LATHAM&WATKINS

Client Alert
News Flash

Latham & Watkins Healthcare & Life Sciences Practice

December 13, 2016 | Number 2051

# President Obama Signs the 21st Century Cures Act Into Law

***The act creates faster, more flexible FDA drug and biologic review, new drug and device approval pathways, increases FDA funding, and reduces EHR administrative burdens.***

On December 13, 2016, President Obama signed into law the 21st Century Cures Act (the Act), which Congress passed with strong bipartisan support. The Act increases mechanisms for the US Food and Drug Administration (FDA) to expedite approval of novel drugs and devices, provides new incentives for developing such products, and directs the US Department of Health and Human Services (HHS) to decrease the administrative burden of electronic health records (EHRs) and increase EHR interoperability. The Act authorizes a number of new and revised approval pathways, and requires FDA to issue several new guidance documents to assist industry in developing new drugs, biologics and devices. Additionally, the Act contains a provision intended to expand the off-label promotion safe harbor for certain manufacturer communications of healthcare economic information to payors, as well as provisions narrowing FDA's jurisdiction over medical software. The Act provides increased funding to the National Institutes of Health (NIH) and FDA to implement the Act's provisions; however, the funding levels have been criticized by some as insufficient.

This article provides a summary of the provisions we believe will have the most significant impact on the pharmaceutical, biotechnology and medical device industries, as well as healthcare providers and healthcare information technology (HIT) developers, including:

- Providing new or modified approval pathways for regenerative medicine therapies and associated devices, breakthrough medical devices, combination products, drug development tools, antimicrobial drugs that treat rare pediatric diseases, and medical countermeasures
- Providing for faster, more flexible FDA review and requiring FDA to issue new guidance on considering patient experience data, real world evidence, and qualified data summaries in drug and biologic application reviews
- Clarifying how drug companies can convey economic information to purchasers, and exempting five categories of medical software from FDA regulation as medical devices
- Providing US$4.8 billion in increased funding for NIH and US$500 million in increased FDA funding, and expanded authority and capacity for both agencies to distribute grants, hire technical talent, and improve internal and external collaboration
- Instructing the HHS to reduce the administrative and regulatory burden of EHRs and increase EHR interoperability

Given the number of new regulatory programs that the Act authorizes, we anticipate a long process for the agencies' implementation, and many opportunities for industry input.

## New or Modified Drug and Biologic Approval Pathways

The Act creates or significantly modifies several FDA approval pathways for drugs and biologic products:

- **Priority Review and Accelerated Approval Pathways for Regenerative Therapy Products:** Section 3033 of the Act allows FDA to grant priority review and accelerated approval to drugs or biologics FDA designates as regenerative advanced therapies. Regenerative advanced therapies are defined as regenerative medicine therapies intended to treat a serious or life-threatening disease or condition, for which there is preliminary clinical evidence to indicate that the drug has the potential to address unmet medical needs for such a disease or condition. Regenerative medicine therapies are defined as cell therapies; therapeutic tissue engineering products; human cell and tissue products; and combination products using any such therapies or products, except for human cellular and tissue-based products regulated solely under section 361 of the Public Health Service (PHS) Act and part 1271 of C.F.R. title 21. Sponsors of designated regenerative advanced therapies are eligible for priority review and accelerated approval through either "surrogate or intermediate endpoints" or "reliance upon data obtained from a meaningful number of sites, as appropriate."

- **Drug Development Tools (DDTs) Review Pathway:** Building on FDA's Drug Development Tools Qualification Program used to qualify new biomarkers, clinical outcome assessments and other DDTs, Section 3011 requires FDA to establish an official review pathway for DDTs to support drug or biologic marketing approval or investigational use. For biomarkers, FDA must issue guidance within three years of enactment describing the qualification review process and establishing a taxonomy of biomarkers for use in drug development.

- **Summary Review for New Indications:** Section 3031 allows FDA to rely upon "qualified data summaries" to support the approval of a new indication for a previously approved drug or biologic. A "qualified data summary" is defined as a summary of clinical data that demonstrates the safety and effectiveness of a drug with respect to a qualified indication; a qualified indication is a drug indication that FDA determines to be appropriate for summary-level review. Under the provision, a supplemental application is eligible for summary-level review if there are acceptable, existing data that demonstrate the drug's safety and effectiveness. All data used to develop the qualified data summaries must be submitted to the agency as part of the supplemental application. FDA must annually publish information regarding the number of summary review applications reviewed and average review time for such applications. While this provision is intended to expedite the approval process for new indications for previously approved drugs, the Act provides FDA with wide discretion to define the contours of the approval process. How FDA will implement this process remains to be seen.

