

THE RESEARCH FOR ALL ACT

Section-by-Section Analysis

SECTION 1. SHORT TITLE.

- ❖ The title of this bill is the “Research for All Act of 2015.”

SECTION 2. SUFFICIENCY OF DESIGN AND SIZE OF CLINICAL TRIALS DURING EXPEDITED REVIEW.

- ❖ Directs the FDA to ensure the design and size of clinical trials for products granted expedited approval under any program within section 506 of the Federal Food, Drug and Cosmetic Act are sufficient to determine the safety and effectiveness of such products for both men and women.

SECTION 3. EXPEDITED REVIEW OF DRUGS AND BIOLOGICAL PRODUCTS TO PROVIDE SAFER OR MORE EFFECTIVE TREATMENT FOR MALES OR FEMALES.

- ❖ Provides increased communication with the FDA and rolling review of applications for new drugs and biologics that will better treat women or men in light of clinical information about sex differences.
 - To be eligible, a product must be intended to: (1) avoid a serious adverse event or treat a serious or life-threatening disease or condition; (2) provide a safer or more effective treatment for men or women than a currently available product; and (3) be supported by results of clinical trials that include and separately examine outcomes for both men and women.
- ❖ Makes clear that nothing in this bill lessens or alters normal safety and effectiveness standards.

SECTION 4. RESEARCH ON SEX DIFFERENCES.

- ❖ Increases the study of female animals, tissues and cells in basic research conducted or supported by NIH. Within 1 year, NIH shall determine when it is appropriate for basic research projects to include both sexes and issue guidelines to ensure the inclusion of both sexes and the analysis of sex differences, as appropriate.
 - In making this determination, NIH shall consult the NIH Office of Research on Women’s Health, the Institute of Medicine, the NIH Office of Laboratory Animal Welfare and appropriate members of the scientific and academic communities. NIH may also conduct outreach and education initiatives to develop a consensus on the influence of sex as a variable in basic research.
- ❖ Provides a clear exception that no specific project shall be subject to any requirement if the NIH Director decides it is inappropriate.
- ❖ Directs NIH to update its guidelines to better enforce the current law on clinical research and include new guidelines related to basic research that reflect the growing understanding that sex differences matter.
- ❖ Requires NIH’s biennial report on inclusion demographics to also track statistics on the use of male and female animals, cells and tissues in basic research.
- ❖ Codifies NIH’s existing Special Centers of Research on Sex Differences.

SECTION 5. GAO REPORTS.

- ❖ Directs GAO to update its 2000 report “*Women’s Health: NIH Has Increased Its Efforts to Include Women in Research*” and its 2001 report “*Women’s Health: Women Sufficiently Represented in New Drug Testing, But FDA Oversight Needs Improvement.*”
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