

American Academy of Pediatrics



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American Academy of Pediatrics
District IX
Position statement

Presented by Hilary A. Perr, M.D. 6087 '99 AUG 16 AIO:32
FDA Stakeholder Meeting
Regulating Dietary Supplements Under the
Dietary Supplement Health and Education Act

7/20/99

Docket No. 99N-1174

I represent the 5500 members of the **American Academy of Pediatrics in California**. We seek to educate the public, the food industry, and government regulatory agencies regarding the **special vulnerabilities of children** to ingested products, such as dietary supplements.

As faculty at the University of California in San Francisco, I see patients as a pediatric gastroenterologist, hepatologist, and nutritionist. My laboratory research focuses on the regulation of intestinal cell behaviors fundamental to normal development, growth, inflammation, wound healing and cancer. Therefore, I possess **substantial unique and relevant expertise as a scientist and clinician**. I am not a paid lobbyist, but, like my many colleagues, am motivated solely by the unfulfilled and urgent need to protect children and promote their health in a world of rapidly changing foods and treatment options with unknown ramifications.

Children are especially vulnerable to novel, impure, or improperly processed "dietary substances" by virtue of an **immature and evolving physiology quite different from adults**. Children frequently differ in the absorption, breakdown, processing, elimination, tissue storage and distribution of ingested substances whether labeled "dietary supplement" or "drug". Further, immunologic protection is less developed, allergic tendencies are greater. A breastfed baby exposed to dietary supplements inadvertently appearing in breast milk may manifest allergy as vomiting, hives, diarrhea, dehydration, respiratory compromise or death. Therefore, a dose or preparation of a dietary supplement that is tolerated or even beneficial to some adult, may be toxic or lethal to a child. Another difficulty arises from the fact that children eat differently than adults, and their food choices may change the potency, processing or side effects of the supplement. **Therefore, for many dietary supplements, the context of age, stage of development, and eating habits is key to determining potential harm, benefit, or safety.**

Because children also have different nutritional needs at different times of life... such as fetal development, infancy or puberty... **Inappropriate consumption of a "dietary supplement", which may replace needed nutrients, has lasting consequences.** Maternal consumption of such products may result in impaired fetal growth or birth defects. A recent disturbing trend in clinical pediatric practice is the phenomenon of children from privileged families with stunted growth and delayed development. These children are essentially starving despite their parent's deliberate efforts to offer only what they perceive as pristine and nutritionally superior foods.

And how could this happen? What are they eating and why? Where are families getting their information? Part of the answer is to be found in your neighborhood grocery.

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Beyond the plethora of individual supplements is the **questionable utility and safety of supplement-enhanced foods, many of which seem targeted to kids**. There are corn chips with kava-kava, a sedating substance that the National Nutritional Foods Association warns against taking if you are under 18, pregnant or nursing, planning to drive or operate heavy machinery. Nowhere does this information appear on the label. There are fruit juices with ginseng, dieters teas with ephedra, "Brain Gum" with phosphatidyl serine. Roberts American Gourmet markets a "memory snack" with ginko biloba, and another snack called "Power Puffs" containing ginseng and bee pollen has the words "ENERGY" emblazoned on the packaging. **Fortified junk foods are still junk. They cannot substitute for food.**

Are these products safe and rational for children? How would we know?

Many labels fail to document the dose, source, species, expiration date or form of the herb. Most packages do not provide 800 numbers for reporting of adverse events. But a clue that such substances should be taken in a specific manner comes from their use in the countries where they originate. In Germany, St. John's Wort is manufactured as a standardized tablet for the treatment of a depressive disorder under the direction of a physician, not as soup for mass consumption. In China, herbal products are procured under the supervision of practitioners experienced in their use, not as a crunchy snack. Does ginko biloba enhance memory? Yes, in individuals already suffering from memory impairment. So why are these products being marketed as snacks and gums to children?

The short term consequences span allergic reaction to drug interactions to death. After drinking liquid echinacea, one woman experienced burning of the mouth and throat, tightening of the chest, diarrhea and hives. Another individual almost died in an effort to wean off the anti-anxiety drug Xanax by taking kava-kava simultaneously. The latest issue of The Berkeley Wellness Letter advises stopping herbal supplements such as St. John's Wort, ginko biloba, and ginseng three weeks prior to surgical procedures to prevent untoward effects on heart rate and blood pressure... information absent from product labels. At least 120 cases of adverse effects including seizures and coma and 3 death have been reported in individuals taking gamma butyrolactone in an effort to improve sleep and athletic performance. Three children died taking ephedra products... a substance advertised to increase energy or facilitate weight loss. Pyrrolizidines contained in many herbal products have been documented to cause hepatic veno-occlusive disease and fetal death.

Long-term consequences are not even known, but rest assured that **children are the ones who are at risk to sustain repeated dosing exposure for the longest duration.**

The American Academy of Pediatrics acknowledges that many supplements and herbs may be beneficial. **We are advocating to insure that use in children is safe, responsible, and appropriate.**

To this end, we strongly urge:

- 1. Labeling the name, dose, preparation, expiration of the supplement**
- 2. Label to state not for pregnant or lactating women or children less than 6 years of age**
- 3. Manufacturer name, address, and phone number to be listed on label**
- 4. Label to include 800 number for adverse reporting, preferably the FDA 800 number, 800-322-4010**
- 5. Dietary supplements MUST BE provided as a SEPARATE supplement and not added to food products**
- 6. Assurance of purity and adherence to GMPs**
- 7. Ideally, product standardization**

8. **Label warning of known adverse reactions to product and potential drug interactions**
9. **Warning to stop supplements 3 weeks prior to surgical procedures**
10. **The label should state that doctors and pharmacists should know of supplement use.**
11. **Until such time as the FDA or manufacturer assures pre-market safety for children, The American Academy of Pediatrics (District IX) cannot recommend such supplement use by anyone less than 18 years old.**
12. **Immediate removal of gamma butyrolactone, its precursors, DHEA and ephedra from the supplement and food market. These are drugs. No further deaths are necessary.**
13. **A media campaign to educate the public regarding the untested safety, utility or content of many products now available.**
14. **Ideally, dietary supplements should be efficacious and all claims of activity and safety should be substantiated by the manufacturer.**
15. **Enforce DSHEA.**
16. **The FDA should allocate research funds to studies addressing the following issues in children: long-term and short-term potential benefits and adverse effects in fetuses, children, and adolescents; age-related pharmacokinetics and metabolism; effects on dietary intake and eating habits; effects on absorption of needed nutrients; effects on subsequent growth and development, and carcinogenic potential.**

The American Academy of Pediatrics in California appreciates the opportunity to participate in this hearing. We offer our expertise to the food industry and the FDA to ensure the common goal of public safety with special emphasis on children's health.

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