

# Life sciences execs say innovation may flee U.S.

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Excessively burdensome regulations issued by the U.S. Food and Drug Administration threaten to bring about a crisis in biotech and medical device innovation, representatives of local life sciences companies and trade groups said Monday to a House subcommittee.

The executives said the FDA has tilted too far in the direction of preventing harm, reducing the benefits patients might receive from innovations, and could cut short the flowering of investment and growth in life sciences.

They spoke to two members of the House Energy and Commerce Committee and its Subcommittee on Health: Rep. Brian Bilbray, a San Diego Republican who is on the energy and commerce committee, and Rep. Michael Burgess, a Republican from Texas and vice chair of the health subcommittee. They held the meeting at UC San Diego's Scripps Institution of Oceanography in La Jolla.

Bill Walton, the former basketball star turned entrepreneur, said he is a beneficiary of innovation from San Diego-based NuVasive and UCSD orthopedic surgeon Steven Garafin. Together, they helped him recover from excruciating pain caused by a spinal injury in a 1974 NBA game that drove him to the brink of suicide.

"I was lucky. I was saved," Walton said, "I came across medical innovators that reconstructed my spine and gave me my life back. I had no idea what life was like without back pain. They saved my life.

"However, while U.S. companies struggle with longer wait times for regulatory approvals and an increasingly uncertain regulatory approval process, our global competitors are streamlining their regulatory systems, which attract capital and companies to their shores," Walton said.

Kevin T. Larkin, president and CEO of Irvine-based TherOx, said an ill-informed FDA advisory panel rejected his company's heart attack treatment, despite its meeting safety and effectiveness goals. For example, he said, of 15 doctors on the panel, just three regularly treated heart attack patients.

"They were concerned about 1.8 percent death rate in the TherOx treatment group. They didn't understand the normal rate was less than 3 percent at the time. They didn't know," Larkin said.

As a result, the company had to lay off half of its employees and heart attack patients lost access to a new and effective treatment.

Joe Panetta, president and CEO of the San Diego-based life science trade group Biocom, told Bilbray his companies see a "disconnect" between FDA advisory committees and the agency's rules.

Bilbray said that problem is exacerbated by the FDA's overzealousness to avoid conflicts of interest. That results in reviewers who, while they may be conflict-free, are also unfamiliar with the subject, he said.

Panetta said the FDA strikes investors as arbitrary and afraid of risks.

"This environment has created a funding crisis for many small and midsize companies," Panetta said, "These are the companies that have been central to the growth of the life-sciences industry over the past 20 years, an industry that has consistently outperformed other sectors through past economic downturns."

Investors have acquired "an absolute fear of innovation," said San Diego biotech veteran Steven Mento, president and CEO of Conatus Pharmaceuticals Inc.

"We're in dire straits. In five years, you're not going to have to worry about regulating innovative drugs, because there's not going to be any," Mento said.