Clinical Trials and the Drugging of Our Children

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Massachusetts General Hospital just completed Phase IV of a clinical trial and are currently recruiting patients for a larger randomized controlled clinical trial. (www.clinicaltrials.gov/ct/show/NCT00181883) The purpose of this trial was to assess the effectiveness and tolerability of Quetiapine, in the treatment of preschool children aged four to six years old with bipolar and bipolar spectrum disorder.

Seroquel is a psychotropic agent that affects multiple neurotransmitter receptors in the brain: serotonin 5HT1A and 5HT2, dopamine D1 and D2, histamine H1 and adrenergic receptors. Side effects include: orthostatic hypotension, tiredness, dizziness, dry mouth, asthenia, constipation, tachycardia, dyspepsia, leucopenia, hypothyroidism, seizures (1 in 125 patients), tardive dyskinesia, neuroleptic malignant syndrome (NMS), cataracts, increase blood concentrations of cholesterol and triglycerides by 11% and 17%, respectively, peripheral edema, weight gain, rhinitis, alteration in results of liver function tests, persistent painful erection of the penis (priapism), and elevated blood sugars.[1]

The safety of this drug with patients under 18 years of age has not been established. It has however been established that this drug can cause serious and fatal side effects on adults.

Some of the inclusion criteria for this trial were: "Subjects must have a DSM-IV diagnosis of bipolar I, bipolar II disorder or bipolar spectrum disorder and currently displaying manic, hypomanic, or mixed symptoms (with or without psychotic features)" according to the DSM-IV based on clinical assessment and confirmed by structured diagnostic interview. Subjects and their legal representative must have a level of understanding sufficient to communicate intelligently with the investigator and study coordinator, and to cooperate with all tests and examinations required by the protocol. For concomitant stimulant therapy used to treat ADHD, subjects must have been on a stable dose of the medication for one month prior to study enrollment. The dose of the stimulant therapy will not change throughout the duration of the study."

What mixed symptoms means in anyone's guess. What about, "level of understanding" in a four year old? A clinical assessment and diagnostic interview is subjective on the clinicians' part, as is the assessment of the mixed symptoms. Giving concomitant therapy to these young children is saying they have not only one but two behavior disorders. Are these perceived disorders caused by a deficiency of quetiapine and/or methylphenidate? Surely not!

Two of the exclusion criteria of this trial were: 1) Judged clinically to be at serious suicidal risk. 2) Current diagnosis of schizophrenia.

I could not find any statistics on suicidal risk for this age group of children or even any incidents, except for suicide pacts dealing with families. The diagnosis of schizophrenia in children four to six years old is rare, and dubious. Obviously any child without a serious unstable illness that exhibits abnormal behavior, judged by clinicians being paid by Big Pharma to conduct these tests, was eligible.

From 1992 to 1995, healthy babies and toddlers in Baltimore were exposed to lead paint dust in a clinical trial for the purpose of determining the effectiveness

1.Genesis Metabolic Therapy 3b, 2727 Quadra Street, Victoria, BC V8T 4E5 www.genesis metabolic.com

of varying degrees of lead paint abatement. The experiment was sponsored by the Environmental Protection Agency and the State of Maryland. It was conducted by researchers at the Kennedy Krieger Institute of John Hopkins University.[2]

Effects and symptoms of lead toxicity include: damages DNA; causes chromosome breaks; lead is absorbed when there is a deficiency of calcium, iron, or zinc; competes with calcium in the body; 95% is stored in bone; also stored in aorta, kidney, brain, adrenals, thyroid, liver; found in red blood cells and urine; poisons and damages cell mitochondria; causes cell death; strongly interferes with cellular detoxification; inhibits enzymes that form hemoglobin; can shorten life span of red blood cells by 50%, causing microcytic anemia; disrupts liver detoxification; accumulates in the kidneys, damaging function; inhibits release of neurotransmitters; causes learning disabilities; lowers IQ; blocks kidney excretion of uric acid (gout); acts as a xenoestrogen; stimulates cell division in breast cancer cells; loss of appetite, tremor, constipation, joint pain, headache, insomnia, metallic taste, muscle ache; interferes with thyroid function.[3]

Nancy Hallaway, in her book, *Turning Lead Into Gold*, documented her plight as a mother and RN, grappling with the medical establishment, trying to find causal factors for her twin boys erratic and uncontrollable behavior. Only after an enlightened doctor, Zigurts Strauts, suggested that the symptoms her boys were displaying may be lead poisoning, and subsequent hair tissue analysis confirmed this, was a definite diagnosis made.

Subjecting babies and toddlers to lead dust, when for decades lead has been known to be a neurotoxin that can cause brain damage and mental retardation, is tantamount to child abuse and, once again, at a University hospital conducting research, this time, with an arm of the government, the EPA. Environmental Protection Agency - what an oxymoron!

