2018 THE NATIONAL LAW JOURNAL

TRAILBLAZERS

WHITE COLLAR, REGULATORY & COMPLIANCE

John R. Manthei

Latham & Watkins LLP

PIONEER SPIRIT John Manthei served as majority counsel for the U.S. House of Representatives Committee on Energy and Commerce, where he advised the full committee, subcommittees and House leadership on FDA issues. In private practice, he continues to assist pharmaceutical, biotechnology, and medical device companies on premarket development, post-market compliance, and related FDA litigation. "In addition to my regulatory expertise, I have been able to use my legislative experience to help life sciences companies navigate Washington to advance their business goals."

TRAILS BLAZED Manthei is now global co-chair of the Latham's Healthcare & Life Sciences practice. Among his matters, Manthei provided regulatory advocacy to Pacira Pharmaceuticals. "The company had fantastic technology that provided nonopioid alternatives for surgical pain. The FDA sent a warning letter saying the scope of the product approval was narrower than it was. We engaged with the agency, ultimately filed a lawsuit and settled. We ended up with better product labeling as a result. There are only three known times when the FDA withdrew a warning letter, and this is one of them." In his role as majority counsel prior to joining Latham, Manthei worked to amend the Controlled Substances Act regulation of GHB. "The drug was horribly abused and needed DEA's aggressive oversight. However, it also had promising therapeutic effects. I was proud to work with the DEA, DOJ and industry to develop it as a treatment while enabling DEA to keep it out of the wrong hands."

FUTURE EXPLORATIONS Innovation is occurring rapidly, and drug discovery tools are getting better. "I'm very optimistic where the life sciences industry is going, with incredible advances across the field. The challenge will be to ensure regulators are in a position to deal with and encourage the innovation. The next 5-10 years will be really exciting."