

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

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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



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

- 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

<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 Demand for Prescription Drugs: A Content Analysis of Television Direct-to-Consumer Advertising
<http://www.annfammed.org/content/5/1/6.full>

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*

www.drcoplan.com

The NERVOUS CHILD

Quarterly Journal of Psychopathology, Psychotherapy,
Mental Hygiene, and Guidance of the Child

AUTISTIC DISTURBANCES OF AFFECTIVE CONTACT

By LEO KANNER

SINCE 1938, there have come to our attention a number of children whose condition differs so markedly and uniquely from anything reported so far, that each case merits—and, I hope, will eventually receive—a detailed consideration of its fascinating peculiarities.

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

www.drcoplan.com

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 first in 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.drconplan.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.drconplan.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.drconplan.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.drconplan.com

Kanner, 1938 → 1943

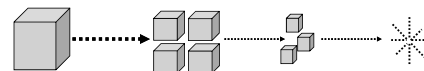
All of this makes the family feel that, in spite of recognized ‘difference’ from other children, there is progress and improvement.

Leo Kanner, 1943

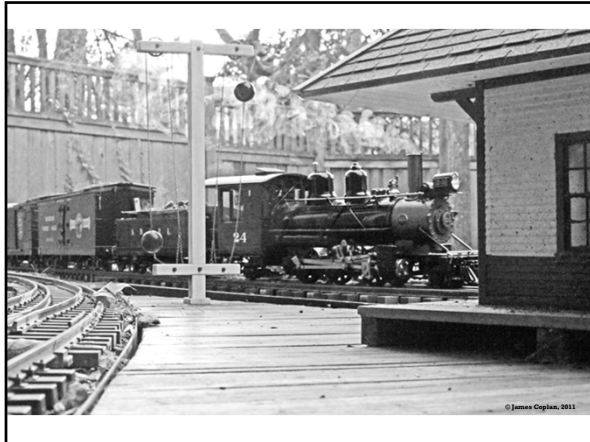
Kanner, L. Autistic Disturbances of Affective Contact. Nervous Child, (2) 217-250, 1943

www.drconplan.com

Over time, the ice melts



www.drconplan.com



Outline

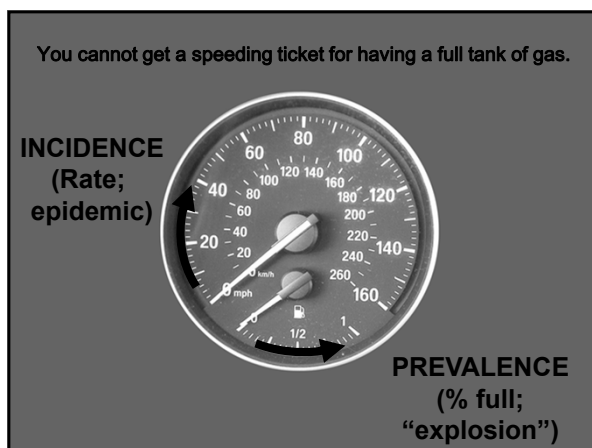
- Definition of Quackery
- The Natural History of ASD
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- The Placebo Effect
- Let the buyer beware

DEFINITIONS

- **Incidence:**
 - Rate of occurrence of new cases per unit time:
 - # of new cases of flu / 1000 persons / week
 - Epidemic = ↑ Incidence
- **Incidence of ASD =**
 - # 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*

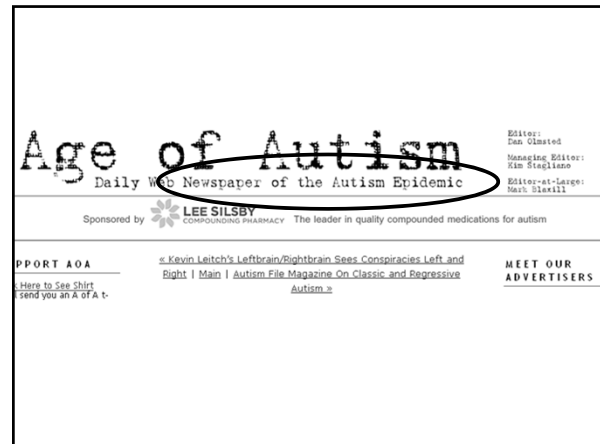
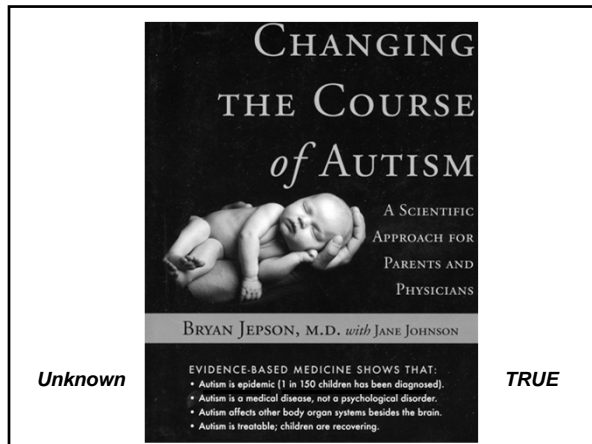


Scientific Illiteracy

“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**)



