-20489.htm>.

FDA Proposes Effective Date of Requirement for Premarket Approval for Class III Preamendments Devices

The FDA is proposing to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the following four class III preamendments devices: Ventricular bypass (assist) device; pacemaker repair or replacement material; female condom; and transilluminator for breast evaluation. Comments on the approval are due by November 23, 2010. More information is available at <http://edocket.access.gpo.gov/2010/2010-21142.htm>.

Public Meetings

FDA to Hold Workshop on Pediatric Neuroprostheses

The FDA has announced that it will hold a public workshop entitled ASK (Assess Specific Kinds of CHILDREN Challenges for Neurologic Devices) Study Children Workshop. The purpose of the public workshop is to solicit comments from academic investigators and clinicians associated with the use, research and/or development of pediatric neuroprostheses regarding approaches for enhancing the protection and promotion of public health in children and adolescents with neuroprostheses. The workshop will be held on September 13, 2010, from 9 a.m. to 5 p.m. in Silver Spring, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-20659.htm>.

FDA Announces Public Workshops

The FDA New Jersey District Office has announced that it will be hosting a public workshop in cosponsorship with the Society of Clinical Research Associates focusing on the relationships among FDA and clinical trial staff, investigators, and institutional review boards. The workshop will be held on November 4 and 5, 2010, from 8 a.m. to 5 p.m. in Jersey City, New Jersey. More information is available at <http://edocket.access.gpo.gov/2010/2010-20834.htm>.

The FDA has also announced that it will be hosting a workshop entitled "Medical Devices & Nanotechnology: Manufacturing, Characterization, and Biocompatibility Considerations" to seek information and comment on manufacturing, characterization, and biocompatibility evaluation of medical devices containing or utilizing nanomaterials and nanostructures, including diagnostics. The workshop will be held on September 23, 2010, 8 a.m. to 5 p.m. in Gaithersburg, Maryland. More information is available at <http://edocket.access.gpo.gov/2010/2010-20837.htm>.

FDA Announces Public Conference

The FDA has announced that it is hosting a public conference entitled "The New Paradigm: Quality and Compliance in Merging and Emerging Cultures." The conference, cosponsored with the Parenteral Drug Association (PDA), will focus on challenges facing the medical products industry in navigating regulatory compliance, achieving worldwide quality improvement, and enhancing quality system controls in an environment of merging and emerging cultures. The conference will be held on Monday, September 13, 2010, from 7 a.m. to 6 p.m.; Tuesday, September 14, 2010, from 7:30

a.m. to 6:30 p.m.; and Wednesday, September 15, 2010, from 7:30 a.m. to 12:15 p.m. in Washington, DC. More information is available at <http://edocket.access.gpo.gov/2010/2010-20844.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
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.