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Medicalization of Mental Disorders: 1970- to the Present

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Medicalization of Mental Disorders: 1970- to the Present

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Presented at the Continuing Education Conference for Social Workers
Charleston, Wv
May, 2013

For more on this topic, see:

www.behaviorandsocialissues.org

Behavior and Social Issues

Vol 15,2 (special issue) and vol. 16,2.

and

Wyatt, W. J. (2009). Behavior analysis in the era of medicalization: The State of the science and recommendations for practioners. *Behavior Analysis in Practice, 2,* 49-57

Medicalization of Mental Disorders: 1970 to the Present Outline

- 1. Introduction
- 2. A Challenge to Organized Psychiatry--Psychiatry's response
- 3. History of the Bio-Causation Movement
- 4. Psychiatry Finds a Partner--Big Pharma
- 5. The Impact of Direct-to-Consumer Advertising
- 6. The Pharmaceutical Industry Extends its Reach
- 7. Kids in the Crosshairs
- 8. Medication Ads: The Serotonin-Depression "Connection"
- 9. Medication Effectiveness

Outline, continued...

- 10. The Congress and the FDA. Will They Intervene?
- 11. Pushback Begins
- 12. Recommendations for Practioners:
 - Know your history
 - Recognize pharmaceutical industry tactics
 - Have basic knowledge of psychotropic medications
 - Avoid the vortex of medicalization
 - Keep contact with the professional community (associations, etc.)
 - Maintain a repertoire of brief, data-based treatments for a variety of client problems
 - Be knowledgeable regarding research said to support bio-causation

The importance of this topic for practioners

 A 35-yr. escalation of emphasis on biological causation has rendered, for many, medications as the treatment of choice.

Non-drug treatment may be cast aside, as a result.

A growing problem for therapists

Psychiatric patients who also receive non-drug treatment:

• 1996-97 44.4%

• 2004-05 28.9%

Archives of General Psychiatry, 10-yr survey of psychiatrists, August, 2008.

- When people believe their problems are biologically caused, they feel less responsibility...
- ...and have less hope for improvement.

Phelan (2002)

Trends in Neuroscience

 Bio causation is related to prejudice, fear and desire for distance...

Haslam, Sayce, Davies (2006)

ACTA Psychiatrica Scandinavica



Difficult times for therapists, continued...

- Parents told to try behavioral interventions for their child (after which medication might be tried)... 95% did so.
- Parents given the drug prescription for their child, and also told to enroll the child in behavioral intervention programs...25% did so.

Pelham (2009)

A similar study...

Patients were given a prescription (anti-depressant) and told to follow up with non-drug therapy.

At three months later:

- Adults: Fewer than 25% had done so.
- Children: Fewer than 50% had done so.

Stettin, et. al, (2006)

Study of 80,000 adults (5,000 children) 2001 to 2003 by

Managed care tracker Medco Health Solutions

And a related phenomenon...When medications become the treatment of choice

- Psychotropic medication errors result in 6,894 deaths per year in the U.S.
- Review of 31 pts'. Charts showed 2,194 medication errors (9 had been self-reported)...
- Over 400 million psychotropic prescriptions written in 2004...
- Over half of psychotropic prescriptions are written by primary care physicians...

Grasso, et al, www.Medscape.com, 2007

And another...

- Looking at school shootings:
- Every school shooter was on psychotropic meds...
 - Caveat: It is highly <u>unlikely</u> that medications caused the shootings...
 - However, a preference for medication may have precluded nondrug intervention...
 - ...As families may have been convinced that other (non-drug) treatment was relatively less important.

A growing problem:

Increasing numbers of clients show up for therapy already convinced that their difficulties are cause by their biology:

- Their Genes
- A chemical imbalance
- exposure to a toxin
- etc.

Question:

Do you know someone who has taken prescription medication for depression?

Caution:

Some disorders are biologically determined, or partly biologically determined.

Autism
Tumor-related
Toxin-related
Endocrine & metabolic related
Genetic-related (Down's syndrome, for example)
Others

Q: What is the empirical evidence that many instances of common disorders, such as:

- depression,
- anxiety disorders,
- ADHD
- Schizophrenia
- Alcoholism

...are caused by genes, chemical imbalances or other bio phenomena?

Consider one of these: Alcoholism

1954: The AMA declared it a "disease"

Typical evidence cited: It runs in families; it ruins one's health; it may cause death.

This was metaphor...

Alcoholism, continued...

Q: But, isn't there evidence of a genetic predisposition to alcoholism?

A: Yes. But what behavior does such a predisposition cause?

Q: ...and does such a predisposition rise to the level that we rightly term alcoholism a "disease"?

A: It's anybody's guess.

MindFreedom sought answers:

July 28, 2003--MindFreedom wrote to three well established organizations that heavily promote the bio-causation model:

- American Psychiatric Association (APA)
- National Alliance for the Mentally III (NAMI)
- Office of the U.S. Surgeon General (OSG)

MindFreedom asked the three organizations several important questions:

Provide any scientifically valid evidence to show that:

- Schizophrenia
- depression
- other disorders, (aside from the obvious--Down's syndrome, autism, tumor-related, etc.)

...are biologically based.

MindFreedom also asked for any evidence for:

- Any physical diagnostic test that can reliably distinguish those so diagnosed, from "normals."
- A chemically balanced "normal" personality, against which a neurochemical "imbalance" could be compared.
- How any psychotropic medication corrects a "chemical imbalance" or decreases likelihood of violence or suicide.

The American Psychiatric Association responded:

Two weeks later, August 12, 2003, a letter from James H. Scully, Jr., MD, Medical Director of APA wrote back:

"The answers to your questions are widely available in the scientific literature and have been for years..."

...and Dr. Scully advised MindFreedom to see these sources (next slide):

...see these sources:

- Introductory Textbook of Psychiatry, 3rd ed., (Andreason & Black, 2001)
- Textbook of Clinical Psychiatry (Hales & Yodofsky, 4th ed., 2003)
- A recent report by the U.S. Surgeon General
- Any recent issue of the American Journal of Psychiatry (Andreason, 2003) or the Archives of General Psychiatry (Barchas, 2003).

MindFreedom checked those sources...

...and replied to Dr. Scully, and to the American Psychiatry Association, ten days later...