Centers for Disease Control and Prevention

MMWR

Morbidity and Mortality Weekly Report

Surveillance Summaries / Vol. 61 / No. 3

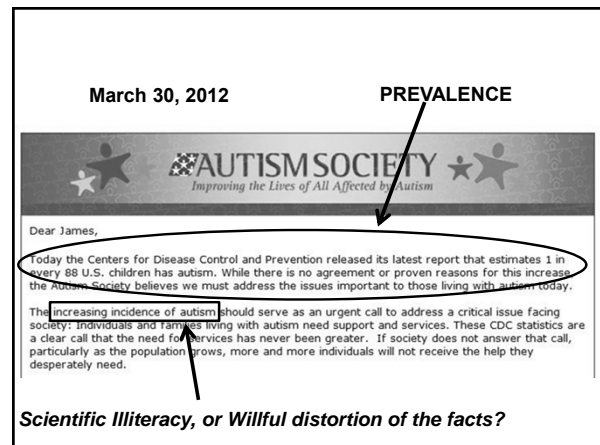
March 30, 2012

Prevalence of Autism Spectrum Disorders — Autism and Developmental Disabilities Monitoring Network, 14 Sites, United States, 2008

TABLE 2. Estimated prevalence* of autism spectrum disorders (ASDs) per 1,000 children aged 8 years, by sex and race/ethnicity — Autism and Developmental Disabilities Monitoring Network, 14 sites, United States, 2008

Site	Total no.	Total no. with ASDs	Sex						Male-to-female prev ratio [‡]
			Total [†]		Male		Female		
			Prev	95% CI	Prev	95% CI	Prev	95% CI	
Total	337,093	3,820	11.3	(11.0–11.7)	18.4	(17.7–19.0)	4.0	(3.7–4.3)	4.6

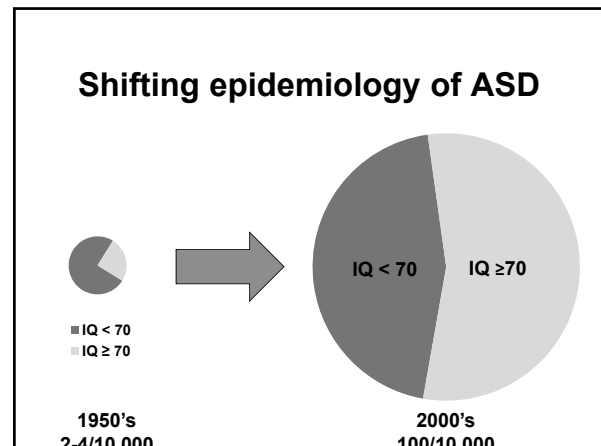
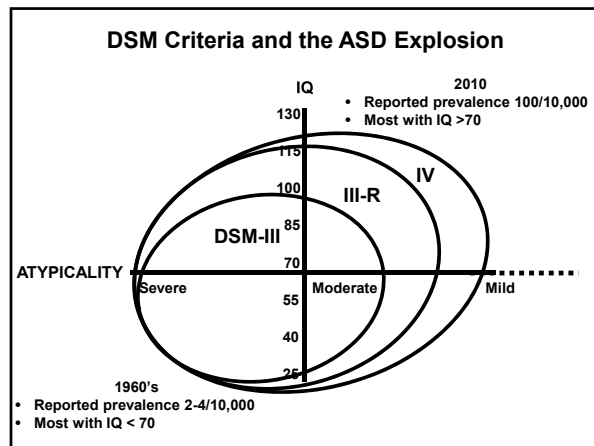
11.3 cases / 1000 children = 1 in 88



- Known causes of ↑ prevalence of children with a Dx of ASD**
(without invoking an increase in incidence)
- Broadening diagnostic criteria
 - Broadening Federal service & reporting requirements
 - Diagnostic substitution
 - Broadening ascertainment methods

DSM Criteria

1980: DSM III <ul style="list-style-type: none"> • Infantile Autism • Autism, Residual State 	6 mandatory, severe, criteria, including: <ul style="list-style-type: none"> • Pervasive lack of responsiveness to other people • Gross deficits in language developmt • Bizarre responses to the environment
1987: DSM-III-R <ul style="list-style-type: none"> • "Infantile autism" replaced by "Autistic Disorder" • "Autism-Residual State" replaced by PDD-NOS 	PDD-NOS includes children who never met full criteria for Autism (as well as children who once met full criteria but improved over time).
1994: DSM-IV <ul style="list-style-type: none"> • Asperger's Disorder 	Menu for Dx: 6 of 16 milder criteria, incl: <ul style="list-style-type: none"> • Lack of spontaneous seeking to share achievements with others • Difficulty sustaining a conversation • Lack of varied social imitative play



Known causes of ↑ 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

Year	Event	Comment
1975	Congress enacts Public Law 94-142: Education for All Handicapped Children (EAHC)	First Federal law requiring the States to provide free and appropriate public education (FAPE) to "all children >5 yrs old, regardless of disability"

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

Year	Event	Comment
1986	PL 99-457: Early Intervention Amendments to PL 94-142	<ul style="list-style-type: none"> •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).

Where is autism?

