Quarterly Roundup

October - December 2015

As a service to clients of Covington & Burling LLP, below is a compilation of recently issued 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

Anti-Corruption

Class Actions

Data Privacy & Cybersecurity

Election & Political Law

Employment

Energy & Natural Resources

Financial Institutions

Financial Services

Food & Beverage

Food & Drug

Futures & Derivatives

Government Contracts

Health Care

Intellectual Property

Litigation

Mergers & Acquisitions

Patent Litigation

Product Liability

Public Policy & Government Affairs

Securities & Capital

Markets

<u>Tax</u>

Trade Secrets

Publications

Anti-Corruption

- "Court Approves UK's First Deferred Prosecution Agreement," (12/11/2015)
- "China Adopts New Rules on Healthcare Donations," (10/29/2015)

Class Actions

"Class Actions for Antitrust Damages Claims Now Available in the UK," (10/1/2015)

Data Privacy & Cybersecurity

- <u>"The New EU Data Protection Law: Key Elements for Business,"</u> (12/21/2015)
- "Administrative Law Judge Dismisses FTC's LabMD Complaint," (11/17/2015)
- "The EU's Highest Court Invalidates Safe Harbor with Immediate Effect," (10/6/2015)

COVINGTON

BEIJING BRUSSELS LONDON LOS ANGELES NEW YORK SAN FRANCISCO
SEOUL SHANGHAI SILICON VALLEY WASHINGTON

Election & Political Law

- "Recent FEC Enforcement Cases Involving PACs and PAC Staff," (10/8/2015)
- "New Report Adds Pressure For Public Companies to Voluntarily Disclose Political Spending," (10/8/2015)

Employment

"International Employment Law Update," (12/16/2015)

Energy & Natural Resources

<u>"The Paris Climate Change Agreement Creates a Range of Opportunities for Companies,"</u> (12/28/2015)

Financial Institutions

- "Questions and Answers: Federal Reserve Proposes Requirements for Long-Term Debt, Total Loss Absorbing Capacity (TLAC), and "Clean" Holding Company," (11/9/2015)
- <u>"Forecasting Regulation of Online Marketplace Lending After Treasury's Request for Information,"</u> (10/15/2015)

Financial Services

- "Expected One-year Delay to the Implementation of MiFID II," (12/3/2015)
- "ESMA Consults on Indirect Clearing Arrangements under EMIR and MiFIR," (11/12/2015)
- <u>"MAR Moves Closer FCA Releases Consultation Paper on Policy Proposals and Changes to Its Handbook," (11/11/2015)</u>
- <u>"ESMA Plans to Consult on Alternative Indirect Clearing Arrangements under EMIR and MiFIR,"</u> (10/12/2015)
- "FCA Hints at Delay to MiFID II Implementation," (10/1/2015)

Food & Beverage

 "Food Labeling: FDA Issues Final Guidance on Voluntary GE Claims on Food Products, One Week After Requesting Information and Comments on "Natural" Claims," (11/25/2015)

Food & Drug

- "FDA Publishes Final Rule on Voluntary Third-Party Auditor Program," (11/17/2015)
- "FDA Publishes Final Rule on Foreign Supplier Verification Program," (11/17/2015)
- "FDA Publishes Final Rule on Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," (11/17/2015)
- "China Adopts New Rules on Healthcare Donations," (10/29/2015)

Futures & Derivatives

 "CFTC Staff Issues Swap Dealer De Minimis Exception Preliminary Report," (12/10/2015)

Government Contracts

<u>"DoD Issues Final Rule Addressing Exclusion of Contractors that Present Supply Chain Risk in National Security System Procurements,"</u> (11/2/2015)

Health Care

"CMS Issues Delayed Proposed Rule Implementing PAMA's New Clinical Laboratory Reimbursement Criteria," (10/7/2015)

Intellectual Property Litigation

"China's Draft Patent Law Seeks Five Fold Increase on Damages Cap for Patent Infringement Cases," (12/9/2015)

Mergers & Acquisitions

"Delaware Supreme Court Affirms Business Judgment Rule in Third-Party Mergers Approved by Disinterested Stockholders," (10/7/2015)

Patent Litigation

"SIPO Issues Detailed Draft Guidance for Patent Administrative Enforcement in China," (10/30/2015)

