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John Allen and Brian Malkin Analyze Congressional Fix to Orphan Drug Exclusivity in Law360

Spencer Fane attorneys John Allen and Brian Malkin wrote the article New Orphan Drug Law Provides A Key Fix For Pharma Cos., recently published by *Law360*.

In the article, which was originally a firm blog post, the team addresses legislative changes affecting orphan drug exclusivity. They outline how these updates resolve prior uncertainty and clarify how exclusivity will be applied moving forward, while also considering the broader impact on drug development and innovation in the rare disease space.

"The amendment [Section 6605 of the CAA] replaces the statutory phrase 'same disease or condition' with 'same approved use or indication within such rare disease or condition.' This change makes explicit what FDA had long maintained: orphan drug exclusivity blocks approval of the same drug only for the same approved use or indication, not for all uses within the broader designated disease," the team wrote.

At the firm, John is a vigorous litigator who focuses on clients' intellectual property rights, creating and strengthening meticulous plans to protect patents, trademarks, trade secrets, and copyrights. With a diverse background in biology, general litigation, and concentrated IP matters, his practical and technological insight lends itself to markedly thorough defense strategies.

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.

Read the team's full article here. Please note, a subscription may be required.