Changes in Federal Law - 3

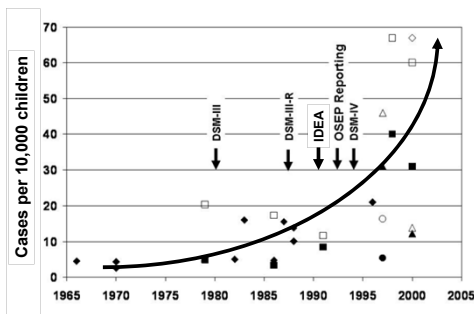
Year	Event	Comment
1990	Congress Amends PL 94-142 again (PL101-476)	<ul style="list-style-type: none"> •Renamed <i>Individuals with Disabilities Education Act</i> (IDEA) •Includes Autism & Traumatic Brain Injury (TBI) as “eligible disabilities” under the scope of the law

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

Changes in Federal Law - 4

Year	Event	Comment
1991	US Department of Education, Office of Special Education Programs (OSEP) requires reporting of autism by the States, starting in 1992.	<ul style="list-style-type: none"> • Coincides with implementation of Part B (3 to 5 yr olds) & Part H (birth to 3) of PL 99-457

Prevalence of Diagnosed ASD, 1965 – 2005



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

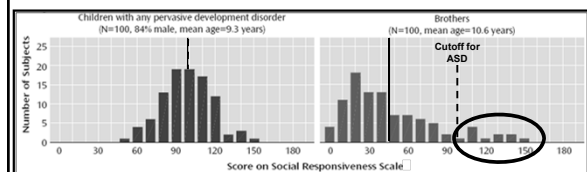
- Expanding diagnostic criteria
- Federal service & reporting requirements
- Diagnostic substitution
- Changes in ascertainment methods

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

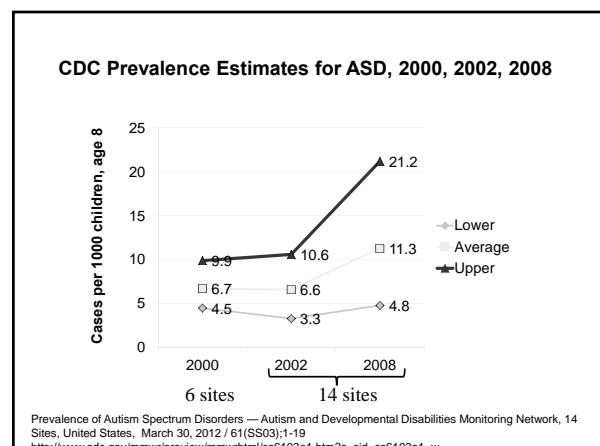
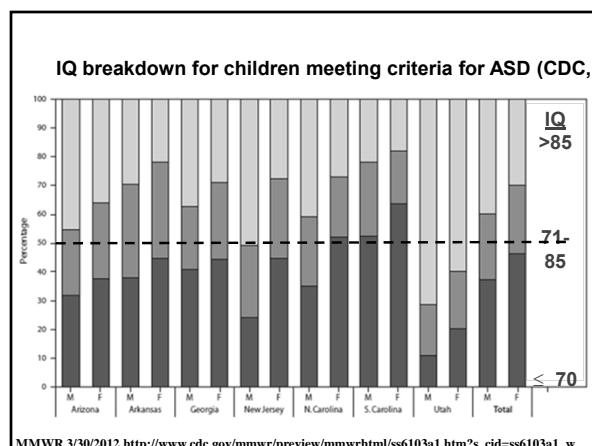
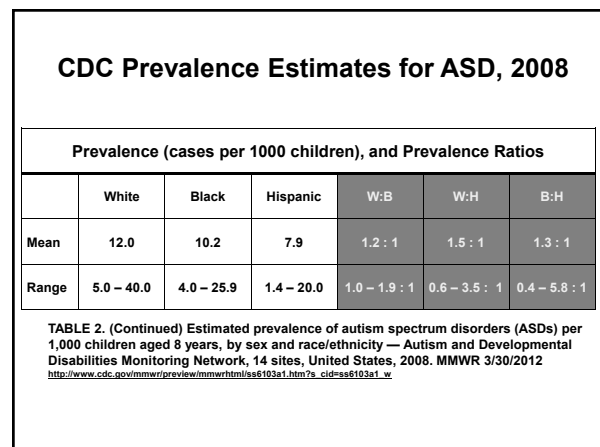
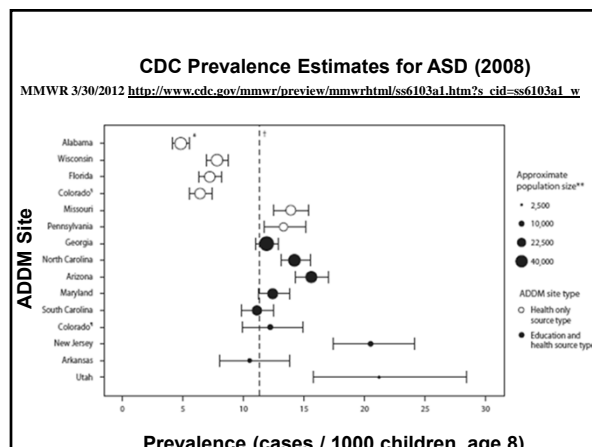
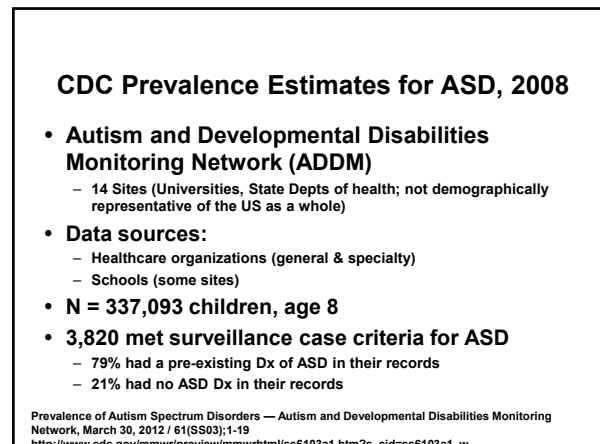
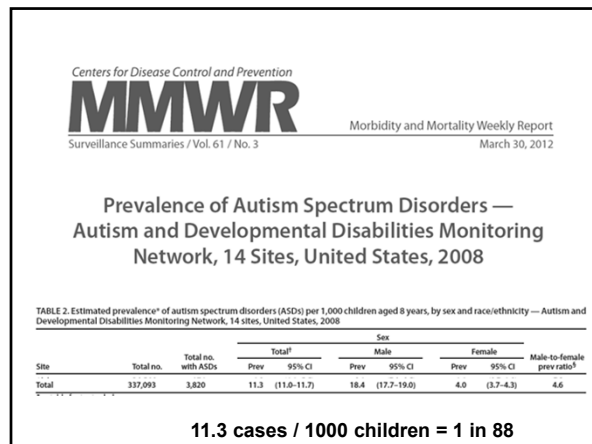
* Proband = the 1st member of a family to be diagnosed; the “index case”

