

EDITOR'S NOTEBOOK/Bernard Rimland, Ph.D.

FDA defeated!**New hope for safe and effective treatments for autism**

After two long years of struggle, the citizenry has won its war against that most sinister bureaucracy, the Food and Drug Administration. The victory will confer profound, vitally important benefits to all Americans, and especially to autistic children and their families.

On October 8th, at 12:27 a.m., Congress passed a bill sponsored by Senator Orrin Hatch (R-UT) and Bill Richardson (D-NM) which prevents the FDA from following through on its plan to classify vitamins and other nutritional supplements as drugs, if they are shown to improve health or a condition such as autism. Since there have been only one or two authenticated deaths due to vitamin overdose in all of human history (resulting from taking thousands of times the RDA of vitamin A) the FDA's plan to keep vitamins out of the hands of citizens was totally unjustified. Prescription drugs—the FDA's prime responsibility—kill an estimated 150,000 Americans each year, and cause many millions of cases of severe sickness, as "side effects." The FDA's attacks against supplements, which improve rather than impair well-being, are proof of the corruptness of that agency. (If you think these words are intemperate, send an SASE marked "FDA testimony.")

Public outrage against the FDA resulted in Congressional offices being hit with a tidal wave of protests from angry constituents (many of them readers of the ARRI—THANK YOU!) When it came time to vote, even the most ardent supporters of FDA tyranny, Representative Henry Waxman and John Dingell, and Senator Edward Kennedy, were afraid to raise their voices against the public outcry, and the bill passed both houses unopposed.

History tells us that we must be vigilant. Unless the administration rids the FDA of the corrupt, incompetent, and backward officials who now dominate that agency, we will, before long, be confronted with further transgressions. In the meantime there are several ways in which we can take advantage of this hard-won victory over the FDA:

1. **Release tryptophan.** Tryptophan is an amino acid that has been used freely, without harm, world-wide for a quarter of a century. The body uses tryptophan to produce the important neurotransmitter serotonin. Many parents and physicians have found tryptophan to be beneficial in autism (ARRI 7/3). In 1988, when one of the five Japanese companies importing tryptophan into the U.S. changed its manufacturing process, a contaminated batch of tryptophan was produced which caused a number of deaths in the U.S. and elsewhere. The FDA, always looking for an opportunity to remove nutritional supplements from the market, immediately banned the sale of tryptophan—except for use in baby formulas and in formulas for patients on IV feeding. Now, six years later, you still cannot buy tryptophan, nor can physicians prescribe it.

When contaminated Tylenol, Sudafed and Perrier were removed from the market, the uncontaminated products were immediately put back on the shelves. Even uncontaminated Tylenol and Sudafed will kill you if you overdose. Not so with tryptophan. But you can buy these drugs freely, while the nutrient tryptophan cannot be bought. Why?

What can you do? Call your representatives and senators. Tell them that you are very pleased the Congress has reined in the FDA on the vitamin issue, but now the FDA must be required to lift the ban on

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tryptophan. If the FDA really believes that tryptophan presents a danger, why is it permitted in baby formulas and IV formulas? Congress must insist that the FDA yield on this issue.

2. **Nutrient therapy.** Now that, at least for the time being, the FDA cannot prohibit citizens from buying vitamins and other nutritional supplements, parents are free to try to help their children—and themselves—with supplements:

Vitamin B6 and magnesium. There are now 18 published studies on the use of high dosage vitamin B6, and often magnesium, in the treatment of autism. Every one of these studies has reported positive results. No study has reported significant adverse effects. No drug comes even close to this record of safety and efficacy. The FDA would have taken high dosage B6 off the market. The studies suggest that on average the best results are seen, if the B6/magnesium is going to help, with dosages of 8 mg of B6 and 3 mg of magnesium per pound of body weight. Other nutrients should also be given (see Editor's note).

Dimethylglycine (DMG). DMG is another safe nutrient that has been found helpful in a great many cases of autism. In the 1980s, the FDA tried to take DMG off the market, but a federal judge ruled in favor of the manufacturer, who claimed that DMG was technically a food and not a drug. While there have been no formal published studies of DMG in autism, thousands of parents and some schools and other facilities have tried it, often with very good, even remarkable, results. And, like other foods, it is certainly non-toxic. Dosage: no one knows the appropriate dosage. We have been suggesting one 125 mg tablet or capsule per day for preschool children, and up to eight per day for good-sized adults, but several mothers (both psychiatrists, interest-

ingly enough) have been trying very large amounts of DMG—large by present standards—on their own autistic sons. One is giving her large adult son 20 capsules per day, the other is giving her five-year-old son 16 per day! Blood and urine tests are normal. It seems to me that very few people need such large amounts, but I could easily be wrong. In any event, these cases add to our conviction that DMG is perfectly safe.

Donna Williams, author of *Nobody Nowhere*, and her husband David Venables have found DMG to be very helpful to them. See Letters, this issue.

In about 5% of cases, parents report that the children get a bit hyper on DMG. A knowledgeable physician tells me that giving one or two 0.8 mg tablets of folic acid, available at health food stores, along with each DMG tablet or capsule, may clear up the problem quickly.

Folic acid. Folic acid is another safe B vitamin which may be helpful in some cases of autism. Good results were seen in the small study reported in ARRI 1/4, using about 0.3 mg of folic acid per pound of body weight, but much larger amounts have been used with little or no adverse effects, unless the patient is epileptic. Research on folic acid in autism is urgently needed.

Individuals with the Fragile X defect (some of whom have been diagnosed as autistic) may need extra amounts of folic acid. The vitamin has been tried experimentally, with mixed results (see ARRI 1/1). The dosages range from about 10 mg to 250 mg per day (total dosage, not per pound of body weight). I am aware of perhaps six to eight cases of Fragile X/autism who have responded very well to the vitamin B6/magnesium therapy. I would like to see research in which Fragile X cases were given folic acid *in addition* to vitamin B6 and magnesium.

Vitamin C. In ARRI 6/1 we reported that vitamin C, at about 50 mg per pound of body weight per day, showed benefit to autistic persons. More data are needed. To say that vitamin C is safe is an understatement. A 1992 study at UCLA showed that men taking vitamin C supplements live six years longer, on average, than men who don't.

The foregoing are just some of the safe, proven and yet-to-be-proven non-drug treatments which hold promise for autism. Now that the threat of FDA interference has greatly diminished, I hope to learn more about these and other supplements. My list includes vitamin E, Coenzyme Q10, carnitine, taurine, pycnogenol, ginkgo biloba, and many other substances. **Parents and physicians, if you try these or any other non-drug treatments for autism, let us hear from you.** We will share what we learn with the readers of ARRI.

Editor's note: To receive information on sources and proper use of B6/magnesium and DMG, send SASE marked "B6/Mg/DMG" (55 cents postage).