

Nutrition & Mental Health

The Quarterly Newsletter of the International Schizophrenia Foundation



Autumn 2003

FROM THE EDITOR

Funding Fraudulence

A year ago in the Autumn issue of *N&MH*, I wrote about the power of placebos, mentioning the Kirsch and Sapirstein report appearing in the July 2002 *Journal of the American Psychological Association*, (APA). These authors, by analyzing the Food and Drug Administration (FDA) database of blinded, randomized, placebo-controlled trials made the startling discovery that antidepressants, thought to be the saviour to millions of suffering people, were in fact barely better than inert placebos.

Moreover, half of the clinical trials sponsored by the pharmaceutical companies failed to find significant drug/placebo difference. Additionally, there were no advantages to higher doses of antidepressants which begs the question of whether these drugs, in fact, have any "true" antidepressant effect at all.

This study ignited much subsequent controversy, pitting psychiatrists with their chemical arsenals against the more benign talking therapies of psychologists. In his commentary on Kirsch's study, Michael Thase, M.D. of the University of Pittsburgh defended the drug paradigm saying that an antidepressant may have only a 10 percent

remission advantage over a placebo but this still means one in ten patients would remit. Kirsch, however, cited the hypothetical of two study patients with Hamilton Depression Rating scores of 20. If the first patient's score is reduced by 10, and the second by nine, technically, the first patient is a responder while the second patient is a nonresponder, but the one point difference in real world terms is insignificant.

The small difference between antidepressant and placebo has been referred to as a "dirty little secret" by clinical trial researchers, nevertheless it's a secret that FDA officials don't seem to want to publicize too much. The tables, however, are now turned. For all the times the orthodox medicine railed against "unproven" natural therapies, it now seems that the whole edifice of research, development and clinical use of pharmaceuticals is fatally flawed. But doesn't the scientific peer review and ethics make such a fraud impossible?

With human nature being what it is, power is often stronger than truth, and the fundamental expression of power is money. When billions of dollars flow through the medical care system, truth becomes grey and malleable. Consider another recent study pub-

lished in the August 20, 2003, *Journal of the American Medical Association (JAMA)* that sheds light on how truth gets distorted. The authors of this *JAMA* meta-analysis wanted to know if funding sources would affect authors' conclusions in supposedly "bias-proof" randomized clinical trials. The researchers studied 370 randomized drug trials in which funding was unknown, or from nonprofit, profit or a combined non-profit/profit sources.

The results are an illustration of truth-bending magic of money. The studied drug was recommended as treatment of choice in 16% of trials funded by nonprofit organizations; 30% of trials not reporting funding; 35% of trials funded by both nonprofit and for-profit organizations; and 51% of trials funded by for-profit organizations. The authors of the analysis convincingly demonstrate that positive bias in interpretation of trial results were common when the pharmaceutical industry funded the research.

Pharmaceutical industry funding has even more insidious effects which challenge scientific reporting and exchange. A growing number of scientists receive all or part of their paycheques from industry. Industry

Nutrition & Mental Health (ISSN 1199-7699) is published quarterly by the International Schizophrenia Foundation, 16 Florence Avenue, Toronto, Ontario, Canada, M2N 1E9. Phone (416) 733-2117, Fax (416) 733-2352. E-mail centre@orthomed.org Copyright by the International Schizophrenia Foundation. ISF Membership is \$35.00 per year which includes a subscription to *Nutrition & Mental Health*. It is recommended that treatment of all health problems be undertaken in consultation with a qualified Health Professional.

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funding of biomedical research, in which psychologists are studying the effects of medications rose from 32% in 1980 to 62% in 2000, according to a recent article in *JAMA* (Vol. 289, No. 4).

The overall effect of corporate sponsorship is potentially chilling to scientific exchange. Take the case, for example, of labs that are developing a medicine they hope to patent. "Sometimes researchers withhold information from even their closest colleagues, and that puts a shadow on the intellectual enterprise." notes James L. McGaugh, Ph.D., who directs the Center for the Neurobiology of Learning and Memory at the University of California, Irvine (UCI). McGaugh summed up the problem thus: "With corporate funding, you have a strong interest in the specific outcomes of the research, and often either direct or indirect pressure to produce specific findings,"

William E. Pelham Jr., Ph.D., a professor of psychology at the State University of New York at Buffalo and director of the Center for Children and

Families there, is a case in point. Pelham, who receives both funding from the National Institutes of Health and pharmaceutical companies to study treatments for attention-deficit hyperactivity disorder, says he has been pressured by a pharmaceutical company to change the text in three journal articles, both to minimize the contribution of psychosocial treatments to the studies' outcomes and to put a positive spin on drug effects.

