# **Quarterly Roundup**

#### July - September 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**

Aerospace, Defense &	Employment	Insurance
National Security	<b>Environmental</b>	Intellectual Property
Anti-Corruption	Financial Services	Litigation
Antitrust & Competition Law	Financial Institutions	International Trade Controls
<u>Competition</u>	Food & Drug	Public Policy & Government
<u>Cybersecurity</u>	Futures & Derivatives	<u>Affairs</u>
Data Privacy & Cybersecurity		<u>Securities</u>
	Government Contracts	White Collar

# **Publications**

#### Aerospace, Defense & National Security

<u>"China Passes New National Security Law,"</u> (7/2/2015)

#### **Anti-Corruption**

- "China Amends Criminal Law: Impact on Anti-Bribery Enforcement," (September 2015)
- "Mead Johnson Pays \$12 Million to Settle FCPA Allegations Relating to Payments to Employees of Chinese Hospitals," (7/29/2015)

#### Antitrust & Competition Law

- <u>"The European Commission Launched Public Consultation on Online Platforms,"</u> (9/24/2015)
- <u>"The EU's Global Reach,"</u> (7/9/2015)

# COVINGTON

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

# **Competition**

"European Court of Justice's Judgment in Case C-170/13 Huawei v ZTE," (7/20/2015)

#### Cybersecurity

"China Solicits Comments on Draft Network Security Law," (7/10/2015)

#### Data Privacy & Cybersecurity

<u>"Advocate General considers EU-U.S. Safe Harbor to be invalid," (9/24/2015)</u>

#### **Employment**

- <u>"U.S. Department of Labor Issues Guidance on Misclassification of Workers,"</u> (7/23/2015)
- <u>"International Employment Update,"</u> (7/13/2015)
- <u>"Service Inventions in China,"</u> (7/10/2015)
- <u>"Department Of Labor Proposes Changes to FLSA White Collar Exemption Rules,"</u> (7/8/2015)

#### **Environmental**

"EPA's Proposed Rule Regulating Pharmaceuticals under RCRA," (9/3/2015)

#### **Financial Services**

<u>"MiFID II Directive and the Markets in Financial Instruments Regulation ("MiFIR"),"</u> (9/30/2015)

#### **Financial Institutions**

"Senators Urge CFPB to Advance Small Business Data Collection Rule," (7/16/2015)

# Food & Drug

- "FDA Publishes Final Rule on CGMPs, Hazard Analysis, and Preventive Controls for Animal Food," (9/18/2015)
- "FDA Publishes Final Rule on CGMPs, Hazard Analysis, and Preventive Controls for Human Food," (9/17/2015)
- "Summary of FDA Advertising and Promotion Enforcement Activities," (9/14/2015)
- "CFDA Issues Two Key Draft Rules on Infant Formula and Medical Foods," (9/8/2015)
- <u>"Summary of FDA Advertising and Promotion Enforcement Activities,"</u> (8/17/2015)
- <u>"2014 End-of-Year Summary of FDA Promotional Enforcement Activity,"</u> (8/11/2015)
- <u>"21st Century Cures Act: Key Provisions Related to Drugs,"</u> (8/7/2015)
- <u>"21st Century Cures Act: Key Provisions Related to Medical Devices,"</u> (7/30/2015)
- "FDA Proposes User Fees and Model Accreditation Standards for Accreditation Bodies and Third-Party Auditors/Certification Bodies under FSMA," (7/28/2015)
- "FDA Issues Supplemental Proposed Rule on Changes to Nutrition Labels," (7/27/2015)
- <u>"APHIS Request for Comments Proposed Changes to Research Facility Reporting</u> <u>Requirements,"</u> (7/10/2015)

#### Futures & Derivatives

"Cybersecurity: Recent CFTC and NFA Activity," (9/11/2015)

