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Save the Date - Upcoming Events

Greenberg Traurig's Life Sciences & Medical Technology Group will once again be hosting 2 events during the 2017 JPMorgan Healthcare Conference in San Francisco.

Monday, January 9, 2017

Lunch Workshop: Insiders' Views of Deal Making
Embarcadero Conference Center
4 Embarcadero Center | 3rd Floor Promenade Level
San Francisco, CA 94111
11:30 a.m - 12:00 p.m. Registration and Networking
12:30 p.m. - 2:00 p.m. Panel Discussion and Lunch

Confirmed Speakers:
Shaun Grady, **AstraZeneca**
Jeremy Sohn, **Novartis**
Paul Jansen, **Sanofi**

Wine Tasting and Networking Reception
Fogo de Chão Brazilian Steakhouse
201 3rd St #100
San Francisco, CA 94103
6:00 p.m. - 9:00 p.m.

Click here to RSVP to these events

Industry Articles and Alerts

In this Issue - Fall 2016:

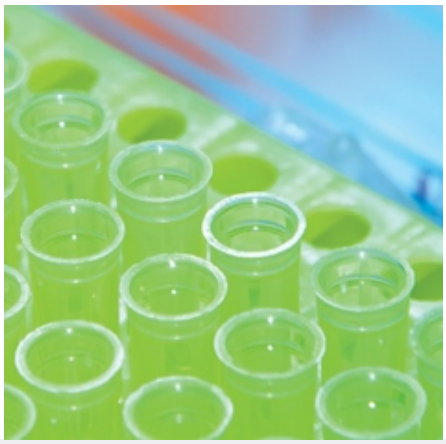
President Obama Signs GMO Labeling Bill into Law
By Charles F. Bass, *Robert Y. Maples, Alan Slomowitz, Washington, D.C.*

Medicare Pre-Claim Review Demonstration for Home Health

Services
By Nancy E.Taylor, Washington, D.C.

FDA Announces Changes to the Nutrition Information on the Labels of Food, Beverages, and Dietary Supplements
By Justin J. Prochnow, Denver and Nancy E. Taylor, Washington, D.C.

READ MORE



Greenberg Traurig in the Industry

Awards and Recognitions

Greenberg Traurig Recognized as "Finance & Transactional Firm to Watch" by LMG Life Sciences

LMG Life Sciences 2016 Guide Names 13 Greenberg Traurig Shareholders Named "Life Science Stars"

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Upcoming Events & Speaking Engagements

Greenberg Traurig Attorneys David J. Dykeman, Rick Taché and Ginger Pigott to Speak at DeviceTalks Boston

David J. Dykeman (Boston), Rick Taché (Orange County) and Ginger Pigott (Los Angeles) will present at DeviceTalks West, on December 12, at the Fairmont Newport Beach. Greenberg Traurig is a founding sponsor of the DeviceTalks series, and attorneys from the firm's global Life Sciences & Medical Technology Group have been featured speakers at every DeviceTalks conference since 2011.

View Recent and Past Events

About Greenberg Traurig's Life Sciences & Medical Technology Group

Our **Life Sciences & Medical Technology Group** supports clients ranging from startups to large multi-national 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 click here.

Greenberg Traurig, LLP is an international, multi-practice law firm with approximately 2,000 attorneys serving clients from 38 offices in the United States, Latin America, Europe, Asia, and the Middle East. The firm is No. 1 on the 2015 *Law360* Most Charitable Firms list, second largest in the U.S. on the 2016 *Law360* 400, Top 20 on the 2015 *Am Law* Global 100, and among the 2015 *BTI Brand Elite*.

For more information please click here.

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- Newsletter Editors
- Life Sciences & Medical Technology Co-Chairs
- Featured in this Issue

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In this Issue - Fall 2016:

President Obama Signs GMO Labeling Bill into Law

By Charles F. Bass, *Robert Y. Maples*, *Alan Slomowitz*, *Washington, D.C.*

On July 29, 2016, President Obama signed into law legislation that creates a nationwide mandatory labeling regime for genetically modified organisms (GMO) in foods. The law directs the Agriculture Department (USDA) to establish, within two years, a national process to identify GMO food products or ingredients that should be disclosed.

The President's signature came 15 days after the House gave final approval to a Senate bill (S. 764) that preempts existing state and local GMO labeling laws and bars similar laws in the future. Vermont, which put its GMO labeling law into effect on July 1, is most immediately affected. Laws on the books but not in effect in Alaska, Connecticut, and Maine also are now moot.
Read more.

