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A former AI regulator, now in industry, says biopharma is reading FDA's guidance wrong

Tala Fakhouri blames both companies and the FDA for creating unnecessary hurdles

By Brittany Trang
Health Tech Reporter

SAN DIEGO — Two years ago, Tala Fakhouri was writing AI policy at the Food and Drug Administration.

Now, after leaving the FDA last summer, she's getting a firsthand look at how the industry is implementing the policies she wrote as chief AI and regulatory strategy officer at Parexel, a contract research organization.

What she sees distresses her. The FDA's intent to be flexible is getting lost in translation, she said, and she's seeing the industry interpreting that guidance in the most conservative way possible in order to avoid risk.

"When we wrote the AI guidance, it was meant to be, flexible, agile, not telling sponsors exactly the steps that they need to do to show that their AI use is credible for a specific context," she told STAT at the BIO conference in San Diego. As part of her role at Parexel, she advises pharma companies on AI policy and how to deploy the technology.

At the FDA, Fakhouri was the associate director for data science and AI policy in the agency's drug division. Now that she's on the other side, she realizes why industry needs the FDA to be more specific, even though the FDA built ambiguity into its policies to be helpful.

"I've been encouraging former colleagues at the FDA to issue more



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Tala Fakhouri, a former FDA official, is chief AI and regulatory strategy officer at Parexel.

use cases, show how you actually expect validation of these AI tools to happen so that industry knows how to use them," she said.

The FDA is trying to speed up clinical trials and drug approvals and modernize its processes, both by using AI and by coming up with methods for assessing AI uses in medicine. Submissions getting bogged down by things the FDA isn't asking for can hinder this effort.

But the blame doesn't lie entirely at the industry's feet — Fakhouri

outlined a few factors, including inconsistencies within FDA divisions and layoffs, that feed this problem.

An FDA spokesperson didn't respond to STAT's request for comment.

Applying guidance that's no longer relevant

Fakhouri says the FDA needs to update or remove a lot of its older guidance related to software and technology, because it's outdated or irrelevant to today's tech tools. But

as long as it's in place, firms will rely on it, even though FDA officials have said at times that they shouldn't.

As an example, she tells the story of how a large pharma company tried to apply decades-old FDA guidance to AI, simply because the FDA has not specifically issued written guidance saying that people do not need to do it.

A company that's written its code in one programming language but needs to translate it to another can use Claude to convert it. However, FDA regulations, ones last updated in 2002, require the company to validate that the software used to translate the code does it in a replicable fashion.

Under that 2002 paradigm, companies would have taken screenshots of every click they do in the software so that if an inspector came, they could have the trail of evidence for the method they used. But Fakhouri described using this method to validate Claude as "insane."

"You cannot do computerized software validation on a probabilistic, nondeterministic type of tool" such as generative AI, she said. But submitters' legal teams are often telling them to do so, just in case.

The agency's device center has issued updated guidance on this topic, moving to a risk-based "computerized software assurance" model, but its drug and biologics divisions have not.

Misalignment between FDA divisions and inspectors

The fear of being inspected motivates many pharma companies' decisions and bogs them down in spending effort on things that don't matter.

For example, when she was at the FDA, Fakhouri worked on a guidance document that specified that the level of oversight and validation for data should be "risk-proportionate" and focus on data that are critical to quality — for example, a biomarker related to cancer progression, and not the patient's home address.

"You cannot monitor every piece of data as if it's critical to quality. It should be the data that matters" that one should monitor, she said. But she sees pharma companies take a more conservative stance.

"FDA does not expect that, EMA does not expect that," she said. "But again, it's this fear of being inspected."

But what's the problem, when FDA inspectors should abide by FDA guidance? According to Fakhouri, the two don't always line up, which is what is feeding the preemptive action on the industry's side.

One thing that would help the inspectors to be more in line with policy is being involved in the process of writing it.

Fakhouri gave the example of the Office of Inspections and Investigations being included on the 2025 FDA guidance on AI, which means that the inspectors were involved in the policy's development and got training on it. That needs to happen more consistently, she said.

This inconsistency isn't just between the reviewers and the inspectors, though. Some FDA divisions have more aversion to risk than others about things like using new, innovative digital health technology in a trial — even though the therapeutic area or the technology isn't more risky in itself.

"A lot of it is related to education

about risk associated with using a technology or something innovative, and that requires training and upskilling of staff, and also more active engagement by staff or their leadership, in how guidances are being reviewed and written," Fakhouri said.

Staffing changes at FDA

Making sure everyone hears about and implements new guidance is one of the jobs of the policy office of the Office of New Drugs, Fakhouri said. The office was eliminated in the FDA job cuts last year.

Besides losing staffing power, Fakhouri thinks that losing experienced staffers also means the agency has less risk tolerance, which is not good for the industry. Experienced staffers are often better at using their judgment to address issues, she said.

"It's very different than a junior staffer coming in. They've never done this work, or their experience is limited, and the responsibility is big, right? You're an inspector or you're a reviewer, it's a big responsibility; you take it very seriously and because you don't have that experience, you're risk-averse," she said.

She said she's worried that the loss of experienced FDA staff means that regulatory flexibility and "agility for regulatory decision-making" may be gone, regardless of who's in charge.

"You can hire a lot of new graduates or younger people. That's great. You have to spend a lot of time and resources training them," she said. "But also, you need to bring in some leaders to help upskill staff to bring it back to what the agency was, in terms of the brain trust, from a year ago."