

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®



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April 19, 2018

The Honorable Lamar Alexander
Chairman, Senate HELP Committee
455 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Patty Murray
Ranking Member, Senate HELP Committee
154 Russell Senate Office Building
Washington, DC 20510

Dear Senators Isakson and Casey:

On behalf of the American Academy of Pediatrics (AAP), a non-profit professional organization of 66,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults, I write in support of the manager's amendment to S. 2315, the *Over-the-Counter Drug Safety, Innovation, and Reform Act*, legislation that will improve the safety and efficacy of over-the-counter (OTC) drugs for children.

The current process for the Food and Drug Administration (FDA) to update OTC monographs is cumbersome and complex, making it hard for FDA to keep up with scientific developments, address safety concerns, and accommodate innovation. Much of the pediatric drug labeling included in the OTC monograph was based on evidence that no longer meets today's rigorous standards for safety and efficacy or was based on incorrect assumptions about how adult data should inform the labeling of drugs in children. Currently, too many OTC drugs with ingredients that have been demonstrated to be unsafe or ineffective, like pediatric cough and cold medicines, legally remain on the market, posing a risk to child health and safety.

The manager's amendment to S. 2315 would give FDA the means to respond to OTC safety concerns in a timely manner as well as to promote innovation in the OTC market. In particular, we appreciate that the manager's amendment contains sufficient language to strengthen FDA's ability to require packaging such as unit dose packaging, to prevent overdose or accidental ingestion by children.

Thank you for your dedication to the health and well-being of children. We look forward to continuing to work with you to ensure passage of this legislation by Congress as soon as possible.

Sincerely,

A handwritten signature in cursive script that reads "Colleen A. Kraft".

Colleen A. Kraft, MD, FAAP
President

CC: The Honorable Johnny Isakson
The Honorable Bob Casey