



UPCOMING EVENT

FALL 2014 / WINTER 2014

Please join us for a wine tasting at First Crush during the 2015 JPMorgan Healthcare Conference and the 8th Annual OneMedForum in San Francisco

Wine Tasting, Networking, Cocktails and Hors d'oeuvres

Monday, January 12, 2015

6:00 p.m. - 9:00 p.m.



First Crush Restaurant & Wine Bar

101 Cyril Magnin Street | San Francisco, CA 94102

Tel: 415.982.7874

RSVP to GTRSVP@gtlaw.com

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Ebola: U.S. Provider Protocol and National Response Update

By Nancy E. Taylor and Danielle F. White, GT Washington, D.C. Office

The Washington, D.C. office of Greenberg Traurig's Health Care Practice has been closely monitoring the spread of Ebola and the federal government's response in the United States and abroad. Accurate and up-to-date information is critical for ensuring clients can make appropriate business and compliance decisions. This GT Alert provides a brief update on the current status of the U.S. response including the latest guidance, information and data.

To view the GT Alert on www.gtlaw.com, please click [here](#).

To view the GT Alert as a PDF, please click [here](#).

Updates to China's Medical Device and Drug Regulations

By George Qi and Dawn Zhang, GT Shanghai Office

China's National Food and Drug Administration (the "National FDA") recently published modified rules for medical device classification, registration, instructions and labels, and liability for medical device production/operation enterprises. The National FDA also published the *Provisions the Supervision and Administration of commissioned Production of Drugs*, which regulate that the application, inspection permit and supervision of the commissioned production of drugs between domestic drug production enterprises.

See the Fall 2014 GT China Newsletter for an overview of these regulations [here](#).

OIG Proposes New Anti-Kickback Law and CMP Safe Harbors

By Robert P. Charrow, GT Washington, D.C. Office; Francis J. Serbaroli, GT New York Office

In early October of this year, the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) proposed regulations with the goal of expanding exceptions to the Anti-Kickback Statute (AKS) and Civil Monetary Penalty (CMP) provisions of the Social Security Act. This GT Alert provides a background of these implications in regard to government payment changes under the Affordable Care Act (ACA).

To view the GT Alert on www.gtlaw.com, please click [here](#).

To view the GT Alert as a PDF, please click [here](#).

Privacy and Data Security Reminders for Mobile Technology Providers

By Ed Chansky and Erica Okerberg, GT Las Vegas Office

Back in August, Greenberg Traurig's Silicon Valley office recently hosted a talk about privacy and software security for mobile technology providers with Nithan Sannappa, an attorney in the FTC's Division of Privacy and Identity Protection. This GT Alert provides a covers three key areas broken up into further detail: Adopting Privacy by Design, Reviewing Privacy Policies, and Tips to Help Avoid Security Traps.

To view the GT Alert on www.gtlaw.com, please click [here](#).

To view the GT Alert as a PDF, please click [here](#).

GT IN THE INDUSTRY

RECOGNITIONS

Five Greenberg Traurig Attorneys Named “Life Science Stars”

Scott J. Bornstein, Lori G. Cohen, David J. Dykeman, Eric D. Hargen and Richard Pettus have been named “Life Science Stars” in [LMG Life Sciences](#) 2014 guide. The guide serves as a resource for in-house counsel identifying leading lawyers and firms in multiple practice areas. These practice areas include intellectual property, regulatory, transactional and non-IP litigation, which play important roles in guiding a product through its lifecycle. To see the GT press release, click [here](#).

GT SPEAKING ENGAGEMENTS

Wayne Elowe and David J. Dykeman Co-Lead a Workshop “From Project Strategy to Exit Deals in Biotech”

On November 19, 2014, Greenberg Traurig's Wayne Elowe and David J. Dykeman co-lead a workshop “From Project Strategy to Exit Deals in Biotech” at the Therapeutics Area Partnerships (TAPS) Conference in Boston, MA. The Workshop focused on key transactions used in monetizing biopharma assets, including M&A, licensing and other collaborative deals from terms sheets to managing ongoing relationships, and provided a perspective on key differences between the U.S. and EU when conducting such deals. For more information on the conference, click [here](#). To see the GT press release, click [here](#).

Ginger Pigott and Michael G. McKinnon Spoke at Device Talks Conference

On November 19, 2014, Greenberg Traurig's Ginger Pigott and Michael G. McKinnon spoke on “Hot Topics: M&A Megadeals, IP, Financing & Product Liability Trends for MedTech Companies” as part of MassDevice.com's Device Talks conference in Orange County, CA. GT was also a sponsor of the event. McKinnon moderated the panel discussion and panelists included Ginger Pigott along with medtech leaders Tony Sine, Executive Vice President, Alphaeon, and Matt Dolan, Director, Business Development, Volcano Corp. For more information on the event, click [here](#). To see the GT press release, click [here](#).

