



PHARMACEUTICAL & MEDICAL DEVICE REGULATORY UPDATE

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Top News

HHS Rule Agenda Describes Proposed Rules on 340b Drug Pricing, Combination Products

The U.S. Department of Health and Human Services ("HHS") recently released its [Agency Rule List—Spring 2015](#), which includes, among other things, expected timelines for rulemakings affecting the pharmaceutical industry. Two proposed rules relate to the 340B drug pricing program: one proposal, expected to be published for comment in July 2015, would impose a \$5,000 sanction for intentionally charging a higher price than the 340B ceiling price; the other, slated for notice-and-comment in December 2015, would add an arbitration process for the resolution of disputes raised by entities that were overcharged for drugs. Items on FDA's agenda include issuing a proposed, single set of regulations for prescription and OTC combination drugs (expected August 2015) and finalizing a rule on post-market safety reporting for combination products (expected April 2016).

EMA Confirms Recommendation to Suspend Medicines Associated with India CRO

Last month, the European Medicines Agency ("EMA") confirmed its [recommendation](#) to suspend a number of medicines for which authorization in the European Union ("EU") was primarily based on clinical studies conducted by a contract research organization based in India. The original recommendation was adopted by the Committee for Medicinal Products for Human Use ("CHMP") in January 2015, following an inspection that revealed systematic manipulations of electrocardiogram data during the conduct of some

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UPCOMING EVENTS

studies of generic medicines over a period of five years. During reexamination of the outcome, CHMP concluded there are lingering concerns about the reliability of the clinical studies and that its recommendation to suspend most of the [related medicines](#) should therefore be maintained, with the exception of one medicine whose concerns were sufficiently addressed and will no longer be suspended.

Justice Department Subpoenas Three Manufacturers of Medical Scopes in Investigation of "Superbug" Outbreak

As part of its investigation of a deadly outbreak of bacterial infections at hospitals, the U.S. Department of Justice ("DOJ") recently [issued subpoenas](#) to three manufacturers of duodenoscopes, devices used to visualize gastrointestinal conditions.

The investigation focuses on concerns that the scopes may have contributed to the spread of drug-resistant "superbugs" during patient procedures. DOJ has requested copies of various communications among the manufacturers, hospital centers, and state and federal agencies, including FDA, to evaluate whether any federal laws were broken.

IRS Says FDA Consent Decree Payment Is Not a "Non-Deductible Fine" or Similar Penalty for Tax Purposes

The Internal Revenue Service ("IRS") recently released a [field attorney advice memorandum](#) stating that the amount a company paid to the United States to disgorge profits under a consent decree with FDA is not considered a non-deductible fine or similar penalty for tax purposes. The consent decree was entered to enjoin the taxpayer pharmaceutical company from marketing drugs that FDA alleged were adulterated under federal statutes. IRS reasoned that although the evidence of FDA's intent in imposing the disgorgement was unclear, the "disgorgement was not a non-deductible fine or similar penalty" because, on balance, the evidence suggests that FDA did not intend for such payment to be punitive.

Chinese Agency Increases Registration Fees for Drugs, Medical Devices

In May 2015, China's Food and Drug Administration ("CFDA") announced it is [raising the registration fees](#) imposed on pharmaceutical drugs and medical devices. A new drug produced in China now faces a registration fee of 624,000 yuan (\$100,637), compared with 35,000 yuan (\$5,645) in 2013. Registration fees for imported products vary by category but tend to be much higher; for example, it costs \$156,423 to register a foreign-made, new drug in China. The increased fees come at a time of significant backlog in regulatory approvals. At the end of 2014, more than 18,500 drug applications were pending approval at CFDA.

Other News

[Senate Bill Would Incentivize Repurposing of Approved Drugs for Rare Diseases](#)

[Appeals Court Vacates FDA's Denial of New Chemical Entity Exclusivity for Fish Oil Drug](#)

[House Committee Examining Fairness, Consistency in FDA's Use of Untitled Letters](#)

[FDA to Study Spousal Influence on Understanding of Prescription Drug Advertising](#)

[EMA Updates Advice on Use of High-Dose Ibuprofen](#)

[NEJM Study: Evidence Insufficient for Many Genes Used in Breast Cancer Tests](#)

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

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Regulatory Updates

FDA Announces Final Rule on Requirements for Blood and Blood Components

In the [May 22, 2015, Federal Register](#), FDA announced a final rule amending regulations applicable to blood and blood components for transfusion or further manufacturing use. The final rule requires testing and other requirements, such as donor education and history, to evaluate safety and purity of donor blood as well as the health of donors during donation.