- **Priority Review Voucher (PRV) Programs:** Section 3013 reauthorizes the Priority Review Voucher (PRV) program for rare pediatric diseases through 2020. A drug designated as a drug for a rare pediatric disease by September 30, 2020, and approved by September 30, 2022, may receive a voucher. The FDA strongly opposed reauthorization of this program, which was set to expire at the end of 2016, based on concerns that the program adversely affects the agency's ability to set and execute public health priorities and strains agency resources, with no evidence the program is effective in incentivizing drug development for rare pediatric diseases. Section 3086 also creates a PRV program for drug or biologic applications for products that qualify as material threat medical countermeasures to prevent or treat harm from a biological, chemical, radiological or nuclear agent, or mitigate harm from a treatment related to those agents.

- **Antimicrobial Limited Population Approval Pathway and Reporting:** Section 3042 allows FDA to approve an antibacterial or antifungal drug as a limited population drug if the drug is intended to treat a serious or life-threatening infection in a limited population of patients with unmet needs, based on the overall benefit-risk profile of such a drug in the intended limited population. The drug's labeling and advertising must prominently include a "Limited Population" statement, and the sponsor must submit to FDA copies of all promotional materials at least 30 calendar days before disseminating those materials. Within 18 months of enactment, FDA must issue draft guidance on the approval criteria and processes for limited population antimicrobial drugs.

## New or Modified Device Approval Pathways

The Act creates or significantly modifies several FDA approval pathways for devices:

- **Breakthrough Device Approval Pathway:** Building on the existing Expedited Access Pathway for devices, Section 3051 requires FDA to establish a program to expedite developing and reviewing devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. Eligible devices must represent breakthrough technologies that offer significant advantages over existing approved or cleared alternatives. FDA must issue guidance on implementing this pathway within one year of enactment.

- **Devices with Regenerative Therapy Products:** Section 3034 requires FDA to issue draft guidance within one year of enactment addressing how FDA intends to streamline the regulatory requirements for devices used with regenerative therapeutic products. Under this section, qualifying devices will be considered Class II moderate risk devices unless FDA determines that the intended use or specific attributes of the device would result in a Class III classification.

- **Combination Product Review Changes:** Under Section 3038, FDA must assign primary responsibility for reviewing a combination product to an FDA Center based on whether the combination product's primary mode of action is either a drug, biologic or device. If a combination product sponsor disagrees with FDA's primary mode of action determination, the Act permits the sponsor to request that FDA provide a substantive rationale for its determination. The sponsor can propose one or more studies to establish the relevance of the chemical action in achieving the product's primary mode of action; and, FDA and the sponsor will collaborate to reach agreement on the design of such studies within 90 calendar days. If the sponsor conducts the agreed-upon studies, FDA must consider the resulting data when reevaluating the product's primary mode of action. FDA must issue final guidance regarding this pre-submission process within four years of enactment.

- **Humanitarian Device Exemption:** Section 3052 raises the population cap on FDA's authority to grant a humanitarian device exemption from 4,000 affected individuals in the United States to 8,000 individuals. The provision also requires FDA to issue guidance defining the criteria for establishing "probable benefit" under the exemption within 18 months of enactment.

- **In Vitro Diagnostic CLIA Waivers:** Section 3057 requires FDA to revise its 2008 guidance on Clinical Laboratory Improvements Amendments of 1988 (CLIA) waivers for in vitro diagnostics within one year of enactment. This provision directs FDA to clarify the appropriate use of comparable performance between a waived user and a moderately complex laboratory user, to demonstrate accuracy.

## Other Programs and Incentives for Device Development

**Medical Device Review Standards and Classification Changes.** Section 3053 creates a process for third-parties to request that FDA recognize standards established by nationally or internationally recognized standards organizations for the purpose of medical device review. Within 60 calendar days of receiving a request for recognition, FDA must render a decision and publish the rationale for its decision. Section 3055 provides device sponsors the opportunity to make recommendations regarding the expertise needed on classification panels. Section 3054 requires FDA to update and publish its lists of 510(k)-exempt Class I and Class II devices within 120 and 210 days of enactment, respectively.

