

# Quarterly Roundup

April - June 2015

As a service to clients of Covington & Burling, below is a compilation of recently issued e-alerts and advisories. Please feel free to share within your organization and to let us know if you would like more information on any of the topics addressed.

## Publication Topics

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### Africa

Anti-Corruption

Antitrust & Competition Law

Communications & Media

Competition

Employment

Employee Benefits

Financial Services

Financial Institutions

Food & Drug

### Government Contracts

Health Care

Insurance

Intellectual Property

International Trade

Controls

Life Sciences

Litigation

Mergers & Acquisitions

### Middle East

Privacy & Data Security

Public Policy & Government Affairs

Section 337

Securities & Capital Markets

Securities Litigation

Tax

White Collar

## Publications

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### Africa

- "Conflict Minerals: The European Parliament Aims to Introduce an EU Mandatory Regime," (5/22/2015)

### Anti-Corruption

- "BHP Billiton Pays \$25 Million to Settle FCPA Allegations Relating to the Sponsorship of Officials at the 2008 Olympic Games," (5/27/2015)
- "Unlocking a Mystery of China Compliance: Fapiaos," (5/21/2015)
- "Brazil's Much Anticipated Decree to Further Combat Corruption Takes Effect," (4/22/2015)

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## **Antitrust & Competition Law**

- ["Belgian Competition Authority Imposes Record Fines - Exemplifies Trends in Cartel Enforcement in the European Union,"](#) (6/23/2015)
- ["China Issues Final IP / Antitrust Rules,"](#) (4/21/2015)

## **Communications & Media**

- ["FCC Enforcement Actions Demonstrate Ramifications of Failing to Cooperate in TCPA Investigations,"](#) (4/22/2015)

## **Competition**

- ["The European Commission Launches Online Commerce Sector Inquiry,"](#) (5/6/2015)

## **Employment**

- ["Labor Dispatch Arrangements in China,"](#) (6/23/2015)
- ["International Employment Update,"](#) (5/12/2015)
- ["Compulsory Health Insurance in Dubai - Update,"](#) (4/1/2015)
- ["SEC Order May Impact Employee Confidentiality Obligations,"](#) (4/1/2015)

## **Employee Benefits**

- ["SEC Order May Impact Employee Confidentiality Obligations,"](#) (4/1/2015)

## **Financial Services**

- ["Protections for Independent Directors Strengthened by Delaware Supreme Court,"](#) (5/18/2015)
- ["ESMA Consults for a Fourth Time on EMIR Clearing Obligation,"](#) (5/14/2015)
- ["Final ESMA Guidelines Clarifying Commodity Derivatives Definitions Under MiFID,"](#) (5/11/2015)
- ["FCA Seeks Input on How to Implement Conduct of Business and Organisational Requirements for MiFID II,"](#) (4/1/2015)

## **Financial Institutions**

- ["Department of Justice and Financial Regulators Win Big in Fair Housing Act Case,"](#) (6/26/2015)

## **Food & Drug**

- ["Veterinary Feed Directives: FDA Final Rule and Draft Guidance,"](#) (6/18/2015)
- ["FDA Issues Final Determination withdrawing the GRAS status of PHOs,"](#) (6/17/2015)
- ["New Draft Guidance on Veterinary Drug Compounding from Bulk Drug Substances,"](#) (6/15/2015)
- ["China Restructures its Drug Pricing Regime,"](#) (6/9/2015)
- ["FDA Releases Draft Guidance for Industry on Voluntary Qualified Importer Program for Food,"](#) (6/9/2015)
- ["Competition in the Pet Medications Industry: FTC 2015 Staff Report,"](#) (6/3/2015)
- ["China Issues Revised Food Safety Law,"](#) (5/20/2015)

- ["Court Allows Vermont's GMO Labeling Law to Go into Effect,"](#) (4/30/2015)

