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October 24, 2007

Dear Colleague:

The leading makers of oral over-the-counter (OTC) cough and cold medicines for children want you to know that we are committed to ensuring that families have continued access to these important medications.

Last week, on October 19, the FDA's advisory committee voted on several recommendations to the agency concerning oral OTC children's medications that are labeled for use to treat symptoms related to the "common cold." It is important to note that the FDA has taken no official action on these recommendations.

Some of the advisory committee's recommendations support the OTC industry's proposed risk-management efforts. These efforts include the voluntary withdrawal by CHPA member companies of oral infant cough and cold medicines announced on October 11, strengthened labeling with regard to safe and proper use, and a national consumer and healthcare professional education campaign.

We do not support, however, some of the committee's recommendations. By a vote of 13-9, the advisory committee recommended to FDA that the active ingredients used to treat symptoms of the common cold should no longer be available for use in children under six years of age. This recommendation was limited to symptoms of the common cold and did not include, for example, expectorants for cough or antihistamines for allergy.

This split vote, which FDA referred to as only a "slight majority" and "less definitive" than other committee recommendations, is the one which is most troubling.

For generations, parents have relied upon these medications when caring for their children's cough and cold symptoms, and we are committed to ensuring these families have continued access to these important medications. Because of this strong commitment, CHPA and our members will support additional scientific research to reconfirm the appropriate dosing for children two-years-old and older, and will support ongoing safety research.

Importantly, we also will launch a major, multi-year educational campaign to help parents and healthcare providers better understand how to safely dose children with OTC cough and cold medicines, and equally as important, when **not** to use them. A key message in our outreach will be the importance of consumer-healthcare professional dialog. The American Academy of Family Physicians and the American Pharmacists Association already have signed on to work with us on this important project, and we anticipate welcoming additional partners to the effort as we move forward.

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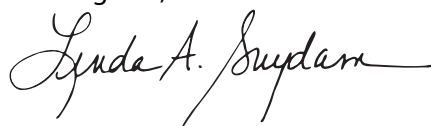
In the meantime, the following key points may be helpful to you as you field consumer questions:

1. **Oral OTC cough and cold medicines for children are—and always have been—safe when used as directed.** Years of poison control safety data indicate no significant safety concerns for these medicines when used as directed. While the majority of parents and other caregivers use these medicines correctly, there are very rare reports of serious adverse events from overdose due to the misuse of these medicines. Our voluntary withdrawal of these infant medicines was conducted due to concerns over this misuse, not safety with the products themselves. For children over the age of two, the data indicate problems with accidental ingestion from medicines that are not properly stored out of the reach of children.
2. **FDA has taken no official action on these recommendations. Oral OTC cough and cold medicines for children over the age of two will remain on the market** while FDA goes through the lengthy process of considering the committee's recommendations and the data presented during the meeting. Parents rely on these medications to help alleviate children's cough and cold symptoms. We will work to ensure that parents have continued access to them and the information needed to safely administer these medicines.
3. **The leading makers of medicines have created an informational web site for parents called www.OTCsafety.org.** The site contains facts about the current environment for OTC cough and cold medicines and tips for safely dosing children. The site also will be the home of our educational campaign, along with other vehicles for disseminating this important information.

We know consumers may have questions regarding OTC medications for children as we enter the cough and cold season. Please understand we are doing our best to make sure they have the necessary information in order to make informed decisions about how to safely and effectively care for their children. To that end, we are developing a handout that will assist you in your consumer interactions. We will distribute this to you via e-mail as soon as it is available.

If you have any questions, concerns, or specific needs, please do not hesitate to contact me. And please visit www.OTCsafety.org for more information.

Kind regards,

A handwritten signature in cursive script that reads "Linda A. Suydam". The signature is written in black ink and is positioned below the text "Kind regards,".

Linda A. Suydam, D.P.A.
President