JONES DAY | **Pharmaceutical & Medical Device Regulatory Update**
Issue 19 | November 2014 JONES DAY




## Jones Day Event

On November 20 and December 4, **Dr. Christian Fulda** will present a webinar on EMA Disclosure of Marketing Authorization Data.

## Top News

**DOJ and Congress Investigating Generic Drug Price Increases**
The Justice Department is investigating generic drug companies for potential violations of antitrust laws related to sudden spikes in prices for what are usually lower-cost alternatives to brand-name drugs. Some insurers are responding to the price hikes by changing reimbursement coverage so that consumers must pay a larger share of the cost of the generic drugs. Private insurers and individual consumers are not the only ones affected, however, as the prices will also directly affect the budgets of Medicare and Medicaid programs.

Congress has also begun looking into the price increases. The Senate Committee on Health, Education, Labor, and Pensions' subcommittee on health and aging has announced a hearing on November 20, 2014, "to get to the bottom of these enormous price increases," according to an October 2, 2014, press release from the subcommittee Chairman Bernie Sanders (I-VT). Senator Sanders and Representative Elijah Cummings (D-MD) jointly sent letters to 14 generic drug manufacturers outlining recent price increases and requesting information about the escalating prices for certain generic drugs manufactured by each of the

## CONTACTS

Mark Mansour
Washington

Laurie A. Clarke
Washington

Cristiana Spontoni
Brussels

Colleen M. Heisey
Washington

Christopher M. Mikson
Washington

Emily K. Strunk
Washington

Katherine M. Llelwellyn
Brussels

Stephanie L. Resnik
Washington

Brigid C. DeCoursey
Washington

Matthew R. Bowles
Washington

Detailed Contact Information

## UPCOMING EVENTS

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

**December 7–11**: **Alexis Gilroy** will speak at the mHealth Summit on untapped markets, reimbursement, and cross-border concerns in the mobile health industry. **Colleen Heisey** will speak on

companies, and then called upon the Obama administration to also take action.

**Sunscreen Innovation Act Clears Congress, Awaits President Obama's Signature**
The House of Representatives has passed the Sunscreen Innovation Act reforming how FDA approves sunscreen ingredients through its Time-and-Extent ("TEA") process. The Senate approved the bill in September 2014, and President Obama is expected to sign the bill, which is designed to speed up approvals for sunscreen products stalled in the U.S. regulatory pipeline. Since 2002, sunscreen makers have filed eight new applications that are still awaiting review, and the last FDA sunscreen ingredient approval was in the 1990s. Many of these pending sunscreen ingredients have been used in other countries for decades, and the bill would streamline review of applications for those ingredients that have been used safely for at least five years in another country. If signed, the new law would require FDA to conclude its review of the eight pending ingredients by the end of 2015. It also calls for FDA to issue regulations for "timely and efficient" review of TEA applications within 18 months of the law's enactment. Under the new law, FDA will also have to report to Congress regularly on efforts to reduce the backlog of applications.

the impact of the Affordable Care Act, net neutrality and broadband law, policy enforcement by FDA & FTC, and laws relating to remote monitoring.

**December 11–12**. **Colleen Heisey** will speak at an ABA/Medical Device Manufacturers Assoc. conference on developing compliance programs.

RELATED PRACTICES

FDA Regulatory & Compliance Counseling

Health Care

Life Sciences


WEBINAR
**EMA Disclosure of Marketing Authorization Data**

November 20, 2014
December 4, 2014

Details

**FDA to Evaluate Drug Warnings in Recurring TV Ads**
According to a recent notice in the *Federal Register*, FDA's Office of Prescription Drug Promotion wants to examine how the public absorbs risk information in repeat television ads for prescription medicines. In the notice, FDA notes that increased exposure to risk information in the ads through repetition may improve "attitudes and recall for product attributes, particularly when the substance of the repeat messages is varied." Using a group of participants diagnosed with seasonal allergies, FDA plans to determine empirically how consumers perceive and process the risk and benefit information, assessing perception, memory, judgments about the ad, and intentions to use the medication advertised. According to FDA, it chose drugs targeting allergy sufferers because the risks associated with those products are typical in number and include a range of side effects, including serious risks.

