Transcript: Director's Corner Podcast - Looking back and moving forward in 2016

Introduction: Welcome to the Director's Corner, an audio podcast series featuring the director of FDA's Center for Drug Evaluation and Research.

Anne Rowzee: Hello, I'm Anne Rowzee from the Office of Communications and I'm joined by CDER's director, Dr. Janet Woodcock, for the Director's Corner. We will once again begin the new year by discussing major events from last year and goals for CDER in the new year. Happy New Year, Dr. Woodcock.

Dr. Woodcock: Thanks. Happy New Year everyone!

Anne Rowzee: Thanks. So, 2015 was another very busy year for CDER so it might be difficult to choose just three but what would you consider the center's top three successes of 2015?

Dr. Woodcock: Well, I'd say, number one was the successful transformation in the Generic Drug Program and getting into a very high level of productivity. That included a whole standing up a whole new IT platform, as well as transformation of the whole generic drug process to a modern process. So that was a huge accomplishment and we're all very proud of it. And then, uh, close behind and related I think was a stand up of the Office of Pharmaceutical Quality which we did early in 2015 and we've been working on it all during the year and people I think worked really hard and very appreciative that we now have a modern quality organization that looks after all pharmaceutical quality who have the same standards. We call that one quality voice and that organization I believe has been launched successfully and is also running for the generic drug review process off the pharmaceutical platform so we're happy about that. And then the third one is really a landmark for FDA. It's the approval of the first biosimilar product in the United States and, uh, that of course is really important. It's a whole new type of product that we're going to see and hopefully, will provide affordability for patients with serious diseases.

Anne Rowzee: Exciting. Um, so then turning to the other side of the coin, what were some of the challenges in 2015 and how did you meet them?

Dr. Woodcock: Well, we didn't expect but there was a very huge push in congress to have new legislation that was partly FDA related drug development related legislation, specifically, in the House of Representatives, the 21st Century cures legislation and so that was very time consuming working with the Hill. And we think we came to a good place but it required a lot of input and effort in discussions on part of many parties. So that was a big effort and then of course, toward the end of 2015, the senate also began considering legislation and we also worked with the staff there and so that was very, you know, intensive as well.

Anne Rowzee: Mm hmm.

Dr. Woodcock: Another challenge that we've had over the years has been hiring enough people and that with the economy improving, it's become. I think, even more challenging for us to get the qualified people. We can't compete with external salaries for the scientists and medical people and top executives and lawyers for that matter and so we really are very down on people and that's putting strain on the staff.

Anne Rowzee: So let's turn the page and talk about this year. What are a few of your goals for the center in 2016?

Dr. Woodcock: Well, I think what's gonna dominate much of our thinking is gonna be the user fee negotiations. They're going on right now. We hope to bring them all to a conclusion in 2016 as far as our part in the negotiations and they would deliver them up the chain and those are very important because of course, we need the staffing and the resources to carry on these programs and so we have the Generic Drug User Fee Program, the Prescription Drug User Fee Program, and the Biosimilar User Fee Program and we have had some early discussions around the OTC Monograph Reform that we're interested in pursing because that program is not adequately staffed to get the monographs out. So that whole collection of negotiations and efforts are gonna, is gonna dominate some of our time. Another area that has gotten a lot of attention, of course, is the First Amendment and the jurisprudence around the First Amendment to the Constitution of the United States and we are currently doing an intensive effort to evaluate how we regulate commercial speech in the light of current jurisprudence and that's going to be another effort. Another one will be the prescription opioid epidemic and what else can be done by FDA. Now there are many other parties that have a more leading role there but we have many things that we can do. We can encourage, which we have done, anecdotes for over dosage. We can work on abuse deterrent formulations and last year we issued a final guidance for innovators. We need to come out with something for generics as well and we can also look at treatment of drug dependency which is very important and been a neglected area 'cause if people can undergo treatment for their dependency, then they can be in a better place and not be vulnerable to overdose. So we'll be, you'll see us working in all those areas as well as continuing to work on the REMS that we have for opioids.

And then finally, I think hiring. Did I mention hiring? Right, we're still gonna have to push on hiring and also leadership development -- which we have a plan for in the center -- and succession planning are important.

Anne Rowzee: Yes. Yeah, so wow, it really sounds like 2016 is shaping up to be another busy year but, you know, if you can make one of those goals happen right now, which would it be?

Dr. Woodcock: If I could have 800 people on board this very minute who aren't here right now, I think we'd all be in a much better position to get all this done in the next year but, unfortunately, this is gonna require a huge amount of work on many folks' part in the center and the agency to get the, the staff we need on board to get all this work done.

Anne Rowzee: Yes. Well, Dr. Woodcock, thank you so much for sitting down and sharing your thoughts with me today and we look forward to see how 2016 shapes up.

Dr. Woodcock: Yes, well, I think it's going to be yet another busy year, maybe full of a new first for the center and we'll hang on for the ride.

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