Sense and Nonsense in the Treatment of ASD:
Protecting your child, and your pocketbook

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ASA-Manhattan Chapter
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Disclosures

- Dr. Coplan is author of Making Sense of Autistic Spectrum Disorders: Create the brightest future for your child with the best treatment options (Bantam-Dell, 2010), and receives royalties on its sale

- This presentation will include a discussion of off-label drug use

www.drcoplan.com

Outline

- Definition of Quackery
- The Natural History of ASD
- Debunking the autism epidemic
- A brief history of Quackery
- The Placebo Effect
- Let the buyer beware

Quackery

- Most quacks sincerely believe in what they are promoting
- Most quack remedies are unproven (rather than “known to be false”)
- Therefore….Quackery's paramount characteristic is promotion, rather than fraud, greed, or misinformation

Quackery - 1

“The promotion, for profit, of a medical remedy known to be false or unproven”  
(FDA)

http://www.quackwatch.org/01QuackeryRelatedTopics/quackdef.html

Quackery - 2

http://www.quackwatch.org/01QuackeryRelatedTopics/quackdef.html
Promotional Techniques

- Create a demand
- Deliver the pitch
- Close the sale
  - Modern advertising originated with 19th Century “patent medicines”
  - Safe & Effective!
  - Satisfaction guaranteed!

Creating a demand
(An autism epidemic: What a wonderful thing it would be)

- If there were an epidemic
  - There would be a specific cause
  - There would be somebody to blame
  - There would be preventive or curative measures

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Natural History: “The temporal course a disease from onset to resolution”
Center for Disease Control & Prevention

ASD has a Natural History

Kanner, 1938 → 1943

“Between the ages of 5 and 6 years, they gradually abandon echolalia and learn spontaneously to use personal pronouns.

“Language becomes more communicative, at the sense of a question-and-answer exercise, and then in the sense of greater spontaneity of sentence formation....”

Kanner, L. Autistic Disturbances of Affective Contact, Nervous Child, (2) 217-250, 1943

www.drcoplan.com
Kanner, 1938 → 1943
“Food is accepted without difficulty. Noises and motions are tolerated more than previously. The panic tantrums subside. The repetitiousness assumes the form of obsessive preoccupations...

Kanner, L. Autistic Disturbances of Affective Contact. Nervous Child, (2) 217-250, 1943

www.drcoplan.com

Kanner, 1938 → 1943
“Reading skill is acquired quickly, but the children read monotonously, and a story or a moving picture is experienced in unrelated portions rather than in its coherent totality...*  

* “Central coherence”  
Kanner, L. Autistic Disturbances of Affective Contact. Nervous Child, (2) 217-250, 1943

www.drcoplan.com

Kanner, 1938 → 1943
“Between the ages of 6 and 8, the children begin to play in a group, still never with the other members of the group, but at least on the periphery alongside the group.

Kanner, L. Autistic Disturbances of Affective Contact. Nervous Child, (2) 217-250, 1943

www.drcoplan.com

Kanner, 1938 → 1943
“People are included in the child’s world to the extent to which they satisfy his needs...

Kanner, L. Autistic Disturbances of Affective Contact. Nervous Child, (2) 217-250, 1943

www.drcoplan.com

Over time, the ice melts

Kanner, L. Autistic Disturbances of Affective Contact. Nervous Child, (2) 217-250, 1943

www.drcoplan.com

All of this makes the family feel that, in spite of recognized ‘difference’ from other children, there is progress and improvement.  