The spoilsport authors of the APA and JAMA studies did a great service for all by exposing as false some deeply cherished assumptions about the objectivity of the scientific method in the face of unlimited dollars and markets. They also debunked the facile argument that "more studies are needed" for orthomolecular treatments to be recommended. Clinician guided, patient-centred orthomolecular therapy has many thousands of adherents whose renewed health is a proof that transcends the flawed double-blind, placebo controlled "gold standard."

—Greg Schilhab

IN BRIEF

Toxic Metal Clue to Autism

A study of mercury levels in the baby hair of children who were later diagnosed with autism has produced startling results. The babies had far lower levels of mercury in their hair than other infants, leading to speculation that autistic children either do not absorb mercury or, more likely, cannot excrete it.

Louisiana doctor Amy Holmes set out to prove that autistic children had been exposed to high levels of mercury. She obtained baby hair from parents who had kept the first cuttings and sent off a few samples for analysis. To her surprise, mercury levels were low. Holmes then conducted a larger study, comparing mercury levels in first baby haircuts from 94 autistic children with those of 45 other children. The mean level in the baby hair of children later diagnosed as autistic was 0.47 parts per million, compared with 3.63 ppm in the others, nearly nine-tenths lower. The more severe the autism, the lower the mercury levels. The mean levels of children with mild, moderate and severe autism were 0.79, 0.46 and 0.21 ppm, respectively.

Most of this mercury came from the mothers and the main sources of exposure, according to the team, were mercury amalgam fillings. In the control group, hair mercury rose in line with the mothers' exposure. But the baby hair of autistic children had consistently low mercury levels, even when the mothers' exposure was high, the team found. One explanation is that there may be a problem with metal uptake. If so, autistic children might also be deficient in metals essential for brain development such as zinc, iron and copper. Alternatively, some children may have a problem excreting mercury. The lack of mercury in hair might be a sign that the metal is being retained in cells rather than getting into the blood, the researchers suggest.

These researchers have now suggested that autistic children might benefit from being given metal-binding agents, or chelators, to rid the body of heavy metals. If these results hold up, metal studies on the brain could unlock some of the mysteries of autism.

—*New Scientist*, 14 June, 2003

from *The New Yorker*



Steve Meyers

"Medicine is giving the eat-drink-and-be-merry model another look."

IN BRIEF

Dementia and Alzheimer's Disease: Environmental Illnesses?

In this study, 2,459 residents of Ibadan, Nigeria, without dementia, and 2,147 African-American residents of Indianapolis, Indiana without dementia (all aged 65 years or older) were followed prospectively for a mean of 5.1 years and 4.7 years, respectively. The age-standardized annual incidence rates were significantly lower among Ibadan residents than among Indianapolis residents for dementia (1.35% vs. 3.24%) and for Alzheimer's disease (1.15% vs. 2.52%). The results of this study indicate that the incidence rates for dementia and Alzheimer's disease are significantly lower among individuals from a non-industrialized country than among those from an industrialized country and suggest that environmental factors play a role in the development of dementia and Alzheimer's disease. There is evidence that exposure to aluminum and other environmental toxins, or chronic consumption of modern processed foods, make it difficult for aged brains to remain healthy.

—*JAMA Volume 285; 6: 2001*

Omega-3 Fatty Acids for Depression

Twenty patients (mean age, 53.4 years) with recurrent unipolar depression, with Hamilton Depression Rating Scale (HAM-D) scores of 18 or higher, were randomly assigned to receive, in double-blind fashion, the ethyl ester of eicosapentaenoic acid (E-EPA; 1 g twice daily) or placebo for 4 weeks. All patients were receiving maintenance antidepressant therapy. At the end of weeks 2, 3, and 4, E-EPA was significantly more effective than placebo ($p < 0.001$), as determined by HAM-D scores. The mean reduction in HAM-D score was 12.4 points in the E-EPA group, compared with 1.6 in the placebo group, and 6 of 10 patients receiving E-EPA, (compared with 1 of 10 patients receiving placebo), achieved a 50% reduction in HAM-D score. No significant side effects were seen. It was concluded that this derivative of EPA either augments the effect of antidepressant medication or has independent antidepressant properties of its own.

