STATEMENT OF JOHN V. KELLY

I served as a member of the New Jersey General Assembly for 18 years leaving office on January 7, 2002. For nine of those years I attempted unsuccessfully to have the U.S. Food and Drug Administration remove unapproved children's prescription fluoride products from the market. These products, drops for infants and tablets for older children have been on the market since the 1950's. I became involved with the issue in 1992 when I was made aware that the New Jersey Department of Health had conducted an epidemiology study comparing the rates of osteosarcoma (bone cancer) in New Jersey's water fluoridated communities to the rates in non-fluoridated communities. Our State Health Department undertook the study because of their concern over other studies which had suggested a relationship between fluoride and osteosarcoma. One national study (Hoover) had found a higher rate of osteosarcoma in young males under 20 living in fluoridat3ed communities. Another study conducted by the National Toxicology Program found a high rate of osteosarcoma in male rats given sodium fluoride. The purpose of the New Jersey study was to determine if there was evidence of a higher rate of osteosarcoma in young men under twenty living in our fluoridated communities. The New Jersey study found that the rate of osteosarcoma in young males under twenty was seven times higher in our fluoridated communities compared to our non-fluoridated communities.

Approximately 17% of New Jersey's water supply is artificially fluoridated. As a result of this relatively low access to fluoride via the water supply a great emphasis is placed in our state in prescribing fluoride drops to infants and tablets to older children living in the remaining 83% of our state which is non fluoridated. Dental authorities and the drug manufacturers allege that use of the products reduce the incidence of tooth decay and [are] safe. In response to the disturbing findings of the New Jersey Health Department study I felt it was prudent to obtain the studies supporting the claims of safety and effectiveness for these prescription fluoride products. I was aware that both federal and state law required these types of studies for approval by the appropriate regulatory agency prior to the marketing of products for which health claims were made.

I initially contacted the American Dental Association, the American Academy of Pediatrics and the American Academy of Dental Pediatrics. These organizations recommended these products and had established the dosage schedules for these products. Each organization advised me that they would provide me with the safety and effectiveness studies on which their recommendations were based. In each case they failed to do so. They [reported] after checking their records that they were not in possession of studies. They advised me that the studies were available from the National Institute of Dental Research. The NIDR advised me that they most certainly had the studies and that they would be more than happy to send them to me within a few days. Six weeks later I contacted NIDR again to follow up on my request. I was informed that they had found no studies in their files! They advised me to contact the FDA to obtain the studies since "they had approved them".

Upon contacting the FDA by phone to obtain the studies I was advised that I needed to file a Freedom of Information Act request which I did on August 26, 1992. [Since] months later I was stunned when I was informed by the FDA that they had no such studies and that the products in question which had been prescribed to millions of infants and children since the 1950's were not approved by the FDA.

On June 3 1993 I petitioned FDA Commissioner David Kessler to remove these unapproved products from the market. On July 18, 1994 Dr. Janet Woodcock,

Director of the FDA Center for Drug Evaluation and Research responded. Dr. Woodcock stated that the basis for the marketing of these fluoride products were the findings of a 1975 FDA Dental Drug Advisory Committee. She claimed that the Committee found "that there is a medical rationale for appropriate vitamin/fluoride preparations". Through my prior FOIA request I had already obtained the minutes of the Dental Drug Committee meeting. The minutes report "there is no evidence that the effect of fluoride is enhanced by combination with vitamins. Therefore there is no satisfactory rationale for the use of these combinations for reducing the incidence of dental caries". I was struck by the fact that this committee issued no written report on their findings and that their minutes do not provide any scientific references to support any of their conclusions. The Committee did vote unanimously to publish their findings in the Federal Register. However, no Federal Register notice was ever published.

The FDA has been aware that systemic fluoride products have been prescribed in violation of federal law since at least 1966. On October 16, 1966 FDA Commissioner Goddard after a review of the literature and consulting leading dental authorities published a Federal Register notice declaring pre-natal prescription fluoride products to be violative products and directed that they be removed from the market until manufacturers could obtain the required NDA's. These 1966 pre-natal products were identical to the products being prescribed to children at the time. Although the mechanism for alleged effectiveness would be different the need to demonstrate safety would be the same. The FDA never took action on these prenatal products. No NDA's were ever filed by manufacturers. The products remain on the market to this day.

In 1975 the FDA advised the manufacturer of Enziflur, a children's combination fluoride/vitamin product to withdraw the NDA which they had filed for their product because their data did not demonstrate that the fluoride's effectiveness was enhanced by being combined with vitamins. At the time the FDA also advised 35 companies that manufactured similar products to remove their products from the market. Supposedly the FDA action was based on the manufacturers inability to substantiate a claim that the fluoride's effectiveness was enhanced by the vitamins which FDA would not tolerate. However, the FDA was quite willing to overlook the fact that the same products were not FDA approved and had not demonstrated safety or effectiveness.

Over the past 8 years in addition to Dr. Woodcock's claim that these products are marketed based on the FDA's 1975 Dental Drug Committee recommendations the FDA has provided me with various excuses for not taking regulatory action against these unapproved products. These include a.) the agency is seriously backlogged, b.) the products generate few complaints and are therefore a low priority, c.) that the products are covered by an OTC Federal Register notice, d.) that the products are part of an FDA (DESI) review, e.) that the products were on the market prior to 1938 and therefore do not require approved NDA's.

I recognize that the FDA has approved NDA's for OTC topical fluoride products such as toothpaste. However the OTC data for topical fluoride cannot be applied to systemic fluoride products which are prescription drugs and have a completely different mechanism for effectiveness and being ingested require thorough toxicological evaluation with the appropriate risk assessment. The Durham-Humphrey Amendment of 1951 requires a prescription for a drug which cannot be safely used without medical supervision. Sodium fluoride is highly toxic. It has a rating of 4 on the toxicity scale, being more toxic than lead but less toxic than arsenic 5.

