



PHARMACEUTICAL & MEDICAL DEVICE REGULATORY UPDATE

Reminder: Jones Day to Host Executive Roundtable and Health Care CLE on May 6

On Tuesday, May 6, Jones Day presents two offerings for our health care and life sciences community:

Executive Roundtable Series: New Frontiers in Health Care and Life Sciences: A Look at the Legal Implications

– Attend in [Washington, D.C.](#) or participate by [webinar](#). The event will be held 1:00 p.m. – 4:00 p.m. (EDT).

The Continuing Expansion of Health Care Enforcement by U.S. and International Authorities: Key Developments and Implications for the Future

– Attend in [Chicago](#) or participate by [webinar](#). The event will be held 9:30 a.m. – 12:15 p.m. (CDT).

Top Stories

FDA Proposes Program to Expedite PMA Review for Critical Devices

Manufacturers of high-risk medical devices [may now obtain expedited review of premarket approval \("PMA"\) submissions for certain products](#). On April 22, FDA proposed the "Expedited Access Premarket Approval Application for Unmet Medical Needs for Life Threatening or Irreversibly Debilitating Diseases or Conditions" ("Expedited Access PMA" or "EAP"), which will speed up the review process for medical devices that meet three criteria: the medical device must (i) treat a life-threatening or irreversibly debilitating disease or condition; (ii) address an unmet medical need; and (iii) have an acceptable, FDA-approved data development plan. Eligible manufacturers can partner with FDA senior management early in product development to establish plans to collect scientific and clinical data to support the device's approval under the EAP.

• [read more below](#)

FDA Officials Provide Regulatory Insights at FDLI Annual Conference

FDA officials and various representatives from the drug, medical device, biologics, and other FDA-regulated industries recently gathered at the Food and Drug Law Institute annual conference in Washington, D.C. Over the course of the two-day conference, several FDA officials commented on recent and future initiatives. Click the link below to read more about what FDA is working on with regard to drugs, biologics, combination products, medical devices, and mobile medical apps.

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Matthew R. Bowles, an associate in the Washington Office, assisted in the preparation of this Update.

Resources

- [Pharmaceutical & Medical Device Regulatory Update Issue 5 Printable Version](#)
- [Jones Day's Health Care Practice](#)
- [Jones Day's Life Sciences Practice](#)

▪ [read more below](#)

FDA Publicly Responds to Opioid Drug Controversy

Federal policymakers appear to be responding to growing national concerns about opioid abuse and increased state efforts to block or limit the use of FDA-approved opioids. In a recent [blog post](#), FDA Commissioner Margaret Hamburg commended the widespread focus by state officials to address the public health issue, while cautioning that policies on opioid use should be science-based and comprehensive. She noted that regulators should not focus on one particular drug, such as Zohydro, but instead should pursue policies targeting abuse triggers in general while respecting proven pain management therapies. Dr. Hamburg's public overture comes on the heels of FDA [approving labeling changes requiring opioid drugs to be labeled for severe pain only](#). To read our previous coverage on this issue, please click the link below.

▪ [read more below](#)

FDA Adopts Proposals to Increase Access to Compliance and Enforcement Data

In 2011, FDA issued for public comment eight draft proposals for making FDA's publicly available compliance and enforcement data more accessible and user-friendly. After receiving extensive comments, FDA adopted all eight proposals, which were outlined in a report issued in April: [Food and Drug Administration Transparency Initiative: Increasing Public Access to FDA's Compliance and Enforcement Data](#). In particular, the report adopts several initiatives to improve the timely disclosure of compliance and enforcement data, develop communication channels for industry stakeholders to provide feedback on data quality, and enhance search tools for data users.

PhRMA Criticizes FDA's Social Media Guidance

Drug makers are [responding with heavy criticism](#) to FDA's [draft guidance](#) on interactive promotional media for drugs and biologics. Among the chief critics is PhRMA, whose [public comment](#) highlights two major concerns with the draft guidance. The group rejects FDA's assumption that manufacturers have total control over third-party content. PhRMA also says the guidance document incorrectly considers any statements by manufacturers on social media as promotional labeling or advertising. This approach could have a chilling effect on speech otherwise protected by the Constitution.