FDA Proposes New Rule on Antimicrobial Animal Drug Sales and Distribution Reporting

In the [May 20, 2015, Federal Register](#), FDA published a proposed rule dictating new reporting procedures for sponsors of approved or conditionally approved new animal drugs with antimicrobial active ingredients. The proposed rule would require sponsors to report species-specific estimates of product sales, will allow sponsors to avoid duplicative reporting, and will ensure that FDA annual summary reports include specific parameters and confidentiality measures. **Comments are due August 18, 2015.**

FDA Seeks Nominations of Bulk Drug Substances for Compounded Animal Drugs

In the [May 19, 2015, Federal Register](#), FDA requested nominations to assist in the development of a list of bulk drug substances that may be used by outsourcing facilities to compound animal drugs, pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA") and in accordance with a recently published [guidance](#). Nomination of substances must include confirmation as bulk drug substances, general background, and specified use for drug compounding. **Nominations are due August 17, 2015.**

FDA Announces Availability of Safety Reporting Portal and Delays Compliance Date for Electronic Submission of Post-Market Safety Reports

In the [May 27, 2015, Federal Register](#), FDA announced the availability of the Safety Reporting Portal for the electronic submission of post-market, individual case safety reports, as required by the [final rule](#) issued one year ago. FDA is also moving the date for compliance to September 8, 2015, and will continue to accept individual case safety reports in paper form for 90 days.

FDA Announces Availability of Summary Report and Requested Labeling Changes for Meropenem Drug

In the [May 28, 2015, Federal Register](#), FDA published a summary report of the pediatric studies of Meropenem pursuant to the Public Health Service Act. FDA found that the drug lacked adequate labeling information for drug safety in newborns and young infants with complicated intra-abdominal infections. The summary report requests certain labeling changes, including dose recommendation information for neonates and infants less than 91 days of age.

FDA Announces Availability of Grant Funds for Multiple Myeloma Service of Memorial Sloan Kettering Cancer Center

In the [May 28, 2015, Federal Register](#), FDA announced the availability of grant funds to the Multiple Myeloma Service of Memorial Sloan Kettering Cancer Center in support of the efforts of the Center for Drug Evaluation and Research. The grant funds will allow for the development of appropriate methodologies to conduct clinical trials for the study of Multiple Myeloma in the Black population.

FDA Classifies Rectal Control System

In the [June 1, 2015, Federal Register](#), FDA published its classification of the Rectal Control system into Class II (special controls). FDA requires testing and labeling to mitigate identified risks.

FDA Classifies Vibrator for Climax Control

In the [May 28, 2015, Federal Register](#), FDA announced the classification of Vibrator for

Climax Control of Premature Ejaculation into Class II (special controls). Labeling, safety, and biocompatibility testing are required to mitigate identified risks, such as pain, burns, and electrical shock.

FDA Classifies Multiplex Nucleic Acid Assay

In the [May 27, 2015, Federal Register](#), FDA announced its classification of Multiplex Nucleic Acid Assay for Identification of Microorganisms and Resistance Markers from Positive Blood Cultures into Class II (special controls). FDA requires labeling and performance characteristics to mitigate identified risks of false results and interpretation errors.

FDA Renews Medical Imaging Drugs Advisory Committee

In the [May 22, 2015, Federal Register](#), FDA announced the renewal of the Medical Imaging Drugs Advisory Committee by the Commissioner of Food and Drugs. The charter has been extended for two years.

FDA Announces Opportunity for Hearing on Proposed Rule Regarding Banned Devices

In the [June 2, 2015, Federal Register](#), FDA announced it will provide an opportunity for an informal hearing in connection with a proposed rule to ban a device with a special effective date. This action is being taken to align the regulations with the FDCA.

FDA Extends Comment Period on Radiation Biodosimetry Draft Guidance

In the [May 28, 2015, Federal Register](#), FDA announced that it is reopening the comment period on the [Draft Guidance for Industry and Food and Drug Administration Staff: Radiation Biodosimetry Devices](#). **Comments are due June 29, 2015.**

FDA Determines Vagifem (Estradiol) Was Not Withdrawn for Reasons of Safety or Effectiveness

In the [May 22, 2015, Federal Register](#), FDA announced its determination that Vagifem (Estradiol) Vaginal Tablets, 25 micrograms, was not withdrawn from sale for reasons of safety or effectiveness. As a result, FDA will not begin procedures to withdraw approval of abbreviated new drug applications ("ANDAs") that refer to this drug product. Also, FDA may continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FDA Determines Regulatory Review Periods for FLUCELVAX and STIVARGA

In recent editions of the *Federal Register*, FDA announced its determinations of the regulatory review periods of the following drugs: [FLUCELVAX](#) and [STIVARGA](#).

FDA Issued the Following Draft and Final Guidance Documents

[Guidance for Industry: M7 Assessment and Control of DNA Reactive \(Mutagenic\) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk](#), May 28, 2015, *Federal Register*.

[Draft Guidance for Industry: Compounding Animal Drugs from Bulk Drug Substances](#), May 19, 2015, *Federal Register*.

[Draft Guidance on Risperidone](#), May 27, 2015, *Federal Register*.