Product Liability

<u>"Does Recent Wave of Pro-Preemption Decisions Signal Promise for Brand-Name Pharmaceuticals?,"</u> (11/12/2015)

Public Policy & Government Affairs

- <u>"The Paris Climate Change Agreement Creates a Range of Opportunities for Companies,"</u> (12/28/2015)
- "Europe's Aviation Policy Takes Off," (12/17/2015)
- "The EU's Digital Single Market: European Commission Seeks Stakeholder Input," (10/1/2015)

Securities & Capital Markets

- <u>"Taking the FAST Track: New Legislation Facilitates Raising Capital and Aims to Simplify Reporting,"</u> (12/18/2015)
- "FAST Act Implications for Underwriters (UPDATE)," (12/15/2015)
- "FAST Act Implications for Underwriters," (12/9/2015)
- <u>"SEC Staff Publishes Staff Legal Bulletin 14H: New SEC Guidance Significantly Narrows the Shareholder Proposal Rule,"</u> (10/27/2015)

Tax

<u>"TEFRA Repealed in Favor of Entity-Level Partnership Tax - The Beginning of the End for Pass-Through Entities?,"</u> (11/4/2015)

Trade Secrets

<u>"U.S. Senate Judiciary Committee Holds Hearing on Trade Secrets Legislation Moving Legislation Closer to Full Senate Consideration,"</u> (12/4/2015)

Blogs

CovAfrica

- Climate negotiation scorecard: how did Africa fare at the COP 21?
- Assessing the Paris Climate Agreement
- Tanzania, Kenya and Nigeria Finally Stepping Up Anti-Corruption Efforts
- Africa's long road to Paris
- Kenyan Government Disavows Controversial Local Ownership Requirement
- Meet Four of the Key Ministers in President Buhari's Cabinet
- Zimbabwe (Re-)Opens to the West
- Cote d'Ivoire and Tanzania: Same Results, Different Reactions
- Four Ways To Improve Existing U.S. Resources for Doing Business in Africa
- Kenya and Nigeria bank on their citizens to help finance ongoing development
- Breaking up is hard to do: the DRC's risky decentralization drive

CovBrands

- UK CMA Opens Investigation into Online Sales of Licensed Sport and Entertainment Merchandise
- FTC Closes Investigation of Watch Manufacturer's "Made in USA" Claims
- French probe of Adidas' online sales restrictions closed
- Covington to provide workshops to Central Saint Martin's MA Fashion Students
- EU's Highest Court Invalidates Safe Harbor with Immediate Effect

CovingtoneHealth

- Agency for Healthcare Research and Quality Releases Draft Report Calling for Further Research into Telehealth
- House Legislation Would Modestly Expand Use of Technology in Treating Mental Health and Substance Use Disorders
- Health Care Providers Continue to Lag Behind Patient Demand for Digital Communications
- Senators Request Information from HHS About Medical Identity Theft Efforts
- OIG FY 2016 Work Plan Includes Review of FDA's Oversight of Networked Devices
- HealthCare.gov to Launch Open Enrollment for 2016 Plan Year on November 1, 2016
- CMS Issues New EHR Meaningful Use Rules
- FDA Regulatory Science Priorities Address Use of Data, Health Information Technology
- The AMA's Telehealth Services Workgroup Convened for its Foundational Meeting to Discuss the Development of New Telemedicine Billing Codes
- HHS Launches Portal Seeking Questions from Mobile Health Application Developers

InsideEnergy&Environment

- The European Commission Adopts Circular Economy Package
- What's the Deal with Low Oil Prices?
- California Enacts Law Requiring 50% Renewables By 2030
- Cairn Energy Compels India to Engage in Arbitration Proceedings
- Can Courts Oblige States to Increase Greenhouse Gas Emission Cuts? Urgenda vs. Dutch State

Inside EU LifeSciences

- Comprehensive Amendments of German Drug Laws upcoming
- European Commission Publishes its 6th Report on the Monitoring of Patent Settlements
- EU Agreement on a General Approach on the Medical Devices Package
- Merck and Generics UK challenge the Commission's 'by object' analysis in Lundbeck