Another recent *Federal Register* notice indicates FDA is also interested in the influence a spouse has on the patient-consumer's understanding of and response to advertising for prescription drugs aimed at the consumer. The study will look at empirical data to evaluate the differences between consumers viewing prescription drug ads with a spouse or partner versus alone.

**FDA's Guidance on Molecular Diagnostics**
Because some diagnostic devices can have many different claims and uses, it is often difficult for companies to determine when they need to separately market different applications of the same device. FDA's recently released guidance document, *Molecular Diagnostic Instruments with Combined Functions*, aimed to clarify the rules applicable to molecular diagnostic devices. "Molecular diagnostic instruments" are defined in the guidance as "critical components of certain in vitro diagnostic devices (IVDs) … [that] are not generally approved/cleared alone, i.e., without an accompanying assay, because their

safety and effectiveness or substantial equivalence cannot be evaluated without reference to the assays they run." In response to industry concerns about marketing and approvals for multiuse devices, FDA stated, "[t]he same instruments may … be used for additional purposes that do not require FDA approval or clearance, such as for basic scientific research-purposes" and do not require separate marketing.

**EMA to Allow Use of Non-EEA Authorized Comparator in Clinical Studies**
The European Medicines Agency ("EMA") has published its revised overarching guideline on biosimilars. The most significant change in the new guidance is that it allows drug developers to use a comparator drug that was authorized outside the European Economic Area ("EEA") in its clinical investigation of a biosimilar. The effective date of the revised guideline is April 30, 2015. Applicants may, however, apply some or all provisions of this guideline beginning October 29, 2014.

**Indian Generic Makers Frustrated by Slow U.S. Approvals**
The ongoing overhaul of the generic drug review process has frustrated generic drugmakers in India. The country's $15 billion pharmaceutical industry supplies around 40 percent of generic drugs in the United States. There is a backlog of applications due to an increased number of generic drug applications from foreign facilities, concerns about adequate inspection of production facilities before final approval, and FDA's limited resources. FDA is aiming to improve the current review time of 30 months to 10 months by 2017, beginning with a 15-month target review time for at least 60 percent of the applications submitted in the year beginning October 2014.

**Other News**
340B Drug Discounts Dropped by HHS

Top FDA Communications Official Stepping Down

Republicans Renew Efforts to Repeal Medical Device Tax

CRS Report: Impact of Medical Device Tax "Relatively Small"

New England Journal of Medicine: 25 Percent of Pharma Marketing Budgets for Digital Media

EU Civil Service Tribunal Annuls Commission Decision on EMA Executive Director

Canada Passes Drug Safety Law

FDA Panel Considers Reversing Ban on MSM Blood Donations

HHS OIG to Analyze FDA Regulatory Policy for Generics, Clinical Trials

USAID Requests Emergency Funds from Congress for Ebola Response

World Bank May Indemnify Ebola Vaccine Manufacturers

Texas Next Target for "Right to Try" Legislation

CEO Indicted for Conspiracy to Sell Unapproved Medical Device

## Regulatory Updates

**FDA Establishes Docket on Patient Participation in Medical Product Discussions**
In the November 4, 2014, *Federal Register*, FDA announced a public docket for comments on Patient Participation in Medical Product Discussions under FDASIA. FDA seeks input from stakeholders on how to obtain the views of patients during the medical product development process and ways to consider patients' perspectives during regulatory discussions.

**FDA Withdraws Approval of 14 NDAs for Failure to File Annual Reports**
In the November 17, 2014, *Federal Register*, FDA withdrew approval of 14 new drug applications ("NDAs") for the multiple holders' repeated failure to file the required annual reports for the applications.

**FDA Proposes Order to Reclassify Rigid Pedicle Screw Systems**
In the November 12, 2014, *Federal Register*, FDA proposed to reclassify rigid pedicle screw systems, a preamendments class III device, into class II (special controls) via an administrative order, citing FDASIA Section 608(b) as the authority for not proposing such a change through notice and comment rulemaking. In the notice, FDA also proposed to require the filing of a premarket approval application or a notice of completion of a product development protocol for the dynamic stabilization systems, currently a subtype of pedicle screws, regardless of the indication for use. It also proposed to require clarification of the device identification of pedicle screw spinal systems, to more clearly delineate between rigid pedicle screw systems and dynamic stabilization systems.

