NAIIS Weekly Summary: April 16, 2026

FDA, Turbulence, and Hope in the Vaccine Ecosystem – Jesse L. Goodman, MD, MPH, Chair, Expert Vaccine Analysis Team (EVAT); Director, Center on Medical Access, Safety, and Stewardship; Professor of Medicine and Infectious Diseases, Georgetown University

Jesse L. Goodman, MD, MPH, gave an overview of the challenges at FDA and across the vaccine ecosystem, as well as some steps to address them.

VIEW SLIDES

Recent Disruptions to FDA
For most of its history, FDA has been shielded from politicization and followed orderly procedures that include opportunities for public input. Under the current administration, the agency has changed significantly:

- Recognized experts and career scientists have been replaced in a chaotic fashion with nonexpert leadership that exerts its power to advance a partisan political agenda.
- New policies have been announced via social and other media without warning and without input from the staff or public.
- The agency's global engagement has diminished, reducing the United States' global leadership role in public health.
- Increased uncertainty about FDA's role and decisions have already decreased public trust in the institution and approved products.
- The Vaccine and Related Biological Products Advisory Committee (VRBPAC), which makes recommendations to the FDA commissioner, has largely been sidelined; there are concerns that unqualified nonexperts will be appointed to support a political agenda, as was the case with the Advisory Committee on Immunization Practices (ACIP).

Upheaval Across the Vaccine Ecosystem
There is turbulence at every point across the vaccine ecosystem, such as the following:

- Uncertainty and unpredictability around FDA's policies and approaches, along with efforts to undermine liability protections, are creating disincentives to industry and investors developing vaccines and other products.

- Decreased National Institutes of Health funding has led to less research.
- Centers for Disease Control and Prevention (CDC) cuts have led to less disease surveillance.
- ACIP vaccine schedule changes have undermined trust in FDA labeling and caused confusion.

EVAT's Role
Established in late 2019 to help journalists better understand the COVID-19 pandemic, EVAT evolved to provide science-based, objective, nonpolitical information on vaccines and disease outbreaks. It continues to inform journalists and other health communicators while also partnering with public health organizations to disseminate factual information. Since inception, it has informed more than 1,300 articles in major media outlets and seeks to diversify its audience.

Signs of Hope
Despite polls showing increasing distrust in vaccines, mostly along political lines, a core group prioritizes vaccines and still wants their children to be protected against vaccine-preventable diseases. Other potentially positive signs are emerging, although many could go either way:

- Some of the Department of Health and Human Services (HHS) secretary's initiatives have been challenged successfully, such as ACIP's recent vaccine schedule changes.
- Recent industry pushback and economic issues suggest the potential for improvements in how FDA interacts with sponsors.
- There has been some recognition within the federal government that disengaging from the World Health Organization puts the United States at a disadvantage.

Although the vaccine ecosystem is complicated, these disruptions could provide an opportunity for changes that result in better support and management of the systems.

The Politics Driving the New FDA Paradigm – Niki Carelli, JD, Principal, DB3; Executive Director, Coalition to Stop Flu

Niki Carelli, JD, outlined the lack of congressional response to FDA changes and the confusion around vaccine policy that has spread under the current administration.

VIEW SLIDES

Ideology Over Expertise
FDA's current leadership is driven by ideology around the government's role in directing Americans health behaviors rather than relevant scientific expertise. The skepticism around vaccines, despite decades' worth of peer-reviewed research, contrasts with calls for loosening guidelines around the use and approval of alternative products, such as peptides, that have

little or no supporting evidence. The current FDA leadership also distrusts the validity of observational and surveillance data.

Congress Fails to Exercise Oversight
Congress has historically deferred to FDA's expertise. This Republican-led Congress has not exercised oversight in response to how FDA is operating now. Notable exceptions are Sen. Ron Johnson, who criticized FDA for blocking novel products for rare diseases, and Sens. Bill Cassidy and Josh Hawley, who want more restrictions on mifepristone. Democrats are more interested in oversight. Congressional committees have requested information about FDA from the HHS secretary, who has been extremely slow to respond.