—*Am J Psychiatry 2002;159:477-479.*

Fish-Heavy Diet May Prevent Pregnancy Blues

Omega-3 essential fatty acids found in certain kinds of seafood may significantly reduce the risk of depression in pregnancy, new research claims. In this study by National Institutes of Health and University of Illinois, researchers found pregnant women who had a deficient intake of omega-3 acids had double the risk of depression than women with a normal to high intake. "During pregnancy, the baby gets omega-3 at the expense of the mother," explains study co-author Dr. John Davis. A developing fetus draws on the fatty acid stores of its mother for optimal neurological growth. The study sought to determine if women are at the greatest risk for depression in the third trimester, when their rate of omega-3 depletion is the greatest. Using British data compiled from 14,541 women who were expected to deliver between 1991 and 1992, the researchers found that in countries where omega-3 intake is the highest, the incidence of depression appears to be the lowest. However, a clinical trial where subjects with different intakes of omega-3 are randomly assigned to comparison groups is needed to draw any conclusions about the relationship between these fatty acids and depression, Davis says.

—*Yahoo HealthScout -News, May 22, 2003.*

Coenzyme Q10 for Parkinson's Disease

Researchers have known of a relationship between CoQ10 and Parkinson's disease (PD) because of prior evidence that PD disease is associated with a defect in a CoQ10-regulated mitochondrial energy pathway. In addition, reduced concentrations of CoQ10 have been found in the blood of people with Parkinson's disease.

In this study, 80 patients with early PD who did not require treatment were randomly assigned to receive, in double-blind fashion, placebo or CoQ10, at a dose of 300, 600, or 1,200 mg/day. After 16 months, compared with baseline, the mean score on the Unified Parkinson Disease Rating Scale increased (worsened) by 12.0 (49.8%) in the placebo group, 8.8 (36.9%) in the 300mg/day group, 10.8 (47%) in the 600-mg/day group, and

6.7 (29.6%) in the 1200-mg/day group. The difference in the change between the 1,200-mg/day group and the placebo group was significant ($p = 0.04$). CoQ10 was well tolerated and no serious adverse effects were seen. The results of the present study suggest that CoQ10 at a dose of 1,200 mg/day slowed the progression of Parkinson's disease. Although no significant effect was seen with smaller doses, there was a trend in favor of a benefit. Previous research has shown that taking large amounts of vitamin C (up to 3,000 mg/day) and vitamin E (up to 3,200 IU/day) also can slow the progression of Parkinson's disease. These findings raise the possibility that taking all three of these nutrients in combination would increase the effectiveness of CoQ10.

—*Arch Neurol 2002; 59: 1541-1550.*

L-Carnitine Treatment of ADHD

Twenty-six boys (aged 6-13 years) with attention-deficit hyperactivity disorder (ADHD) were randomly assigned to receive, in double-blind fashion, either carnitine or placebo in alternating eight weeks cycles. The dose of L-carnitine was up to 4 g/day, taken in two divided doses after meals. The children were considered treatment responders if there was either a 30% decrease or a normalization in the Child Behavior Checklist (CBCL) or a 30% decrease in the number of "most severe" ratings on the Conners teacher (CT)-rating scale, compared with baseline.

Among the 24 boys who completed treatment, the proportion of responders according to the CBCL rating scale was 54% in the L-carnitine group and 13% in the placebo group ($p < 0.02$). The proportion of responders according to the CT rating scale was 50% in the L-carnitine group and 17% in the placebo group ($p < 0.05$).

The results of this study indicate that supplementation with L-carnitine significantly decreases attention problems and aggressive behavior in boys with ADHD. Because this nutrient plays a key role in energy metabolism, correction of carnitine deficiency might enhance overall performance, thereby improving attention span and other aspects of behaviour.

