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Pharma Could Lose Some Commercial Info Protections As Part of FDA's Misinformation Campaign

by Sarah Karlin-Smith

Commissioner says agency's speech restrictions to protect confidential commercial information 'have gone too far,' and may need to be modified to tackle spread of misinformation. Experts also said US FDA needs to do a better job conveying the uncertainty inherent in its work.

US Food and Drug Administration Commissioner Robert Califf wants to work with Congress to fix some of the laws that restrict FDA from revealing certain confidential commercial information as part of his effort to tackle the proliferation of medical misinformation.

"We have a deficit that is a special one at the FDA, in that often we have information which by law we cannot reveal," Califf said on 5 October at a Reagan-Udall Foundation for the FDA event.

"I personally believe that this has gone too far. That we need to work with Congress and fix some of the laws so that there can be more transparency," Califf said.

He likened the needed changes to other government transparency pushes over the years such as the creation of ClinicalTrials.gov.

"I was a clinical trialist for most of my career and it never made sense to me that human experiments should be considered proprietary, commercially protected information by companies. You're going to do an experiment on human beings that should be publicly available."

His remarks came in reaction to a new Reagan-Udall report produced for FDA that looked at how consumes and other stakeholders, find, consume and perceive FDA-related health information. (Also see "*Prebunk: FDA Needs To Get Ahead Of Misinformation, But It Likely Can't Drive The Effort*"

- Pink Sheet, 5 Oct, 2023.)

The commissioner asked for the report to help him advance his communication goals. (Also see "*Califf Kicks Off Commissionership With Pledge To Counter Misinformation*" - Pink Sheet, 17 Feb, 2022.)

Califf has previously argued that releasing information related to complete response letters could offer the agency an opportunity to fight misinformation. (Also see "*US FDA's Califf Says Publishing Complete Response Letters Could Help Fight Misinformation*" - Pink Sheet, 26 Apr, 2022.)

FDA is not allowed to publish these letters, which document why they are declining to approve a drug, and concerns have arisen that companies may sometimes misrepresent or downplay their contents. Former FDA Commissioner Scott Gottlieb also explored making at least some of these letters publicly available when there was a clear public health rationale for doing so. (Also see "*Complete Response Letters: US FDA Trying To Identify Subsets For Public Release*" - Pink Sheet, 16 Jan, 2018.)

Stock Market Concerns

FDA may also have a difficult time implementing some of the recommendations in the Reagan-Udall report due to laws that govern how it can communicate about material information, Califf said.

The report, for example, encourages pre-briefing partners and outside spokespeople ahead of any agency announcement that might trigger the spread of misinformation or falsehoods.

For instance, if FDA was about to make an announcement related to a dermatology product, the report suggests engaging with relevant health professional groups to prepare them with the communication materials that might address questions from patients on this announcement. The report also talks about engaging with companies that produce or sell FDA-regulated products to coordinate product-related announcements.

But because many agency decisions impact stock prices, FDA has to "reveal all the information to everyone at the same time," Califf said. "We can't even reveal it to the people who ... work for the company that's going to be involved."

Paperwork Reduction Act

The commissioner also suggested that the Paperwork Reduction Act poses barriers for adequate public communication and collection of public opinion by FDA.

The act keeps FDA "from interacting with people directly in the way that would be most effective or even asking them what they think," Califf said.

The law impacts how federal agencies collect information from the public to ensure it doesn't overburden the public and that collected information serves a useful purpose.

"I think we've got to figure out about that because we spend, as many of you know, a lot of time right now with patient groups, with consumer groups that are represented by people who we have a lot of reliance on and lot of respect for, but it would be a lot better if we can interact directly with bigger parts of the American public to find out what they are thinking and what their knowledge gaps are."

Branding And Avoiding the Next VAERS

Not all of the recommendations from the Reagan-Udall report would require new agency authorities.

One suggestion encourages FDA to avoid lengthy and technical names for titles, announcements and other publicly facing information.

"Carefully selecting names that do not require additional context to understand, or that clearly describe the takeaway being represented, can limit new misconceptions," the report says.

The directive appears to stem from common misconceptions around the reports in FDA's Vaccine Adverse Event Reporting System that are exploited by anti-vaxxers. The Reagan-Udall paper cites a study conducted at the University of Pennsylvania that found the name of VAERS contributes to the public's misconceptions that there is a direct relationship between vaccines and reported adverse events to the system. In actuality, the reports do not indicate causality.

However, the Reagan-Udall report stops short of calling for a name change for VAERS, saying "changing the name of an existing project will not address broader lack of clarity about the content."

Communicating Uncertainty, Admitting Mistakes

The VAERS example gets into one of the agency's top challenges – figuring out how to convey the level of certainty or uncertainty involved in scientific and regulatory decisions.

Those challenges were highlighted during the COVID-19 pandemic as the FDA struggled to clearly convey potential vaccine safety signals or describe the level of certainty around promise seen with treatments under development. (Also see "*Reassuring Safety Inquiry But Botched Comms Leads To Mixed Headlines For Pfizer Bivalent Vax*" - Pink Sheet, 16 Jan, 2023.) and (Also see "*Plasma Authorization Raises Fears Of Politically-Influenced COVID-19 Vaccine Decisions, Compromised FDA*" - Pink Sheet, 24 Aug, 2020.).

In some cases, FDA opted to make updates quietly, perhaps hoping to avoid public attention.

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(Also see "*All Myocarditis, Pericarditis Cases With COVID-19 Vaccines Now Must Be Reported To VAERS*" - Pink Sheet, 13 Sep, 2022.)

"We need to be transparent with our public about what we know, but also what we do not know," said Lori Freeman, the CEO of the National Association of County and City Health Officials at the Reagan-Udall event.

FDA needs to take a leadership role in helping different communicators think about how they are going to convey uncertainty, said Michael Wagner, a professor of Journalism and Mass Communication at University of Wisconsin.

When discussing a public health strategy, for example, it is important to describe it as "the best option we have," not a perfect one, he said. "It's not always the case that following the strategy means we're going to solve the problem completely, that we're going to eliminate people from getting COVID or spread COVID."

"It's about mitigating risk. And so the way that we communicate uncertainty becomes critically important," Wagner said.

Consistent, clear communication about uncertainty will make it harder for people to share things that are untrue, he said.

Another thing that is a "trust booster" is to admit when FDA has fallen short of a goal, Wagner said.

"Was there a time when communication wasn't as clear as it could have been and that led to people having uncertainty about what the right thing to do is? Admitting that and saying here's how we've correct that shortcoming can be really effective."