...The sources Dr. Scully had cited did not provide evidence in support of bio-causation of Depression, schizophrenia, etc.

Rather, (next slide)...

From Dr. Scully's first suggested source...

Introductory Textbook of Psychiatry:

"Much of the current investigative research in psychiatry is directed toward the goal of identifying the pathophysiology and etiology of major mental illnesses, but this goal has been achieved for only a few disorders (Alzheimer's disease, multi-infarct dementia, Huntington's disease, and substance induced syndromes such as amphetamine-related psychosis or Wernicke-Korsakoff syndrome") (p. 23).

From Dr. Scully's next suggested source:

Textbook of Clinical Psychiatry

"Although reliable criteria have been constructed for many psychiatric disorders, validation of the diagnostic categories as specific entities has not been established" (p. 43).

And from the next...

U.S. Surgeon General's Report.

"The precise causes (etiology) of mental disorders are not known" (p. 49).

And from the journals that Dr. Scully had recommended...

MindFreedom wrote to Dr. Scully, asking that he refer to specific issues of the more than 200 volumes of each journal...

Dr. Scully, Medical Dir. Of the American Psychiatric Association, replied, in writing, as follows:

 He provided no additional citations, references or empirical evidence in support of bio-causation.

 He provided an APA position statement that included the following precepts (next slide):

American Psychiatric Association's position statement (continued)...

- ...mental disorders are "neurobiological."
- "...brain science has not advanced to the point where scientists or clinicians can point to readily discernible pathologic lesions of genetic abnormalities that in and of themselves serve as reliable or predictive biomarkers of a given mental disorder or mental disorders as a group..."

A conclusion

 The American Psychiatric Association urged a blind faith acceptance of the biological causation model of many common mental disorders. Q: What has brought about this heightened acceptance of biocausation among both the public and professional cultures?

...and what does that mean for our non-drug treatment efforts?

One answer: The awesome power of directto-consumer advertising.

Legalized in 1996

MEDICATION GUIDE

AMBIEN CR® (ām'bē-ən see ahr) C-IV (zolpidem tartrate extended-release tablets)

Read the Medication Guide that comes with AMBIEN CR before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your doctor about your medical condition or treatment.

What is the most important information I should know about AMBIEN CR?

After taking AMBIEN CR, you may get up out of bed while not being fully awake and do an activity that you do not know you are doing. The next morning, you may not remember that you did anything during the night. You have a higher chance for doing these activities if you drink alcohol or take other medicines that make you sleepy with AMBIEN CR. Reported activities include:

- driving a car ("sleep-driving")
- · making and eating food
- talking on the phone
- having sex
- · sleep-walking

Call your doctor right away if you find out that you have done any of the above activities after taking AMBIEN CR.

Important:

- 1. Take AMBIEN CR exactly as prescribed
- Do not take more AMBIEN CR than prescribed.
- Take AMBIEN CR right before you get in bed, not sooner

2. Do not take AMBIEN CR if you:

- · drink alcohol
- take other medicines that can make you sleepy. Talk to your doctor about all of your medicines. Your doctor will tell you if you can take AMBIEN CR with your other medicines.
- · cannot get a full night's sleep

What is AMBIEN CR?

AMBIEN CR is a sedative-hypnotic (sleep) medicine. AMBIEN CR is used in adults for the treatment of a sleep problem called insomnia. Symptoms of insomnia include:

- trouble falling asleep
- · waking up often during the night

AMBIEN CR is not for children.

AMBIEN CR is a federally controlled substance (C-IV) because it can be abused or lead to dependence. Keep AMBIEN CR in a safe place to prevent misuse and abuse. Selling or giving away AMBIEN CR may harm others, and is against the law. Tell your doctor if you have ever abused or have been dependent on alcohol, prescription medicines or street drugs.

Who should not take AMBIEN CR?

Do not take AMBIEN CR if you are allergic to anything in it. See the end of this Medication Guide for a complete list of ingredients in AMBIEN CR.

AMBIEN CR may not be right for you. Before starting AMBIEN CR, tell your doctor about all of your health conditions, including if you:

- have a history of depression, mental illness, or suicidal thoughts
- have a history of drug or alcohol abuse or addiction
- · have kidney or liver disease
- have a lung disease or breathing problems
- are pregnant, planning to become pregnant, or breastfeeding

Tell your doctor about all of the medicines you take including prescription and nonprescription medicines, vitamins and herbal supplements. Medicines can interact with each other, sometimes causing serious side effects. **Do not take AMBIEN CR with other medicines that can make you sleepy.**

Know the medicines you take. Keep a list of your medicines with you to show your doctor and pharmacist each time you get a new medicine.

How should I take AMBIEN CR?

- Take AMBIEN CR exactly as prescribed. Do not take more AMBIEN CR than prescribed for you.
- Take AMBIEN CR right before you get into bed.
- Do not take AMBIEN CR unless you are able to stay in bed a full night (7-8 hours) before you must be active again.
- Śwallow AMBIEN CR Tablets whole. Do not chew or break the tablets. Tell your doctor if you cannot swallow tablets whole.
- For faster sleep onset, AMBIEN CR should NOT be taken with or immediately after a meal.
- Call your doctor if your insomnia worsens or is not better within 7 to 10 days. This may mean that there is another condition causing your sleep problems.
- If you take too much AMBIEN CR or overdose, call your doctor or poison control center right away, or get emergency treatment.

What are the possible side effects of AMBIEN CR? Serious side effects of AMBIEN CR include:

- getting out of bed while not being fully awake and do an activity that you do not know you are doing. (See "What is the most important information I should know about AMBIEN CR?)
- abnormal thoughts and behavior. Symptoms include more outgoing or aggressive behavior than normal, confusion, agitation, hallucinations, worsening of depression, and suicidal thoughts or actions.
- memory loss
- · anxiety
- severe allergic reactions. Symptoms include swelling of the tongue or throat, trouble breathing, and nausea and vomiting. Get emergency medical help if you get these symptoms after taking AMBIEN CR.

Another factor

Psychiatry's answer to a crisis?

Embrace medicalization

...details to follow...

