Statement of Rep. Diana DeGette – As Prepared for Delivery Energy and Commerce Subcommittee on Health Hearing: "21st Century Cures: Modernizing Clinical Trials"
July 9, 2014

Mr. Chairman, I want to thank you for holding this hearing today.

Through the previous hearings and roundtables we have held on various topics within the 21st Century Cures initiative, we have already learned a tremendous amount about what role Congress should play in helping to further advance and accelerate treatment and cures.

The hearing today will focus on a very important area which has the potential to help millions of patients facing chronic and often incurable conditions – modernizing clinical trials.

The Food and Drug Administration (FDA) has taken great steps in this area – particularly with more flexible approaches to drug and device development. And, the agency is continuing to work on using existing authorities to adapt to advancing technology and new discoveries.

However, there may be areas in which Congress could provide more clarity for FDA, as well as address some challenges that have persisted within the clinic trials settings.

For example, I have introduced legislation in the past that would, among other things, address the lack of consistency across agencies as it relates to human subject research. Currently, there is much confusion for researchers and institutions that receive support from more than one agency due to multiple, and sometimes conflicting, regulations.

As we will hear from our witnesses, there are other areas in which we could help modernize clinic trials without compromising the high safety and efficacy standards we should continue to hold ourselves to.

I look forward to the testimony today and to learning more about this important topic.

Thank you.