Leo Kanner, 1943

www.drcoplan.com
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DEFINITIONS

- Incidence:
  - Rate of occurrence of new cases per unit time:
    - # of new cases of flu / 1000 persons / week
      - Epidemic = Incidence
    - # of new cases / 1000 children / year =
      - # of newborns / 1000 / year with ASD +
      - # of cases of autistic regression / 1000 / year
  - The incidence of ASD is unknown

DEFINITIONS

- Prevalence:
  - % of population affected at a moment in time:
    - Prevalence of left-handedness = 10%
    - “Explosion” ~ Used loosely for Prevalence
  - Prevalence of children with a Dx of ASD:
    - 1950’s: 2-4/10,000
    - 2010: ~100/1,000 (i.e., about 1%)
  - But
    - We are not sure whether actual prevalence has changed
    - Incidence cannot be determined from prevalence

You cannot get a speeding ticket for having a full tank of gas.

Scientific Illiteracy

“Worldwide Pandemic of Autism”
http://www.americanchronicle.com/articles/view/125995
New Research Hope for US Autism Families - 1 in 100 US Kids Affected
Clifford G. Miller
October 28, 2009

Little notice was taken in 2006 when Dr Francis S. Collins MD PhD’s unequivocal evidence to the US House of Representatives should have resolved a controversy raging for two decades over the causes of the worldwide pandemic of autism in children. (FALSE)
11.3 cases / 1000 children = 1 in 88

Known causes of \( \uparrow \) prevalence of children with a Dx of ASD

- Broadening diagnostic criteria
- Broadening Federal service & reporting requirements
- Diagnostic substitution
- Broadening ascertainment methods

<table>
<thead>
<tr>
<th>DSM Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>1980: DSM III</td>
</tr>
<tr>
<td>- Infantile Autism</td>
</tr>
<tr>
<td>- Autism, Residual State</td>
</tr>
<tr>
<td>6 mandatory, severe, criteria, including:</td>
</tr>
<tr>
<td>- Pervasive lack of responsiveness to other people</td>
</tr>
<tr>
<td>- Gross deficits in language development</td>
</tr>
<tr>
<td>- Bizarre responses to the environment</td>
</tr>
<tr>
<td>1987: DSM-III-R</td>
</tr>
<tr>
<td>- &quot;Infantile autism&quot; replaced by &quot;Autistic Disorder&quot;</td>
</tr>
<tr>
<td>- &quot;Autism-Residual State&quot; replaced by PDD-NOS</td>
</tr>
<tr>
<td>PDD-NOS includes children who never met full criteria for Autism (as well as children who once met full criteria but improved over time).</td>
</tr>
<tr>
<td>1994: DSM-IV</td>
</tr>
<tr>
<td>- Asperger's Disorder</td>
</tr>
<tr>
<td>Menu for Dx: 6 of 16 milder criteria, incl:</td>
</tr>
<tr>
<td>- Lack of spontaneous seeking to share achievements with others</td>
</tr>
<tr>
<td>- Difficulty sustaining a conversation</td>
</tr>
<tr>
<td>- Lack of varied social imitative play</td>
</tr>
</tbody>
</table>
Known causes of \( \uparrow \) prevalence of children with a Dx of ASD

- Broadening diagnostic criteria
- Broadening Federal service & reporting requirements
- Diagnostic substitution
- Broadening ascertainment methods

Changes in Federal Law - 1

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1975</td>
<td>Congress enacts Public Law 94-142: Education for All Handicapped Children (EAHC)</td>
<td>First Federal law requiring the States to provide free and appropriate public education (FAPE) to “all children &gt;5 yrs old, regardless of disability”</td>
</tr>
</tbody>
</table>

But……

“Handicapping Conditions” (PL 94-142; 1975)

- Mentally Retarded
- Learning Disabled
- Speech impaired
- Hearing / Vision Impaired
- Seriously emotionally disturbed
- Orthopedically impaired
- Multi-handicapped
- Other health impaired

Where is autism?