"Psychiatry's Anxious Years"

NY Times (Nelson, 1982)

- 1970-1980—a drop in medical school grads choosing psychiatry---11% to 5%.
 - Relatively low pay
 - Family practice emphasis
 - Psychoanalytic confusion
 - Fringe Treatments & loss of esteem
 - "Intruder" professions

Psychiatry's response to this crisis?

Strategy conferences held.

<u>Solution:</u>

- Become more medical, and
 - Attack the intruders
 - •The DSM-III (1980)

Organized psychiatry's attacks on non-medical "intruders" quickly became vicious.

Some examples follow:

Hospital & Community Psychiatry (Bursten, 1981):

"Medicalization" of disorders is useful "to rally the troops...to thwart the attackers...Economics demands that we be medical...we use the term to rout the enemy within."

Another example

American Journal of Psychiatry (Havens, 1981)

"(Psychiatrists must) speak with a united voice...to buttress (our) position against the numerous other mental health professionals seeking patients and prestige."

Another

Paul Fink, President-elect of Am. Psychiatric Assn. 1988:

"(Non-psychiatrists) don't have the training to make the initial evaluation and diagnosis...(and) are not trained to understand the nuances of the mind..."

And another

 Melvin Sabshin, Medical Director of the American Psychiatric Assn., testimony before the New York State Legislature, 1988:

"Do the grave and inevitable risks to the quality of patient and medical care in hospitals outweigh the dubious, purported benefits associated with hospital privileges for these non-physician practioners?"

Conclusion:

- Organized psychiatry's 35-year emphasis upon biological causation has been motivated, in part, by <u>non-science</u> based factors including:
 - Protection of its turf from "outsider" professionals
 - Re-establishing its esteem

Big Pharma sees an opening

Pharmaceutical Company Financial Interests

Drug makers ask themselves, "How can we achieve symbiosis with organized psychiatry?"

<u>Answer:</u> Promote the biological causation model of disorders.

Big Pharma works its magic.

Some examples follow.

The marketing of psychotropic medications: Successful?

- 2001-2004:
 - 49% increase in Rx of ADHD drugs in children under 5 years.
 - 23% increase in overall usage of ADHD drugs.

Medco Health Johnson, 2004

2001-2002

- Top ten revenue producing drugs included:
 - Zyprexa
 - Zoloft
 - Paxil

• \$7.5 billion in sales in the U.S.

Vaczek, 2003

2009

- •Top ten revenue producing drugs included:
 - Zyprexa
 - Risperdal
 - Effexor

\$12.1 billion in sales in the U.S.

Health and Life (2010)

Adult use of ADHD drugs:

•100% increase – 2000 to 2004

Medco Health Solutions AP, 9-16-2005

More children taking anti-psychotic drugs.

Children ages 2 to 5:

1999-2001 1 in 1,300 (appx.)

2007 1 in 630

5-yr-olds, only:

1999-2001 1 in 650

2007 1 in 329

Olfson (2010), Journal of the American Academy of Child & Adolescent Psychiatry.

1995-2000, the number of pharmaceutical industry jobs in:

...research & development fell by 2%, ...while jobs in marketing drugs rose by 59%

*Boston University Health Reform Project (Sagar & Socolar, 2001)

*Data obtained form the website of PhRMA

Direct-to-consumer advertising: Its indirect effect on physicians' prescribing practices.

Journal of the American Medical Association

(Kravitz, Epstein, Feldman, Franz, Azari, Wilkes, Hinton & Franks, 2005)

Subjects & Method:

152 family doctors were visited unannounced 298 times by actors posing as patients.

The "patients" pretended to have symptoms of either major depressive disorder or adjustment disorder with depressed mood.

At some visits the "patients" said, "I saw an ad for Paxil on TV. Doctor, do you think Paxil could help me?"

At other visits the "patients" said that they had seen an ad for "an anti-depressant" on TV, but didn't specifically mention Paxil.

At still other visits the "patients" made no reference to medication.

Results

Rx of Paxil when the "patients" exhibited major depressive disorder*:

• V	lention	of "	Paxil"	27.4%
V	ICHUUH	Ul	ranıı	L/.+/

Mention of "a drug"2.0%

No mention of drugs 4.2%

^{*}Similar percentages for adjustment disorder

Big Pharma's impact on:

- American Psychiatric Association
- Congress
- Several high profile psychiatrists

Pharma worked the American Psychiatric Association

- By 2006, the drug industry supplied about 30% of the financial support of the organization.
 - Drug ads in psychiatry journals
 - Exhibits at the annual conference
 - Sponsorship of fellowships, conferences and industry symposia at the conference.

New York Times, July 12, 2008

Example: Pfizer*

2003 conference, San Francisco

*(Maker of Zoloft & Sinequan--antidepressants)

- Paid for 4 CE symposia, with 20 presenters.
- Each symposium included free dinner for attendees.
- Display booth, free copies of:
 - The Memory Bible (Small, 2003)*
 - The Quiet Room (Schiller & Bennett, 1996)*

*Books authors present to autograph their books.

American Psychiatric Association Clean-up Effort

March 2009--

- Announced it was ending free medical education seminars and meals sponsored at its conference by drug companies.
- (Earlier, drug makers had said they would stop giving out small gifts--pens, flash drives, etc.).

Mr. Pharma Goes to Washington

- 1998 to 2006:
 - 1,400 bills
 - \$759 million spent on lobbying.
 - More than 50 former House members working as lobbyists
 - More than 12 former Senators also as lobbyists
 - more than 800 other former federal officials working as lobbyists

Ismail 2006

PublicIntegrity.org

Big Pharma Pays Psychiatrists

- Dr. Charles B. Nemeroff, Emory University
- Dr. Frederick K. Goodwin, NPR
- Dr. Joseph Biederman, Harvard Medical School
- Dr. Alan Schatzberg, Stanford University

Dr. Charles B. Nemeroff

Emory University Medical School Former editor of *Neuropsychopharmacology*

 Principal investigator--\$3.9 million grant from NIMH to study
 GlaxoSmithKline drugs.

 July 15, 2004, signed a letter to university officials stating he would earn less than \$10,000 a year from GSK, to comply with federal rules.

...Dr. Nemeroff

Same day, earned \$3,000 for a GSK presentation in Jackson Hole
 Wyoming.

Dr. Nemeroff's take from GSK that year? \$170,000.

