Pharmaceutical & Medical Device Regulatory Update
Vol. II | Issue 1 | January 2015 JONES DAY

Top News

FDA Publishes FY2015 Medical Device Guidance Agenda

As part of its MDUFA III negotiations with industry, FDA agreed to publish and seek feedback on an annual list of prioritized draft and final guidance documents that the Agency intends to publish in the coming year. This year's list, just published, includes an "A-list" of guidance documents that will be published and a "B-list" of documents that the Agency intends to publish as resources permit.

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FDA Health IT Regulation and Telehealth High on Legislative Agenda for Health Care

A new congress was sworn in on January 3, 2015, and with it a new opportunity for advancing legislation. Although the Republican party now controls both houses, it still lacks a supermajority in the Senate, which may make legislation more difficult to pass. Although few pieces of legislation have actually been introduced in the few weeks this Congress has been in session, according to a recent analysis by Politico, several themes from the last congressional session (2013–2014) are likely to reemerge in this Congress.

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White House Regulatory Agenda Forecasts Drug and Device Regulations for 2015

The White House's most recent Unified Agenda outlines several major drug and device rules and proposed rules FDA intends to issue in the coming year. The Unified Agenda is generally a good

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UPCOMING EVENTS

indicator of the administration's priorities for the coming year; however, these priorities can shift, and thus the dates are not firm.

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FDA Panel Recommends Approval of First Biosimilar Application

An FDA advisory panel made history last week when, for the first time, it recommended approval of a biosimilar drug, which is a highly similar version of a biologic therapeutic product. The FDA Oncologic Drugs Advisory Committee unanimously voted to recommend that the Agency approve a biosimilar cancer drug for all five indications in the application. The vote is a significant step to FDA approval and subsequent marketing of the first biosimilar in the United States. Markets outside the United States have been quicker to establish regulations for approving biosimilars, and the biosimilar at issue is already sold in more than 40 countries. Although FDA may not consider drug prices when making approval decision, cost is clearly an important issue for patients, who are advocating for the drug's approval to lower treatment costs. According to a Rand Corporation analysis, biosimilars could offer a cost savings of approximately $44 billion over the next 10 years.

Drug Manufacturers Get Reprieve from Drug Tracking Requirements

Due to concerns about disruptions to the supply chain, FDA has posted guidance informing the pharmaceutical industry that it does not intend to enforce drug tracking requirements before May 1, 2015. The Drug Supply Chain Security Act ("DSCSA"), requiring drug trading partners to capture, maintain, and provide the subsequent purchaser with transaction information for certain prescription drugs, was set to take effect on January 1, 2015 for manufacturers, wholesale distributors, and repackagers. The compliance policy is limited to the requirements in the DSCSA that trading partners provide and capture product tracing information and does not cover other requirements, such as verification related to suspect and illegitimate products and requirements related to authorized trading partners.

January 16, 2015: **Laura Laemmle-Weidenfeld** will speak in the American Telemedicine Association's webinar *Fraud and Abuse Issues Arising in Telemedicine*.

February 24, 2015: **Laura Laemmle-Weidenfeld** will speak as a panelist at the American Conference Institute's program *Professional Responsibility and Legal Ethics in Life Sciences*.

March 4–7, 2015: **Michael Carvin** will speak at the American Bar Association's *16th Annual Conference on Emerging Issues in Healthcare Law*.

April 22–23, 2015: **Cristiana Spontoni** will speak at the 1st Annual Women Leaders in Life Sciences Law Conference program *Pharmaceutical and Medical Device Regulatory Developments* in the session *Issue Spotting: Updates on the Substantive Legal Developments Affecting Life Sciences Companies in 2015 and Beyond*.

RELATED PRACTICES

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FDA Gets Mixed Signals at LDT Workshop

FDA's final guidance on its proposed regulation of laboratory developed tests ("LDTs") is expected in 2015, and debate over whether FDA has the authority to regulate these tests and how it should do so was on full display during an FDA-hosted workshop early this year. The two-day workshop featured a six-segment program organized by issue, during which participants heard from public commenters as well as panelists selected by FDA to represent an array of viewpoints on the six topics.