Changes in Federal Law - 2

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1990</td>
<td>PL 99-457: Early Intervention Amendments to PL 94-142</td>
<td>Extends FAPE to children age 3-5, mandated to take effect by 1991 (Section 619, Part B) Creates Early Intervention for children 0-3 (Section 619, Part H).</td>
</tr>
</tbody>
</table>

Where is autism?
Changes in Federal Law - 3

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1990</td>
<td>Congress Amends PL 94-142 again (PL101-476)</td>
<td>• Renamed <em>Individuals with Disabilities Education Act</em> (IDEA)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Includes Autism &amp; Traumatic Brain Injury (TBI) as &quot;eligible disabilities&quot; under the scope of the law</td>
</tr>
</tbody>
</table>

Prior to 1990, according to Federal regulations, *Autism did not exist.*

Changes in Federal Law - 4

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1991</td>
<td>US Department of Education, Office of Special Education Programs (OSEP) requires reporting of autism by the States, starting in 1992.</td>
<td>• Coincides with implementation of Part B (3 to 5 yr olds) &amp; Part H (birth to 3) of PL 99-457</td>
</tr>
</tbody>
</table>

Known causes of ♦ prevalence of children with a Dx of ASD

• Expanding diagnostic criteria
• Federal service & reporting requirements
• Diagnostic substitution
➢ Changes in ascertainment methods

Prevalence of Diagnosed ASD, 1965 – 2005

Ascertainment Methods for ASD

• Old: Count already-identified cases
  – School data
  – Medical clinics
• New: Search for unrecognized cases
  – Siblings of probands*
  – Population Screening
    • Children
    • Adults

* Proband = the 1st member of a family to be diagnosed; the "index case"


11 of 100 “non-ASD” brothers of ASD probands met criteria for ASD on the Social Responsiveness Scale

11.3 cases / 1000 children = 1 in 88

CDC Prevalence Estimates for ASD, 2008

- Autism and Developmental Disabilities Monitoring Network (ADDM)
  - 14 Sites (Universities, State Dept of health; not demographically representative of the US as a whole)
- Data sources:
  - Healthcare organizations (general & specialty)
  - Schools (some sites)
- N = 337,093 children, age 8
- 3,820 met surveillance case criteria for ASD
  - 79% had a pre-existing Dx of ASD in their records
  - 21% had no ASD Dx in their records

http://www.cdc.gov/mmwr/preview/mmwrhtml/ss6103a1.htm?s_cid=ss6103a1_w

IQ breakdown for children meeting criteria for ASD (CDC, 2000, 2002, 2008)

Prevalence (cases per 1000 children, age 8)

<table>
<thead>
<tr>
<th>AddM Site</th>
<th>Prevalence (cases / 1000 children, age 8)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>11.3 cases / 1000 children = 1 in 88</td>
</tr>
</tbody>
</table>

CDC Prevalence Estimates for ASD (2008)

Prevalence (cases per 1000 children, and Prevalence Ratios)

<table>
<thead>
<tr>
<th>White</th>
<th>Black</th>
<th>Hispanic</th>
<th>W:B</th>
<th>W:H</th>
<th>B:H</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>12.0</td>
<td>10.2</td>
<td>7.9</td>
<td>1.2 : 1</td>
<td>1.5 : 1</td>
</tr>
<tr>
<td>Range</td>
<td>5.0 – 40.0</td>
<td>4.0 – 25.9</td>
<td>1.4 – 20.0</td>
<td>1.0 – 1.9 : 1</td>
<td>0.6 – 3.5 : 1</td>
</tr>
</tbody>
</table>

http://www.cdc.gov/mmwr/preview/mmwrhtml/ss6103a1.htm?s_cid=ss6103a1_w
CDC Data

- Internal variability
  - Overall prevalence
  - Ethnic ratios
  - IQ distribution (proportion with IQ > 70)
- 21% of CDC “cases” had no mention of ASD in their records. What does this mean?
- Need for random sampling with testing, rather than relying on secondary source information

The spatial structure of autism in California, 1993–2001

Health & Place
Volume 16, Issue 3, May 2010, Pages 539-546
Soumya Mazumdar, Marissa King, Ka-Yuet Liu, Noam Zerubavel and Peter Bearman
Institute for Social and Economic Research and Policy
Columbia University, New York, NY, USA

“Hot Spots”
- Increased risk of having a child with Autism, compared to state-wide average

Adjusted autism risk = 4x State-wide average

Population Screening: Where have all the adults gone?

