



October 2, 2017

Scott Gottlieb, MD, Commissioner
U.S. Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. FDA–2017–D–2163 for “Child-Resistant Packaging Statements in Drug Product Labeling”

Dear Commissioner Gottlieb:

On behalf of the American Academy of Family Physicians (AAFP), which represents 129,000 family physicians and medical students across the country, I write in response to the draft guidance for industry entitled “Child Resistant Packaging Statements in Drug Product Labeling” as [published](#) in the August 3, 2017 *Federal Register*.

The AAFP is dedicated to preventing adverse drug events in children. To achieve this, the AAFP has joined the larger public/private partnership known as [The PROTECT Initiative: Advancing Children’s Medication Safety](#), as well as the [Up and Away and Out of Sight](#) educational campaign. Because of our dedication to preventing adverse drug events in children, the AAFP appreciates that the FDA released this draft guidance to assist manufacturers, packagers, and distributors choose child-resistant packaging (CRP) statements in prescription and over-the counter human drug product labeling. We encourage our members to participate in these campaigns and to educate their patients about how to reduce the number of adverse drug events that happen each year in the United States. The PROTECT initiative pulls together government agencies, members of the pharmaceutical industry, consumer groups, medical professional organizations and others, to examine the problem of medication overdose in children and come up with manageable solutions. The Up and Away and Out of Sight campaign aims to educate families using a three-pronged strategy:

- Remind parents and caregivers about safe medication storage;
- Provide parents and caregivers with information and tools to keep children safe; and
- Encourage parents and caregivers to take action to safeguard children.

The program also will provide a printed public service announcement, an informational pamphlet, a doctor's office poster, a tip sheet, a video, and coloring pages. We encourage the CDC to continue these important educational initiatives.

The AAFP has a number of ideas to improve the guidance. First, the AAFP supports its application to product labeling for child resistant drug products. Second, while the draft guidance suggests language to convey that a drug product is child resistant, we suggest expanding the language to note

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those products that are not child resistant. Third, we suggest that all drug products contain the warning language "Keep out of sight and reach of children." Fourth, the AAFP encourages FDA to consider whether graphic warning labels would help convey the potential danger of children's ingestion of drug products. Fifth, as this voluntary draft guidance applies to medications supplied by manufacturers the AAFP recommends that it apply to medications dispensed in a pharmacy. Sixth, we strongly encourage the FDA to apply this guidance to all nicotine delivery devices, especially liquid nicotine bottles. The AAFP strongly supports labeling of all tobacco products warning potential users of health hazards and believes such labeling should be prominently displayed on packaging and advertisements with clear wording.

We appreciate the opportunity to provide these comments and make ourselves available for your questions. Please contact Robert Bennett, Federal Regulatory Manager, at 202-232-9033 or rbennett@aafp.org with any questions or concerns.

Sincerely,

A handwritten signature in black ink, appearing to read "John Meigs, Jr.", with a stylized flourish and the initials "MS" at the end.

John Meigs, Jr., MD, FAAFP
Board Chair