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

Vitamin B6 vs. fenfluramine: a case study in medical bias

Spend a few minutes, please, studying the accompanying table. Don't just rush by it. Linger. Look at the numbers. Think about them. What do they mean?

The first research study showing that larger than normal amounts of vitamin B6 was helpful to autistic children was published a quarter century ago, in 1965. Since that time 15 additional studies have been published . . . several based on hundreds of autistic individuals. That is, roughly, one research study every two years. Each of these 16 studies reported positive results — that is, each study clearly showed that some segment of the population of autistic persons benefitted to a significant degree by being given greater than normal amounts of B6. In a field where inconsistent, contradictory results are the rule, that is a remarkable record of consistency.

These positive results have been reported by researchers from five countries: England, Germany, the U.S., France, and most recently, Italy. In all of these studies but the first three, magnesium has been used along with the B6, as a result of our 1973 report showing the need to use extra magnesium.

The table shows parallel data for the drug fenfluramine. The first reported use of fenfluramine in autism appeared in the *New England Journal of Medicine*, in 1982. The national news media heralded it as a "breakthrough." Despite the fact that the initial report was not even a study, but rather an open clinical trial on three children; despite the fact that there was substantial evidence that fenfluramine achieved its major effect — lowering serotonin — by poisoning brain cells, and despite the fact that the Physicians Desk Reference (PDR) listed death as one of the known "side effects," researchers and physicians rushed to try fenfluramine on autistic patients.

We were able to find 31 published reports describing the use of fenfluramine with autistic persons published between 1982 and 1990. That is nearly 6 times the publication rate for articles on B6 use in autism. Unlike the consistently positive series of B6 studies, fewer than half of the fenfluramine studies produced encouraging results for any segment of the autistic population, and two-thirds reported significant **adverse** effects in the population studied. In contrast, no significant adverse effects have been reported in any of the 16 B6 studies. (The difference in toxicity is not surprising, since every cell of every living person **needs** B6 and magnesium to stay alive. No cell in anyone's body needs fenfluramine. Nutrients are given to facilitate or enable metabolism — drugs, to interfere with metabolism.)

Approximately 30% of the patients on whom fenfluramine has been tried have reportedly shown some improvement, as compared to about 45% for those given B6 (and magnesium).

My purpose here is not really to single out fenfluramine for criticism — most of the other drugs commonly used to treat autistic children and adults are not much better, nor much worse, in terms of efficacy and safety. Fenfluramine serves merely to illustrate the strong bias among medically trained people against the use of nutrients and for the use of drugs.

On any rational grounds: scientific evidence, efficacy, safety (both short-term and long-term), and economy (about $20 per month versus, often, hundreds of dollars per month), B6 and magnesium are the obvious first choice. If B6 and magnesium do not help after a six- to eight-week trial (and they won't, about 55% of the time), and the autistic person's behavior is intolerable, **then** drugs might be considered. But unfortunately, most families tell me their physicians strongly oppose the use of a vitamin, and urge that drugs be used instead.

This pro-drug bias harms our children. Why the bias against B6 and magnesium? Many reasons. Among them: economics, dogma, politics, lack of information—the list is long, and the discussion would not be appropriate for this venue.

For a copy of our earlier editorial on B6 and magnesium (ARRI 1/4), our table which compares B6 and magnesium against various drugs in terms of parent ratings, and our publication 39E which summarizes the 16 studies and answers questions most commonly asked, send us a 9x12 self-addressed, stamped envelope (52 cents postage). Our 60 minute video on B6 can be rented for $8, or purchased for $16 (add $1 for postage and handling).

Comparison: Publications Reporting Use in Autism of B6, Fenfluramine

	B6	Fenfluramine
Year 1st study/autism	1965	1982
No. of studies/autism	16	31
Av. no. of studies/yr.	0.6	3.4
No. of studies with definite positive results*	16 (100%)	13 (42%)
No. of studies/significant adverse effects**	0 (0%)	20 (65%)
% of subjects improving	45%	30%

* "Definite positive results" include improvement in behavior, speech, biochemical indices, or electrophysiological measures

** "Significant adverse effects" include weight loss, lethargy, aggression, dizziness, gastrointestinal problems, sleep disturbances, etc.

UPDATE: Sound sensitivity/auditory training

In ARRI 4/4, I discussed the common problem of hypersensitivity to certain sounds in autism, described briefly the auditory training technique developed by French physician (now retired) Guy Berard, and mentioned the then forthcoming book *Sound of a Miracle*, by Annabel Stehli, about the remarkable recovery of Stehli's autistic daughter from autism, following 10 days of auditory treatment. I promised to keep ARRI readers updated. So . . . .

1. The double blind study by Dr. Steve Edelson and me, evaluating Berard Training on a sample of autistic children, is nearing completion. Most of the data, including the three-month followup, have been collected. Data analysis is underway.

2. The U.S.-made device for auditory training is in the prototype-test mode. Too early to know how well it works, what it will cost, and when it will become available.

3. We have received well over 1,500 inquiries from parents, audiologists and others. We are maintaining a list of all those interested, and will be writing these people in detail when there is firm, useful news to impart. (Not yet, regrettably!)

Many of those who have contacted us are impatient. We understand that, and are doing the best we can, with our limited resources. Right now the Berard auditory training is not available in the U.S. Sorry! Be patient.

4. In addition to the two suggestions for helping sound-sensitive persons we provided in the last ARRI (use earplugs or ear protectors; use magnesium supplements, 100-300 mg/day), we now offer another possibility: you may wish to try small doses of nutrients or drugs which raise serotonin levels. (Low serotonin may cause sensory sensitivity.)

We have completed a preliminary analysis of drugs reported as helpful by the parents of sound-sensitive autistic children. Imipramine is clearly the best bet for sound sensitive autistic children, with valium and phenobarbital being distant seconds. Theoretically, Prozac might also be helpful. Fenfluramine, since it lowers serotonin, should probably be avoided.

Temple Grandin, author of *Emergence: Labeled Autistic*, tells me imipramine does not reduce her sound sensitivity but helps her accept it better. She warns against excessive dosage and suggests starting at 1 mg/day per 6 lbs. body weight, with maximum dosage of about 1 mg/day per 3 lbs.