**Guidance on 510(k) Requirement for Device Modifications:** Section 3059 requires FDA to issue final guidance regarding when a 510(k) premarket notification is required to be submitted for a modification or change to a legally marketed device. This final guidance must be issued within one year after the date on which the comment period closes for the draft guidance.

**Human Subject Protection and Institutional Review Boards for Device Trials:** Section 3023 requires the Secretary of HHS to harmonize the differences between the HHS and FDA Human Subject Regulations, to avoid regulatory duplication and allow multi-site trials to use joint or independent IRB review. Section 3024 gives FDA the same flexibility that HHS and NIH have under the Common Rule to waive or alter informed consent requirements for trials with minimal risk. Section 3056 removes the requirement that device sponsors must use a local Institutional Review Board (IRB) for clinical trials to allow use of centralized models.

## Faster, More Flexible FDA Review and Modernized Clinical Trial Design Requirements

**Inclusion of "Patient Experience Data":** Effective for approvals granted 180 days after enactment, Section 3001 requires FDA to issue a brief public statement regarding any patient experience data and related information submitted and reviewed as a part of a §505(b) drug or §351(a) biologic approval. This includes data collected by patients and their families; patient advocacy organizations; disease research foundations; researchers; or drug manufacturers, intended to provide information about patients' experiences with a disease or condition, including the impact of the disease, or related therapy, on patients' lives and patient treatment preferences. Sec. 3002 requires FDA, within 18 months of enactment, to issue draft guidance addressing the collection of patient experience data and its use in informing regulatory decision-making.

**Consideration of "Real World Evidence":** Under Section 3022, FDA must establish a program to evaluate the potential use of real world evidence to support the approval of new indications for previously approved drugs, and to support or satisfy post-approval study requirements. Real world evidence is defined as data regarding the usage, risks or benefits of a drug derived from sources other than randomized clinical trials. FDA must establish a draft framework for a real world evidence program within two years and issue guidance within five years of enactment.

**Complex Adaptive Trial Design Meeting and Guidance:** Building on draft guidance issued in February 2010, Section 3021 requires FDA to hold a public meeting within 18 months of enactment, and to issue new guidance addressing the use of complex adaptive and other novel clinical trial designs in new drug and biologic applications. The guidance must address how such novel trial designs can satisfy the §505(d) substantial evidence standard for FDA approval of drug products; how sponsors can obtain feedback on technical modeling and simulation issues; the types of qualitative and quantitative information that should be submitted for review; and recommended analysis methodologies.

**Least Burdensome Review Training and Revisions:** Section 3058 requires FDA to conduct an audit within 18 months of enactment to ensure all FDA employees involved in reviewing premarket submissions are adequately trained regarding the meaning and implementation of least burdensome review requirements. FDA must publish a final audit report within 30 calendar days of audit completion. This section also clarifies that FDA must consider the least burdensome means necessary when requesting additional information for reviewing premarket approval applications.

**Publicly Available Expanded Access Policy:** Section 3032 requires the manufacturer or distributor of one or more investigational drugs to make their compassionate use policy publicly available by the later of 60 calendar days after enactment or the first initiation of a Phase 2 or Phase 3 study of the drug.

**Drug Surveillance Program Edits:** Section 3075 makes targeted edits to FDA's drug surveillance program, including requiring FDA to publish best practices in using the Adverse Event Reporting System for drug and biologic product safety surveillance activities.

## Clarification of FDA Jurisdiction

**Healthcare Economic Information:** Section 3037 classifies as not false or misleading certain healthcare economic information when the manufacturer of the product conveys that information to a payor, formulary committee, or other similar entity with knowledge and expertise in the area of healthcare economic analysis, carrying out its responsibilities for the selection of drugs for coverage or reimbursement. Such information will not be considered false or misleading if it relates to an approved indication; is based on competent and reliable scientific evidence; and includes, where applicable, a conspicuous and prominent statement describing any material differences between the healthcare economic information and the drug or biologic's approved labeling. This provision expands on the off-label promotion safe harbor for healthcare economic information that Congress added to the US Federal Food, Drug, and Cosmetic Act as part of the 1997 Food and Drug Administration Modernization Act, and which FDA has yet to interpret publicly.