...Dr. Nemeroff

- 2003--Failed to disclose financial ties to drug companies whose drugs he had favorably reviewed. Blamed the journal.
- 2004--Emory Univ. conflict-of-interest committee revealed Nemeroff's failures to disclose conflicts of interest in trials of drugs from Merck, Lilly, Johnson & Johnson.

...Dr. Nemeroff

 2006--Failed to disclose financial ties to Cyberonics Co. controversial device he had reviewed favorably. Blamed a clerical mix-up. (Note: He edited that journal.)

"...this paper was a paid piece of marketing,"

Emory Associate Dean Claudia R. Adkinson July 20, 2006.

Dr. Frederick K. Goodwin

Former host, now-defunct NPR program, "The Infinite Mind"*

 Sept 20, 2005—On the air: "As we'll be hearing today, modern treatments--mood stabilizers in particular--have been proven both safe and effective in bi-polar children...Left untreated, they could develop brain damage."

*"The Infinite Mind" was heard in more than 300 markets. It was canceled by NPR, following disclosures about Dr. Goodwin.

...Dr. Goodwin

 Same day--Was paid \$2,500 by GSK for a promotional talk about its mood stabilizer, Lamictal, in Naples FL.

That year--Was paid \$329,000 by GSK.

...Dr. Goodwin's reaction?

 "...it didn't occur to me that my doing what every other expert in the field does might be considered a conflict of interest."

and...

 "These companies compete with each other and cancel each other out" (because he consults for so many drug makers at once).

Dr. Frederick K. Goodwin

Dr. Joseph Biederman

Harvard Medical School

- Renowned child psychiatrist
- Proponent of anti-psychotic drugs for children
- Earned \$1.6 million from drug makers, 2000-2007.
- Failed to report most of it to Harvard.

...Dr. Biederman

at the APA meeting, 2008

• From the *Proceedings*:

"In another industry-supported symposium, Joseph Biederman, MD, also laid out an enlightened view of the spectrum of bipolar disorder..."

 Report on proceedings at the meeting of the American Psychiatric Association, July, 2008.

Dr. Alan F. Schatzberg

Stanford University

 2008--President-elect of American Psychiatric Association.

 Owned \$4.8 million in stock in a drug development company.

Another conclusion:

- The pharmaceutical industry's marketing efforts (to psychiatrists, Congress, consumers) have worked....
- Sales of medications, including psychotropic medications, have escalated at the same time.

Marriage

Psychiatry

Pharmaceutial Industry

Cementing this marriage together is:

Biological causation theory

Reinforcers of this marriage:

Money and power

Big Pharma's new target... ...children.

U.S. Children diagnosed with bi-polar disorder:

1994.....20,000

2003.....800,000

Children's use of anti-psychotic meds shows corresponding increase.

Olsen, et. al, *Archives of Gen Psychiatry*2007

More Kids on Psychotropic Drugs

		Of those, % on
	One drug	multiple drugs
Netherlands	2.9%	8.5%
Germany	2.0%	5.9%
U.S.	6.7%	19.2%

Child & Adolescent Psychiatry and Mental Health, October, 2008

U.K. <u>anti-psychotic</u> prescriptions for kids soar

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• 1992.....4 in 10,000 children
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• 2005.....7 in 10,000 children

The U.S.? "We're No 1"

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• 1996.....23 in10,000
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• 2001.....45 in 10,000

Pediatrics, May, 2008

Florida Medicaid kids on antipsychotic meds

2000
 9,364 children

2006 18,137 children

Most common diagnosis for these children? ADHD, for which anti-psychotics are not approved.

Medicaid Review Panel finding, May 30, 2008

Advertizing and the "Serotonin-depression connection."

First: The experts

"...the evidence (of a serotonin-depression connection) actually contradicts these claims."

Elliott Valenstein, 1998

"A serotonin deficiency for depression has not been found"

Joseph Glenmullen (2000) Harvard Medical School "...I never saw any convincing evidence that any psychiatric disorder, including depression, results from deficiency of brain serotonin."

David Burns, winner of the A. E. Bennett Award given by the Society for Biological Psychiatry for his research on serotonin metabolism.

"...no abnormality of serotonin in depression has ever been demonstrated."

David Healy, former secretary of the British Association for Psychopharmacology, 2004.

"We have hunted for big simple neurochemical solutions for psychiatric disorders and have not found them."

Kenneth Kendler, co-editor-in-chief of Psychological Medicine, 2005.

"Advertisements that claim depression is caused by a chemical imbalance and that anti-depressants correct it, are false and should be banned."

Jonathan Leo and Jeffrey Lacasse, Public Library of Science Medicine, 2007 "The chemical imbalance theory (of depression) is a 'useful metaphor' but shouldn't be used when talking to patients."

Wayne Goodman, Chair Psychopharmacologic Advisory Committee U.S. FDA

Does all of that matter?

Inquiring minds want to know.

Here are some examples of Big Pharma's advertising.

"Celexa helps to restore the brain's chemical imbalance."

Forest Pharmaceuticals, 2005

"LEXAPRO appears to work by increasing the available supply of serotonin...In people with depression and anxiety, there is an imbalance of serotonin..."

Forest Pharmaceuticals, 2005

"When you're clinically depressed...the level of serotonin ...may drop...The medicine doctors now prescribe most is Prozac."

Eli Lilly, 1998

"...depression may be related to an imbalance of natural chemicals...Zoloft works to correct this..."

Pfizer, 2004

"(Pristiq) is thought to work by changing the (brain's) levels of norepinephrine and serotonin."

Wyeth Pharmaceuticles, April, 2010

Conclusion:

Pharmaceutical Industry advertising is <u>not</u> to be believed.

Anti-depressant and anti-psychotic medications—

Are they effective, as advertized?

Studies are revealing.

Tofranil & Paxil: Common Antidepressants.

<u>Sources</u>: 6 studies; 718 patients took one of these meds for 6 to 11 weeks.

Findings:

- Meds were no better than placebo, for mild to moderate depression (Hamilton Depression Scale scores below 23 (out of 50).
- Slightly better than placebo for severe depression.

Fournier, et. al (2010)

JAMA

Another Review

Sources: 85 studies of 12 anti-depressants.

