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FDANEWS PRESENTS THE

BIOSIMILARS REGULATION, LAW & POLICY

At a Crossroads?

SEPT. 28, 2017

LAW OFFICES OF ARENT FOX • WASHINGTON, DC

Agenda

8:00 a.m. – 8:30 a.m. Registration

8:30 a.m. – 8:45 a.m. Welcoming Remarks from the Chairpersons

Brian Malkin, Counsel, Arent Fox
George O'Brien, Partner, Hogan Lovells

8:45 a.m. – 9:30 a.m. Keynote Address: The Biosimilars Scene — The View from the Biosimilars Council

Christine Simmon, Executive Director, Biosimilars Council

9:30 a.m. – 10:45 a.m. Panel 1: Regulatory Issues — The Interchangeability Conundrum

Biosimilars are highly similar versions of a single, reference biological product with no clinically-meaningful differences in terms of safety, purity, and potency. The United States is the only jurisdiction in the world with the further opportunity for a higher level of similarity — interchangeable biosimilars — but can this standard be met? This panel will discuss the ins-and-outs of the FDA's recently issued guidance for interchangeable biosimilars and what's ahead on the regulatory front, including the role of the FDA's Advisory Committees. This session will take a deep dive into the FDA's recent interchangeable biosimilars guidance in the wake of the FDA's previous biosimilar guidances and approvals (or disclosed complete response letters/non-approvals) to attempt to read the tea leaves on when and if we will see interchangeable biosimilars approved in the U.S. in the near future. Panelists will also discuss how current and future biosimilars may be dispensed based on recent trends in state pharmacy laws.

Bruce Leicher, Senior Vice President & General Counsel, Momenta
Suzanne Sensabaugh, President and Principal Consultant, HartmannWillner

Moderator: **Brenda Huneycutt**, Vice President, Regulatory Strategy and FDA Policy, Avalere

10:45 a.m. – 11:00 a.m. Networking Break

11:00 a.m. – 12:15 p.m. Panel 2: Approval Issues — Detecting the Trends

There are now five licensed biosimilar products and several more in various stages of development, including multiple products under review by the FDA. This session will review the small but growing set of previously licensed biosimilar products to begin to identify significant trends. For example, what is the nature and amount of data supporting licensure of these biosimilars? Have best practices emerged for

navigating Advisory Committee meetings? Are there strategies that biosimilar sponsors have used to expedite development or approval time? Are there tools, such as citizen petitions, that reference product sponsors can use to influence FDA's decision-making? In addition, this session will also look at the impact of the next iteration of the Biosimilars User Fee Act (BsUFA II), which will become effective on October 1, 2017. What changes can sponsors expect to review timelines and overall likelihood of first-cycle approval? Will increased communication with the agency result in fewer complete response letters?

Gillian Woollett, MA, DPhil, Senior Vice President, Avalere
Brian Stone, Vice President Assistant Global General Counsel Regulatory, Mylan
Debra Barngrover, PhD, RAC, Senior Consultant at Biologics Consulting

Moderator: **David Fox**, Partner, Hogan Lovells

12:15 p.m. – 1:30 p.m. Luncheon Keynote: Biosimilars Regulation — The View from FDA

Steven Kozlowski, Director Office of Biotechnology Products at OPQ/CDER/FDA (Invited)
Leah Christl, Ph.D., Associate Director, Therapeutic Biologics and Biosimilars Team, FDA (Invited)

1:30 p.m. – 2:45 p.m. Panel 3: Post-Market/Pharmacovigilance Issues — The Latest FDA and FTC Initiatives and Strategic Challenges

This session will look at the present and future FDA and FTC initiatives to encourage biosimilar competition while allowing for enhanced tracking and tracing of post- market issues, including planned improvements in AERS and pilots of new post-market-drug-monitoring strategies. Current challenges in pharmacovigilance, potential adverse drug reactions, biological product naming, and pharmacoepidemiology will be discussed, along with the need for enhanced monitoring of current good manufacturing practices (cGMPs) for marketed biological products.

Nancy Lin, PhD, Senior Epidemiologist, OptumInsight and chair, Science Committee, Biologics and Biosimilars Collective Intelligence Consortium (BBCIC)
Elizabeth Jex, Attorney Advisor, Office of Policy Planning, FTC

Moderator: **Brian Malkin**, Counsel, Arent Fox

2:45 p.m. – 3:45 p.m. Panel 4: Intellectual Property Issues — Rights, Litigation & Impact of BPCIA

Intellectual Property Rights, primarily patents and exclusivity, are the main tools referenced biological product manufacturers will use to safeguard their interests. The Biologics Price Competition and Innovation Act (BPCIA) created a new pathway for biosimilar approval but did it create an equally effective mechanism for pre-launch patent litigation like the Hatch-Waxman Act? What are the tools for both referenced biological product and biosimilar manufacturers to use to effectively protect and enforce or challenge patents before product launch and what have been the stumbling blocks? What do experienced biosimilar product litigators see as the future in this arena and will more joint defenses come to play as more biosimilar manufacturers enter the field or will it all be one-on-one battles? And to the extent some battles are won by biosimilar applicants, how will this affect future research and development for biological products, including modified biological products seeking additional exclusivity? What role will IPR and other post-grant challenges

have on the "patent dance" and litigation strategies?

Matt Blischak, Vice-President and General Counsel, Global Specialty IP Litigation, Teva Pharmaceutical
Matthew T. Lord, Patent Counsel, Eli Lilly and Company

Moderator: **Brian Malkin**, Counsel, Arent Fox

3:45 p.m. – 4:00 p.m. Networking Break

4:00 p.m. – 5:00 p.m. Panel 5: Analysis of Hottest Topics and Open Mike

This session, comprised of speakers from earlier panels, will analyze the most problematic issues in the biosmilars space and respond to questions from the audience on topics such as EU v.US regulation and harmonization.

Brian Malkin, Counsel, Arent Fox
Nancy Lin, PhD, Senior Epidemiologist, OptumInsight and chair, Science Committee, Biologics and Biosimilars Collective Intelligence Consortium (BBCIC)
Gillian Woollett, MA, DPhil, Senior Vice President, Avalere

Moderator: **George O'Brien**, Partner, Hogan Lovells