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David Blumenthal, MD, MPP
National Coordinator
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
Hubert H. Humphrey Building, Suite
729D, 200 Independence Ave., SW
Washington, DC 20201

Re: Request for Information Regarding the PCAST Report

Dear Dr. Blumenthal:

On behalf of C-Change, I want to thank you and the President's Council of Advisors on Science and Technology (PCAST) for the opportunity to comment on the report, "Realizing the Full Potential of Health Information Technology To Improve Healthcare for Americans: The Path Forward."

The mission of C-Change is to eliminate cancer as a major public health problem at the earliest possible time by leveraging the expertise and resources of our members. A 501(c)(3), C-Change is comprised of approximately 150 of the Nation's cancer leaders from the private, public, and non-profit sectors. These leaders collaborate on issues spanning the continuum of research, prevention, and care - *that cannot be solved by one organization or even one sector alone.*

C-Change recognizes the important potential of health information technology in achieving our Nation's goals to improve patient safety, patient care quality, system efficiency, and ultimately patient outcomes. Similarly, we value the role that information systems play in clinical research and information-based research. In cancer care, clinical research and patient care are inextricably linked. With recent advances made in the understanding of genetic diseases, we stand on the brink of being able to tailor medicines to the specific needs of individual patients. Information-based research is critically important to making strides in personalized medicine targeting more and more refined subpopulations. The HIPAA Privacy Rule, in its current state, poses major barriers to clinical and information-based research.

We appreciate the concerns raised on pages 47-48 of the PCAST report regarding the barriers that the HIPAA Privacy and Security Rules impose. Echoing our public comments from 9/13/10 on the Modifications to the HIPAA Privacy, Security, and Enforcement Rules Under the Health Information Technology for Economic and Clinical Health Act ("HITECH"), our Nation needs a more comprehensive approach to research privacy as recommended in the 2009 Institute of Medicine (IOM) report, [Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health through Research](#), if it is to benefit fully from the potential health advances that may be possible under HITECH. Similarly, the HIPAA Privacy Rule will impede our Nation's progress to improve healthcare through other important safety and efficacy programs, such as post-market surveillance and comparative effectiveness research initiatives, and our general commitment to stimulate innovation as a global leader in science.

The IOM report concluded that the HIPAA Privacy Rule does not adequately protect patient privacy and that it significantly impedes research. C-Change aims to change the HIPAA Privacy Rule and related research and health data policies to strengthen patient privacy protection and accelerate cancer research. The barriers imposed by HIPAA are typically expressed in terms that are meaningful to researchers including selection bias, inefficiency, procedural burdens, and abandoned studies. Translating these barriers into a patient perspective, HIPAA creates challenges to finding cures for all types of patients so that health disparities are not perpetuated; finding cures rapidly that are also affordable; making the patient experience more simple and predictable; and honoring the trust that patients imparted to researchers by continuing to make experimental treatments available. In addition, the resulting cost burden of these barriers weighs heavily on the healthcare and research system in terms of time, dollars, and the opportunity cost of now infeasible research.

In terms of the implementation goals for health information technology, we recognize that the vast majority of cancer care is not delivered in large cancer centers across the country. Continuing to provide incentives and support for smaller organizations to invest in and embrace technology is key to optimizing the impact of adoption and, provides an important practical step towards improving access and reducing health disparities stemming from rural geography and low population density.

We support the need to standardize data collection to promote system efficiency and interoperability. The benefits in continuity of care for patients and the uniformity of data for research would result in short- and long-term benefits in health outcomes. However, the HIPAA Privacy Rule remains a barrier to accessing this information in a timely, affordable, and meaningful manner.

The metadata approach appears to be a thoughtful strategy for enabling the expression of patient preference and improving data security. PHI, however, remains a critical component to meaningful records-based research. Loss of PHI through the metadata approach would render our investment in accumulating data useless for the purpose of discovering future improvements for patient safety, quality, and outcome. Again, we support finding a more workable framework than the current HIPAA Rules to improve data privacy and security and unencumber live-saving research.

Once again, we appreciate the opportunity to comment on this report. If the perspective of our multi-sector membership can assist ONC or PCAST in efforts to strengthen patient privacy protection and accelerate cancer research, we are happy to act as a resource.

Thank you for considering this input. If we can be of further assistance, please contact Alison Smith, Vice President, Strategic Initiatives asmith@c-changetogether.org or 708-267-5166.

Sincerely,



Tom Kean, MPH
Executive Director