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Medicalization of Mental Disorders: 1970- to the Present

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For more on this topic, see:

www.behaviorandsocialissues.org
Behavior and Social Issues
Vol 15,2 (special issue) and vol. 16,2.

and

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
10. The Congress and the FDA. Will They Intervene?
11. Pushback Begins
12. Recommendations for Practitioners:
   • 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 practitioners

- 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)
  \textit{Trends in Neuroscience}

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

  Haslam, Sayce, Davies (2006)
  \textit{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.

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...

And another...

- Looking at school shootings:
- Every school shooter was on psychotropic meds...
  - Caveat: It is highly unlikely that medications caused the shootings...
  - However, a preference for medication may have precluded non-drug 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.
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 Ill (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:


- 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...


“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 bio-causation among both the public and professional cultures?

...and what does that mean for our non-drug treatment efforts?
One answer:
The awesome power of direct-to-consumer advertising.

Legalized in 1996
MEDICATION GUIDE

AMBRIEN CR® (am-be-an se-ah) 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?

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 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.
• Swallow 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.

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 nights 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.

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.
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.

**Solution:**

- 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:
“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.”
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 non-science based factors including:
  - Protection of its turf from “outsider” professionals
  - Re-establishing its esteem
Big Pharma sees an opening
Drug makers ask themselves, “How can we achieve symbiosis with organized psychiatry?”

**Answer:** 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.

<table>
<thead>
<tr>
<th></th>
<th>1999-2001</th>
<th>2007</th>
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<tbody>
<tr>
<td>Children ages 2 to 5:</td>
<td>1 in 1,300 (appx.)</td>
<td>1 in 630</td>
</tr>
<tr>
<td>5-yr-olds, only:</td>
<td>1 in 650</td>
<td>1 in 329</td>
</tr>
</tbody>
</table>

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 from the website of PhRMA
Direct-to-consumer advertising: Its indirect effect on physicians’ prescribing practices.
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*:

- Mention of “Paxil” 27.4%
- 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.
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.
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
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...”

Dr. Alan F. Schatzberg
Stanford University

- 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

• Pharmaceutical 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

<table>
<thead>
<tr>
<th>Country</th>
<th>One drug</th>
<th>Multiple drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Netherlands</td>
<td>2.9%</td>
<td>8.5%</td>
</tr>
<tr>
<td>Germany</td>
<td>2.0%</td>
<td>5.9%</td>
</tr>
<tr>
<td>U.S.</td>
<td>6.7%</td>
<td>19.2%</td>
</tr>
</tbody>
</table>

*Child & Adolescent Psychiatry and Mental Health, October, 2008*
U.K. anti-psychotic prescriptions for kids soar

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

The U.S.? “We’re No 1”

- 1996.................23 in 10,000
- 2001.................45 in 10,000

*Pediatrics, May, 2008*
Florida Medicaid kids on anti-psychotic meds

- 2000 9,364 children
- 2006 18,137 children

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

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.”

“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 not to be believed.
Anti-depressant and anti-psychotic medications—
Are they effective, as advertised?

Studies are revealing.
Tofranil & Paxil: Common Antidepressants.

Sources: 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.

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

Conclusion: “Paroxetine is not better than placebo in therapeutic effectiveness and acceptability in treating acute major depression.”

George D. Lundberg, Ed-in-Chief
Harvard School of Public Health
Another Review

• 38 Studies of anti-depressants (Zoloft, Paxil, Serzone, Celexa, Effexor, etc.), 1987 to 1999.

• Dependent measure: The 50-point Hamilton Depression Scale.

• Results:
  • Mean improvement, drug groups = 10 points
  • Mean improvement, controls = 8 points

  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 primary care physicians.

Results:

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

Hepner, et al., Annals of Internal Medicine
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)
Anti-psychotics are widely used...

...But there is a catch:
Discontinuation rate by 18 months (due to side effects):

64% to 82%,

(Depending on which anti-psychotic was taken.)

Leiberman, et. al, 2005

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 28 interactions weekly 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%.

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

- “Antipsychotic drugs should no longer be regarded as an acceptable routine treatment for aggressive challenging behavior in people with intellectual disability.”