### **Government Contracts**

- ["HRSA Proposes Calculation of 340B Ceiling Prices, Implementation of Manufacturer Civil Monetary Penalties,"](#) (6/22/2015)
- ["Supreme Court Reverses 4th Circuit: Statute of Limitations Not Tolled During Wartime for Civil Fraud Claims,"](#) (5/27/2015)

### **Health Care**

- ["OIG Publishes New Guidance for Compliance Oversight by Health Care Boards,"](#) (5/4/2015)
- ["CMS Releases New Reimbursement Guidance for Biosimilars,"](#) (4/7/2015)

### **Insurance**

- ["UK Supreme Court Restricts Scope of "All Sums" Principle in Mesothelioma Employers' Liability Insurance Cases to Defence Costs,"](#) (6/23/2015)

### **Intellectual Property**

- ["Supreme Court Holds that TTAB Decisions May Have Preclusive Effect in Federal Court Actions,"](#) (4/2/2015)

### **International Trade Controls**

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- ["State and Commerce Departments Propose Revisions of Key Export Control Definitions,"](#) (6/12/2015)
- ["Iran, Global Powers Agree to Parameters for Long-Term Nuclear Deal,"](#) (4/3/2015)

### **Life Sciences**

- ["OIG Publishes New Guidance for Compliance Oversight by Health Care Boards,"](#) (5/4/2015)

### **Litigation**

- ["U.S. Supreme Court To Address Plaintiffs' Ability To Sue For Violations Of Federal Law, Including The FCRA, Despite Suffering No Concrete Harm,"](#) (4/28/2015)

### **Mergers & Acquisitions**

- ["Protections for Independent Directors Strengthened by Delaware Supreme Court,"](#) (5/18/2015)

### **Middle East**

- ["Investment Opportunities in Kuwait,"](#) (5/28/2015)

### **Privacy & Data Security**

- ["The EUs Digital Single Market Strategy,"](#) (5/6/2015)
- ["FCC Enforcement Actions Demonstrate Ramifications of Failing to Cooperate in TCPA Investigations,"](#) (4/22/2015)

### **Public Policy & Government Affairs**

- ["Reshuffle of Directors-General at European Commission,"](#) (6/25/2015)

- ["Congressional Investigations and the Life Sciences Industry,"](#) (6/25/2015)
- ["Financial Services Industry Congressional Investigations,"](#) (4/17/2015)

### **Section 337**

- ["Federal Circuit Requires Complainants to 'Do the Math' in Domestic Industry Analysis,"](#) (5/13/2015)

### **Securities & Capital Markets**

- ["SEC Proposes 'Pay for Performance' Disclosure Rule,"](#) (5/1/2015)

### **Securities Litigation**

- ["SEC Order May Impact Employee Confidentiality Obligations,"](#) (4/1/2015)

### **Tax**

- ["Tax Newsletter,"](#) (April 2015)

### **White Collar**

- ["Supreme Court Reverses 4th Circuit: Statute of Limitations Not Tolled During Wartime for Civil Fraud Claims,"](#) (5/27/2015)
- ["Financial Services Industry Congressional Investigations,"](#) (4/17/2015)
- ["SEC Order May Impact Employee Confidentiality Obligations,"](#) (4/1/2015)

## **Blogs**

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- [Africa's Tripartite Agreement: Another Step toward Integration?](#)
- [Nigeria Sends Clear Signal of Getting Serious about Tax Enforcement](#)
- [Kaberuka's Last AfDB Annual Meeting Begins and Ends on High Notes](#)
- [President Adesina and the Years Ahead for the African Development Bank](#)
- [What the Home Battery Could Mean for Africa](#)
- [AGOA Should Do More to Strengthen Intellectual Property in Africa's Creative Sectors](#)
- [AGOA moves forward: Reviewing last week's reauthorization in the U.S. Senate](#)
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- [Competing smarter: Assessing the report from the President's Advisory Council on Doing Business in Africa](#)

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### **CovBrands**

- [German Federal Supreme Court confirms successor liability for coffee roasters in spite of corporate restructuring](#)
- [FTC Announces First Consent Order With a Retail Tracking Company](#)

