JONES DAY | **Pharmaceutical & Medical Device Regulatory Update**
Vol. II | Issue 17 | November 2015 JONES DAY

Top News

FDA Undertaking Efforts to Improve Review of Combination Products
Robert Califf, nominee for FDA Commissioner, recently coauthored an update regarding changes the agency is making to better facilitate the review of combination products, which involve drug, device, and/or biological products as constituent parts. Efforts are also aimed at improving consultations between FDA's product-specific centers (which have increased significantly since 2003).

Califf referenced a report recently released by FDA's Office of Planning regarding intercenter coordination with respect to combination product applications. Califf endorsed the study's findings and recommendations, such as issuing more guidance on the topics, enhancing and simplifying data access and sharing among staff, revising current standard operating procedures for premarket review and compliance strategies, and updating and maintaining an internal directory for intercenter contacts.

President Announces New Initiatives to Address Opioid Abuse
In the wake of an opioid abuse epidemic, President Obama announced last month that the administration will continue taking steps to enhance the training of health care professionals who prescribe painkillers and to increase access to drug abuse treatment programs. The presidential memorandum instructs federal agencies to train their physician employees in proper prescribing practices, among other things.

CONTACTS

Edgar Asebey
Miami

Maureen Bennett
Boston / San Francisco

Cristiana Spontoni
Brussels

Colleen M. Heisey
Washington

Christian B. Fulda
Munich

Chiang Ling Li
China

Katherine M. Llewellyn
Brussels

Stephanie L. Resnik
Washington

Matthew R. Bowles
Washington

Mitsutaka Okano
Tokyo

Katherine S. Makielski
Chicago

Tony Chen, Michele Goodman, and Erin Shi assisted in the preparation of this Update.

Detailed Contact Information

UPCOMING EVENTS

December 2, 2015: Maureen Bennett will give a presentation on *International Clinical Research Issues* to the Boston Bar

This announcement follows similar initiatives proposed this year, such as new spending to curb overprescribing and special task forces to coordinate prevention efforts among health practitioners and law enforcement officers. Opioid abuse has garnered serious attention of public health authorities in recent years, as according to some estimates, deaths attributable to heroin overdoses have quadrupled in the last decade.

Court Rules Drugmakers Not Required to Provide Orphan Drugs to Certain Covered Entities Under 340B Program

Last month, in the case of *PhRMA v. U.S. Department of Health & Human Services* ("HHS"), a federal district court held that pharmaceutical companies are not required to provide orphan drugs to certain covered entities at reduced prices under the 340B Program, regardless of how the drugs will be used by the covered entities.

At issue was rulemaking activity related to section 340B(e) of the Public Health Services Act, which states that for certain covered entities, "the term 'covered outpatient drug' shall not include a drug designated [under statutory orphan drug provisions] for a rare disease or condition." The case involved a challenge to the validity of an interpretive rule promulgated by HHS, following a prior ruling by the same court that HHS lacked authority to promulgate a legislative rule implementing certain provisions of the 340B Program. In its final interpretive rule, HHS took the position that drug manufacturers must provide orphan drugs under the 340B Program when a drug is used for indications other than the rare disease or condition for which it was designated an orphan drug. The court invalidated this rule, finding that it contravenes the plain language of section 340B(e). As a result, all drugs designated as "orphan drugs" will be excluded from the 340B program for certain covered entities.

CDRH Aims to Focus Regulatory Science on Data Science, Digital Health, Cybersecurity

On October 20, 2015, FDA's Center for Devices and Radiological Health ("CDRH") issued a report on Regulatory Science Priorities (FY2016). The report summarizes CDRH's top 10 regulatory science needs for the coming year, which include: leveraging "big data" for regulatory processes, improving the quality and effectiveness of reprocessing reusable medical devices, enhancing the performance of digital health and medical device cybersecurity, and collecting and using patient experiences and preferences in regulatory decisions. According to the document, regulatory science facilitates CDRH's decision-making by developing well-founded analytical tools and methodologies that reflect the perspectives of multiple disciplines and enable data-driven decisions.

Safe Harbor Ruling: MEPs Call for Clarity and Effective Protection

On October 15, 2015, members of European Parliament ("MEPs") debated the impact of the recent European Court of Justice ("ECJ") ruling that the Safe Harbor agreement on data transfers to the United States is not safe. MEPs called on the European Commission to clarify the legal situation following the ruling and demanded immediate action to ensure effective data protection for EU citizens. See the Jones Day *Alert* for more information.

