Pharmaceutical & Medical Device Regulatory Update
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Jones Day Announcements

Last month, the Food & Drug Law Institute released a new book titled *Bringing Your Pharmaceutical Drug to Market*, an extensive summary of key business, regulatory, and legal issues associated with commercializing a pharmaceutical drug in the United States. The book includes two chapters by Jones Day attorneys. Chris Mikson, M.D. contributed the chapter on "Submitting a New Drug Application (NDA)," which discusses general components of an NDA as well as FDA's expedited review programs. Colleen Heisey and Matt Bowles coauthored the chapter on "Working with Healthcare Professionals," which addresses significant legal authorities and voluntary guidelines applicable to drug manufacturers when interacting with health care providers in clinical research, product marketing, corporate governance, and other contexts.

Also last month, Edgar Asebey accepted an appointment to the Business Advisory Board of the Torrey Pines Institute for Molecular Studies ("TPIMS"). The nonprofit institute's scientists conduct research in fields associated with a wide variety of major medical conditions, including multiple sclerosis, cancer, heart disease, Types I and II diabetes, macular degeneration, pain management, Alzheimer's disease, inflammatory disorders, AIDS and other infectious diseases, regenerative medicine, obesity, transplant rejection, muscle wasting syndrome, rheumatoid arthritis, and new methods for drug discovery. Mr. Asebey's prior work experience in patent evaluation and technology

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UPCOMING EVENTS

licensing at the National Institutes of Health will help support TPIMS's laudable mission.

Top News

House Committee Unanimously Advances 21st Century Cures Bill

On May 21, 2015, the House Energy & Commerce Committee voted unanimously to advance H.R. 6, the 21st Century Cures Act, which aims to accelerate the pace of innovative medical therapies through a variety of regulatory reforms, including expedited FDA review for "breakthrough" medical devices and the use of surrogate markers in clinical trials. By a 51–0 vote, the Committee approved the bill with a new amendment earmarking $550 million for FDA to implement the new requirements and exempting user fees from federal budget sequestration. The bill is expected to be considered on the House floor in June 2015. Meanwhile, parallel legislation in the Senate remains at the committee level but may be pushed forward with emerging bipartisan support.

May 28, 2015: **Alexis Gilroy** will speak at PLI's Health Care IT 2015 Program in New York, NY, during a session titled *Telemedicine, Telediagnostics, and Mobile Health*.

May 28, 2015: **Chris Mikson, M.D.** will speak at a meeting of the Society of Physician Entrepreneurs in Washington, D.C., on the topic of government regulation of telemedicine.

June 16, 2015: **Cristiana Spontoni** will present at the Plasma Protein Forum in Washington, D.C., during a panel presentation titled *Changing the Global Perspective on Compensation: Focus on Patient Need*.

RELATED PRACTICES

- FDA Regulatory & Compliance Counseling
- Health Care
- Life Sciences

Drug Manufacturer Brings Preemptive Suit Against FDA to Promote Off-Label Uses

Earlier this month, a pharmaceutical manufacturer filed action against FDA in a New York federal court, asserting a constitutional right to inform physicians about alternative, unapproved uses of its prescription drug product. The action represents an unusual step of preemptively suing for declaratory relief on the issue, as FDA has not accused the company of any violation. In the past, FDA has fined drug companies for promoting their products for "off-label," or unapproved, uses. The instant litigation follows a 2012 decision by the U.S. Court of Appeals for the Second Circuit, which overturned the conviction of a drug sales rep after determining his off-label communications were truthful and not misleading. FDA recently announced it will hold a public meeting this summer to address restrictions on promotion of unapproved uses.