GlobalPolicyWatch

- This Week in Congress A Year-End Review
- Assessing the Paris Climate Agreement
- Looking Forward After the FAA's Drone Registration Regulation
- This Week in Congress December 14, 2015
- Change gathers pace Europe's plans for tax transparency and a common tax base
- This Week in Congress December 7, 2015
- The EU Turkey summit of 29 November 2015 : A "Re-Energised" Relationship
- This Week in Congress November 30, 2015
- What's New in the TPP's Intellectual Property Chapter
- High Wire Balancing Act in Paris Climate Talks
- <u>The Trans-Pacific Partnership Investment Chapter: Maintaining Important Protections for U.S. Investors Overseas</u>
- Hosting the G20 Leaders is an Opportunity for Turkey on Growth and Stability
- This Week in Congress November 16, 2015
- The TPP's Electronic Commerce Chapter
- Zimbabwe (re-)opens to the West
- This Week in Congress November 9, 2015
- Will President Obama's New Overtime Regulations Shrink Corporate Restricted Classes?
- Appropriations 2016: The Tough Road Ahead for Speaker Ryan
- This Week in Congress November 2, 2015
- This Week in Congress: October 26, 2015
- Four Ways To Improve Existing U.S. Resources for Doing Business in Africa

- This Week in Congress October 19, 2015
- New Report Adds Pressure For Public Companies to Voluntarily Disclose Political Spending
- Congress considers aviation safety in new world of drones
- Kenya and Nigeria bank on their citizens to help finance ongoing development
- Latin America's Slump Masks Big Economic Differences
- What Motivates the Freedom Caucus?
- Building a EU Capital Markets Union
- EU's Highest Court Invalidates Safe Harbor with Immediate Effect
- Next steps for TPP Deal
- This Week in Congress October 5, 2015

InsideGovernmentContracts

- <u>Time Is On My Side: DoD Hears Industry Concerns Additional Time Provided to Implement Security Controls Under New Cyber Rule</u>
- DoD Retreats on Evaluation of Price Reasonableness
- High Court to Resolve Split of Authority on "Implied" False Claims
- Federal Felony Convictions and Delinquent Taxes Must be Reported Under New FAR Rule
- FAR Council Finalizes Federal Contractor Minimum Wage Rule
- OSAI Issues Guidance on the Government Contractor Defense for Certified Anti-terror Technologies
- DoD Proposes DFARS Changes in Attempt to Promote Voluntary Disclosure of Defective Pricing
- VA Proposes to Make VOSB Verification Easier Under the Veterans First Contracting Program
- The Pitfalls of Changing a Pending Proposal
- Contractor Defeats Government's Opportunistic Allegations of Fraud
- DoD Issues Final Rule Addressing Exclusion of Contractors that Present Supply Chain Risk in National Security System Procurements
- NDAA Vetoed for Now Includes New Cybersecurity Provisions for Contractors
- No Money for Nothing Eighth Circuit Limits Relators' Ability to Recover a Share of Government Settlements of Qui Tam Suits
- "We Mean It, Maaannnn"—New Proposed Regulation Seeks to Encourage Higher-Quality Proposals by Boosting Enforcement of Five-Bidder Limit in Two-Phase Procurements for High-Value Construction Contracts
- <u>DoD Issues Targeted Class Deviation Updating Recently Adopted Cybersecurity DFARS</u>
 Clauses
- Defense IG's Criticism of DCMA Is Cold Comfort for Government Contractors

- No Cost Contract Award is No Problem According to GAO
- National Security M&A Trump Card for DoD?

InsideMedicalDevices

- CDRH Schedules January 2016 Cybersecurity Workshop
- Congress Enacts 2-Year Moratorium on Medical Device Excise Tax
- CFDA Restructures Medical Device Adverse Event Regulations
- LDT Update: FDA and CMS Testify Before the House Energy & Commerce Subcommittee Following Year of Debate on Oversight of LDTs
- OIG Work Plan Includes Review of FDA's Oversight of Networked Devices
- Recent Reports Claim Improvements in FDA's Review of Medical Device Submissions
- FDA's Office of Planning Issues Report on Review Process for Combination Products
- FDA CDRH Announces Regulatory Science Priorities for FY 2016
- EU Agreement on a General Approach on the Medical Devices Package
- HHS Launches Portal Seeking Questions from Mobile Health Application Developers