Medicare Pre-Claim Review Demonstration for Home Health Services

By *Nancy E. Taylor*, *Washington, D.C.*

Beginning Aug. 1, 2016, the Centers for Medicare & Medicaid Services (CMS or Agency) will implement a three-year pre-claim demonstration for home health services in Illinois, followed by Florida, Texas, Michigan, and Massachusetts. The demonstration will begin in Florida no earlier than Oct 1, 2016; in Texas, it will begin no earlier than Dec. 1, 2016. In Michigan and Massachusetts, it will begin no earlier than Jan. 1, 2017.
Read more.

FDA Announces Changes to the Nutrition Information on the Labels of Food, Beverages, and Dietary Supplements

By Justin J. Prochnow, Denver and Nancy E. Taylor, Washington, D.C.

On May 20, 2016, the FDA announced that it finalized changes to the Nutrition Facts panel on the labels of packaged foods and beverages, as well as changes to the Supplement Facts panel on the labels of dietary supplements. The final regulations were published in the Federal Register on May 27, 2016. The final version of the revisions to regulations pertaining to the nutrition information are on the FDA website, as well as the final version of the revisions to the regulations pertaining to serving sizes and the Recommended Amounts Customarily Consumed (RACC). The FDA website also contains summaries and information links for the new revisions, including examples of the new format for the Nutrition Facts panel and side by side comparisons.
Read more.

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Awards and Recognitions

In this Issue - Fall 2016:

Greenberg Traurig Recognized as "Finance & Transactional Firm to Watch" by LMG Life Sciences

Global law firm Greenberg Traurig, LLP was named "Finance & Transactional Firm to Watch" at the *LMG Life Sciences* awards ceremony, Sept. 14th in New York City. In addition, David J. Dykeman, patent attorney, co-chair of the firm's global Life Sciences & Medical Technology Group and the Intellectual Property (IP) Group in Boston, was shortlisted for "Patent Strategy & Management Attorney of the Year – Massachusetts." The awards recognize and honor the leading firms, in-house counsel teams and lawyers that have played an important role in the life sciences industry during the past year.

"Greenberg Traurig's global Life Sciences & Medical Technology Group is pleased to be recognized by *LMG Life Sciences*," said David C. Peck, group co-chair and a shareholder in the firm's Fort Lauderdale office. "We continue to represent leading companies, research institutions, and investors in major corporate and M&A deals, IP strategy and litigation, major products liability cases, and regulatory matters."

LMG Life Sciences 2016 Guide Names 13 Greenberg Traurig Shareholders Named "Life Science Stars"

The *LMG Life Sciences* 2016 Guide's "Life Science Stars" includes 13 shareholders from global law firm Greenberg Traurig, LLP: Scott J. Bornstein (New York); Robert P. Charrow (Washington, D.C.); Lori G. Cohen (Atlanta); David J. Dykeman (Boston); Eric D. Hargan (Chicago); Melissa Hunter-Ensor, Ph.D. (Boston); David C. Peck (Fort Lauderdale); Richard C. Pettus (New York); Ginger Pigott (Los Angeles); Justin J. Prochnow (Denver); Barry J. Schindler (New Jersey); Nancy E. Taylor (Washington, D.C.). The guide serves as a resource for in-house counsel identifying leading lawyers and firms in multiple practice areas.

According to its website, *LMG Life Sciences'* research involved over 1,000 online surveys and interviews with nearly 600 attorneys in the United States, as well as a review of public information and feedback from clients within the industry. This qualitative process of peer opinion, market feedback, and independent research led to their list of highest profile, most sought-after, and best-attorneys working in life sciences.

Daily Report Selects GT's Atlanta Products Liability and Pharmaceutical, Medical Device, & Healthcare Litigation practices as 2016 Litigation Department of the Year Winner

Greenberg Traurig, LLP's Atlanta Products Liability and Pharmaceutical, Medical Device & Health Care Litigation practices have been chosen by the *Daily Report* as 2016 Law Firm Litigation Department of the Year winners. The firm was selected in the Product Liability category for its work delivering high stakes results for clients in the medical device and pharmaceutical fields.

Greenberg Traurig was one of five firms selected, and this is the second consecutive year the firm has been chosen as the winner in this category. Results will be published November 9 in *Daily Report's* annual Litigation Department of the Year special section. Recipients will be honored at a reception at the Ritz-Carlton in Buckhead that evening.

