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New York

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Events & Speaking Engagements

MassBio's The Convergence of Medical Device & Drugs: The Future of Combination Products

MassBio's Convergence of Medical Device & Drug symposium will explore many of the diverse aspects impacting the future of combination products and feature discussions from industry experts and researchers. On May 12, 2017 from 1:30 - 2:45, Greenberg Traurig's David J. Dykeman (Boston) will moderate and participate in the "Innovation & Development" panel.

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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Industry Articles and Alerts

Amgen Inc. v. Sandoz Inc. Expected to Clarify BPCIA Obligations

By Scott J. Bornstein, Cort W. Welch, New York

The Biologics Price Competition and Innovation Act of 2009 (BPCIA) established an abbreviated approval process for biosimilar applications, but that process forces drug makers to navigate uncertain obligations for an applicant's disclosure of its application and notice of commercial marketing. On Jan. 13, 2017, the U.S. Supreme Court granted *certiorari* in *Amgen Inc. v. Sandoz Inc.* to hear arguments regarding the BPCIA's notice and disclosure requirements. Specifically, the Court will determine: (1) whether the BPCIA's disclosure requirements are mandatory for biosimilar applicants; and (2) whether the BPCIA's notice requirements effectively grant certain reference products an extended exclusivity period.

Read more.

Telemedicine: The Link to New Value-Based Payment Models

By Sabrina R. Gallo, Miami

The health care reimbursement landscape continues to change. Both governmental and private payers are trying to move away from traditional fee-for-service (FFS) payment models that reimburse pursuant to the number of services provided to those that reimburse based on quality or value. The Affordable Care Act established tools such as the Medicare Shared Savings Program and the Center for Medicare and Medicaid Innovation whose combined focus is utilizing alternative, value-based payment models that seek to achieve better care, smarter spending and healthier people.

Continue Reading (subscription required).

Read more.

In this Issue - Spring 2017:

Awards and Recognitions

Greenberg Traurig Adds Former FDA Director Karen Corallo

Karen C. Corallo has joined Greenberg Traurig's Washington, D.C. office as of counsel in its Health & FDA Business Practice. Corallo previously served as the Director of the U.S. Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) Division of Drug Imports, Exports, Recalls, and Shortages. Before that, she was Associate Chief Counsel in the FDA's Office of Chief Counsel where she handled enforcement work across all FDA-regulated commodities. At Greenberg Traurig, she will represent industry clients on pharmaceutical, medical device, foods, cosmetic, biologics, and other FDA-related matters, as well as on a wide range of health care issues.

In addition to her recent government work, Corallo was a commercial litigation partner in a global law firm and in-house counsel at a *Fortune 100* company. While with the FDA, Corallo authored and implemented the FDA's global drug imports strategy, participated in rule-making, and spearheaded important drug policy initiatives for the agency.

Corallo received her J.D. with highest honors from South Texas College of Law in 1984 and her B.A., *summa cum laude*, *Phi Beta Kappa* in English Literature from the University of Texas at Austin in

1979. She is admitted to practice in Texas. Currently, her practice in the District of Columbia is limited to matters and proceedings before federal courts and agencies.

Greenberg Traurig Trial Victory Named Top Defense Verdict of 2016

Greenberg Traurig's trial win on behalf of C.R. Bard, Inc. was recognized as a "Top Defense Verdict of 2016" by *Courtroom View Network (CVN).* In February 2016, a team led by Lori G. Cohen (Atlanta) obtained a complete defense verdict on behalf of C. R. Bard, Inc. in *Sherrer v. Boston Scientific, et al.,* Case No. 1216-CV27879, in the 16th Judicial Circuit of Missouri. C.R. Bard is a *Fortune* 500 medical device manufacturer of women's health products.

According to *CVN*, the Top 10 Defense Verdicts of 2016 are not only based on the potential amount of damages, but the facts of the case, the parties and attorneys involved, and the potential broader impact of the verdict.

The *Sherrer* trial was the first time jurors have been asked to simultaneously consider claims against two pelvic mesh manufacturers. According to *CVN*, because of the small number of actual trials in mesh cases "any jury verdict is significant, but the added complexity of two mesh devices manufactured by different companies implanted in the same plaintiff lands this trial in our number 1 spot." The plaintiff had requested $28 million in compensatory damages, claiming that the companies' pelvic mesh implants rendered her incontinent and suffering from pain and other ailments. The plaintiff also sought punitive damages against both defendants.

