Nutrition & Mental Health

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40 YEARS OF HOPE ISF

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FROM THE EDITOR

The Dangers of Off-Label Prescribing

In the last 35 years, orthomolecular medicine has progressed from its perception as an unproven theory, to its status today as a legitimate and safe alternative to treat mental illness. To witness the speed at which natural molecules go from research to the shelf, compared to the glacial progress of drug trials, it would seem that orthomolecular treatment of mental illness has at last come of age. But the innate human proclivity to believe, to progress and to hope–qualities which gave us orthomolecular sanity to begin with–also leaves us vulnerable to new trends which threaten to regress us back to the dark ages when drugs were our only choice.

The danger to orthomolecular medicine is intrinsic to the economics of health care in general. To contemplate the scale of the pharmaceutical industry is to invite comparisons to the oil industry: a massive, vertically-integrated, trillion-dollar, juggernaut which transcends borders and eclipses the power of any government. The business of illness is unimaginably lucrative. Once you have created a product no one can copy, locked consumers into a perpetual contract for it and spurred demand by marketing into new territories, you have re-created the proverbial golden goose. Pharmaceutical companies have richly exploited the third part of this triad in a scheme referred to as "off-label" drug dispensation. The way it works is deceptively easy. The Food and Drug Administration (FDA) has always required that drugs used in the USA be proven both safe and effective, but only for a particular condition, and mindful of contraindications such as age, gender and other health conditions. Information on labels, in the Physicians Desk Reference and in any advertising may only indicate a drug's use for a specific condition. Drugs prescribed for a disease not listed officially are considered to be off-label medications. For all the safeguards the FDA puts up, however, the laws have been written so that physicians may prescribe a drug for a use not indicated in the approved labeling if it seems "reasonable or appropriate." Since the majority of information available to physicians is controlled by an army of roving drug reps, is it any wonder that half of all prescriptions in the USA are now written for off-label purposes? What physicians most need to explain to patients is that "off-label" means that no rigorous scientific studies have been conducted for the new use of the drug, and its safety or efficacy is simply unknown.

Sometimes these new indications for old drugs are warranted. Take for example the solid science behind the discovery that most stomach ulcers are caused by the *Helicobacter pylori* bacterium. With this revelation, pharmaceutical companies could expand the market for antibiotics, as doctors now frequently prescribe them off-label to treat ulcers.

Yet, despite the benefits of some off-label prescribing, its potential for misuse threatens sound mental health treatment, as psychiatry becomes enmeshed in the practice. Prozac, though originally approved for depression is now prescribed off-label for obsessive-compulsive disorder, panic disorder and even chronic pain. Wellbutrin, an atypical antidepressant, underwent a name change to Zyban, and is now the star anti-smoking drug. Risperdal, a leading drug for schizophrenia, has now become a popular off-label treatment for Alzheimer's and dementia. Today, 65% of Risperdal's prescriptions are for unapproved treatments, generating an additional $929 million in retail sales.

Sometimes the zeal for off label experimentation blurs the line between body and mind. Chlorpromazine, a powerful antipsychotic, has been used off-label in the treatment of hiccups, and Clonidine, a drug for high blood pressure, is used with Ritalin for the treatment of attention deficit disorder. This combined treatment has been associated with reports about sudden deaths after prolonged use.

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It is recommended that treatment of all health problems be undertaken in consultation with a qualified Health Professional.

Editor/Production: Greg Schilhab

Managing Editor: Steven Carter

Editorial Cont'd

What if a pharmaceutical company finds there are no "bonus" diseases for a drug to gain market share? No problem, when new diseases can so easily be created. Indeed, child psychiatry presents the greatest market potential for the drug industry, as lobbying has allowed schools to decree mandatory treatment for newly invented "diseases." The result has been a surfeit of off-label treatments for attention deficit hyperactivity disorder (ADHD), conduct disorder (CD), oppositional defiant disorder (ODD), severe emotional disability (SED), and whatever else is dreamt up. Today, 80% of all medications prescribed to children are not approved for such use by the FDA.