Siblings of probands



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

Constantino, J.N., et al., Autistic social impairment in the siblings of children with pervasive developmental disorders. *Am J Psychiatry*, 2006. 163(2): p. 294-6



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



Mazumdar, King, Liu, Zerubavel and Bearman, 2010

Adjusted autism risk = 4x State-wide average



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.
2010 PLoS ONE 5(7): e11551.

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)

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?”

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

http://www.iancommunity.org/ian_research_reports/adults_on_the_autism_spectrum_september_2009

"Missing" adults: The NHS Survey



Autism Spectrum Disorders
in adults living in households
throughout England

*Report from the Adult Psychiatric
Morbidity Survey 2007*

<http://www.ic.nhs.uk/pubs/asdpsychiatricmorbidity07>

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**

<http://www.ic.nhs.uk/pubs/asdpsychiatricmorbidity07>

NHS Survey 2007

Phase 1

- Autism Quotient (20-Item Screen)
- N=2,854



Phase 2

- ADOS (Autism Diagnostic Observation Schedule)
- N=618



Overall prevalence of ASD: 1 %

- ➡ **•Males: 1.8% (1 in 56)**
- ➡ **•Females: 0.2% (1 in 500)**

<http://www.ic.nhs.uk/pubs/asdpsychiatricmorbidity07>

NHS Survey 2007

Prevalence of ASD (ADOS 10+), by age

All adults	2007		
	Age group		
	16-44	45-74	75+
	%	%	%
ASD (ADOS score of 10+) ^a	1.1	0.9	0.8

Prevalence x Age: Not statistically significant

<http://www.ic.nhs.uk/pubs/asdpsychiatricmorbidity07>

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”**

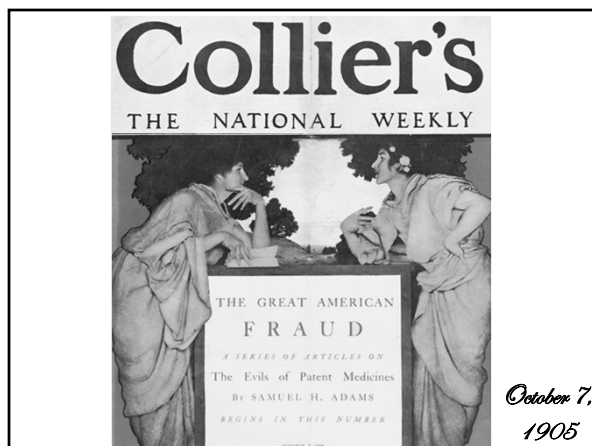


Outline

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

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.

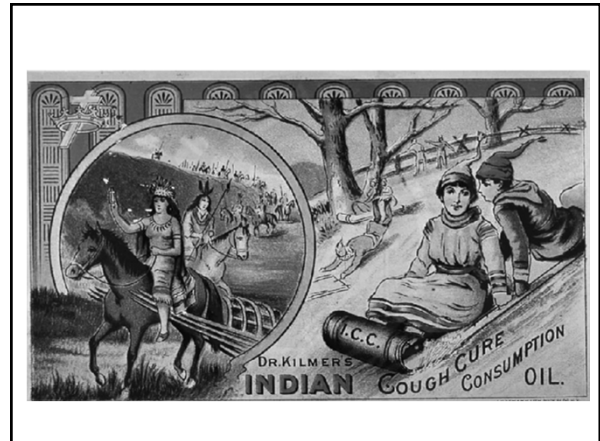
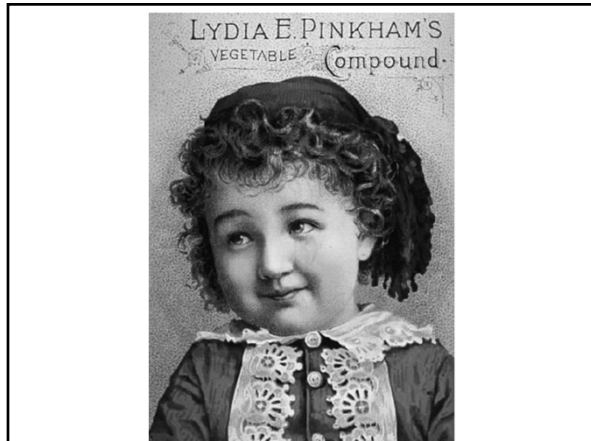
The Toadstool Millionaires: A Social History of Patent Medicines in America before Federal Regulation

