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A Chat With Jeff Shuren: FDA Device Center Chief Worries About Agency Staffing; Talks MDUFA V, Pandemic, More

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The head of the US agency's device center spoke with *Medtech Insight* in an exclusive wide-ranging interview about his priorities for the future, the nuances of the MDUFA V user-fee negotiations, how COVID-19 has changed the agency, and more.

Jeff Shuren, director of the US Food and Drug Administration's Center for Devices and Radiological Health (CDRH), recently talked to *Medtech Insight* about lessons learned from the COVID-19 pandemic, warned that some agency staff are only staying on until the crisis is over, and how the Medical Device User Fee Amendments (MDUFA V) negotiations are going.

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Q **Medtech Insight: This past year has been difficult on a lot of people, but I think in some ways, maybe even more difficult on the FDA. Kind of talk to us a bit about some of the challenges you faced during the pandemic and some of the challenges you see maybe continuing forward as you're still dealing with this pandemic.**

A Jeff Shuren: Workload and its impact on the well-being of my CDRH colleagues is at the top of my list. For example, based on where we are now and where we want to be

after COVID-19, although we continue to take steps to address the large influx of COVID and non-COVID submissions, we may see some additional workload issues as EUA holders start coming in with 510(k)s or de novo submissions for their devices, that were authorized for use during the pandemic.

Also, staying abreast and optimally ahead of new technologies, as well as generating and getting access to critical data to support timely decision-making, such as to resolve postmarket safety signals quickly rather than continued uncertainty from patients and providers about the impacted devices, continue to be big challenges.

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And lastly, our IT systems are outdated and siloed. Our staff are constantly having to go in and out of different systems to get their work done and end up doing a lot of things manually. We spend extra time to find or incorporate information. Under our Digital Transformation initiative, we're in the process of implementing interoperable agile platforms and moving our data to the cloud, but it takes time and a lot of money.

However, we've been planning this transition as well as saving and securing funds for several years to help make this happen.

Q **It's been a very long year, but we've been reporting on the fact that your staff have taken on all this extra workload and are burning out. Are things calming down? Are you worried you're going to lose some talented officer? And what are your concern for your staff and how you're handling those concerns.**

A Shuren: Well, to put things in perspective, in 2020 CDRH received over 17,000

traditional premarket submissions; a little more than we had in recent years. And then we received over 5,600 pre-emergency use authorizations and emergency use authorization submissions. So that resulted in an overall increase in premarket submissions of about 38%, or if you looked at it as 510(k)s; about 150% increase in the number of 510(k)s.

In addition, we had a leverage about 130 people full-time or part-time to address issues related to shortages of critical medical devices and the work increased dramatically, but our staff did not. Every office in CDRH has been impacted particularly since we had to reallocate some of our staff and resources from product areas less impacted to those with increased submission volumes and to engage in other COVID-related work.

The reality is that many of our staff are burned out and we could very well lose talented people as we continue to prioritize COVID-related work. I know of some people who have stayed just to help address the pandemic but plan to leave once we are back to the new normal.

To address this we've made changes in our processes and policies, conducted submission triage and prioritizations to better manage the workload, aggressively hired with a record year of net new employees. But we are also very grateful for the one-time funding we received from Congress, which has allowed us to hire additional termed staff and temporarily use contractor support to address some of the critical COVID response work.

We've also focused on wellness for CDRH colleagues, including through the creation of a virtual wellness center, and most recently launching a pilot on giving our staff breaks before and after internal one-hour meetings.

Q **I recently wrote a *story featuring Janet Woodcock*, where she said the agency may be coming to a new kind of world where a larger portion of your staff may be working remotely. Is that something you guys are looking at; kind of making some of these changes you've had over the past year more**

permanent?

A Shuren: We are looking at that. Certainly it's an agency-wide issue, but I'm not going to be surprised that we're going to anticipate more people doing more teleworking.

Q **There are a number of areas where the FDA has been struggling with during the pandemic. What is your plan to start ramping up some of these inspections and certain product reviews after the pandemic is over, because you'll be able to hopefully move more of your resources back to some of those normal day-to-day activities?**

A Shuren: Well, we're not even waiting for the pandemic to be over. The FDA has been actively preparing to resume standard operations for inspections.

> *"FDA is transitioning to standard operations for domestic inspections beginning July 1 and will continue to prioritize mission critical work for foreign inspections."*

The agency explained its plans in the recently published resiliency roadmap for FDA inspectional oversight. And consistent with the roadmap, the FDA is transitioning to standard operations for domestic inspections beginning July 1 and will continue to prioritize mission critical work for foreign inspections.

