



PHARMACEUTICAL & MEDICAL DEVICE REGULATORY UPDATE

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Jones Day Announcement

Jones Day welcomes [Maureen Bennett](#) to its Health Care and Life Sciences Practice. She has managed the negotiation of multiparty clinical research collaboration agreements in numerous jurisdictions around the world, including agreements with hospitals, physician practices, and independent research entities. Maureen's practice also includes a focus on regulatory compliance and ethical issues associated with the conduct of international clinical research, including patient recruitment, pharmacovigilance, clinical data management, anticorruption, and informed consent issues.

Top News

Commissioner Hamburg Resigns After Six-Year Tenure as FDA Head

Dr. Margaret Hamburg has [announced](#) she will resign from her post as FDA Commissioner in March 2015, citing her long service to the Agency and the heavy demands it entailed. FDA's chief scientist Dr. Stephen Ostroff will serve as the Agency's head until President Obama nominates a new commissioner.

House Committee Considers 21st Century Cures Draft, Senate Coordinates Sister Bill

In January 2015, the House Energy and Commerce Committee released a [discussion draft](#) of the 21st Century Cures Act, a bipartisan bill aimed at overhauling how FDA regulates drugs and devices, which builds on an effort known as the 21st Century Cures Initiative.

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Joseph M. Cardosi and Laura E. Malament, associates in the Washington Office, assisted in the preparation of this Update.

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The initiative launched in April 2014 and has been the subject of many congressional hearings and roundtables, as well as several white papers. Corresponding to the release of the 21st Century Cures discussion draft, two top Republicans from the Senate Health, Education, Labor and Pensions ("HELP") Committee released "[Innovation for Healthier Americans](#)," a report aimed at "identifying and advancing specific steps to better align public policy to support medical innovation and patient access to new medicines and technologies," focusing primarily on ways to improve FDA and the National Institutes of Health ("NIH").

The report, which calls for stakeholder feedback by February 23, 2015, was a precursor to a [February 3, 2015](#) announcement from Senators Lamar Alexander (R-TN) and Patty Murray (D-WA), the Chairman and Ranking Member of the Senate HELP Committee, that they are launching a bipartisan initiative to examine the process for providing safe treatments, devices, and cures to patients and the roles of the FDA and NIH in that process.

Similar to the work done on the 21st Century Cures Initiative, the senators are creating a bipartisan working group and plan to hold a series of hearings. Any resulting legislation will likely complement the House's intended 21st Century Cures Act.

The lengthy and long-anticipated 21st Century Cures Act discussion draft addresses regulation of drugs and biologics with an eye toward speeding up approvals (Title I); enhancing discovery and development of new treatments (Title II); changes to the clinical trial process (Title III); reforms for NIH and FDA related to research, hiring, and succession planning (Title IV); and revamping certain aspects of medical device regulation (Title V).

View a summary of each title by following the link below.

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White House Releases More Details on President's Precision Medicine Initiative

President Obama [has revealed](#) more details about the Precision Medicine Initiative, an interagency project aimed at revolutionizing the way health care professionals treat certain diseases. The initiative, first announced in the State of the Union address, aims to harness recent medical discoveries and accelerate the transition from conventional "one-size-fits-all" medical treatments to personalized medicine, tailored to individual patient needs. The cornerstone of the initiative is a volunteer cohort of at least one million Americans who will provide researchers with data needed to make personalized treatments possible. The President's 2016 budget proposes funding the initiative to support the development of the volunteer cohort and address privacy concerns about collecting and sharing sensitive health data on such a large scale. The rest of the investment will go toward identifying genomic drivers in cancer for more effective cancer

UPCOMING EVENTS

February 12, 2015: Scott A. Edelstein will speak at a webinar on *U.S. Cooperative for International Patient Programs: Legal Issues in US/Mexico Cross-Border Telemedicine*.

February 23–24, 2015: Mark Mansour will speak at the Food and Drug Law Institute's program *Introduction to Food Law and Regulation: The Legal Framework for Food Regulation*.

February 24, 2015: Laura Laemmle-Weidenfeld will speak as a panelist at the American Conference Institute's program *Professional Responsibility and Legal Ethics in Life Sciences*.