“Since 1% of adults don’t have ASD, doesn’t that prove we’re in an epidemic?”

Socioeconomic Inequality in the Prevalence of Autism Spectrum Disorder: Evidence from a U.S. Cross-Sectional Study
Durkin MS, Maenner MJ, Meaney FJ, et al.

Prevalence increased with increasing SES* in a dose-response manner, with prevalence ratios relative to medium SES of 0.70 for low SES, and of 1.25 for high SES, (P<0.001).

*SES: Socioeconomic status (income, education)
Ascertainment of adults with ASD

- There is no agency tracking developmental data on adults
  - Census Bureau?
  - Social Security?
  - Selective Service?
  - IRS?

Interactive Autism Network On-Line Survey

THE MISSING MIDDLE

As we have examined our data, and spoken with adults with ASD and their families, we have begun to suspect that there is one large group currently missing from participation in the IAN Research project: adults who are not under guardianship but who nevertheless need assistance...in between the very high functioning independent adults, many with Asperger's...and individuals under guardianship.

These individuals are legal adults, who must decide whether to consent to participate in research for themselves. If a person with ASD who is not under guardianship says "I don't..." the answer is "no."

“Missing” adults: The NHS Survey

NHS Survey 2007

- National, random sample of survey of adults living independently in the community
- Excludes persons in institutional settings
  - Group Homes, Hospitals, Mental Health Facilities, Residential Centers, Prisons, etc
- Therefore, under-counts adults with disability

Prevalence of ASD (ADOS 10+), by age

<table>
<thead>
<tr>
<th>All adults</th>
<th>2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age group</td>
<td></td>
</tr>
<tr>
<td>16-44</td>
<td></td>
</tr>
<tr>
<td>45-74</td>
<td></td>
</tr>
<tr>
<td>75+</td>
<td></td>
</tr>
</tbody>
</table>

Overall prevalence of ASD: 1%
- Males: 1.8% (1 in 56)
- Females: 0.2% (1 in 500)
Population screening suggests that the prevalence of ASD among today’s senior citizens is identical to the prevalence among today’s children.

If true:
Not only is there no epidemic –
There has not even been an “explosion”

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- Definition of Quackery
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**Promotional Techniques**
- Create a demand
  - Deliver the pitch
- Close the sale

**Quack Therapies: The Pitch**
- Simple yet mysterious
- All-powerful, yet safe
- Able to cure multiple conditions
- Supported by Testimonials
- Thrive as the underdog: persecuted by, or challenger to, standard medical practice
Simple yet Mysterious

Over and over again, throughout the history of patent medicines, promoters have pierced through the darkness yet enshrouding illness and come up with the perfect remedy. They have done so, often, by conceiving a completely new theory of disease, a monistic theory with a one-shot therapy, and the panacea is the medicine advertised.

The Toadstool Millionaires: A Social History of Patent Medicines in America before Federal Regulation

James Harvey Young, PhD

http://www.quackwatch.org/13Hx/TM/11.html

Simple, yet Mysterious

- The “Back to Nature” approach
  - Herbal & biological concoctions / “All Natural”
  - The restorative power of mother nature

- The “High Tech” approach
  - Scientific-sounding jargon / “Gee whiz”
  - Methods shadowed legitimate science
    - Magnetism: 1850s-70s
    - Electricity 1880s-1900
    - Radioactivity 1900-30
    - Radio waves 1930-50
    - Biochemistry
    - Stem cells

http://www.collectmedicalantiques.com/quack5.html

Terms for Office Treatment - Payable in advance - Six Visits for $10, Twelve for $20, Eighteen for $30, Twenty-four for $40, Thirty for $50, for each Disease, as the Doctor thinks the case may require

