ADD – ADHD
Attention Deficit Disorder and Hyperactivity Disorder Options

James Biddle, MD
Disclaimer

Disclaimer – this is simply an educational presentation and is not intended to diagnose or treat any individuals. Diagnosis and treatment of any disease should be done by a licensed health care practitioner in an office setting.
Who We Are…

Asheville Integrative Medicine

Evolving the Standard of Health Care for All,
While Empowering You to Enjoy Optimal Health.

832 Hendersonville Road, Asheville, NC 28803
828-252-5545
www.docbiddle.com
Who We Are…

Physician-Selected Nutritional Supplements

832 Hendersonville Road, Asheville NC 28803
828-210-0188
www.nutrientsetc.com
Who I am.....

• BA in Biology 1984, University of Missouri – Columbia (genetics & evolution).

• M.D. 1989 @ University of MO – Columbia.

• Internal Medicine 1992 in Portland OR – Board Certified; recertified in 2002 and 2012.

• Practicing Integrative Medicine in Asheville since 1997.

What I do….

“Integrative Medicine”

Holistic, Nature’s Template, Scientific, Orthomolecular, Sherlock Holmes…

- Bio-Identical ‘Natural’ Hormones
- Diabetes and Nutrition
- Cardiovascular Support
- Allergies, ADD, Autism
- Arthritis and Fatigue
- Toxic Metal Syndromes
- “Challenging Cases”
History of ADD-ADHD:

• 1902 - First described medically when English pediatrician George Still described “Frontal Lobe Syndrome” which some claim is analogous to ADHD.

• 1937 - Dr. Bradley in Providence, RI reported that a group of children with behavioral problems improved after being treated with stimulant medication.

• 1957 - The stimulant methlyphenidate became available.

• 1960 - The concept of hyperactivity not being caused by brain damage was first described by Stella Chess as "Hyperactive Child Syndrome."
ADD-ADHD, now grouped as ADHD
  - “Hyperkinetic Disorder” in UK

Neurobehavioral disorder
  - Inattention and/or hyperactivity-impulsivity.
  - Significant functional impairment.

Dramatic increases in office-based diagnoses.
Dramatic increases in pharmacological management.
ADD-ADHD: Stats

- In the years 1990-1993, ADHD outpatient visits increased from 1.6 to 4.2 million per year (Swanson, Lerner, and Williams, 1995).
- During those visits, 90% of the children were given prescriptions, 71% of which were for MPH.
- In 1990-1993, production of MPH in the U.S. rose from 1,784 kg to 5,110 kg.
- Stimulant prescription prevalence for children in the U.S. ranged 6% urban (Safer, Zito, and Fine, 1996) to 7% rural (Angold and Costello, 1997).
- Analyses of managed care datasets reveal a 2.5-fold increase in prescribing in the 1990-1995 time period.
ADD-ADHD: Stats

• 2003 - Ages 4-17:
  – 4.4 million diagnosed with ADHD
  – 2.5 million receiving medication treatment.
  – 7.8% of school-aged children have ADD-ADHD diagnosis reported by their parent.
    – www.cdc.gov/ncbddd/adhd
What’s Gone Wrong?

• Over-diagnosis and misdiagnosis.
• ADHD is a clinical diagnosis.
• Suppression of symptoms of an epidemic.
• No attention to underlying causes.
• Altered Neuro-Physiology? (i.e Frontal Lobe Syndrome from biochemical rather than physical trauma).
• Another way to address the problem?
What’s Gone Wrong? ‘The Medicalization of America’

http://www.stanford.edu/~kocabas/onbeingsane.pdf


• "On Being Sane in Insane Places" - David L. Rosenhan. 8 pseudopatients got themselves admitted to 12 inpatient psych wards, then acted completely normal. They then watched how the staff continued to view them as crazy, and document it in the med records. Average = 19 days (7-52).
ADD-ADHD Diagnosis

- The American Psychiatric Association (APA) recognizes ADD as a mental disorder, though the cause is unknown, and there is no medical test for it.
- Children are diagnosed through subjective observations of a child’s behavior.
ADHD Types

1. **Combined Type:** both A1 and A2 are met for the past 6 months

2. **Predominantly Inattentive Type:** A1 but not A2 is met for the past six months

3. **Predominantly Hyperactive-Impulsive Type:** A1 but not A2 is met for the past six months.