February 25, 2015: Tracy Stitt will moderate at the Food and Drug Law Institute's program *Counterfeiting: Strategies for Supply Chain Security, Patient Safety and Brand Protection*.

March 4–7, 2015: Michael Carvin will speak at the American Bar Association's *16th Annual Conference on Emerging Issues in Healthcare Law*.

April 22–23, 2015: Cristiana Spontoni will speak at the 1st Annual [Women Leaders in Life Sciences Law Conference](#) program *Pharmaceutical and Medical Device Regulatory Developments, Issue Spotting: Updates on the Substantive Legal Developments Affecting Life Sciences Companies in 2015 and Beyond*.

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treatments, modernizing FDA's regulatory infrastructure, and developing an IT framework for secure exchange of health data. Whether Congress will fund the President's Precision Medicine Initiative and his other [health care proposals](#) will depend on the coming [budget negotiations](#).

President's Proposed FY 2016 Budget Includes Increased Funding for FDA

President Obama's [2016 fiscal year budget proposal](#) seeks a nine percent increase over FDA's FY 2015 funding levels—to be used for continued implementation of food safety legislation, to improve medical product quality and safety, and to further fund needed staffing increases and overhead. An [FDA fact sheet](#) highlights how funds would be allocated within FDA by product category. In its [Justification of Estimates](#), FDA reports that the proposed budget is structured around FDA's strategic plan framework and would be divided among four major activities: food safety, medical product safety, medical countermeasures, and "other activities" that would include consolidating FDA's facilities, tobacco control, and color certification.

FDA Considers Approaches for Regulating Next-Generation DNA Sequencing

The President's Precision Medicine Initiative calls for the increased use of diagnostic tools, such as genomic sequencing, to tailor treatments to specific patients. In December 2014, FDA released a [discussion paper](#) describing the challenges posed by the large amount of data produced by next-generation sequencing and the shortcomings of FDA's traditional regulatory model intended for single-disease detection. FDA will host a [workshop](#) on February 20, 2015, to receive public comments as it considers how to regulate these complex tools.

FDA Revises Draft Guidance on Drug Promotional Materials

FDA recently released [updated draft guidance](#) on how to explain risks to consumers in advertisements and labeling for prescription drugs, particularly the "consumer brief summary." In the draft guidance, FDA noted concern that consumers are overwhelmed by how risks are currently presented and encouraged the use of "fact boxes" written in "consumer friendly language" instead of long lists of potential side effects. FDA also called for sponsors to more directly state who should not use the advertised product, rather than issuing vague warnings or contraindications.

Mexican Health Ministry Establishes Requirements for Approving Biotech and Biosimilars

The Mexican Ministry of Health recently completed a [regulatory framework for registering biosimilar drugs and biotechnologies](#) used in treating common chronic conditions like diabetes, arthritis, and hypertension. The regulation establishing the guidelines and requirements for approval takes effect this month. Requirements include manufacturing process controls, clinical trial procedures, and reference drug qualifications.

European Court of Justice Rules on Orphan Drug Market Exclusivity

On January 22, 2015, the General Court of the European Court of Justice [held](#) that an orphan medicinal product that has the same therapeutic indication as a previously authorized orphan but that has been independently authorized enjoys 10 years of independent market exclusivity. The case was bought by Teva against a decision of the European Medicines Agency to reject the marketing authorization application for the generic version of the previously authorized orphan (imatinib) on the basis that the later and independently authorized orphan (nilotinib) continued to have market exclusivity for the therapeutic indication in question. Teva's action was dismissed.

Other News

[Study Finds Adverse Event Reporting for Drugs "Deeply Flawed"](#)

[FDA Introduces Simplified "Compassionate Use" Form](#)

[FDA Finalizes Rules to Increase Oversight of Defibrillators, Citing Thousands of Device Failures](#)

[FDA Estimates Biosimilar Approval Process Takes 860 Hours](#)

[FDA Reopens Comments on Generic Drug Rule](#)

[FDA to Host Webinar on Mobile Medical Applications and Medical Device Data Systems](#)

[FDA Denies Requests to Ban Dental Amalgam](#)

[FDA Recaps 2014 Accomplishments](#)

[FDA Releases Updated Form for Annual Reports for Drugs and Biologics](#)

