JONES DAY | **Pharmaceutical & Medical Device Regulatory Update**
Issue 16 | October 2014 JONES DAY

Top Stories

FDA Releases Framework for Overseeing Laboratory Developed Tests

FDA recently released two draft guidance documents laying out FDA's proposed framework for regulating Laboratory Developed Tests ("LDTs") as medical devices; the first addresses FDA's *Framework for Oversight of Laboratory Developed Tests (LDTs)* and the second explains *FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)*. Ultimately, FDA intends to end its policy of enforcement discretion toward LDTs but will not regulate LDTs unless or until at least one of the draft guidance documents is finalized. If finalized as proposed, enforcement discretion for LDTs will gradually disappear over the next decade, as FDA implements a final framework based on the draft guidance. Read the *Jones Day Commentary*, including a timeline and an explanatory chart, here.

EMA Issues Policy on Proactive Publication of Certain Data in Drug Applications

On October 2, 2014, the European Medicines Agency ("EMA") adopted a highly anticipated policy on the publication of certain clinical data contained in marketing authorization applications. For applications filed as of January 1, 2015, and for line extension applications filed as of July 1, 2015, EMA will proactively release an application's clinical reports and individual patient data in conjunction with the agency's decision on the application, allowing the general public and researchers to access the data. While intended to reduce duplicative clinical trials and foster innovation, this development will deeply

CONTACTS

Mark Mansour
Washington

Laurie A. Clarke
Washington

Colleen M. Heisey
Washington

Christopher M. Mikson
Washington

Emily K. Strunk
Washington

Stephanie L. Resnik
Washington

Brigid C. DeCoursey
Washington

Matthew R. Bowles
Washington

Detailed Contact Information

UPCOMING EVENTS

Oct. 28: **Laurie Clarke** will speak in Berlin, Germany, on medical device labeling and compliance & UDI implementation.

Nov. 12: **Colleen Heisey** will moderate an ABA Health Law Section webinar on off-label marketing and free speech, focusing on the impact of *Caronia*.

Nov. 13: **Alexis Gilroy** will speak in New York City on telehealth issues at a dermatology course at Memorial Sloan

affect business and intellectual property strategies of drug companies, as it may result in the release of commercially confidential information ("CCI"). Applicants may request redaction of CCI from the publications, but EMA will scrutinize whether such requests meet the policy's strict description of CCI. There is also some expectation that the limited use of the data for noncommercial purposes will be circumvented. The policy is EMA's first step toward clinical data transparency, and the agency plans further action in 2015 or later.

FDA Issues Final Guidance on Cybersecurity in Medical Devices, Calls on Health Care and Public Health Community for Ideas on Collaboration

October is National Cybersecurity Awareness Month, and FDA has accordingly issued its final guidance on *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*.

Kettering Cancer Center.

Nov. 13–14: **Christian Fulda** will speak in Brussels, Belgium on European and U.S. transparency standards at the FDLI Conference.

November 20: **Laurie Clarke** will speak at an ABA Health Section webinar on medical device fundamentals.

RELATED PRACTICES

FDA Regulatory & Compliance Counseling

Health Care

Life Sciences

The guidance contains recommendations for medical device manufacturers on cybersecurity management and information to include in a premarket submission. FDA's recommendations focus on what manufacturers can do before marketing products to ensure the data collected and transmitted by the device is secure. For example, FDA cautions against unsecured distribution of passwords and not updating security software updates and patches to medical devices and networks. These recommendations supplement earlier FDA guidance documents addressing cybersecurity related to medical devices. Later this month, FDA, in collaboration with the Department of Health and Human Services and the Department of Homeland Security, will hold a public workshop titled *Collaborative Approaches for Medical Device and Healthcare Cybersecurity* to identify health care and public health cybersecurity challenges and how stakeholders can work together to address these challenges. FDA is soliciting comments on this topic through ***November 24, 2014***.

Industry Critical of Social Media Draft Guidances; FDA Reopens Comment Period

In June 2014, FDA released draft guidance documents for drug and device manufacturers on presenting risk benefit information and correcting third-party misinformation on social media. The comment period had been closed for just under two weeks when FDA reopened the docket through October 29, 2014, to allow more time for interested parties to submit comments. Industry has thus far been critical of the guidance documents, arguing that FDA needs to provide additional clarity on expectations, that the agency has overstepped its authority in regulating manufacturer speech, and that, if followed, the guidance would have a chilling effect on industry. Public health groups, however, contend the voluntary nature of the guidance documents are not enough to protect public health and should contain enforcement mechanisms.