—*Prostagl Leukot Essent Fatty Acids 2002; 67: 33-38.*

—Greg Schilhab

BOOK REVIEW

The Natural Medicine Guide to Bipolar Disorder

by Stephanie Marohn
Hampton Roads, Inc. 2003
217 pages, Softcover \$14.95

More than three million people in the United States suffer from bipolar disorder, an illness hallmarked by mood swings from manic phases of intense activity and impulsiveness, to debilitating depression. Such profound instability can lead to complete disability and place the person at greater risk for job loss, divorce and substance abuse. Between the promise of drugs and the reality of chronic medicating, there are natural therapies which can help restore balance to the bipolar person's mood and life. *The Natural Medicine Guide to Bipolar Disorder* by Stephanie Marohn is a complete survey of these complementary therapies.

The book is divided broadly into two parts. In the first half, Marohn covers the basics of bipolar disorder, from the alarming statistics of three million cases in the USA, to the genetic and environmental factors which contribute to the formation of this illness. Bipolar disease, like schizophrenia, has sub-classifications. Type I bipolar disease is characterized by the full gamut of moods, from severe depression to mania, but with an emphasis on the manic end of the scale. Bipolar Type II, the more common type, predominates on the depressive end of the mood spectrum. Other shades of the disorder are cyclothymic disorder, a milder form of the classic bipolar symptoms, and mixed episodes, where the manic and de-

pressive states can exist at the same time. Rapid cycling or ultra rapid cycling are variants of both type I and II where the cycle frequency can be increased greatly.

Marohn touches on the historical aspects of the disease from the first attempts to explain depression and mania in Greek medicine, on through the middle ages, to the enlightenment and the 20th century with its pharmacological model. Some of the more famous persons in history from William Blake, Ernest Hemingway and Winston Churchill up to modern times with Margot Kidder, are well known sufferers. Marohn also uses the wealth of historical research to show that there is, in fact, an artistic aspect to bipolar disease, and some of the our most revered composers and artists achieved great heights of creativity in their manic phases.

The causes of bipolar disease are as yet unknown, but Marohn reminds us that the body, mind and spirit are inseparable, and thus, the factors involved in this illness can be quite broad. In her "Causes, Triggers and Contributors"

chapter, she lists the top twenty factors which can contribute to bipolar disease. Genetic vulnerability, stress, chemical toxicity, food allergies, intestinal dysbiosis, and hypoglycemia are some of the many commonly implicated causes of the disorder.

In Part II, entitled "Natural Medicine Treatments for Bipolar Disorder," Marohn introduces to us the physician Dietrich Klinghardt's healing model to help us understand and implement the eclectic therapies found in the rest of the book. This five-level model encompasses the physical body, the electromagnetic body, the mental body; the intuitive body

and the spiritual. A given therapy acting on one specific level may also bridge or trickle down to other levels. Biological medicine, for example, acts on both the physical and electromagnetic body, where Applied Psychoneurobiology acts on the physical, mental and intuitive simultaneously.

Marohn then delves into many therapeutic options based on case studies and interviews with leading doctors and practitioners in biochemistry, allergy-elimination, biological and anthroposophic medicine. There are valuable summaries of the work of William Walsh, Ph.D. in methylation, fatty acids and mental illness; Bradford Weeks' biological/anthroposophic approach to patients; Julia Ross' discussion of amino acid therapy; and Dr. Devi Nambudripad's Allergy elimination technique (NAET).

To illustrate the many other ways beyond our western medical model that bipolar disease can be seen, Marohn introduces, at the end of the book, Malidoma Some, a celebrated African healer and teacher of the Shamanic view on mental illness. Some describes how, in African cultures, many mental illnesses are regarded as messages and harbingers of the spirit world. Far from being seen as "patients," these people are encouraged to accept mental symptom as a call from beyond and the beginning of a "birth of the healer" in themselves. To accept this journey they become revered and play a central role in their tribe and community.

The Natural Medicine Guide to Bipolar Disorder casts a wide holistic net to help us appreciate the complexity of bipolar disease. Those with this disorder and any reader who wants a comprehensive understanding of this illness, will find this book is well organized, introducing many new personalities in the healing fields. These practitioners emphasize the human side of the illness in a positive life-affirming approach. Marohn's book is worth the read to gain a fresh perspective on mental illness.

—Greg Schilhab

