PINK SHEET
CITELINE REGULATORY

01 Feb 2024 | **News**

Califf's Top Priorities For New Year: Misinformation And Evidence Generation

by Brenda Sandburg

FDA Commissioner is 'pretty excited' about obtaining high quality evidence in the postmarket space, noting agency's collaboration with NIH. He cites need to address the low cost of generic drugs as a factor in drug shortages.

US Food and Drug Commissioner Robert Califf's top two priorities in 2024 are combating misinformation and improving evidence generation.

Speaking at the UCSF-Stanford Center of Excellence in Regulatory Science and Innovation (CERSI) annual summit in San Francisco last month, Califf said it doesn't help if the agency makes good decisions if people don't understand them or get counter information that is not grounded in science.

"I'm not saying that we're perfect at FDA. We make mistakes, like everybody, but I don't know of anybody who's claiming that the misinformation situation is under control at this point in terms of what's best for society," he stated.

During a session devoted to medical misinformation Califf noted the hurdles the agency faces. He said not having an opinion on issues that could save lives is a real problem. (Also see "*Combatting Misinformation: FDA's Califf On Use Of Facts, Opinion And Emotion*" - Pink Sheet, 24 Jan, 2024.)

Countering medical misinformation has been a key focus for Califf since he began his second term as commissioner in February 2022. (Also see "*Califf Kicks Off Commissionership With Pledge To Counter Misinformation*" - Pink Sheet, 17 Feb, 2022.)

As part of that effort, the agency launched a webpage titled Rumor Control, with factual statements and supporting evidence about the safety of COVID-19 vaccines. (Also see "*US FDA*

Commissioner Califf Takes On Misinformation, Starting With 'Rumor Control'" - Pink Sheet, 5 Aug, 2022.)

Califf has also called on those outside the agency to play a role in fighting misinformation. At last year's J.P. Morgan Healthcare Conference, Califf contended that companies have a responsibility to respond when third parties publicize inaccurate information about their products. (Also see "*US FDA Mulls Granting Regulated Industry Flexibility To Respond To Misinformation*" - Pink Sheet, 10 Jan, 2023.)

And in a JAMA viewpoint piece published online in January, Califf and Peter Marks, director of FDA's Center for Biologics Evaluation and Research, urged the clinical and biomedical community to redouble its efforts to dilute misinformation with scientific evidence.

Reconfiguring Postmarket Evidence Generation

Califf said he chose evidence generation as a priority because if FDA's decisions are not based on high quality evidence, there's a greater chance they are not the right decisions.

"This is immediately obvious when you're in my job and you look across the span of what people are worked up about and contesting," he said. "Most of the time when things are contested the evidence is not what it really should be but a decision has to be made. When the evidence is clear cut, it's a lot easier to make a decision."

"And here's where I'm pretty excited because the big focus now is on the postmarket arena," he added.

Califf noted that the focus in development of medical products has been on weeding out things that don't work. He said that despite all the lectures he goes to about how good we are at picking out targets, about 90% of the time things do not go into human trials and do not make it to market.

"But once something is on the market, there's a question who owns that space in terms of all the evidence that needs to be generated for questions that are still left on the table. Like how does a new treatment compare to the old treatments? How do you combine treatments? How long should you give it? In many cases, even what's the best dose because remember, the requirement at FDA is not that you have the right dose it is that you have a dose that's better than nothing," Califf said.

"So here we're working closely with NIH, with its new leader, and thinking about how we might reconfigure the evidence generation system in the postmarket space," he stated. "I believe that it's fair to say that the FDA sort of owns the premarket space in terms of federal agencies, but if you say who owns the postmarket space, it's actually all of us."

Califf noted FDA's plans to collaborate with NIH on postmarket evidence generation at a meeting last year but he has not described what this will entail. (Also see "*Califf Plans US FDA, NIH Collaboration On Postmarket Evidence Generation*" - Pink Sheet, 25 May, 2023.)

In remarks at a Regan Udall Foundation for the FDA meeting in November, Califf said the fragmentation of responsibility in the postmarket space means there is no national system to generate the evidence needed to opitimize screening, diagnosis and treatment among the multitude of medical products on the market. He acknowledged there was a call for creation of a more favorable regulatory enivronment for simplified, less labor-intensive post-market trials and said a joint FDA-NIH committee is working on this problem.

Shortages And Low Cost Drugs

Califf said the third priority on his list is the decline in life expectancy. He noted that this is not a primary issue for FDA, but said it is something we all have to be concerned about.

"How can it be that we're clearly the world's innovators who are developing the best ideas and technologies for the world, and yet our life expectancy is at the bottom of the pile in terms of high-income countries?" he asked.

Califf voiced this concern in a panel discussion with his predecessors. Former acting commissioner Janet Woodcock commented that low life expectancy is not the result of problems that can be treated with drugs and cautioned against trying to address them with medicine. (Also see "*New Year's Predictions From FDA Leadership Past And Present: GLP-1s, Mental Health, Big Data*" - Pink Sheet, 8 Jan, 2024.)

Fourth on Califf's list is dealing with low-cost medical products.

"It's not something I expected to be on my list. But beginning with infant formula and going on through the drug shortages that we're seeing, we've got a problem in this country, which is related to the way our markets work," he stated.

"If you tell a bunch of smart business people who know something about medicine and healthcare, 'we have an array of things you can work on, some of them make a big profit and some of them either make no profit or lose money,' where do you think they're going to spend their time?" he asked.

"So, we're seeing a situation where we're having constant, hundreds of threatened shortages in generic drugs. And the lower the cost of the generic drug, the greater the risk of shortage," Califf said. "And then of course, when we have a shortage, everybody's looking around, like how could that possibly happen in the US. Well, it's happening because it's not part of the business of the way medical products are handled to make sure that there's a reliable, resilient industry there."

Califf has previously placed blame for drug shortages on intermediaries like group purchasing organizations and distributors who are taking too large a cut of generic drug sales and are not willing to pay for quality. (Also see "*Califf's New Spin On US FDA Staffing: Attrition Rate Is Too Low*" - Pink Sheet, 22 Jun, 2023.)

The Association for Accessible Medicines proposed measures that the FDA and Congress could take to end shortages in a white paper published last year. The generic industry trade group recommended establishment of a drug shortage stockpile and giving hospitals incentives to negotiate multi-year fixed-price contracts for generic drugs, among other things. (Also see "*AAM Calls For Congress And FDA To End Shortages By Easing Up On Generics Quality, Pricing*" - Pink Sheet, 4 Jul, 2023.)