The following was reported in The New York Post, February 29, 2004 -

AIDS Tots Used As "Guinea Pigs"
By Douglas Montero

The state Health Department has launched a probe into potentially dangerous drug research conducted on HIV-infected infants and children at a Manhattan foster-care agency, The Post has learned. Some 50 foster kids were used as "guinea pigs" in 13 experiments with high doses of AIDS medications at Manhattan's Incarnation Children's Center, sources said. Most of the ICC experiments were funded by federal grants and in some cases, pharmaceutical companies. They used city foster children, who were sent to the Catholic Archdiocese-run facility by the Administration for Children's Services. ICC was involved in 36 different experiments, according to the National Institutes of Health Web site. One study researched "HIV Wasting Syndrome," which studied how a child's body changes when his medication is altered. A handful of the experiments involved combining up to six AIDS drugs–so-called "cocktails"–in children as young as 3 months, and another explores the reaction of not one, but two doses of the measles vaccine in kids ages 6 to 7 months. Other studies tested the "safety," "tolerance" and "toxicity" of AIDS drugs. "They are torturing these kids, and it is nothing short of murder," said Michael Ellner, a minister and president of Health Education AIDS Liaison, an advocacy group for HIV parents. Biochemist Dr. David Rasnick, a visiting scholar at the University of California at Berkeley and an expert in AIDS medication, was outraged because the drugs, alone or combined, have "acute toxicity which could be fatal." He said the drugs' side effects include severe liver damage, cancerous tumors, severe anemia, muscle wasting, severe and life-threatening rashes and "buffalo hump," where fatty tissues accumulate behind the neck.[4] To use children

in facilities such as this for federally funded chemical/drug experiments is reminiscent of the Holocaust! Another case involved a 29 month old toddler named Simon who was subjected to an uncontrolled drug experiment. As reported in The Washington Post, Dr. Lawrence Diller commented, "I was flabbergasted when I later learned from his mother that Simon saw a highly respected child psychiatrist and was now taking Lithium, Zoloft, and Risperdal, three psychiatric drugs at once. I don't know who felt crazier, Simon or I."[5]

In 2002, the U.S. Congress passed the Best Pharmaceuticals for Children Act. This Act expands programs that push drug companies to test and label their products intended for children's use, including newborns. Before this Act was passed, there was a U.S. Senate meeting held November 19, 2001. At this meeting Senator Christopher Dodd from Connecticut reported that in the previous seven years before 1997, there had been 11 clinical trials and two new products on the shelves of America for children. In the three years since then, there were 400 clinical trials and 40 new products on the shelves. He also said, "Less than 20% of all pharmaceutical products on the shelves today are for children. Senator DeWine and I thought we ought to fix that."[6]

At this same meeting, neurologist Fred A. Baughman Jr., M.D., a well known opponent of the diagnosis of ADD and ADHD made several comments. "This Act, it appears, refers primarily to psychotropic drugs, none of which are prescribed for diseases, but rather, for normal children with normal, emotional/behavioral problems (none proved to be diseases). The question I have of the "Best Pharmaceuticals for Children Act," is, should there be any such pharmaceuticals at all? With no disease on the "risk" side of the "risk" vs. "benefit" equation, the only physical risk in such treatment situations, is that which is borne by the drugs themselves. All of them are brain-altering (that is how they work) and brain-damaging, short- and long-term." "We do know, Senators Dodd and DeWine, that the children labeled ADHD have no *bona fide*, demonstrable disease; that they were normal before the drug ingestion was begun. In fact, the risk/benefit ratio for ADHD (illusory, invented, fraudulent) "treated" with Ritalin, Adderall, Dexedrine, any drug, is simply not justifiable. The incessant claims of psychiatry, the AMA, AAP and the rest of medicine, that ADHD is a disease, are fraudulent. Invite them to the Senate, swear them, and extract the truth of the matter. It would not be a moment too soon; we have 6 million schoolchildren taking these narcotics. And exactly as all of psychiatric and medical academia refers, throughout their peer-reviewed literature, to such disorders as diseases, when none of them are, their drug trials all say exactly what paymaster, Big Pharma wants them to say–that one drug is better than the one before it, that two drugs are better than one; three better than two. If there were any truth in their research, no normal child labeled diseased, abnormal and drugged, could possibly have a better life, short- or long-term than the just as normal, un-drugged, control subject."[6]

I would like to reclassify this act as The Worst Pharmaceuticals for Children Act.

According to Medco Health Solutions, Inc., (www.medcohealth.com) a leading pharmacy benefit manager, children are the fastest growing category of users of antipsychotic drugs. They reported the number of children ages 19 and younger using antipsychotic medicines rose 73% from 2001 to 2005. Their analysis indicates that children are receiving the latest generation of antipsychotics–known as atypical antipsychotics, including risperidone, olanzapine, clozapine, ziprasidone and quetiapine–at a much higher rate than adults. Of the patients prescribed antipsychotics, children received the newer atypi-

cal drugs 97% of the time rather than the older treatments. Medco's chief medical officer, Dr. Robert Epstein has said, "...these drugs are not without their risks. There is evidence that the risk of diabetes and metabolic disorders from using atypical antipsychotics could be much more severe for pediatric patients than adults."[7]

In the fall of 2005, the FDA called for black-box warnings on several antidepressant drugs, including Prozac, Paxil and Zoloft, because of indications that they triggered suicidal thinking in some patients. On February 9, 2006, a federal expert advisory panel recommended several drugs widely used to treat attention-deficit hyperactivity disorder should carry a prominent "black box" warning because of reports that they may have caused sudden deaths or serious complications. They also reported about 10 percent of 10-year-old American boys are taking such medications.

