

President's Council of Advisors on Science and Technology (PCAST)

EIGHTEENTH MEETING

April 16, 2012

MINUTES Conference Call

Members Present: John P. Holdren (Co-Chair), Eric Lander (Co-Chair), William Press (Vice Chair), Maxine Savitz (Vice Chair), Rosina Bierbaum, Chris Chyba, S. James Gates Jr., Mark Gorenberg, Shirley Ann Jackson, Chad Mirkin, Ernest J. Moniz, Craig Mundie, Ed Penhoet, Barbara Schaal.

Members Absent: Christine Cassel, Richard C. Levin, Mario Molina, Eric Schmidt, David E. Shaw, Ahmed Zewail.

Staff: Danielle Evers, Amber Hartman Scholz, Deborah Stine

Public Attendance: Approximately 50 listeners.

Video Webcast Archive: The archive of the audio recording is available at www.whitehouse.gov/ostp/pcast.

The President's Council of Advisors on Science and Technology (PCAST) convened by teleconference in open session at 4:30 p.m. with Dr. John Holdren presiding on Monday, April 16, 2012.

Agenda Item 1: Welcome from PCAST Co-Chairs

Dr. Lander greeted the PCAST members and those members of the public in attendance on the call. Drs. Lander and Holdren thanked the working group and co-chairs of the two studies on the agenda for their efforts.

Agenda Item 2: Public Comment – No request to make a public oral comment was received.

Agenda Item 3: Advanced Manufacturing Partnership (AMP) Steering Committee Study Update

Dr. Lander introduced the topic noting that this report builds on the prior work of PCAST in its 2011 *Report to the President on Ensuring American Leadership in Advanced Manufacturing*. He then introduced co-chairs of the Advanced Manufacturing Partnership Steering Committee, Dr. Susan Hockfield and Mr. Andrew Liveris.

Susan Hockfield and Andrew Liveris alternately described the recommendations made by the PCAST working group on advanced manufacturing in the Steering Committee's report, which is entitled *Capturing Domestic Competitive Advantage in Advanced Manufacturing*. Dr. Hockfield noted that the Steering Committee conducted extensive consultations with stakeholders, including four regional meetings, as it prepared its report. The Steering Committee's recommendations fall into three areas: enabling innovation, securing the talent pipeline, and improving the business climate. Mr. Liveris described the recommendations related to enabling innovation, emphasizing the importance of public-private partnerships to identify promising opportunities for co-investment and thereby accelerate technology development. Dr. Hockfield then took up a discussion of the talent pipeline, including recommendations related to improving the image of manufacturing and strengthening the employer-community college linkage. Mr. Liveris closed the discussion by covering issues related to the business climate, including tax reform, smart regulation, more open trade, and clean energy.

PCAST members asked questions about the role and size of the recommended centers and how they will interface with other Federal Agencies, about the importance of the private revenue bond recommendation, and about how to communicate the potential of new manufacturing technologies to the broad public.

After general discussion of the report, a motion was made and seconded to approve the report pending editorial revisions. PCAST unanimously approved the report by a voice vote.

Agenda Item 4: Propelling Innovation in Drug Discovery, Development and Evaluation Study Update

Eric Lander introduced the topic referencing previous PCAST public discussions. He briefly described the needs in this sector -- to accelerate innovation, to decreasing the time and cost to develop drugs to meet unmet medical needs, and to strengthening the drug innovation ecosystem that is facing a unique set of challenges.

Eric Lander further outlined the report, entitled *Propelling Innovation in Drug Discovery, Development, and Evaluation*, which recommends a number of actions. The first recommendation is to continue supporting work within the Federal Government such as the National Center for Advancing Translational Science and the Regan-Udall Foundation. The second recommendation emphasizes the need for partnership efforts across a wide range of public-private entities to fill scientific knowledge gaps, increase clinical trial efficiency, and generate new pre-regulatory documents through a proposed public-private Partnership to Accelerate Therapeutics. The next three recommendations deal with drug approval pathways for serious unmet medical needs: expanding the accelerated approval pathway; developing a new Special Medical Use pathway; and a study of a possible adaptive approval pathway.

Recommendation six suggests ways to improve communication to the public and to monitor the benefits and risks of drugs in the post-marketing phase. The seventh recommendation seeks to improve FDA management and communication in several ways including through the establishment of a new FDA Commissioner's Management Advisory Board. The final, eighth recommendation is to examine the economic incentives for new drugs.

Ed Penhoet noted the study included a broad base of participation including a wide variety of stakeholders and that a wide consensus from the participants emerged through the process.

PCAST members inquired about how to incentivize the development of drugs that provide unique societal benefit. After general discussion of the report, a motion was made and seconded to approve the report pending editorial revisions.

PCAST unanimously approved the report by a voice vote.

Dr. Holdren adjourned the meeting at approximately 5:20 p.m.

Respectfully Submitted:



Deborah D. Stine
Executive Director
President's Council of Advisors on Science and Technology

Approved:



John P. Holdren
Co-Chair
President's Council of Advisors on Science and Technology



Eric Lander
Co-Chair
President's Council of Advisors on Science and Technology