**Medical Software Safe Harbors from Device Regulation:** Driven by concerns that FDA will over-regulate healthcare information technology (HIT) by classifying new software technology as a regulated device, Section 3060 identifies five specific categories of medical software that will not be considered medical devices. These five categories are software that are:

- For administrative support of a healthcare facility. This includes processing and maintaining financial records; claims or billing information; appointment schedules; business analytics; information about patient population; admissions; practice and inventory management; analysis of historical claims data to predict future utilization or cost-effectiveness; health benefit eligibility determination; population health management; and laboratory workflow

- For maintaining or encouraging a healthy lifestyle, unrelated to the diagnosis, cure, mitigation, prevention or treatment of a disease or condition

- To serve as electronic patient records, including patient-provided information, to the extent such records are intended to transfer, store, convert formats or display the equivalent of a paper medical chart, so long as such records were:

    - Created, stored, transferred or reviewed by healthcare professionals or individuals working under a healthcare professional's supervision

    - A part of certified health information technology

- Such function is not intended to analyze patient records, including medical image data, for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;

- For transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results, findings by a healthcare professional with respect to such data and results, general information about such findings, and general background information about such laboratory test or other device, unless such function is intended to interpret or analyze clinical laboratory test or other device data, results, and findings; or

- For displaying, analyzing or printing medical information; supporting or providing recommendations to a healthcare professional regarding diagnosis or treatment; or enabling the independent review of such recommendations, as long as the software is not intended to process or analyze medical images or signals from an in vitro diagnostic device or signal acquisition system

These provisions provide greater detail for implementing the above categories, including exceptions if FDA makes a finding that use of such software would be reasonably likely to have adverse health consequences and FDA publishes a notification for such a finding, including the rationale, and allows for at least 30 calendar days of public comment.

## Medical Countermeasures, Vaccines and Other Changes

**Medical Countermeasures Budgeting and Review.** Section 3083 requires HHS to annually develop a five-year budget plan that addresses identified medical countermeasure priorities, including with respect to chemical, biological and nuclear agents; novel or emerging infectious diseases; and the corresponding efforts to develop qualified countermeasures, security countermeasures, and pandemic and epidemic products.

**Advisory Committee on Immunization Practices (ACIP) Review.** Sections 3091 clarifies the timeline for ACIP review following FDA licensure of any vaccine or new indication for a vaccine. Section 3092 requires the Centers for Disease Control and Prevention (CDC) to conduct a review of ACIP vaccine review processes.

**Reusable Medical Devices.** Section 3059 requires FDA, within 180 days of enactment, to identify and publish a list of reusable medical devices for which 510(k) reports must include validated instructions for use and validation data regarding cleaning, disinfection and sterilization, and on which a substantial equivalence determination may be based.

## Increased FDA and NIH Funding and Hiring Authority

**Increased FDA and NIH Funding.** Section 1002 establishes the FDA Innovation Account and provides FDA with US$500 million to implement the initiatives described above. The Act also creates the NIH Innovation Account and appropriates US$4.8 billion to this account over 10 years, beginning in Fiscal Year (FY) 2017. The US$4.8 billion is allocated to the following initiatives: the Precision Medicine Initiative (US$1.4 billion); the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative (US$1.6 billion); cancer research (US$1.8 billion); and regenerative medicine using adult stem cells (US$20 million). This US$5.3 billion in funding is discretionary, rather than mandatory, meaning Congress must approve withdrawals from these accounts each year through the appropriations process. Many commenters have expressed concern, however, that this US$500 billion FDA appropriation is not enough to cover FDA's additional responsibilities under this Act. The Act also contains several provisions that expand FDA's ability to hire and retain employees, with a focus on scientific and technical expertise, and

requires FDA to establish one or more pilot Intercenter Institute(s) for a major disease area or areas, within one year of enactment.

