Summary of the Patient Engagement Advisory Committee
November 15, 2018

Introduction:

The Patient Engagement Advisory Committee to the Food and Drug Administration (FDA) met on November 15, 2018, to discuss and make recommendations on the topic "Connected and Empowered Patients: e-Platforms Potentially Expanding the Definition of Scientific Evidence." The recommendations will address how FDA can leverage patient-generated health data, such as social media, sensors and patient-driven registries, to better engage patients and consumers as empowered partners in the work of protecting public health and promoting responsible innovation. Social media and other web platform enablers are facilitating the growth of virtual patient communities. Increasingly, patients and healthcare consumers are using these platforms to share their health experiences and seek information from other patients and consumers, rather than their healthcare providers alone.

Presentations:

Jeffrey Shuren, M.D., J.D., Director, Center for Devices and Radiological Health (CDRH), FDA, welcomed the committee and public and provided opening remarks.

Thomas Gross, M.D., MPH, Director, Office of Surveillance and Biometrics, CDRH, FDA presented on the Applications of Postmarket Regulatory Tools Supporting Use of Patient- Generated Health Data.

Owen Faris, Ph.D., Director, Clinical Trials Program, CDRH, FDA, presented Real-World Evidence Guidance.

Guest Speaker, Shilpa Venkatachalam, Associate Director, Patient Centered Research, Global Healthy Living Foundation (GHLF) presented on Patient-driven Registries.

Speaker, Rachel Rath, MPH, Deputy Director of National Evaluation System for Health Technology Coordinating Center (NESTcc), Medical Device Innovation Consortium (MDIC), presented on the Challenges with Registries and Opportunities through NESTcc.

Marisa Cruz, M.D., Senior Medical Advisor, Digital Health Unit, CDRH, FDA, presented on Digital Health Technology.

Industry Speaker, Paul Coplan, Sc.D., MBA, Vice President & Head of Medical Device Epidemiology, Johnson & Johnson presented the Industry Perspective on Digital Health Technology.

Speaker Jen Horonjeff, Ph.D., Founder/CEO, Savvy Cooperative presented the Overview of Social Media.

Hesha Duggirala, Ph.D., MPH, Chair, FDA Data Mining Council presented on Social Media for Postmarket Monitoring

Open Public Hearing:

Fourteen open public hearing speakers presented and provided comments. Speakers included patients, research organizations, industry, patient advocacy groups and other members of the public.

Round Table Discussions:

The audience was asked to discuss a theoretical postmarket medical device scenario covering the potential use of patient-generated health data to identify and confirm a safety concern. Participation in the roundtable discussion was completely voluntary. At the conclusion of the roundtable discussions, the FDA representatives presented the comments generated by the audience members to the PEAC members.

Open Public Comment:

Four open public comment speakers provide comments on the roundtable discussions.

FDA Questions and Committee Discussion:

The committee discussed FDA's postmarket regulatory activities including advising manufacturers on the development of postmarket studies (such as defining the study design, patient population, and outcomes of interest), performing surveillance for adverse events, issuing recalls, and communicating signals to the public. The panel agreed that patient-generated health data should be used, to inform these postmarket processes for medical devices by collecting data on surveillance for adverse outcomes, issuing recalls and signal management. They mentioned that not all types of patient-generated health data would be applicable in all the processes. In addition, the committee agreed that the Agency needs to take the following steps:

- Standardize how data is collected, used and applied in the various situations
- Ensure language communicated to patients about how the data being collected will be used is clear and understandable
- Ensure data collected is de-identified

- Ensure a high level of integrity with the data collected

The committee made recommendations on the potential challenges that exist for using patient-generated health data to inform regulatory activities including; results that do not reflect the true outcomes, data quality and integrity issues, and the ability to account for confounding factors. The committee agrees that while the agency is making strides with patient-generated health data, more needs to be done. As a result, the committee made the following additional recommendations to the Agency:

- Build more trust between patients, industry, vendors and the government
- Consider socioeconomic disparities in access and use of certain technologies such as sensors and smartphones
- Encourage the involvement of patient organizations in the collection of data
- Ensure that patients are educated on the use of their devices, how the data is being collected, and that the language is clear
- Ensure that the patients are true patients and not reflective of influencers or other "fake patients"
- Develop standard data elements and formats in which data is collected and reported

The committee discussed how internet-connected digital health technology and social media could be used to identify people living with certain medical conditions and under-represented populations for inclusion in clinical trials for medical devices. The committee agreed that researchers using this approach to identify and recruit patients for clinical studies should adhere to strict privacy issues with this approach to clinical trial recruitment. The committee would like the Agency to:

- Set a framework for the type of data that can be used
- Develop standards around the consent to data collection. Patients need to understand what they are consenting to, the duration of their consent, if they will have access to their own data and if they are able to rescind their consent in the future if they no longer wish to have their data used
- Use social media as a tactic for data collection and not a stand-alone strategy. Efforts should be made to personally reach out to communities and patients, not just rely on social media. Encourage the identification of under-represented patients by frequenting places they may visit in their daily life (such as coffee shops and worship centers) instead of relying solely on social media

The committee made recommendations on the practices that they would want to be put in place to protect patients' privacy. Including, language that informs patients about some possible uses of their data in medical research, clearly explains informed consent, is transparent, and informs patients how to access their data. The Committee believes that the Agency should do as much as possible to inform individuals about the use and application of their data. The Committee also suggested that patients should have access to their data to use and share.

The committee discussed other mechanisms or approaches that they would like the FDA to use to communicate information about medical devices, including the FDA website, Facebook posts, YouTube,

email blasts to subscribers, blogs, Twitter, webinars and leveraging patient organizations. The Committee would also like to see refinements made to the user interface on FDA's website to make it more user friendly and easier for the user to find content. They also emphasized that the FDA is one of the most trusted sources of medical device information and should be involved in generating and disseminating safety messages. The Committee emphasized the importance of including healthcare providers and patient organizations when disseminating information.

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