Desipramine, a tricyclic antidepressant rife with side-effects and contra-indications, received FDA approval for treating adult depression. Yet, off-label, it was given to children for ADHD, until it was implicated in the deaths of eight children. The anticonvulsant Depakote has been used off-label for children for bipolar disorder, and is the primary suspect in at least four deaths. Ritalin, the premiere ADHD drug, carries a warning against its use in children younger than six years. Yet, in 1994, 3,000 prescriptions for Prozac were written for children under the age of one. To peer into the cradle of an excitable one-year-old child whose mind wanders as it explores the new world unfolding, and to know someone views such behaviour as a mental illness needing drugs, is to come face to face with the worst expression of marketing off-label drugs.

Mental illness, whether genetic or environmental, expressed through mood or perception, is a disorder of molecules, not a drive to market. The orthomolecular counterpoint we shout in reply–Molecules Natural to the Body, in Amounts to Optimize Health!– seems so simple and self-evident we feel sure the message will prevail in the end. However, in the face of a multi-billion dollar game, hasn't truth become a bit player to economics? All that remains is our reason to serve as gatekeeper for the molecular purity of the body.

–Greg Schilhab

Announcing a Special Double Issue of the Journal of Orthomolecular Medicine

THE SAFETY AND EFFICACY OF VITAMINS

Readers of *Nutrition & Mental Health* who do not subscribe to the *Journal of Orthomolecular Medicine* may wish to take advantage of the special offer to purchase this double issue detailing how vitamins are used as safe, effective treatments in orthomolecular medicine.

Some of the leaders in orthomolecular medicine including Abram Hoffer, Alan Gaby, Patrick Holford, Andrew Saul, Stephen Lawson and Bradford Weeks contributed to this important issue. The comprehensive articles cover: the historic legal battles to have vitamins declared as safe effective treatments; the politics of establishing "safe upper limits;" vitamin A and beta carotene in immunity and cancer; the pharmacology of niacin; optimim vitamin B_6 levels for a healthy population; the side effects of over-the-counter drugs; the trials of vitamin C acceptance in orthodox medicine; the diversity of uses for vitamin D; and vitamin E's long path to confirmation as an effective cardiovascular supplement. Be informed about issues at the forefront of orthomolecular medicine by ordering your copy today!

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16 Florence Avenue, Toronto, ON, Canada M2N 1E9
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from the New Yorker

"Not much–Just flushing out my arteries..."

IN BRIEF

Cannabis a Trigger for Schizophrenia?

A new study shows cannabis can act as a trigger for schizophrenia. A German study showed 35% of sufferers first reported symptoms in the month they first took cannabis. Cannabis use was also twice as frequent among people just diagnosed with schizophrenia as in a group of non-schizophrenics. Psychiatrist Heinz Haefner of Ruprecht Karls University in Heidelberg says the drug doesn't cause schizophrenia, but he does say it is related to its appearance. The study carried out at the University's Central Institute for Mental Health appears in the *Nerven-heilkunde Science Journal*. The researcher stated that "the findings are of significant interest for the current discussion about whether to take cannabis out of regulation." He also warns against schizophrenics using cannabis as self-therapy.

–www.Ananova.com Thurs. 11th July, 2002

Moderate Weight Lifting Relieves Anxiety

Moderate resistance exercise reduced anxiety in male and female volunteers, whereas study participants who engaged in intense resistance exercise did not experience the same benefit. In this study, 84 volunteers were tested to determine their maximum resistance exercise ability and then were randomly divided into three groups. One group was assigned to perform exercises at a moderate 50% of their ability, while the second group was asked to perform at 80% of their ability. A third group, acting as a control group, was assigned to watch a video on resistance training. Anxiety levels, mood states, blood pressure, and heart rate were assessed before the exercise session began, immediately after, and at 20, 60, 120, and 180 minutes after the session finished. The results from this study indicated that there was a significant reduction in anxiety 180 minutes following resistance exercise performed at 50%. Thus, it is possible that a single episode of resistance exercise would be associated with similar mood benefits for both novice and experienced weightlifters.