Many clinical laboratories and pathologists argued that Clinical Laboratory Improvement Amendments regulations are sufficient and that the interpretation of such tests is the practice of medicine, an area outside FDA's purview. Some are concerned that the regulatory framework is too burdensome, would stifle innovation, and that FDA does not have the resources to implement it, which will impair patients' access to not only LDTs but also to other in vitro diagnostic devices undergoing a similar review process. They emphasized the need for a balance between safety and innovation. Others see a role for FDA in regulating the validity of the tests now that they have become so common and are used to diagnose and make treatment decisions for complex and advanced diseases. Biotech investors want a clear path forward and asked FDA to limit the uncertainty by

issuing the rule sooner rather than later and to make the process for determining which test falls into which category of regulation more transparent. Representatives of patient and disease-centered groups also conveyed different messages: Some groups focused on the need for prompt access to diagnostic tests and the expected delay in diagnosis due to FDA regulation, while others discussed the negative impacts of false positive and false negative test results on patients and expressed their hope that FDA regulation would help ensure the safety and effectiveness of such tests. A few commenters encouraged FDA to issue supplemental guidance documents on sub-issues like clinical validity and classification, or to reissue another draft guidance after a first round of public comments. FDA officials' comments during the workshop did not shed any light on what they intend to do in the coming months. ***Comments on the LDT Framework and Notification guidances are due February 2, 2015***. Read Jones Day's in-depth analysis of the guidance.

FDA Requires Superiority for New Orphan Drug Exclusivity
In response to an unfavorable court ruling, in late December, FDA issued a "policy clarification" indicating the Agency will not substantively change its stance on withholding exclusivity for new orphan drugs that are essentially the same as previously approved medications. In the court order, a U.S. District Judge found that FDA's role in granting exclusivity was "merely ministerial." FDA interpreted the ruling to mean that a new orphan drug with a previously approved active ingredient and indication must demonstrate superiority in order for the agency to grant exclusivity for new drug. Given the pace of new orphan drug designation, FDA's policy is likely to be tested again in the near future.

CJEU Decides Landmark Stem Cell Patentability Case
The European Court of Justice ("CJEU") recently held that a nonfertilized human ovum, the development of which has been stimulated by parthenogenesis (i.e., in the absence of paternal DNA), should not be regarded as a human embryo within the meaning of the EU Biotech Directive (98/44/EC) if it does not have the inherent capacity to develop into a human being. The definition of a human embryo is key to the patentability of inventions using such organisms because, under the Biotech Directive, "human embryos" are not patentable. This decision, which has been eagerly awaited by the biotech industry, is expected to open the door to the patenting of more stem cell technologies.

First Stem Cell Therapy Recommended for Approval in the EU
The European Medicines Agency's Committee for Medicinal Products for Human Use has recommended the first advanced therapy medicinal product containing stem cells for approval in the European Union. The product treats limbal stem cell deficiency, a rare eye condition that can result in blindness.

Other News
FDA Launches New Drug Quality Office to Improve Pharmaceutical Industry

FDA Posts New Database of Searchable Guidance Documents

FDA Approves 41 New Drugs in 2014, Highest Number Since 1996

31 Digital Health Devices Cleared in 2014

Pharma Petitions Supreme Court to Strike County Take-Back Program

Senators Reintroduce Canadian Drug Import Bill

FDA Forms New Advisory Committee for Compounded Medications

Pharmaceutical Companies Outraged over UK Cancer Drug Fund Cuts

FDA to Ease Ban on Blood Donations by Gay Men

Court Reverses FDA Ruling Blocking Generic Celebrex

Massachusetts Considering Legal Action for Painkiller Marketing

Regulatory Notices

FDA Announces FY2015 Guidance Document Agenda
In the January 9, 2015, *Federal Register*, FDA announced the availability of the guidance documents it intends to publish in fiscal year 2015. (See above "Top News" story for additional details.) FDA has also established a docket, where stakeholders may comment on the Agency's guidance document priorities, provide comments and/or propose draft language for the specific topics, suggest topics for new or different guidance documents, and comment on the applicability of previously issued guidance documents. ***Comments due March 10, 2015***.