The *Sherrer* trial began Nov. 30, 2015, and the jury began deliberations Feb. 1, 2016. On the afternoon of Feb. 2, 2016, the jury announced a complete defense verdict for C.R. Bard and co-defendant Boston Scientific. Greenberg Traurig serves as national coordinating counsel and trial counsel for C.R. Bard in the national and international pelvic mesh litigation.

Greenberg Traurig Advises Biotest AG and Biotest Pharmaceuticals Corporation in the Sale of U.S. Therapy Business to ADMA Biologics, Inc.

Wayne H. Elowe (Atlanta) led the Greenberg Traurig team representing Biotest AG in the sale of its US therapy business. Greenberg Traurig Shareholders Stacey Orr Gallant (Atlanta) and Gerald L. Baxter (Atlanta) also were key members of the transaction team.

Biotest AG recently announced that it had agreed to a deal to sell major assets from its U.S. subsidiary Biotest Pharmaceuticals Corporation (BPC) to ADMA Biologics, Inc. The deal, which is expected to close later this year, will involve the sale by BPC of certain assets of its US therapy business, according to an ADMA Biologics press release, found at this link: http://bit.ly/2jkWvFm

Biotest Pharmaceuticals Corporation is a wholly owned subsidiary of Biotest AG, a German global provider of plasma products.

In this Issue - Spring 2017:

Events and Speaking Engagements

Health Care Coverage and Health Care Fraud and Abuse – The Current State and What Lies Ahead

On April 5, 2017, Nancy E. Taylor (Washington, D.C.) and Michael J. Cherniga (Tallahassee) led a timely discussion regarding today's top-of-mind health care issues, including a brief review on the status of the Affordable Care Act changes and perspectives on developments in fraud and abuse laws. The event was held at the Greenberg Traurig Washington, DC Office.

MedTech Partnering Day at Greenberg Traurig Boston Office

On March 28, 2017, Greenberg Traurig's Life Sciences & Medical Technology Group hosted the 4th MedTech Partnering Day at the Greenberg Traurig Boston office from 8:30 a.m. – 2 p.m. The event connected some of New England's most innovative emerging medtech companies with strategic partners Philips and Smith & Nephew to maximize opportunities for collaboration, new business development, and market expansion. This event gathered more than 75 innovators and leaders from across the medical device and technology industries and featured the GT's Karen C. Corallo (Washington, D.C); David J. Dykeman (Boston) and David C. Peck (Fort Lauderdale). We were thrilled to have representatives of Philips Ventures and Smith & Nephew participating with presentations from their medical device and healthcare divisions. Once again, Greenberg Traurig partnered with MassMEDIC and Leading Business

Ventures to produce this event.

Greenberg Traurig's Food & Beverage Group Presented and Exhibits at Natural Products Expo West

Justin J. Prochnow (Denver), Rick L. Shackelford (Los Angeles), Edward T. Schultz (Los Angeles), and Anthony J. Cortez (Sacramento) presented at this year's Natural Products Expo West convention, held March 8, to March 12, 2016, at the Anaheim Convention Center. This event is the world's largest natural, organic, and healthy products expo, attracting more than 77,000 industry professionals annually.

Greenberg Traurig's seminar, "All Natural to Zero Calories: The A to Z of Claims," took place March 10, 2017. The seminar discussion included strategies to avoid food labeling litigation, as well as defending against and limiting the risk of such claims; labeling regulatory requirements; the impact on equity investments and M&A deals; and the latest update on the BPA Prop 65 listing. This is the third year the firm has presented at Expo West. Greenberg Traurig is also a returning exhibitor.

Greenberg Traurig Shareholder Jed Dwyer speaks at the Latin America Compliance Congress for Life Sciences and the Global Anti-Corruption & FCPA Compliance Congress

Jed Dwyer (Miami) participated in a panel discussion at the Latin America Compliance Congress for Life Sciences and the Global Anti-Corruption & FCPA Compliance Congress, held Jan. 31-Feb.1, in Miami.

Dwyer was a member of the panel that covered "Battling Corruption – Lessons Learned and Legal Insights on Legislative Trends and Investigation Programs."

The Latin America Compliance Congress for Life Sciences and the Global Anti-Corruption & FCPA Compliance Congress are attended by top corporate executives in the pharmaceutical, medical device and biotechnology industries, as well as compliance, ethics and legal affairs experts responsible for understanding and complying with bio/pharmaceutical and medical device regulations in Latin America.