[Draft Guidance for Industry: Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish an Acute Reference Dose \(ARfD\)](#), June 1, 2015, *Federal Register*.

[Draft Guidance for Industry: Established Conditions: Reportable Chemistry, Manufacturing, and Controls Changes for Approved Drug and Biologic Products](#), June 1, 2015, *Federal Register*.

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

- [Guidance for Industry on Formal Meetings with Sponsors and Applicants for Prescription](#)

Drug User Fee Act Products

- Medication Guide Requirements

FDA Announced the Following Collections Have Been Submitted to OMB

- State Enforcement Notifications
- Petition to Request an Exemption from 100 Percent Identity Testing of Dietary Ingredients: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements
- Record Retention Requirements for the Soy Protein and Risk of Coronary Heart Disease Health Claim
- Spousal Influence on Consumer Understanding of and Response to Direct-to-Consumer Prescription Drug Advertisements
- Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products
- MedWatch: The Food and Drug Administration Medical Products Reporting Program

FDA Announced the Following Collections Have Been Approved by OMB

- Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring
- Requests for Inspection by an Accredited Person Under the Inspection by Accredited Persons Program
- Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body
- Guidance for Industry: Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic
- Current Good Manufacturing Practices for Blood and Related Regulations for Blood Components and Requirements for Donor Testing, Donor Notification, and "Lookback"

EU Regulatory Notices

EMA Publishes Concept Paper on New Guidance for Importers of Medicinal Products

On May 29, 2015, EMA published a [concept paper](#) on new guidance for importers of medicinal products. The aim of the new guidance would be to provide additional instruction on the Good Manufacturing Practice ("GMP") requirements that apply to importers and the extent to which those requirements cover different entities involved in import activities. The concept paper also acknowledges that the increased complexity of supply chains is at odds with the application to importers of GMP requirements, which are traditionally oriented to activities performed at true manufacturing sites. **Comments are due August 29, 2015.**

EMA Publishes Draft Guideline on Gene Therapy Medicinal Products

On May 20, 2015, EMA published the draft guideline on the quality, nonclinical, and clinical aspects of gene therapy medicinal products ("GTMPs"). The [guideline](#) defines scientific principles and provides guidance for the development and evaluation of GTMPs intended for use in humans and presented for marketing authorization. Comments are due August 31, 2015.

European Parliament Resolves to Tackle Antimicrobial Resistance

On May 29, 2015, the European Parliament adopted a [resolution](#) aimed at improving patient safety and fighting antimicrobial resistance. The resolution calls for research into new antimicrobial drugs and urges Member States to ensure there are sufficient health care professionals trained or specialized in infection prevention and control and hospital hygiene. It also encourages the EU to promote and take part in any global initiative aimed at combating antibiotic resistance, and to support research in this field. The resolution was adopted by a vote of 637–32, with 10 abstentions.

EMA Recommends New Medicinal Products

EMA has recommended granting marketing authorizations for the following medicinal products: [Nivolumab BMS \(nivolumab\)](#) for the treatment of adult patients with advanced, squamous non-small cell lung cancer; [Keytruda \(pembrolizumab\)](#) for the treatment of adult patients with advanced melanoma that cannot be surgically removed or where the

cancer has spread to other parts of the body; [Unituxin \(dinutuximab\)](#) for the treatment of high-risk neuroblastoma in children; and the extended use of [Imbruvica \(ibrutinib\)](#) to include the treatment of patients with Waldenström's macroglobulinaemia, a rare blood cell cancer.

EMA Launches Public Consultation on Good Pharmacovigilance Practices

EMA has launched a [public consultation](#) on Module XVI addendum I (Educational materials) of its guidelines on good pharmacovigilance practices. The draft guidelines provide guidance for the marketing authorization holder/applicant regarding the submission of draft educational materials to the competent authority of the EU Member State, and guidance to the relevant competent authority regarding the assessment of such educational materials. **Comments are due June 30, 2015.**

Upcoming Meetings, Workshops, and Conferences

Drugs and Biologics

[Public Hearing on Generic Drug User Fee Amendments of 2012—Regulatory Science Initiatives](#), **June 5, 2015**, in Silver Spring, MD.

[EMA Workshop on Therapeutic Use of Bacteriophages](#), **June 8, 2015**, in London, UK, and via webcast.

[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 Exploring Naloxone Uptake and Use](#), **July 1–2, 2015**, in Silver Spring, MD.

[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.

[Public Meeting on Patient-Focused Drug Development for Alpha-1 Antitrypsin Deficiency](#), **September 29, 2015**, in Silver Spring, MD.

Medical Devices

[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 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

June 17–18, 2015: Pharmacy Compounding Advisory Committee

July 9, 2015: Oncologic Drugs Advisory Committee

July 7–8, 2015: Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products 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 Rapamune to treat LAM, a very rare lung disease (May 28, 2015)

FDA approves two therapies to treat IBS-D (May 27, 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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