- See [www.amenclinic.com](http://www.amenclinic.com) for testing.
ADD-ADHD Diagnosis

DSM-4 Criteria:

A. Either (1) or (2):

1. Six (or more) of the following symptoms of **inattention** have persisted for at least 6 months to a degree that is maladaptive and inconsistent with developmental level:
   - Often fails to give close attention to details or makes careless mistakes in schoolwork, work, or other activities.
   - Often has difficulty sustaining attention in tasks or play activities.
ADD-ADHD Diagnosis

DSM-4 Criteria:

• Often does not seem to listen when spoken to directly.

• Often does not follow through on instructions and fails to finish schoolwork, chores, or duties in the workplace (not due to oppositional behavior or failure to understand instructions).

• Often has difficulty organizing tasks and activities.
ADD-ADHD Diagnosis
DSM-4 Criteria:

• Often avoids, dislikes, or is reluctant to engage in tasks that require sustained mental effort (such as schoolwork or homework).

• Often loses things necessary for tasks or activities (e.g., toys, school assignments, pencils, books, or tools).

• Is often easily distracted by extraneous stimuli.

• Is often forgetful in daily activities.
ADD-ADHD Diagnosis

DSM-4 Criteria:

A. 2. six (or more) : Hyperactivity

- Often fidgets with hands or feet or squirms in seat.
- Often leaves seat in classroom or in other situations in which remaining seated is expected.
- Often runs about or climbs excessively in situations in which it is inappropriate (in adolescents or adults, may be limited to subjective feelings of restlessness).
- Often has difficulty playing or engaging in leisure activities quietly.
- Is often "on the go" or often acts as if "driven by a motor".
- Often talks excessively.
ADD-ADHD Diagnosis
DSM-4 Criteria:

A. 2. Impulsivity
   - Often blurts out answers before questions have been completed.
   - Often has difficulty awaiting turn.
   - Often interrupts or intrudes on others (e.g., butts into conversations or games).

B. Some hyperactive-impulsive or inattentive symptoms that caused impairment were present before age 7 years.

C. Some impairment from the symptoms is present in two or more settings (e.g., at school [or work] and at home).
ADD-ADHD Diagnosis

DSM-4 Criteria:

D. There must be clear evidence of clinically significant impairment in social, academic, or occupational functioning.

E. The symptoms do not occur exclusively during the course of a Pervasive Developmental Disorder, Schizophrenia, or other Psychotic Disorder and are not better accounted for by another mental disorder (e.g., Mood Disorder, Anxiety Disorder, Dissociative Disorder, or a Personality Disorder).
ADD-ADHD Diagnosis

DSM-4 Criteria:

Differential Diagnosis:

- Age-Appropriate Behaviors in Active Children;
- Mental Retardation;
- Understimulating Environments;
- Oppositional Behavior;
- Another Mental Disorder;
- Pervasive Developmental Disorder;
- Psychotic Disorder;
- Other Substance-Related Disorder Not Otherwise Specified.
Critics of ADHD

"A.D.D.--A DUBIOUS DIAGNOSIS?" 1995
Learning Matters Inc. – a PBS documentary

- Ciba-Geigy funds CHADD (Children and adults with ADHD) founded in 1987.
- “CHADD tells parents that ADD stems from a chemical imbalance in the brain … a psychostimulant corrects that imbalance…”
Critics of ADHD

- “The ADHD Fraud - How Psychiatry Makes ‘Patients’ Out of Normal Children” by Fred Baughman Jr., MD
- 1985 = 500,000 US children ADHD.
- now = 5 - 7 million US children ADHD.
- Genetic or environmentally triggered?
- It’s a symptom complex, not a disease!
Critics of ADHD

• The myth of attention deficit-hyperactivity disorder: symptoms resulting from multiple causes.

• Weinberg WA, Brumback RA. J Child Neurol. 1992 Oct;7(4):431-45; discussion 446-61. Department of Neurology, University of Texas-Southwestern Medical Center, Dallas. PMID: 1469255
ADD-ADHD
Alternative Differential Diagnosis:

2. “Hunter in a Farmer’s World” by Thom Hartmann.
3. “Divergent Thinkers” = 20% – e.g. Thomas Edison “The Edison Trait” author Lucy Jo Pallidino.
4. Personality Styles - Jungian temperament theory by David Keirsey of “Please Understand Me”.
5. Overstimulating Environments – TV and games get kids addicted to too much dopamine.
ADD-ADHD BioMedical Model

- Charles Gant MD, PhD “ADD and ADHD: Complementary Medicine Solution.”
- Ken Bock MD “Healing the New Childhood Epidemics: Autism, ADHD, Asthma, and Allergies.”
- Science-based approaches.
- Safer, more natural, fewer drugs.
- BioMedical Differential Diagnosis > > >.
ADD-ADHD BioMedical Differential Diagnosis:

Nutritional: Food Allergies, Additives, and Dietary Imbalances (Carbs, Protein, Fats).