Findings:

- 37 of 38 that produced positive results were published
- 3 of 36 with negative results were published
- 11 with negative or questionable results were written as if the drug had worked.

Turner, et al., NEJM, 2008

Another Review

Sources: 29 published and 11 unpublished randomized trials from five major databases on patients with acute moderate-to-severe major depression.

<u>Findings</u>: Paxil was better than placebo at improving symptoms but worse than placebo at causing dropout due to side effects.

<u>Conclusion</u>: "Paroxitine is not better than placebo in therapeutic effectiveness and acceptability in treating acute major depression."

GeorgeD. Lundberg, Ed-in-Chief

The Medscape Journal of Medicine (2008)

Harvard School of Public Health

Another Review

- 38 Studies of anti-depressants (Zoloft, Paxil, Serzone, Celexa, Effexor, etc.), 1987 to 1999.
- <u>Dependent measure</u>: The 50-point Hamilton Depression Scale.

• Results:

- Mean improvement, drug groups = 10 points
- Mean improvement, controls = 8 points

Kirsch, et. al, (2002)

Prevention & Treatment

Yet another review:

Sources: 19 studies of top-selling anti-depressants.

Primary result: Placebo accounted for 75% of improvement.

Kirsch & Saperstein, 1998

Prevention & Treatment

Mood meds' medical methods

2-yr study of *depression* treatment (meds) by <u>primary care</u> physicians.

Results:

- Over 40% did not follow long-term follow-up guidelines.
- Fewer than 40% met guidelines for patients who were nonresponsive to medication tx.

Hepner, et al,., Annals of Internal Medicine

Who knew?

Participants: 202 depressed adults:

Results: Group physical exercise just as helpful as medication.

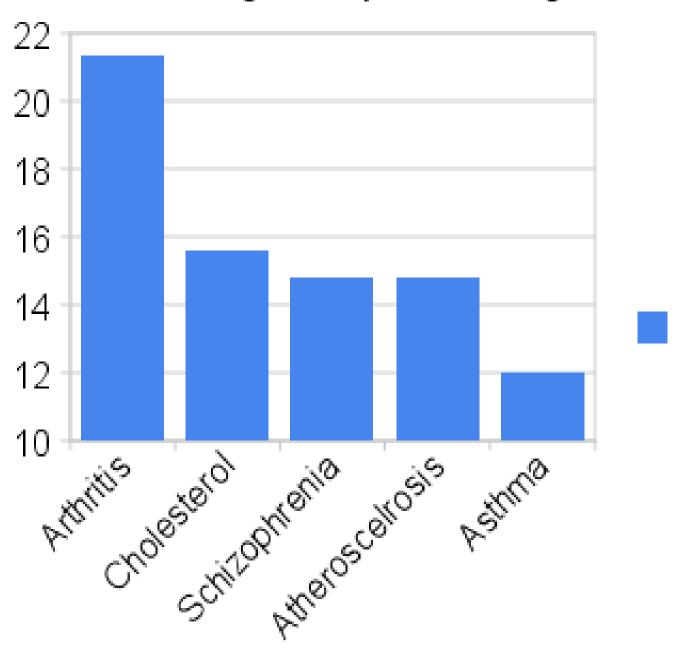
Blumenthal, et al., Psychosomatic Medicine

What about Anti-psychotic Medications?

A world-wide study showed anti-psychotic meds are used nearly as often as drugs that control cholesterol::

Maggon (2009)

Leading Therapeutic Categories



Anti-psychotics are widely used...

...But there is a catch:

<u>Discontinuation</u> rate by 18 months (due to side effects):

64% to 82%,

(Depending on which anti-psychotic was taken.)

Leiberman, et. al, 2005

New England Journal of Med.

Alzheimers & antipsychotics

- Anti-psychotics given to 165 advanced Alzheimer's patients provided no benefit for patients with mild behavioral problems, but were associated with marked deterioration in verbal skills.
- Up to 60% of Alzheimer's patients in nursing homes (in the UK) are given the drugs to control behavior such as aggression.

Report of the All-Party Parliamentary Group on Dementia Jeremy Wright, Chair, UK

Drug reps visit primary care doctors

Primary care doctors have an average of <u>28</u> interactions <u>weekly</u> with drug company reps.

• If a drug rep got 1 min. with a doctor, the doctors prescription for that drug increased 16%.

• 3 min.—52%.

Basler, (2008). *AARP Bulletin, 49,* 20,24,26.

Anti-psychotic meds for the DD population? A review of 8 studies

- "Antipsychotic drugs should <u>no longer</u> be regarded as an acceptable routine treatment for aggressive challenging behavior in people with intellectual disability."
- Placebo showed greater change than anti-psychotics.

Tyrer, et al., Lancet (2008)

Will the Congress or the FDA intervene?

The Congress? Who am I kidding?

 The pharmaceutical industry spent over \$22 million lobbying congress in 2007.

 As a result, efforts to limit drug industry advertising fell by the wayside.

The Congress, remember...

- More than 50 former members of the U.S. House of Representatives, and more than a dozen former U.S. Senators, now work as drug industry lobbyists.
- Over 800 former federal officials now are employed as drug industry lobbyists.
- There are far more drug industry lobbyists in Washington than members of Congress.

Will the FDA make significant changes?

Not likely

- FDA: Science and Mission at Risk
 - Inadequate staffing
 - Poor retention
 - Out-of-date technology
 - General lack of resources

Report of the FDA's Science Board, 2007

The FDA...

 ...found "serious problems" at drug test sites 348 times, 2000-2005. Only 26 investigators were disqualified from conducting further clinical studies.

Daniel Levinson
HHS Inspector General, 2007

FDA, cont'd...

 Bush administration removed FDA restrictions on off-label drug ads in medical journals.*

 Removed requirement that drug makers submit articles to FDA before sending them to doctors.

*Off-label: Use of a drug for a non-FDA approved condition

Federal Prosecutors vs. FDA

- March 2009--Federal prosecutors said:

 (1)The antidepressants Lexapro & Celexa (both, Forest Pharmaceuticals) are no better than placebo for children, and...
 - (2) ...the company swayed pediatricians with spa visits, fishing trips, tix to sports events & Broadway shows.
- Yet, <u>April 2009</u>--<u>FDA approved Lexapro</u> for adolescents.