State Medical Boards Promote Model Telemedicine Policy

On April 26, the Federation of State Medical Boards adopted a model policy on direct-to-consumer telemedicine. The nonbinding policy statement will likely encourage individual state medical boards to implement standards that advance the use of telehealth technologies in the practice of medicine. For more information, read the recent [Jones Day Commentary](#).

Other News

[Mylan Recruits Second Major FDA Official for Regulatory Division](#)

[House Health Subcommittee Calls for Ideas to Advance Telehealth](#)

[DOJ Indicts Two for Fraud, Distributing Misbranded Drugs](#)

[Pew Report Assesses DQSA Serialization and Traceability System](#)

[N.Y. Times Editorial: For Drugs that Save Lives, a Steep Cost](#)

[FDA Warns Against False Autism Treatment Claims](#)

[FDA Approves Alternative to the Pap Smear](#)

[FDA Issues Proposals to Address Risks of Vaginal Mesh Used to Treat Organ Prolapse](#)

[Manhattan Project for Policy Research Issues FDA Report Card on FDA Drug Approval Times](#)

[FDA Warns Against Cancer-Spreading Risk of Uterine Fibroid Procedure](#)

[GDUFA FY2015 Self-Identification Period Is May 1-June 1, 2014](#)

[JAMA Study Says Free Prescription Samples Costly to Patients](#)

[New Epidural Corticosteroid Labels Must Warn of Rare But Serious Neurologic Problems](#)

[FDA Issues Reminder on Combination Acetaminophen Drugs](#)

[China Backs Away from Price Controls on Basic Drugs](#)

[Russia Mulls Lifting Medical Advertisement Ban](#)

[Scientists Use Cloning to Make Stem Cells Matched to Two Adults.](#)

Regulatory Updates

CDRH Launches New eSubmissions Pilot Program

On May 1, CDRH announced the [eSubmissions Pilot Program](#), a new pathway to guide medical device manufacturers through constructing and submitting their 510(k) materials electronically without having to submit a hard copy or a compact disc. Participation in the pilot program is limited to unbundled, traditional 510(k) submissions for classified devices in either the Cardiac Diagnostic Devices Branch or the Peripheral Interventional Devices Branch. Organizations interest in participating should submit a request to CDRH by **September 30**.

FDA Issues Proposed Rule to Regulate E-Cigarettes

On April 25, FDA announced a [proposed rule](#) to bring electronic cigarettes (e-cigarettes) under the regulatory authority of the Center for Tobacco Products. The Family Smoking Prevention and Tobacco Control Act immediately subjected cigarettes and smokeless tobacco to FDA regulation, but Congress also gave FDA authority to "deem" other products subject to FDA regulation. FDA's latest proposal exercises that authority and would subject additional products, such as certain e-cigarettes, gels, cigars, and pipe tobacco, to FDA regulation because they meet the statutory definition of "tobacco products." As an initial matter, the proposal would prohibit the sale of such products to individuals under the age of 18 and require the display of health warnings on product packaging and in advertisements. Accessories of tobacco products would not be regulated under the proposal.

Comments are due July 9.

CDRH Promotes Experiential Learning Program

FDA is inviting medical device industry, academia, and health care facilities to participate in its Experiential Learning Program ("ELP") for medical devices. As described in the May 1 [Federal Register](#), the ELP provides a formal training mechanism for regulatory review staff to visit research, clinical, manufacturing, and health care facilities to observe firsthand how medical devices are designed, developed, and utilized. The program includes several focus areas based on device type. Organizations interested in participating should submit a request to CDRH by **June 2**, which should include a description of the facility relative and preferred focus area. Requests can be based on this [sample form](#).

