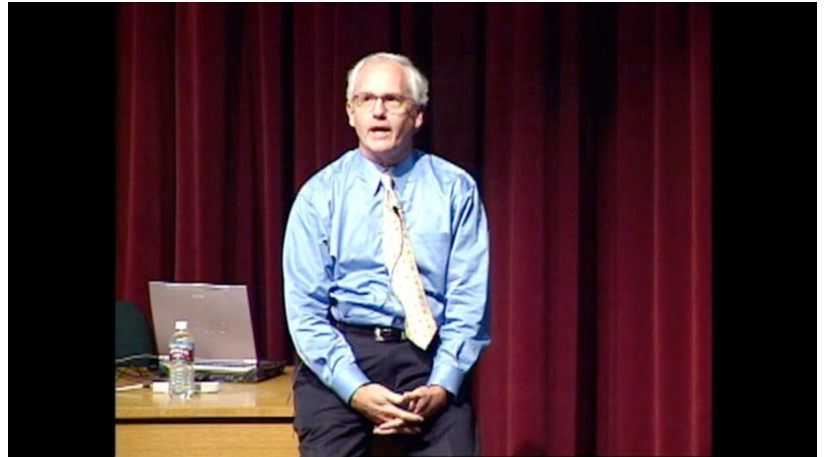


URL: <https://stvp.stanford.edu/blog/videos/fda-and-medicare>

Yock emphasizes that in MedTech, there are two forces that can make your life miserable- the FDA and Medicare. He emphasizes the importance of understanding how medicare will handle new technology. Same with the FDA; there are different pathways through the FDA and sometimes it takes longer than a year and that can be a problem in getting a technology through.



Transcript

So some of you know this but I just want to emphasize in Medtech, there are these two powerful forces that really can make your life miserable.. One is called the FDA and one is called Medicare; both government agencies for some reason.. We've talked a little bit about how Medicare pays for things and you have to understand how Medicare is going to pay for your new technology.. If you can't get that technology reimbursed by Medicare, you're not going to have a technology.. Nobody is going to support it and when you're launching your idea, you have to have a very precise answer about how Medicare is going to handle it.. Same for the FDA, there are different pathways through the FDA.. I just loaded up one thing that shows that for one pathway called the PMA pathway on average, you're talking about longer than a year to get approval from the FDA.. It can be a lot longer than that.. That's a fundamental problem in getting medical technology through.. That's way different than what some of you are used to thinking about with hardware and software...