**NIH Strategic Plan and Administrative Review.** The Act includes several changes to the NIH's authority that are directed toward increasing access to NIH funds and reducing administrative burden, such as:

- Granting NIH the authority to support high-risk, high-reward research through transactions other than contracts, grants or cooperative agreements, for projects that are a part of the Precision Medicine Initiative, and for up to 50% of the funds available in the NIH Common Fund
- Granting the National Center for Advancing Translational Sciences the authority to conduct and distribute grants through the end of Phase 2-B of development (previously, this authority was limited to through Phase 2-A)
- Requiring the Office of Management and Budget (OMB) to establish the Research Policy Board to recommend changes to research regulations that would minimize administrative burden

## Reducing the Burden of Maintaining Electronic Health Records (EHRs)

The Act includes several changes intended to identify and decrease the regulatory and administrative burdens associated with EHRs, including:

**Development of EHR Strategy.** Within one year of enactment, HHS, in consultation with industry stakeholders, must develop a strategy for reducing the regulatory and administrative burdens of using EHRs. The strategy must prioritize Meaningful Use incentives; EHR incentive payments to Medicaid providers; HIT certification; and various alternative payment models and systems, including the Merit-Based Incentive Payment System and the Value-Based Purchasing Program.

**Physician Delegation of CMS Documentation Requirements.** Section 13103 clarifies the circumstances in which physicians, consistent with applicable state law, may delegate EHR documentation requirements in Centers for Medicare and Medicaid Services (CMS) regulations to non-physician personnel performing a scribe function — provided the physician has signed and verified the documentation.

**HIT Certification for Medical Specialties and Sites of Service.** Section 13103 requires ONC to encourage or recognize voluntary HIT certification for use in medical specialties and sites of service for which no such technology is available, or where more technological advancement or integration is needed. The provision also requires HHS to adopt voluntary HIT certification for pediatric healthcare providers within two years of enactment.

**Meaningful Use Attestation Statistics.** Starting within six months of enactment, section 4001 requires HHS to submit a quarterly report to the ONC HIT Advisory Committee summarizing Medicare and Medicaid Meaningful Use attestation statistics to assist in informing standards adoptions.

**Significant Hardship Exemptions from Meaningful Use.** Under Section 4002, HHS must exempt eligible professionals and hospitals from Meaningful Use payment adjustments if compliance is not possible because the professionals' and hospitals' certified EHR technology has been decertified under an ONC-recognized program.

## Improving Access through New EHR Interoperability Standards, Reports and Studies

The Act includes several changes intended to improve patient access and EHR interoperability, such as:

**New Enforcement Powers against Information Blocking.** Section 4004 authorizes the HHS Office of Inspector General (OIG) to investigate claims that an HIT developer, healthcare provider or health information exchange (HIE) engaged in information blocking. Information blocking is a practice that interferes with, prevents or materially discourages the ability of authorized persons to access, exchange or use EHRs. Prohibited information blocking practices include charging unreasonable fees, contractually agreeing to restrict an authorized exchange, and developing or implementing HIT likely leading to fraud or waste. Any HIT developer, entity offering certified HIT, or HIE that OIG determines to have committed information blocking is subject to civil monetary penalties, not exceeding US$1 million per violation, and providers will be referred to the appropriate agency to be subject to appropriate disincentives under applicable law.

**Interoperability Attestations for ONC Certification.** Section 4002 requires the Secretary to develop new interoperability standards for ONC certification within one year of enactment and through notice and comment rulemaking. These standards are intended to eliminate barriers to data exchange, and will be required as a condition of ONC certification. An HIT developer or entity will be required to attest that it:

- Does not or will not engage in information blocking or any other action that may inhibit the appropriate exchange, access and use of electronic health information unless for legitimate purposes specified by the Secretary
- Does not prohibit or restrict communication regarding HIT usability, interoperability, security or relevant information regarding user experience; the business practices related to exchanging electronic health information; and the manner in which an HIT user has used such technology
- Has published Application Program Interfaces (APIs) and allows health information from such technology to be accessed, exchanged and used without special effort, including providing access to all data elements of a patient's EHR to the extent permissible under privacy laws
- Has successfully tested the real-world use of the technology for interoperability in the setting in which such technology would be marketed

**Increasing Interoperability.** Section 4003 requires the ONC, in consultation with the National Institute of Standards and Technology (NIST) and stakeholders, to create a voluntary framework and agreement for the secure exchange of health information.

**EHR Reporting System.** Section 4002 creates a grant program to establish an EHR reporting system that will help providers choose EHR products. Within one year of enactment, HHS must convene relevant stakeholders to develop reporting criteria that will include categories such as security, usability and user-centered design, conformance to certification testing, and other appropriate categories for measuring the performance of EHR technology. The reporting criteria must be designed as to not unduly burden small and startup HIT developers.

