2023 Life Sciences Summit Recap

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DLA PIPER

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The DLA Piper Life Sciences Summit brought together pharmaceutical, biotechnology, and medical device companies from around the world to discuss emerging trends and challenges facing the industry. This recap covers the main points of the summit sessions.

BY THE NUMBERS

7 sessions	27 speakers
180 attendees	13 represented countries

Political and legal challenges facing the life sciences industry

WHO

Richard Burr, Former US Senator, Principal Policy Advisor, Chair, Health Policy Strategic Consulting practice, DLA Piper

Jim Greenwood, Former Congressman, Senior Policy Advisor, Chair, Life Sciences Policy Practice, DLA Piper

What

Companies in the life sciences sector are currently facing tremendous uncertainty in Washington, DC. Among their concerns are the tensions of a coming election year, pressure by policymakers to reduce health care costs, and declining investments by the federal government into some areas of life sciences. During this session, former US Senator Richard Burr and former Congressman Jim Greenwood emphasized that organizations in the industry should be proactively reaching out to experienced advisors to help guide them through the quickly shifting regulatory environment.

Big takes

- The uncertain and often chaotic environment of federal policy making was on full display as the House of Representatives grappled with the speakership, a drama that was unfolding the night before the DLA Piper Life Sciences Summit took place.
- Former Congressman Greenwood tapped into his biopharmaceutical experience to give a lay of the land on the unique challenges facing many companies in the wake of the implementation of the healthcare and drug-related provisions in the Inflation Reduction Act.

"Washington, DC is operating in crisis management mode. Life sciences companies need to be forward thinking in their government affairs engagements and start setting the table for potential changes in Congress and the White House in 2025 so as not to fall behind."

— Richard Burr, Former US Senator and DLA Piper Principal Policy Advisor

The market for innovation: The current state of life sciences financings and M&A

WHO

Andy Gilbert, Global Co-Chair, Life Sciences sector, DLA Piper

Philip Ross, Global Chairman, J.P. Morgan Healthcare Investment Banking

What

The current state of life sciences financings and M&A has evolved from early 2022, when many predicted a financial downturn. What we have seen instead is a boom in the debt markets and an uptick of investment in an array of therapeutic areas.

REQUIREMENTS FOR A HEALTHY MARKET

These healthy market ingredients may be affected by the loss of past years' stability and predictability as well as the fluctuating political and regulatory environment.

Big takes

- Geopolitical concerns will remain a focus in financing and M&A.
- China is a big player in licensing US products, and the skill of negotiation in these situations is key.
- AI will play a major role in drug development. Investments and prospects are already strong.
- Inflation Reduction Act (IRA)
  - Full economic impact remains uncertain
  - There may be several unintended exclusions, such as orphan drugs
  - Likely to impact valuation, drug access, innovation, and competition, particularly for biosimilar drugs.

"Despite current challenges in capital markets, innovative therapies are still being developed and funded."

— Andy Gilbert, Global Co-Chair, Life Sciences sector, DLA Piper

Protecting your IP around the world in the era of an ever-changing patent landscape: The UPC and beyond

WHO

Nicole Endejann, Partner, DLA Piper

Gualtiero Dragotti, Partner, DLA Piper

Amy Lydon, Partner, DLA Piper

Chris Jewell, SVP and General Counsel, Taiho Oncology

Ken Peist, VP, Intellectual Property, Dermavant Sciences

What

Global IP protection and enforcement is crucial for pharmaceutical and medical device manufacturers in the life sciences sector. During this session, panelists discussed how IP strategies need to be considered across all stages of the therapeutic life cycle, from research and development, to market launch, and beyond.

Big takes

- Industry innovators need to secure patent protection in strategic markets, to gain both patent and regulatory exclusivity against aggressive generic drug makers.
- Securing exclusivity in the patent and IP spaces promotes reinvestment in costly but necessary product research and development.
- Our discussion of the newly launched European Unitary Patent system covered the advantages and disadvantages of applying for a unitary patent and offered early insights gained from patent infringement litigation before the European Unified Patent Court.

"The patent landscape is rapidly shifting and evolving. Industry leaders have to establish firm footing for global IP protection and enforcement strategies."

— Amy Lydon, Partner, DLA Piper

The future of drug pricing in the wake of the Inflation Reduction Act

WHO

Kirsten Axelsen, Senior Policy Advisor, DLA Piper

Rachel Portman, Policy Advisor, DLA Piper

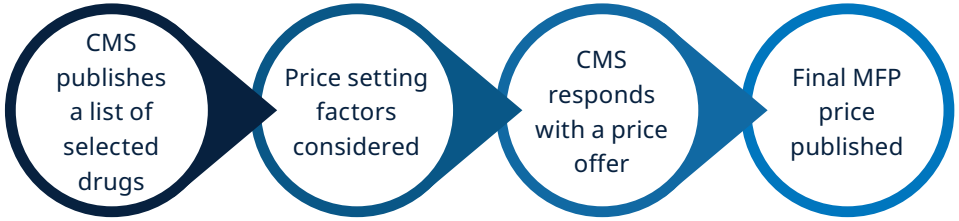
Angela Riemer, Vice President, Global Policy and Public Affairs, Oncology, Pfizer

What

The Inflation Reduction Act (IRA), signed into law in 2022, includes a number of provisions related to healthcare and drug pricing. These provisions are expected to have a significant impact on life sciences companies and the lives of millions of Americans. One of the provisions authorizes the Secretary of Health and Human Services to negotiate prices for selected drugs covered under Medicare Part D directly with manufacturers.