OIG Recommends Improvements for HHS Grant Administration and Oversight

The Office of Inspector General ("OIG") of HHS recently released two reports on HHS grantmaking activities, calling for improved postaward administration and oversight of HHS grantees. In August 2015, OIG issued a report noting weaknesses in the National

Association's Health Law Education Committee.

December 10, 2015: Colleen Heisey will give a presentation on *FDA Regulation and Enforcement of Social Media* at the FDLI Annual Enforcement, Litigation, and Compliance Conference in Washington, D.C.

RELATED PRACTICES

FDA Regulatory & Compliance Counseling

Health Care

Life Sciences

Institutes of Health's ("NIH") processes for administering grants after they are awarded and reviewing the progress of grantees toward their stated objectives. According to the report, OIG reviewed a sample of 100 awards from FY2011 and concluded that NIH approved 13 percent of grants even when progress reports submitted by the grantees did not contain the required information, and that NIH awarded $7.2 million to four grantees when the grantees reported that their established project goals were not met or were removed. OIG noted that while project goals may be modified for any number of legitimate reasons, NIH staff did not document in all cases whether such modifications would have a material impact on the effectiveness of the grant. In addition, OIG found that while only 1 percent of the grant files reviewed did not contain all required documents, 19 percent contained documents that were submitted late. To address these issues, OIG recommends that NIH: (i) establish a formal quality assurance program to ensure the timely submission and review of grant file documents; and (ii) revise its policies and procedures to require documentation of conclusions regarding grantee progress and whether changes in project goals should result in a reconsideration of grant funding.

- Read More

China Considers Compulsory Licenses to Pharmaceutical Patents

In September 2015, China's National Health and Family Planning Commission ("NHFPC") issued a Three-Year Action Plan for Treating Cancer (2015–2017). Among the measures proposed for increasing the society's capacity to fight cancer is the patent-compulsory license. For drugs that domestic companies still cannot copy, the action plan contemplates using "drug price negotiation to accelerate the commercialization of relevant drugs by lowering the procurement price." NHFPC has tailored the messages vaguely, keeping the public guessing whether the government will use the compulsory license to socialize patent-protected drugs or will use the threat of the compulsory license to bargain down drug prices in negotiation. In 2012, the State Intellectual Property Office of China ("SIPO") released detailed Compulsory Patent License Rules, which provided a road map for compulsory license applicants. Although SIPO has not granted any compulsory license, NHFPC's action plan should alert innovators that they need to take proactive measures to avoid losing the full benefits of their patents in China.

EU PRIME Scheme Begins Consultation Period

On October 26, 2015, the European Medicines Agency ("EMA") launched a public consultation on the key features of its new priority medicines ("PRIME") scheme. PRIME aims to strengthen support for medicines with the potential to benefit patients who presently have no treatment options or that may offer a major therapeutic advantage over existing treatments. Through the scheme, EMA will offer early and enhanced scientific and regulatory support to medicine developers to optimize the generation of robust data and enable accelerated assessment. To be granted a marketing authorization in the EU, medicines that benefit from PRIME during their development will have to demonstrate that their benefits outweigh their risks, as with any other medicine. PRIME is planned for the first quarter of 2016.

Other News

Following Commercial Speech Lawsuit, FDA Removes Warning Letter from Database

Senators Propose Extending Open Payments Reporting to Nurse Practitioners, Physician Assistants

Pharmaceutical Company Faces Multijurisdiction Subpoenas into Drug Pricing Practices

FDA Inspector Cites Startup for "Uncleared" Blood Testing Device

Senate Committee Continues to Debate "21st Century Cures" Counterpart Legislation

FDA Confirms Plan to Harmonize Regulations with HHS's Recently Proposed Updates to the Common Rule

FDA Releases Draft Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Certain Leftover Human Specimens

Regulatory Updates

FDA Proposes Rule on Classification of Pediatric Medical Crib and Pediatric Medical Bassinet
In the October 8, 2015, *Federal Register*, FDA proposed to rename pediatric hospital beds as pediatric medical cribs and establish special controls for these devices. FDA is also proposing to establish a separate classification regulation for medical bassinets, previously under the pediatric hospital bed classification regulation, as a class II (special controls) device. The proposed regulation for both pediatric medical cribs and medical bassinets would also include the Consumer Product Safety Commission's mattress flammability standards for the mattresses intended for use with these devices. In addition, this proposed rule would require prescription use of pediatric medical cribs and bassinets. ***Comments due December 7, 2015***.