FDA Clarifies Policy on Orphan-Drug Exclusivity
In the December 23, 2014, *Federal Register*, FDA clarified its policy regarding certain aspects of orphan-drug exclusivity due to a recent court decision interpreting provisions of the Food Drug and Cosmetic Act ("FDCA"), as amended by the Orphan Drug Act. (See "Top News" story above for additional details.) ***Effective December 23, 2014***.

FDA Issues Proposed Rule on Electronic Distribution of Prescribing Information
In the December 18, 2014, *Federal Register*, FDA proposed a rule amending its prescription drug and biological product labeling regulations to require electronic distribution of the prescribing information for health care professionals, which is currently distributed in paper form on or within the package. ***Comments due March 18, 2015***.

FDA Proposes to Amend Regulations for Embryo Donation and Related Labeling
In the December 31, 2015, *Federal Register*, FDA proposed amendments to the human cells, tissues, and cellular and tissue-based products (HCT/Ps) regulations regarding donor eligibility and related labeling for human embryos. FDA is proposing the revisions in response to comments from stakeholders regarding the importance of embryos to individuals and couples seeking access to donated embryos. ***Comments due March 31, 2015***.

FDA Releases Sunscreen Feedback Letters
In the January 7, 2015, *Federal Register*, FDA announced the availability of letters containing its initial determinations and feedback on safety and effectiveness data submitted by sunscreen manufacturers. The letters sought to demonstrate that certain active ingredients are generally recognized as safe and effective and not misbranded for use in over-the-counter sunscreen drug products. FDA is taking this action under the Sunscreen Innovation Act. ***Comments due February 23, 2015***.

FDA Files Minutes of Closed Advisory Committee Minutes with Library of Congress
In the December 30, 2014, *Federal Register*, FDA announced that, as required by the Federal Advisory Committee Act, the Agency has filed with the Library of Congress the annual reports of FDA advisory committees that held closed meetings during fiscal year 2014.

FDA Authorizes Two New EUAs for Ebola Detection
In the December 24, 2014, *Federal Register*, FDA announced two Emergency Use Authorizations for in vitro diagnostic devices that detect the Ebola Zaire virus.

FDA Extends Comment Period for Rare Pediatric Disease Priority Review Vouchers
In the December 24, 2014, *Federal Register*, FDA announced that it has extended the comment period regarding the Agency's implementation of the Rare Pediatric Disease Priority Review Vouchers Program. ***Comments now due February 16, 2015***.

FDA Publishes Website for Independent Assessment of Medical Device Submissions

In the December 22, 2014, *Federal Register*, FDA announced the release of its final implementation plan for reviewing medical device submissions, published as part of an independent assessment of that process. The assessment is part of the FDA performance commitments relating to the Medical Device User Fee Amendments of 2012 (MDUFA III), which reauthorized device user fees for fiscal years 2013–2017.

FDA Amends Medical Device Classification Procedures
In the December 24, 2014, *Federal Register*, FDA amended its regulations for petitioning for device reclassification to update mailing addresses for the petitions.

FDA Determines that Certain Drugs Not Withdrawn from Sale for Safety or Effectiveness
FDA determined that the following drugs were not withdrawn from sale for reasons of safety or effectiveness: TAGAMET (Cimetidine) Tablets, OPTICROM (cromolyn sodium) Solution/Drops, CAPOZIDE (captopril and hydrochlorothiazide) Tablet, LEVATOL (penbutolol sulfate) Tablet, CUTIVATE (fluticasone propionate) Cream, MIRCETTE (desogestrel and ethinyl estradiol, and ethinyl estradiol) Tablet, AVANDAMET (metformin hydrochloride (HCl) and rosiglitazone maleate) Tablet, IQUIX (levofloxacin) Solution/ Drops, NIRAVAM (alprazolam) Orally Disintegrating Tablets, FLUDEOXYGLUCLOSE F-18 Injectable, PARCOPA (carbidopa and levodopa) Orally Disintegrating Tablets, ALBALON (naphazoline HCl) Solution/Drops, and REYATAZ (atazanavir sulfate) capsules.