Any Pushback? Anybody?

- Medical schools at:
 - Stanford
 - Mount Siani
 - Yale
 - U. Penn and others...

...Offer classes to teach medical students "how to effectively <u>spar</u> with the drug reps" by asking aggressive questions.

Dr. Ethan Halm,
Mt. Siani School of Medicine,
AP, November 2007

"Counter-detailers help doctors wade through drug company marketing."

Headline, Boston Globe, 2-26-07

The state of <u>Pennsylvania</u> hired 11 experts who made over 1,200 visits to doctor's offices to describe drugs' actual benefits and side effects.

Drug industry trade group PhRMA said PA's consultants are not held to same standards as drug company reps in their presentations.

AP, March 2008

JAMA 2006

"Although physician groups, the manufacturers, and the federal government have instituted self-regulation of marketing, research in the psychology and social science of gift giving indicates that current controls will not satisfactorily protect the interests of patients."

Brennen, et.al, from paragraph 1, article titled "Health industry practices that create conflicts of interest."

JAMA

Catherine De Angelis, MD,

Editor -in-Chief

Impugning the Integrity of Medical Science: Adverse Effects of Industry Influence

- "...profound influence from the pharmaceutical industry and medical device industries...because physicians have allowed it to happen."
- "...a glimpse of one company's (Merck) apparent misrepresentation of research data and its manipulation of research studies...'

continued...

JAMAApril 16, 2008

- "Merck employees (were) working...to prepare manuscripts and subsequently recruiting external, academically affiliated investigators to be authors..."
- "Recruited authors were commonly the sole author on the manuscript and offered honoraria for their participation."

Article on Rofecoxib litigation by J.S. Ross, et. al.

JAMA (Same article)

Draft title (8 Merck scientists as authors)

Rofecoxib <u>does not delay</u> the onset of Alzheimer's disease: Results from a randomized, double-blind, placebo-controlled study.

Published title, with added first, second & third authors from UCSD, NYU & Pivotal Research

A randomized, double-blind, study of Rofecoxib in patients with mild cognitive impairment

JAMA

Catherine DeAngelis, M.D. Editor-in-Chief

"The influence that the pharmaceutical companies, the for-profits, are having on every aspect of medicine...is so blatant now you'd have to be deaf, blind and dumb not to see it...We have just allowed them to take over, and it's our fault, the whole medical community."

Associated Press, Sept. 14, 2008

JAMA February 10, 2009

Industry-sponsored Clinical Research:

A Broken System

by

Marcia Angel, MD

"...sponsoring companies...often design the studies; perform the analyses; write the papers; and decide whether, when, and in what form to publish the results."

Conclusions:

- Psychiatry has embraced non-science in order to protect its esteem and turf.
- Big Pharma has also thrown empiricism under the bus, regarding both biological causation and the effectiveness of psychotropic medications.
- Organized psychiatry and the pharmaceutical industry have become symbiotic:

Bio-causation = drug treatment.

Recommendations for your practice.

Recommendation 1

Learn about the history of, and reinforcers for, adoption of the bio-causation model...

...Learn why, in our culture today, pills trump skills.

2

Understand the tactics of the pharmaceutical industry:

- Payoffs to physicians.
- Downplay of dangerous drug side-effects.
- Overstatement of drug effectiveness.
- Canceled studies where preliminary results were not positive.
- Ghostwritten studies.
- Etc.

3

Develop a working knowledge of psychotropic medications.

Common Anti-depressants*

- SSRIs: Paxil, Prozac, Zoloft, Desyrel, Pristiq, Celexa, Lexapro, Luvox.
- <u>Side effects</u>: OD may be fatal, nervousness, GI tract distress, headache, risk of suicide (esp. for children), sexual dysfunction, rash, agitation, weight gain, drowsiness, insomnia, restlessness, increased sweating. Takes 2-3 weeks to work.
 - *Note: The body of research indicates that placebo effects account for the majority of effectiveness of all anti-depressants.

Anti-depressants, continued...

- <u>Tri-cyclics:</u> Elavil, Tofranil, Sinequan, Pamelor, Vivactil, Norpramin
- <u>Side effects</u>: OD may be fatal; colenergic antagonists (dry mouth, urine & feces retention), poor bp accomodation, decreased REM sleep. Takes 2-3 weeks to work.

Anti-depressants, continued...

- MAOIs: Parnate, Nardil, Marplan.
- OD may be fatal, hypertension, stroke. Takes 2-3 weeks to work.

Anti-depressants, continued...

- *SNRIs: Effexor, Remeron, Ascendin.
- Side effects: OD can be fatal.
 - Note: May work in about one week.
 - *Serotonin & Norepinephtine Reuptake Inhibitors

Anti-depressants, continued

- *NDRIs: Wellbutrin (Zyban)
- *(Norephinephrine & Dopamine Reuptake Inhibitors. AKA "Atypical antidepressants")
- <u>Side-effects</u>: Generally the same as SSRI's. An exception is that NDRIs do not tend to cause sexual dysfunction. Note:
 Wellbutrin is the only NDRI that is approved by the FDA.

Common Anti-Anxiety meds

- Buspar, Klonopin, Librium, Serax, Valium, Vistaril, Zanaz, Ativan, Luvox, Prozac, Tranzene, Equanil, Halcyon, Versed.
- <u>Side effects:</u> Addiction, euphoria, difficult withdrawal, with overdose may appear dizzy or drunk. (Note: Usually not life threatening)

Common Anti-Psychotic meds

- Haldol, Stelazine, Thorazine, Trilafon, Risperdal, Zyprexa, Clozaril,
 Geodon, Loxitane, Mellaril, Moban, Navane, Prolixin, Serontil.
- <u>Side effects:</u> Autonomic difficulties (cardio problems, etc.), EPS (tardive dyskinesia)*.

(Note: Usually not addictive, not life threatening if taken in OD)

*Note: Often other medications such as Artane and Cogentin are Rx'd simultaneously, to control the EPS.

Common drugs for mania

- Lithobid (lithium), Depakote, Eskalith, Neurontin, Tegratol,
 Topamax.
- Side effects: Highly toxic, may cause tremors, cardio/renal difficulty.