FDA Announces Pilot Project for Risk Evaluation and Mitigation Strategies
In the October 6, 2015, *Federal Register*, FDA announced the beginning of a pilot project for the submission of final approved Risk Evaluation and Mitigation Strategies ("REMS") and certain REMS summary information electronically in a standard Structured Product Labeling ("SPL") format. The pilot is intended to help application holders, FDA, and other interested stakeholders evaluate a potential approach to converting REMS into SPL format and evaluate the usefulness of the REMS information to be provided in SPL format. ***Requests to participate due December 7, 2015***.

FDA Announces Availability of Electronic Common Technical Document Technical Conformance Guide
In the October 6, 2015, *Federal Register*, FDA announced the availability of an Electronic Common Technical Document ("eCTD") Technical Conformance Guide to supplement the guidance for industry titled "Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications." The eCTD provides specifications, recommendations, and general considerations on how to submit eCTD-based electronic submissions to the Center for Drug Evaluation and Research or the Center for Biologics Evaluation and Research. ***Comments due November 20, 2015***.

FDA Announces Recommendations for Acceptable Amounts of Residual Solvents in Pharmaceuticals
In the October 16, 2015, *Federal Register*, FDA announced the availability of draft recommendations for a new permitted daily exposure ("PDE") for the residual solvent triethylamine and a revised PDE for the residual solvent methylisobutylketone, according to the maintenance procedures for the guidance for industry titled "Q3C Impurities: Residual Solvents." The document is intended to recommend acceptable amounts for the listed residual solvents in pharmaceuticals for the safety of the patient. ***Comments due December 15, 2015***.

FDA Reopens Comment Period for CMC Draft Guidance
In the October 6, 2015, *Federal Register*, FDA announced that it would reopen the comment period for the draft guidance published on June 1, 2015 titled "Established Conditions: Reportable Chemistry, Manufacturing, and Controls ("CMC") Changes for Approved Drug and Biologic Products; Draft Guidance for Industry." ***Comments now due January 4, 2015***.

FDA Reopens Comment Period on Prescription Drug User Fee Act
In the October 14, 2015, *Federal Register*, FDA announced it is reopening the comment period for the notice of public meeting published on May 13, 2015. FDA invites comments

as the Agency begins the process to reauthorize the Prescription Drug User Fee Act. ***Comments now due April 29, 2016***.

FDA Orders Classification of the Physiologic Simulation Software Device
In the October 21, 2015, *Federal Register*, FDA issued an order classifying the coronary vascular physiologic simulation software device into class II (special controls). Required risk-mitigation measures include software verification, validation, and hazard analysis to address false negative results and clinical testing to address false positive results.

FDA Publishes List of Approved Premarket Approval Applications
In the October 6, 2015, *Federal Register*, FDA published a list of premarket approval applications ("PMAs") that have been approved. Approved PMAs include, but are not limited to, Impella 2.5 System, Adherus AutoSpray Dural Sealant, Medtronic CoreValue System, and others.

FDA Reclassifies Shortwave Diathermy for All Other Uses
In the October 13, 2015, *Federal Register*, FDA issued a final order to reclassify shortwave diathermy for all other uses, a preamendments class III device, into class II (special controls), and to rename the device ''nonthermal shortwave therapy.''

FDA Amends Animal Drug Regulations
In the October 13, 2015, *Federal Register*, FDA amended the animal drug regulations to reflect application-related actions for new animal drug applications ("NADAs") and abbreviated new animal drug applications ("ANADAs") during July and August 2015. The animal drug regulations are also being amended to reflect a change of sponsor, a change of sponsor's address, a revised food safety warning, the voluntary withdrawal of approval of a NADA, and a technical amendment.

FDA Withdraws Approval of New Animal Drug Application for Penicillin G Procaine
In the October 13, 2015, *Federal Register*, FDA announced it is withdrawing approval of a NADA providing for the use of penicillin G procaine in medicated feed of poultry and swine. This action is being taken at the sponsor's request because this product is no longer manufactured or marketed.