However, there are inherent challenges in planning foreign inspections in light of the time involved. So the agency estimates that given the length of time required to plan foreign inspections, no foreign surveillance inspections conducted by inspectors traveling from the US will likely be achievable before September 2021 when using US-based staff.

However, the FDA's foreign offices were already performing a limited number of

foreign surveillance inspections during this year.

The device program has and will continue to participate in the *Medical Device Single Audit Program* – MDSAP – and this participation has continued throughout the public health emergency. In fact, we've leveraged MDSAP audit reports in lieu of FDA surveillance inspections. For example, in 2020 MDSAP audits that we received were conducted over 2,800 medical device manufacturing facilities and the MDSAP program was able to pivot to perform some types of audits remotely.

And then the agency has been exploring the use of other approaches to complement its inspection program. For example, our Office of Regulatory Affairs [the lead office for all the FDA's field activities] implemented a voluntary remote regulatory assessment that it has been using with medical device facilities for the past few months. And right now these assessments, which are not inspections by the way, involve interactions with facilities using established virtual platforms. And in the future they're going to be looking at the use of other tools and probably pilot those and certainly encourage any companies who are participating in these assessments to provide their feedback to the agencies so have a better understanding of what's working, what's not working and what can be improved.

Q **Let's delve a bit into the *MDUFA V user-fee negotiations*. We've been kind of following you guys as you've been talking with industry. There are a number of disagreements between the agency and industry, including whether the FDA has actually met its MDUFA IV obligations, whether the agency is allowed to use the fees to pay for modernizing its IT infrastructure – things like that. And I think in one of the April meetings, the last minutes that I saw, you kind of talked about creating a working group to kind of address some of these issues, and you also kind of talked about the Total Product Life Cycle Advisory Program, or TAP, program.**

Tell us about some of those disagreements and how you're addressing those with the with industry, and also tell us a little about the TAP program and kind of how you envision that.

A Shuren: The program is overall working well. I mean this is going to be our fifth MDUFA agreement. And since its inception, the MDUFA program has led to more transparent, predictable and efficient processes. I mean these changes have led to measurable improvements in patient access to innovative, safe and effective devices. And if you don't believe it, you guys report every year on even the number of innovative technologies authorized by CDRH.

As you've noted over the past decade, those numbers continued to go up and up and up.

I'll say on the flip side, MDUFA has been primarily focused on the premarket review portion of the total product life cycle, whereas many of the challenges facing device makers occurred during the development and evaluation phase prior to premarket review; the true "*Valley of Death*."

In fact, many of the holdups and adverse decisions made during premarket review stem from not getting it right; if you will the companies are not getting it right in the development and evaluation phase.

There are also challenges encountered after FDA authorization such as coding, coverage reimbursement and adoption by health care providers. If given the right support during the development and evaluation phase, many device makers could be better positioned to succeed with payers, providers and patients.

During the pandemic we saw the transformative impact of near and real-time interactions between developers and CDRH experts getting devices developed, evaluated and authorized quickly.

However, that level of engagement by the FDA is not feasible on an ongoing basis because we don't have the capacity to do so, let alone to even engage in greater interactions with many sponsors who participate in our Breakthrough Devices program.

Pre-submission meeting requests are popular. The number of requests we receive grows every year, but it can hit a three-month process, focus on addressing limited questions, and if there are more questions you have to request another pre-sub and the cycle starts again.

And we would like to provide meeting a greater level of premarket engagement than during COVID with more touch points, real-time interactions, and a more proactive strategic and problem-solving approach. We call it the TPLC advisory program, or TAP. It includes building at our review capacity to allow for these kinds of real-time interactions and adds a new member to the team that we call a TAP advisor who will provide a concierge style of strategic support, address basic questions and ensure that the right experts and support are available quickly when you need. If implemented, we believe it would be the biggest game-changer we've seen since the first MDUFA was enacted almost 20 years ago. We also would like to see investments in a more robust signal management program.

It's critical for not just assuring that authorized devices remain safe and effective once on the market, but to also inform future device modifications and new technologies subject to premarket review. And that said, I would be concerned about a program that looks backwards, not forwards.

Right now though, we're still in the midst of negotiations, so it's too early to project any outputs.

Q **Well, one of the things I think it seemed industry was a little skeptical about was not that you know these pre-submission meetings and extensive pre-submission meetings wouldn't be helpful but the idea that other stakeholders – the payers and providers – would be willing to join in in these meetings. Are you concerned about that at all and what would you tell industry about that kind of skepticism?**

A Shuren: Well, first off, the opportunity to include other stakeholders is purely

voluntary. Some companies have well-established relationships with appropriate patient groups and provider groups, and with payers and they may not need that additional service. We can think about it as you've got a menu of services to pick from. It's all voluntary on the part of the company.

