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Doublespeak: Clinton administration announces new testing requirements on medicine for children but supports legislation allowing "off-label" drug promotion

President Clinton's announcement today to require drug makers to test whether their medicines are safe and effective for children does nothing to protect children from the widespread dangers of off-label prescriptions, said Public Citizen's Health Research Group.

The group released a study showing drugs frequently prescribed for children have not been adequately tested, and warned that legislation on the Food and Drug Administration pending in the Senate will substantially increase the threat of "off-label" use -- when a drug is prescribed in a way not approved by the FDA.

"In 1994, over 3 million prescriptions for five drugs were prescribed to children without adequate studies being conducted on their safety and effectiveness. These include drugs for treating asthma, depression and nausea," said Dr. Sidney Wolfe, Director of Public Citizen's Health Research Group. Under an amendment to Senator James Jeffords' (R-Vt) anti-FDA Bill (S. 830), drug companies will be allowed to promote off-label uses of their products by sending articles from medical journals to doctors. "Such wholesale promotion of off-label usage exposes children to potentially dangerous drugs. Today's announcement ignores that danger," said Wolfe.

Although drugs can currently be prescribed for off-label use, companies cannot promote their products for off-label use directly to doctors. "This provision undercuts the basic premise of the nation's drug approval process that products must be proven safe and effective for a particular use prior to marketing," said leading pediatrician and President of the American Foundation for AIDS Research (AmFAR) Dr Arthur J. Ammann.

The study found that for the five drugs listed below there are articles published in well-known medical journals that describe the use of these drugs in children despite there being no adequate tests of the drugs' safety and effectiveness for children.

"Under the new legislation, drug companies could get approval for a drug for some narrow use and then heavily promote it for much broader uses in children such as those mentioned below," said Wolfe.

Ralph Nader, Founder

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DRUGS AND NUMBER OF PRESCRIPTIONS IN WHICH NO INFORMATION WAS AVAILABLE IN THE PROFESSIONAL PRODUCT INFORMATION FOR THE AGE GROUP BEING TREATED. DATA FROM 1994. ¹			
Drug (Purpose)	Brand Name	Total Prescriptions	Age Group Treated
albuterol (asthma)	Proventil or Ventolin Inhalation Solution	1,626,000	under 12
cromolyn sodium (asthma)	Intal Nebulizer Solution	109,000	under 2
cromolyn sodium	Intal Inhalation Aerosol	399,000	under 5
fluoxetine (anti-depression)	Prozac	349,000	under 16
fluoxetine	Prozac	3,000	under 1
paroxetine (nausea and vomiting)	Paxil	248,000	under 16
promethazine	Phenergan Syrup	663,000	under 2
TOTAL		3,397,000	

¹ Data from IMS America, Ltd.

Albuterol (Proventil, Ventolin) Inhalation Solution is approved by the FDA for the treatment of asthma.

Pediatric Use: Safety and effectiveness of albuterol inhalation solution and solution for inhalation in children below the age of 12 years have not been established. (Proventil Inhalation Solution professional product information Physicians' Desk Reference 51st edition, 1997, page 2527)

Cromolyn sodium (Intal) Nebulizer Solution is approved by the FDA to prevent asthma attacks.

Pediatric Use: Safety and effectiveness in children below the age of 2 years have not been established. (Intal Nebulizer Solution professional product information Physicians' Desk Reference 51st edition, 1997, page 2186)

Cromolyn sodium (Intal) inhalation aerosol is approved by the FDA to prevent asthma attacks.

Pediatric Use: Safety and effectiveness in pediatric patients below the age of 5 years have not been established. For young pediatric patients unable to utilize the Inhaler, Intal Nebulizer Solution is recommended. Because of the possibility that adverse effects of this drug could become apparent only after many years, a benefit/risk consideration of the long-term use Intal Inhaler is particularly important in pediatric patients. (Intal Inhalation Aerosol professional product information Physicians' Desk Reference 51st edition, 1997, page 2185)

Fluoxetine (Prozac) is approved by the FDA for the treatment of major depressive episode, obsessive-compulsive disorder and bulimia nervosa.

Usage in Children: Safety and effectiveness in children have not been established. (Prozac professional product information Physicians' Desk Reference 51st edition, 1997, page 935)

Paroxetine (Paxil) is approved by the FDA for major depressive episode, obsessive compulsive disorder and panic disorder.

Pediatric Use: Safety and effectiveness in the pediatric population have not been established. (Paxil professional product information Physicians' Desk Reference 51st edition, 1997, page 2681)

Promethazine (Phenergan) Syrup is approved by the FDA for allergy, motion sickness, nausea and vomiting, sedation and pre- and postoperative use.

Pediatric Use: This product should not be used in children under 2 years of age because safety for such use has not been established.