FDA Issued the Following Draft and Final Guidance Documents

- *Radiation Biodosimetry Devices—Draft Guidance for Industry and Food and Drug Administration Staff*, December 30, 2014, *Federal Register*. ***Comments due March 30, 2015***.
- *DSCSA Implementation: Product Tracing Requirements—Compliance Policy*, December 23, 2014, *Federal Register*.
- *Transfer of a Premarket Notification (510(k)) Clearance—Questions and Answers Draft Guidance for Industry and Food and Drug Administration Staff*, December 22, 2014, *Federal Register*. ***Comments due March 22, 2015***.
- *Bioequivalence Recommendations for Specific Products*, updated December 30, 2014, *Federal Register*.
- *Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) from Adipose Tissue: Regulatory Considerations; Draft Guidance for Industry*, December 24, 2014, *Federal Register*. ***Comments due February 23, 2015***.
- *Minimal Manipulation of Human Cells, Tissues, and Cellular- and Tissue-Based Products; Draft Guidance for Industry and Food and Drug Administration Staff*, December 23, 2014, *Federal Register*. ***Comments due February 23, 2015***.
- *Bioequivalence Recommendations for Methylphenidate Hydrochloride Extended-Release Oral Suspension*, December 24, 2014, *Federal Register*.
- *Providing Regulatory Submissions in Electronic Format—Standardized Study Data*, December 18, 2014, *Federal Register*.
- *Guidance for Industry on Providing Regulatory Submissions in Electronic Format-Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act*, December 18, 2014, *Federal Register*.

FDA Announced that the Following Collections Have Been Submitted to OMB

- Guidance for Industry on Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic
- Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring
- Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program
- Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice
- State Petitions for Exemption From Preemption
- Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice
- Certification to Accompany Drug, Biological Product, and Device Applications or Submissions
- Guidance for Industry: Fast Track Drug Development Programs: Designation, Development, and Application Review

- Draft Guidance for Industry, Researchers, Patient Groups, and Food and Drug Administration Staff on Meetings with the Office of Orphan Products Development
- Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics

FDA Announced the Opportunity to Comment on the Following Proposed Information Collections

- Waiver of In Vivo Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles—21 CFR 514.1(b)(7-8) (OMB Control No. 0910-0575)—Extension
- Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices

Upcoming Meetings, Workshops, and Conferences

Drugs and Biologics
The Seventh Annual Sentinel Initiative Public Workshop, **February 5, 2015**, in Washington, D.C.

Public Meeting on Breast Cancer Patient-Focused Drug Development, **April 2, 2015**, in Silver Spring, MD.

Public Meeting on Chagas Disease Patient-Focused Drug Development, **April 28, 2015**, in Silver Spring, MD.

Medical Devices
Webinar on FDA's Medical Device Clinical Trials Program, **January 22, 2015**.

Public Workshop—Optimizing FDA's Regulatory Oversight of Next Generation Sequencing Diagnostic Tests Public Workshop, **February 20, 2015**, in Silver Spring, MD.

Advisory Committees
January 22, 2015: Anti-Infective Drugs Advisory Committee Meeting (to discuss NDAs for isavuconazonium sulfate capsules and isavuconazonium sulfate for injection, for the proposed indications of treatment of invasive aspergillosis and mucormycosis)

February 20, 2015: Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee (to discuss premarket approval of a spine-spacing device)

February 27, 2015: General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee Meeting (to discuss, make recommendations on, and vote on information regarding the premarket approval application panel-track supplement to expand the indication for use for an injectable implant device to include subdermal implantation for hand augmentation to correct volume deficit in the hands)

March 4, 2015: Vaccines and Related Biological Products Advisory Committee Meeting (to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccines for the 2015–2016 influenza season)

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

Recent Drug and Device Approvals/Clearances

First-of-kind device to treat obesity (January 14, 2015)

Anti-clotting drug Savaysa (January 08, 2015)

Weight-management drug Saxenda (December 23, 2014)

Opdivo for advanced melanoma (December 22, 2014)

Rapivab to treat flu infection (December 22, 2014)

New antibacterial drug Zerbaxa (December 19, 2014)

Viekira Pak to treat hepatitis C (December 19, 2014)

Lynparza to treat advanced ovarian cancer (December 19, 2014)

Pathogen reduction system to treat platelets (December 19, 2014)

Xtoro to treat swimmer's ear (December 17, 2014)

First pathogen reduction system to treat plasma (December 16, 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.