FDA Withdraws New Drug Applications and Abbreviated New Drug Applications
In the October 13, 2015, *Federal Register*, FDA announced that it is withdrawing approval of 67 new drug applications ("NDAs") and 128 abbreviated new drug applications ("ANDAs") from multiple applicants. The holders of the applications notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

FDA Issued the Following Draft and Final Guidance Documents:
Guidance for Industry and Review Staff: Nonclinical Safety Evaluation of Reformulated Drug Products and Products Intended for Administration by an Alternate Route, October 28, 2015, *Federal Register*.

Guidance for Industry: Evaluating the Effectiveness of New Animal Drugs for the Reduction of Pathogenic Shiga Toxin-Producing E. Coli *in Cattle*, October 19, 2015, *Federal Register.*

Guidance for Industry: Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act, October 8, 2015, *Federal Register*.

Guidance for Industry: Integrated Summary of Effectiveness, October 8, 2015, *Federal Register.*

Guidance for Industry: Acceptability of Draft Labeling to Support Abbreviated New Drug Application Approval, October 6, 2015, *Federal Register*.

Draft Guidance for Industry: Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers for Human Use, October 22, 2015, *Federal Register*. ***Comments due December 21, 2015.***

Draft Guidance for Industry and FDA Staff: Manufacturing Site Change Supplements: Content and Submission, October 21, 2015, *Federal Register*. ***Comments due January 19, 2016.***

Draft Guidance for Industry: Recommendations for Microbial Vectors Used for Gene Therapy, October 14, 2015, *Federal Register*. ***Comments due December 14, 2015.***

Draft Guidance for Industry and FDA Staff: General Considerations for Animal Studies for Medical Devices, October 14, 2015, *Federal Register*. ***Comments due January 12, 2016.***

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

- Investigational Device Exemptions Reports and Records
- Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that Are Not Individually Identifiable
- Medical Device User Fee Cover Sheet, Form FDA 3601
- Medical Devices; Inspection by Accredited Persons Program
- Center for Devices and Radiological Health Appeals Processes
- Quantitative Information in Direct-to-Consumer Television Advertisements
- Recommended Recordkeeping for Cosmetic Good Manufacturing Practices
- Administrative Detention and Banned Medical Devices
- Guidance on Reagents for Detection of Specific Novel Influenza A Viruses

FDA Announced that the Following Collections Have Been Submitted to OMB:

- MedWatch: The Food and Drug Administration Medical Products Reporting Program
- Guidance for Industry on Generic Drug User Fee Cover Sheet
- Guidance for Industry on Formal Meetings with Sponsors and Applicants for Prescription Drug User Fee Act Products
- Guidance for Industry on Formal Dispute Resolution

FDA Announced that the Following Collections Have Been Approved by OMB:

- Medical Device Labeling Regulations
- Medical Device Recall Authority
- Formal Evidentiary Public Hearing
- Reclassification Petitions for Medical Devices
- User Fee Cover Sheet, Form FDA 3397

EU Regulatory Notices

CHMP Recommends Extensions for Seven Therapeutic Indications
During its October 19–22, 2015 meetings, the Committee for Medicinal Products for Human Use ("CHMP") recommended extensions of indication for Cubicin, Edurant, Emend, Volibris, Xalkori, and two extensions of indication for Cosentyx.

Inductos to Remain Suspended in EU, Pending Resolution of Manufacturing Issues
On October 23, 2015, the CHMP has recommended the suspension of Inductos, an implant used to help new bone develop in patients with spinal disc problems and leg fractures. EMA started a review of Inductos following an inspection by Dutch and Spanish authorities, which found the production site of the absorbable sponge to be noncompliant with manufacturing requirements. Specifically, the inspectors noted that the

manufacturer, located in the United States, did not have adequate measures in place to prevent particle contamination of the sponges. Hence, the CHMP concluded that Inductos should be suspended until the manufacturing issues are satisfactorily addressed.

EMA Issues Recommendations to Minimize Risk of Rare Brain Infection PML with Tecfidera
On October 23, 2015, the CHMP gave new advice for doctors and patients in order to minimize the risk of progressive multifocal leukoencephalopathy ("PML") in patients treated with the multiple sclerosis medicine Tecfidera ("dimethyl fumarate"). PML is a rare brain infection caused by the John Cunningham virus. EMA has recommended that a complete blood count should be performed before starting treatment with Tecfidera and every three months during treatment. Additionally, a baseline MRI should be available as a reference (usually within three months).

