

URL: <https://stvp.stanford.edu/clips/smart-regulation-with-clear-guidelines>

Rock Health CEO Halle Tecco discusses viewing regulatory approvals as a competitive advantage. While supporting the role of the FDA in protecting patients, Tecco also advocates for a more clear process for FDA approval in the healthcare space.



## Transcript

So the question was around the regulatory burden on entrepreneurs and how my organization kind of supports entrepreneurs to that process.. So I mean just today we had the CTO of HHS, Health and Human Services, in our office talking to our entrepreneurs about what they are working on.. So just being able to kind of bring someone in and talk to many people at once is really helpful.. We've never been afraid of the FDA.. In a lot of ways I think of the FDA as a competitive advantage because if you can get FDA approval like CellScope, they got FDA approval, it takes your competitors that much longer to get to that point.. And the FDA really is around to protect patients and we've met with them and we know that they're intent is to protect patients.. So as long as there is a clear process for getting FDA approval, then I think that's a fair thing that we have in our society.. I think where it gets challenging is when it's unclear that - that process is unclear.. And there is a lot of uncertainty around the mobile health guidelines.. And so if you put a - so medical devices have long been regulated by the FDA..

If you claim to treat or diagnose anything, you have to get approved by the FDA.. So the million dollar question is if you put an app, a healthcare app on your smartphone, does that turn your smartphone into a medical device? And does that app need to be regulated? And for a long time we didn't -- we still don't quite know what the FDA is going to do, but they are starting to put out guidelines.. And for me I would rather have very clear guidelines of what's regulated and what's not than ambiguity, because that's when entrepreneurs step back and say well I'm not going to invest in building this because I don't know if the FDA is going to come down on me.. But when we have kind of clear processes and understanding, and a process that's not too expensive, then I think its something that is necessary in society...