Hormonal: Thyroid, Adrenals, Testosterone.
Infection-Inflammation: Gut Dysbiosis/ Candidiasis, chronic Strep, Lyme, Viruses (HSV, CMV, EBV, etc), atypicals (mycoplasma & chlamydia pneumo).

Toxicities: Lead, Mercury, Arsenic, Antimony, Solvents, Pesticides, etc.
SAD: Standard American Diet

• Refined Carbohydrates
  ✓ Empty Calories
  ✓ Deficient in Fiber

• Bad Fats
  ✓ Excess Hydrogenated Fats
  ✓ Deficient in Essential Fatty Acids

• Deficient in Vitamins and Minerals
Low Protein, High Carbs correlate with ADHD:


Healthy Diet

- Adequate protein
- High fiber
- Low glycemic index
- Healthy fats
- Increase essential fatty acids
- Consider Feingold Diet
- Eat organically
Food and Additive Allergy

- Consider relationship to foods when indicated (esp. caffeine, milk, wheat).
- Avoid artificial sweeteners = aspartame & sucralose.
- Consider an Allergy Elimination Diet:
- Doris Rapp M.D. documented alterations in EEGs while children were challenged with allergens. The EEG results corresponded with dramatic behavior changes in the children, including hyperactivity. - *Is this Your Child? Discovering and Treating Unrecognized Allergies in Children and Adults* by Doris Rapp.
Food and Additive Allergy

- Avoid artificial colorings and additives.
- Especially avoid tartrazine, yellow food coloring.
- Test for food allergies.
- Test for inhalant allergies with “end-point titration” and “oral drop desensitization”.
“Favourable effect of a standard elimination diet on the behavior of young children with attention deficit hyperactivity disorder (ADHD): a pilot study.”

40 ADHD kids - 62% showed at least 50% improved behaviour on both the Conners list and the ADHD Rating Scale at the end of a 2-week elimination diet.

Food and Additive Allergy

- 26 ADHD kids on elimination diet = 19 (73%) responded favorably, P < .001. On open challenge, all 19 children reacted to many foods, dyes, and/or preservatives.
- A double-blind placebo-controlled food challenge (DBPCFC) was completed in 16 children. There was a significant improvement on placebo days compared with challenge days (P = .003).
- Atopic children with ADHD had a significantly higher response rate than the nonatopic group.

Food and Additive Allergy

• 24 hyperactive preschool-aged boys.
• Baseline 3 weeks, a placebo-control 3 weeks, experimental diet of 4 weeks.
• > 50% exhibited a reliable improvement in behavior and negligible placebo effects.
• Several non-behavioral variables improved on the experimental diet, particularly halitosis, night awakenings, and latency to sleep onset.

Food and Additive Allergy


Food and Additive Allergy

Nutrient Supplements

“Rational dosages of nutrients have a prolonged effect on learning disabilities.” 19 L.D. kids in crossover RCT with “nutrient supplements” x 2 yrs.

All showed significant academic and behavioral improvements within a few weeks or months.

Some children gained 3 to 5 years in reading comprehension within the first year of treatment.

All children in special education classes became mainstreamed, and their grades rose significantly.

2 more yrs ‘open label’- the difference in scores between the 2 groups reached statistical significance (P < .01).

“Do nutrient supplements and dietary changes affect learning and emotional reactions of children with learning difficulties? A controlled series of 16 cases.”

16/32 L.D. kids in RCT “nutrient supplements” x 22 wks.

• Significantly-improved behaviour at school, at home, and in the clinic.
• Significantly-greater gains in reading skills.
• Increased IQ scores of 5 to 35 points (mean = 17.9) for the experimental group were twice the control group (mean = 8.4).