"On the surface, it is hard to believe," said Curt Furberg, professor of public health sciences at North Carolina's Wake Forest University Medical School, who voted for the black-box warning. "What is also interesting is this condition is not really recognized in other countries–you wonder what we are treating. I am sure there are patients who need these drugs, but it is not 10% of all 10-year-old boys."[8]

Black-box warnings are intended to alert physicians and patients that a drug may carry significant risks; fewer than 10 percent of prescription drugs carry them, according to a 2002 study. IMS Health, which tracks the industry, said sales of all ADHD drugs totaled $3.1 billion in 2004, the Associated Press reported.[9]

In 2000, Dr. Jerry Rushton found that Prozac, Zoloft and Paxil were being prescribed widely for children for not only depression, but also for school phobia, anxiety disorders, bed-wetting, eating disorders, and ADHD.[10]

FDA statistics compiled by an industry research firm indicate that Prozac "was prescribed 349,000 times to pediatric patients under 16, including 3,000 times to infants under one year of age."[11]

It is inconceivable that doctors would prescribe an antidepressant to an infant. It appears that modern psychiatry believes children at any age can be diagnosed with a psychiatric disorder. With the recent addition of "road rage" or now clinically termed intermittent explosive disorder, as a bona fide psychiatric disorder, there seems to be no human behavior, emotion, or condition that is safe from being labeled a pathology. Now watch as Big Pharma, on the heels of this new condition, will once again tout a chemical formula to the rescue.

It is obvious that infant children and adolescent lives have been put at risk of harm for profit and are being exploited in the drug industry by the academic medical research industrial complex (AMRIC). These children are dependant on others to make decisions on their behalf. They are unable to protect themselves, and are increasingly being sought as "risk bearing" subjects to test drugs whose safety is unknown.

Clinical trials on infants and children are an outrage and should be outlawed. Giving an antipsychotic drug, which has horrific side effects to children is nothing less than chemical child abuse. Whatever happened to the Declaration of Helsinki that was adopted by the World Medical Association in 1964? Its attention was focused on sick patients. The children in the trials that the author highlighted, were not suffering from life-threatening conditions requiring such invasive and high risk interventions. It cannot be argued that the potential benefit outweighed the risks and discomfort. None of the experiments described served the children's best interest, and the Hippocratic Oath, "primum non nocere" did not deter these doctors from conducting these medical atrocities.

The tenth finding in Daniel Green-

berg's *The Hidden Dynamics of the Great American Scientific Enterprise: 10 Findings from an Irreverent, Exhaustive Exploration of the Scandalous, the Outrageous, the Ridiculous, the Wasteful, and, Yes, Much Good, in Scientific Research,* says this: "A relentless quest for money pervades science-and almost anything goes to acquire it, including commercial deals between universities scientists and industry that trade away basic traditions of science: openness, collegiality, and protection of human subjects of research. In scientific journals and in conferences, conscience-stricken scientists despair over ethical erosion in their profession. Debates rage over codes of conduct to assure ethical behavior, but the lure of mammon remains a powerful force in the life of science."[12]

As for rightly prescribed medication, according to Dr. Braugman, over six million children in the US have been diagnosed with speculative psychiatric "disorders," for which they are given one or often a cocktail of psychoactive drugs that expose them to critical hazards, even though, these children's diagnosis have not been significantly validated. What is the validity of pathologizing "behavior disorders" altogether? Many professionals and lay people question the legitimacy of an ADHD diagnosis and continually accuse those who promote drugs for children to be in collusion with the drug industry.

Clinicians are continually using trial and error on a case-by-case basis around the world, exposing children to the horrors of side effects. Read the adverse effects of these psychotropic drugs again, and consider that millions of children take these pills every day.

Doctors like Abram Hoffer and Doris Rapp have approached behavior problems in children in a much different manner. They look at a child's diet and environment to discover any allergies or toxicities that may be causative factors in behavior and physical symptoms. Heavy metals and chemical toxicities are often the cause of uncontrolled anger and aberrant behavior. Food intolerance and allergies, chemical and environmental sensitivities, and nutritional deficiencies explain many behavior difficulties and pathological symptoms including lethargy, hyperactivity, digestive problems, sinusitis, mania, eczema and cognitive dysfunction. Treating behavior disorder by examining a child's past and present exposure to toxic elements in his environment including pesticides, chemicals used in the food and cosmetic industries, and determining food allergies and nutritional deficiencies should be the initial focus in treating these children.

As awareness of orthomolecular medicine continues to grow globally, we can only hope that practicing doctors and researchers in the AMRIC will be pressured, and dare I say enlightened to an orthomolecular approach to clinical studies and medical practice.

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