A Case Study in Confusion
The regulatory framework for updating the annual influenza vaccine is a case study in confusion:

- In June 2025, FDA announced plans to revise the regulatory framework for seasonal influenza vaccine approval—via a quote from an anonymous FDA officer in a journal article. It is unclear what FDA can do to accomplish its stated goals of improving the strain match for the vaccine, and FDA has not responded to questions from stakeholders.
- In late December 2025, emails from Vinay Prasad, MD, MPH, director of the Center for Biologics Evaluation and Research (CBER; note that Dr. Prasad has since left the FDA), came to light alleging that the COVID-19 vaccine was responsible for the deaths of children and calling for changes to vaccine approval, including changes to the annual influenza vaccine approval framework.
- In February 2026, FDA refused to consider Moderna's application for a new mRNA influenza vaccine; after direct engagement from the White House, FDA agreed to accept the application with some caveats.
- FDA has approved the strains for the 2026–27 seasonal influenza vaccine, but plans for related guidance are unclear and might not involve stakeholder engagement.

What's Next?
Some members of Congress have weighed in behind the scenes. They are more comfortable engaging on FDA regulatory issues than on vaccines generally, because the topic feels less politically fraught, even for Republican members. The Prescription Drug User Fee Act (PDUFA) is up for reauthorization. Depending on the outcome of the midterm elections, one or both parties might feel emboldened to do more on FDA oversight.

It appears that the White House is interested in less disruption and more stability for the near future. The White House has urged HHS to focus on other agenda items, such as food safety and the environment. Following Dr. Prasad's resignation this month, a new CBER director will be appointed, so the fate of proposed policy changes is unknown. It is also unclear how much the White House will intervene in FDA operations.

QUESTIONS & ANSWERS
Q: How could PDUFA be leveraged by Congress?

Niki Carelli (DB3): Those user fees are negotiated between industry and FDA, but actually have to be approved by Congress. And it's a pretty weedy topic, obviously, so, staffers, who work on these issues tend to be pretty darn knowledgeable about FDA. It wouldn't be necessary for them to touch on any of the issues we've talked about as part of PDUFA reauthorization, but if there was interest in engaging on the things that have been happening at FDA—and I suspect among some of those staffers that work on FDA issues there is some interest—it would be a really natural vehicle to do that or, at minimum, to have more back-and-forth with the agency to try to get some answers or shape what they're doing behind the scenes from Congress' perspective.

Jesse Goodman (EVAT): I can just add something to that. It's also a place where industry can sometimes bring up issues, and these things about predictability and following a normal guidance process. I'm sure there will be issues across the board, and there could be benefit to the vaccine ecosystem, to the extent that industry's willing to bring some of these issues up. They've been reluctant because they're mostly focused on drug pricing, so they have limited ammunition. But I think that is a potential avenue to demand more impartiality from the agency on these scientific issues.

Q: How much of what we're seeing reflects a genuine change in scientific perspective versus a shift in messaging to align with the public sentiment or potential financial interests.

Niki Carelli (DB3): I think it's genuine. You can't say that across the board, but I think for the most part, we have appointees that just have a different view of what the role of agencies should be and what scientific evidence should look like in order to approve products, especially certain types of products. So, I think they are very honest in their concerns and in what they say that they would like to see and change about what the agency does.

Jesse Goodman (EVAT): There's a whole spectrum of stuff going on, and it's hard to ascribe one set of motivations, but some of this is quite hypocritical. For example, Niki mentioned the peptides. So they come up with a list of these things that are really uncharacterized as to their safety in humans, and there are these communities that are injecting themselves with these things [peptides]. A drug or vaccine company could not come near to doing what's being done, and it appears FDA—they believe in freedom when it comes to those peptides, but [when it comes to] vaccines with trials in 40–50,000 people and very well-characterized safety, they are targets of criticism about safety issues. So there are aspects of this that are quite unbalanced or biased, but I would like to also agree that some of these scientific leaders—they don't have much experience in vaccines or clinical medicine or infectious disease recently, so they come at it with, like, this academic view about trials. Well, when I was in FDA, I was critical about observational data, and we were always trying to improve it. You have to recognize the limitations of that kind of data, so there are some legitimate critiques, but [now] they're blown out of proportion, and then all the evidence that doesn't fit someone's preconceived notions is ignored. And then also, there's this substantial body of people who benefit economically from "alternative medicine," who sell packages to protect you from measles with vitamins and this and that. And so, there's a lot of different motivations here, some based on legitimate critiques.

