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Ex-FDA Chief Counsel On Relationships, Consensus-Building

By **Clarice Silber**

Law360 (July 27, 2021, 3:32 PM EDT) -- Stacy Cline Amin, the former chief counsel of the U.S. Food and Drug Administration, used the building of relationships and consensus as a core tenet when she worked in legal posts across the top levels of government over a span of 10 years.

Amin, who joined Morrison & Foerster in June to co-lead its FDA regulatory and compliance practice, told Law360 Pulse that whether it was working as an attorney for committees in the U.S. House and Senate, as a lawyer in the White House counsel's office, or as the top-ranking counsel for the FDA, her approach was always marked by working to reach common ground among stakeholders.

In a recent interview with Law360 Pulse, Amin talked about her experience serving as the chief counsel of the FDA amid the global coronavirus pandemic, the difference between her work in Congress and at the White House, and the importance of relationship-building. This interview has been edited for length and clarity.

How did you know you wanted to work for the government and more specifically in a high-level counsel role?

I was a corporate lawyer at a big New York-based firm in the D.C. office when I first finished up my clerkship. A lot of my friends were working in government at the time — in the White House counsel's office or at the Department of Justice, or in Congress — and I was so impressed by the work they were doing as young lawyers. They were writing laws, they were taking on really important enforcement matters at the Department of Justice, they were getting Supreme Court justices confirmed. I just found their work really fascinating and at that time in my career — I was young, I wasn't married, and I didn't have any kids — I really wanted to take on something that was really exciting and challenging like that myself.

So I worked hard to get an opportunity in government, and my first opportunity was in Congress in the House of Representatives on the House Energy and Commerce Committee. And at that time, I could not have envisioned where my career would take me and the sorts of issues that I would be right in the middle of. I don't think anyone could have envisioned. But I'm very happy that I wound up at FDA and then a life sciences practice, and I realized very quickly when I went to work in Congress that my passion was really for public health and FDA's regulatory authority.

How did you end up moving to the White House, and would you say that is a very different beast than acting as a counsel for those in Congress?

The White House counsel role was different than other roles that I had before or had been in since, because it was really a role where I was coordinating across a lot of different agencies. There were some similarities, though, to how I approached the role. I approached the role as one of consensus-building.

Say there was a tri-agency rulemaking between [the Department of Health and Human Services], the Labor Department and the Treasury Department — we worked on a number of those rulemakings while I was in the counsel's office — and then you'll also in that scenario have lawyers from the Department of Justice, and lawyers from the Office of Management and Budget that have an equity in the work that the agencies are doing. I viewed it as my role — when there were disagreements among the lawyers — to include everybody in the conversation, and to just keep discussing the issues until common ground consensus could be reached.

And that was my approach to every issue that I worked on in the counsel's office, and it didn't matter whether the issue was one where there were disagreements across the agencies, or if there were disagreements with lawyers who were political appointees and career appointees — or it could be both — but my role was one to make sure that the issues were well considered and elucidated, and to reach consensus among all of the lawyers that were involved. And I think some of my colleagues [saw] the way that I approached my role to be a model in how to work with agencies and how to problem-solve.

What would you describe as the most challenging part of your job serving as chief counsel of the FDA amid the height of the pandemic?

Definitely the period of the pandemic was the most challenging period that I was at FDA, although … there was a lot happening at FDA during my tenure overall. And even before the pandemic, I went through everything from a Thanksgiving romaine lettuce recall, to a government shutdown, to mystery vaping illnesses from the summer of 2019, and the e-cigarette epidemic. There's always an emergency at FDA, and because its jurisdiction is so large and there are so many different product centers at FDA, there's almost always an emergency happening in one part of the agency, and that's what FDA leadership is going to be involved in.

Even if from one center to another they might have a break in time between emergencies, it's always very exhausting for the leadership at the agency. So … what I think was the most challenging was keeping the agency's spirits up during this time. The people in the agency that were working on COVID-19 started really in January, and I imagine [it] is still going for many people in the agency. I got a rest starting in January of 2021, but my day would start at like 5:30 or 6 in the morning, my phone would start ringing; if I hadn't showered by 5 in the morning I could forget about it for the day because it was just emergency after emergency, and it wouldn't stop ringing until usually after midnight and every day it was like that nonstop for a year.

And I know that everybody working on COVID-19 were working under similar circumstances or sometimes working overnight multiple nights in a row to try to get things done — but just really the crushing workload. We've never been working so hard before, and we were always just doing our best to make science-based decisions with the evidence that we had. But the criticism and the scrutiny was nonstop, and it was a really hard time for the staff at FDA, because no matter what we did, something that we did wasn't good enough. We were either moving too slow and putting people's lives at risk, or we were moving too fast and putting people's lives at risk. It was very hard for the agency to endure sort of that constant scrutiny that it was under, and so just trying to keep people's spirits up during that.

This is an agency with a staff that was dealing with the same personal challenges that everyone in the world was dealing with — lack of child care and concern about loved ones, and concern about their own safety. Just being a manager during that time was really challenging, but I do think that, at least in my own office of chief counsel, we didn't have any departures from my team during that time period. I tried to do a good job as a manager of making sure my staff didn't burn out, and that they were taking care of themselves, and that they were recognized for their extraordinary work.

Right now the biggest story with the FDA is its controversial approval of Biogen's Alzheimer's drug aducanumab and subsequent call for an independent investigation into that approval. How unusual is this situation and what kind of legal exposure could the FDA be up against?

It definitely does not happen very often that a label is revised so quickly after, or some of the other aspects. For example, the call from the FDA commissioner for an [Office of Inspector General] investigation is not something that I have seen very often.

But I wouldn't really be able to comment on any potential vulnerabilities and the decision-making without having seen the data that the agency itself reviewed in making its decisions. I would note, when [Dr. Janet Woodcock, the acting FDA commissioner] was questioned about this, and in the statement that she made calling for the investigation, she reaffirmed her confidence in the decision-making, and the ultimate decision, and the team at FDA and their integrity, so I do have a lot of faith and confidence in Dr. Woodcock and her judgment.

But I don't know the details. Without having seen the facts myself or the details, it's hard to really pass judgment.

What's the most important skill for someone who wants to go into a counsel role that they don't learn in law school?

Probably the most important skill for me was relationship-building. A lot of your work as a general counsel is problem-solving and consensus-building. In order to do both of those things, you really need to have formed strong relationships with the people that you're working with in an organization, and I think I was able to be successful in my role, both in finding creative solutions to problems and in building the consensus necessary to execute those solutions because I had put the effort into building strong relationships with my colleagues.

I was always straight with the people that I worked with, and they realized very quickly in working with me that I didn't come with like a hidden agenda, or I didn't come with my own agenda, but I was just there as their lawyer to help them. And that was a skill that I think enabled me to build trusting relationships with my colleagues.

--Editing by Alyssa Miller.