<u>InsidePoliticalLaw</u>

- PATH Act Requires 501(c)(4) Organizations To Provide Notice To IRS After Formation
- Congressional Spending Bill Shuts Down Key Goals of Campaign Finance Reform
 Community
- SEC Fines Should Prompt Firms Engaged in Political Intelligence To Revisit Insider Trading Policies
- Thanksgiving Treat: Executive Branch Gift Rules in for Rewrite
- FEC Provides Some Answers To Candidates and Super PACs
- Will President Obama's New Overtime Regulations Shrink Corporate Restricted Classes?
- California Approves Strict Rules on Super PAC Coordination
- New Report Adds Pressure For Public Companies to Voluntarily Disclose Political Spending

InsidePrivacy

- FTC Releases Agenda for First-Ever PrivacyCon
- FTC Issues Policy Statement on Native Advertising
- Oracle Settles FTC Deception Charges
- The New EU Data Protection Law: Key Elements for Business
- Congress Passes the Cybersecurity Act of 2015
- Privacy Weekend: Provocative Articles We're Reading Now
- FTC Settles COPPA Charges With Two App Developers
- FTC Obtains Record \$100 Million Settlement with LifeLock

- LIBE Committee Votes in Favor of the GDPR
- Political Agreement on the EU General Data Protection Regulation Start of a New EU Privacy Era?
- Wyndham Settles FTC Charges
- Senators Introduce Online Terrorist Activity Reporting Bill
- European Institutions Reach Agreement on EU Cybersecurity Rules
- FTC Appeals Dismissal of Data Security Complaint Against LabMD
- FTC Approves New "Selfie" Verifiable Parental Consent Mechanism Under COPPA
- Ninth Circuit Hears FTC's Throttling Case Against AT&T
- FTC Hosts Cross-Device Tracking Workshop
- Administrative Law Judge Dismisses FTC's LabMD Complaint, Finding Insufficient Evidence of "Substantial Injury" to Consumers
- Third Circuit Resurrects State Law Claims Against Google in Safari Cookie Tracking Lawsuit
- NLRB Says Employer Can Use GPS Device to Track Employees
- FCC Says It Will Not Require Websites to Honor 'Do Not Track'
- A Closer Look at CISA's Cybersecurity Information-Sharing Provisions
- Cox Communications to Pay \$595,000 in Data Breach Settlement
- European Commission issues guidance on the impact of the Schrems (Safe Harbor) ruling of the EU's Highest Court
- Trans-Pacific Partnership Trade Agreement May Authorize Cross-Border Data Flows
- FTC Announces Final Agenda for Cross-Device Tracking Workshop
- CEA Releases Guidelines on Privacy and Security of Personal Wellness Data
- California AG Issues Guidance for Consumers on Managing Mobile Location Privacy
- Senate Passes Cybersecurity Information Sharing Legislation
- Schrems (Safe Harbor) Judgment German Data Protection Authorities Issue Position Paper
- Device IDs alone are not PII under the VPPA, New York district court rules.
- Third Circuit: TCPA Suit By Roommate Who Answered Prerecorded Call Can Proceed
- House Passes Bill Expanding Privacy Rights of EU Citizens in Wake of Schrems Ruling
- FTC to Hold Workshop on Cross-Device Tracking
- Article 29 WP On the Schrems Ruling (Safe Harbor) Latest Developments and Next Steps
- FTC Releases Agenda for November 5th "Start with Security" Conference
- Free Cartoon Network App User Not a "Subscriber" Under VPPA, Rules Eleventh Circuit
- HHS Launches Portal Seeking Questions from Mobile Health Application Developers

- Debate in the European Parliament's LIBE Committee on the Schrems ruling
- Covington Attorneys Author Chapter on the Challenges of Managing Third-Party
 Outsourcing Risks
- California Requires a Warrant To Search Electronic Communications
- Three-Bill Package Makes Revisions to California's Data-Breach Notification Statute
- New California Law Regulates Voice Recognition Technology in Smart TVs
- EU's Highest Court Invalidates Safe Harbor with Immediate Effect
- Company Agrees to Establish Chief Privacy Officer to Settle Cal. AG's Call-Recording Allegations
- UK ICO Issues Largest Ever Fine In Connection With Automated Marketing Calls
- <u>EU Parliament Policy Report Takes Dim View of EU Commission's "Pro-Market" Policies</u> on Big Data and Smart Devices
- <u>EU's Highest Court Rules on Applicable Law and Territorial Powers of the National Data Protection Authorities</u>

TechMedia

Rules on Net Neutrality and Roaming Charges Finally Adopted

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