Alliance for a Stronger FDA Budget Priorities Webinar Series

Summary of Webinar with Dr. Jeff Shuren, Director for the Cnter for Devices and Radiological Health (CDRH)

April 29, 2022 | Moderated by Wayne Pines and Nancy Myers

Dr. Jeffrey Shuren, Director of FDA's Center for Devices and Radiological Health (CDRH) provided an information-packed webinar for the Alliance on April 29, 2022. CDRH's 1,900 employees oversee 230,000 medical devices produced at more than 25,000 manufacturing facilities around the world and 19,000 premarket submissions. They have approved a record number of novel devices, with an average of over 100 per year.

CDRH has dealt with more than 8,000 emergency use and pre-emergency requests since the start of COVID-19. They have authorized about 2,300 medical devices in response.

Significant efforts have been made to increase engagement and transparency during this time. CDRH has issued over 350 frequently asked questions and provided many modifications, 28 COVID guidances that have been modified 21 times, and responded to 420,000 inquiries. They have held 107 town hall webinars, originally holding one every week and now every other week. They were engaged with NIH from the ground level in their RADx program. They set up the capability for the US Government to conduct independent evaluations of tests. He also strongly praised CDDRH's staff for stepping up during the pandemic.

There have been ramifications for non-COVID work. They had seen challenges developing pre-COVID, and constantly provide a guesstimate as to CDRH's workload. MDUFA IV resulted in a big workload, including 3,000 more submissions than CDRH had been prepared for. Last year saw the highest number of 510(K) submissions in 15 years. They hired more term-appointment staff with COVID Supplemental funds. They also got temporary help from contractors and have changed policies and procedures. The backlog has now been reduced by 45%. Dr. Shuren said they will fairly soon start to open the door for pre-submissions. The goal is to be back to normal by the end of the year. They also want to transition from emergency use to full use authorizations for several items, and have put out two guidance documents for comment, with the goal of issuing final guidances by the end of this year.

Strategic priorities for 2022-2025 include developing a modern and diverse workforce that reflects the public; enhance organizational agility and resilience, learning from COVID and making CDRH a desirable workplace for both employees' current needs and their future interests even if not at CDRH; and working on health equity so that no patient is left behind. People must

have access to healthcare. Unrepresented populations can be helped with technology being used as a bridge, including technology in the home.

He spoke about several goals as well. CDRH had a goal that by the end of 2020, over 50% of manufacturers of novel technologies for the US market intend to bring their device to the US first or in parallel with other major markets. By the end of 2020, over 60% of those makers of novel technologies did intend to come to the US first. For 2025 they have set a goal that over 50% of those manufacturers in fact do bring their devices to the US first or in parallel with other major markets.

They also have a complimentary goal on safety that over 75% of the time, FDA identifies and acts on significant safety signals related to medical devices marketed in the US and other major markets first or in coordination with regulatory agencies of other major markets. The submission tracker created for 510(k)s is going to be expanded for other submission types with a greater ability for accepting more smart regulator templates for submissions, beyond 510(k)s that they created last year.

For 2022 they will put a spotlight on some regulatory science research opportunities, including a final report on the pre-certification pilot. They have an upcoming meeting of the Patient Engagement Advisory Committee to talk about considerations in augmented reality and virtual reality, including in special populations. They are planning to put out final guidance on clinical decisions towards software later this year. They are building a Digital Health Policy Navigator to help determine if a product is something that is regulated as a medical device or not by the Center and what are the applicable policies. There will also be draft guidance on the use of a change control plan for technologies that are enabled with artificial intelligence machine learning, explaining what needs to be done if a manufacturer wants to have a plan for making changes and how the manufacturer validates them that CDRH would then review.

With respect to cybersecurity Dr. Shuren spoke about the 2023 budget request for $5 million for a serviceable program on device cybersecurity, and for authorities included PATCH Act introduced in the House (H.R. 7084) and the Senate (S. 3983).

He also called for an expansion of authorities similar to the CARES Act to require reporting for critical devices.

Regarding MDUFA, he said CDRH has taken public comments and are looking to wrap up and send the final package to Congress by the end of next week. A big source of funding for the Center, it will have improved performance goals, if Congress enacts the recommendations. It will also support a pilot for what they call the Total Product Lifecycle, TPLC, Advisory Program or Pilot or TAP.

Dr. Shuren responded to several questions, including:

- ***Congressional criticism of being unresponsive and not meeting deadlines*** **–** Considers it "tough love" and something that helps FDA improve.
- ***How to increase transparency*** **–** Dr. Shuren would like to continue to hold town hall meetings if CDRH has the capability. It has been a great experience in real time but is a

question of what FDA can do with available resources. He would like to put out additional information. It does take time, but there is the ongoing question of how to put it out, the format to use, and how to put it out in a useful way.

- ***Changes in regulatory framework –*** The paradigms developed in 1976 do not work well today. COVID EU authority gave CDRH the ability to respond. There is a need to have agile regulations that provide greater flexibility in how manufacturers can meet standards. Changes in the law will be required.
- ***Next technologies –*** Robotics, genomics, **probiotics** for detection of various pathological conditions, closed loop organs, miniaturization, non-invasive endoscopic surgery, technology that is fit for the home, and simplicity. What we have today is too complex for people. Looking for greater use of breath tests. There is a symbiosis between technology and humans. Technology will increasingly be part of life, which is exciting, but for which CDRH is not prepared.
- ***Advancing health equity –*** When asked about how health equity could be a priority in device review, he said that technology that is going to either make it easier for patients to be able to get access, or technology that is tailored to populations that did not have it before, could potentially be good candidates for breakthrough or safer technologies programs. Technologies that are in those programs would also be candidates for the new TAP pilot.
- ***Unfunded mandates –*** When asked if there are bills that he is worried about that could create unfunded mandates, he said there is not a part of CDRH that does not need more. He said that user fees are for premarket work, while post market gets short shrift.
- ***How COVID has changed the way Dr. Shuren thinks about his job –*** He again praised CDRH's staff and their dedication. He believes COVID has informed strategic priorities, and how the workplace is designed. There is more collaboration between employer and employees. Staff must be trusted, encouraged to constantly try new things, and trusted to be wrong, or people can never be better.