James Harvey Young, PhD

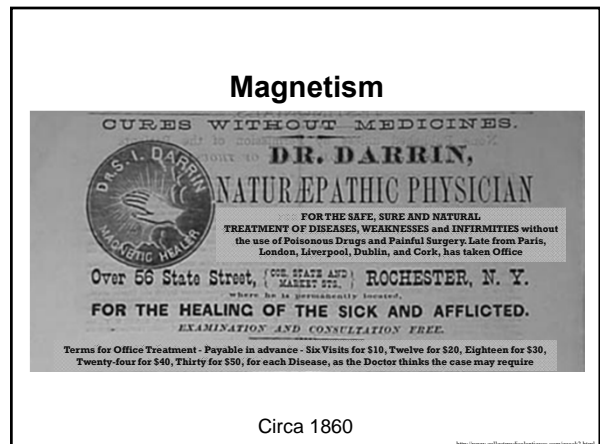
<http://www.quackwatch.org/1986/TM11.html>

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>



Circa 1860

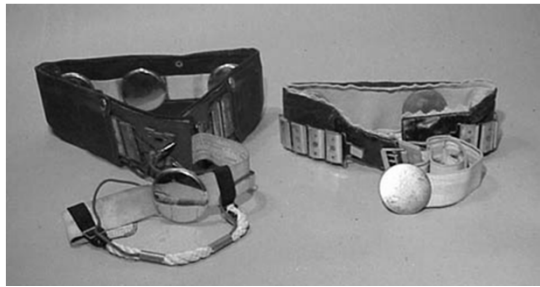
Electricity

**The
Heidelberg
Alternating
Current
Electric
BELT
Circa 1900**




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.

The mioxrls Electric Belt, circa 1920



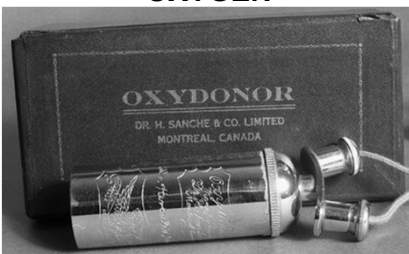
<http://www.collectmedicalantiques.com/quack2.html>



FLASH GORDON

Original Medium: Newspaper comics
Distributed by: King Features Syndicate
First Appeared: 1934
Creators: Don Moore (writer) and Alex Raymond



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*


<http://www.americanartifacts.com/smma/advert/ay33.htm>

Ultraviolet light



http://www.ucar.edu/learn/1_5_1.htm
<http://www.collectmedicalantiques.com/quack5.html>

**"Violet Ray Generators"
Ozone (O₃)**



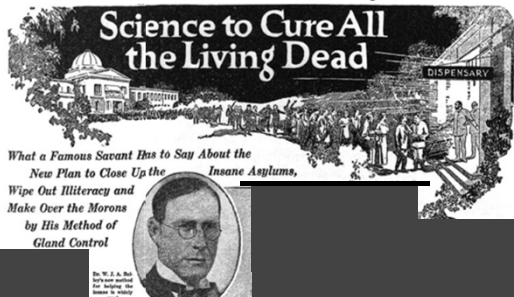
- 1915 – 1950
- Ozone = key ingredient in smog

"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"

http://www.bbc.co.uk/1/health/2002/02/020227n_id-3
<http://www.mtm.org/quack/devices/uv.htm>

Radioactivity

Science to Cure All the Living Dead




What a Famous Savant Has to Say About the New Plan to Close Up the Insane Asylums, Wipe Out Illiteracy and Make Over the Morons by His Method of Gland Control

“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.”

Scientific American, 8/93

RadiThor Drops: Radium + Thorium



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

Scientific American, 8/93




Forty Two Tablets of Genuine Arium
Price One Dollar

Take two tablets with glass of water before or after each meal. To derive the most beneficial effects Arium should be taken regularly and as directed. Read enclosed circular.

Associated Radium Chemists Inc.
NEW YORK DISTRIBUTED BY PARIS
MASTIN & CO.
NEW YORK CITY

Ebay listing

Revigator: Re-Invigorate your tired tap water with RADIUM



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

<http://www.mtn.org/quack/devices/revig.htm>



Radium Ore Revigator Company

CAPITAL, \$2,000,000.00 20,000 Shares Preferred Stock 40,000 Shares Common Stock Par Value, \$25.00 per Share Not Assessable

THIS CERTIFIES THAT *James L. Johnson* is the owner of *Four (4)* Shares of the Preferred Capital Stock of **RADIUM ORE REVIGATOR COMPANY**

Transferable on the books of the Company by endorsement hereon and surrender of this Certificate.

RADIUM ORE REVIGATOR COMPANY is a Nevada corporation, with a capital stock of \$2,000,000.00, divided into 20,000 shares of preferred stock and 40,000 shares of common stock, each class of the par value of \$25.00 per share.

\$25.00

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.*

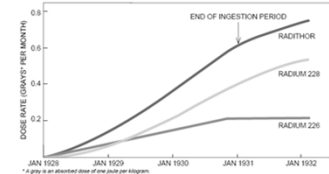


<http://www.americanartifacts.com/items/advertis/34a.jpg>
<http://www.americanartifacts.com/items/scott/scotdr.htm>

Eben Byers – RadioThor Victim



EBEN H. BYERS, afflicted and killed by radioactivity, as he appeared in his prime, several years before his consumption of Radium, and in the development of his tumor and, in 1912, in six months, the would-be sought radioactive poisons from disintegrates elements.



SKELETAL RADIOACTIVITY in Byers is shown in graphs based on estimates of the potency of Radium and the quantity consumed, because some decay products are more radioactive than the radium from which they derive, the dose rate increased even after Byers stopped taking the medicine.

Scientific American, 8/93

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Target Conditions

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

TRY HIRSCHHEIMER'S
INFALLIBLE
COUGH CURE
CONSUMPTION CURE

FOR COUGHS, COLDS, AND BRONCHIAL AFFECTIONS

TRY IT!
To Cleanse the Throat.

