Science Board to the Food and Drug Administration
FDA White Oak Campus, Building 31, The Great Room (Rm. 1503A)
10903 New Hampshire Ave, Silver Spring, Maryland 20993
April 23, 2018

AGENDA

9:00 a.m. **Opening Introductions**
Mark McLellan, PhD, Science Board Chair

9:05 a.m. **Conflict of Interest**
Rakesh Raghuwanshi, MPH, Designated Federal Officer, Science Board, FDA

9:10 a.m. **Chief Scientist's Update**
RADM Denise Hinton, Acting Chief Scientist, FDA

9:20 a.m. **Final Report from the CBER Research Program Review Subcommittee**
Barry Byrne, MD, PhD, Subcommittee Chair

10:20 a.m. **Patient Affairs Initiative at FDA**
Samir Shaikh

11:20 a.m. **Break**

11:30 a.m. **Commissioner's Update and Overview of Afternoon Discussion**
Scott Gottlieb, MD, Commissioner of Food and Drugs, FDA

12:30 p.m. **Lunch**

1:15 p.m. **Afternoon Discussion Session**

1. Lack of interoperable EHRs, weak incentives for data sharing, and concerns about patient privacy and cybersecurity are important barriers to the ability of providers and researchers to leverage predictive analytics to improve patient safety and enhance productivity across the medical research ecosystem.

   How can the agency work with other stakeholders to create regulatory use cases for high quality data sets that can provide market incentives to address and overcome these barriers?

2. Drug repurposing could be an important tool for identifying promising alternative, non-addictive treatments for acute and chronic pain.

   How could the agency leverage its existing tools and authorities to identify potential alternatives, and work with other stakeholders to encourage the testing and development of these products in a time frame that could meaningfully impact the current opioid crisis?

3. Bringing together the FDA's current critical data assets in a single secure computing environment could allow for the rapid development and testing of promising drug development tools (including virtual control arms and *in silico* modeling); facilitate the training and validation of AI and machine learning programs both externally and internally; and improve the agency's ability to meet Congressional requirements of the 21st Century Cures Act relating to qualified data summaries and expanded drug indications across diseases that share common genetic or protein pathways.

   How can the agency achieve these goals while still protecting confidential commercial information?

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4. Clinical trial participation remains low among some minority groups, and in some geographic regions.

   How can we use existing digital architecture like EHRs and innovative training modules to help clinicians operating in these environments bring clinical trial participating to the point of care in under-represented communities, and lower both the technical and cost barriers to more diverse clinical trials participation that better reflects these communities?

3:30 p.m. **Open Public Hearing**

4:30 p.m. **Final Thoughts, and Closing Comments**
Mark McLellan, PhD, Science Board Chair