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10 Nov 2021 | **Interviews**

Khushboo Sharma: Improving Regulatory Science, From Industry To FDA And Back

by Ben Comer

From pre-med to pharma lab rat to deputy director of operations at the FDA, Khushboo Sharma, a 2021 In Vivo Rising Leader and current VP of science and regulatory affairs at BIO, has spent her career pursuing a goal she says the FDA and biopharma industry have in common: ensuring that innovative drugs get to patients.

Back To Rising Leaders Gallery

When Khushboo Sharma left the FDA to join the Biotechnology Innovation Organization (BIO) in April 2021, as VP of science and regulatory affairs, she ended an 11-year stint at the agency with several notable accomplishments. “One of the things that I really wanted to do at FDA was be a part of the user fee negotiations,” said Sharma, who worked most recently as deputy director for operations at the Center for Drug Evaluation and Research’s (CDER) Office of New Drugs (OND).

Sharma’s participation in 2020 and early 2021 as one of the lead negotiators on the FDA’s negotiation steering committee – a group tasked with hammering out the details of the seventh Prescription Drug User Fee Act (PDUFA) reauthorization, alongside drug industry representatives – capped off a five-year period Sharma described as her most exciting time at the agency.

In 2018, CDER director Janet Woodcock outlined the FDA’s plans to modernize the OND. (Also see "*Office Of New Drugs Reorg Is Bigger Than Expected: US FDA Adds 11 Review Divisions* " - Pink Sheet, 4 Jun, 2018.) Sharma helped to lead the modernization initiative, overseeing changes to OND’s regulatory review and business processes. While not a highly visible aspect of the agency’s inner workings, the merging of regulatory policy with regulatory operations under the OND reorganization dealt fundamentally with making the drug regulatory process run as efficiently as

possible, said Sharma. “My last five years at FDA really helped shape my career, and was probably the most exciting time being there,” she said.

KHUSHBOO SHARMA

In addition to working on the OND’s reorganization and helping to negotiate PDUFA VII – which Congress will need to authorize by the end of September 2022 – Sharma also managed CDER’s formal dispute resolution program, as well as the expanded access program. CDER’s dispute resolution program allows drug sponsors to appeal FDA decision making related to drug development, new drug or generic drug review, and postmarketing oversight. The expanded access program, also known as compassionate use, helps patients with life threatening or serious diseases get access to unapproved, investigational products outside of clinical trials.

Expanding Access

Beginning in 2012, Sharma moved from her initial FDA position as a project manager in Chemistry, Manufacturing and Controls (CMC) Regulatory Affairs, and took on roles of increasing responsibility at the OND. She went from senior regulatory health project manager, to associate director for regulatory affairs, followed by OND team lead and then OND chief of staff, before becoming deputy director of operations at OND in May 2019.

The federal Right to Try Act was signed into law by former President Donald Trump in May 2018, and Sharma got to work on how Right to Try would be implemented alongside the preexisting expanded access program. The Right to Try Act essentially allows patients to bypass the FDA, by allowing patients, via physician consent, to request access to an investigational drug directly from the drug manufacturer or sponsor. Importantly, Right to Try does not mandate access to a drug for qualifying patients; drug sponsors are ultimately responsible for granting a patient access to an unapproved drug. The same is true for the FDA’s expanded access program.

Despite not playing a formal role in the Right to Try process, the FDA does provide information about the law on its website. The agency has also worked to streamline expanded access requests, through pilot programs such as Project Facilitate, and by making it easier for physicians to request access to a drug on behalf of a patient.

Sharma worked on making the application process easier, she said, so it was less “burdensome for a doctor to submit the information for a patient.” That work was where Sharma felt “most connected to patients … There are a lot of times when you make regulatory decisions at the FDA,

but you are dealing with companies," she said. With expanded access, "you can see that direct line to the patient, so it was very rewarding."

Early Industry Exposure

Sharma began her undergraduate degree at Pennsylvania State University with the intention of following a pre-med track into medical school, but realized "very quickly, after one summer," that she did not want to be a doctor. "But I still wanted to do something in science … I wanted to be involved in cutting edge science to help patients, just not as a doctor," she said.

Penn State had a newly established undergraduate biotechnology program, one of the few available in the early aughts. Sharma decided to major in biotechnology, with a minor in microbiology. It was a new and emerging subject area, which appealed to Sharma's sensibilities. "I've always been the type of person that, if there's a traditional pathway, I don't want to do it." The biotechnology program "piqued my interest in how science can change and innovate, and how drugs are made," she said.

At one of Penn State's career fairs, Sharma landed an internship with *Janssen Biotech Inc.*, a division of *Johnson & Johnson*. For a junior in college, it was "a great step into the field," remembered Sharma. "I made pH buffers and ran HPLCs [high performance liquid chromatography machines] for an entire summer, just soaking in everything I could as part of a small biotech company."

Janssen hired Sharma as a full-time employee upon completion of her undergraduate degree, and she worked at the company "as a lab rat for the first few years," and got experience "doing early and late-stage drug development on therapeutic biologics," including Remicade (infliximab). "That experience really drew my interest in biotechnology as a field."