FOR DYSPEPSIA
——-
BRONCHITIS AND BRONCHIAL AFFECTIONS
——-
It's the only medicine for the Throat, it has no equal.

ECKMAN'S
ALTERATIVE

Contains Twelve Per Cent. of Alcohol by Weight, or Fourteen Per Cent. by Volume. Used as a solvent.

FOR ALL THROAT AND LUNG DISEASES INCLUDING
BRONCHITIS, BRONCHIAL CATARRH, ASTHMA, RAY FEVER, COUGHS AND COLDS, AND CATARRH OF THE STOMACH AND BOWELS, AND

TUBERCULOSIS (CONSUMPTION)

DIRECTIONS
For Adults.—Take a teaspoonful about half hour before meals and when retiring. After taking the contents of the first bottle the dose may be increased to two teaspoonfuls. When accustomed to it tablespoonful doses should be taken.

For Children.—Half dose.

If the taste of the ALTERATIVE is not liked, it may be combined with milk or water, or a mouthful of water may be taken immediately after.

Shake well before taking.

TWO DOLLARS A BOTTLE

PREPARED ONLY BY
ECKMAN MEDICAL CO.,
LABORATORY
PHILADELPHIA, PENNA.
U. S. A.

Dr. Morse's Indian Root Pills.
The Best Family Pill in use.
FOR SALE EVERYWHERE.

DR. JACOBS' LOVE POTION

A Hygienic Tonic for the Married or Those Intending to Marry, Both Male and Female.

It is a pleasant and sure way of getting on the right track in the case of life, and also the best way to keep the system in a strong, healthy and active state. Love, sympathy, health and deep personal affection. A potent tonic will surely give the best health. Numerous cases of our many concentrated cases are in physical form, have reached thousands in the homes of all countries. Taking by day and night, morning and evening, from health and happiness. Nothing is Equal in Tonic up the System and Improving Mutual Relations.

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

"The Germ of All Life is Electricity"

My sister had suffered a great amount from Chronic Rheumatism for MANY YEARS and could find no relief from medicines or applications. She has been using your Electric Flesh Brush for a short time, and is RELIEVED FROM ALL PAIN, and is perfectly cured.

Mrs. Liza Land Parker.



It cures

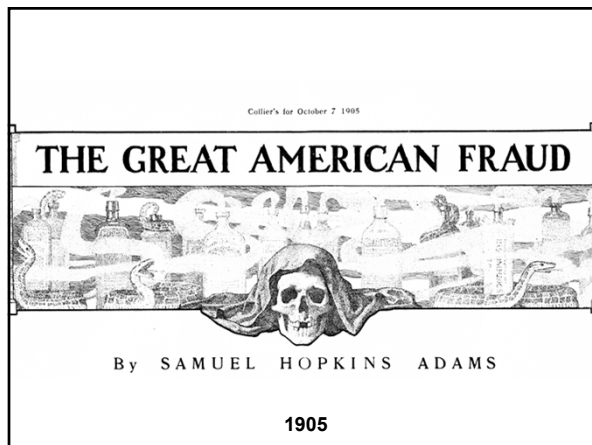
Rheumatism and diseases of the blood, Nervous complaints, Malaria, Palpitations, Paralysis and pain caused by impaired circulation, Indigestion, Liver trouble, &c, &c...

TESTIMONIALS

Space forbids our publisher from including all letters of gratitude...

Money returned if not as represented

<http://www.americanartifacts.com/items/scott/scot9.gif>



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.

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

Testimonials

- The ignorant drug-taker, returning to health from some disease which he has overcome by the natural resistant powers of his body, dips his pen in gratitude and writes his testimonial. The man who dies in spite of the patent medicine - or perhaps because of it - doesn't bear witness to what it did for him. We see recorded only the favorable results: the unfavorable lie silent.

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

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.

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

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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

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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

New Zealand Colostrum and Bioactive Colostrum



For children, we carry a product that is **100% Pure New Zealand Colostrum** and it comes in a delicious **Cherry Chewable form** (120 chewables per bottle) as well as capsule and powder form. It is a completely safe, non-toxic natural food supplement free of pesticides, hormones or antibiotics.


[Click here to purchase New Zealand Colostrum.](#)

[BUY NOW](#)

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>

HBOT



Testimonials

- ▼ HBOT Testimonial 1
- ▼ HBOT Testimonial 2
- ▼ HBOT Testimonial 3
- ▼ HBOT Testimonial 4
- ▼ HBOT Testimonial 5
- ▼ HBOT Testimonial 6
- ▼ HBOT Testimonial 7
- ▼ HBOT Testimonial 8
- ▼ HBOT Testimonial 9

<http://www.hbot.com/>

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Powerful yet safe?


