The FDA is there to protect patients? Bullsh*t

Mass Device

The FDA is not equipped to determine which therapies will benefit which patients, according to medical device legend Dr. Tom Fogarty.

Fogarty (l) and Abele

The FDA isn't capable of living up to its mandate to balance risk and safety for patients, according to medical device legend Dr. Tom Fogarty, a serial medtech entrepreneur who's also a consultant for the federal watchdog agency.

Speaking alongside Boston Scientific [1] (NYSE:BSX [2]) co-founder John Abele at this week's AdvaMed 2012 conference in Boston, Fogarty said even doctors sometimes have difficulty figuring out whether a patient will benefit from a certain therapy.

"The fact is that we as physicians have a hard time, in some situations, determining what a risk is and what a benefit is, and when it will work for 1 patient but it won't work for another patient," Fogarty said. "And to think that an outside agency is prepared to do that is just wrong. They can't do that. ... The changes to technology outpace the ability of FDA and [the Centers for Medicare & Medicaid Services] to keep track of it."

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