### **InsideCompensation**

- [ERISA Advisory Council Considers Model Lump Sum Window Disclosures](#)
- [More Guidance on New Cost-Sharing Limit](#)
- [Foreign Compensation and the Long Reach of Code Section 409A](#)
- [Recent Case Illustrates Importance of Careful Plan Drafting](#)
- [409A Correction for Unvested Amounts Clarified](#)
- [SEC Proposes "Pay for Performance" Disclosure Rule](#)
- [EEOC Proposes New Restrictions for Health Awareness Programs](#)
- [Vodafone Announces Progressive Global Maternity Policy, Touching on Two Hot Topics in Employee Benefits](#)
- [Update on Final Rule for the Family Medical Leave Act](#)
- [Supreme Court Makes New Rule in Analyzing Pregnancy Discrimination Act](#)
- [SEC Order May Prompt Employers to Review Employee Confidentiality Obligations](#)
- [IRS Issues Warning on Documentation Requirements for 401\(k\) Plans](#)

### **CovingtonHealth**

- [Department of Defense Contract To Overhaul Electronic Health Records System](#)
- [Iowa Supreme Court Strikes Down Ban on Use of Telemedicine to Prescribe Abortion-Inducing Drugs](#)
- [CMS Releases Additional Medicare Data; Expands Access to Data for "Commercial" Purposes](#)
- [21st Century Cures Act with EHR and Telehealth Provisions Passes Through Committee with Flying Colors](#)
- [Federal Court Enjoins Texas' Restrictions on Telemedicine](#)
- [May 2015 EU mHealth Round-Up](#)
- [American Medical Informatics Association Report Makes Recommendations for EHR Systems](#)
- [Several States Enact Telehealth Parity Laws in 2015](#)

- [ONC Releases Updated EPHI Guide](#)
- [New Efforts to Combat Health Information Blocking](#)
- [Moving to the Cloud: Privacy and Other Key Considerations for Healthcare Entities](#)
- [Cyber Attacks on Health Data Increasing, Primary Cause of Data Breaches, Group Finds](#)
- [CMS Releases Part D Prescriber-Level Data as Part of Larger Transparency Effort; Some Stakeholders Express Concern](#)
- [House Cures Draft Includes Provisions to Expand Access to Data, Facilitate Research](#)
- [Washington State Enacts Telehealth Parity Law](#)
- [Senate HELP Committee Announces EHR Working Group](#)
- [FTC Staff Submit Comments On ONC's Draft Shared Nationwide Interoperability Roadmap](#)
- [Teladoc Embarks on Road to an IPO](#)
- [ONC Data Brief Describes Positive Trends in the Adoption of EHR Systems](#)
- [Continuing Developments on Telemedicine in the U.S. Senate](#)
- [CMS Releases Proposed Rules Modifying Stage 2 of EHR's Meaningful Use Requirements](#)
- [Digital Health Venture Funding and M&A Activity in the First Quarter of 2015](#)
- [Webinar Invite: Moving to the Cloud: Privacy and Other Key Considerations for Healthcare Entities](#)
- [FDA Regulation of mHealth Updates](#)
- [Article 29 Working Party Clarifies 'Health Data' in the Wellbeing App Context](#)
- [The Joint Commission Issues Health IT-Related Patient Safety Alert](#)
- [House Bill Repealing the Medicare SGR Includes Telehealth Provisions](#)
- [CMS Releases Proposed Rules for Stage 3 of EHR's Meaningful Use Program](#)
- [Moving to the Cloud: Some Key Considerations for Healthcare Entities](#)

### **InsideEnergy&Environment**

- [The Road to Paris 2015: EU Emissions Trading Scheme and its Application to Non-EEA Airlines – Enforcement on the Rise?](#)
- [DECC Announces Early Closure of UK Renewables Obligation](#)
- [The Uncertain Future of the UK Renewables Obligation: A Three-Part Series](#)
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- [U.S. Appeals Court Rejects, as Premature, Challenge to EPA's Clean Power Plan](#)

