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Vitamin B6 study: autistic symptoms reduced, immune system more normal

A new study by P. Menage et al. of France is the eighteenth consecutive study to show that megadose vitamin B6 and magnesium can significantly reduce autistic symptoms. In addition, the study detected immune system abnormalities in male autistic subjects, and found that these abnormalities were corrected by B6/magnesium therapy.

Menage and colleagues analyzed the lymphocytes of 10 autistic children (seven boys and three girls) and 10 non-disabled control subjects. The autistic boys, but not the autistic girls, showed a significant decrease in one subset of T lymphocytes (T CD4+ CD45RA+). This same immune system anomaly was first noted in autistic children and adults by Reed Warren and colleagues in 1990; in the Warren study, however, the anomaly was more pronounced in females.

Following the immune system tests, five of the male study subjects received megadose B6 and magnesium treatment for eight weeks. The researchers report treatment "was marked by an overall improvement of their disorders....Particularly, improvement was observed for certain autistic symptoms (lack of interest in people, abnormal eye contact, impairment in verbal and nonverbal communication)."

In addition, the researchers found that vitamin B6/magnesium treatment "corrected the relative deficit of the T CD4+ CD45RA+ subset without changing the number of CD4+ T lymphocytes in the five autistic boys."

"Even though there exists no obvious relationship between the correction of the T cell deficit and the clinical improvement of autism," the researchers say, "our results as those of Warren et al. pose the problem of the role of the immune system in the appearance and/or clinical course of the syndrome." They note that a number of immune system abnormalities have been reported in autistic subjects in recent years.

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"CD4+ CD45RA+ T lymphocyte deficiency in autistic children: effect of a pyridoxine-magnesium treatment," P. Menage, G. Thibault, C. Barthelemy, G. Lelord, and P. Bardos; *Brain Dysfunct*, 1992, 5:326-333. Address: Pascal Menage, Hopital Bretonneau, 2, bd Tonnelle, F-37044 Tours Cedex, France.

Clomipramine: study positive, but significant side effects noted

In 1992, Charles Gordon and colleagues reported that clomipramine (Anafranil), a drug used to treat obsessive-compulsive behaviors, was effective in reducing autistic children's symptoms (see ARRI 6/2). Now the same researchers report additional positive findings following a larger trial of the drug.

In their new study, Gordon et al. tested 12 autistic subjects on clomipramine or placebo, and another 12 subjects (including the seven in their first study) on clomipramine or desipramine (an antidepressant which, unlike clomipramine, does not directly alter serotonin levels).

The researchers report that "clomipramine was superior to both placebo and desipramine on ratings of autistic symptoms (including stereotypies), anger, and compulsive, ritualized behaviors." In addition, the researchers say, reciprocal social interaction improved, and the self-injurious behaviors of the four subjects "were markedly diminished"—a finding of particular interest since previous behavioral and medical interventions had failed to control their self-injury. Parents of 19 of 24 study subjects elected to continue clomipramine treatment after the study ended.

Although most side effects seen in this study were minor, two subjects experienced cardiac abnormalities on clomipramine and one had a grand mal seizure. The researchers recommend caution in administering clomipramine to individuals with seizure disorders, and say that electrocardiographic monitoring should be performed on individuals taking the drug. Some subjects taking the other drug, desipramine, experienced irritability, temper outbursts, and aggression. While aggressive outbursts were not reported in subjects taking clomipramine in this study, ARRI has received a growing number of anecdotal reports of such outbursts (see letters, page 6).

Gordon et al. say their findings indicate that "biological links between compulsions and stereotyped, repetitive behaviors in autistic disorder should be explored," and encourage researchers to conduct controlled trials of other drugs that inhibit serotonin uptake.

Two other research groups have reported success in treating autistic symptoms with clomipramine. James Brasic et al. found the drug significantly reduced stereotyped movements and compulsive behaviors in most of their five subjects, and Christopher McDougle et al. saw "significant improvement in social relatedness, obsessive-compulsive symptoms, and aggressive and impulsive behavior" in four of five subjects (see ARRI 7/3).

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"A double-blind comparison of clomipramine, desipramine, and placebo in the treatment of autistic disorder," Charles T. Gordon, Rosanne C. State, Jean E. Nelson, Susan D. Hamburger, and Judith L. Rapoport; *Archives of General Psychiatry*, Vol. 50, June 1993. Address: Charles T. Gordon, Child Psychiatry Branch, National Institute of Mental Health, Room 6N240, Bldg. 10, 9000 Rockville Pike, Bethesda, MD 20892.

Editorial: *FDA battle continues—keep fighting!*

On December 15, 1993, the FDA's new Regulations on Dietary Supplements will go into effect, except—thank heaven!—there is still a six-month grace period. If the FDA is not blocked by Congress, the results will be disastrous for the millions of Americans who take nutritional supplements—and especially for autistic children and adults, many of whom benefit enormously from taking certain supplements (see related story on page 1).

Because Congress spent so much time with the budget, NAFTA, and the Brady Bill, action on the bills intended to keep the FDA leashed was delayed until Congress reconvenes on January 25, 1994. Thus we have a few more weeks. Your help is critical. Please: Visit, if possible, your Senator and Representative at their local offices, before they return to Washington, D.C. on January 25. If you can't visit, phone or write them!

Urge, first of all, that they vote for a moratorium on the FDA's enforcement of its Dietary Supplement Regulations, to give Congress time to protect the public. In addition to supporting the moratorium, the Senators should be urged to co-sponsor the Hatch Bill (S 784), while Representatives should be urged to co-sponsor HR 509 *and* HR 1709. Passage of these bills will prevent the FDA from destroying our historical right to buy safe, non-toxic nutritional supple-

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