Advanced Therapy for Melanoma Receives Positive Opinion
On October 23, 2015, the CHMP recommended authorizing Imlygic (talimogene laherparepvec) for the treatment of adults with melanoma that cannot be removed by surgery and that has spread either to the surrounding area or to other areas of the body (regionally or distantly metastatic) without affecting the bones, brain, lung, or other internal organs. Imlygic is a first-in-class advanced therapy medicinal product derived from a virus, that has been genetically engineered to infect and kill cancer cells.

Public Workshop to Explore the Role of PK/PD Measurements in Clinical Use of Certain Anticoagulants
EMA is calling for statements of interest from experts and stakeholders to attend a workshop on the role of pharmacokinetic and pharmacodynamic ("PK/PD") measurements in direct oral anticoagulants ("DOACs"), scheduled for November 23, 2015, in London. The main objectives of the workshop are: (i) to understand problems related to the use of DOACs in clinical practice, in the overall population of patients, and in certain subgroups of patients; (ii) to address the need to further guide clinical decision-making on dose adjustment during routine use of DOACs, when major bleedings occur, or when acute surgery is needed; and (iii) to develop recommendations regarding PK/PD measurements that can be implemented based on current data.

PRAC Meeting Includes Referrals on HPV Vaccines
During its October 5–8, 2015, meetings, the Pharmacovigilance Risk Assessment Committee ("PRAC") discussed three ongoing referrals on SGLT2 inhibitors, human papillomavirus ("HPV") vaccines, and Tysabri. The PRAC did not initiate or conclude a safety referral. A record of the discussions will be provided in the minutes of the meeting, which will be published following the next PRAC meeting in November 2015.

Initiative Aims to Support Use of Existing Patient Registries in Clinical Practice
EMA has launched an initiative on patient registries aimed at making better use of existing registries as a source of high-quality post-authorization data for regulatory decision-making, and to facilitate the establishment of new registries if needed. Registries collect information over time on patients who are diagnosed with a particular disease or who receive particular treatment. The patient registry initiative will explore ways of dealing with current challenges faced by companies and regulators in using existing registries and establishing new registries if needed.

Upcoming Meetings, Workshops, and Conferences

Public Workshop entitled "Osteoporosis Drug Development: Moving Forward," **November 4, 2015**, in Silver Spring, MD. ***Comments due October 7, 2015***.

Public Meeting on Drug Interactions with Hormonal Contraceptives: Public Health and Drug Development Implications, **November 9, 2015**, in Silver Spring, MD.

Public Meeting on Labeling Lower-Dose Estrogen-Alone Products for Symptoms of Vulvar and Vaginal Atrophy, **November 10, 2015**, in Silver Spring, MD. ***Comments due October 16, 2015***.

Public Meeting titled "Modernizing the Regulatory System for Biotechnology Products," **October 30, 2015**, in Washington, DC. ***Comments due November 13, 2015***.

Public Workshop titled "Standards-Based Approach to Analytical Performance Evaluation of Next Generation Sequencing In Vitro Diagnostic Tests," **November 12, 2015**, in Silver Spring, MD.

Public Workshop titled "Use of Databases for Establishing the Clinical Relevance of Human Genetic Variants," **November 13, 2015**, in Silver Spring, MD. ***Comments due November 25, 2015***.

Office of Women's Health Update on Strategic Priorities and Initiatives for Nurses, **November 18, 2015**, in Silver Spring, MD.

Office of Women's Health General Update on Strategic Priorities and Initiatives, **November 30, 2015**, in Washington, D.C.

Public Meeting on Reauthorization of the Biosimilar User Fee Act, **December 18, 2015**, in Silver Spring, MD. ***Comments due January 19, 2015***.

Advisory Committees
Bone, Reproductive, and Urologic Drugs Advisory Committee, **November 3, 2015**, in Silver Spring, MD.

Anesthetic and Analgesic Drug Products Advisory Committee, **November 6, 2015**, in Silver Spring, MD.

Joint Meeting of the Cellular, Tissue, and Gene Therapies Advisory Committee and the Oncologic Drugs Advisory Committee, **November 18, 2015**, in Silver Spring, MD.

Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee, **November 18, 2015**, in Washington, D.C.

Peripheral and Central Nervous System Drugs Advisory Committee, **November 24, 2015**, in Silver Spring, MD.

Psychopharmacologic Drugs Advisory Committee, **December 1, 2015**, in Silver Spring, MD.