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- [Anatomy of a Nigerian Oil Scandal: Audit of National Oil Company Fuels Momentum for Sectoral Reform](#)
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- [FERC Staff to Measure Grid Investment Effectiveness](#)
- [Risk and Reward in the UK Continental Shelf: Key Developments in Q1 2015](#)
- [The Impact of Distributed Generation On Electric Utilities: How Big, How Likely and How Soon?](#)
- [Federal Agencies Join Forces to Procure Solar Electricity](#)

#### **Inside EU LifeSciences**

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- [New Draft EMA-Guideline On Clinical Development Of Fixed Combination Medicines](#)
- [May 2015 EU mHealth Round-Up](#)
- [The Italian Competition Authority launches a sector inquiry in relation to vaccines for human use](#)
- [European Court to Clarify Responsibilities and Liability for Medical Devices](#)

#### **GlobalPolicyWatch**

- [Reshuffle of Directors-General at European Commission](#)
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- [The United States and India Sign a 10-Year Defense Agreement and Set the Stage for Increased Defense Cooperation](#)

- [As We Were Saying, Tax Reform is Dead](#)
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- [G20 Mildly Optimistic about Growth, Worried About Greece, Annoyed at the US](#)
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- [The Iran Framework Agreement: Structure and Open Issues](#)
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- [Which Way Nigeria?](#)

### **InsideGovernmentContracts**

- [New Proposed Rule and Accompanying Guidance May Impose Additional Cybersecurity Burdens on Contractors Handling CUI](#)
- [New Obligations to Disclose Labor Law Violations Could Expose Contractors to Defamation Liability](#)
- [Seventh Circuit Rejects Doctrine of Implied False Certification to Establish False Claims Act Liability](#)
- [HRSA Proposes Calculation of 340B Ceiling Prices, Implementation of Manufacturer Civil Monetary Penalties](#)
- [OMB Issues Final Guidance Implementing FITARA](#)
- [FAR Council Beefs Up Small Business Subcontracting Rules](#)
- [CBCA Takes Pragmatic View When Finding Jurisdiction Over A Sponsored-Subcontractor CDA Appeal](#)
- [The D.C. Circuit’s Message to Injured Government Contractor Employees: ‘There’s an Exclusive Remedy For That’](#)
- [Proposed “Fair Pay and Safe Workplaces” Regulations Clarify New Responsibilities for Government Contractors](#)
- [Recent GAO Bid Protest Decisions Remind Contractors of Strict Filing Requirements](#)
- [DoD Moves Forward with Stricter Sourcing Requirements for PV Devices](#)
- [DCAA’s 4th Annual Report to Congress Will Look Familiar to Many...](#)
- [Renewed Pressure to Definitize Letter Contracts](#)
- [Lost in Transmission: Email Failure Results in Untimely Size Protest](#)
- [Contracting Officers Must Soon Separately Justify Awards to Offerors Proposing High-Percentage or “Pass-Through” Subcontracting](#)
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- [Potential Relief for Contractors Subject to Rapid Reporting Requirements](#)
- [An Acceptable Proposal: Set Appropriately High, Clear Standards for DoD’s Auditors and LPTA Competitions](#)
- [DLA Energy Plans to Make Utility Privatizations More Effective and Streamlined](#)
- [College’s Falsification of Grades and Attendance Records May Trigger FCA Liability](#)
- [Supreme Court’s Denial of Cert Means Questionable Future for Certain Cooperative Agreements](#)
- [Doubts Raised About GSA’s New Vision for Federal Contracting](#)

- [GAO Reports Highlight Ongoing Struggles in Reforming IT Acquisitions and Operations](#)
- [Recent Application of “International Agreement” Exception Raises Questions Regarding Bid Protest Challenges to Foreign Military Sales](#)
- [Agency’s Continued Evaluation of Bids Does Not Violate CICA Stay](#)
- [FAR Council Issues Interim Rule Implementing LGBT Protections](#)
- [Federal Agencies Join Forces to Procure Solar Electricity](#)
- [GAO Sustains Protest Based On Improper Actions Of Acquisition Services Contractor](#)
- [SEC and State OIG Allege that Contractors’ Policies, Procedures, and Agreements Suppress Whistleblowing](#)
- [Another Attempt at Defense Procurement Reform Begins](#)
- [GAO Upholds Restriction on Using Consultants to Develop a Proposed Technical Approach](#)