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Some highlights from the A-list include final guidance documents concerning laboratory developed tests ("LDTs"), expedited premarket approval ("PMA") of devices intended for urgent and life-threatening conditions, exempting certain Class I and Class II reserved medical devices from premarket notification, biocompatibility testing, review of sterility information for devices marked sterile, balancing premarket and postmarket data collection for devices subject to PMA, and validation and labeling of medical devices reprocessed in health care environments. Draft guidance topics from the A-list include decision-support software, general wellness products, and medical device accessories, all of which could play heavily into FDA's regulation of health information technology ("health IT"). FDA additionally identifies unique device identifiers, informed consent, and benefit-risk considerations for IDE submissions.

The B-list includes only one potential final guidance, which pertains to finalizing existing draft guidance documents. The draft guidance documents on the B-list touch on direct-to-consumer genetic testing, patient access to information, interoperability, transferring ownership of a premarket notification, and 3D printing, among others.

Finally, FDA also lists final guidance documents that issued in 2005, 1995, and 1985 as part of a collaborative retrospective review with industry to determine whether any of the guidance documents issued in those years should be revised or withdrawn and seeks comments from industry toward that end. FDA will provide such lists annually through 2025 to ensure that all documents older than 10 years have been reviewed by that time.

FDA has established a docket to receive comments, and interested parties should provide comments on any of the above by March 10, 2015, pursuant to a January 9, 2015 *Federal Register* notice.

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At the top of the legislative agenda, Congress is expected to address FDA's role in regulating medical devices that are also health IT. Although FDA has indicated it will exercise enforcement discretion as a means of excluding the lowest risk health IT from the Agency's medical device regulatory scheme, industry and members of Congress from both parties believe that legislation is required to "clarify" FDA's role in regulating these technologies, particularly with regard to clinical-decision support software, which still lingers in a gray area of regulation. It is likely that either the SOFTWARE Act or MEDTECH Act, both introduced last session, will serve as a template for whatever legislation is introduced this session to address this issue.

Expanding telehealth coverage is also likely to be a priority in this Congress. The 21st Century Cures initiative, which seeks to create a comprehensive piece of legislation with the goal of "getting more cures and treatments to patients more quickly," was begun last year by Energy and Commerce Committee Chairman Fred Upton (R-MI) and Rep. Diana DeGette (D-CO). The initiative intends to produce a discussion draft within the month and "move quickly." Politico reports that the 21st Century Cures package will almost certainly seek to expand Medicare coverage of telehealth services through one or more potential vehicles, including waiving restrictions on certain services (such as home health and hospice care), or expanding coverage to certain entities (such as federally qualified health clinics). Cost is likely to be a key factor in determining the manner in and extent to which Congress extends telehealth services to more patients.

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In the medical devices realm, the Unified Agenda notes proposed rules for making packaging and labeling inserts for home-use devices available electronically, the format and content of substantial equivalence reports, and several regarding radiologic, mammography, and sun lamp devices. Final rules for medical devices listed in the Unified Agenda concern the use of certain symbols in labeling, laser device performance standards, and postmarket safety reporting for combination products.

In the area of drugs and biologics, the Unified Agenda lists proposed rules forthcoming on the topics of abbreviated new drug applications and related patent issues, electronic prescribing information, investigational new drug annual reporting, current good manufacturing practices for drug product outsourcing facilities, regulations on drug compounding, national licensing standards for prescription drug wholesale distributors and third-party logistics providers, and revoking the general safety test regulations that duplicate biologic license application requirements. Final rules listed for drugs and biologics include establishment registration and listing requirements, labeling requirements for pregnancy and lactation, revising reporting requirements surrounding drug shortages, supplemental applications proposing labeling changes, drugs that have been removed for reasons of safety or effectiveness, and administrative destruction of drugs that are refused admission to the United States.

The Unified Agenda also contained a half dozen anticipated proposed or final rules regarding various over-the-counter drug products and a final rule regarding blood products for transfusion or further processing.

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