Nutrient Supplements

- P-5-P (activated B6), 25 mg once or twice daily to support serotonin.
- Magnesium 200-600 mg per day.
- EFAs = Essential Fatty Acids from fish oil and ground flax seeds.
- Vitamin B-12, Vit C, Zinc, Selenium, Tyrosine, and others as guided by testing.
Nutrient Supplements: Vitamin B6 = Pyridoxine

11 ADHD kids and 11 controls:

Serotonin levels were significantly decreased in blood of ADHD kids vs controls. No differences in B6 levels.

Four ADHD kids -> oral doses of pyridoxine resulted in increased serotonin and a very large increase in the B6 content of blood in these hyperactive patients.

Vitamin B Deficiency


Vitamin B Deficiency


Mineral Deficiencies: Magnesium

“Improvement of neurobehavioral disorders in children supplemented with magnesium-vitamin B6. I. Attention deficit hyperactivity disorders.”

- 40 ADHD kids Rx with Mg & B6 (6 mg/kg/d Mg, 0.6 mg/kg/d vit-B6) > 8 weeks.
- Started with lower RBC Mg levels than 36 controls.
- Hyperactivity and aggressiveness were reduced
- School attention was improved.
- Significant increase in RBC Mg. When the Mg-B6 treatment was stopped, clinical symptoms reappeared in few weeks, with a decrease in RBC Mg values.

Mineral Deficiencies: Iron

“Effects of iron deficiency on attention and learning processes in preschool children: Bandung, Indonesia.”

• RTC giving iron to ½ of kids for 8 weeks.
• Pre- and post-treatment psychological tests showed that IDA (iron-deficiency anemia) produces alterations in cognitive processes related to visual attention and concept acquisition, alterations reversed with iron treatment.
• Ferritin > 50!
Mineral Deficiencies

- Lozoff, B: **Iron** and learning potential in childhood, Bulletin of the *NY Academy of Science*, vol. 65(10), 1989, pp. 1050-1066
Mineral Deficiencies


Amino Acid Deficiencies

Supplementation with flax oil & vitamin C improves the outcome of ADHD.

- Alpha linolenic acid (ALA)-rich nutritional supplementation in the form of flax oil and antioxidant emulsion.
- Post-supplementation levels of RBC membrane fatty acids were significantly higher than pretreatment levels or the levels in controls.
- Significant reduction in total hyperactivity scores of ADHD children derived from ADHD rating scale.

Essential Fatty Acid and Phospholipid Deficiency

Gastro-Intestinal

• Nutritional Deficiencies could be due to poor intake and/or impaired digestion and gut function.
  – Test for H. pylori.
  – Treat dysbiosis/candidiasis.
  – Test HCL – Heidelberg gastrogram.
  – Digestive Enzymes with meals
  – Acidophilus after meals.
Thyroid Disorders

Lead and ADHD

• The Center for Disease Control, or CDC, estimates that more than three million children have lead toxicity at any point in time in America.

• Their criteria for diagnosis is a serum lead level of ten mcg/dl or higher. Children get lead toxic easy since they absorb fifty percent of the lead they’re exposed to, while adults only absorb about ten percent.
Lead and Children

When a mother’s blood has low levels of lead, even below the CDC’s cut-off level of 10 mcg/dl, their neonatal babies show a dose-effect trend towards both poorer attention and poorer motor control.


By age two, low levels of lead still below 10 mcg/dl are directly correlated with decreased IQ.

Lead and Children

- Preschoolers with **blood lead** levels from 10 to 25 mcg/dl show measurable behavioral changes when compared to those with levels less than 10 mcg/dl.

- In first graders, **hair lead levels** correlate with children’s attention-deficit behavior in the classroom.
  - Tuthill RW. Hair lead levels related to children's classroom attention-deficit behavior. *Arch Environ Health* 1996;51(3):214-220
Lead and Children

- At age twelve, hyperactive kids have higher **blood lead levels** than non hyperactive kids. They also have higher urine lead levels after given a binding agent for lead.

- At ages eleven to thirteen, lifetime low-level lead **exposure** correlates with emotional and behavioral deficits.
Lead and Children

• From ages seven to eleven, **bone lead levels** correlate with antisocial and delinquent behaviors, aggression, and attention deficits.

• At ages eight thru thirteen, hyperactive kids have **higher urine lead levels** after being challenged with a lead-binging agent than their own siblings.
Lead and ADHD


Is your home is a safe and lead-free environment?

- Have your house tested for the presence of lead paint dust.
- Test your drinking water for lead, or you can filter it for safety.
- Our children deserve to have us look for underlying and reversible causes for their developmental and behavioral challenges.
Is your home is a safe and lead-free environment?