Greenberg Traurig Hosts Inaugural MedTech Partnering Day

On October 23, 2014, Greenberg Traurig's Life Sciences & Medical Technology Group hosted its inaugural MedTech Partnering Day at the firm's Boston office. 75 medtech executives attended this first of its kind event, which connected 23 innovative emerging medtech companies from 7 different states and Canada with representatives from Boston Scientific and Johnson & Johnson to maximize opportunities for collaboration, new business development and market expansion. Attorneys from 5 Greenberg Traurig's offices (Atlanta, Boston, Ft. Lauderdale, London, and New York) attended the event, including 4 speakers: Paul Maher (London), David Peck (Ft. Lauderdale), Daniel Smulian (New York) and David Dykeman (Boston). The new MedTech Partnering Day will take place in 2015. To see the GT press release, click [here](#).

Antonio Gallegos Co-Presented a Webinar “Recent FSMA Updates and What the FDA Expects from You”

On October 16, 2014, Antonio Gallegos co-presented with food industry consultant and former FDA official Charles Breen, on recent changes to FDA's proposed regulations with a focus on product testing and supplier verification, and guidance on how to show compliance to the FDA. Antonio provided an overview of the type of pathogen testing and supplier verification programs that the FDA is proposing, and his insights on compliance and legal issues raised by the proposal. To see the full webinar, click [here](#).

Greenberg Traurig's Boston “Conversation With” Series Welcomed MassBio President & CEO

On September 12, 2014, Greenberg Traurig's Boston office hosted Robert Coughlin, President & CEO of Massachusetts Biotechnology Council (MassBio) as the featured speaker for its “Conversation With” monthly breakfast series. Coughlin discussed the recently released MassBio Impact 2020 report, a strategic assessment of the state of the biotechnology and life sciences cluster in Massachusetts. The extensive report issues a call to action for Massachusetts stakeholders—across industry, academia, healthcare networks, payers and government—to take steps to safeguard the Commonwealth's leadership position in life sciences and innovation. The discussion was co-moderated by Greenberg Traurig attorneys' David J. Dykeman, Michael E. Pastore and Jamey L. Tesler. To see the GT press release, click [here](#).

Greenberg Traurig Attorneys Dykeman, Peck and Jacxsens Presented at DeviceTalks Boston

On July 15, 2014, David J. Dykeman, David C. Peck and Christiana P. Jacxsens spoke at the DeviceTalks conference at The Westin Boston Waterfront in Boston, MA. Hosted by online journal MassDevice.com, DeviceTalks is a conversation among leaders, and an evening for an exchange of ideas, insight and contacts among the pioneers of the medical technology industry. Dykeman moderated the panel discussion “Hot topics: M&A Mega-Deals, IP, Financing, and Products Liability Trends for MedTech Companies,” Peck and Jacxsens served as panelists. They were joined by medtech leaders Jed Cohen, Managing Director of Leerink Partners, Dirk M. Kuyper, President and CEO of IlluminOss Medical, and Jeremy Sohn, Managing Director of MPM Capital. To see the GT press release, click [here](#).

Greenberg Traurig Attorneys David J. Dykeman and Roman Fayerberg Spoke at Medical Design & Manufacturing (MD&M) East Conference

On June 9, 2014, David J. Dykeman and Roman Fayerberg spoke at the Medical Design & Manufacturing (MD&M) East Conference in New York City. Dykeman and Fayerberg presented “Protecting Your Intellectual Property (IP) When Working with Your Suppliers.” This session addressed conducting intellectual property due diligence and protection strategies for large and small companies, gaining insight into foreign filing considerations, licensing and distribution, and updates on technology confidentiality and branding strategies. To see the GT press release, click [here](#).



Life Sciences & Medical Technology

GREENBERG TRAUIG'S LIFE SCIENCES & MEDICAL TECHNOLOGY GROUP

Our Life Sciences & Medical Technology Group supports clients ranging from start-ups to large multinational public companies and not-for-profit care providers, as well as investors, venture capital and private equity funds, investment banks and public agencies. Our wide-ranging work encompasses numerous industry sectors, including biomedical engineering, biotechnology, chemistry, cosmetics, dietary supplements, disease management, drug delivery, EMR, billing and coding, immunology, medical devices, microbiology, nanotechnology, pharmaceuticals, stem cells and vaccines. For more information on our Life Sciences and Medical Technology Group, please visit <http://www.gtlaw.com/Experience/Industries/Life-Sciences-Medical-Technology>.

Greenberg Traurig, LLP is an international, full-service law firm with approximately 1750 attorneys serving clients from 36 offices in the United States, Latin America, Europe, the Middle East and Asia. In the U.S., the firm has more offices than any other among the Top 10 on *The National Law Journal's* 2012 NLJ 250. For additional information, please visit www.gtlaw.com.

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