#### **Government Contracts**

- <u>"DoD Issues Interim Rule Addressing New Requirements for Cyber Incidents and Cloud Computing Services,"</u> (8/27/2015)
- "OMB Issues New Draft Cyber Guidance for Contractors," (8/12/2015)
- "Department of Defense Proposed Rule on Evaluating Commercial Prices Raises More Questions Than it Answers," (8/10/2015)

#### **Insurance**

- <u>"Good News for California Asset Transfers: Insurance Now Follows the Assets,"</u> (8/26/2015)
- <u>"In Landmark Reversal, California Supreme Court Holds That Insurance Assignments Are Allowed Without Consent,"</u> (8/21/2015)

#### **Intellectual Property Litigation**

"SIPO is Reinforcing its Role in Patent Protection in China," (7/7/2015)

#### **International Trade Controls**

- "U.S. Treasury and Commerce Departments Issue Amended Regulations to Further Ease U.S. Sanctions Against Cuba," (9/21/2015)
- <u>"United States, EU, Other Global Powers Reach Comprehensive, Long-Term Nuclear Deal with Iran,"</u> (7/15/2015)

#### Public Policy & Government Affairs

 <u>"Country by Country Reporting - The European Commission Weighs Its Options,"</u> (8/25/2015)

#### **Securities**

- "SEC Adopts Pay Ratio Disclosure Rule," (8/10/2015)
- <u>"SEC Proposes Rules on Clawback Policies,"</u> (7/6/2015)

#### White Collar

- <u>"The SEC's Proposed Modernization of Its Rules for Administrative Proceedings,"</u> (9/28/2015)
- <u>"DOJ Issues New Guidance on Pursuing Individual Accountability for Corporate</u> <u>Wrongdoing,"</u> (9/11/2015)
- "HM Revenue & Customs Consultation: A Potential New Corporate Criminal Offence of Failing to Prevent the Facilitation of Tax Evasion," (9/10/2015)

# **Blogs**

#### **CovAfrica**

- The SDGs, business, and the development challenge
- From the AGOA Forum in Gabon to the WTO Ministerial in Nairobi

- China, India and Japan Set to Host Major Summits To Further Strengthen Ties with <u>Africa</u>
- China Sneezes: Could Africans benefit from a devalued yuan?
- Gabon To Host Back-to-Back African Investment Forums
- Nigeria (Again) Contemplates Mandatory Stock Exchange Listing Legislation
- Francophone and Technophile: French-Speaking Africa's Budding Tech Scenes
- Obama in Kenya: A report from the field and a recap of the Global Entrepreneurship Summit
- Ghana Set to Ban Non-Degradable Plastics
- Africa and the Global Entrepreneurship Summit: A Natural Fit
- President Buhari Comes to Washington
- A Reauthorized U.S. Export-Import Bank is Central to U.S. Commercial Success in <u>Africa</u>
- Africa's Middle Class: Not Hype But Challenging To Get Right

# **CovBrands**

<u>CJEU gives guidance on 3D shape marks</u>

# **InsideCompensation**

- Employees in France and Germany May No Longer Have to Respond to Work-Related Emails Out of Working Hours
- Legal Developments Affect Open Enrollment for 2016
- SEC's New Pay Ratio Disclosure Rule Explained
- Will Cybersecurity Best Practices Morph into Cyber Mandates?
- Closing the Backdoor on Roth Conversions of After-Tax Amounts?
- Time to Focus on Directors' Pay?
- Labor Department Addresses Worker Misclassification
- Changes to IRS Determination Letter Program Raise Practical Questions
- Reformation Claim May Proceed Despite Clear Plan Terms, Sixth Circuit Holds
- Interim Guidance for Expatriate Health Plans
- What Every ERISA Fiduciary Should Consider About Float Income
- Pension De-Risking Gets New Rules: IRS Shuts Down Lump Sum Offers to Retirees While Connecticut Increases Safety of Group Annuity Contracts
- Bipartisan Tax Group Releases Savings & Investment Report
- DOL Proposes to Expand Overtime Protection
- SEC Proposes Clawback Rule
- Marriage Equality Decision Is Big News (But May Have Little Impact on Private Sector Employee Benefit Plans)