Japan Begins Pilot Program for Accelerating Innovative Drugs Initially Developed in Japan

On May 8, 2015, Japan's Ministry of Health, Labor, and Welfare ("MHLW") commenced a pilot program to accelerate the development of certain pharmaceutical products whose applicants commit to conducting their initial product launches in Japan ("Sakigake Designation System"). Under the Sakigake Designation System, the MHLW may designate a drug for accelerated development if (i) the product is epoch-making, (ii) the product targets a serious disease, (iii) the product is significantly effective at treating the disease, and (iv) the applicant intends to develop the product and apply for product approval in Japan ahead of the rest of world. Such designation will provide preferential treatment for the new drug application, including a shortened review time from the typical 12 months to a period of six months. After the pilot, the MHLW will hold a hearing to consider extending the program.

FDA Withdraws Collection of Draft Guidances that Were Never Finalized

FDA has announced it is withdrawing 47 draft guidance documents the agency published as far back as 1991 but never finalized because of higher priorities and resource issues. Pursuant to its Good Guidance Practices, FDA typically issues guidance in draft form and solicits public comment before publishing the final version. Noting a heavy workload in recent years due to increased requests by the public for guidance, FDA acknowledged the 47 withdrawn documents had simply become outdated. The action marks an effort by FDA to improve the transparency of its policymaking. In recent times, some federal lawmakers

have criticized FDA for "using guidance that appears to create new requirements without the benefit of notice and comment, but with the expectation that the public comply."

Report Shows Most New Drugs Now Undergo Special Approval Process
According to *The New York Times*, a majority of recent drug developments have involved therapies eligible for one or more of FDA's special approval processes, such as Priority Review and Orphan Drug designation. Usually reserved for urgent, life-saving products, these expedited pathways often demand less evidence of efficacy than the typical approval process, and as a result, many companies have been refocusing their research on applicable therapies. The 21st Century Cures legislation aims to add another special approval process for so-called "dormant" therapies.

German Court Holds that Umbrella Trademarks Are Permissible for Some Pharmaceutical Products
Last month, the German Federal Administrative Court issued a decision holding that, under certain circumstances, umbrella trademarks may be used for a portfolio of pharmaceutical products with different active ingredients where the products are labeled in the same indication and have a similar mode of action. However, whether physicians and consumers are misled by an umbrella, or common, trademark for products with different active ingredients must be decided on a case-by-case basis.

Other News
FDA Revises "Q&A" Draft Guidance on Implementation of Biosimilars Act

Following "Superbug" Outbreak, FDA Advisory Committee Urges Better Sterilization Practices for Duodenoscopes

EMA to Screen Medical Literature for 400 Active Substance Groups

FDA Considers Tougher Regulation of Homeopathic Medicines

Rise of Stem-Cell Clinics Comes Amid Regulatory Uncertainty

Patient Groups Say FDA Advisory Committees Lack Expertise for Biosimilars

Federal Court Orders Government to Release Potentially Exculpatory Evidence in Internet Pharmacy Case

EU Issues Final Opinion on Safety of Dental Amalgam and Alternatives

Regulatory Updates

FDA Publishes Draft Recommendations for Study Data Standardization Plans
In the May 18, 2015, *Federal Register*, FDA published draft recommendations for sponsors' use when creating Study Data Standardization Plans, as referenced in a recently published guidance for industry. Standardization Plans are intended to assist FDA in identifying potential data standardization issues in clinical and nonclinical studies and should include information such as sponsor information, product information, completed studies and standards, and planned studies and standards. ***Comments due July 2, 2015***.

FDA Supports Logical Observation Identifiers Names and Codes
In the May 18, 2015, *Federal Register*, FDA published its support for the use of Logical Observation Identifiers Names and Codes ("LOINC") in regulatory submissions to the Center for Drug Evaluation and Research ("CDER") and the Center for Biologics Evaluation and Research ("CBER"). FDA encourages all applicants and sponsors to use LOINC codes for clinical test results in investigational study data to help align data standards in clinical research nationwide. ***Comments due June 29, 2015***.