But other companies are not in that situation. And our experience has been that a number of the players are very willing to come to the table, and that's the patient community, that's been in the provider community, and on occasion in the payer community.

But one of the things we'd also like to see as we roll out the program is for us to have the capacity to build a better relationship with payers.

I have to tell you and not all payers are the same. It's not one-size-fits-all and we have a number of payers who have been actively interested and taking advantage of those opportunities if they're offered.

Q **I want to talk about some of the issues around legislative affairs. There has been talk about the FDA needing new, explicit legal authorities, such as regulating lab developed tests and oversight of certain medical software. You also talked a couple years ago about having "legislative Legos," as you called it, to let the FDA have more authority to modify regulatory powers. Can you talk about those issues, and have you been talking to congressional offices about the need for more regulatory powers?**

A Shuren: The FDA's long-stated interest in legislation is to provide a holistic, more modern oversight framework for in vitro diagnostics with the goal of assuring that all tests are accurate and reliable in lieu of our taking administrative actions to achieve the same objective.

And the need to provide such assurances for all tests was further underscored by our experiences with COVID-19 tests. We continue to look forward to working with Congress, HHS and others on that legislation.

> *"I believe we will continue to have more virtual interactions rather than face-to-face meetings."*

In regard to *regulatory Legos*, or agile regulation, the current device regulatory framework was enacted by Congress about 45 years ago, and it wasn't designed for the modern technologies of today. It's no longer fit for purpose.

Besides engagements, another lesson learned from the pandemic is the importance of regulatory flexibility that we were able to provide under our emergency use authorization authorities once a public health emergency is declared but not at other times. The flexibility to narrowly tailor the regulatory pathway for a given type of technology and use that can be rapidly designed to focus on the right things to reasonably assure safety and effectiveness, in the least burdensome manner and applied in a risk-based approach.

We think this agile regulatory approach, which would require legislations … would better assure patient safety while providing voluntary streamlined pathways for industry. There would be options. This isn't about changing the US regulatory standard, but rather how to a best meet them instead.

Q **Speaking of regulations, you've recently been publishing a slew of guidances. Are these guidances coming out so frequently in the past few months as a result of a backlog caused by the pandemic, and can we expect to see a continued intensity with which you've been publishing these guidances?**

A Shuren: I think it's a combination of several factors. The pandemic is one. As CDRH also sees a slowdown in guidance publication following change in administration. As the new administration fills positions, new people get up to speed on the issues. I think it's reasonable to expect that we'll be back to a more regular cadence of guidance publications in the coming months.

Q **One regulation we've been looking forward to is the draft, harmonized *Quality System Regulation*. Is there any update on when we can expect to see that?**

A Shuren: It continues to be a top priority and we are moving it forward. Ultimately that's a decision above my pay grade and the other eyes are put onto the document. I can't give you a set timetable, but we certainly are looking to have it out this year.

Q **All right, well, we'll keep our ears and eyes open for that. The FDA has adopted some nontraditional means of doing its business during this pandemic, such as having webinars and doing desk inspections. We kind of touched on a little bit at that earlier. What are some things during the pandemic that you think are either going to be permanent or will continue in some hybrid form, and what are some things that you think will revert back to the way that they were done?**

A Shuren: Well, I'm not sure anything will return to exactly the way they were done before, in part because I believe we will continue to have more virtual interactions rather than face-to-face meetings ranging from public meetings to advisory committee meetings, meetings with industry and other stakeholders to save everyone more time and resources. And I see us increasingly using virtual platforms and tools to enhance our external outreach and communications.

I also think we'll see more work being performed in a virtual shared environment, both externally, such as *Remote Regulatory Assessments* or hybrid inspections, premarket review, as well as internally at the FDA as more people will be teleworking, as we've discussed just a moment ago.

Q **This is always my favorite question to ask, but is there anything that we haven't touched on that you think is worth mentioning?**

A Shuren: Well, it's nice to see some light at the end of the tunnel. The pandemic continues to plague our country and our planet, but it's also provided us with silver linings, such as lessons learned that could and should be applied not only for the next

> emergency, but during peacetime as well.
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> That includes opportunities where so many of us work together more closely, collaboratively and quickly than ever before. My hope is that we implement and build on these lessons learned so that we all, in particular patients and consumers, are better for it.