Join Jones Day for FDLI Program on Hatch-Waxman
The Washington Office of Jones Day will be hosting the Food and Drug Law Institute program, "Celebrating the 30th Anniversary of the Hatch-Waxman Amendments: The Past, Present and Future of Generic Drugs," on Thursday, September 19, 2014. Speakers include a keynote by Rep. Henry A. Waxman and Jones Day's very own Gaspar LaRosa. For more information or to register, see FDLI's program page.

Top Stories

FDA Introduces "Purple Book" for Biologics
On September 9, 2014, FDA released the first edition of the "Purple Book," which is the analogue to the Orange Book for biologics. The Orange Book has long been used by regulators and doctors to look up approved drugs and their therapeutic equivalents. The new Purple Book will perform a similar function for biological products licensed by FDA under the Public Health Service Act, although unlike the Orange Book it does not include a listing of patents. The Purple Book lists the date a biological product was licensed and whether FDA determined the biologic to be biosimilar to or interchangeable with a reference biological product. Biosimilar and interchangeable biological products will be listed under the reference product to which biosimilarity or interchangeability was demonstrated. The Purple Book will also note whether FDA evaluated the biological product for reference product exclusivity and the expiration date of any exclusivity. FDA provides additional background information on its website.

FDA, Global Regulators Team Up to Advance Ebola Treatments
A coalition of pharmaceutical regulators from across the globe, including FDA, the European Medicines Agency, and authorities in China, Brazil, Australia, and South Africa, came together earlier this month in hopes of finding a medical solution to the Ebola virus outbreak in West Africa. Announced in a statement by the World Health Organization, more than 150 international leaders in clinical research, regulatory, legal, finance, and ethics met for a two-day discussion about potential Ebola therapies and vaccines. Although none of the compounds discussed is approved for human use, the group hopes to spur evaluation and development of certain treatments that have shown

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promising results in animal studies. In the past, there has been limited research into Ebola treatments because the disease's rarity and deadly nature make it difficult to study in humans. Regulators may attempt to accelerate development of new drugs by allowing manufacturers to access investigational therapies and validate new manufacturing methods through a less rigorous process. In a related measure last month, FDA warned consumers to be aware of products claiming to prevent or treat the Ebola virus, since currently no such drugs have been FDA-approved.

White House Orders Inventory of Infectious Agents at Federally Funded Labs
After several recent mishandlings of infectious agents at federal labs, the White House's National Security Council and Office of Science and Technology Policy issued a memo to all federal agencies conducting life-sciences research. The memo ordered all federally funded labs that handle animal or plant materials that are infectious agents or toxins to spend a month reviewing safety and security plans. In a recent blog post, NIH Director Dr. Francis Collins said his agency is "taking remedial action and precautionary steps to improve our lab safety protocols and procedures, minimize the risk of recurrence, and increase timely reporting of potential problems." NIH has also issued a Guide Notice to all of its grantees regarding safety standards for research conduct to raise awareness.

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Resources

- *Pharmaceutical & Medical Device Regulatory Update* Issue 14 Printable Version
- Jones Day's FDA Regulatory & Compliance Practice
- Jones Day's Health Care Practice
- Jones Day's Life Sciences Practice

DEA Sets New Quota Limits for Prescription Painkillers
On September 8, 2014, the Drug Enforcement Agency ("DEA") announced aggregate production quotas for Schedules I and II controlled substances and List I chemicals manufactured in 2015. The production limits will increase for several painkillers, including oxymorphone (for conversion), ephedrine (for sale), and cocaine. Ten other drugs will see their quotas decrease. DEA updates the production quotas every year, which determines how much of a controlled substance will be available for national medical, scientific, and industrial use.

Some Predict New Drug Approvals May Achieve Record Year
According to Center for Drug Evaluation and Research reports, FDA has approved 27 new drugs so far this year. If things proceed at this rate, *The Wall Street Journal* estimates total approvals in 2014 could come close to 2012 levels, which saw 39 medicines approved—the highest annual total in more than a decade. Last year, FDA approved only 27 new drugs. Total new drug approvals are difficult to predict, given that the number of applications and requests for additional information may vary significantly from year to year. However, there is some indication that industry and FDA are achieving greater efficiencies with the process, as 89 percent of approvals last year happened within the first cycle of review.