FDA Announces Availability of Grant Funds
In the May 18, 2015, *Federal Register*, FDA announced the availability of grant funds for

the support of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use ("ICH"). The funds will support the ICH in developing a set of international guidelines for the development and registration of safe, effective, and high-quality medicine in the most efficient and cost-effective manner, preventing unnecessary duplication of clinical trials, minimizing the use of animal testing, and providing public assurance for the protection of all subjects during clinical trial.

FDA Withdraws Draft Guidance Documents
In the May 6, 2015, *Federal Register*, FDA announced the withdrawal of 47 draft guidance documents, published before December 31, 2013, that were never finalized. The action is intended to improve the efficiency and transparency of the guidance development process. ***Comments due June 5, 2015***.

FDA Requests Nominations for the Vaccines and Related Biological Products Advisory Committee
In the May 11, 2015, *Federal Register*, FDA published a request for nominations for nonvoting industry representative(s) to serve on the Vaccines and Related Biological Products Advisory Committee for CBER. Industry organizations interested in participating in the selection of the nonvoting industry representative(s) should notify FDA. ***Nominations and Interest Letters due June 10, 2015***.

FDA Determines SODIUM SULAMYD Drug Products Were Not Withdrawn for Reasons of Safety or Effectiveness
In the May 13, 2015, *Federal Register*, FDA announced it determined that SODIUM SULAMYD (sulfacetamide sodium) Ophthalmic Solution and Ophthalmic Ointment were not withdrawn due to safety or effectiveness reasons. This determination allows FDA to approve any future or pending abbreviated new drug applications for this product, if all other legal and regulatory requirements are met.

FDA Determines Regulatory Review Periods for Certain Drug Patents
In recent issues of the *Federal Register*, FDA published its determinations of the regulatory review periods for the following drugs and/or medical devices: HVAD ROTARY BLOOD PUMP, OVUGEL, GATTEX, ISTENT TRABECULAR MICRO-BYPASS STENT, OSENI, SYNRIBO, COFLEX INTERLAMINAR TECHNOLOGY, and SIGNIFOR.

FDA Issued the Following Draft and Final Guidance Documents
Revised Guidance for Industry: Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Genotoxicity Testing, May 13, 2015, *Federal Register*.

Guidance for Industry: Administrative Applications and the Phased Review Process, May 6, 2015, *Federal Register*.

Guidance for Industry: Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the Electronic Common Technical Document Specifications, May 6, 2015, *Federal Register*.

Draft Guidance for Industry and FDA Staff: Adaptive Designs for Medical Device Clinical Studies, May 18, 2015, *Federal Register*.

Draft Guidance for Industry, FDA Staff, and Other Stakeholders: Patient Preference Information—Submission, Review in PMAs, HDE Applications, and De Novo Requests, and Inclusion in Device Labeling, May 18, 2015, *Federal Register*.

Draft Guidance for Industry: Investigational New Drug Applications Prepared and Submitted by Sponsor-Investigators, May 15, 2015, *Federal Register*.

Draft Guidance for Industry: Revised Recommendations for Reducing Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products, May 15, 2015, *Federal Register*.

Draft Guidance for Industry: Investigational Enzyme Replacement Therapy Products:

Nonclinical Assessment, May 13, 2015, *Federal Register*.

Draft Guidance for Tobacco Retailers: Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order, May 13, 2015, *Federal Register*.

Draft Guidance for Industry: Biosimilars: Additional Questions and Answers Regarding Implementation of the Biologics Price Competition Innovation Act of 2009, May 13, 2015, *Federal Register*.

Draft Guidance for Industry and FDA Staff: Leveraging Existing Clinical Data for Extrapolation to Pediatric Uses of Medical Devices, May 6, 2015, *Federal Register*.

Draft Guidance: Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System, May 6, 2015, *Federal Register*.

Draft Guidance for Industry: Bioequivalence Recommendations for Clozapine, May 6, 2015, *Federal Register*.

