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Supply Chain: A Science Food, Drug And Device Industries And US FDA Should Study – Califf

by [Malcolm Spicer](#)

Topping Califf's list of getting ready for future is "a vast need at the FDA for integrative data science." In a review he conducted of improvements agency centers are targeting, each listed supply chain information as top concern.

Robert Califf noted the obvious about the four months since he became US Food and Drug Administration commissioner in remarks to an advisory panel. He also probably surprised the panel with somewhat pessimistic observations on regulated industries' impact on consumers' health and wellness.

"Food has obviously taken up much more of my time than I expected," Califf said early in his presentation during a 14 June online meeting of the agency's Science Board.

In addition to leading the FDA's response to an infant formula shortage sparked by the closing, on the same day in February he was confirmed as commissioner, of a major production facility due to contamination problems and the related widespread recall of formula made there, Califf recently testified on consecutive days before House and Senate committees wanting answers about the problem. (Also see "[Democrats, Republicans Agree US FDA's Food Safety Programs Need Help, Disagree On How](#)" - HBW Insight, 26 May, 2022.)

He has much more on his plate in his second stint at the FDA helm, of course. While staying abreast of the agency's current work and problems, Califf says the FDA structure affords him a seat for longer-term views.

"I do think we have a very strong group of center directors who can manage their own business ... my role is to look beyond immediate to the needs that we have FDA in the right position for the future," he said.

No 'System To Anticipate Supply Chain Problems'

Topping his list of getting in the right position is “a vast need at the FDA for integrative data science,” said Califf, who also encouraged regulated industries to better understand the agency's processes (*see related story below*).

In a review he conducted of improvements agency centers are targeting, each one listed supply chain information as its top concern. It's a concern because the FDA is outside the separate data networks used by each manufacturer, marketer or other entity in the industries it regulates.

Supply chain data “is considered proprietary confidential information for each company. There is no ability to combine the information. And while it's increasingly digitized within each company, it's not shared with any federal agency and so we don't have a system to anticipate and pre-empt supply chain problems,” the commissioner said.

Califf pointed out a lack of transparency into food, drug and medical device firms' supply chains when he testified in congressional hearings on the infant formula shortage. He noted the agency has asked Congress for authority to require formula and medical food manufacturers to notify the FDA when disruptions in their supply chains are anticipated. (Also see "[Requiring Infant Formula, Medical Food Shortage Updates Included In US FDA Budget Request](#)" - HBW Insight, 30 May, 2021.)

US FDA Commissioner Admonishes Health Care Stakeholders To Know Agency Better, Help More

By [Malcolm Spicer](#)

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Califf was candid during Science Board meeting about agency's limits, such as disseminating accurate information in response to rampant misinformation during COVID-19 pandemic. “We need to call out people who are outside the FDA ... because this vast universe of information out there is way bigger than we can handle on our own,” he said.

[Read the full article here](#)

“We've got to be able to integrate all the various sources of knowledge as best we can in the post-market phase for the public health. Not in the interest of any individual product, but for the public health,” he told the Science Board.

Data are available from many types of medical technologies health care professionals provide to consumer.

“But we're only taking advantage of a fraction of that to improve health,” Califf added.

“All you’ve got to do is think about devices laden with software and realize there are many issues we need to address today with the information that’s going to be derived from these data most of which are not being used.”

In a same-day presentation he made online for a Food and Drug Law Institute conference, Califf suggested “a national system that allows some entity, perhaps the FDA, to see what’s going on, make sure the supply is getting where it needs to go, do stress testing, and anticipate where there may be shortages” (*see related story below*).

Each of the FDA’s centers also included “optimizing the systems for inspections, investigations and system quality” as goals in Califf’s review.

“I think we need to accelerate the use of predictive algorithms helping us go to the right places at the right time and understand the information that we’re saying about these vast industries that we’re regulating,” he said.

Chronic Diseases Need Industries’ Focus

Drug and medtech firms also should assess their performance and set goals for changes targeting improving public health, the commissioner suggested.

Consumers’ health care and nutrition decisions are pushing the country’s overall health in the wrong direction as seen in the World Health Organization’s recent update on life expectancies worldwide.

“We just passed a negative milestone. The average American is expected to live five years shorter than the average person in other economically developed countries. I want to say that again, five years shorter. Despite all of our prowess, all of our innovation, we have worse health outcomes than any other high-income country and we’re moving in a negative direction, not a positive direction,” Califf said.

Califf offered that he and other FDA officials have “sort of joked within us that we need a center for vices and bad decisions.”

But while consumers’ decisions are increasing the prevalence of chronic diseases, medical

Califf Floats Third-Party Supply Chain Monitoring To Fight Product Shortages

By [Derrick Gingery](#)

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The US FDA commissioner’s call for the agency or someone else to watch supply chains and anticipate problems sounds a lot like a generics industry idea from 2011.

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product industries largely aren't working on treatments for those, he added.

"The cause of this is not mysterious in terms of the diseases. It's common chronic diseases that we all know, heart disease, lung disease, kidney disease, mental health issues with suicide and gun violence. We've got to pick up the pace here on common chronic disease. I think for a whole variety of reasons this has not been the focus of the science community at this point."

'Maintain Intensity' Sparked By Pandemic

On a more short-term outlook, Califf doesn't expect the FDA's, regulated industries' or medical, health care and nutrition researchers' workloads to get any lighter very soon.

"We're going to have to maintain the intensity because the virus is not holding still. It's continuing to evolve in ways that we're going to have to respond to and there are issues around preparing for future pandemics in a time of climate change on how we're going to require the best of science," he said.

Disruption in the global food supply chain from Russia's invasion of Ukraine already is affecting prices and causing scarcity in some areas. Califf cautioned that agricultural supply data point to the disruption having a more severe impact than currently expected.

Research models indicate scarcity likely will increase and rationing will be necessitated in some areas as "a balance that's going to have to be reached while you fix a problem that you've discovered," he told the Science Board.

"Just to make sure everybody's awake, [the] prediction was we're going see a lot of that over the next year because of the impact of the Ukraine war in addition to the fact that our supply chains in the US are tenuous right now."