MEDTECH INSIGHT
CITELINE COMMERCIAL

13 Jul 2022 | **News**

Q&A: FDA Chief Califf Talks Clinical Trial Diversity, Using AI/ML For Inspections, User Fees, And More

by Shawn M. Schmitt

The commissioner of the US agency, Robert Califf, answered questions on a variety of timely issues at a 12 July fireside chat. Here are three key takeaways for medtech.

Robert Califf, the commissioner of the US Food and Drug Administration, is concerned that a laser focus on ensuring diversity in clinical trials is a sideshow from the real problem: "lack of equity in our health care system."

Speaking at a 12 July fireside chat sponsored by the Alliance for a Stronger FDA, the agency head said that if the disparity was fixed and health equity was ensured, "clinical trials will follow suit."

"But having said that, …we'll work hard on helping to increase diversity in clinical trials," Califf added.

Below are three memorable questions answered by the commissioner during the chat. Questions have been edited by *Medtech Insight* for clarity and brevity.

Q **Obviously user fees are an important component of FDA's ability to do its work. And obviously we're almost to the August recess of Congress. What are the implications for the agency if user-fee legislation isn't passed by August?**

A Robert Califf: There are enormous implications for the agency, as you know. On the medical products side this is a very significant part of funding. And basically, we have to lay people off if the user fees don't go through. And even if we approach that cliff,

we are very dependent right now on hiring people. We're in the period of the Great Resignation.

I've noticed that certainly, in my life in Silicon Valley, people came and went fairly rapidly from one organization to another. And who wants to work in an organization if you're afraid that these jobs are not even going to exist in the next short period of time? So we really need to avoid that. But in addition to that, we've got to consider the consequences for the public, for the American people. If the user fees are not funded, …we'll review products as quickly as we can, but the timelines go away. And the commitment to the timelines goes away, because there's no way you could meet those commitments. We wouldn't have the people to do it.

…It's just hard for anyone to believe that the user fees wouldn't get passed, but it's really important that we get them passed so that the transition into the next phase can occur without disrupting employment and function at the FDA.

Q **The FDA has talked about the importance of embracing and advancing diversity. And you also talk about in the budget the importance of addressing health equity, which connects more broadly to priorities in the [Biden] administration. What are your thoughts on that?**

A Califf: [There is a] national malaise in terms of health, as evidenced by life expectancy, but you know, the functionality of the population matches the life expectancy data. It's driven by disparities. There's a human reason to deal with disparities, it's pretty obvious from my perspective, and even if I didn't believe in that as a matter of national strength we need to deal with the equity issue.

"Machine learning and AI – I think one of the biggest uses by FDA in the near future is going to be to help us with inspections."

A ...In addition to that, we have, of course, diversity in clinical trials, something I've worked on a long time. But a caution there. I worry sometimes that the focus on diversity in clinical trials is really sort of a distracting maneuver from the underlying issue of lack of equity in our health care system. Because I'm pretty sure that if we fix the lack of equity in our health care system, the clinical trials will follow suit. But having said that, ...I'm all for and we'll work hard on helping to increase diversity and clinical trials.

And then the final thing is within FDA, we have work to do on equity, we have a shortage of people of color, and Hispanic people in the leadership roles at FDA. And so, watch for those, it's going to be a very active effort on our part to diversify the workforce. And as we're now living in a hybrid work environment, that means we can recruit from other places and include people who might not be able to move to Silver Spring, for example, and include them in the workforce so we got some real opportunity there.

Q **Talk about leveraging machine learning at the FDA.**

A Califf: Overall, a really exciting. area. ...Machine learning and AI – I think one of the biggest uses by FDA in the near future is going to be to help us with inspections. We simply can't just physically inspect every place at a rate that would be optimal. But as we get more and more access to data, we can have the inference about where to go for inspections based on where the risk is. And you know, that's sort of underway, but it's a standard part of business now and I think it's going to become a standard part of FDA.