FDA Proposes Reclassification of Transvaginal Pelvic Surgical Mesh as Class III Device

In the May 1 [Federal Register](#), FDA issued a proposal to reclassify surgical mesh for transvaginal pelvic organ prolapse repair from class II to class III, based on the tentative determination that general controls and special controls together are not sufficient to provide reasonable assurance of safety and effectiveness. In a separate [notice](#), the Agency outlined when premarket approval would be required: within 90 days of the effective date of a final order on the proposal or on the last day of the 30th calendar month after the reclassification becomes effective, whichever occurs later. In addition, FDA proposes to reclassify urogynecologic surgical mesh instrumentation from class I to class II with special controls. Comments **on these proposals are due July 30**.

FDA Classifies Eyelid Weight as Class II Ophthalmic Device

In the April 21 [Federal Register](#), FDA classified eyelid weight into class II (special controls). Used in the gravity-assisted treatment of incomplete eyelid closure, eyelid weight may be adhered to the outer skin of the upper eyelid or implanted into the upper eyelid. External eyelid weights are exempt from premarket notification, but the implantable versions are subject to 510(k) requirements. Previously cleared devices must comply with special controls requirements by April 21, 2015.

FDA Issues Emergency Use Authorization for IV Diagnostic Device for H7N9 Flu Virus

In the April 17 *Federal Register*, FDA issued an emergency use authorization ("EUA") for an in vitro diagnostic device for detection of the novel influenza A (H7N9) virus. Under its EUA authority, FDA may approve new drugs or new indications for approved drugs for actual or potential public health emergencies. Recent EUA actions have focused on various strains of influenza.

FDA Issues Report on Compliance and Enforcement Data Transparency

In the April 23 *Federal Register*, FDA announced the availability of a report entitled *Food and Drug Administration Transparency Initiative: Increasing Public Access to FDA's Compliance and Enforcement Data*. The report summarizes findings and recommendations from eight working groups established to enhance the transparency and public accessibility of FDA's compliance and enforcement data.

FDA Reopens Selection Period for Industry Reps on Pharmacy Compounding Advisory Committee

In the April 21 *Federal Register*, FDA reopened the period for pharmaceutical and pharmacy compounding organizations to nominate nonvoting industry representatives to serve on the Pharmacy Compounding Advisory Committee for CDER. Any organization interested in participating may send a statement of interest by **May 5**, either by email to PCAC@fda.hhs.gov or by mail to CDER.

FDA Issued the Following Guidance Documents:

- *Providing Information About Pediatric Uses of Medical Devices*. May 1 *Federal Register*.
- *Final Guidance for Industry on Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulation*. April 23 *Federal Register*.
- *Draft Guidance for Institutional Review Boards, Industry, Investigators, and FDA Staff on Live Case Presentations During Investigational Device Exemption (IDE) Clinical Trials*. April 17 *Federal Register*. **Comments due July 16.**
- *Draft Guidance for Industry and FDA Staff on Endotoxin Testing Recommendations for Single-Use Intraocular Ophthalmic Devices*. April 17 *Federal Register*. **Comments due July 16.**
- *Draft Guidance for Industry and FDA Staff on Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval*. April 23 *Federal Register*. **Comments due July 22.**
- *Draft Guidance for Industry and FDA Staff on Expedited Access for Premarket Approval Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Disease or Conditions*. April 23 *Federal Register*. **Comments due July 22.**
- *Surveying, Leveling, or Alignment Laser Products*. May 5 *Federal Register*. **Comments due August 4.**

FDA Withdraws 3 NDAs and 41 ANDAs at Request of Application Holders

In the April 22 *Federal Register*, FDA announced the withdrawal of three new drug applications ("NDAs") and 41 abbreviated new drug applications ("ANDAs") at the request of the application holders because they are no longer marketing these pharmaceuticals. For more information about the withdrawn applications, see Table 1 in the *Federal Register* issue.

