



---

UNIVERSITY OF VIRGINIA

May 16, 2015

The Honorable Fred Upton, Chairman  
The Honorable Frank Pallone, Ranking Member  
Energy and Commerce Committee  
United State House of Representatives  
2125 Rayburn House Office Building  
Washington, DC 20515

Dear Chairman Upton and Ranking Member Pallone:

I write to thank you and your Committee members for your leadership in advancing the 21<sup>st</sup> Century Cures initiative. I am especially pleased to support the provision adding 'research' to the definition of 'health care operations'. This will allow HIPAA-protected yet unprecedented assured access to data on how care in all settings affects the outcomes and care needs of all patient types. Today, this critical information is largely wasted by unworkable requirements to obtain individual consent for every single use of clinical records for research purposes.

This change is long overdue. Efficient access to records by researchers while maintaining patient privacy will unlock a vast amount of information on care delivered in different places to different patients, including smaller care settings where much care across the nation is delivered today. These latter data include people with multiple comorbidities who are increasingly common as a result of our aging population. Academic clinical trial sites commonly exclude such patients.

The evidence we can gain from access from such rich data sources touches all levels and kinds of biomedical and health research from supporting hypothesis generation for translational research to making clinical care process improvements and using such information relating to access, quality, and safety of care for public health advancements, including development of better measures for evaluation and continuous improvement. Similarly, I support the language that seeks to remove the duplicative research reviews by both the FDA and OHRP for some clinical trial research. This duplication is confusing at the minimum; in addition, the capacity of the FDA to perform inspections puts them in the best position to assure appropriate patient protections.

Thank you again for your important leadership. I wish to assure that Committee that HIPAA will not be weakened by this legislative change which is certain to improve the nation's capacity to deliver better care at lower cost. Please contact me at [d.detmer@gmail.com](mailto:d.detmer@gmail.com) if you would like follow up on these comments.

Sincerely,

A handwritten signature in cursive script that reads "Don Eugene Detmer".

Don E. Detmer, MD, MA