Magnetism

FOR THE SAFE, SURE AND NATURAL TREATMENT OF DISEASES, WEAKNESSES and INFIRMITIES without the use of Poisonous Drugs and Painful Surgery. Late from Paris, London, Liverpool, Dublin, and Cork, has taken Office

Circa 1860

http://www.collectmedicalantiques.com/quack2.html

CURES WITHOUT MEDICINES. DR. DARRIN, NATURAL PATHIC PHYSICIAN

FOR THE SAFE, SURE AND NATURAL TREATMENT OF DISEASES, WEAKNESSES and INFIRMITIES without the use of Poisonous Drugs and Painful Surgery. Late from Paris, London, Liverpool, Dublin, and Cork, has taken Office

Circa 1860
FOR NERVOUS DISEASES of all kinds, impotency, rheumatism, sciatica, lame back, railroad back, insomnia, melancholia, kidney disorder, Bright's disease, disorders of the liver, female weakness, poor circulation, weak heart action and almost every known disease and weakness.

Electricity

The Heidelberg Alternating Current Electric BELT Circa 1900

FLASH GORDON
Original Medium: Newspaper comic
Distributed by: King Features Syndicate
First Appearance 1934
Creator: Alex Raymond

The mioxrls Electric Belt, circa 1920

OXYGEN

Claimed to cure virtually all diseases by forcing oxygen into the body. Proponents of Dr. Sanche’s theory of “Diaduction” went by the name The Fraternity of Duxanimae

“Violet Ray Generators” Ozone (O₃)

• 1915 – 1950
• Ozone = key ingredient in smog

“Relieves feelings of melancholy, stimulates circulation, treats rheumatic pain, nervous disorders, lumbago, neuritis, calms the nerves, effective in the treatment of cystitis and gonorrhea, stimulates the blood to increase beauty and health, removes facial blemishes, aids in the removal of dandruff and prevents hair loss”
“Many members of the medical profession believe that Dr. Bailey’s method for the treating of insanity will be the means of freeing many asylum inmates.”

Radioactivity

RadiThor Drops: Radium + Thorium

“Radithor vial from a curio shop was still dangerously radioactive, 70 years after its original purchaser had nearly drained it.”

Revigator: Re-Envigorate your tired tap water with RADIUM

“Cures high blood pressure, cancer, goiter, stomach trouble, arthritis, neuritis, female trouble, rheumatism, kidney trouble, constipation, eczema, piles, and more!”

Quack Therapies: The Pitch

- Simple yet mysterious
- All-powerful, yet safe
- Able to cure multiple conditions
- Supported by Testimonials
- Thrive as the underdog: persecuted by, or challenger to, standard medical practice
Dr. Scott’s Electric Flesh Brush  
~ 1880 - 1910

- DIRECTIONS: The brush may be used daily. It always does good; cannot harm.

Eben Byers – RadioThor Victim

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Target Conditions

- Severe, Chronic & Untreatable
  - TB ("The Captain of Death")
  - Cancer
  - Heart Disease
- OR
- Strong Psychological Component
  - Depression
  - Pain
  - Impotence
Quack Therapies: The Pitch

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Testimonials

- While many of the printed testimonials are genuine enough, they represent not the average evidence, but the most glowing opinions which the nostrum vender can obtain.

Testimonials & Placebo Effect

*They see my advertising. They read the testimonials. They are convinced. They have faith…..and so they get well.*

There it is in a nutshell; the faith cure...The faith inspired by the advertisement ... does the work - or seems to do it. If the public druggist can convince his patron that she is well, she is well - for his purposes.
Quack Therapies: The Pitch

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Patent Medicine as the Underdog

- “It is pardonable in you to want to know these formulas, for they are good. But you must not ask us to reveal these valuable secrets, to do what you would not do yourselves.”