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

Fatal hypermagnesemia in a child treated with megavitamin / megamineral therapy

PEDIATRICS®
OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

Pediatrics 2000;105:18-
DOI: 10.1542/peds.105.2.e18

Chelation



MMWR
Weekly
March 3, 2006 / 55(08);204-207

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

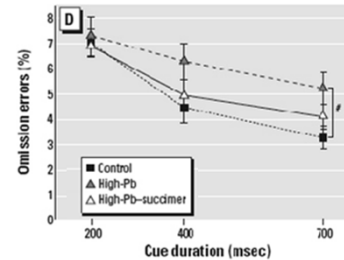
Chelation

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

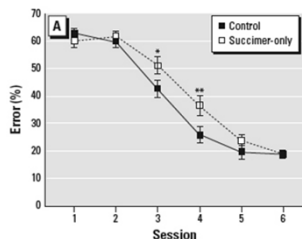
Diane E. Stangle,¹ Donald R. Smith,² Stephane A. Beaudin,³ Myla S. Strawderman,² David A. Levitsky,^{1,2} and Barbara J. Strupp^{1,2}

¹Department of Psychology, Cornell University, Ithaca, New York, USA; ²Department of Environmental Toxicology, University of California, Santa Cruz, California, USA; ³Division of Nutritional Sciences, Cornell University, Ithaca, New York, USA

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



but *impairs* learning in rats not exposed to lead



Succimer itself is capable of causing cognitive impairment

Stangle et al, 2007

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

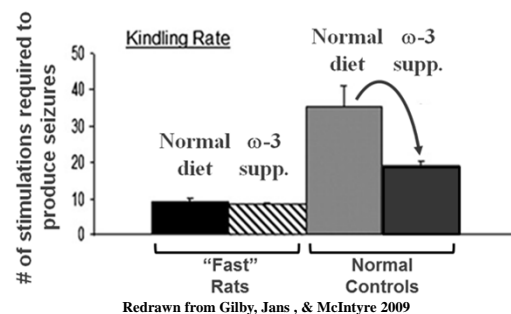
Chronic omega-3 supplementation in seizure-prone versus seizure-resistant rat strains: a cautionary tale

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

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



Omega-3 Fatty Acids

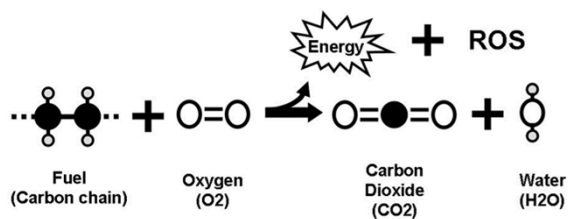
"Individual responses to omega-3 supplementation...were highly specific to the animals' genetic background. Consequently, caution is encouraged when treatment strategies are considered for the broad spectrum of disorders linked to EFA deficiencies.....omega-3 supplementation on its own is not the silver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

Gilby, Jans, & McIntyre 2009

OXYGEN

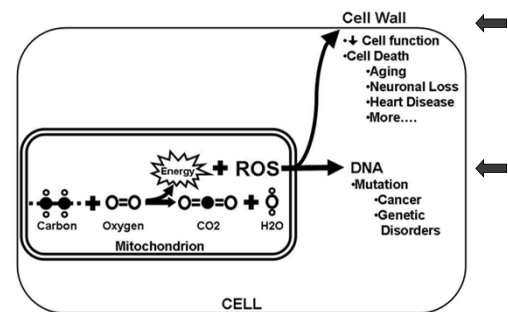


Oxidation - 1



* ROS = Reactive Oxygen Species

Oxidation - 2

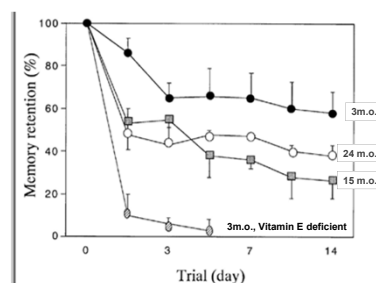


Memory loss following Hyperoxia in rats

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

Fukui, K., et al. Impairment of learning and memory in rats caused by oxidative stress and aging, and changes in antioxidative defense systems Ann N Y Acad Sci, 2001, v 928, 168-175

Memory Loss following Hyperoxia in rats



Fukui, K., et al. Impairment of learning and memory in rats caused by oxidative stress and aging, and changes in antioxidative defense systems Ann N Y Acad Sci, 2001, v 928, 168-175

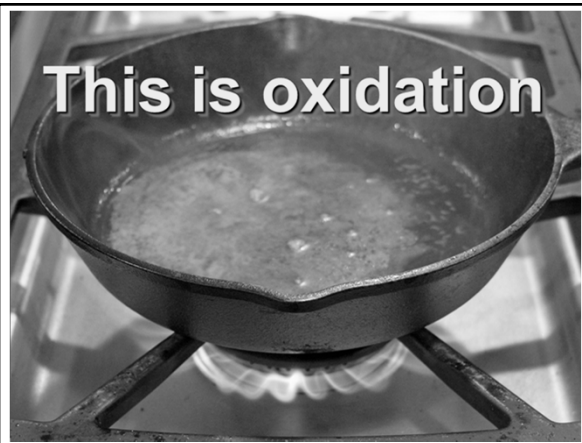
Hyperoxia \Rightarrow Brain Cell Death

1. Hyperoxia causes inducible nitric oxide synthase-mediated cellular damage to the immature rat brain. *Pediatric Research* 2003
2. Oxygen causes cell death in the developing brain. *Neurobiological Disorders*, 2004.
3. Hyperoxic exposure leads to oxidative stress and ensuing microvascular degeneration and diminished brain mass and function in the immature subject. *Stroke*, 2006
4. Estradiol attenuates hyperoxia-induced cell death in the developing white matter. *Annals of Neurology*, 2007
5. Hyperoxia causes maturation-dependent cell death in the developing white matter. *Journal of Neuroscience* 2008