FDA Issues New Roadmap for Strategic Priorities 2014–2018

Last week, Commissioner Hamburg announced the release of FDA's new strategic planning document setting out the Agency's goals for the next four years. It establishes a framework for integrating five strategic priorities: regulatory science, globalization, safety and quality, smart regulation, and stewardship. For example, in the introduction to the Roadmap, Hamburg noted that globalization has increased the number of FDA-regulated products coming into the U.S. from overseas, adding to the complexity of the Agency's many responsibilities. In a related blog post, Hamburg stated: "Although each priority is significant in and of itself, the priorities are also interconnected and must not be addressed in isolation.

Other News
FDA Releases Generic Drug Regulatory Science Priorities for FY2015

FDA Launches Campaign to Help Doctors Spot Counterfeit, Unapproved Drugs

NIH Distributes $10 Million for Study of Sex Differences in Drug Research

FDA Seeks to Advance Targeted Medicines Through Enhanced Biomarkers

FDA Sets First Fee for New Priority Review Voucher Intended to Accelerate Certain Pediatric Medicines

CMS Open Payments Releases Sunshine Act Data Revealing Drug and Medical Device Payments to Providers

FDA Announces New "Data Dashboard" to Provide Easy Access to Inspection, Compliance, and Recall Data

3D Technologies Poised to Change How Doctors Diagnose Cancers

U.S. Marshals Seize Illegal Botanical Painkiller from California Facility

Regulatory Updates

FDA Seeks Comments on Health Care and Public Health Cybersecurity Collaboration
In the September 23, 2014, *Federal Register*, FDA announced a public workshop and request for comments on *Collaborative Approaches for Medical Device and Healthcare Cybersecurity* (see below for public workshop information), in collaboration with other government agencies to identify health care and public health cybersecurity challenges and how stakeholders can work together to address these challenges. ***Comments due November 24, 2014***.

FDA Reopens Comment Period on Social Media Draft Guidances
In the September 29, 2014, *Federal Register*, FDA announced it was reopening the comment period for the draft guidances titled *Internet/Social Media Platforms with Character Space Limitations: Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices* (*Federal Register*) and *Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices* (*Federal Register*), in response to a request for additional time. *Comments due October 29, 2014*.

FDA Issues Report on Risk Evaluation and Mitigation Strategies
In the September 25, 2014, *Federal Register*, FDA has issued a report titled *Standardizing and Evaluating Risk Evaluation and Mitigation Strategies (REMS)*. This report describes FDA's findings concerning strategies to standardize REMS, where appropriate, with the goal of reducing the burden of implementing REMS on practitioners, patients, and others in various health care settings. ***Comments due November 24, 2014***.

FDA Extends Comment Period for Informed Consent Guidance
In the September 26, 2014, *Federal Register*, FDA announced it would extend the comment period for the *Draft Guidance for Industry and Food and Drug Administration Staff: Informed Consent Information Sheet*. ***Comments due October 27, 2014***.

FDA Announces Fee Rate for Rare Pediatric Disease Priority Review Voucher for FY2015
In the October 1, 2014, *Federal Register*, FDA issued a notice establishing the rare pediatric disease priority review fee rate for FY2015 at $2,562,000 and outlining FDA's procedures for payment. ***Effective October 1, 2014 through September 30, 2015***.

FDA Publishes Quarterly Safety and Effectiveness Summaries for PMAs

In recent Federal Register notices, as required by regulation, FDA published a quarterly list of available safety and effectiveness summaries of premarket approval application ("PMA") approvals and denials for the first and second quarters of 2014.

FDA Issued the Following Draft and Final Guidance Documents
Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories: Framework for Oversight of Laboratory Developed Tests (LDTs) and *Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories: FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)*. October 3, 2014, *Federal Register*. ***Comments due January 30, 2015***.

Guidance for Industry and Food and Drug Administration Staff: Content of Premarket Submissions for Management of Cybersecurity in Medical Devices. October 2, 2014, *Federal Register*.

Guidance for Industry and Food and Drug Administration Staff: Custom Device Exemption. September 24, 2014, *Federal Register*.

Draft Guidance for Industry and Food and Drug Administration Staff: Policy Clarification for Fluoroscopic Equipment Requirements. September 25, 2014, *Federal Register*. ***Comments due December 24, 2014***.

