



October 18, 2019

Honorable Richard Shelby  
Senate Committee on Appropriations  
304 Russell Senate Office Building  
Washington, DC 20510

Honorable Patrick Leahy  
Senate Committee on Appropriations  
437 Russell Senate Office Building  
Washington, DC 20510

Honorable John Hoeven  
Senate Appropriations Subcommittee on Agriculture,  
Rural Development and Food and Drug Administration  
338 Russell Senate Office Building  
Washington, DC 20510

Honorable Jeff Merkley  
Senate Appropriations Subcommittee on Agriculture,  
Rural Development and Food and Drug Administration  
437 Russell Senate Office Building  
Washington, DC 20510

Dear Chairmen Shelby and Hoeven and Ranking Members Leahy and Merkley:

I write on behalf of Safe Kids Worldwide, a grass roots network of more than 420 coalitions across the nation with the mission of preventing unintentional injury among kids 19 and under. Such injuries are the number one killer of children in that age group in the United States. Medication dosing errors are among the preventable injuries on which we work to reduce. Thus, the need for complete and clear labeling and age recommendations for the youngest set of pain sufferers is critical. We appreciate that the Committee made a strong statement and set an aggressive timetable for the Food and Drug Administration (FDA) to allow weight-based dosing information on acetaminophen products for children six months to two years of age.

This has been an issue for far too long, dating back to the last century. In 2011, an FDA expert panel voted unanimously in favor of allowing this acetaminophen labeling instruction, as did an FDA advisory panel 15 years before that. In April 2012, Safe Kids wrote to the FDA Commissioner requesting the agency to take this action. To this day, the label on non-prescription acetaminophen tells parents and caregivers of children 6 to 23 months to "consult a doctor" or "ask a doctor." Safe Kids coalition leaders have a unique understanding of the concerns a parent faces every day. It is impractical and risky to add on this challenge of needing to contact a doctor for dosing instructions as a child is crying in pain. Paradoxically, manufacturers of non-prescription ibuprofen have been able to state specific dosing instructions for children 6 months to 23 months for more than 15 years.

We support the Committee's instruction to the agency to provide an aggressive timetable and plan for updating the monograph to allow weight-based instructions on acetaminophen products for kids 6 to 23 months. By copy of this letter to Acting FDA Commissioner Norman Sharpless, we urge the agency to take action on this matter. Thank you for your leadership.

Sincerely,

A handwritten signature in blue ink, appearing to read "Anthony Green".

Anthony Green  
Chief Advocacy and Network Officer