–Medicine & Science in Sports & Exercise 1999; 31:456-462

Sage to Combat Alzheimers

Alzheimer's is one of the most common forms of dementia, affecting some 10 million people worldwide, making it one of the most active areas of pharmaceutical research. Scientists at the northern English universities of Newcastle and Northumbria searched for Alzheimer's treatments by checking the writings of herbalists working four centuries ago, and found a marked improvement in the memory capabilities of people taking sage oil extract. The finding was consistent with a discovery by researchers at the Universities' Medicinal Plant Research Center that sage protects a key chemical destroyed in Alzheimer's. "This research does have serious implications for people suffering from Alzheimer's disease, as it will inform drug research and development," lead researcher Nicola Tildesley said, noting sage has no side effects.

–Reuters Health-2003; 08-29

Treatment of Autism Spectrum Children with Fat-Soluble Thiamine

In a pilot study, the clinical and biochemical effects of 50 mg fat-soluble vitamin B_1 or thiamine tetrahydrofurfuryl disulfide (TTFD) on 10 autistic spectrum children were investigated. TTFD was administered twice daily for two months and symptomatic responses were determined through the use of the computer assessed Autism Treatment Evaluation Checklist (ATEC). Urine from patients was examined at outset, after 30 days and after 60 days of treatment and the concentrations of excreted toxic metals and other parameters were determined.

Out of 10 patients, 6 had initial urine samples containing arsenic in greater concentration than healthy controls. Traces of mercury were seen in urine from all of these autistic children. Following administration of TTFD an increase in cadmium excretion was seen in 2 children and in lead in one child. Nickel was increased in the urine of one patient during treatment. The study authors concluded that thiamine tetrahydrofurfuryl disulfide appears to have a beneficial detoxification effect on some autistic children.

–Neuroendocrinol Lett, 2002; 23(4): 303-8

Omega-3 Fatty Acids in Major Depressive Disorder. A Preliminary Double-blind, Placebo-controlled Trial.

Patients with depression have been extensively reported to be associated with the abnormality of omega-3 polyunsaturated fatty acids (PUFAs), including significantly low eicosapentaenoic acid and docosahexaenoic acid in cell tissue contents and dietary intake. In this study, the researchers conducted an 8-week, double-blind, placebo-controlled trial, comparing omega-3 PUFAs (9.6 g/day) with placebo, in addition to the usual treatment in 28 patients with major depressive disorder. Patients in the omega-3 PUFA group had a significantly decreased score on the 21-item Hamilton Rating Scale for Depression than those in the placebo group. From the preliminary findings in this study, omega-3 PUFAs could improve the short-term course of illness and were well tolerated in patients with major depressive disorder.

–Eur Neuropsychopharmacol. 2003; 13(4):267-71

Double-blind, Placebo-controlled Study of L-carnosine Supplementation in Children with Autistic Spectrum

L-Carnosine, a naturally occurring dipeptide, can enhance frontal lobe function or be neuroprotective. This study investigated 31 children with autistic spectrum disorders in an 8-week, double-blinded study to determine if 800 mg L-carnosine daily would result in observable changes versus placebo. Outcome measures were the Childhood Autism Rating Scale, the Gilliam Autism Rating Scale, the Expressive and Receptive One-Word Picture Vocabulary tests, and Clinical Global Impressions of Change. After 8 weeks on L-carnosine, children showed statistically significant improvements on the Gilliam Autism Rating Scale and the Receptive One-Word Picture Vocabulary test. Improved trends were noted on other outcome measures. Although the mechanism of action of L-carnosine is not well understood, it appears effective in treating some aspects of autism.

–J Child Neurol, 2002, (11):833-7

BOOK REVIEW

Treating Autism: Parent Stories of Hope and Success

By Stephen M. Edelson Ph.D and Bernard Rimland, Ph.D

Autism Research Institute Publication

2003, 385 pages, Softcover US $20

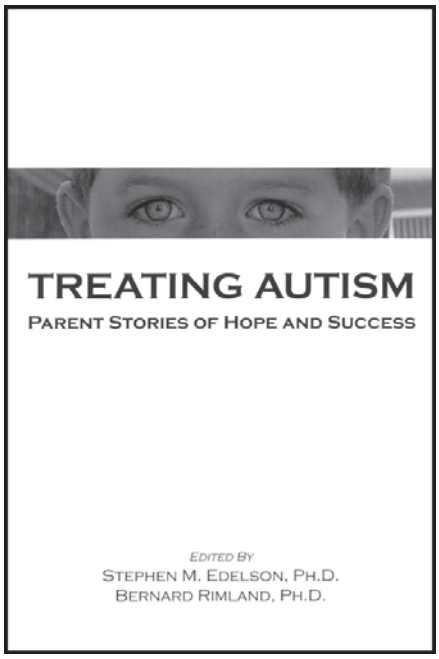
Every parent raising an autistic child could undoubtedly write a book about their experiences in the face of this implacable and devastating disorder. *Treating Autism* is very much a chorus of such stories–those of despair and struggle, and those of hope in the search for treatment for their children.

