

114TH CONGRESS
1ST SESSION

H. R. 2436

To amend the Public Health Service Act with respect to appropriate age groupings to be included in research studies involving human subjects.

IN THE HOUSE OF REPRESENTATIVES

MAY 19, 2015

Mrs. BLACKBURN (for herself and Mrs. CAPPS) introduced the following bill;
which was referred to the Committee on Energy and Commerce

A BILL

To amend the Public Health Service Act with respect to appropriate age groupings to be included in research studies involving human subjects.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. APPROPRIATE AGE GROUPINGS IN CLINICAL**
4 **RESEARCH.**

5 (a) INPUT FROM EXPERTS.—Not later than 180
6 days after the date of enactment of this Act, the Director
7 of the National Institutes of Health shall convene a work-
8 shop of experts on pediatrics and experts on geriatrics to
9 provide input on—

1 (1) appropriate age groupings to be included in
2 research studies involving human subjects; and

3 (2) acceptable scientific justifications for ex-
4 cluding participants from a range of age groups
5 from human subjects research studies.

6 (b) GUIDELINES.—Not later than 180 days after the
7 conclusion of the workshop under subsection (a), the Di-
8 rector of the National Institutes of Health shall publish
9 guidelines—

10 (1) addressing the consideration of age as an
11 inclusion variable in research involving human sub-
12 jects; and

13 (2) identifying criteria for justifications for any
14 age-related exclusions in such research.

15 (c) PUBLIC AVAILABILITY OF FINDINGS AND CON-
16 CLUSIONS.—The Director of the National Institutes of
17 Health shall—

18 (1) make the findings and conclusion resulting
19 from the workshop under subsection (a) available to
20 the public on the website of the National Institutes
21 of Health; and

22 (2) not less than biennially, disclose to the pub-
23 lic on such website the number of children included
24 in research that is conducted or supported by the
25 National Institutes of Health, disaggregated by de-

- 1 developmentally appropriate age group, race, and gen-
- 2 der.

