

National Leaders Unite Behind "Include Me In" Legislation to Promote Participation in Clinical Research

By Norman M. Goldfarb

In a joint press conference earlier today, April 1, 2019, President Donald Trump, Vice President Mike Pence, Senate Majority Leader Mitch McConnell, Senate Minority Leader Chuck Schumer, and Speaker of the House Nancy Pelosi joined hands in promising bipartisan legislation to address the national patient enrollment crisis in clinical research studies.

The proposed legislation, "The National Include-Me-In Act," will initiate a \$1 billion program to educate the public and match willing patients with clinical studies. President Trump personally committed to tweet at least once per day until, as he said, "we have built a wall around this national emergency and crushed it big league."



President Trump and Speaker Pelosi engage in a spirited discussion about adaptive trial design

President Trump personally committed to enroll in a Phase I clinical study by the end of the year, saying, "Nobody is going to enroll in my First Man study before me." Speaker Pelosi, in a clever repartee, said, "We'll just have to see who the 'first man' is around here."

Speaker Pelosi and President Trump announced a friendly competition as to whether more Democrats or Republicans would enroll in clinical studies in fiscal year 2020. The legislation will include a requirement that party affiliation be collected from all study participants, along

with age, gender, ethnicity, etc. There was some jesting as to whether self-declared independents, socialists and libertines would have to take an oath of membership in the Republican or Democratic parties to be eligible for the “bonus” stipends in the legislation. Both party leaders agreed that in-clinic voter registration would be offered to “anyone with a pulse.” “And we’ll know they *have* a pulse,” joked Vice President Pence.

To industry concerns about a provision in the law that requires pharmaceutical executives to participate in their own studies, Minority Leader Schumer quipped, “You’d have to be sick to charge those outlandish prices — let’s find a cure for that.”

Majority Leader McConnell had to leave the press conference early for a study of a promising new drug to treat over-excitability. “We all recognize the tragic consequences of over-excitability, or ‘OXY,’ as it is commonly known. FDA Commissioner Scott Gottlieb has assured me that this new medication will receive Game-Breaker status,” he said.

The press conference ended with a stirring rendition of “Include me in, I’ll do my share, include me in, it’s only fair” to the tune of the National Anthem.

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