Other News
Health Spending Expected to Resume Climb, But Somewhat Slower than Last Decade

CBO Predicts Lower Spending for Medicare and Medicaid

In Some European Countries, Cancer Causes More Deaths than Cardiovascular Disease Does

U.S. Marshals Seize Drug Products from Online Distributor

Five New England Governors Ask FDA to Withdraw Approval for Zohydro

FBI: Hackers May Be Targeting Valuable Medical Device Data

Federal Aid for Disabled Children Now Greater than Welfare Payments

Regulatory Updates

FDA Announces Fee Rates for Using Tropical Disease Priority Review Voucher in FY2015
In the August 27, 2014, *Federal Register*, FDA announced the fee rate for tropical disease priority review vouchers, in addition to the normal PDUFA fee, will be $2,562,000. The user fee is effective for any application received on or after October 1, 2014, and is due upon submission of the drug application along with any other fee due under PDUFA.

FDA Classifies EGR1 Gene FISH Test As Class II Device
In the September 3, 2014, *Federal Register*, FDA issued a final order classifying early growth response 1 ("EGR1") gene fluorescence in-situ hybridization ("FISH") test system for specimen characterization into class II (special controls). ***Effective October 3, 2014***.

FDA Establishes Public Docket on Treatments for Duchenne Muscular Dystrophy
In the September 4, 2014, *Federal Register*, FDA announced its establishment of a public docket to discuss issues related to developing drugs for Duchenne Muscular Dystrophy. FDA received a proposed draft guidance from interested parties in June of this year and seeks additional guidance and public comment. ***Comments due October 6, 2014***.

FDA Determines Levonorgestrel Drug Not Withdrawn for Reasons of Safety or Effectiveness
Since the last Jones Day Update, FDA determined that JADELLE (levonorgestrel) Implant, 75mg was not withdrawn for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications for the drug, if all other legal and regulatory requirements are met.

FDA Corrected the Docket Numbers in Two August 1, 2014, *Federal Register* Publications
Biosimilar User Fee Rates for Fiscal Year 2015

Outsourcing Facility Fee Rates for Fiscal Year 2015

FDA Corrected the RIN Numbers in Its June 10 and August 14, 2014, *Federal Register* Publications
Postmarketing Safety Reports for Human Drug and Biological Products

FDA Issued the Following Guidance Documents
Draft Guidance for Industry on Controlled Correspondence Related to Generic Drug Development. August 27, 2014, *Federal Register*.

Guidance for Industry and FDA Staff: Highly Multiplexed Microbiological/Medical Countermeasure In Vitro Nucleic Acid Based Diagnostic Devices. August 27, 2014, *Federal Register*.

Guidance for Industry: Recommendations for Screening, Testing, and Management of Blood Donors and Blood and Blood Components Based on Screening Tests for Syphilis. August 28, 2014, *Federal Register*.

Draft Guidance for Industry, Electronic Exchange of Documents: File Format Recommendations, developed for use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products. August 28, 2014, *Federal Register*.

Draft Guidance for Industry: Electronic Submission of Lot Distribution Reports. August 29, 2014, *Federal Register*.

Information Collection Activities

FDA Announced that the Following Collections Have Been Submitted to OMB for Approval
Information Collection Activities Under Guidance for Industry on Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B (*comments due September 26, 2014*).

Information Collection Activities Under Guidance for Industry on Fees for Human Drug Compounding Outsourcing Facilities (*comments due October 2, 2014*).

Upcoming Meetings, Workshops, and Conferences

Drugs and Biologics
Third Annual Patient Network Meeting, Under the Microscope: Pediatric Drug Development, will held **September 10, 2014**, in Washington, D.C.

Public Meeting on Methodological Considerations in Evaluation of Cancer as an Adverse Outcome Associated With Use of Non-Oncological Drugs and Biological Products in the Postapproval Setting will be held **September 10–11, 2014**, in Silver Spring, MD.

Public Workshop on Revamping Microbiological Test Methods for Contact Lenses, Products, and Accessories will be held **September 12, 2014**, in Silver Spring, MD.

FDA/PQRI Conference on Evolving Product Quality will be held **September 16–17, 2014**, in Bethesda, MD.

Public Meeting on GDUFA Policy Development will be held **September 17, 2014**, in Hyattsville, MD.