[First Ebola Vaccine Arrives in Liberia](#)

Regulatory Updates

FDA Proposes Rules for 505(b)(2) Applications and ANDAs

In the [February 6, 2015, Federal Register](#), FDA issued a proposed rule to implement Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") governing the approval of 505(b)(2) applications and abbreviated new drug applications ("ANDAs"). According to FDA, it has been implementing the MMA directly from the statute for several years and now seeks to amend its regulations to codify current practice and policy. The proposed rule aims to streamline requirements related to submission of certain patent information, including: Paragraph IV certifications, corrections and changes, timing of submissions, amending or supplementing patent certifications, notification of commercial marketing, and notification of court actions or documented agreements. **Comments due May 7, 2015.**

European Agency Launches Central Repository to Facilitate Assessment of Medicines Safety Reports

On January 26, 2015, the European Medicines Agency launched an [electronic repository](#) for periodic safety update reports ("PSURs") and their assessment reports. The central platform, created in accordance with the pharmacovigilance legislation of the EU, will contain all information related to PSURs in the EU with the aim of facilitating the assessment of PSURs by medicines regulatory authorities in the EU.

FDA Authorizes Emergency Use of IV Diagnostics for Ebola Detection

In the [February 9, 2015, Federal Register](#), FDA issued three emergency use authorizations, one of which was amended after initial issuance, for three in vitro diagnostic devices for detection of the Ebola virus in response to the 2014 Ebola virus outbreak in West Africa.

FDA Reopens Docket for Comments on GDUFA

In the [February 6, 2015, Federal Register](#), FDA reopened the docket to solicit public comment on certain topics related to implementation of the Generic Drug User Fee Amendments of 2012 ("GDUFA") and the GDUFA Commitment Letter that accompanies the legislation. **Comments due March 9, 2015.**

FDA-CDER Continues Site Tours Program, Invites Pharma to Participate

In the [February 6, 2015, Federal Register](#), FDA announced it will continue CDER's Regulatory Project Management Site Tours and Regulatory Interaction Program. In this program, small groups of regulatory project managers observe operations of pharmaceutical manufacturing and packaging facilities, laboratories, and regulatory affairs operations. According to FDA, the purpose of the program is not to inspect, assess, judge, or perform a regulatory function but is meant rather to improve mutual understanding and to provide an avenue for open dialogue. **Pharmaceutical companies may submit proposed agendas to the Agency by April 7, 2015.**

FDA Republishes PMA Order for Automated External Defibrillator

In the [February 3, 2015, Federal Register](#), FDA republished its final order Effective Date of Requirement for Premarket Approval for Automated External Defibrillator (originally published in the [January 29, 2015, Federal Register](#)) to correct an inadvertent omission of

a comment regarding adverse tissue reaction as a risk to health and the Agency's response to that comment. The final order requires the filing of premarket approval applications ("PMA") for automated external defibrillator ("AED") systems, which consist of an AED and those AED accessories necessary for the AED to detect and interpret an electrocardiogram and deliver an electrical shock (e.g., pad electrodes, batteries, adapters, and hardware keys for pediatric use). **Effective May 4, 2015 (for AEDs and accessories legally marketed by that date).**

FDA Modifies Recognized Consensus Standards for Medical Devices

In the [January 27, 2015, Federal Register](#), FDA published modifications it is making to the list of standards FDA recognizes for use in premarket reviews. This publication will assist manufacturers that elect to declare conformity with consensus standards to meet certain requirements for medical devices.

FDA Invites Comments on WHO Recommendations for Narcotics

In the [January 27, 2015, Federal Register](#), FDA solicited comments for preparing the United States's position concerning recommendations by the World Health Organization ("WHO") to impose international manufacturing and distributing restrictions on certain drug substances under international treaties. These recommendations will be discussed during a meeting of the United Nations Commission on Narcotic Drugs in Vienna, Austria, in March 2015. Comments due February 26, 2015.

FDA Issued the Following Draft and Final Guidance Documents

[Revised Draft Guidance for Industry: Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Human Prescription Drugs](#), February 9, 2015, [Federal Register](#). Comments due May 11, 2015. (this document supersedes now-withdrawn [Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements](#), 69 FR 6308 (February 10, 2004)).

