



Brian Malkin Discusses the Future of FDA Regulation on FDA Watch Podcast

Spencer Fane attorney [Brian Malkin](#) was recently featured on the FDA Watch podcast, joining host Wayne Pines for an episode titled "[An Evolving Direction for Drug Oversight](#)."

In the episode, Brian speaks on key developments shaping the future of FDA regulation and oversight. He explores potential leadership priorities under FDA Commissioner Heidi Overton, emerging issues affecting pharmaceutical and biotechnology companies, drug pricing, artificial intelligence in drug development, new approach methodologies (NAMs) as alternatives to animal testing, and evolving considerations for generic drug manufacturers. The episode also highlights recent FDA news and regulatory developments impacting the pharmaceutical, medical device, food, and cosmetics industries.

When discussing the FDA's level of clarity on AI and how companies are using it for drug development, Brian said, "I've not seen a great improvement in AI for the selection of drug candidates. AI is useful in compiling a lot of data together, but you still need to evaluate it. It has its places to be used, but I believe the FDA's guidance is thin in this regard."

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 is a Partner in the Spencer Fane Washington, D.C. office.

Listen to Brian's full podcast episode [here](#).