FDA Issues Corrections Regarding Withdrawal of Certain ANDAs

In the May 1 *Federal Register*, FDA issued two corrections to its March 27 notice regarding the withdrawal of certain approved abbreviated ANDAs for prescription drugs containing more than 325 mg of acetaminophen. The corrections **confirm** the withdrawal of three additional ANDAs and **clarify** that four other ANDAs were voluntarily withdrawn.

FDA Amends Animal Drug Regulations for Approvals of Ceftiofur Sodium, Gentamicin, Xylazine

In the April 15 *Federal Register*, FDA announced amendments to its animal drug regulations to reflect approval actions of new animal drug applications and abbreviated new animal drug applications in March, including Gentamicin, Xylazine, and ceftiofur sodium powder for injection. Marketing exclusivity and patent information are available in FDA's [Green Book](#).

FDA Determines Regulatory Review Periods for Drug and Biologic Patents

In recent issues of the *Federal Register*, FDA published determinations regarding the regulatory review periods for patent extensions of [BRILINTA](#) and [YERVOY](#).

FDA Announces Opportunity for Hearing on Proposed Revocation of Biologics License

In the April 30 *Federal Register*, FDA announced an opportunity for a hearing on a proposal to revoke

the biologics license (U.S. License No. 103) issued to Allergy Laboratories, Inc. for the manufacture of nonstandardized allergenic extract Dust, House Mixture. The proposed revocation is based on available scientific and medical information that does not support the safety and effectiveness of this nonstandardized allergenic extract. **Comments are due June 30.**

Collection of Information Approved for FDA

The Office of Management and Budget has approved FDA's collection of information for *Guidance for Industry on Expedited Programs for Serious Conditions-Drugs and Biologics*. More information is available in the May 1 [Federal Register](#).

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

- [Color Additive Certification Requests and Recordkeeping](#) (**comments due May 23**).
- [Animal Drug User Fee Act Cover Sheet](#) (**comments due May 23**).
- [Animal Generic Drug User Fee Act Cover Sheet](#) (**comments due May 23**).
- [Guidance for Industry on Pharmacogenomic Data Submissions](#) (**comments due May 28**).
- [Radioactive Drug Research Committees](#) (**comments due May 30**).
- [Orphan Drugs Products: Common European Medicines Agency/Food and Drug Administration Application Form for Orphan Medicinal Product Designation](#) (**comments due June 16**).
- [Customer/Partner Service Surveys](#) (**comments due June 16**).
- [Risk and Benefit Perception Scale Development](#) (**comments due June 20**).
- [Medical Devices; Device Tracking](#) (**comments due June 24**).
- [Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery](#) (**comments due June 30**).

Upcoming Meetings, Workshops, and Conferences

Drugs and Biologics

Public Workshop by the Institute of Medicine on [Characterizing and Communicating Uncertainty in the Assessment of Benefits and Risks in Drug Regulatory Decision-Making](#), with an opportunity for comment. Originally scheduled in February 2014, the meeting has been rescheduled for **May 12** in Silver Spring, MD. **Comments are due June 11.**

Public Meeting on Postmarketing [Requirements for the Class-Wide Extended-Release/Long-Acting Opioid Analgesics](#), with an opportunity for comment. The meeting will be held **May 19-20** in Silver Spring, MD. **Comments are due June 19.**

Public Meeting on [Inborn Errors of Metabolism Patient-Focused Drug Development](#), with an opportunity for comment. The meeting will be held **June 10** in Silver Spring, MD. **Comments are due August 11.**

Public Workshop on [Pediatric Clinical Investigator Training](#) will be held **September 22** in Bethesda, MD.

Advisory Committees

- [May 6-7: Circulatory System Devices Panel of the Medical Devices Advisory Committee Meeting](#)
- [June 17: Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee Meeting](#)
- [June 25: Oncologic Drugs Advisory Committee Meeting](#)
- [October 16: Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee Meeting](#)

For more comprehensive listings of FDA meetings, please visit these FDA web pages:

- [Workshops & Conferences \(Medical Devices\)](#)
- [Meetings, Conferences, & Workshops \(Drugs\)](#)
- [Workshops, Meetings & Conferences \(Biologics\)](#)
- [FDA Advisory Committee Calendar](#)

Enforcement Updates

Recent Product Recalls

Recent drug recalls have included four injectable products for particulate matter contamination.

