

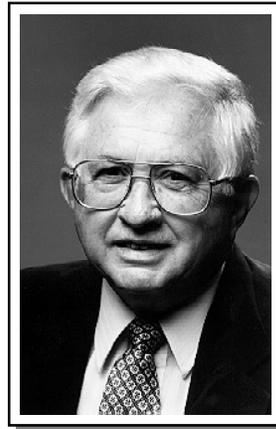
Assemblyman Kelly calls Kids Fluoride Supplements “Fluorosis Risk”

Asks FDA to take action

October 27, 2000

Assemblyman John V. Kelly (R-36) today petitioned FDA Commissioner Jane Henney to take regulatory action against children's fluoride supplements. The products, drops and tablets, are prescribed for children living in areas with non-fluoridated water to reduce dental caries. Kelly cited recent studies including the cover story of the July issue of The Journal of the American Dental Association which demonstrated that fluoride works topically not internally. Kelly's petition included two recent studies* reviewing all the data on children's supplements. It was clearly documented that children's fluoride supplements do not prevent dental caries but do contribute to dental fluorosis, which can range from mild white spots to severe mottling of the teeth. The products which are not FDA approved are on the market

proved to be effective", Kelly said. "They then have to spend millions more to repair the fluorosis caused by these products. Thousands



of pediatricians, dentists and parents are under the false but logical impression that these prescription products are approved by the FDA as being safe and effective. Kelly said, "children today are at risk of overexposure from multiple fluoride

sources in their dental products, diet and environment". The Physicians Desk Reference Manual lists many possible side

"in the case of an unapproved drug for caries prevention, there can be no medical or legal justification for putting any of the population at risk, particularly children and especially infants."

effects of fluoride supplements. An unapproved drug can be no medical justification for any subset of particularly children. Kelly's letter to FDA Commissioner Henney wrote "the products have not had clinical trials and cannot demonstrate the safety

and effectiveness and submit them for FDA approval. They have not done so. Fifty years is a long time - even for the FDA".

chemical sodium fluoride in existence prior to 1938. According to Kelly, the only pre-1938 use of sodium fluoride his office has been able to identify is as an insecticide and rodenticide. FDA classifies children's fluoride supplements as "unapproved new drugs". "Parents are spending millions of dollars annually on products that have not been

*Community Dentistry and Oral Epidemiology, Ismail,1999, Volume 27, pages 48-56, "Fluoride Supplements and Fluorosis, A Meta-Analysis." Journal of

Public Health Dentistry, Burt, Volume 59,
Number 4, Fall 1999, pages 269-274, "The
Case for Eliminating the Use of Dietary
Fluoride Supplements for Young Children.