LAW360

Portfolio Media. Inc. | 230 Park Avenue, 7th Floor | New York, NY 10169 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Ex-FDA Chief On Election Year Healthcare Policy

By **Mark Payne**


Stacy Cline Amin

Law360 (April 16, 2024, 1:44 PM EDT) -- Stacy Cline Amin has seen many sides of the evolving healthcare policy landscape and says presidents set policy through priority issues and how they run the federal agencies tasked with overseeing the nation's health.

After stints in BigLaw corporate practices, the Harvard Law-educated Amin served during the Obama years under Republican lawmakers on health-focused committees in both the U.S. House and Senate.

With the advent of the Trump administration, she jumped to the executive branch and a deputy general counsel role at the U.S. Department of Health and Human Services. Between 2018 and 2021, she was chief counsel at the Food and Drug Administration,

Today, she's leading the healthcare regulatory and compliance practice at Morrison Foerster LLP.

With drug price controls high on the list of Biden priorities and Trump seeking to return to the White House, Amin talked to Law360 about march-in rights — a Biden proposal to let the federal government seize "taxpayer-funded" prescription drug patents that are deemed too expensive and lease them to other entities — the Inflation Reduction Act and healthcare issues where the two candidates may see eye to eye.

This election is unique because we've seen both party's assumed nominees actually be president. How have President Biden and former President Trump differed in running the agencies responsible for federal health policy?

I think when looking at who will be president there are two parts of that that are important. One aspect of it is what are the issues that will be a priority for them, and then the other part of it is, as you asked about, how they will administer the agencies and, of course, there are a certain number of political appointees that fill the top spots at the agencies.

The big question, I think, is if President Trump is elected, what will the FDA's leadership look like? Who will be the commissioner? Who will fill some of those top political spots that are very influential in shaping policy? And who will be the top lawyer?

What would we likely see from both men regarding running those agencies if they were reelected?

I actually think that we would see a lot of emphasis on the same issues in the Trump administration that we see the Biden administration focusing on. We have seen a huge focus on drug pricing and competition from President Biden. That was a major focus of President Trump's administration. I think it would continue to be a focus under either president in the coming years. It has become a very bipartisan issue, and there's a lot of pressure on the FDA, as well as other federal agencies, to develop policies to promote competition and lower pricing.

We've seen, under both presidents, the agencies taking on issues that previously would have been considered third-rail issues. One example of that is the importation of lower-priced foreign drugs to the U.S. Drug importation was for many decades considered a third rail that only the most extreme policymakers supported. The rulemaking authorizing importation plan was proposed and finalized under President Trump and a plan was approved under President Biden. It's illustrative of the extreme measures both parties are willing to take to address this politically sensitive issue.

We've seen the Inflation Reduction Act get passed and implemented in the Biden administration. I think it is unlikely to be undone in a Trump administration.

Likewise, we see the Biden administration talking a lot about march-in rights. It was also a topic of conversation in the Trump administration. I think it will continue to be a focus under either administration.

We see the Biden administration spending a lot of time looking at drug shortages as an issue and I think that would continue to be a focus in the Trump administration.

Where do you see differences in their approaches?

In a Trump administration, you might see resurgence of interest in access to investigational treatments. In the Biden administration, there has been a big focus on bias and issues related to bias, transparency and diversity in clinical trials. I'm not sure we would see that continue if there were a Trump administration.

At the end of the Trump administration, there was an executive order issued that was sort of to the opposite effect of some of the efforts that have been underway in the Biden administration on diversity, bias and transparency.

You served as the FDA's chief counsel. What has the FDA done during the Biden administration, and how has its work compared to the Trump administration, as it applies to what would come across the chief counsel's desk?

Anything that the White House or the HHS secretary is interested in comes across the desk of the chief counsel, so any of the issues I just mentioned are ones where the chief counsel would be involved — drug pricing, drug shortages and supply chain issues, abortion issues, abortion access issues and anything that's a priority to HHS or the White House.

There are a number of significant administrative law cases working their way through the courts that will impact the FDA. Obviously, the litigation over mifepristone is a big one, but also the Supreme Court's consideration of Chevron deference and the Loper Bright and Relentless cases [both challenging a rule that requires commercial fishing vessels to pay for compliance monitors]. How that gets decided and how the agencies react to it will be a big issue for the chief counsel in either administration in the future.

Of course, the FDA has been rulemaking on laboratory-developed tests. The FDA intends to regulate lab-developed tests as any other medical device. There will be significant litigation over that rulemaking. That will definitely be on the chief counsel's desk.

Would any recent or upcoming Supreme Court decisions, such as Chevron, impact how agencies like the FDA or HHS develop policy?

There has been a shift in how the courts respond to agencies and a general shift in the last five to 10 years in how the courts are looking at administrative law. That shift has already had a significant impact on the FDA and how the FDA does policymaking. A lot of resources are devoted to making sure to justify in writing scientific decisions that the agency makes in order to prepare for litigation that could come after and that ultimately that takes time, and it slows down the process.

There's already been an impact in terms of the amount of resources devoted to justifying scientific decision-making in anticipation of litigation, where the agency is afraid that the courts will be skeptical of the agency's decision making. I think that impact will be even larger if Chevron deference gets overturned or narrowed.

We've seen the battle over the Medicare drug price negotiations. What's your perspective on how well the drug price negotiations are going, and what is expected on that front?

There are a lot of aspects of the process that are unfair to the pharmaceutical industry. I think there's a lot of validity to the legal challenges that have been brought up. I support pretty much all of the arguments that have been made in those lawsuits, and I think we'll see how the litigation plays out. We've seen some district court decisions but haven't seen any appellate court decisions yet. There are some significant constitutional challenges that have been raised to the implementation of the Inflation Reduction Act as well as the statute as it stands.

What does it mean for Big Pharma?

It's not just Big Pharma. It's the entire life sciences sector, as well as consumers, who are going to be negatively impacted by the law and its implementation. I'm seeing it in my own practice already. It's already impacting how investment decisions get made, and I'm already seeing market distortions in terms of what sorts of molecules and what investors are interested in funding.

It's impacting decisions in terms of what indications are being pursued for drug development. There has been lots of discussion about even potentially delaying market entry because companies are interested in waiting until they have their most lucrative indication, whereas it used to be the case that you would get on the market as soon as you could and add indications as your research program justifies those expanded indications. Those sorts of things have a very significant negative impact on consumers, as well as some of the impacts we're already seeing in the life sciences sector.

--Editing by Karin Roberts.
