Pharmaceutical & Medical Device Regulatory Update
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Top Stories

President Obama Signs Executive Order on Combating Antibiotic-Resistant Bacteria
Last week, President Obama signed an Executive Order and issued a national strategy to spur action within the federal government to address the public health challenge of antibiotic-resistant bacteria. The Order creates a national task force led by the Secretaries of the Department of Health and Human Services ("HHS"), Department of Defense, and Department of Agriculture, charged with submitting a five-year action plan by February 15, 2015. The Order also directed HHS to propose regulations for hospitals to better manage antibiotic use. President Obama also announced a $20 million prize for a diagnostic test that hospitals could use in identifying resistant infections quickly. The President's Council of Advisors on Science and Technology concurrently issued a report warning that "this brewing problem has become a crisis."

FDA and Tech Firms Address Regulatory Challenges Posed by Mobile Medical Devices
Silicon Valley technology firms investing heavily in mobile medical devices and apps are increasingly confronting the challenges of clearing U.S. regulatory approval processes.

Although FDA has said it is not interested in regulating most medical apps that simply track calories or help manage prescriptions, FDA will regulate apps that measure and display physiological parameters, such as blood glucose, or allow active, remote monitoring, such as the progress of labor, as medical devices, according to guidance issued last year. Meanwhile, developers of mobile medical apps have asked for

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clarification of federal HIPAA rules in the context of rapidly changing health IT, arguing "the risks of potential disclosure should be weighed again against the anticipated benefits of wider sharing and easier access to crucial health data."

Schnedar to Lead CDER Office of Compliance
Cynthia Schnedar will serve as the new director of the Center for Drug Evaluation and Research ("CDER") Office of Compliance. The position has been without a permanent director since January 2014, when Howard Sklamberg was promoted to Deputy Commissioner for Global Regulatory Operations and Policy. Schnedar has served as the Deputy Inspector General at the Department of Justice since 2010. In an email to CDER staff, Director Janet Woodcock said, "Her expertise in law enforcement, and extensive experience as an attorney and leader in the federal government, enables her to bring a valuable mix of knowledge and ability to analyze complex statutory and regulatory issues." Schnedar assumes the position on October 6, 2014.

Bill to Fix Sunscreen Ingredient Approval Process Clears the Senate
The Senate has passed the Sunscreen Innovation Act through a unanimous consent agreement. The bill, which passed the House of Representatives in late July 2014, aims to streamline how new ingredients for over-the-counter sunscreen products are approved. The sunscreen bill now returns to the House of Representatives for further action. Several over-the-counter sunscreen ingredients have languished in the current FDA approval process for 12 years, with the last ingredient being approved in the 1990s. Concerns that consumers in the U.S. were not able to take advantage of new sunscreen technologies prompted Congress to investigate and address the backlog.

FDA May Consider Heart Health Risks of Testosterone Drugs
Citing a sharp increase in the number of men using testosterone drugs in recent years, FDA recently convened a joint advisory committee meeting on testosterone replacement therapy ("TRT"). The committee focused on the appropriate patient population for TRT and the potential risk for major adverse cardiovascular events, such as stroke or heart attack, associated with TRT. The Advisory Committee voted 20–1 for FDA to impose new labeling requirements, including providing additional risk information and to restrict TRT to those with low testosterone due to medical conditions, which would prevent the marketing of TRT for age-related testosterone issues. The committee also recommended further studies to assess the risks associated with long-term use of TRT. FDA is not required to follow advisory committee recommendations but often does so.

Other News
Canadian Clinical Trial Oversight Questioned

WHO Confirms Over 4,200 Diagnosed Ebola Infections in West Africa

FDA Issues Emergency Use Authorization for Ebola Detection Assay

Labs Must Send Test Results to Patient Consumers

Generic Injectable Medicines Still in Short Supply

Several Obesity Medications Scheduled for FDA Review

Regulatory Updates

FDA Issues Emergency Use Authorization for Ebola IVD
In the September 17, 2014, *Federal Register*, FDA announced it had issued an Emergency Use Authorization for an in vitro diagnostic device to detect of the Ebola Zaire virus (detected in the West Africa outbreak in 2014) at the request of the Department of Defense.

FDA Withdraws Approval from Three ANDAs for Products Containing Propoxyphene

In the September 12, 2014, *Federal Register*, FDA withdrew approval of three abbreviated new drug applications ("ANDAs") for products containing propoxyphene. FDA found the products are no longer shown to be safe due to risks of potentially serious and even fatal heart rhythm abnormalities. The holders of these ANDAs waived their opportunity for a hearing. ***Effective September 12, 2014***.

FDA Proposes to Reclassify External Pacemaker Pulse Generator Through Administrative Order
In the September 15, 2014, *Federal Register*, FDA withdrew a 2011 proposed rule and associated guidance document that sought to reclassify external pacemaker pulse generator ("EPPG") devices, a preamendments class III device, into class II (special controls). FDA simultaneously issued a proposed administrative order that seeks the same reclassification described in the withdrawn proposed rule. This substitution of an administrative order in place of a proposed rule reflects FDASIA's changes to FDA's device reclassification process, shifting it from a rulemaking process to an administrative order process. In the proposed order, FDA also proposes to amend the device identification and reclassify pacing system analyzers ("PSAs") into class II (special controls). Specifically, FDA proposes to reclassify as Class II devices single- and dual-chamber PSAs, which are currently classified with EPPG devices, and triple-chamber PSAs, which are postamendments class III devices. FDA is proposing this reclassification based on new information pertaining to the device. FDA states the proposed action would implement certain statutory requirements. ***Comments due December 15, 2014***.