"Our Pharmaceutical, Medical Device and Health Care group continues to produce outstanding results for clients who find themselves in a wide variety of legal situations, including high profile, very public trials," said Ted Blum, managing shareholder of the Atlanta office. "This group's success is due in large part to the exemplary leadership of renowned litigator Lori G. Cohen, and her effort recruiting and training a top trial team of talented attorneys. Her win record is virtually unmatched, and this distinction from the *Daily Report* is confirmation that she and the entire practice are one of the best in the country."

Greenberg Traurig's Pharmaceutical, Medical Device and Health Care Practice represents some of the largest pharmaceutical and medical device companies in the world with the most significant product liability litigation affecting their industry, and the firm's Atlanta office plays a primary role in that effort. The Atlanta team continues to lead the firm in serving as preferred, coordinating, and national counsel for clients like Medtronic, Inc., Teva Pharmaceuticals, Inc., Takeda Pharmaceuticals, C.R. Bard, Inc., W.L. Gore & Associates, Novartis, Sandoz Inc., Kimberly-Clark Corporation, and Alcon Laboratories, Inc.

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In this Issue - Fall 2016:

Recent and Past Events and Speaking Engagements

Greenberg Traurig Attorneys David J. Dykeman, Rick Taché and Ginger Pigott to Speak at DeviceTalks Boston

David J. Dykeman (Boston), Rick Taché (Orange County) and Ginger Pigott (Los Angeles) will present at DeviceTalks West, on December 12, at the Fairmont Newport Beach. Greenberg Traurig is a founding sponsor of the DeviceTalks series, and attorneys from the firm's global Life Sciences & Medical Technology Group have been featured speakers at every DeviceTalks conference since 2011.

Dykeman will moderate the panel discussion, "Leadership Track: Hot Topics: M&A, IP and Product Liability Trends Impacting Medtech " He will be joined by Rick Taché and Ginger Pigott; Eric Geismer, Executive Vice President and General Counsel Caldera Medical Group.

Specific topics include:

- M&A trends from the perspective of both acquirer and seller
- IP protection is key to a successful exit
- Financing best practices from early stage to exit
- Products liability litigation - what every medtech company needs to know

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Greenberg Traurig's Lori Cohen and Sara Thompson to Speak at American Conference Institute's Drug & Medical Device Litigation Conference

Lori Cohen (Atlanta) and Sara Thompson (Atlanta) are scheduled to speak at the American Conference Institute's 21st Drug & Medical Device Litigation Conference, taking

place in New York December 5th-7th. Lori will be moderating the opening GC and CLO Roundtable: “What Keeps Me Up at Night When Faced With a Products Liability Action” on the first Main Conference Day on December 6th. Later on December 6th, Sara will be part of an Afternoon Breakout Session on “Mock Medical Device Preemption Motion to Dismiss: Formulating a Robust Defense Strategy for Sales Reps in the OR, MDR-based claims, Off-Label and More.” Greenberg Traurig is also serving as a Lead Sponsor of the conference.

Greenberg Traurig’s Lori Cohen Spoke at Louisiana Bar Association’s 16th Annual Class Action/Complex Litigation Symposium

Lori Cohen (Atlanta) spoke at two panels at the Louisiana Bar Association’s 16th Annual Class Action/Complex Litigation Symposium on November 11th in New Orleans. She spoke on a panel on “Women Lawyers in the Complex Litigation Courtroom; Tips and Views from Inside the Well,” as well as a panel discussion on a range of topics including the bellwether selection process; consolidation and multi-plaintiff trials; and live trial testimony via satellite transmission.

Greenberg Traurig’s IP Group to Speak at The Boston Bar Association’s Life Sciences Conference

On November 10, 2016, the Boston Bar Association will host its Life Sciences Conference featuring panels that will explore the interplay between the life sciences sector and the law. In session one, from 9:15 am to 10 am PT, Fang Xie (Boston) will speak on the panel, “Patent Subject Matter Eligibility in Biotech – Perspectives from the Industry, USPTO and Private Practice.” The session will discuss how to improve strength of patents and avoid some of the pitfalls in patent subject matter eligibility. In session two, from 10:15 am to 11 am PT, Dr. Melissa Hunter-Ensor (Boston) will speak on the panel, “The Impact of Brexit on the Life Science Industry.” Chinh H. Pham (Boston) is on the conference’s Advisory Committee.