Q: In the absence of [clear vaccine recommendations from the ACIP], there's concern about what will happen in the fall respiratory disease season with regard to COVID-19 vaccine. Have you heard about whether VRBPAC is going to meet to actually select the 2026–27 COVID vaccine strain?

Niki Carelli (DB3): I have not. That shouldn't be inferred that they won't, I just don't know.

Jesse Goodman (EVAT): I would just express my feeling, not based on data or even inside information. I think they [FDA] may still make it difficult for approvals of new vaccines and things, but I think they've realized that politically interfering with people's access, who want access, is not popular, so my sense is they'll allow strain change considerations on a normal epidemiological basis. That's just my feeling. But, you know, what we're missing out on is getting improved COVID vaccines, getting improved flu vaccines, just because basically any innovation in vaccines, and particularly in mRNA vaccines, has been kind of shut down.

Niki Carelli (DB3): I think that's a great point. Just to amend what I said, if you take VRBPAC out of the question and just reframe it as, "Do I think that there will be COVID vaccines on the market in the fall?" I totally agree with Jesse. I think the president and the secretary have been very clear that they want folks who want access to vaccines to be able to have them, and I think we've seen pushback from some of the secretary's allies who would like to see the COVID vaccine off the market. And there's a reason that it is still on the market, and it is because of that promise, and the president and the secretary have been very clear that that's a line. I don't know how they will do it, but I would expect that there will be some way that they will have a COVID vaccine on the market in the fall.

Q: It was just posted on Truth Social by the president himself that Erica Schwartz is going to be the nominee for CDC director. Have you all heard anything about Dr. Schwartz?

Niki Carelli (DB3): She seems like a really traditional pick. I have not heard any concerns about her stance on vaccines or anything else. I've heard really good things. She seems extraordinarily well qualified. I think we'll learn more now that she's the official nominee. Someone sent me that there's also been, also in True Social, a post about the other folks that are going to come along with her. So, Sean Slavensky, as CDC chief operating officer; I believe he is coming from Walmart and seems to be well qualified. And Dr. Jennifer Shuford, as the CDC deputy director and chief medical officer—she's a state health officer, and I've heard nothing but great things about her. And Dr. Sara Brenner as senior counselor for public health to the HHS secretary; she's currently with FDA, and my limited interactions with her has been really great at asking questions about broader—I wouldn't say "social determinants of health," but that's how I would shorthand it—all the things that go into protecting, somebody and population-level health. So, it looks like a pretty normal, traditional slate of nominees, and we'll learn more about them as they're vetted. But I'm really encouraged; hopefully, it's a new chapter for CDC.

Jesse Goodman (EVAT): I don't know the individual, personally, but I would certainly wish her luck. Obviously, Dr. [Susan] Monarez was very qualified. I think it just will be really important for whoever it is to advocate for the public health responsibility of the agency.

Comment: Dr. Jennifer Shuford is currently the commissioner of the Texas Department of State Health Services. See this Washington Post article about the proposed nominees. Maybe the fact that there's a package of nominees is a way to protect [the CDC leadership] from the secretary.

