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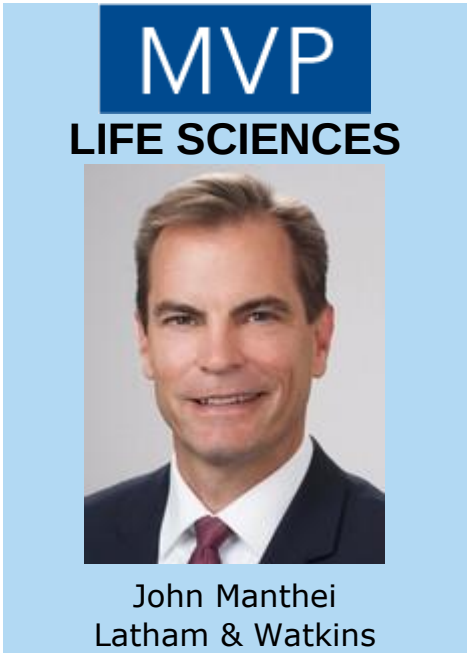
# Life Sciences MVP: Latham & Watkins' John Manthei

By **Y. Peter Kang**

*Law360, Los Angeles (December 13, 2016, 2:44 PM EST)* -- Latham & Watkins LLP's John Manthei served as lead counsel for Pacira Pharmaceuticals Inc. in a dispute that prompted a rare formal withdrawal of a U.S. Food and Drug Administration warning letter, earning himself a spot on Law360's list of Life Sciences MVPs.



John Manthei
Latham & Watkins

Manthei, a Washington, D.C.-based partner and global co-chair of Latham's health care and life sciences practice, chalks up his success in the past 12 months to his strong understanding of the science behind his clients' businesses and the law firm's stable of talented life sciences attorneys.

"One of the strengths Latham has is a broad and deep practice that enables us to service the diverse needs that [life sciences] companies have," he said. "It runs the gamut from regulatory issues, fraud and abuse issues, corporate counseling, licensing, antirust or litigation. We have structured our practice to work with companies in one spot. It makes us efficient and able to partner with companies in a unique way."

Some of the qualities that sets him apart, Manthei said, are a "deep understanding of the science, stepping back and seeing what's being regulated and why, and working with clients to achieve their business objectives."

The firm's collegial environment and the skilled attorneys in the life sciences practice doesn't hurt either, Manthei said.

"The practice here at Latham has been growing," he said. "It's a remarkably talented group of people and fun to be a part of it."

One high-profile case Manthei's team handled was a successful challenge of an FDA warning letter regarding off-label marketing for Pacira's non-opioid painkiller Exparel, the New Jersey drugmaker's flagship product.

The bet-the-company litigation in which Pacira challenged the FDA and U.S. Department of Justice on

First Amendment grounds compelled federal health regulators to withdraw the warning letter, marking just the third time the FDA has done so in its history. The drugmaker had sued the FDA in September 2015 for allegedly violating the Administrative Procedure Act and restricting Pacira's commercial speech.

As part of a December 2015 settlement, labeling changes were made that reaffirmed the off-label, or unapproved, uses of Exparel, along with a rescission letter from the FDA formally retracting its September 2014 warning letter related to certain promotional materials.

The outcome was a resounding victory for Pacira that reflects Manthei's shrewd negotiating skills, FDA regulatory know-how and strategic problem-solving, according to Latham. Manthei said it absolutely ranked near the top of his career achievements.

"It's among the cases that I've enjoyed being a part of the most," he said. "[Pacira is] a fantastic company with a fantastic product that is making a major contribution to providing non-opiate alternatives in an area where it's desperately needed."

Manthei said the case taught him to encourage companies to not be afraid of defending their position in the face of regulatory scrutiny.

"If your position on the science or the statute are at odds with the FDA, companies should not be afraid to defend themselves," he said. "You should always attempt to work collaboratively, but there are times where you shouldn't be afraid to defend yourself either."

Manthei also represented Boston Scientific Corp. and medical device industry advocacy group Medical Device Manufacturers Association in negotiations with the FDA, the White House and Congress over the 21st Century Cures initiative, which was recently passed by Congress and is expected to receive presidential approval. The attorney played a key role in negotiating the proposed legislative and administrative reforms, Latham said, including drafting several provisions of the landmark proposal.

The bill, which also includes other legislation on mental health policy, would change research prioritization and medication review rules at the FDA and the National Institutes of Health, and medication development rules for everything from new antibiotics to medical devices.

Looking ahead, Manthei said it was an exciting and dynamic time in the life sciences industry.

"There is so much innovation that is occurring," he said. "There is a lot of different technology out there that is improving drug development and biotech development at a time when the pace of innovation is only getting faster and faster."

--Additional reporting by John Kennedy and Michael Macagnone. Editing by Edrienne Su.

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