Supreme Court Saves Affordable Care Act Again

## **CovingtoneHealth**

- Report Outlines Plan for Precision Medicine Database
- <u>Chairman of Senate HELP Committee Calls for Delay of EHR Stage 3 Rules</u>
- OCR Plans to Move Ahead with HIPAA Audits, Reports Say
- UK Government Launches Cybersecurity Service for Healthcare Organizations
- Proposed Rule Would Amend Federal "Common Rule" Requirements
- E-Prescribing of Controlled Substances Now Permissible in All States.
- Multistakeholder Group Seeks Comment on Draft Framework for IoT Device Manufactures
- Cybersecurity Risks with Connected Devices
- Senate Approves Bill to Ease Meaningful Use Requirements In Ambulatory Surgery Setting
- The Proposed Medicare Telehealth Parity Act of 2015 Would Expand Medicare Reimbursement for Telehealth Services
- <u>E-Health Legislative Summary: The Veterans E-Health & Telemedicine Support Act of 2015</u>
- Comments Requested on Draft Guide on Securing Electronic Health Records on Mobile <u>Devices</u>
- Digital Health Venture Funding, M&A and IPO Activity in the First Half of 2015
- Hospital Fined for Using Unsecured File Sharing Application
- FDA to Focus on "Complementary" Diagnostics in Addition to Companion Diagnostics
- Nine States Join Interstate Medical Licensure Compact
- The Independence at Home Demonstration Project Completes its First Year and Saves over \$25 Million

#### InsideEnergy&Environment

- Greater Sage-Grouse Numbers Rise as FWS Poises to Announce the Bird's ESA Listing Status
- EU Court of Justice Decides on Complex Articles Under REACH
- Risk and Reward in the UKCS: Recent Positive Development
- A Watch List of Possible Changes in EPA's Final Clean Power Plan
- Supreme Court Decisions Raise Questions about Future Judicial Scrutiny of EPA's Clean Power Plan

#### Inside EU LifeSciences

- <u>General Court Makes Interim Order to Protect Confidentiality in Pari Pharma</u> <u>Transparency Case</u>
- IVD Regulation and Companion Diagnostics EU Council Dramatically Changes Definition

- Italian Medicines Agency Publishes Public Assessment Reports of Medicines Authorised <u>Through the National Procedure</u>
- Mandatory registration and logo for UK online sales of medicines
- MHRA grants second scientific opinion as part of the Early Access to Medicines Scheme
- European Commission Published Non-Confidential Version of Servier Decision

# **GlobalPolicyWatch**

- The SDGs, business, and the development challenge
- This Week in Congress: September 28, 2015
- From the AGOA Forum in Gabon to the WTO Ministerial in Nairobi
- This Week In Congress September 21, 2015
- Benefits and Barriers to Expanded U.S.-Cuba Trade
- China, India and Japan Set to Host Major Summits To Further Strengthen Ties with <u>Africa</u>
- <u>EU US Umbrella Agreement about to be concluded: towards a transatlantic approach to data protection?</u>
- This Week in Congress September 14, 2015
- <u>EU US Umbrella Agreement about to be concluded: towards a transatlantic approach to data protection?</u>
- California Penalizes Campaign, Committee for Coordination Violation
- This Week in Congress September 8, 2015
- China Sneezes: Could Africans benefit from a devalued yuan?
- Lock Down of Nuclear Site: False Alarm, with a Lesson Learned
- Tax Transparency In the EU
- China Issues Draft Network Security Law
- OPINION: Bipartisan Trade Secrets Legislation Is Back
- SAFETY First: Using the SAFETY Act to Bolster Cybersecurity
- This Week in Congress August 3, 2015
- Obama in Kenya: A report from the field and a recap of the Global Entrepreneurship Summit
- This Week in Congress July 27, 2015
- Ghana Set to Ban Non-Degradable Plastics
- This Week in Congress July 20, 2015
- President Buhari Comes to Washington
- There will be no Grexit
- This Week in Congress July 13, 2015
- The last act of the Greek crisis negotiations?