### **InsideMedicalDevices**

- [FDA Issues Draft Guidance on Determining when Data from Foreign Clinical Studies Can Support Device Submissions](#)
- [FDA Issues Draft Guidance Concerning the Use of Electronic Informed Consent in Clinical Investigations](#)
- [CFDA Focuses on Enforcement of Medical Device Good Manufacturing Practices](#)
- [European Court of Justice To Clarify Device Liability of Notified Bodies](#)

### **InsidePoliticalLaw**

- [New Insights on FARA Enforcement Emerge from DOJ Letter to Sen. Grassley](#)
- [Hawaii Pay-To-Play Law Survives Legal Challenge](#)
- [“Market Value” to Events with No Entrance Fee Explained](#)
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- [A Renewed Push Coming for Disclosure of Political Intelligence Gathering?](#)
- [Gift Tax Certainty at Last?](#)

### **InsidePrivacy**

- [EU General Data Protection Regulation – First day of ‘trilogue’ discussions](#)
- [Highlights of the Canada Digital Privacy Act 2015](#)
- [Supreme Court Strikes Down Ordinance Authorizing Warrantless Searches of Hotel Records](#)
- [FCC Ruling Tightens TCPA Restrictions; Dissenters Warn of Increased Class-Action Abuse](#)
- [Covington Webinar: The EU General Data Protection Regulation – What’s Next and What It Means For Your Business](#)
- [Updates to State Data Security and Breach Notification Laws — Connecticut and Oregon](#)

- [Council Agrees Common Approach on EU General Data Protection Regulation – Negotiations With Parliament and Commission on Final Text To Begin Imminently](#)
- [Update on the Cybersecurity Directive – over to Luxembourg?](#)
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- [Dutch Parliament Adopts Data Breach Notification Obligation and Increases Fines](#)
- [Supreme Court Limits Criminal Law's Reach to Social Media Posts; Avoids First Amendment Issue](#)
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- [Supreme Court to Consider Whether A Settlement Offer for Complete Relief Moots a Plaintiff's TCPA Claim](#)
- [FTC's Throttling Case Against AT&T to be Heard by Ninth Circuit](#)
- [Digital Advertising Alliance Will Begin Enforcing its Mobile Guidance September 1, 2015](#)
- [Draft House Cures Legislation Would Amend Federal Privacy Laws \(Third Post in a Series\)](#)
- [Draft House Cures Legislation Would Amend Federal Privacy Laws \(Second Post in a Series\)](#)
- [Ninth Circuit Asks California Supreme Court to Define the Scope of Song-Beverly Act](#)
- [Department of Justice's Cybersecurity Unit Provides New Guidance and Best Practices for Cyber Incident Response](#)
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- [HIPAA Settlement Follows Unsecured Paper Records Disposal](#)
- [FCC's Agenda for April 28th Broadband Consumer Privacy Public Workshop](#)
- [House Passes Cybersecurity Information Sharing Bills](#)

- [European Commission Targets May 28th for Conclusion of Safe Harbor Negotiations](#)
- [FTC Announces First Consent Order With a Retail Tracking Company](#)
- [House Committees Approve Information Sharing and Data Breach Notice Bills, Setting Stage for Floor Vote](#)
- [Brazil Extends the Consultation Period on Its Draft Data Protection Law until April 30](#)
- [Court Grants Summary Judgment on VPPA Claims Against Hulu Based on Lack of 'Knowing' Disclosure](#)
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- [FCC Issues Public Notice Concerning Closed Captioning Reporting Procedures](#)
- [Less Than One Month Until May 29, 2015 Pre-Auction Licensing Deadline](#)
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