- **A blood lead** test screens for on-going lead exposure of last 3 months.
- **Hair analysis** assesses recent or past exposure and the ability to excrete lead.
- **“Provoked” Urine** test estimates a person’s total body burden of lead. **Urinary Porphyrins**!
What about Hg?

- Mercury is the most toxic, non-radioactive element on the planet.
- It remains detectable in the blood for only 3-6 weeks.
- As it leaves the blood it enters every organ, every cell, and every subcellular organelle in the body.
Mercury and Coal

- Largest source of mercury is our coal-burning power plants.
  - Emit 48 tons of mercury into the air each year.
  - EPA reports that rainfall in New England now contains thirty times the “safe” level of mercury for surface water.
  - EPA also blames mercury for neurological damage to 60,000 American babies each year (more U.S. citizens than died in the entire Vietnam War).  

> Physicians for Social Responsibility
• "On average, for each 1000 lb of environmentally-released mercury, there was a 43% increase in the rate of special education services and a 61% increase in the rate of autism."

➢ “Environmental mercury release, special education rates, and autism disorder: an ecological study of Texas” *Health and Place*; 17 February 2005 ; U. Texas Health Science Center in San Antonio.
Pandora’s Box - Hg in Dental Amalgams:
via Stuart Freedendfeld, M.D

• Average filling = 1 gram and is 50-55% Hg.
• The mercury in one filling would cause a 10-acre lake to be closed to swimming and fishing.
• Over 100 million new amalgam fillings placed each year (75-80% still).
• 50 million grams (or about 27.5 tons) of mercury are being newly placed into the mouths of patients every year.
Mercury and Dental Fillings

- World Health Organization reported in 1991 that our leading exposure to mercury is our dental fillings. Silver fillings usually contain fifty percent mercury (Americans average eight fillings per person).

- Although dentists have been taught that dental mercury is inert, 1998 U.S. Senate Hearings confirm that it does evaporate and get absorbed into our bodies.

- Mercury amalgam fillings have been banned by several progressive European countries, including Switzerland and Sweden.
Dental Amalgams:

- Mercury levels in feces are 13-fold higher with dental amalgams, and these levels vary with the amount of amalgam surfaces.
- More than 25% of the original mercury is gone from dental amalgams after the first five years.
- Mercury is bio-concentrated by the placenta - it concentrates 8-fold in the fetus.
Dental Amalgams:

- Imagine 17mcg/day absorbed by a pregnant mother during a 270-day pregnancy.
- We were concerned about the 237 mcg of mercury injected into our children over their first two years in vaccines.
- Should we not give serious concern to the 4590 mcg given to the mother-fetus unit over the more vulnerable 9 month gestation?
Dental Amalgams:

- **60,000 babies** per year in the US are born with neurodevelopmental disorders due to neonatal exposure to mercury.
- The EPA estimated that **1 baby in 6** is born with a blood mercury level that exceeds the Agency’s safety threshold, or 300,000 infants/year. *Env Health Persp* 112(5); 562-70.
Vaccine safety and efficacy?

ELI LILLY: THIMEROSAL

• Merthiolate as a preservative in the final concentration of 1/10,000 could be toxic for tissue cells, lymphocytes, etc.

J.W. Smith, Ph.D., Head of the Biological Regulatory Requirements Department at Eli Lilly—September 7, 1971.
Vaccine safety and efficacy?

ELI LILLY: THIMEROSAL

• We have found that for tissue culture work, the merthiolate must be in the concentration of less than 1/1,000,000 in order not to be toxic to the tissue cells.

   J.W. Smith, Ph.D., Head of the Biological Regulatory Requirements Department at Eli Lilly—September 7, 1971.
Vaccine safety and efficacy?

Safe Levels Of Organic Mercury:

- EPA---------0.1 mcg/kg/Day
- ASTDR----0.3 mcg/kg/Day
- FDA--------0.1 mcg/kg/Day
- WHO-------3.3 mcg/kg/Week

DTaP, Hib, Hep.B = **total 62.5mcg** --- exceeded all “safe” levels combined.
Mercury in Vaccines

- Until about 1989 pre-school children got only 3 vaccines (polio, DPT, MMR). By 1999 the CDC recommended a total of 22 vaccines to be given before children reach the 1st grade, some given to newborns within the first 24 hours of birth. Many of these vaccines contained mercury.