- A Reauthorized U.S. Export-Import Bank is Central to U.S. Commercial Success in <u>Africa</u>
- China, the Middle East and the Global Economy–Where Might the "Silk Road" Lead?
- China's New National Security Law
- EU Policy Update—July
- This Week in Congress July 6, 2015
- Africa's Middle Class: Not Hype But Challenging To Get Right

# InsideGovernmentContracts

- Beware Of Employment Law Issues Amidst A Potential Government Shutdown
- OHA and COFC Agree: Mentor/Protégé JV Agreements Must Be Specific to Avoid <u>Affiliation</u>
- Proposed Counterfeit Parts Rule Envisions New Restrictions, Universal Applicability for DoD Contractors
- In Long-Running CAS Case, the Court of Federal Claims Rejects a Government Attempt to Get Another Bite at the Apple
- GAO Holds That Contractor's Letters Are, In Fact, Agency-Level Protests
- Obama Signs Executive Order Mandating Paid Sick Leave
- GSA Seeks Input on Eliminating IT Schedule 70's Two-Year Experience Requirement
- DoD IR&D Projects May Not Be So "Independent" For Long
- Administration Appears Poised to Issue Another Executive Order Affecting Contractors and Their Employees
- GSA Seeks Industry Input on Cybersecurity Schedule Offerings
- DOD Issues Interim Rule Addressing New Requirements for Cyber Incidents and Cloud Computing Services
- A Closer Look At DOD's Proposed Price Reasonableness Rule
- SBA OHA: In Three-Factor Test to Determine Small Business Manufacturers, No Single Factor is Determinative
- Lock Down of Nuclear Site: False Alarm, with a Lesson Learned
- Updated DoD IG Guidance Signals New Enforcement Emphasis for DCAA Auditors
- <u>COFC: Contractor Stuck With Bill For Substantially Higher Than Expected Costs Under</u> <u>Firm-Fixed Price Requirements Contract</u>
- Contractors (Respectfully) Request that the President Stop Issuing Executive Orders Focused on Contractors
- OMB Issues New Draft Cyber Guidance for Contractors
- Recent CRS Report Reveals Long-Term Trends in GAO Protests
- <u>Bill Providing for Congressional Approval of Major Rules Passes House of</u> <u>Representatives</u>
- SAFETY First: Using the SAFETY Act to Bolster Cybersecurity

- DoD Issues Three Cloud Computing and Security Documents for Public Comment
- Ninth Circuit Narrows Application of the False Claims Act's Public Disclosure and First to File Bars
- Labor Department's Interpretation of the FLSA's "Suffer or Permit" Standard Triggers More Compliance Burdens for Government Contractors
- New Zealand to Join WTO Government Procurement Agreement, Will Become a "Designated Country" Under the TAA
- U.S., U.K. Governments Seek Cyber Innovations from Private Sector
- USAID Publishes Final Rule Extending Partner Vetting to Assistance Awards
- Competing Bills Focus on Cybersecurity Information Sharing But Final Language and Ultimate Passage Remain Unknown
- D.C. Circuit Creates Circuit Split Regarding Jurisdictional Nature of the False Claims Act's First-to-File Rule
- Judge Rejects Government's Objections and Orders 1st Bifurcated FCA Trial of Its Kind
- Self-Reporting Provision at Heart of New Inversion Rules
- Supreme Court grants certiorari in VA procurement case