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 Yervoy to reduce the risk of melanoma returning after surgery (October 28, 2015)

FDA approves first-of-its-kind product for the treatment of melanoma (October 27, 2015)

FDA approves new treatment for rare metabolic disorder (October 23, 2015)

FDA approves new therapy for certain types of advanced soft tissue sarcoma (October 23, 2015)

FDA approves new treatment for advanced pancreatic cancer (October 22, 2015)

FDA approves new drug to treat hyperkalemia (October 21, 2015)

FDA approves first Factor X concentrate to treat patients with rare hereditary bleeding disorder (October 20, 2015)

FDA approves Praxbind, the first reversal agent for the anticoagulant Pradaxa (October 16, 2015)

FDA expands approved use of Opdivo in advanced lung cancer (October 9, 2015)

FDA allows marketing of the first nucleic acid-based test to detect multiple pathogens from a single sample of cerebrospinal fluid (October 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.

Jones Day FDA Regulatory & Compliance Counseling Contacts

Edgar Asebey
Miami
+1.305.714.9707
easebey@jonesday.com

Maureen Bennett
Boston/San Francisco
+1.617.449.6884/
+1.415.875.5772
mbennett@jonesday.com

Cristiana Spontoni
Brussels
+32.2.645.14.48
cspontoni@jonesday.com

Colleen M. Heisey
Washington
+1.202.879.3449
cmheisey@jonesday.com

Christian B. Fulda
Munich
+49.89.20.60.42.200
cfulda@jonesday.com

Chiang Ling Li
China
+852.3189.7338
chianglingli@jonesday.com

Katherine M. Llewellyn
Brussels
+32.2.645.14.47
kllewellyn@jonesday.com

Mitsutaka Okano
Tokyo
+81.3.6744.1606
mokano@jonesday.com

Stephanie L. Resnik
Washington
+1.202.879.5458
sresnik@jonesday.com

Matthew R. Bowles
Washington
+1.202.879.3604
mbowles@jonesday.com

Katherine S. Makielski
Chicago
+1.312.269.4269
kmakielski@jonesday.com

Follow us on:

Jones Day is a legal institution with 2,400 lawyers on five continents. We are One Firm Worldwide[SM].

JONES DAY | **Pharmaceutical & Medical Device Regulatory Update**
Vol. II | Issue 17 | November 2015 JONES DAY

Top News

OIG Recommends Improvements for HHS Grant Administration and Oversight

The Office of Inspector General ("OIG") of HHS recently released two reports on HHS grantmaking activities, calling for improved postaward administration and oversight of HHS grantees. In August 2015, OIG issued a report noting weaknesses in the National Institutes of Health's ("NIH") processes for administering grants after they are awarded and reviewing the progress of grantees toward their stated objectives. According to the report, OIG reviewed a sample of 100 awards from FY2011 and concluded that NIH approved 13 percent of grants even when progress reports submitted by the grantees did not contain the required information, and that NIH awarded $7.2 million to four grantees when the grantees reported that their established project goals were not met or were removed. OIG noted that while project goals may be modified for any number of legitimate reasons, NIH staff did not document in all cases whether such modifications would have a material impact on the effectiveness of the grant. In addition, OIG found that while only 1 percent of the grant files reviewed did not contain all required documents, 19 percent contained documents that were submitted late. To address these issues, OIG recommends that NIH: (i) establish a formal quality assurance program to ensure the timely submission and review of grant file documents; and (ii) revise its policies and procedures to require documentation of conclusions regarding grantee progress and whether changes in project goals should result in a reconsideration of grant funding.

In September 2015, OIG issued a report calling for improved mechanisms for the sharing of information between HHS grantmaking agencies to mitigate grantee risks, such as poor performance or misuse of grant funds. In the report, OIG notes various sources that grant officials may use to assess risks, including alerts noting negative audit findings and a number of databases that contain information regarding a grantee's payment history, past audit findings, and exclusion/debarment status. According to OIG, while grantees may receive funding from several HHS agencies, and grant officials report using information available from other HHS agencies to mitigate grantee risks, there is no systematic method for sharing risk information across awarding agencies. To improve information sharing across HHS agencies and facilitate HHS program integrity initiatives, OIG recommends that HHS's Office of the Assistant Secretary for Financial Resources: (i) consider implementing databases that integrate various sources of existing information on HHS grant applicants and recipients; (ii) establish an HHS-wide source of adverse findings from audits of grantees; and (iii) facilitate interagency sharing of information about grantee performance.

- Homepage