SpencerFane®

Spencer Fane Duo to Explore U.S. Pharmaceutical Law Developments at International Conference

Spencer Fane is pleased to sponsor the Medicines for Europe 20th Legal Affairs Conference on June 8-9 in Athens, Greece. Attorneys Brian Malkin and Jeremy Lowe present at the event.

Every year, this conference gathers industry leaders, EU policymakers, authorities, and health care stakeholders to explore two decades of European pharmaceutical law and policy with a focus on follow-on hybrid products (505(b)(2) NDAs in the US), generic and biosimilar drug products. Topics range from pharma legislation reform to SPC updates and patent quality.

Brian and Jeremy will lead the roundtable discussion, Developments in the U.S.: the FDA's Skinny Label Dispute and the 2026 Appropriations Act. The team will examine recent legal and policy developments in the U.S. affecting generic and biosimilar drug manufacturers, focusing on challenges involving the FDA's "skinny label" pathway – the practice of seeking FDA approval for a version of a branded drug that excludes (or "carves out") patented or protected uses from the label, how the 2026 Appropriations Act has impacted generic drugs where having the same inactive ingredients (Q1) in the same amounts (Q2) is critical to demonstrate similarity, and how inter parte review of patents has evolved due to the U.S. Patent and Trademark Office's discretionary denial process. Brian and Jeremy will further highlight the implications of these developments for market access, patent strategy, and transatlantic regulatory alignment.

At Spencer Fane, Brian streamlines processes for clients navigating the complex intersection of patent law and food and drug law, leveraging unique public and private sector experience, in-depth creative and strategic analysis, and advanced

negotiation tactics to meet and exceed stakeholder expectations.

Brian and Jeremy co-lead the firm's Life Sciences and FDA Market Team, and Jeremy leads the firm's Patent Litigation and Hatch-Waxman and Biologics Litigation Market Teams, focusing on high-value litigation engagements across a range of technical sectors and jurisdictions and providing strategic counsel on regulatory compliance, Hatch-Waxman litigation, BPCIA litigation, and Federal Circuit appeals.