Greenberg Traurig’s Anna B. Laakmann to speak at FDLI’s “Introduction to Drug Law and Regulation” Program

On November 2, Anna B. Laakmann (Washington, D.C.) will be speaking for two sessions at FDLI’s Introduction to Drug Law and Regulation program titled “Origins and Overview of the Organizational Structure of the FDA and the Regulation of Drugs” and “FDA’s Regulatory Processes” held at Ropes & Gray in Washington, D.C.

Greenberg Traurig’s Lori Cohen Spoke at Mass Torts Made Perfect

Lori Cohen (Atlanta) spoke at a panel on Thursday, October 20th on "Why the Most Successful Trial Teams Include Women” at Mass Torts Made Perfect (MTMP) in Las Vegas. MTMP is the largest gathering of plaintiff mass torts attorneys in the nation and Lori was one of the few defense counsel invited to speak at the event.

Greenberg Traurig’s Anna B. Laakmann Presented Webinar for FDAnews on False Claims Act Liability for Regulatory Noncompliance

On October 19, Anna B. Laakmann (Washington, D.C.) presented a webinar for FDAnews titled “False Claims Act Liability for Regulatory Noncompliance: An Update for Drug and Device Manufacturers.” Laakman discussed how regulatory noncompliance can form the basis of an FCA enforcement action by the government and highlighted areas of regulatory risk and discuss key developments about the implied certification theory of FCA liability.

Greenberg Traurig Shareholders David J. Dykeman and Eric D. Hargan Presented at ACS Clinical Congress' Program: "Innovation and Invention in Surgery"

David J. Dykeman (Boston) and Eric D. Hargan (Chicago) presented present at the American College of Surgeons' (ACS) Clinical Congress on Oct. 16-20, 2016 at the Washington D.C. Convention Center. The ACS Clinical Congress provides education and training opportunities for surgeons, residents, medical students, and surgical team members. They spoke at ACS' one-day program, "Innovation and Invention in Surgery," which outlined the process of developing, protecting, funding, and commercializing innovations and inventions in surgery. Dykeman presented on "Intellectual Property Considerations for Surgeons" and Hargan discussed "Regulatory Considerations, Clinical Trials and the FDA."

Greenberg Traurig's Justin J. Prochnow and Greg Sperla Spoke at Nutrition Law Symposium

Greenberg Traurig, LLP attorneys Justin J. Prochnow (Denver) and Greg Sperla (Sacramento) presented at the 12th Annual Nutrition Law Symposium in Lehi, Utah October 14. Prochnow spoke on the "FDA/GMP" panel, focusing on regulatory compliance, including:

- Good Manufacturing Practices (GMP) for dietary supplements;
- Inspections;
- Responding to Form 483 Inspection Observations and warning letters; and
- Updated nutrition Federal labeling regulations

For more information, click here.

Greenberg Traurig Shareholder Sean McKenna Moderated Panel at Texas Hospital Association Conference

Sean McKenna (Dallas) moderated a panel discussion at the annual Texas Hospital Association Conference held Oct. 10th – 11th in Austin, TX. The presentation, entitled "Enforcement Update," addressed current regulatory issues in health law and consequences related to health care fraud and abuse. The two-day conference was co-presented by the Health Law Section of the State Bar of Texas and featured continuing legal education from national and regional health law experts. McKenna presented with Nathaniel Kummerfeld and Joshua Russ, both Assistant United States Attorneys in the Eastern District of Texas.

Greenberg Traurig Patent Attorney Dr. Fang Xie Spoke at the Trans-Pacific Health Sciences Dialogue at Harvard Medical School

Dr. Fang Xie (Boston) was a panelist for the session "Managing Intellectual Property in Asia" at the Trans-Pacific Health Sciences Dialogue conference at Harvard Medical School, Boston on September 29. Dr. Xie and the other panelists discussed challenges and opportunities for biotech companies, including retaining US commercialization rights in license deals.

Greenberg Traurig Attorneys David J. Dykeman and Christiana C. Jacxsens Spoke at DeviceTalks Boston

David J. Dykeman (Boston) and Christiana C. Jacxsens (Atlanta) presented at DeviceTalks Boston, on September 28, at the Boston Marriott Long Wharf. Greenberg Traurig is a founding sponsor of the DeviceTalks series, and attorneys from the firm's global Life Sciences & Medical Technology Group have been featured speakers at every DeviceTalks conference since 2011.