W.A. Talbot, owner of Piso’s Consumption Cure, and president of the Proprietary Medicine Association, speaking out against the AMA’s support of pure food and drug legislation, 1905

The Great American Fraud; Samuel H. Adams, Colliers, 1905

Complementary and Alternative Medicine in ASD

“déjà vu all over again”

CAM for ASD

- Highly promoted
  ➢ Simple, yet mysterious
  ➢ Powerful, yet safe
  ➢ Treats multiple causes of ASD
  ➢ Supported almost entirely by testimonials
  ➢ The underdog - oppressed by conventional medicine

Simple yet mysterious

- Back to Nature
  ➢ Dietary supplementation / restriction
    ➢ Megavitamins / Other supplements
    ➢ Gluten Free / Casein Free diet
  ➢ Chiropractic
  ➢ Homeopathy
  ➢ Antifungal therapy
  ➢ Refusal of immunizations
- High Tech
  ➢ Therapeutic listening
  ➢ Secretin
  ➢ Chelation
  ➢ Hyperbaric Oxygen
Individuals with autistic spectrum disorders and with other neurological or autoimmune conditions often have leaky gut syndrome and immune deficiencies. Colostrum is an amazing immune system enhancer which has had specific results in healing the compromised intestinal lining of the leaky gut. Food allergies and sensitivities disappear, often permanently, and research shows that colostrum provides an immune function that can act like a natural mini "immunization process", protecting the body from the multitudes of unwanted infectious diseases.

http://www.clayforautism.com/supplementsforchildren.html

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Deaths from mineral imbalance
- Chelation
- Hyperoxia
- ?Omega-3 Fatty Acids

Fatal hypermagnesemia in a child treated with megavitamin / megamineral therapy

Chelation

Deaths Associated with Hypocalcemia from Chelation Therapy --- Texas, Pennsylvania, and Oregon, 2003--2005
Chelation

Chelation with succimer reduces error rate in lead-exposed rats:

Succimer Chelation Improves Learning, Attention, and Arousal Regulation in Lead-Exposed Rats but Produces Lasting Cognitive Impairment in the Absence of Lead Exposure

Diane R. Stangle, Donald R. Smith, Phyllis A. Bousin, Myriam S. Strubesdorfer, Donald A. Leichty, and Rodney J. Brown

Department of Psychology, Cornell University, Ithaca, New York, USA. Department of Environmental Toxiology, University of California, Santa Cruz, California, USA. Division of Nutritional Sciences, Cornell University, Ithaca, New York, USA.

but impairs learning in rats not exposed to lead

Succimer itself is capable of causing cognitive impairment

Omega-3 Fatty Acids

Omega-3 Fatty Acid supplementation reduces time to first seizure in normal controls

Chelation with succimer reduces error rate in lead-exposed rats:

but impairs learning in rats not exposed to lead

Omega-3 Fatty Acids

Chronic omega-3 supplementation in seizure-prone versus seizure-resistant rat strains: a cautionary tale

Gilby K, Jans J, & McIntyre D. Neuroscience v163, #3, 20 October 2009, p 750-758

Subjects:

• “Fast” rats
  • Rapid induction of seizures via electrical stimulation to the brain (“kindling”)
  • Behaviors reminiscent of ADHD (hyperactivity) / ASD (repetitive grooming) / poor learning ability
• “Slow” Controls (~ “normal subjects”)

Omega-3 Fatty Acids

Chronic omega-3 supplementation in seizure-prone versus seizure-resistant rat strains: a cautionary tale

Gilby K, Jans J, & McIntyre D. Neuroscience v163, #3, 20 October 2009, p 750-758

Omega-3 supplementation:

• Fast rats
  • ↑ Impulsivity
  • No reduction in risk of seizures
• Normal controls
  • ↑ risk of seizures

Redrawn from Gilby, Jans, & McIntyre 2009
Omega-3 Fatty Acids

“Individual responses to omega-3 supplementation...were highly specific to the animals’ genetic background. Consequently, caution is encouraged when treatment strategies are considered for the broad spectrum of disorders linked to EFA deficiencies.....omega-3 supplementation on its own is not the silver bullet.”