Customer complaints identified glass or metal particles in some injection vials, mostly traced to defects in the suppliers' products. Another company recalled 11 lots of skin-whitening products out of concern that their labels made unapproved medical claims. There also were two dietary supplement recalls last month for containing drug ingredients.

In the area of medical devices, there was a recall for the power docking stations of certain infusion pumps. The docking stations sometimes failed to power up their attached infusion pumps, an error that could inadvertently stop the infusion.

There have been no new biologic recalls since the last *Jones Day Pharmaceutical & Medical Device Regulatory Update*.

Click [here](#) for a complete listing of FDA Recalls.

Recent Warning Letters

There have been several enforcement actions made public since the last *Jones Day Pharmaceutical & Medical Device Regulatory Update*.

FDA recently warned six medical device manufacturers for failing to comply with the Quality Systems Regulation. According to the warning letters, the companies had inadequate procedures for process validation, environmental controls, handling customer complaints, and corrective and preventive actions. The Agency also took action against a manufacturer of biological products for CGMP violations observed at its facility in Mexico.

In another action, FDA cited a compounding pharmacy for not having valid individual prescriptions for each drug produced and for operating in unsanitary conditions.

There also has been an uptick in enforcement actions related to laboratory and clinical studies. FDA recently warned a pathology laboratory for failing to adhere to Good Laboratory Practice regulations during two nonclinical studies. In addition, the Agency posted warning letters related to Investigational Device Exemptions and Institutional Review Board violations, including one notice to a sponsor/clinical investigator.

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

According to its website, the Office of Prescription Drug Promotion ("OPDP") has issued no warning letters in the last 60 days.

Click [here](#) for a complete listing of 2014 OPDP Warning Letters.

Recent Drug and Device Approvals

[FDA approves Zykadia for late-stage lung cancer](#) (April 29).

[FDA approves first human papillomavirus test for primary cervical cancer screening](#) (April 24).

[FDA Approves Sylvant For rare Castleman's Disease](#) (April 23).

[FDA approves Cyramza for stomach cancer](#) (April 21).

[FDA approves Ragwitek for short ragweed pollen allergies](#) (April 17).

[FDA approves Tanzeum to treat type 2 diabetes](#) (April 15).

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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FDA issued a [draft guidance document outlining the Expedited Access Program](#), providing useful tips on developing the sponsor's data plan, preparing for benefit-risk determinations, and presenting appropriate manufacturing information to FDA. The guidance elaborates how an applicant can demonstrate that the device "addresses an unmet medical need." A medical device will meet this criteria when it is either a breakthrough technology that offers a significant, clinically meaningful advantage over an existing technology or approved alternatives, there is no approved alternative treatment or means of diagnosis, or it is otherwise in the patient's best interest.

FDA simultaneously issued a second [draft guidance on Balancing Premarket and Postmarket Data Collections for Devices Subject to PMA](#). More specifically, this guidance describes how FDA considers the role of postmarket information in determining the extent of data that should be collected in the premarket setting to support premarket approval, while still meeting the statutory standard of reasonable assurance of safety and effectiveness—a balance that is important to achieve for timely patient access to important new technology without compromising patient safety, which is precisely the goal of the EAP program.

The Expedited Access PMA for medical devices builds on the [Innovation Pathway Pilot](#) and FDA's experience with expedited drug review programs, and it is intended to facilitate patient access to important treatments sooner than would otherwise be available. The public has until July 22 to comment on the draft guidance documents.

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FDA officials and various representatives from the drug, medical device, biologics, and other FDA-regulated industries recently gathered at the Food and Drug Law Institute ("FDLI") annual conference in Washington, D.C. Over the course of the two-day conference, several FDA officials commented on recent and future initiatives.