[Draft Guidance for Industry: Individual Patient Expanded Access Applications: Form FDA 3926](#), February 6, 2015, [Federal Register](#). **Comments due April 7, 2015.**

[Draft Guidance for Industry and FDA Staff: Medical Devices and Clinical Trial Design for the Treatment or Improvement in the Appearance of Fungally Infected Nails](#), January 27, 2015, [Federal Register](#). **Comments due April 27, 2015.**

[Draft Guidance for Industry and FDA Staff: Premarket Studies of Implantable Minimally Invasive Glaucoma Surgical \(MIGS\) Devices](#), February 11, 2015, [Federal Register](#). **Comments due May 12, 2015.**

[Guidance for Industry and FDA Staff: Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communication Devices](#), February 9, 2015, [Federal Register](#).

[Guidance for Industry and FDA Staff: Mobile Medical Applications](#), February 9, 2015, [Federal Register](#) (updated, original issued September 25, 2013).

[Guidance for Industry: S10 Photosafety Evaluation of Pharmaceuticals](#), January 27, 2015, [Federal Register](#).

FDA Announced that the Following Collections Have Been Submitted to OMB

- Export of Food and Drug Administration Regulated Products: Export Certificates
- Medical Device Labeling Regulations
- Appeals of Science-Based Decisions Above the Division Level at the Center for Veterinary Medicine
- Blood Establishment Registration and Product Listing
- Class II Special Controls Guidance Document: Labeling of Natural Rubber Latex Condoms

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

- General Licensing Provisions: Section 351(k) Biosimilar Applications
- Extension: Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle
- Biosimilars User Fee Cover Sheet; Form FDA 3792
- Revised Draft Guidance for Industry: Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Human Prescription Drugs

FDA Has Determined that the Following Drug Products Were Not Withdrawn from Sale for Reasons of Safety or Effectiveness

- [LYMPHAZURIN \(Isosulfan Blue\)](#)

Upcoming Meetings, Workshops, and Conferences

Drugs and Biologics

[FDA/Xavier University PharmaLink Conference on Leadership in a Global Supply Chain](#), **March 25–27, 2015**, in Cincinnati, OH.

[Public Meeting on Breast Cancer Patient-Focused Drug Development](#), **April 2, 2015**, in Silver Spring, MD.

[Public Meeting on Chagas Disease Patient-Focused Drug Development](#), **April 28, 2015**, in Silver Spring, MD.

[Public Workshop: Gastroenterology Regulatory Endpoints and the Advancement of Therapeutics \(GREAT III\)](#), **March 30–31, 2015**, in Silver Spring, MD.

[Public Meeting on Functional GI Disorders Patient-Focused Drug Development](#), **May 11, 2015**, in Silver Spring, MD.

Medical Devices

[Public Workshop—Optimizing FDA's Regulatory Oversight of Next-Generation Sequencing Diagnostic Tests Public Workshop](#), **February 20, 2015**, in Silver Spring, MD.

[FDA-Hosted Webinar: Overview of Medical Device Data Systems, General Wellness Devices, and Medical Device Accessories](#), **February 24, 2015**, online.

Advisory Committees

[February 20, 2015: Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee](#) (to discuss premarket approval of a spine-spacing device)

[February 23–24, 2015: Pharmacy Compounding Advisory Committee](#) (to discuss proposed revisions to the list of drug products that may not be compounded under the exemptions provided by the FDCA because the drug products have been withdrawn or removed from the market for reasons of safety or effectiveness)

[February 24, 2015: Joint Meeting of the Dermatologic and Ophthalmic Drugs Advisory Committee and Ophthalmic Devices Panel of the Medical Devices Advisory Committee Meeting](#) (to discuss an NDA for combination products used to treat progressive keratoconus or corneal ectasia following refractive surgery)

[February 27, 2015: General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee Meeting](#) (to discuss information regarding the premarket approval application panel-track supplement to expand the indication for use of an injectable implant device to include subdermal implantation for hand augmentation to correct volume deficit in the hands)

[March 4, 2015: Vaccines and Related Biological Products Advisory Committee Meeting](#) (to

discuss and make recommendations on the selection of strains to be included in the influenza virus vaccines for the 2015–2016 influenza season)