Draft Guidance for Industry and Food and Drug Administration Staff: Content and Format for Abbreviated 510(k)s for Early Growth Response 1 (EGR1) Gene Fluorescence In-Situ Hybridization (FISH) Test System for Specimen Characterization Devices. September 26, 2014, *Federal Register*. ***Comments due December 26, 2014***.

Information Collection Activities

FDA Announced the Following Collections Have Been Submitted to OMB for Approval
Data to Support Drug Product Communications as Used by the Food and Drug Administration (*comments due to OMB October 30, 2014*)

Good Laboratory Practice Regulations for Nonclinical Studies (*comments due to OMB October 27, 2014*)

Generic Clearance for the Collection of Qualitative Feedback on FDA Service Delivery (*comments due to OMB October 22, 2014*)

Upcoming Meetings, Workshops, and Conferences

Drugs and Biologics
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.

Public Meeting and Scientific Workshop on the topic of Female Sexual Interest/Arousal Disorder (FSIAD) will be held **October 27–28, 2014**, in Silver Spring, MD.

The First Annual Neonatal Scientific Workshop—Roadmap for Applying Regulatory Science to Neonates will be held **October 28 and 29, 2014**, in Silver Spring, MD.

Public Meeting on Development and Regulation of Abuse-Deterrent Opioid Medications will be held **October 30–31, 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.

FDA Industry Meeting: Electronic Postmarket Safety Reporting Updates will be held

October 27, 2014, in Silver Spring, 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 (BCI) Devices for Patients With Paralysis and Amputation will be held **November 21, 2014**, in Silver Spring, MD.

Advisory Committees
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 21, 2014: Pulmonary-Allergy Drugs Advisory Committee

October 30, 2014: Cardiovascular and Renal Drugs Advisory Committee

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

November 14, 2014: Ophthalmic Devices Panel of the Medical Devices Advisory Committee

November 24, 2014: Anesthetic and Analgesic Drug Products 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 web pages:
Meetings, Conferences, and Workshops (Drugs)

Workshops, Meetings, and Conferences (Biologics)

Workshops and Conferences (Medical Devices)

FDA Advisory Committee Calendar

Enforcement Updates

Recent Product Recall
Since the previous *Update*, FDA issued a recall for injection products labeled with an incorrect expiration date.

Click here for a complete listing of FDA Recalls.

Recent Warning Letters
FDA continues to issue letters to medical device manufacturers for violations of the Quality Systems Regulations, including in-process sampling and issues related to dealing with nonconforming product and corrective actions. FDA also warned a medical device manufacturer for marketing a Class II medical device without obtaining premarket

clearance when the device was not otherwise exempt or approved.

FDA recently warned a drug compounding facility for insanitary conditions that led to contaminated products and a drug manufacturing facility for failure to pay its annual Generic Drug User Fee. Finally, FDA cited a the sponsor of a medical device clinical study for violations of the investigational device exemptions regulations, specifically for issues related to proper monitoring of the study, informed consent, and failing to notify FDA that the institutional review board had withdrawn approval of one of the clinical investigators.

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

Since the last *Update*, the Office of Prescription Drug Promotion ("OPDP") issued one warning letter citing a drug maker for listing unapproved uses and overstating the drug's efficacy in promotional materials, including educational technique flashcards and a journal ad. The journal ad in question was also submitted to the Agency under the Bad Ad Program.

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

Recent Drug and Device Approvals/Clearances
FDA clears glucose monitoring system for use in hospital critical care units (September 24, 2014)

FDA allows marketing of the first test to identify five yeast pathogens directly from a blood sample (September 22, 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.

Jones Day FDA Regulatory & Compliance Counseling Contacts

Mark Mansour
Washington
+1.202.879.3883
mmansour@jonesday.com

Laurie A. Clarke
Washington
+1.202.879.3498
lclarke@jonesday.com

Colleen M. Heisey
Washington
+1.202.879.3449
cmheisey@jonesday.com

Christopher M. Mikson
Washington
+1.202.879.3669
cmikson@jonesday.com

Emily K. Strunk
Washington
+1.202.879.3778
estrunk@jonesday.com

Stephanie L. Resnik
Washington
+1.202.879.5458
sresnik@jonesday.com

Brigid C. DeCoursey
Washington
+1.202.879.3651
bdecoursey@jonesday.com

Matthew R. Bowles
Washington
+1.202.879.3604
mbowles@jonesday.com