Working in the lab, however, was not Sharma's end goal, and she began to toy with the idea of going to business school or enrolling in a PhD program. "I remember my boss [at Janssen] telling me, 'If you want to run a lab, go get a PhD. If you want to run a company one day, get an MBA.' So, I decided to get my MBA," said Sharma. Janssen was supportive of that decision and "helped me go back to school." Sharma continued to work at Janssen full-time and worked on her MBA part time.

Sharma's role at Janssen changed as well, and she moved from the lab to working in a "regulatory project management-type role, helping to write the CMC sections for INDs and NDAs." She was involved in the process of preparing the BLA for Janssen's Stelara (ustekinumab), which reaffirmed her interest in regulatory science. And then she got engaged to be married.

With her fiancé living in the Washington DC area, Sharma made plans to relocate, and realized "there are not that many pharmaceutical companies" in the DC area. But she wanted to stay in

pharmaceuticals and regulatory science, and decided that a job with the nation's top regulatory agency would be an excellent way to learn regulatory policy. "I applied on [USAJobs.gov] for every FDA project manager position that I could find," said Sharma. "It took me a while, but luckily enough, I got a job in 2010 as regulatory health project manager, in the CMS division," now called the Office of Pharmaceutical Quality. In managing the quality sections of the applications submitted to the FDA for review, "I got to see things from the other side," she said. Two years later, she moved to the OND, and steadily climbed the ladder over the next eight years, culminating in the position of OND deputy director of operations.

FDA During COVID-19

Sharma was deputy director when COVID-19 hit. The OND was tasked with overseeing all the regulatory operations for the FDA's COVID-19 therapeutics response, and Sharma needed to ensure that a functioning, streamlined process existed for evaluating the "thousands of new INDs and pre-INDs coming in, and to make sure they were getting reviewed … We needed to be on top of that, and not be the bottleneck when the applications came in." It was a 24-hour, seven days a week job, for over a year, she said.

In addition to streamlining existing processes within the agency, new capabilities needed to be established as well, such as virtual advisory committee meetings. "I was involved in guidances that came out for how to conduct [COVID-19] clinical trials, and how FDA would run meetings," said Sharma. "There was a lot of regulatory guidance that companies and investigators and other people were looking for, so FDA needed to work around the clock."

Sharma offered kudos to "every single review person and every single project manager and to the administrative staff at FDA, who rolled up their sleeves, even if they weren't directly involved, and asked how they could help." Now that Sharma has left the FDA and joined BIO, she still checks in on her friends, to see how they are holding up. FDA staffers are "doing such great work, and the good press and the bad press sometimes gets to people, and you just want to make sure they are okay," said Sharma. "To this day, they are going above and beyond."

Asked what she will miss most about working at the FDA, Sharma said the people and leadership were "just phenomenal." She also said that she will miss "being in the know, and being at the center of all the new things coming at you." The biggest difference between working in the private sector, and working for the government at the FDA, said Sharma, was speed. "There are people doing the review work and trying to get things done, but the administrative burden of being in the public sector does sometimes slows things down," she said.

During her time at the agency, Sharma worked under four different FDA commissioners: Stephen Hahn, Scott Gottlieb, Robert Califf and Margaret Hamburg; she also worked closely with Janet Woodcock, currently the FDA's acting commissioner. All the commissioners had their pros and cons, said Sharma, who (reluctantly) named Scott Gottlieb as her favorite. Gottlieb "made the

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most impact for the agency ... He helped get the resources we needed and really helped to cast FDA in a positive light," she said.

Revolving Door

As the FDA negotiation team's work on PDUFA VII was wrapping up, Sharma was thinking about her next move, and feeling like she had "done everything that I wanted to do at FDA." When BIO reached out with a job opportunity, it was unexpected, but it "made me think that it was the right time." Sharma was not sure that she wanted to join a drug company right away, but she liked the idea of influencing policy from an industry perspective.

Sharma's experience working at the FDA during the COVID-19 pandemic "really brought a number of pressing issues to the forefront, and there's just so much more work that needs to be done." Issues such as advancing remote clinical trials and the use of digital health technology, using real world data to change the clinical paradigm, and increasing diversity in clinical trials, are all "core areas" Sharma is working on in her role at BIO.

Her perspective is valuable, as someone who worked initially in the biotech industry, spent over a decade at the one of the world's top drug regulators, and is now advocating for policy change on behalf of the pharma and biotech industries. Asked about the one piece of advice she would give to biopharma executives about working with the FDA, Sharma said: "Be patient and listen." Just because FDA declined a meeting, or appears to be "taking forever," does not mean they are not working on an issue.

"FDA wants to make sure that they come up with the right policy that helps the industry at large. And they are doing their best," she said. "FDA has the same goal as industry, which is public health, and making sure that innovative drugs get to patients. The pharmaceutical executives, at least the people I have talked to at BIO, understand that very well, and it is encouraging to see."

Potential For Califf's Second US FDA Commissioner Term Surprises, Excites Stakeholders

By Derrick Gingery

14 Oct 2021

Many supporters believe Robert Califf checks all the boxes, but if nominated he would also face many familiar confirmation challenges.

Read the full article here