[March 4, 2015: Science Board to the FDA Meeting](#) (to provide the Board with progress reports on certain activities and to seek input regarding approaches to regulatory science training coordination)

[March 9, 2015: Dermatologic and Ophthalmic Drugs Advisory Committee](#) (to discuss an NDA for a cytolytic drug for treatment of submental fat in adults and to discuss development of systemic pediatric treatments for atopic dermatitis that does not respond to topical therapies)

[March 18, 2015: Anesthetic and Analgesic Drug Products Advisory Committee Meeting](#) (to discuss an NDA for treatment to reverse moderate or deep neuromuscular blockade induced by rocuronium or vecuronium)

[March 19, 2015: Joint Meeting of the Pulmonary-Allergy Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee](#) (to discuss a supplemental NDA for daily maintenance treatments for asthma)

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 Drug and Device Approvals/Clearances

[FDA approves Lucentis to treat diabetic retinopathy in patients with diabetic macular edema](#) (February 6, 2015)

[FDA approves TissuGlu, first tissue adhesive for internal use](#) (February 4, 2015)

[FDA approves Ibrance for postmenopausal women with advanced breast cancer](#) (February 3, 2015)

[FDA expands uses of Vyvanse to treat binge-eating disorder](#) (January 30, 2015)

[FDA expands approved use of Imbruvica for rare form of non-Hodgkin lymphoma](#) (January 29, 2015)

[FDA takes steps to improve reliability of automated external defibrillators](#) (January 28, 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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PHARMACEUTICAL & MEDICAL DEVICE REGULATORY UPDATE

Top News

House Committee Considers 21st Century Cures Draft, Senate Coordinates Sister Bill

In January 2015, the House Energy and Commerce Committee released a [discussion draft](#) of the 21st Century Cures Act, a bipartisan bill aimed at overhauling how FDA regulates drugs and devices, which builds on an effort known as the 21st Century Cures Initiative. The initiative launched in April 2014 and has been the subject of many congressional hearings and roundtables, as well as several white papers.

Corresponding to the release of the 21st Century Cures discussion draft, two top Republicans from the Senate Health, Education, Labor and Pensions ("HELP") Committee released "[Innovation for Healthier Americans](#)," a report aimed at "identifying and advancing specific steps to better align public policy to support medical innovation and patient access to new medicines and technologies," focusing primarily on ways to improve FDA and the National Institutes of Health ("NIH"). The report, which calls for stakeholder feedback by February 23, 2015, was a precursor to a [February 3, 2015 announcement](#) from Senators Lamar Alexander (R-TN) and Patty Murray (D-WA), the Chairman and Ranking Member of the Senate HELP Committee, that they are launching a bipartisan initiative to examine the process for providing safe treatments, devices, and cures to patients and the roles of the FDA and NIH in that process. Similar to the work done on the 21st Century Cures Initiative, the senators are creating a bipartisan working group and plan to hold a series of hearings. Any resulting legislation will likely

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complement the House's intended 21st Century Cures Act.

The lengthy and long-anticipated 21st Century Cures Act discussion draft addresses regulation of drugs and biologics with an eye toward speeding up approvals (Title I); enhancing discovery and development of new treatments (Title II); changes to the clinical trial process (Title III); reforms for NIH and FDA related to research, hiring, and succession planning (Title IV); and revamping certain aspects of medical device regulation (Title V). A summary of each title is provided below.

Title I. Title I would require FDA to include patient experience data when assessing the risks and benefits of certain therapies and to issue guidance describing the use of surrogate endpoints in the drug-approval process. In addition, it would permit FDA to give early approval to breakthrough therapies and provide a new pathway for approving antibiotics based on the limited and specific patient populations who need them. Another provision of this title seeks to ease patient access to drugs outside of approved clinical trials, commonly referred to as "compassionate use." In order to accelerate new cures for high-need populations, the bill would provide funds to repurpose already-approved drugs for new indications and "streamline" data review for such applications. Title I would also expand exclusivity for several categories of drugs, including new antibiotics, orphan drugs, and certain new drug products if they have an added patient or public health benefit over a previously approved version of the same drug. Perhaps most controversial, one discussion draft proposal would provide up to 15 years of marketing exclusivity for drugs that petition for and receive designation from the Department of Health and Human Services ("HHS") as a "[dormant therapy](#)."