**FDA Issues Order Debarring Armando Santos for 12 Years**
In the November 10, 2014, *Federal Register*, FDA issued an order debarring Armando Santos from providing services to any person who has an approved or pending drug product application for 12 years. FDA cited Mr. Santos's conviction on seven felony counts for federal health care offenses, including health care fraud and false statements.

**Corrections and Amendments to Prior FDA Notices**
- RIN Numbers in Additions and Modifications to the List of Drug Products that Have Been Withdrawn or Removed from the Market for Reasons of Safety or Effectiveness Original: 79 FR 37687; Corrected: 79 FR 68395
- Updating the Division of Freedom of Information's Contact Information
- Changing URL for the Webcast for Meeting of the Science Board to the FDA

**FDA Issued the Following Draft and Final Guidance Documents**
- *Draft Guidance for Industry: Rare Pediatric Disease Priority Review Vouchers*. November 17, 2014, Federal Register. ***Comments due January 16, 2015***.
- *Guidance for Industry: Combined Functionality for Molecular Diagnostic Instruments*. November 12, 2014, *Federal Register*.
- *Guidance for Industry: Specification of the Unique Facility Identifier System for Drug Establishment Registration*. November 6, 2014, *Federal Register*.
- *Draft Guidance for Industry: Bioequivalence Recommendations for CONCERTA (methylphenidate hydrochloride) Extended-Release Tablets*. November 6, 2014, *Federal Register*. Comments due January 5, 2015.

**FDA Announced the Opportunity to Comment on the Following Collections**
- Prescription Drug Marketing Act of 1987; Administrative Procedures, Policies, and Requirements

**FDA Announced the Opportunity to Comment on the Following Proposed Collections**
- Export of Food and Drug Administration Regulated Products: Export Certificates
- Spousal Influence on Consumer Understanding of and Response to Direct-To-Consumer ("DTC") Prescription Drug Advertisements
- Impact of Ad Exposure Frequency on Perception and Mental Processing of Risk and Benefit Information in DTC Prescription Drug Ads
- Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals
- Appeals of Science-Based Decisions Above the Division Level at CVM
- Investigational New Drug Regulations
- Extralabel Drug Use in Animals

**FDA Announced the Following Collections Have Been Submitted to OMB for Approval**
- Guidance for Industry on Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices

## Upcoming Meetings, Workshops, and Conferences

**Drugs and Biologics**
The Seventh Annual Sentinel Initiative Public Workshop will convene on **February 5, 2015**, in Washington, D.C. to discuss a variety of topics on active medical product surveillance.

**Medical Devices**
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**
November 19, 2014: Science Board to the FDA (to discuss data related to anesthetics and sedation drugs in children)

November 24–25, 2014: Anesthetic and Analgesic Drug Products Advisory Committee (to discuss the risks–benefits balance of epidural steroid injections for inflammation and pain management)

December 2, 2014: Blood Products Advisory Committee Meeting Announcement (to hear scientific data related to reconsideration of the current blood donor deferral policy for men who have had sex with another man since 1977)

December 3, 2014: Blood Products Advisory Committee Meeting Announcement (to sit as a device classification panel for computer software and accessories; to hear information about the emergence of the chikungunya virus in the Western Hemisphere; to hear information about rapid surveillance for Middle Eastern Respiratory Syndrome coronavirus)

December 4, 2014: Anti-Infective Drugs Advisory Committee Meeting Announcement (to discuss issues related to clinical development programs and clinical trial designs for antibacterial products for the treatment of patients with serious bacterial infections for which there are limited or no therapeutic options)

December 5, 2014: Anti-Infective Drugs Advisory Committee Meeting Announcement (to discuss an NDA for urinary tract and intra-abdominal infections)

December 11, 2014: Pediatric Oncologic Subcommittee of the Oncologic Drugs Advisory Committee Meeting Announcement (to gauge investigator interest in exploring potential pediatric development plans for three products in various stages of development for adult cancer indications)

December 12, 2014: Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee (to discuss premarket approval of a spine-spacing device)

December 18, 2014: Bone, Reproductive and Urologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee (closed meeting to discuss whether FDA should permit further clinical development of an existing investigational drug product)

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 has not issued any press releases announcing new drug and device approvals/ clearances since the last *Update*.

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

**Cristiana Spontoni**
Brussels
+32.2.645.14.48
cspontoni@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

**Katherine M. Llewellyn**
Brussels
+32.2.645.14.47
kllewellyn@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