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ARRI Alert:

Disaster looms! FDA anti-nutrient rules near

Unless Congress acts in the next few weeks to stop the FDA, new regulations created by the FDA will go into effect which will prevent you from buying significant amounts of vitamins, minerals, amino acids, and other nutritional supplements. The new regulations may also make it a criminal offense, punishable by huge fines and long prison sentences, for the ARRI, or any other publication, to tell you the positive results of research on any nutritional supplement, unless prior approval was granted by the FDA. It will not matter if the statement is true (e.g., that there are now 17 published studies showing that vitamin B6 and magnesium is helpful in 47% of autistic children). It will matter only that the FDA has not approved a "health claim." Making a "health claim" without prior FDA approval will be a crime.

Forget about getting "prior approval" from the FDA, if the new regulations go into effect. The FDA has a 40-year history of bitterly opposing the public's right to buy vitamins and other supplements. The only "health claim" the FDA has ever approved for a nutrient in many decades is the use of calcium to prevent osteoporosis.

Although most of the research in autism has been done on vitamin B6, there are also other natural substances, found in food—all very safe—which have been reported to bring about significant improvement in many autistic children. These include DMG, folic acid, vitamin C, coenzyme Q10, and tryptophan. An Israeli researcher is looking at another nutrient, carnitine, that may help autism. Further research on the value of these supplements in autism is desperately needed. There is little chance that such research will take place under FDA restrictions.

On page 2 of this issue of ARRI, we report a study at Yale showing that reducing the tryptophan intake of an autistic woman made her symptoms worsen. In her new book, *News From the Border*, Jane McDonnel tells how giving tryptophan to her autistic son brought on improvement . . . until the FDA took tryptophan off the market in 1988 because one batch, from one Japanese company, contained a contaminant. After contaminated Tylenol, Sudafed, Perrier and other products were removed from the shelves, you could then immediately buy the products again. Not so with tryptophan, which is very safe—much safer than Tylenol or Sudafed. The FDA will not let you buy it.

Why is the FDA so hostile to nutritional supplements? Here is a direct quotation from the FDA's Final Report of its Dietary Supplements Task Force (May 1992): "The Task Force considered various issues...including...what steps are necessary to ensure that the existence of dietary supplements on the market does not act as a disincentive for drug development."

Incredible! The FDA ***admits*** it is prejudiced against nutrients because it wants us to buy drugs! (A family may spend $10-$15 a month on B6 and magnesium for an autistic child, as against $200 a month for drugs.)

Please write and call your Senators and Representatives (especially your Representatives) today to ask that they co-sponsor the Hatch Bill (S 784) in the Senate and the Richardson Bill (HR 1709) in the House. These bills are needed to keep the FDA from grossly interfering with our right to buy supplements.

Call 202-224-3121 and ask to be switched to the office of your Senator or Representative. Ask to speak with the person most concerned with health matters, and tell him or her how strongly you feel that Congress should prevent the FDA from interfering with our right to purchase nutrients. Then write, call or visit the local office. Visits to the local office are far more effective than calls or letters to the Washington offices.

Mark October 19

Mark Tuesday, October 19 on your calendar. PBS will broadcast as one-hour documentary on Facilitated Communication, on the *Frontline* program (check local station for time). The program took almost one year to produce, and was completed with the cooperation of Rosemary Crossley in Australia and Douglas Biklen in the U.S. It also includes interviews with researchers who question the validity of F/C.

Clomipramine: positive findings, cautions

A new study adds to encouraging reports that clomipramine, a drug used to treat obsessive-compulsive behaviors, also may be effective in reducing autistic symptoms.

James Brasic and colleagues tested clomipramine on five autistic boys between the ages of seven and 12, beginning with 25 mg per day and increasing to 200 mg daily. The researchers report that the stereotyped movements of four of the subjects dropped markedly, while three subjects exhibited significantly fewer compulsive behaviors. They conclude that "clomipramine is effective for the reduction of adventitious movements, including stereotypies, and compulsions in prepubertal autistic boys."

A 1992 study by Christopher McDougle et al. reported "significant improvement in social relatedness, obsessive-compulsive symptoms, and aggressive and impulsive behavior" in four of five autistic young adults treated with clomipramine. Earlier, Charles Gordon and colleagues found that clomipramine was effective in reducing repetitive and compulsive behaviors, lowering anger levels, and normalizing speech patterns.

Clompiramine (also known by its most common brand name, Anafranil) appears to work by inhibiting the re-uptake of the brain messenger chemical serotonin. Higher than normal levels of serotonin occur in approximately one third of autistic children.

The most common serious side effect of the drug reported to date is seizures, and the *Physician's Desk Reference* (PDR) recommends that "caution should be used in administering Anafranil to patients with a history of seizures or other predisposing factors" including concomitant use with other drugs that lower the seizure threshold. The PDR adds that "rare reports of fatalities" have been recorded in individuals using clomipramine, but that it is not clear whether these deaths were due to clompramine or other medications.

ARI has received several anecdotal

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