- Placebo showed greater change than anti-psychotics.

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, April 2009--FDA approved Lexapro 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 spar 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 Pennsylvania 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
“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.”
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...
“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.
Rofecoxib does not delay the onset of Alzheimer’s disease: Results from a randomized, double-blind, placebo-controlled study.

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

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.
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.
Develop a working knowledge of psychotropic medications.
Common Anti-depressants*

- **SSRIs**: Paxil, Prozac, Zoloft, Desyrel, Pristiq, Celexa, Lexapro, Luvox.

- **Side effects**: 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...

- **Tri-cyclics**: Elavil, Tofranil, Sinequan, Pamelor, Vivactil, Norpramin

- **Side effects**: 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 & Norepinephrine Reuptake Inhibitors*
**Anti-depressants, continued**

- **NDRIs**: Wellbutrin (Zyban)

  *(Norepinephrine & Dopamine Reuptake Inhibitors. AKA “Atypical antidepressants”)*

- **Side-effects**: 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


- **Side effects:** Addiction, euphoria, difficult withdrawal, with overdose may appear dizzy or drunk. (Note: Usually not life threatening)
Common Anti-Psychotic meds

- **Side effects:** 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, Tegretol, Topamax.

- **Side effects:** Highly toxic, may cause tremors, cardio/renal difficulty.
Common drugs for ADHD

- Adderall, Ritalin, Concerta, Cylert, Dexadrine, Strattera, Metadate, Methylin

- **Side effects:** 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 data-based 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...
Gottesman’s 1991 table is reproduced in many textbooks, but never had been critically analyzed until 2006:

From Gottesnam’s Table

First-degree relatives’ concordance for schizophrenia:
- Children 13%
- Siblings 9%
- 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 **only European studies**, and mainly **older** studies ("...European populations between 1920 and 1987")
  - Done by **investigators devoted to genetic theories** who advocated sterilization of schizos.
  - Done **non-blind**: They knew whether one sibling was schizophrenic, in determining concordance of the other.
  - Vague, **non-standardized diagnostic criteria**.
## More recent, U.S. studies

<table>
<thead>
<tr>
<th>Author</th>
<th>% of first-degree relatives concordant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tsuang, et. al. (1980)</td>
<td>4.3%</td>
</tr>
<tr>
<td>Pope, et. al. (1982)</td>
<td>0.0%</td>
</tr>
<tr>
<td>Abrams &amp; Taylor (1983)</td>
<td>2.9%</td>
</tr>
<tr>
<td>Guze, et. al. (1983)</td>
<td>3.6%</td>
</tr>
<tr>
<td>Baron, et. al. (1985)</td>
<td>5.1%</td>
</tr>
<tr>
<td>Kendler, et. al. (1985)</td>
<td>3.6%</td>
</tr>
</tbody>
</table>

Note: Studies included more than 2,000 bio relatives, 146 of whom had been diagnosed schizophrenic.
Deconstruction of Gottesman, cont’d

Gottsmann used **proband** calculation method:

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

\[
\frac{3+3}{10+3} = \frac{6}{13} = 46\% \text{ concordance}
\]

**Pairwise method (preferred).**

\[
\frac{3}{10} = 30\% \text{ concordance}
\]
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:
Resources

THE GENE ILLUSION:
Genetic Research in Psychiatry a Psychology Under the Microscope

By Jay Joseph, Psy.D.

Retail price $26.95 paperback, $29.95 hardcover.

Available at Amazon.com and Barnes & Noble
Available in the United Kingdom from PCCS

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 much cited in support of genetic theories. His book shows that, fi genes, 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 or the history of twin research ever published.
Resources

Taking America Off Drugs

Why Behavioral Therapy is More Effective for Treating ADHD, OCD, Depression, and Other Psychological Problems

STEPHEN RAY FLORA
The Myth of Depression as Disease

LIMITATIONS AND ALTERNATIVES TO DRUG TREATMENT

Allan M. Leventhal and Christopher R. Martell
Foreword by Marsha Linehan

Resources
Resources
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

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shyness

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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.