Q: Pfizer's Lyme disease vaccine is a decent candidate that is going to require FDA approval. What do you think is going to happen in the process for this vaccine and other new vaccines in the pipeline?
Jesse Goodman (EVAT): As Niki pointed out, there is an open leadership position there at CBER now, and I think if they can appoint someone who doesn't come in there with some specific agenda about either the career FDA staff and the role of the agency or an agenda about vaccines, but comes in there as a knowledgeable person who wants a normal process. … I'd like to express my admiration for the staff and career leadership at FDA who have hung on through some very difficult times, like being overruled. Most of the vaccine safety people are gone or have been transferred to other parts of FDA, so there's been horrendous disruption. But I think there's still a core of some incredibly amazing, experienced public servants there who want to do the right thing if a new leader comes in and is not just intent on manipulating the situation or pleasing the secretary. In other words, if they're kind of left alone to do their job, I think those vaccines can be evaluated. A new vaccine like that Lyme vaccine, where there's some questions about clinical trial results—that's the classic thing that needs the experts to do a good review, pros and cons, and that needs to go to an advisory committee. And it's also the classic thing that will need an ACIP that knows what it's doing. So, if ACIP is reconstituted with people who don't know about vaccines or infectious diseases, but do have very strong, non-science-based opinions about vaccines, that could be difficult. But I'm cautiously hopeful that, with the exception of some of the most determined anti-vaccine activists—which, of course, Kennedy was one, and some of his colleagues are still pursuing that very strong agenda, like suing Kennedy currently. But with the exception of that, mostly they're very pissed off about what happened with COVID vaccines, and I'm sort of hoping that the temperature can go down, at least on other things, and that there can be objective assessments. I think if there aren't, the vaccine industry will be disincentivized, or if liability protections are changed, the vaccine industry will be [greatly affected] and innovation will be greatly disincentivized, and, we will pay the price. I mean, we're paying the price now with measles and pertussis and rotavirus and everything else. But we're going to really pay a price if we don't innovate going forward, if we're not ready for the next pandemic. So I think that's a critical question that your questioner asked and something we really need to keep an eye on. And it's also something where I would hope the saner voices in the White House could look at it and say, "Okay, this isn't something we want to mess with here. Let's let the science prevail."

Q: Moderna's vaccine is approved by the European Medicines Agency (EMA), right? So obviously, approvals based on science and evidence are occurring outside the United States. How do you see that impacting the White House administration, looking at the loss of U.S. leadership? But also, how does FDA look at that in terms of their process?
Niki Carelli (DB3): That's a great question. I think folks have tried to make the case to the White House and the agency that, when we talk about America first, we're now in a position

where we're not the first anymore. There are products that are getting approved elsewhere. I think going back to that earlier question about whether some of these decisions come from genuine scientific disagreement, or are they just sort of a front for other things—I do think that there is genuine disagreement about the value of certain types of trials and the value of certain products versus the risk profiles [of those products]. So, from an FDA perspective, I don't think that they're going to be moved by the fact that products are approved elsewhere. I think they are focused, and appropriately so, across any administration, on making sure that, from their perspective, the products that are approved meet the standards that they think are necessary to be effective and safe for the U.S. population. In the White House … certainly there's a broad concern about potentially losing the innovation race, and I know folks have made the point to the White House about the increasing number of early-stage trials that are happening in China. And so I do think there's some receptivity to that, but I don't know whether that will trickle down into being helpful to get individual products past this FDA if they're not already inclined to do so.

Jesse Goodman (EVAT): I thought Niki's answer was excellent. I would say that scientifically, for example, EMA and FDA and CBER, they don't always have to do the same thing, but generally there's a lot of communication, and particularly on public health issues. There's a lot of movement not toward having the same standards but toward alignment on the science and the body of knowledge that's needed. So, I think it would take a lot to reach a very different decision, but I don't think that's out of the question. I think we need to see the data. And FDA needs to see the data, and that was one of the biggest concerns about what happened with Moderna. FDA was basically saying, and I think the center director even said, "I don't want to see the data. I want this to go away." Well, if something looks 20% more effective than current flu vaccines, why wouldn't you want to see the data? And so, I think we'll see how it plays out, but again, this gets to the access point, and I agree with Niki, that people in the White House and HHS recognize that the same people who are supporting them on many of these issues don't want the government standing in their way of getting something if they want it. So that's a dynamic here as well.

Announcements

- Registration for the 2026 National Adult and Influenza Immunization Summit, May 19-21, 2026, at the Crowne Plaza Atlanta Perimeter at Ravinia, in Atlanta, GA, is reaching capacity. Invitees are encouraged to register as soon as possible (https://www.izsummitpartners.org/2026-naiis/).