October 23, 2007

Linda A. Suydam, D.P.A.
President
Consumer Healthcare Products Association
900 19th Street NW, Suite 700
Washington, DC 20006

Dear Dr. Suydam,

As you know, on October 19, 2007, the Nonprescription Drugs Advisory Committee of the Food and Drug Administration (FDA) and the Pediatric Advisory Committee recommended that over-the-counter cough and cold medications for children under the age of six years should be removed from the market. The panel found that while there was no evidence that these products were effective in children under the age of six, there was evidence that some children had been harmed, and have even died, from taking these products.

This recommendation comes on the heels of the voluntary withdrawal by Consumer Healthcare Products Association (CHPA) of products marketed for use in children under two. CHPA's action was taken in accordance with the association's own conclusions regarding the lack of safety and effectiveness data on these products. I commend CHPA for that decision.

However, I was disappointed to read reports that CHPA intends to "fight the new recommendations" of the advisory panel.[1] I had hoped that CHPA would show the same leadership and interest in protecting the health and well-being of children under the age of six as it showed toward children under two by similarly withdrawing those products.

As you know, the panel concluded by an overwhelming margin that cough and cold medications had not been proven to be effective in children under age six and that there needed to be additional studies conducted. Given that conclusion, and the fact that unproven cough and cold products could also expose children to injury and even death, there is no justification for the continued marketing of those products for children under six. Drug companies should not be

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[1] Gardiner Harris, *F.D.A. Panel Urges Ban on Medicine for Child Colds*, New York Times (Oct. 20, 2007) (online at http://www.nytimes.com/2007/10/20/washington/20fda.html?ref=health).

permitted to market products whose benefits have not been proven to outweigh their risks to either children or to adults.

I sincerely hope that CHPA will take prompt action to ensure that the advisory committee's recommendations are promptly carried out by your member companies. There is no need for CHPA to wait for FDA to complete what will surely be a lengthy rule-making process to change the monograph for these products. American children cannot afford that kind of delay.

Sincerely,

Henry A. Waxman
Chairman

cc: Tom Davis
Ranking Minority Member