#### **InsideMedicalDevices**

- FDA Proposes Amending the Definition of "Intended Use"
- <u>CDRH Schedules Next Generation Sequencing Workshops</u>
- The Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests Convenes its Inaugural Meeting
- IVD Regulation and Companion Diagnostics EU Council Dramatically Changes <u>Definition</u>
- Multistakeholder Group Seeks Comment on Draft Framework for IoT Device Manufactures
- Cybersecurity Risks with Connected Devices
- FY 2016 Medical Device User Fees Announced
- Bill Introduced to Streamline and Clarify Combination Product Regulatory Process
- <u>21st Century Cures Act Passes the House: Contains Key Provisions Related to Medical Devices</u>
- FDA to Focus on "Complementary" Diagnostics in Addition to Companion Diagnostics

#### InsidePoliticalLaw

- <u>California Penalizes Campaign, Committee for Coordination Violation</u>
- What's Next for the SEC Pay-to-Play Rule Challenge?
- Highlights from Wagner; D.C. Circuit Upholds Contributions Restrictions But Limits Ruling

# InsidePrivacy

EU-U.S. Safe Harbor: Judgment in the Schrems Case Scheduled For October 6

- Advocate General Considers EU-U.S. Safe Harbor to be Invalid
- Start With Security: Key Takeaways from the FTC's Data Security Conference
- Following TCPA Omnibus Order, Court Reaffirms Prior Ruling in Dismissing TCPA Text Message Lawsuit Against AOL
- UK Government Launches Cybersecurity Service For Healthcare Organizations
- Proposed Rule Would Amend Federal "Common Rule" Requirements
- Data Localization Requirements Through the Backdoor? Germany's "Federal Cloud", and New Criteria For the Use of Cloud Services by the German Federal Administration
- What You Need to Know About Germany's Cybersecurity Law
- EU US Umbrella Agreement about to be concluded: towards a transatlantic approach to data protection?
- Regulators in the U.S. and U.K. Monitoring Mobile Apps and Websites Directed at Children
- China Amends Criminal Law Related to Data Privacy and Cybersecurity
- DoD Issues Interim Rule Addressing New Requirements for Cyber Incidents and Cloud Computing Services
- Web Standards Group Releases Candidate Recommendation As Part of Broader "Do Not Track" Review
- Third Circuit Upholds FTC's Data Security Authority in FTC v. Wyndham
- FTC Releases Agenda for September 9th "Start with Security" Conference
- Cybersecurity Risks with Connected Devices
- <u>OMB Issues New Draft Cyber Guidance for Contractors</u>
- Multistakeholder Group Seeks Comment on Draft Framework for IoT Device <u>Manufactures</u>
- China Issues Draft Network Security Law
- FTC Seeks Public Comment on New Proposal for Parental Verification Method Under COPPA Rule
- Neiman Marcus Asks Full 7th Circuit to Consider Standing Ruling in Breach Suit
- SAFETY First: Using the SAFETY Act to Bolster Cybersecurity
- UK Supreme Court Will Hear Google's Appeal in Important Privacy Case
- Fiat-Chrysler Recalls 1.4 Million Vehicles In Response to Security Vulnerability
- Pocket Dials Are Not Private, Sixth Circuit Says
- Progress on EU GDPR Reform: International Aspects Debated
- Data Breach Plaintiffs Allege Enough Risk of Harm for Suit to Proceed, Appeals Court Rules
- Ten Key Takeaways From Last Week's TCPA Order
- China Releases Draft of New Network Security Law: Implications for Data Privacy & Security

- <u>Carriers Agree to \$3.5 Million FCC Fine For Alleged Privacy Violations</u>
- Privacy Weekend: Provocative Articles We're Reading Now
- Senate Panel Debates Law Enforcement Access to Encrypted Communications
- Draft Regulations in China Preview Stricter Rules on Internet Advertising
- FTC Releases "Start with Security" Guide to "Practical Lessons" From Data Security Enforcement Actions

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