Title II. Title II of the draft bill would create an "Innovative Cures Consortium," broader than, but based on, the EU's Innovative Medicines Initiative, to pool the resources of industry, government, and academia to accelerate cure development and delivery by nongovernment entities. Under this title, FDA would be required to issue guidance on accelerating certain therapies, including regenerative medicine and genetic technologies for rare diseases. Title II also proposes definitions for "health software" and related terms that would be incorporated into the Federal Food, Drug, and Cosmetic Act ("FDCA"), which does not currently define these terms. The discussion draft also contains a notation indicating that the drafters are struggling with how to ensure that the definition does not inadvertently exempt products that should be regulated. Data sharing is another key aspect of the draft bill. Title II would

require increased data sharing from entities receiving federal funding (through federally funded health insurance programs or NIH grants, for example) and would establish a data-sharing framework to enhance patient treatment and care. The proposed draft legislation would also call for FDA to issue guidance on the coordination of regulatory activities for combination products. The discussion draft contains placeholders for subtitles that would address regulation of diagnostic devices and health care data interoperability, but no further details are available yet.

Title III. Title III focuses on clinical trials and the challenges of balancing the protection of human subjects and resource efficiency for those conducting the trials. One way the bill addresses these challenges is by encouraging the use of adaptive clinical trials, which use prospectively designed benchmarks as decision points to make study design changes. The draft bill would require HHS to provide assistance to any federal agency trying to improve oversight of human subject research, particularly with regard to vulnerable populations. Provisions in this title would also provide a mechanism for FDA to periodically evaluate post-approval studies, taking into account any recent changes in medical practice. Finally, Title III would establish a global pediatric clinical trial network to engage with foreign regulatory entities and share knowledge on pediatric research.

Title IV. Title IV puts a greater focus on the various agencies involved in the discovery, development, and delivery of therapeutic products. Title IV contains proposals to increase research funding for and decrease the administrative burdens on NIH. The discussion draft seeks to accelerate vaccine approval by proposing a 180-day standard timeline and an expedited review process for the Centers for Disease Control and Prevention ("CDC") to evaluate vaccines. Title IV also contains significant proposals related to FDA. It would create a process for FDA to designate eligible infectious diseases for priority review vouchers at least every five years and calls on FDA to issue final guidance on changes to approved biologics. The discussion draft also includes a succession-planning provision addressing how FDA should handle retirements of critical personnel and would promote professional development throughout FDA. The discussion draft also proposes revisions to the Sunshine Act, namely, exempting certain industry-sponsored educational activities from reporting requirements. A provision addressing telemedicine would improve the delivery of health care to Medicare beneficiaries. Title IV contains several other provisions relating to Medicare, which is not the focus of this publication. Finally, this title proposes to ease restrictions on experimental

medical devices, subject to listing and informed consent requirements, among others.

Title V. Title V concentrates primarily on medical devices but also contains provisions related to drugs. Certain drugs and biosimilars designated as "American-Manufactured" would be granted an exclusivity extension of undetermined length. Title V would also require FDA to update its Good Manufacturing Practices guidance for drug products. Concerning medical devices, the discussion draft would extend FDA's use of third-party device reviews to two new areas: facility inspections and the assessment and certification of "a facility's capability to evaluate and implement" modifications to approved or cleared devices. Title V also creates premarket notification requirements for Class I devices, relaxes requirements for predicate device indications and humanitarian device exemptions, proposes changes to the classification review process, and sets out supply chain security measures for medical devices similar to those enacted for drugs in 2013. Finally, the draft bill would define "valid scientific evidence" in the medical device context, would require FDA to decide whether to recognize medical device standards developed by outside organizations within 60 days of publication, and would direct FDA to train medical device regulators to use the "least burdensome approach," including publishing updated guidance on the subject.

Although the discussion draft from the 21st Century Cures Initiative is not a formal legislative proposal, the 350-page document has the appearance of a bill in most respects, save a few placeholders and notes. Going forward, the committee will collect comments on the draft and will likely take up the legislation later this year.

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