Gilby, Jans , & McIntyre 2009

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Oxidation - 1

![Diagram of Oxidation - 1]

* ROS = Reactive Oxygen Species

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Oxidation - 2

![Diagram of Oxidation - 2]

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Memory loss following Hyperoxia in rats

- Maze-learning task before & after exposure to hyperoxia
- Maze-learning was impaired after oxidative stress
- None of the rats recovered their learning ability


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Memory Loss following Hyperoxia in rats

![Graph of Memory Loss following Hyperoxia in rats]

Hyperoxia → Brain Cell Death

3. Hyperoxic exposure leads to nitrative stress and ensuing microvascular degeneration and diminished brain mass and function in the immature subject. Stroke, 2006
5. Hyperoxia causes maturation-dependent cell death in the developing white matter. Journal of Neuroscience 2008

CAM for ASD

- Highly promoted
- Simple, yet mysterious
- Powerful, yet safe (claimed)
- Treats multiple causes of ASD
- Supported almost entirely by testimonials
- The underdog - oppressed by conventional medicine

Any Questions?
“Autism is now understood as a multi-functional disorder that may, among other things, involve:

• Heavy metal damage to brain cells
• Autoimmune damage to the brain cells
• Intestinal inflammation
• Persistent yeast, viral and bacterial infections
• Cellular energy processing dysfunction (Kreb Cycle dysfunction)

All these processes can be helped by increasing oxygen flow to the tissues and cells in the brain as well as in the guts. This is where the Hyperbaric Oxygen Chamber comes in…."


CAM for ASD

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HBOT

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All these processes can be helped by increasing oxygen flow to the tissues and cells in the brain as well as in the guts. This is where the Hyperbaric Oxygen Chamber comes in…."


Testimonials

"My son Jakob, started to talk after only ONE of your clay baths. We could not believe how much these baths changed our lives. Meryl D. (Florida)

My son use to only grunt and yell and scream in communication... After a few months of your baths he started talking... He is set to start kindergarten next year and his preschool teachers say he is going to be just fine. I want to thank you for being there when we needed you. I tell all my friends about you." Jodie M. (Nevada, MO)

After TWO baths of LL’s Magnetic Clay, my daughter started talking... Thank you so much for giving me my daughter back!" Lisa N. (Sacramento, CA)

Show me the evidence

• Chance observations are not evidence
  ➢ Secretin
• Coincidence is not evidence
  ➢ Umbrellas do not cause rain
• Testimonials are not evidence
  ➢ The plural of “anecdote” is not “data”
• Even sworn testimony is not evidence, in the scientific sense
### Show me the evidence

- Evidence = Observations or measurements that have been gathered by standardized, repeatable methods, to determine the validity of a hypothesis
  - Animal models
  - Case-control studies
  - Randomized controlled trials

### Randomized Controlled Trials (RCTs)

- What do controlled trials control?
  - Improvement due to the natural history of the disorder, irrespective of treatment
  - Subject selection bias
  - Expectation effects (placebo, nocebo)

### Subject selection bias

- Experimental Group & Control subjects must be similar on all relevant variables
  - Age
  - Gender
  - Socioeconomic Status
  - Other (IQ, general health status)
  - Willingness to be randomized

### Outline

- Definition of Quackery
- The Natural History of ASD
- Debunking the autism epidemic
- A brief history of Quackery
- The Placebo Effect
- Let the buyer beware
Expectation Bias - 1

• *We see what we expect to see*

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Expectation Bias – 1
(We see what we expect to see)

• Placebo effect: Perceived improvement in the absence of active treatment
  – Reported improvement on dummy pills
• Nocebo effect: Perceived deterioration in the absence of active treatment
  – Reported “side effects” on dummy pills