Common drugs for ADHD

- Adderall, Ritalin, Concerta, Cylert, Dexadrine, Strattera,
 Metadate, Methylin
- <u>Side effects:</u> Especially in younger (age 6 and under) children, may cause irritability, crying spells, sleep disturbance. Weight loss? Addictive if used illegally.
 - Note: Typically not addictive if taken as Rx'd. No need for step-down.

Acknowledge that, at times, medications are effective. Avoid a "drugs never helped anybody" approach.

Avoid sliding into the vortex of medicalization. The world of psychiatric hospitals, psychiatry and the insurance industry can pull you in.

Stay in touch with the therapeutic community:

- Journals
- On-line discussions
- Associations
- Attend conferences
- Develop a support network.

For each client problem, have at the ready a databased description that shows how a behavioral/non-medical method has worked with the same or a similar problem.

Have a working knowledge regarding the state of research that is usually cited as evidence of biological causation.

Some examples follow...

Jay Joseph and Johathan Leo De-construct Gottesman, 1991

Gottesman's 1991 table is reproduced in <u>many</u> <u>textbooks</u>, but never had been critically analyzed until 2006:

Joseph, J. & Leo, J (2006). Genetic relatedness and the lifetime risk for being diagnosed with schizophrenia: Gottesman's 1991 Figure 10 reconsidered. *The Journal of Mind and Behavior, 27,* 73-90.

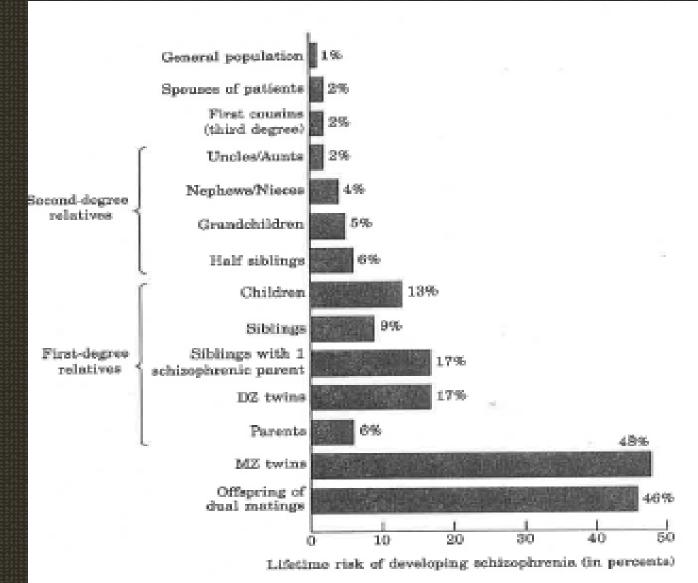


Figure 1: Gottesman's 1991 Figure 10 of the "Grand Average Risks for Developing Schizophtenia Compiled from the Family and Twin Studies Conducted in European Populations Between 1920 and 1987." From Schizophrenia Genesis: The Origins of Madness (Gottesman, 1991, p. 96), New York, W.H. Freeman and Company, Copyright © 1991 by I.I. Gottesman, Reprinted with permission.

From Gottesnam's Table

First-degree relatives' concordance for schizophrenia:

Children	13%
----------	-----

Siblings9%

Sibs w/1 schizo parent
 17%

• DZ twins 17%

• If one parent 6%

Weighted mean = **11%-12%** (appx.)

(Note: population base rate = 1%)

From Gottesman's table, cont'd

Concordance for:

MZ (identical) twins 48%
Offspring of dual matings 46%

A closer look at the Gottesman table

- Gottesman used <u>only European studies</u>, and mainly <u>older</u> studies
 ("...<u>European</u> populations between 1920 and 1987")
 - Done by <u>investigators devoted to genetic theories</u> who advocated sterilization of schizos.
 - Done <u>non-blind</u>: They knew whether one sibling was schizophrenic, in determining concordance of the other.
 - Vague, non-standardized diagnostic criteria.

More recent, U.S. studies

<u>Author</u>

% of first-degree relatives concordant

Tsuang, et. al. (1980) 4.3%

Pope, et. al. (1982) 0.0%

Abrams & Taylor (1983) 2.9%

Guze, et. al. (1983) 3.6%

Baron, et. al. (1985) 5.1%

Kendler, et. al. (1985) 3.6%

Note: Studies included more than 2,000 bio relatives, 146 of whom had been diagnosed schizophrenic.

Deconstruction of Gottesman, cont'd

Gottsman used <u>proband</u> calculation method:

Proband method (What Gottesman used): 10 sib pairs, 3 of whom are concordant for schizophrenia.

3+3 <u>6</u> = 46% concordance

10+3 13

Pairwise method (preferred).

<u>3</u> = 30% concordance

10

Gottsman deconstructed, cont'd

The same-sex vs. opposite-sex puzzle of DZ twins:

Same-sex DZ twins and opposite-sex DZ twins share the same amount of genetic material (50%).

Across 5 studies, 1934-1965, concordance rates:

Same sex DZ =12.3%

Opposite sex DZ=4.7%

How do we explain this difference?

What to conclude from Gottesman's review?

It provides little in the way of evidence to support genetic contributions to schizophrenia...

...and is contradicted by more recent studies that are better done and show a concordance rate of about 3.5% for schizophrenia among first degree relatives.

Shouldn't we believe the studies of identical (MZ) twins who were reared apart?

They typically show concordance rates of 30%-50% for disorders such as schizophrenia.

Confounds include:

- Family adoption practices, often economics driven.
- Equal levels of physical attractiveness
- Equal rates of reaching puberty
- Adoption agency practices
- Ages of adoption

Recommendation 8, cont'd...

What about:

- Studies of brain imaging (fMRI; PET)?
- Studies done on autopsy?

Don't they show consistent differences between the brains of disordered patients and normals?

Yes, but they do not show the direction of causation.

Another conclusion

The research commonly cited in support of biological causation of mental disorders comes from two areas:

- 1. Genetic family studies such as those described by Gottesman and...
- 2. Studies of brain imagery and chemistry.

The former are unconvincing, and the latter do not reveal the direction of causation.

Resources are available.