Dykeman moderated the Executive Track panel discussion, "Hot Topics: M&A, IP, Financing and Products Liability Trends Impacting MedTech Companies." He was joined by Christiana Jacxsens; Dr. Omar Amirana, Senior Vice President, Allied Minds; Jeff Mann, Senior Managing Counsel, Med-Surg at Boston Scientific; Martha Shaddan, CEO, Rotation Medical; and Patrick West, Partner, Mirus Capital.
Specific topics included:

- M&A trends from the perspective of both acquirer and seller
- IP protection is key to a successful exit
- Financing best practices from early stage to exit
- Products liability litigation - what every medtech company needs to know

Greenberg Traurig's Rick Shackelford and Daniell Newman Spoke at FDLI Conferences in Washington, D.C. and San Francisco

On Sept. 14-15, Rick L. Shackelford (Los Angeles) spoke at the FDLI's Washington, D.C. conference entitled "Food Advertising, Labeling and Litigation." At that conference, Shackelford was part of a panel discussion that explored the biggest issues surrounding food industry litigation, how to avoid litigation, and what to do if your company or client finds itself on the receiving end of a lawsuit.

On Sept. 22-23, Daniell K. Newman (Los Angeles) presented a training course at the Food and Drug Law Institute (FDLI) conference in San Francisco entitled "Introduction to Food Law and Regulation." The training course covered general requirements for food labeling, including meat and poultry, as well as imports and international issues.

Greenberg Traurig's Eleanor (Miki) A. Kolton Spoke at HIPAA Compliance Boot Camp Seminar

Eleanor (Miki) A. Kolton (Washington, D.C.) presented a session entitled "Handling Medical Record Confidentiality Breaches: Best Practices for Worst –Case Scenarios" during the National Business Institute's HIPAA Compliance Boot Camp Training Seminar on September 22. The session provided an analysis of the strict requirements, ambiguous definitions, growing security threats, and other issues that can make HIPAA compliance a challenging endeavor. A major focus was to help practitioners and their clients remain effective in everyday practice while assisting to ensure full compliance with HIPAA.

Key topics included: exploring the essentials of HIPAA; picking up cutting-edge security techniques and technologies; knowing what is and is not permissible when using various forms of electronic communications; protecting against security threats; and analyzing HIPAA enforcement trends.

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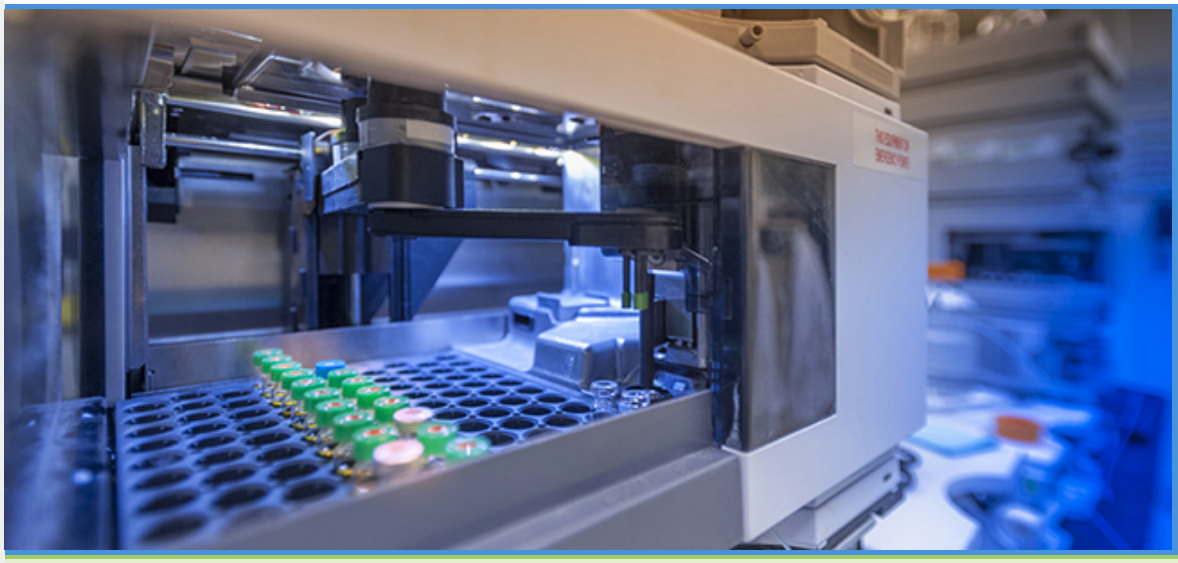

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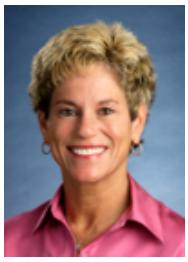

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