MINUTES OF THE
SCIENCE BOARD TO THE FDA MEETING
FDA White Oak Campus, Building 31, The Great Room (Rm. 1503A)
10903 New Hampshire Ave. Silver Spring, MD 20993

Monday, April 23, 2018

The Science Board to the FDA (Science Board) meeting was convened at approximately 9:00 a.m.

Members Present
Cynthia A. Afshari, PhD, DABT
Anthony Bahinski, PhD, MBA, FAHA
Rhondee Baldi, MD, MSHS (consumer representative)
Lynn R. Goldman, MD, MPH
Barbara B. Kowalcyk, PhD
Mark R. McLellan, PhD (chair)
Theodore Reiss, MD, MBE
Minnie Sarwal, MD, PhD
Scott Steele, PhD
Laura Tosi, MD
Connie Weaver, PhD (via phone)
Xiang-qun Xie, MD, PhD
Michael Yaszemski, MD, PhD

Designated Federal Officer
Rakesh Raghuwanshi, MPH, Office of the Chief Scientist

FDA Representatives
RADM Denise Hinton
Dr. Scott Gottlieb
Dr. Peter Marks
Dr. Carolyn Wilson
Samir Shaikh
Andrea Furia-Helms
Elaine Johanson
Dr. Vahan Simonyan
Dr. Bakul Patel
Dr. Sean Khozin

Following member introductions, Mr. Raghuwanshi provided the conflict of interest statement for the meeting.

The following is a summary of the discussion. Additional information and specific details may be obtained from the transcript of the meeting. The transcript may be viewed on the Science

Board to the Food and Drug Administration web page approximately 6 – 8 weeks after the meeting.

Summary of Committee Discussions and Recommendations

Final Report from the CBER Research Program Review Subcommittee

- Recommendations from the report:
    - Research Priorities- develop a center-wide horizon scanning process
    - Adaptive scientific infrastructure- develop contingency plan to provide the ability to shift resources and projects
    - Research Collaborations
    - Research Reviewer Model- designate some amount of protected time, consider sabbatical program, and assure appropriate travel funding for investigators to stay abreast of developments in their field

Patient Affairs Presentation

- Develop unified and systematic standards to meet patient needs through patient engagement initiatives
- Patient engagements activities include
    - Creating patient inquiry points for FDA
    - Focus on education and navigation
    - Educating patients about the regulatory process
    - Public-Private partnerships- currently creating a diverse 16-member committee that will include patients, caregivers, professional organizations, rare diseases areas
- Comments from Science Board Members regarding patient affairs presentation
    - Health literacy
    - Standardize approach in engaging patients to communicate with new patients
    - Patient Affairs should better coordinate with CSFAN, also cross collaboration between agencies to utilizes best practices
    - Utilize social media as communication tool for patients

Commissioner's Update by Scott Gottlieb, MD, Commissioner of Food and Drugs

- Continuous manufacturing and data management – areas of interest
    - Continuous manufacturing- uncertainty in a course of development program
        - Critical to engage with sponsors throughout process to limit uncertainty and errors, reduces costs, and reduce cycle time and adaptive clinical trials
    - Data management- move towards an active and specifically tailored regulatory science outcomes, patient safety, standardizing is needed
- Patient advocacy
- More opportunities for future workforce

- Knowledge management system- Efficacy and optimal capability in answering clinical questions

Afternoon Discussion

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?

   - Discussion included:
     - Partnerships with clinicians with incentives
       - Reliable health information provided to clinicians through applications on mobile devices and clinicians can provide FDA with data
     - Artificial intelligence potentially a solution
     - Agency engaging in stakeholder activities, possibly thinking of creating a working consortium
     - Mindful of data integrity
     - Privacy a huge hurdle to consider
     - Improve data sharing within DHHS and offices within FDA
     - Funding to hire and retain highly skilled data scientists

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 underrepresented communities, and lower both the technical and cost barriers to more diverse clinical trials participation that better reflects these communities?

   - Discussion includes:
     - Move clinical trials to the community
     - Provide clinicians self-efficacy to have tools to engage patients in clinical trials
     - Exclusions in clinical trials an issue, need to discuss ways to include more people

Open Public Hearing

No comments

Final Thoughts and Closing Comments by Mark McLellan, PhD, Science Board Chair

- Didn't discuss question 2 or 3 on agenda- will discuss another time
- Potentially create a subcommittee to discuss more in depth questions 1 and 4 on agenda
- Next Meeting Scheduled in October 2018

I certify that I attended the April 23, 2018, meeting of the Science Board and that these minutes accurately reflect what transpired.

_____/s/_____ _____/s/_____

Rakesh Raghuwanshi, MPH
Designated Federal Officer

Mark McLellan, Ph.D.
Chair