- The cumulative amount of mercury being given to children in this number of vaccines would be an amount 187 times the EPA daily exposure limit.
Mercury in Vaccines

• In the 1990s approximately 40 million children were injected with mercury-containing vaccines.

• Between 1989 and 2003, there has been an explosion of autism. The incidence of autism (and other related disorders) went from about 1 in 2,500 children to 1 in every 166. Currently there are more than a half million children in the U.S. that have autism.
Mercury in Vaccines

• Since mercury was removed from childhood vaccines, the increase in reported rates of autism and other neurological disorders (NDs) in children not only stopped, but actually dropped sharply – by as much as 35%.

History has a way of repeating itself:

**Pink Disease** - delayed onset of symptoms & 1/500 affected; symptoms included:

- pink hands, peeling pink hands, peeling skin, infections, irritability, poor muscle tone.
- GI problems – diarrhea, constipation, encephalitis, tremors/seizures, sound/light sensitivity, immune system dysregulation.

Does this remind you of anything???
Does heavy metal toxicity play a role in my child’s condition?

Food for thought:


Heavy Metal Detox:

- Reduce Exposures.
- Nutrients to support detox pathways, especially methylation, sulfation, and glutathione production.
- Natural Chelators.
- Synthetic Chelators.
Reduce Toxic Exposure:

- Avoid amalgam fillings.  [www.iaomt.org](http://www.iaomt.org)
  – Foundation for Toxic-Free Dentistry: 1-800-331-2303
  or  [www.bioprobe.com](http://www.bioprobe.com) ,  [www.altcorp.com](http://www.altcorp.com)

- Avoid Hg-containing fish.
- Drink purified water.
- Eat organic foods.
- Avoid hydrogenated fats.
Exercise and Attention

- Exercise Daily.
- Use “Rebounder” or mini-trampoline for 15 min. each morning.
- Consider movement, visual and/or auditory integration techniques.
Testing

**Functional Lab Testing:**

- CDSA (comprehensive digestive stool analysis) and Intestinal Permeability.
- Essential Fatty Acid Analysis.
- Amino Acid Analysis. Urinary Porphyrins.
- Hair Analysis and Chelation Challenge.
- Inhalant Allergies (End-Point Titration and Oral-Drop Desensitization).
- Try to avoid Methylphenidate. See [www.breggin.com](http://www.breggin.com) to read about the dangers of Methylphenidate.
Methylphenidate

- First available in 1957
- Methylphenidate (hydrochloride)
- Schedule II drug - Controlled Substances Act
- Can be addictive, enhance brain activity and increase alertness and energy.
- Elevates blood pressure, heart rate, and respiration.
- Very high doses can lead to irregular heartbeat and high body temperature.
Methylphenidate

“[Methylphenidate] is a mild central nervous system stimulant.

• The mode of action in man is not completely understood, but [Methylphenidate] presumably activates the brainstem arousal system and cortex to produce its stimulant effect.

• There is neither specific evidence which clearly establishes the mechanism whereby [Methylphenidate] produces its mental and behavioral effects in children, nor conclusive evidence regarding how these effects relate to the condition of the central nervous system.”

– Novartis Pharmaceuticals Corporation, East Hanover, NJ 07936 © 2001 Novartis.
Methylphenidate

“[Methylphenidate] should not be used in children under six years, since safety and efficacy in this age group have not been established.

Sufficient data on safety and efficacy of long-term use of [Methylphenidate] in children are not yet available.”

– Novartis Pharmaceuticals Corporation, East Hanover, NJ 07936 © 2001 Novartis.
ADHD Industry

- Morgan Stanley Dean Witter
  - ADHD “underdiagnosed”,
  - Predicted market to grow from $600 million to $1.4 billion in 2005.
    - Miller, Monica. [Methylphenidate] Goes to Court: Class Actions, Custody and Damages.

- [Methylphenidate] sales for nine months of 2007 were $271 million.
  - January 6, 2008
Methylphenidate

- Journal of American Medical Association study Methylphenidate and Clonidine use.
  - 200K children age 2-4 over five year period.
  - Patients in HMOs – 310% increase in Methylphenidate Rx.
  - Midwestern Medicaid – 300% increase.
  - Mid-Atlantic – 170% increase.
  - Midwestern – 28,200% increase in Clonidine (Rx with Methylphenidate increasingly).
Methylphenidate in Court

• Dawson et al. v. Ciba-Geigy et al.
  – Ciba-Geigy, now Novartis Pharmaceuticals
  – New Jersey class action suit seeking relief under Consumer Fraud Act.