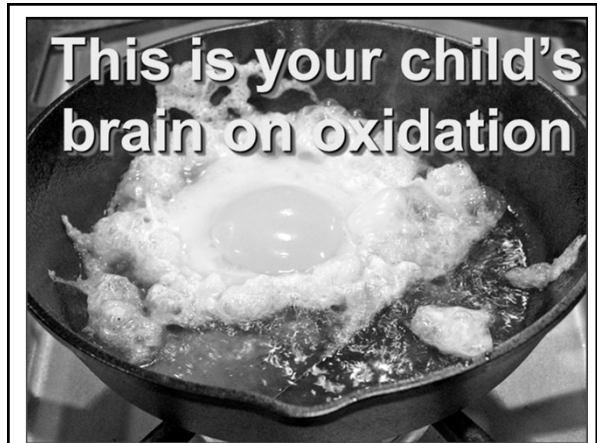
**This is your
child's *Brain***



This is oxidation



**This is your child's
brain on oxidation**

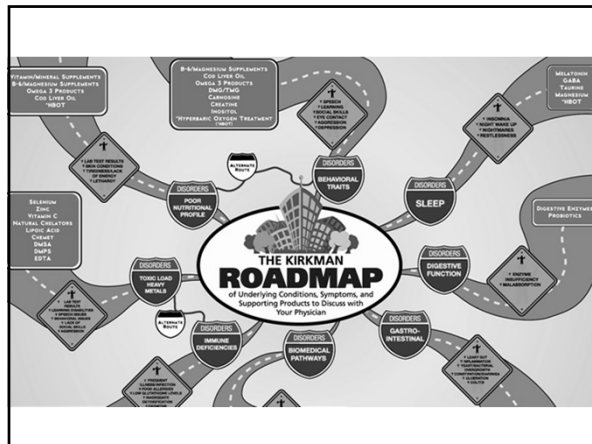


Any Questions?



CAM for ASD

- Highly promoted
- Simple, yet mysterious
- Powerful, yet safe (claimed)
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HBOT

"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...."*

<http://www.the-autism-clinic.com/hyperbaric-oxygen-chamber.html>

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Testimonials

ClayForAutism.com

Home
How to Order
LL's Magnetic Clay
Success Stories
Support Paks
Test Your Child
Special Supplements
FAQs
ABCs of Autism
Autism Symptoms
Asperger's Syndrome
Autism & Mercury
Resources & Links
About Us
Contact Us
Privacy Policy
Return Policy

Call Toll-Free (877) 562-6039 Outside USA Call (520) 877-2637

Autism Symptoms Improve Using Special Clay Bath

Safe Chelation Therapy for Autistic Children Gets Impressive Results!

<http://www.clayforautism.com/autism.html?s=gaw5>



"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)

<http://www.clayforautism.com/autism.html?s=gaw5>

Show me the evidence

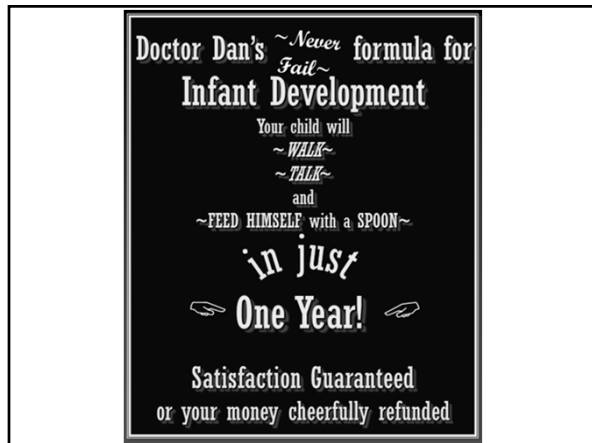
- Chance observations are not evidence
 - ❖ Secretin
- Coincidence is not evidence
 - ❖ Umbrellas do not cause rain
- Testimonials are not evidence
 - ❖ The plural of "anecdote" is not "data"
- Even sworn testimony is not evidence, in the scientific sense

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

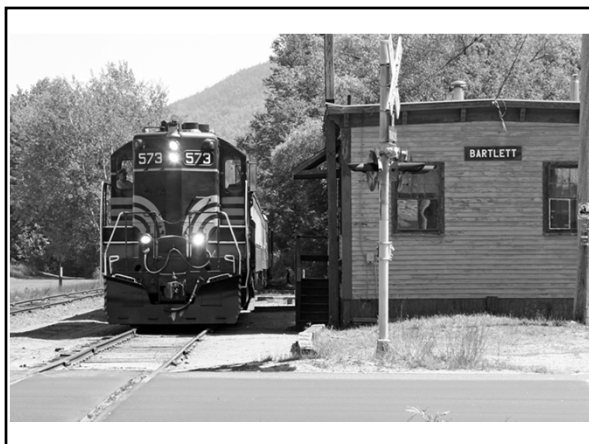
Randomized Controlled Trials (RCTs)

- 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*

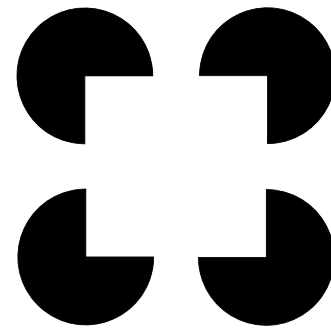


Outline

- 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

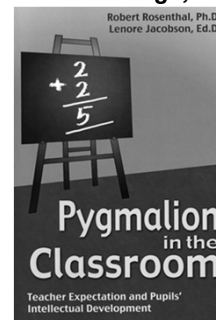
- ***We see what we expect to see***



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

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



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***



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

Omega-3 fatty acids supplementation in children with autism: a double-blind randomized, placebo-controlled pilot study.

Amminger, G.P., et al., Biol Psychiatry, 2007. 61(4): p. 551-3

- 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

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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
http://reformed-theology.org/html/issue11/politics_of_medicine.htm

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



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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
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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!