FDA Small Business and Industry Assistance Regulatory Education for Industry Conference will be held on **September 18–19, 2014**, in Bethesda, MD,

Public Meeting on Patient-Focused Drug Development for Hemophilia A, Hemophilia B, von Willebrand Disease, and Other Heritable Bleeding Disorders will be held on **September 22, 2014**, in Silver Spring, MD.

Public Meeting on Patient-Focused Drug Development for Idiopathic Pulmonary Fibrosis will be held on **September 26, 2014**, in Silver Spring, MD.

Public Workshop on Innovations in Breast Cancer Drug Development—Next-Generation Oncology Trials, Breast Cancer Workshop will be held on **October 21, 2014**, in Bethesda, MD.

Training Course for Clinical Investigators on Scientific, Ethical, and Regulatory Aspects of Clinical Trials will be held **November 4–6, 2014**, in College Park, MD.

Medical Devices
International Medical Device Regulators Forum will be held **September 15–19, 2014**, in Washington, D.C.

Public Meeting of Circulatory System Devices Panel of the Medical Devices Advisory Committee will be held on **October 8, 2014**, in Gaithersburg, MD.

Public Workshop on Additive Manufacturing of Medical Devices: An Interactive Discussion on the Technical Considerations of 3D Printing will be held **October 8–9, 2014**, in Silver Spring, MD.

Training Course for Clinical Investigators on Scientific, Ethical, and Regulatory Aspects of Clinical Trials will be held **November 4–6, 2014**, in College Park, MD.

Public Workshop on Brain–Computer Interface Devices for Patients with Paralysis and Amputation will be held **November 21, 2014**, in Silver Spring, MD.

Advisory Committees
September 11, 2014: Endocrinologic and Metabolic Drugs Advisory Committee Meeting

September 12, 2014: Endocrinologic and Metabolic Drug Products Advisory Committee Meeting

September 17, 2014: Joint Meeting of the Bone, Reproductive, and Urologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee

September 18, 2014: Joint Meeting of the Bone, Reproductive, and Urologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee

September 18, 2014: Cellular, Tissue, and Gene Therapies Advisory Committee Meeting

September 23, 2014: Pediatric Advisory Committee Meeting

October 1, 2014: Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee

October 16, 2014: Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee Meeting

October 20, 2014: Dermatologic and Ophthalmic Drugs Advisory Committee

November 3–4, 2014: Risk Communications Advisory Committee Meeting

November 6, 2014: Cellular, Tissue and Gene Therapies Advisory Committee

For more comprehensive listings of FDA meetings, please visit these FDA webpages:
Meetings, Conferences, and Workshops (Drugs)

Workshops, Meetings, and Conferences (Biologics)

Workshops & Conferences (Medical Devices)

FDA Advisory Committee Calendar

Enforcement Updates

Recent Product Recall
A pharmaceutical company has recalled four product lots of ascorbic acid, glutathione, magnesium chloride, and Tropi/Cyclo/Phenyl/Tobra/Flurb products after its independent testing laboratory indicated that they may not be sterile. A topical cream product manufacturer recalled a mole, wart, and skin tag remover for lack of FDA approval.

Click here for a complete listing of FDA Recalls.

Recent Warning Letters
Since the last Update, FDA cited six facilities for failure to pay the facility fee as required by the Generic Drug User Fee Amendments Act of 2012. A Montana physician was also cited for violating the clinical investigation regulation governing retention of study records.

FDA posted numerous warning letters citing facilities for a variety of Quality System Regulation violations. Recipients of warning letters included manufacturers of medical monitoring devices, such as oximeters and glucose strips. Other recipients included manufacturers of thermotherapy systems, cord blood processing systems, negative pressure wound therapy equipment, MRI infusion pumps, injection equipment, and various types of catheters, as well as a repackager for sterile towels and drapes.

Click here for FDA's Warning Letters Home page (scroll down for listing of recently posted Warning Letters).

The Office of Prescription Drug Promotion ("OPDP") has not issued any warning letters since the last Update.

Click here for a complete listing of 2014 OPDP Warning Letters.

Recent Drug and Device Approvals
FDA allows marketing of the first test to assess risk of developing acute kidney injury (September 5, 2014)

FDA approves Keytruda for advanced melanoma (September 4, 2014)

For additional information on drug and device approvals and clearances, please visit FDA's webpages on Drug Approvals and Databases (includes biologics) and Device Approvals, Denials, and Clearances.