



NEW JERSEY STATE LEGISLATURE

ASSEMBLYMAN
JOHN V. KELLY
242 WASHINGTON AVENUE
(USE GRANT AVE. ENTRANCE)
NUTLEY, NJ 07110
(201) 667-6123
FAX (201) 667-9614

LEGISLATIVE OFFICES
36TH DISTRICT
BERGEN-ESSEX-PASSAIC COUNTIES

ASSEMBLYMAN
PAUL DIGAETANO
71 UNION AVENUE
RUTHERFORD, NJ 07070
(201) 933-0533
FAX (201) 933-4044

June 3, 1993

Dr. David Kessler, M.D., Commissioner
United States Food and Drug Administration
Rockville, Maryland 20857

Dear Commissioner Kessler:

My office has been reviewing the issue of fluoride supplements for children since last August. My concern originated from a report that the New Jersey Department of Health had conducted a study and found the incidence of osteosarcoma to be significantly higher in fluoridated communities versus non-fluoridated ones. The New Jersey findings, released in November, supported similar findings, by larger national studies and by the National Toxicology Program.

The Food and Drug Administration Office of Prescription Drug Compliance has confirmed, to my surprise, that there are no studies to demonstrate either the safety or effectiveness of these drugs, which FDA classifies as unapproved new drugs.

The presence of these drugs on the market at this time appears to be contrary to the 1962 amendment to the Food, Drug, and Cosmetic Act, which requires prescription drug applications to provide evidence of effectiveness and the 1938 amendment requiring evidence of safety. There does not appear to be any scientific or legal reason for these products to be on the market at this time.

With the mounting volume of evidence suggesting fluoride's harmful effects it is irresponsible to permit these products to be prescribed to the most vulnerable segment of our population--children.

I am therefore requesting that the public interest be served and the products be removed from the market immediately.

Sincerely,

John V. Kelly
Assemblyman 36th District

JVK:knb