Here are some suggested sources:

Jay Joseph, Psy.D. Licensed Psychologist/Auth Offices in Oakland (Rockridge District) and Haywar

fices in Oakland (Rockridge District) and Haywa jayjoseph22@aol.com Telephone: (510) 295

THE GENE ILLUSION:

Genetic Research in Psychiatry a Psychology Under the Microscop

By Jay Joseph, Psy.D.

Algora Publishing, 2004. Retail price \$26.95 paperback, \$29.95 hardcover. 4

Available at <u>Amazon.com</u> and Barnes & Nobl Available in the United Kingdom from PCCS B

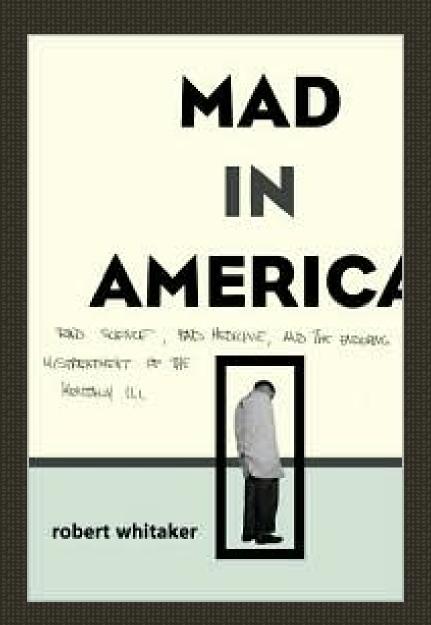
Click here to read a review of the UK edition of The Gene Illusion by Richard Holdsworth of the ESRC Centre for Genomics in Society, Univers

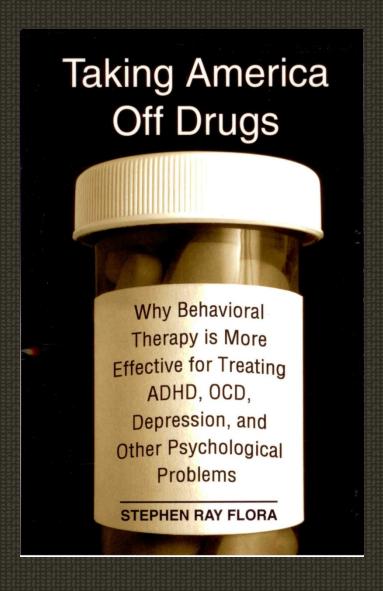
Click here for a chapter-by-chapter description of The

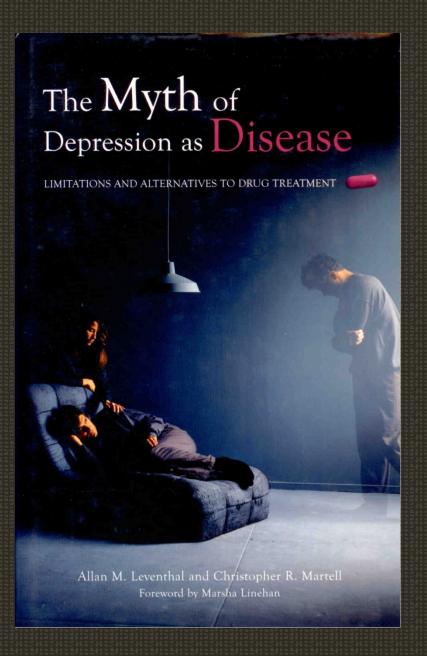
What are the forces shaping who we are, how we live, by our environment, or by our genes? These very old ques debate. Increasingly, we are told that research has confirm influencing psychiatric disorders, personality, intelligence, :

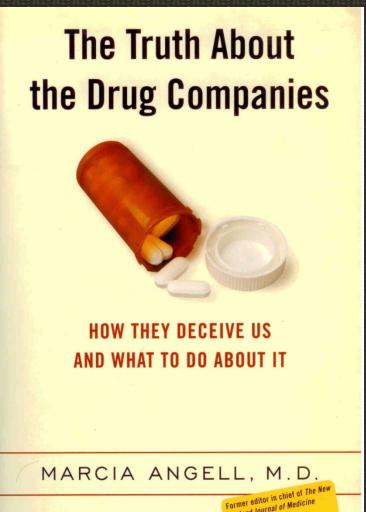
Jay Joseph's timely, challenging book provides a muchcited in support of genetic theories. His book shows that, fagenes, family, twin and adoption research has been plague methodology, and a reliance on unsupported theoretical as how this greatly flawed research has been used in support agendas. This is particularly evident in Chapter 2, which co the history of twin research ever published.











England Journal of Medicine Winner of the Polk Award

America Fooled Page 1 of 2

Resources

"The single most important book for anyone prescribing or anyone taking antidepressants to read today." -William Glasser, M.D.

AMERICA FOOLED

The Truth About Antidepressants, Antipsychotics and How We've Been Deceived

By Dr. Timothy Scott

View the Table of Contents

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Read Chapter 7, "Tricks of the Trade"

"Have You Been Fooled?" Quiz

Professional Readers' Responses

About the Author

Dr. Scott Comments on Research Design

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Why is this a Non-Profit Effort?

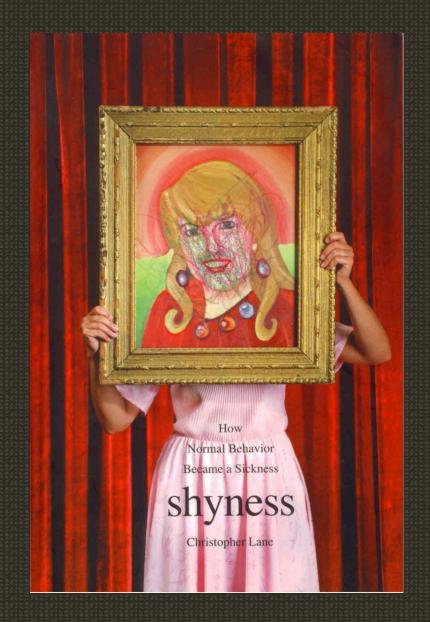
Book Price & Shipping Costs

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11/13/2006



Another resource

Primer on Psychotropic Medications

Matthew L. Israel

Available on the Judge Rotenberg Center website: www.jrc.org

Another resource

CriticalThinkRx.org

by

David Cohen

The End.

Thank you.