**Patient Access to EHRs.** HHS is required to issue guidance to HIEs regarding best practices for patient access to EHRs, ensuring that electronic health information provided to patients is private, secure, accurate, verifiable, and that required patient authorizations are easily exchanged. Section 4007 requires

the GAO to study patient matching and barriers to patient access to their own electronic health information.

## Medicare and Medicaid Changes

The Act also includes a number of Medicare and Medicaid changes, including important reimbursement changes for providers of infusion drug therapy and durable medical equipment suppliers:

- The Act accelerates to January 1, 2018, the planned implementation of the Medicaid reimbursement limitation for durable medical equipment (DME), which was previously scheduled to take effect January 1, 2019, and will cap Medicaid reimbursement at Medicare payment amounts.

- In contrast, the Act extends by six months the transition period under which the Medicare program is reducing reimbursement rates for DME on a nationwide basis according to payment amounts set through the DMEPOS Competitive Bidding Program.

- The payment amount for Part B drugs infused through DMEPOS items is changed to Average Sales Price (ASP) plus 6%, rather than an amount based on the manufacturers' Average Wholesale Price.

- A new payment system for home infusion services will be established beginning in 2021 to reimburse home infusion services providers for the professional services and monitoring services associated with home infusions (including nursing services), which are not currently separately paid by Medicare.

- Medicare Administrative Contractors (MACs) must publish local coverage determinations and explanations concerning coverage decisions at least 45 days before the effective date of that determination, beginning 180 days after enactment.

- The Act creates a new Pharmaceutical and Technology Ombudsman within CMS to address the coverage, coding and payment concerns of pharmaceutical, biotechnology, medical device and diagnostic product manufacturers.

- Starting in 2018, HHS must publish the prices of items and services that are available in hospital outpatient departments or ambulatory surgical centers. This site-of-service price transparency aims to allow seniors to better control their out-of-pocket costs.

- The Act does not expand telehealth coverage. Rather, the Act provides that CMS and MedPAC must submit information to Congress regarding the current use of telehealth services in Medicare and Medicaid, and how telehealth services can be expanded going forward.

## Conclusion

The 21st Century Cures Act was passed with strong bipartisan support in both houses of Congress and consistent backing from the White House. The Act delegates to FDA significant authority to implement new or significantly changed approval pathways for drugs, biologics and devices, and provides US$500 million to FDA to implement these changes. The Act also instructs HHS to develop a strategy for reducing the administrative and regulatory burden of EHRs and increase EHR interoperability. Drug, biologic and device sponsors should consider how these changes affect their regulatory strategies, and engage with FDA in its implementation of these new policies. Providers and HIT developers should likewise engage with HHS and the ONC to shape the coming EHR reporting and interoperability changes, and consider how the Medicare and Medicaid changes impact their operations and reimbursements.

If you have questions about this *Client Alert*, please contact one of the authors listed below or the Latham lawyer with whom you normally consult:


**John Manthei**
john.manthei@lw.com
+1.202.637.2211
Washington, D.C.

**Dan Meron**
daniel.meron@lw.com
+1.202.637.2218
Washington, D.C.

**Stuart Kurlander**
stuart.kurlander@lw.com
+1.202.637.2169
Washington, D.C.

**J. Benneville Haas**
ben.haas@lw.com
+1.202.637.1084
Washington, D.C.

**Nicole Liffrig Molife**
nicole.liffrig@lw.com
+1.202.637.2121
Washington, D.C.

**Eric Greig**
eric.greig@lw.com
+1.202.637.3330
Washington, D.C.

**Susan Ambler Ebersole**
susan.ebersole@lw.com
+1.202.637.1016
Washington, D.C.

**Morgan Rettig**
morgan.rettig@lw.com
+1.202.637.2163
Washington, D.C.

**Barrett Tenbarge***
barrett.tenbarge@lw.com
+1.202.637.2288
Washington, D.C.

**** Barrett Tenbarge is an associate in Latham and Watkins' Washington D.C. office and is licensed to practice law in Indiana only. All of his work is supervised by a member of the D.C. Bar.***


**You Might Also Be Interested In**

**Amarin Settles Off-Label Promotion Case Against the FDA**

**CMS Finalizes Long-awaited Rule Implementing ACA's Overpayment Reporting Requirements**

**Perspective on Ground-Breaking Settlement Between Pacira and the FDA**

**Lessons From Latham & Watkins' Representation of Pacira Pharmaceuticals in Ground-Breaking Settlement With FDA**