The FDA has no record of any of these products being on the market prior to 1938 as they incorrectly they claim. The FDA can only demonstrate that sodium fluoride powder/crystal was available in bulk form prior to 1938. The FDA is aware that the primary use of sodium fluoride prior to 1938 was as a rodenticide and insecticide and that it was not used to reduce dental caries (as reported in) the Merck Index at that time. It is not until 1960 that the Merck Index lists sodium fluoride for reducing dental caries for the first time.

The FDA not only has a long history of ignoring the violative status of these products, but of also misrepresenting the status of these products to both the public and [elected officials]. In January of 1993 the FDA rejected a petition filed by an individual concerned about possible adverse side effects of the products. In denying the petition the FDA never made the petitioner aware that the product in question was not even FDA approved. In fact, in the response FDA Associate Commissioner gave the petitioner the [impression the] product was approved and that to remove the product would deny the public the "benefit" of the product. The Associate Commissioner also falsely implied that the FDA possessed animal toxicity studies supporting the safety of the products.

The FDA has also misrepresented the status of these products to Congress. On [May 8, 2000], Congressman Ken Calvert, Chairman of [the Subcommittee on Energy and Environment]wrote to the Commissioner of the FDA and asked whether or not the FDA had ever approved or denied an NDA for any systemic fluoride product for reducing dental caries. Associate Commissioner [Melinda K.] Plaisier responded that the FDA had never approved or rejected any NDA for any such products. No mention was made by the Associate Commissioner of the FDA action regarding the 1966 pre-natal products or the 1975 fluoride/vitamin products. In addition the Associate Commissioner also reported to the Congressman that the products in question were part of an ongoing FDA review known as DESI which was not yet completed. The FDA had made it clear to my office over the years that these fluoride products are not part of the DESI review. The DESI review concerns products which were approved by the FDA after the manufacturer submitted an NDA demonstrating safety. These DESI products were approved between 1938 and 1962. In 1962 the Food Drug and Cosmetic Act was amended to require additional studies demonstrating the effectiveness of drugs, in addition to the safety studies. The FDA has never approved any NDA for these products. The manufacturers have never demonstrated either safety or effectiveness to the agency. And as far as we can ascertain with the exception of the Enziflur NDA there is no record of any manufacturer even approaching the FDA. Congressman Calvert also questioned FDA as whether they considered dental fluorosis to be a cosmetic effect or an adverse health effect. Strangely, the FDA passed the buck to the Surgeon General and reported to the Congressman that the Surgeon General considered dental fluorosis to be a cosmetic effect. The FDA ignored the fact that the agency reports that "fluorosis promotes plaque" [A]nd that dental fluorosis is indicative of enzyme poisoning. The FDA seemed to have forgotten that it is the FDA which advises the Surgeon General and the CDC about the safety and effectiveness of drugs and their side effects and not the other way around. The FDA is the only federal agency with the authority to make these determinations.

Both the Surgeon General and CDC have ignored my inquiries as to the statutory and regulatory basis for them promoting the use of these unapproved drugs recommended on their website.

The FDA has been aware for at least the past 35 years that these unapproved products were being prescribed to millions of infants and children. They have been fully aware of the potential side effects of these products as listed in numerous publications such as the NTP Toxicological Fluoride Profile, the Physicians Desk Reference, Clinical Toxicology of Commercial Products and the Merck Index. The FDA has allowed these children [and their] to endure adverse health effects and has allowed their parents to be defrauded out of millions of dollars for products which the FDA does not recognize as either safe or effective. By ignoring the law for 35 years the FDA has made it clear that their concern is well being of industry not the public.

COST OF FLUOROSIS

The FDA Center for Drug Evaluation and Research (CDER) has pointed out "various kinds of toxicity have been attributed to ingestion of fluoride, including dental fluorosis, bone fracture, reproductive, renal, gastrointestinal and immunological toxicities; genotoxicity and carcinogenicity". The FDA is in the process of evaluating data on fluoride effect on bone strength. The FDA has placed the cart in front of the horse by allowing the marketing of these products while health concerns remain unaddressed.

The manufacturers and doctors who promote children's prescription fluoride drops and tablets misrepresent the products as being dietary supplements. As a result the products are freely prescribed with the only consideration being the fluoride level of a communities' water supply. The reality is that fluoride is not an essential nutrient. It is a highly toxic product which is claimed by proponents to reduce dental caries. Its toxicity and the medical claim are the basis for the prescription requirement and its FDA status. Dietary supplements are not prescription products because dietary supplements are not prescription drugs. Children's fluoride drops and tablets are prescription products because they are prescription drugs. It is difficult to believe that the FDA would allow drugs to be prescribed not an evaluation of the patient but rather on an evaluation of the patient's water supply.

Over the years the FDA has removed a number of children's fluoride products from the market. While the FDA has taken action against Enziflur and other manufacturers in cases where products were found to have sub potency or preservative deficiencies, the FDA always ignored the fact that these same products were not FDA approved as being safe or effective.

The FDA has allowed parents to be defrauded out of millions of dollars for products for which are not recognized by the FDA as being safe or effective. The FDA has allowed parents to endure the medical cost of these adverse effects such as dental fluorosis which the CDC says is...epidemic...rampant???

Hand written notes

Page 1:
The FDA, the only Federal Agency, with the authority to evaluate and approve products for which health claims are made has been fully aware for at least 35 years. DOES NOT RECOGNIZE