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Expectation Bias – 2
(If you wish it hard enough, it is no dream)

• Pygmalion Effect
  – aka Rosenthal Effect; Teacher Expectation effect
• Randomly selected students were labeled “exceptionally bright”
• “Bright” students’ scores rose on objective measures, compared to controls
• Moral: If you believe in a therapy strongly enough, your belief alone is enough to create objective change

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Pygmalion and Galatea by Jean-Leon Gerome (1824-1904)
Expectation Bias - 3

To minimize expectation bias:
• Random assignment to treatment group
• Blinding to group assignment
  – Of the subject (or parents)
  – Of the experimenter
  – Of the person who assesses outcome
• “Sham Treatment” (placebo arm)
  – Sham therapy resembling actual therapy
    • “Sugar pills”
    • Even sham surgical procedures!

Double-Blind, placebo controlled RCTs:

• Chelation: None
• Gluten: None
• Yeast: None
• Megavitamins / Minerals: None

Omega-3 Fatty Acids


• 6 wk double-blind RCT
• N = 13 (5 - 17 yrs); ASD + severe behavior d/o
• 1.5 g/d omega-3 fatty acids supplementation
• Aberrant Behavior Checklist (ABC) at 6 weeks
• Omega-3 FA grp: hyperactivity & stereotypy

Therapeutic listening

• Bettison
  – Treatment group improved
  – Sham-treatment control group improved by exactly the same amount
• 3 other controlled studies: No consistent benefit, and in one case, treatment group did less well than controls

Randomized Controlled Trials

• HBOT
  – Rossignol 2009
    • Poor methodology
    • Inconsistent findings (benefits seen in 5 of 29 behavioral measures (inconsistent results: improvement on eye contact on one measure, but not social awareness or social interaction on another)
  – CARD 2009: No effects seen with HBOT

CAM for ASD

• Highly promoted
• Simple, yet mysterious
• Powerful, yet safe (claimed)
• Treats multiple causes of ASD
• Supported almost entirely by testimonials
  ➢ The underdog - oppressed by conventional medicine
The Underdog

______ M.D., has been accused by the New York State Board for the Office of Professional Medical Conduct... of "gross negligence and incompetence." ... And what are Dr. ____’s sins? She keeps people out of hospitals and uses injections of vitamins and chelation therapy.....

Dr. ____ is not the only fine physician under attack in the U.S. There exists a campaign to deny Americans access to complementary and alternative medicine....

Politics of Medicine: Another Attack on Alternative Medicine

Exposed: Wikipedia Holds Bias against Natural Health

10/5/2010 - Wikipedia entries for alternative and natural medicine... consistently have severe censorship, misinformation, and vandalism. Since Wikipedia is an extremely popular reference site on the internet with over 16 million articles this bias towards conventional medicine negatively affects the accessibility of accurate natural health information....

http://www.naturalnews.com/alternative_medicine.html

Outline

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Stay Calm

- Beware of allegations of cause or claims of cure that rest on the premise of an autism “epidemic”
  - No one knows the incidence of ASD
  - The prevalence of diagnosed cases in children has risen, but even that may be attributable to changing diagnostic criteria and methods
  - NHS study suggests that the true prevalence of ASD has not changed in 50 years

Recognize the Pitch

- Simple, yet mysterious
- Powerful, yet perfectly safe
- Treats multiple causes of ASD
- Supported almost entirely by testimonials
- The underdog - oppressed by conventional medicine
Show me the data

- Epidemiologic evidence & animal models to confirm causation
- Randomized Controlled Trials to demonstrate safety & efficacy
  - Parents need to demand, and then be willing to enroll their children, in RCTs

Follow the money

- Who else is advocating a particular therapy, other than
  - parents who have already spent money it, and
  - vendors who make their livelihood providing it?

Thank you!