FDA Issues Administrative Orders Proposing Device Classifications and Reclassifications
FDA recently issued final orders to classify Dengue Virus Test Reagents and Tryptase Test Systems as Class II devices with special controls. FDA additionally proposed reclassifying the salivary stimulatory system and iontophoresis devices intended for any purposes other than as an aid in the diagnosis of cystic fibrosis or as a combination drug/device product, which are both Class III devices, into class II (special controls). For the salivary stimulatory system, FDA proposes premarket notification and renaming the device "electrical salivary stimulatory system." For iontophoresis devices, FDA proposes amending the device identification to encompass all of those indications.

FDA Issued the Following Draft and Final Guidance Documents
Draft Guidance on Estradiol. September 22, 2014, *Federal Register*. Comments due November 21, 2014.

Unique Device Identification System: Small Entity Compliance Guide. September 10, 2014, *Federal Register*.

Draft Guidance for Industry: ANDA Submissions—Refuse to Receive for Lack of Proper Justification of Impurity Limits. September 17, 2014, *Federal Register*. *Comments due November 17, 2014*.

ANDA Submissions—Refuse-to-Receive Standards. September 17, 2014, *Federal Register*.

Information Collection Activities

FDA Announced that OMB Has Approved the Collection of Information About the Following
Testing Communications on Biological Products

Electronic Submission of Allegations of Regulatory Misconduct Associated with Medical Devices

Providing Waiver-Related Materials in Accordance with Draft Guidance for Industry on Providing *Postmarket Periodic Safety Reports in the International Conference on Harmonisation E2C(R2) Format*

Prescription Drug Advertisements

Eye Tracking Study of Direct-to-Consumer Prescription Drug Advertisement Viewing

Medical Devices; Exception From General Requirements for Informed Consent

Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile

FDA Announced the Opportunity to Comment on the Following Proposed Information Collections
Survey of Health Care Practitioners for Device Labeling Format and Content (*comments due November 12, 2014*).

Application for FDA Approval to Market a New Drug (*comments due October 17, 2014*).

FDA Announced the Following Collections Have Been Submitted to OMB for Approval
Generic Clearance for the Collection of Qualitative Feedback on FDA Service Delivery (*comments due to OMB October 22, 2014*).

FDA Makes Corrections to the Following Federal Register Notices
Postmarketing Safety Reports for Human Drug and Biological Products Electronic Submission Requirements

- RIN Number on June 10, 2014, *Federal Register*
- RIN Number on August 14, 2014, *Federal Register*

Revocation of General Safety Test Regulations that are Duplicative of Requirements in Biological License Applications on August 22, 2014, *Federal Register*

- The document proposed to amend the biologics regulations by removing the general safety test requirements for biological products. The document published with the incorrect title.

Draft Guidance for Industry: Electronic Submission of Lot Distribution Reports; Availability

- The document was published with the incorrect docket number on August 29, 2014, *Federal Register*.

Upcoming Meetings, Workshops, and Conferences

Drugs and Biologics
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
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.

Public Workshop on Collaborative Approaches for Medical Device and Healthcare Cybersecurity will be held **October 21–22, 2014**, in Arlington, VA.

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 23, 2014: Pediatric Advisory Committee Meeting

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

October 8, 2014: Circulatory System 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

October 30, 2014: Cardiovascular and Renal Drugs Advisory Committee

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

December 12, 2014: Orthopaedic and Rehabilitation Devices Panel of the Medical Devices 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 and Conferences (Medical Devices)

FDA Advisory Committee Calendar

Enforcement Updates

Recent Product Recalls
Since the previous *Update*, three manufacturers have issued recalls for drugs or devices. Two drug manufacturers recalled their products for mislabeled shipping cartons and foreign particulate matter. One medical device manufacturer recalled its product for electrical problems that posed a risk of electric shock.

Click here for a complete listing of FDA Recalls.

Recent Warning Letters
Since the previous *Update*, FDA has continued to cite manufacturers for failure to pay their Generic Drug User Fees, with two more manufacturers receiving recently posted warning letters. A compounding pharmacy was cited for producing drug products without receiving valid prescriptions for individually identified patients as well as deficiencies in sterile drug production. Two manufacturers were cited for current Good Manufacturing Practices and Quality Systems Regulation violations, primarily insufficient recordkeeping and a lack of quality controls. One of those manufacturers was also cited for failing to fulfill its annual registration and listing requirements for the last two years.

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) issued one warning letter since the last Update. One manufacturer was cited for making false and misleading claims in a commercial email ("e-Pharm alert") containing unsubstantiated superiority claims.

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

Recent Drug and Device Approvals/Clearances
FDA approves Trulicity to treat type 2 diabetes (September 18, 2014)

FDA approves Movantik for opioid-induced constipation (September 16, 2014)

FDA approves weight-management drug Contrave (September 10, 2014)

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

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