FDA Announced the Opportunity to Comment on the Following Proposed Information Collections
• Medical Device Reporting: Manufacturer, Importer, User Facility, and Distributor Reporting

FDA Announced that the Following Collections Have Been Submitted to OMB
• Administrative Practices and Procedures
• Variations in the Physical Characteristics of Generic Drug Pills and Patients' Perceptions

FDA Announced that the Following Collections Have Been Approved by OMB
• Extra Label Drug Use in Animals
• FDA Recall Regulations
• Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice
• Dispute Resolution Procedures for Science Based Decisions on Products Regulated by the Center for Veterinary Medicine
• Generic Clearance for the Collection of Qualitative Feedback on Food and Drug Administration Service Delivery

EU Regulatory Notices

EMA Consults on Draft Guideline on Development of Fixed Combination Products
On May 13, 2015, the European Medicines Agency ("EMA") published its draft guidelines on clinical development of fixed combination medicinal products. The document provides guidance on the clinical strategy to be considered when developing a "fixed combination" medicinal product, or a product that contains two or more active substances within a single pharmaceutical form. Comments due November 15, 2015.

Pharmacovigilance Committee Initiates Two New Safety Reviews
The Pharmacovigilance Risk Assessment Committee initiated two new safety reviews at its May 2015 meeting. The reviews concern Tysabri (natalizumab) used to treat multiple sclerosis and inhaled corticosteroids used to treat chronic obstructive pulmonary disease.

EU Publishes Summaries of Marketing Authorizations
On May 5, 2015, the EU published summaries of marketing authorizations granted during February and March 2015.

EMA Strengthens Rules on Declaration of Interests
EMA has updated its rules on declarations of interests for scientific committee members and experts. The updates further strengthen EMA's policy by restricting involvement of experts in the scientific assessment of medicines if such experts plan to assume

employment in the pharmaceutical industry. The updates also include a revised guide on how to complete EMA's declaration of interest form.

Upcoming Meetings, Workshops, and Conferences

Drugs and Biologics
FDA Science Forum 2015, **May 27–28, 2015**, in Silver Spring, MD.

2015 International Society for Pharmaceutical Engineering/ Food and Drug Administration/ Product Quality Research Institute Quality Manufacturing Meeting, **June 1, 2015**, in Washington, D.C.

Public Meeting on the Generic User Fee Amendments of 2012, **June 15, 2015**, in Silver Spring, MD.

FDA/AFDO Conference titled *In Motion: Science Transforming Policy in Food, Drug, and Medical Device Regulation*, **June 20–24, 2015**, in Indianapolis, IN.

Public Meeting on Prescription Drug User Fee Act, **July 15, 2015**, in Silver Spring, MD.

FDA/PDA Conference titled *Mission Possible: Patient-Focused Manufacturing, Quality, and Regulatory Solutions*, **September 28–30, 2015**, in Washington, D.C.

Medical Devices
Public Hearing on Generic Drug User Fee Amendments of 2012—Regulatory Science Initiatives, **June 5, 2015**, in Silver Spring, MD.

FDA/AFDO Conference titled *In Motion: Science Transforming Policy in Food, Drug, and Medical Device Regulation*, **June 20–24, 2015**, in Indianapolis, IN.

FDA Public Workshop titled *Robotically-Assisted Surgical Devices: Challenges and Opportunities*, **July 27–28, 2015**, in Silver Spring, MD.

Advisory Committees
June 1, 2015: Transmissible Spongiform Encephalopathies Advisory Committee

June 4, 2015: Joint Meeting of the Bone, Reproductive, and Urologic Drugs Advisory Committee, and the Drug Safety and Risk Management Advisory Committee

June 8, 2015: Risk Communications Advisory Committee

June 9, 2015: Endocrinologic and Metabolic Drugs Advisory Committee

June 10, 2015: Endocrinologic and Metabolic Drugs Advisory Committee

June 11, 2015: Pulmonary-Allergy Drugs 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

Recent Notable Drug and Device Approvals/Clearances

FDA approves spinal cord stimulation system that treats pain without tingling sensation (May 8, 2015)

FDA approves additional antibacterial treatment for plague (May 8, 2015)

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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