Janet Woodcock, the Director of the Center for Drug Evaluation and Research (CDER) said FDA is focusing significant attention on statutorily mandated initiatives on drug tracking, pharmacy compounding, and antibacterial drugs. Woodcock also indicated FDA expects several applications for biosimilars this year and that FDA is developing additional guidance to assist sponsors with those submissions, including guidance to further explain what data is needed to demonstrate biosimilarity and interchangeability, as well as clarifying labeling requirements.

In a separate panel focused exclusively on biosimilars, a panel of experts including Jones Day's [Christopher Mikson](#) discussed recent developments on critical issues such as the draft guidance on biosimilarity standards, concomitant lack of guidance on interchangeability, state laws on substitution, the debate over product names, recent filings of patent suits, and that no biosimilar applications have been approved by FDA to date.

John Weiner, the associated director of policy in FDA's Office of Combination Products indicated a draft guidance on current good manufacturing practices ("CGMP") would be forthcoming in 2014. A "combination product" is a product that combines two or more of a drug, biologic, or medical device. The draft guidance will clarify the CGMP requirements set forth in a January 2013 final rule. After the CGMP guidance, industry can expect guidance on human factors in the use of combination products.

In the area of medical devices, Jeffrey Shuren, director of the Center for Devices and Radiological Health ("CDRH"), indicated CDRH hopes to establish a formal process for

medical device manufacturers to join meetings between FDA and the Centers for Medicaid and Medicare to discuss how clinical trials could account for issues related to reimbursement. Another FDA official spoke on the Agency's recent efforts to regulate mobile medical apps, emphasizing that FDA uses the term "apps" to better connect with software developers, but that FDA regulation of medical device software (synonymous with mobile medical apps in many cases), is independent of the software's platform. Companies marketing products they believe might be subject to FDA regulation, but have not yet sought clearance, are encouraged to contact FDA to discuss whether and how their product is regulated by FDA.

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States Continue Protest Zohydro Approval; Massachusetts Bans Sales

Several states have protested [FDA's approval of hydrocodone drug Zohydro ER](#) based on concerns that a lack of abuse-deterrent features creates a higher-than-acceptable risk of abuse. In March, [attorneys general](#) from six states sent a letter to Health and Human Services Secretary Kathleen Sebelius asking her to overturn FDA's approval of Zohydro ER. Last week, Massachusetts Gov. Deval Patrick announced that Zohydro ER may not be sold in the state because its current form does not guard against potential conversion to rapid release. According to [Reuters](#), the manufacturer of Zohydro called the state's ban misguided and noted that other painkillers without abuse-resistant technologies are already on the market. This letter follows similar [requests](#) by other state attorneys general and [proposals](#) by federal legislators to reverse the drug's regulatory approval.

DEA Acts on FDA Proposed Rescheduling of Hydrocodone Combination Products

In late February, the U.S. Drug Enforcement Agency issued a [notice of proposed rulemaking to reschedule hydrocodone combination products from schedule III to schedule II](#) of the Controlled Substances Act ("CSA"). The proposed rule was in response to a recommendation issued by FDA last year around the same time that the agency approved Zohydro (see story above), a single-entity hydrocodone product. Single-entity products are already listed in schedule II of the CSA; however, Zohydro is the first single-entity hydrocodone product to enter the marketplace. Comments *on the proposed rule are due April 28*.

Senator Proposes Bill to Reverse Approval of Hydrocodone Drug

On March 13, Sen. Joe Manchin (D-WV) introduced a [bill](#) to overturn FDA's marketing approval of Zohydro ER, an opioid drug made from pure hydrocodone. According to *The Wall Street Journal*, the drug has been criticized by more than 24 state attorneys general and several federal legislators concerned about abuse and potential overdose deaths. A similar bill was introduced in the House of Representatives by Rep. Stephen Lynch (D-MA), Rep. Hal Rogers (R-KY),

and 11 other cosponsors. FDA approved the drug last year over the objections of a medical advisory panel. FDA Commissioner Margaret Hamburg continues to defend the drug's approval for select pain treatments.

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