2022.11.14 HHS Convening to Advance Patient Safety

Transcript of remarks by FDA Commissioner Robert Califf

Robert Califf: Thanks. It's great to be here with you as a long-standing intensive care unit director for 35 years. I very much relate to a lot of the things that I've heard today. And I'm saddened to, you know, see the new data about the deterioration in patient safety, but I know this is related to so many of the factors that you're going to discuss. I am uplifted whenever I come up to this floor to think about John Eisenberg, who taught me a lot about this in my younger days, a lot of fond memories of that. And I'll quickly go through a few things about the FDA.

Next slide. First thing is just to point out that safety, I think, as you all know is the core bedrock of the function of the FDA and its mission. But right there with safety is also advancing the public health by speeding innovation. I know many of you struggle with this two-sided coin of how do we push innovation at the same time, they were trying to maintain a safe environment. I want to call attention to the third part of the mission, they're accurate information. I'm going to come back to that in just a second.

Next slide. There are three areas where we've worked hard recently to improve our effort and safety. The first is modernizing the methods that we use to develop more efficient pathways in the context of so much stress that you're all under. Second is just to know that we've learned a lot during the pandemic, a lot of things not to do and a lot of things that we should do better, and I hope we can carry those forward. And third and critical to all of this, I think, is the integration of technology, not for technology's sake, but actually to make the lives and work of our healthcare workers more efficient and more productive.

Next slide. I just want to -- I cannot stress this enough that modernization within the federal agencies of the technology infrastructure, I think, is essential to the work that you do. And I want to ask you to help us out in this regard because my experience in the private sector says you got a lot better technology on average than we have. And -- but we need to be working together to be able to share information in a modern technology sentence.

Next slide. Keep pushing through this slide. I didn't realize it was in segments. But what we really need to go to, we believe that FDA is to get out -- go back one. Go back. We're going forward instead of back. There we go. We need to get out of the system we're now in. When we put products on the market, they're out there and you're using them. A lot -- we don't know a whole lot about what happens when they're used and we don't have an efficient system to measure what's happening. What we need to do is go to a system where active surveillance is the norm. We embed studies or randomized trials or cluster randomized trials or whatever it takes to figure out what to do with those products in how they interface with the healthcare systems that you're running. And I can say with great confidence, there's not a technological limitation to making this happen. The limitation is the same cultural phenomenon that had been hurting us with patient safety all along.

Next slide. This is my depiction of the current system in terms of information flow. You have a lot of blobs up there. They're not connected to each other. They're each incentivized to optimize their own well-being regardless of what it does to the well-being of the system as a whole.

Next line. What we would hope at FDA is we've got something that looks like this. We're all talking about patient-centeredness. I don't think you have to ask too many patients in the American healthcare system as to whether they think it's patient-centered to get the answer as to our success in that regard. And I would argue that a good bit of it has to do with really centering around patients. And very importantly, I was so pleased to see Bob talk about the quadruple aim, not just the triple aim because it's abundantly clear now. But unless we have a stable, happy workforce doing their work, it's going to be very hard to have a safe environment. If we set around that and let the information flow equitably to all sides, I think we'll be in a much better system.

Next slide. And then lastly, I think people know this is always essential to what I say these days and it's essential from the FDA's perspective. So much of the patient harm that we see today is because of misinformation, not just people in society, but also our frontline clinicians are diluted with information, some of which is accurate, and much of which is inaccurate. And we need to work together and we need your help to battle this. The federal government cannot tackle this alone.

Next slide. This is the last slide. Just to make a point, we're working hard on this and with our fellow federal agencies, but we're going to need to all work together to start the ball moving in the right direction. Thank you.