The book is divided into four parts, and begins with Bernard Rimland's own story of how his son Mark was diagnosed as autistic at an early age. Rimland's lifelong determination to help him resulted in his founding the Autism Research Institute (ARI) in 1967, whose mandate was to serve as a center for collecting, analyzing and disseminating research on the cause of and treatment for this disorder.

In addition to giving parents information, Rimland's ARI began to be inundated with intriguing reports from parents themselves. "I removed milk from my child's diet, and he's a new person," "I started my daughter on the megadose nutrients, and she's talking now," "We eliminated yeast, and the tantrums stopped." After years the leads given by parents numbered in the thousands, all pointing to sometimes dramatic improvements when their autistic children began using biochemical/nutritional interventions. All these hopeful reports which were met with a complete lack of interest in orthodox medical circles, motivated Rimland and Edelson to formalize the collection of parent data using a series of standardized questionnaires and checklists. The treatment methods that have evolved from the combined efforts of parents and professionals, are referred to collectively as the Defeat Autism Now! (DAN!) program.

John Green and Stephen Edelson contribute valuable material to this part of the book. Green speaks from his perspective as a physician who has successfully treated many autistic individuals and provides the reader with an excellent introduction to the DAN! approach. Dr. Edelson discusses what he would do if he were the parent of an autistic child and suggests ways in which parents may determine if a treatment truly helped their child.

Part II is a collection of vignettes written by 31 parents, which tell of the tribulations they endured with their untreated autistic children, along with their triumph using the DAN! approach. Some of these children have recovered from autism, others have greatly improved and are much more likely to connect emotionally with others. These parent stories come from many perspectives, and the severity of their child's disorder varies considerably. The diversity of successful outcomes gives the reader hope that their own struggle raising an autistic child can be greatly helped by pooling resources and experiences. In reading some of these stories we are struck by the collective intelligence and grit of the parents: many are written by physician-parents, others by couples who became self-taught experts themselves and authored their own books on treating autism.



Part III contains 58 letters to the editor of the *Autism Research Review International*, the journal of the ARI. These accounts were written by parents and some professionals to report their experience with vitamin B_6, magnesium and dimethylglycine (DMG). These letters are categorized by age, and one can read about improvements in young children, teenagers and adults. Rimland states that of all the biomedical treatments for autistics, including drugs, the use of vitamin B_6 with magnesium has received the most scientific support, including 11 double-blind studies. The published evidence for DMG is less solid, however one can still read many letters of endorsement for this very safe and often highly effective nutritional supplement.

Part IV consists of several appendices which serve as self-help tools for parents to help themselves become immersed into a new approach to autism. There is a list of resources with internet links as well as a glossary of biomedical terms and information. One important inclusion is the ARI's *Treatment Effectiveness Survey*, which parents can use to rate the effects of the interventions they have tried. The authors encourage parents to send these surveys to ARI which publishes the results on a regular basis. The value of these contributions is immediately apparent when reading Rimland's tabled summarizations comparing the safety and efficacy of nutritional supplements and diets. These few pages are a gold mine of data collected over decades from the 22,300 parents who have already contributed their observations.

The *Autism Treatment Effectiveness Checklist* is another tool which allows parents to evaluate the progress of their child's response to nutritional interventions. Professionals and researchers also use the checklist to evaluate the efficacy of various treatments.

Autism's complexity makes every child a biochemical "black box," inscrutable to orthodox scientific methods. Absolute answers are few. Rimland and Edelson have wisely sought another path in *Treating Autism* by collecting and collating the pool of individual experiences to find orthomolecular patterns of healing. This is a wonderful book, sure to give those with autism hope that this disease can be successfully treated.

–Greg Schilhab