MEMORANDUM

To: Lauren Lattany
From: Kyla Ross
Date: July 9, 2014
Re: 21st Century Cures: Modernizing Clinical Trials

Briefing Speakers: Dr. Roy S. Herbst of Yale Cancer Center, Dr. Sundeep Khosla of the Center for Clinical and Translational Science (Mayo Clinic), Dr. Jay Siegel of Johnson & Johnson, William V. Murray of Medical Device Innovation Consortium, Dr. Robert Meyer of University of Virginia School of Medicine, Paula Brown Stafford of Quintiles, Dr. Aaron Kesselheim of Brigham and Women's Hospital

It takes about 14 years and $2 billion to introduce a new drug on the market. A large portion of this time is spent recruiting patients for clinical trials. Recruiting and retaining participants is one of the most difficult aspects of medical research due to several reasons. Among them include the lack of a central registry for patients and doctors, low awareness of clinical trial opportunities and low retention rates among patients. This briefing discussed the various ways Congress can efficiently and effectively improve the clinical trial process.

Proposed Solutions

Participant diversity – Dr. Siegel discussed the need for a more diverse and broadly represented sample of patients in clinical trials. Trial results should represent the demographics of patients who actually require and will use the tested drug. For example, men and women sometimes require varied dosages of prescription drugs due to their biological differences. Without female representation in a trial, women are prescribed the same way as their male counterparts. Dr. Siegel called for collaboration among agencies like the NIH and FDA to increase awareness among potential patients about the importance and necessity of clinical trial volunteers.

Trial efficiency – A major problem with the current clinical trial process is its inefficiency, especially concerning cost and time. Ms. Stafford recommended transitioning from the current outdated analog design process to one that is global and digital, better reflecting society's increasing reliance on technology. Dr. Siegel spoke about a standardized system of electronic health records (eHR) which could be used in clinical trials, data collection, and observational studies. Access to e-records provides researchers with access to doctors who, in turn, have access to more patients. This could improve the chances for patient recruitment. Another suggestion was a central trial registration network for patients and doctors to personally access themselves. Lastly, Ms. Stafford discussed how researchers can avoid unnecessary, extraneous data collection by narrowing their scope during the trial design procedure.

Partnerships – Several speakers mentioned creating more partnerships between federal agencies, academia, patient groups, and the health care industry regarding clinical trials. A collaborative effort and environment allows for larger-scale trials and lower costs.

Patient engagement – Currently, patients play a relatively passive role in the clinical trial process. Dr. Siegel suggested having the trial results directly reported by patients, rather than by an objective measurement scale. He also recommended including patients in the design of the trial, in order to better retain their participation throughout the process.