Greenberg Traurig Shareholders Speak at Medical Device Business Development: Mergers, Acquisitions & Corporate Strategy Conference

Barbara A. Jones (Boston) and Joshua M. Samek (Miami) spoke at the 3rd Annual Medical Device Business Development: Mergers, Acquisitions & Corporate Strategy Conference, Jan. 30 - 31, 2017, in Atlanta, Georgia.

Jones served a chairperson for the Jan. 31 program, providing welcome and closing remarks and introducing each panel presentation throughout the day. Jones served as a panelist for the interactive discussion, "Evaluating the Current M&A Landscape & Its Impact on Medical Device Industry Competition." Led by senior-level executives from the largest medical device companies, this session covered recent business development transactions and current opportunities for growth in various segments of the industry, and forecasted the potential impact on the competitive landscape.

Both Jones and Samek were panelists for "Case Study: Transactional Insight into Emerging Market Acquisitions." This panel covered strategies for identifying optimal deal structures for emerging markets, effective due diligence surrounding tax incentives, and overcoming challenges in anti-trust and anti-competition clauses.

Greenberg Traurig's Life Sciences & Medical Technology Group Holds Deal-Making Workshop and Networking Reception in San Francisco

For the third consecutive year, Greenberg Traurig's Global Life Sciences & Medical Technology Group hosted two events coincident with the JP Morgan Healthcare Conference in San Francisco.

On Jan. 9, 2017, from 11:30 a.m. – 2 p.m., the Group presented "Insiders' Views of Deal Making," a lively and informative panel discussion that featured seasoned executives from leading life sciences companies. Speakers shared best practices and pitfalls of deals, including M&A, licensing, joint ventures and strategic collaborations.

The panel was moderated by the co-chairs of Greenberg Traurig's Global Life Sciences & Medical Technology Group, David J. Dykeman (Boston) and David C. Peck (Fort Lauderdale), as well as Fiona Adams (London).

The program was followed by a private wine tasting and networking reception attended by more than 300 healthcare industry executives and investors.

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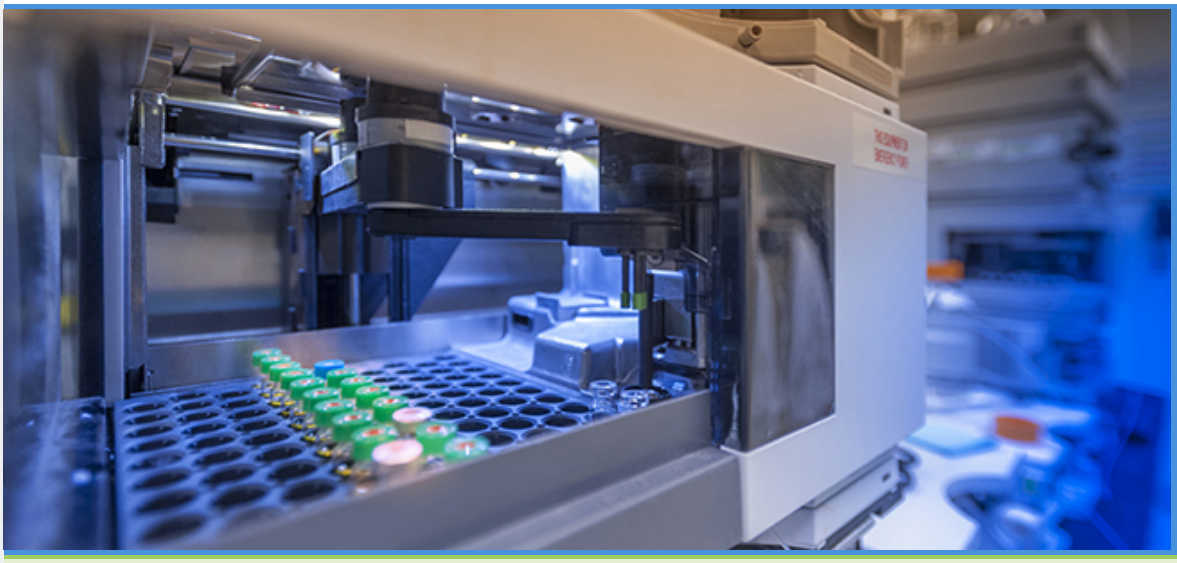

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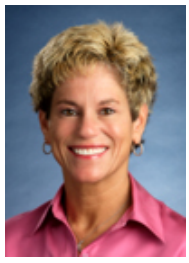

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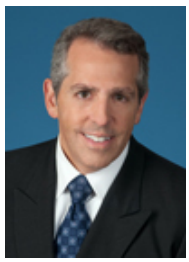

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