

United States Senate

WASHINGTON, DC 20510

April 27, 2016

Francis S. Collins, MD, PhD
Director, National Institutes of Health
Building 1, Room 126
1 Center Drive
Bethesda, Maryland 20814

Dear Dr. Collins:


We write to urge you to take steps to improve data collection on children participating in clinical trials funded by the National Institutes of Health (NIH). Investment in child health research is critical, not only to guarantee that children benefit from important scientific advances, but also to better understand how chronic diseases develop and persist later into adulthood.

As you know, NIH policy requires that children be included in NIH-sponsored clinical trials unless there is reason to exclude them. This is in line with policies already in place at NIH requiring the inclusion of women and minorities in NIH research. However, we are concerned that NIH is not systematically tracking the ages of children included in all of its clinical trials relevant to child health. For example, there is a big difference between a clinical trial that enrolls one seventeen-year-old, versus a clinical trial that includes tens, if not hundreds, of children of varying ages.

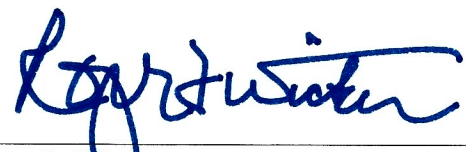
As a result, we are unable to determine whether children as a whole, or particular pediatric subpopulations, are underrepresented in federally funded biomedical research. This also leaves researchers with little information about how different pediatric subpopulations fare in these clinical trials. While NIH-funded research is required to include women and minorities to allow for the collection of data on the sex/gender and race/ethnicity of enrollees in clinical trials, the same principle has not been applied to children enrolled in clinical trials, even though this information is readily available.

Therefore, we ask that you improve data collection and report on the numbers of children in the various pediatric age groups enrolled in clinical studies. We are pleased with the ongoing work in Congress to address this issue and to improve representation in medical research more broadly. Too often, children get left behind as treatments are developed for adults, and we appreciate the work you have done to reverse this trend and improve access to treatments for children. It is critical that we continue to make progress on this front and ensure that the pediatric research community has access to this data to improve pediatric representation in clinical trials.

Sincerely,



Jack Reed
United States Senator



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United States Senator

Bob Casey, Jr.

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United States Senator

Edward J. Markey

Edward J. Markey
United States Senator

Shelley Moore Capito

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United States Senator

Chris Murphy

Christopher S. Murphy
United States Senator

Debbie Stabenow

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United States Senator

Elizabeth Warren

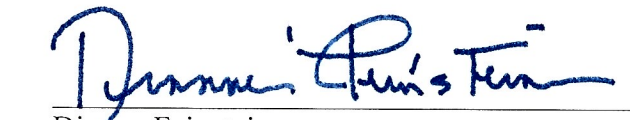
Elizabeth Warren
United States Senator

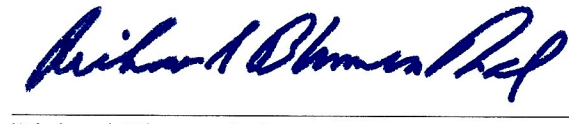
Dick Durbin

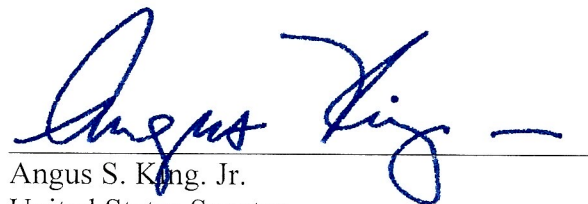
Richard J. Durbin
United States Senator

Al Franken

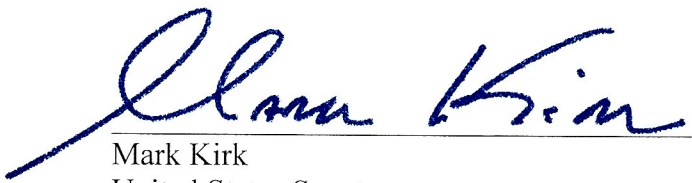
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Dianne Feinstein
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