PARKINSON'S ACTION NETWORK

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April 29, 2015

The Honorable Fred Upton
Chairman, Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Diana DeGette
Committee on Energy & Commerce
2322A Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton and Representative DeGette,

Thank you for your continued work on the 21st Century Cures Initiative. I write today to urge you to take action to integrate electronic health records (EHRs) with ClinicalTrials.gov in order to increase clinical trial recruitment and retention.

The potential to gather data on thousands – even millions – of patient encounters provides an unprecedented opportunity to make the connection between research and healthcare delivery. By requiring that clinical trial opportunities posted on ClinicalTrials.gov include pretrial screening information using standardized technical vocabularies, EHR systems will be able to compare relevant trial requirements to a patient's clinical and claims data without exposing the patient's private information. EHRs can enable clinical decision support functionality when a patient exhibits certain diagnostic factors that match pre-trial eligibility requirements for relevant clinical trial opportunities. By examining clinical indicators for potential participation in research, providers will be able to easily identify, as well as provide information on, relevant trials that may be beneficial to an individual's care. Patients and doctors could then decide whether participation in a trial makes sense for them.

We are supportive of the provision (Sec. 1102) included in the discussion draft of the *21st Century Cures Act* released today but do hope the language can be strengthened to require trial sponsors to submit trial eligibility criteria – inclusion and exclusion criteria – as coded values so EHRs and other technology can easily match patients to trial opportunities. The current language says NIH shall, to the extent feasible, give consideration to health care terminology and eligibility criteria for electronic matching to coded data. NIH should revise ClinicalTrials.gov to accept and present this information and make its database accessible by provider EHRs.

This provision could help address a large barrier in the discovery of new treatments – low recruitment and retention rates in clinical trials – and the costs that flow with these barriers. One contributing factor to the slow drug-approval rate for Parkinson's is the community's low clinical trial participation rate. At least seventy-one percent of people with Parkinson's report they are unaware of available clinical trials in their area.

We encourage Congress to consider requiring such standards as part of the ClinicalTrial.gov database and to provide funding to the National Institutes of Health to achieve an expansion of the database's architecture to achieve this goal. We believe this is a low cost way to positively impact the entire discovery, development, and

delivery process. Thank you again for your leadership. If you have any questions, please contact Jennifer Sheridan Palute, PAN's director of policy, at jpalute@parkinsonsaction.org or 202-638-4101 ext. 112.

Sincerely,

Ted Thompson, J.D.
Chief Executive Officer