PROCESS FOR PRICE SETTING IN IRA

CMS selects the drugs, determines, and publishes a Maximum "Fair" Price



Big takes

- Global drug policy pressures around the world affect investment in biopharma and drug development.
- The presentation highlighted the IRA's key provisions and expected effects for companies in the biopharmaceutical space.
- From an industry perspective, it has been challenging to prepare for and navigate implementation of the IRA as there is a lack of transparency regarding how data and information from the manufacturer will be used by CMS and, therefore, how to make accurate and effective business decisions in this new regulatory reality.
- The IRA introduces some uncertainty for drug companies in the areas of research and development and incentives for bringing new drugs to market.

"The Inflation Reduction Act's full impact on drug pricing and innovation is still emerging. To be ready for these coming changes, companies need to understand the short- and long-term implications of the law."

— Kirsten Axelsen, Senior Policy Advisor, DLA Piper

Strategies for companies expanding globally

WHO

Jeff Baglio, Partner, DLA Piper

Victoria Rhodes, Partner, DLA Piper

Maruti Narayan, Partner, DLA Piper

Subin Baral, Global Deals Leader, Life Sciences, Ernst & Young

Prof. Dr. Katharina Janus, President and CEO, ENJOY STRATEGY

What

Life sciences companies face a variety of challenges when expanding and doing business globally. The US stands as the largest market in this sector, making it a crucial target for expansion. Life science companies need to develop a global plan for business development from the start and consider what partnerships may be necessary to reach desired markets.

Big takes

- Companies often look to other markets, such as the EU, as test cases before entering the competitive US market.
- Before accessing a new market, partnerships, rather than acquisitions, are often a good first step. For smaller companies, this is often the only way to access certain markets.
- Talent acquisition is another consideration for strategic growth, with the US being an attractive recruiting market.
- Regulatory schemes may differ greatly between jurisdictions and need to be taken into consideration when developing a regulatory program.
- The COVID-19 pandemic has allowed companies to fill gaps in care through remote provision of services. These resource shifts have opened the door to previously unconsidered joint ventures.

"Companies must keep global expansion top of mind if they are looking to grow in any significant manner. Despite all of the incentives being put forth by regions, that still means targeting the US for commercialization, and potentially China, as the two leading markets globally."

— Jeff Baglio, Partner, DLA Piper

The rise of Big Data: Legal challenges raised by artificial intelligence and other data science trends

WHO

Danny Tobey, Partner, DLA Piper

Aviva Wein, Assistant General Counsel, Products Liability, Johnson & Johnson

Michael Haughney, Director, Global Compliance Monitoring and Analytics, Bristol Myers Squibb

Michele Adeleye, Vice President and AGC, Chief Counsel Digital, Pfizer

What

This lively discussion explored how AI is one of the most horizontal technologies in history. Because AI permeates all sections of company operations when integrated, its governance cannot be properly managed by one individual (CTO, CCO) or one group. Instead, companies are best served by creating collaborative groups combining tech, legal, compliance, and other departments to build structural compliance and risk-management systems.

Big takes

INTEGRATION

- Integrate AI guidelines and lexicon across the company to ensure understanding.
- Subject matter knowledge paired with emotional intelligence is crucial to effectively communicate the information to non-tech-savvy employees.
- Education at all levels is critical to ensure data and algorithms can be understood by end users.
- Transparency and explainability are paramount to mitigate risk to your organization.

LITIGATION

- AI's broad impact requires companies to assess risks from various perspectives including privacy, compliance, litigation, patents, clinical, and commercial.

- Regulatory shifts have begun defining AI as a "product" for purposes of product liability case law, and courts may soon do the same.
- Data scientists and software developers must understand how their final product is used in order to comply with regulations and defend against lawsuits, such as those alleging a violation of the learned intermediary defense.

"We don't need a crystal ball to see that AI is already transforming the world. The emergence of generative AI points to a future where AI is inevitability embedded at every level, so companies should start to think about the issues now, before they have to play catch-up."

— Danny Tobey, Partner, DLA Piper

FDA regulation of new medical technologies

WHO

Geoff Levitt, Of Counsel, Co-Chair, FDA Regulatory Practice, DLA Piper

Perham Gorji, Partner, DLA Piper

Keo Shaw, Of Counsel, DLA Piper

Karen Day, Senior Counsel, Pfizer

Monaya Krause, Chief Global Regulatory Counsel, GE HealthCare

Anne Baker, Director of Legal Affairs, Regulatory, Quality & Compliance, Dexcom

What

With the transformative pace of medical innovation, there is a great deal of FDA regulatory activity with respect to new technologies. This session delved into industry concerns about FDA expectations for new medical technologies amid legal challenges to FDA's authority.

Big takes

- FDA's final guidance on clinical decision support (CDS) software continues to be controversial, but industry is charting an uneasy path forward.
- The recent guidance on prescription drug related use software (PDURS) leaves a lot of room for interpretation.
- Cybersecurity remains a crucial topic. New guidance has been outlined regarding cybersecurity controls on different devices, which would require companies to revamp existing policies and procedures.
- The Supreme Court is currently considering whether to hear litigation involving mifepristone. Medical product companies are watching closely to see if the courts set a precedent for diminishing FDA's authority over drug approvals. That result would increase regulatory uncertainty and may suppress innovation.

"Life sciences companies are working to navigate the complex, evolving regulatory landscape for safe, groundbreaking innovations in new medical technologies. Their path is marked by challenges, and the way they are persistently tackling these very challenges marks the future of healthcare."

— Perham Gorji, Partner, DLA Piper