• Alleges that Novartis conspired with American Psychological Association and “Children and Adults with ADHD” (CHADD) to boost Methylphenidate sales, since 1950s.
Methylphenidate in Court

- Alleges that CHADD received $748,000 from Ciba-Geigy from 1990-1994 alone.
- Alleges plan between APA and Novartis to create diagnoses of ADHD and to include these illnesses in the Diagnostic and Statistical Manual of Mental Disorders (DSM), and to encourage the overdiagnosis of these disorders to promote Methylphenidate as choice drug.
Methylphenidate and Custody

• Carroll family of NY
  – School reported parents to Child Protective Services when parents stopped giving Methylphenidate to son Kyle.
  – Kyle had become “withdrawn insomniac with no appetite” who had no improvements in reading level (cause for taking Methylphenidate).

• Miller, Monica. [Methylphenidate] Goes to Court: Class Actions, Custody and Damages.
Methylphenidate and Cardiac Risks

• Long-Term use of Methylphenidate may have caused 14 year old boy’s death.

• Matthew Smith of Pontiac, MI died of heart attack after 10 years of taking Methylphenidate.
Methylphenidate
FDA Label Warnings

The following have been reported with use of Methylphenidate and other stimulant medicines.

1. Heart-related problems:
   – sudden death in patients who have heart problems or heart defects
   – stroke and heart attack in adults
   – increased blood pressure and heart rate
2. Mental (Psychiatric) problems:

- **All Patients**
  - new or worse behavior & thought problems
  - new or worse bipolar illness
  - new or worse aggressive behavior or hostility

- **Children and Teenagers**
  - new psychotic symptoms (such as hearing voices, believing things that are not true, are suspicious) or new manic symptoms.

Methylphenidate FDA Label Warnings

- FDA alert - an animal study of Methylphenidate has produced a "weak signal" that the drug may have the potential to cause cancer.

The DEA regards Methylphenidate as a "drug of concern".

Abusers may dissolve the tablets in water and inject the mixture, producing a high similar to cocaine.

This can block small blood vessels and damage the lungs and retina of the eye.
Stimulants:

- Cocaine
  - $\text{C}_{17}\text{H}_{21}\text{NO}_4$

- Methylphenidate
  - $\text{C}_{14}\text{H}_{19}\text{NO}_2$
Methylphenidate more potent than Cocaine

• Cocaine blocks 50% dopamine receptors causing euphoria from dopamine build up in brain
  – Methylphenidate similar to cocaine in make-up, predicted by Volkow to have similar effects on the dopamine, but would block fewer dopamine transporters.

• Typical dose of 0.5 mg/kg given to children blocked 70% of dopamine transporters, more than cocaine. Researchers “shocked.”

• Methylphenidate takes more than one hour for its effect, not as addictive; use in childhood increases addiction to other substances more intense, later in life. Long-term effect on brain?
Methylphenidate versus Nutritional Supplementation

- Twenty children with attention deficit/hyperactivity disorder (AD/HD) were treated with either Methylphenidate (10 children) or dietary supplements (10 children) and tested for audio and visual performance and attention.

- Subjects in both groups showed significant gains for both tests administered.
The dietary supplements included vitamins, minerals, phytonutrients, amino acids, essential fatty acids, phospholipids, and probiotics.

“Findings support the effectiveness of food supplement treatment in improving attention and self-control in children with ADHD and suggest that food supplement treatment of ADHD may be of equal efficacy to Methylphenidate treatment.”
ADD-ADHD BioMedical Treatments:

**Nutritional:** Food Allergies, Additives, and Dietary Imbalances (Carbs, Protein, Fats).

**Deficiencies:** Vitamins, Minerals, Amino Acids, Essential Fatty Acids, Neurotransmitters (esp dopamine).

**Hormonal:** Thyroid, Adrenals, Testosterone.
ADD-ADHD BioMedical Treatments:

**Infection-Inflammation:** Gut Dysbiosis/ Candidiasis, chronic Strep, Lyme, Viruses (HSV, CMV, EBV, etc), atypicals (mycoplasma & chlamydia pneumo).

**Toxicities:** Lead, Mercury, Arsenic, Antimony, Solvents, Pesticides, etc.