Enhancing Your Behavioral Practice in the Era of Bio-psychiatry and Big Pharma

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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

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 Behavioral Practitioners:
   - Know your history
   - Recognize pharmaceutical industry tactics
   - Have basic knowledge of psychotropic medications
   - Avoid the vortex of medicalization
   - Keep contact with the behavioral 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
   - Avoid behavioral jargon, with clients
   - Gently refute common misrepresentations of behavioral methods.

Objective 1: Describe the importance of this topic for behavioral practitioners

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

- Behavioral treatment may be cast aside, as a result.

A growing problem for behavioral 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 behavioral 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…
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...

Recall the spate of 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 behavioral treatment…
- ...As families may have been convinced that other (non-drug) treatment was relatively less important.

ASR #1

When a client believes that his problems in functioning are due to his genes, or due to a chemical imbalance, he feels:
a. There is greater hope for improvement, with proper medication.
b. There is less hope for improvement.
c. His chances for improvement are neither enhanced nor lessened.
Between the mid 1990s and the mid 2000s, the number of psychiatric patients who received non-drug therapy, along with medication:

a. Remained about the same.
b. Rose from about 28% to about 44%
c. Declined from about 44% to about 28%

A growing problem:
Increasing numbers of clients show up for therapy already convinced that their difficulties are caused by their biology:

- Their Genes
- A chemical imbalance
- Exposure to a toxin
- etc

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

Organized psychology has pushed the bio model

Headline: “Public recognizes depression as illness”
“Ten years ago... only 38% viewed depression as a serious medical illness... Today nearly three quarters (believe that)... We’ve come a long way.”

David L. Shern, Ph.D.,
The National Psychologist (2007). 16, 15

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

Objective 2: Describe evidence of pervasive bio-causation that has been provided by psychiatry

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 a 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 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.”
- There has been, “…remarkable scientific and clinical progress (in the) understanding of disorders that afflict and are mediated by the brain…”
- “…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 urges a blind faith acceptance of the biological causation model of many common disorders.

ASR #3

MindFreedom challenged several organizations to provide evidence that common disorders are caused biologically. One organization responded. It was:

a. The American Psychiatric Association
b. Office of the U.S. Surgeon General
c. NAMI
d. The American Psychological Association

ASR #4

The American Psychiatric Association’s Medical Director, Dr. Scully, provided several sources to MindFreedom, as evidence of widespread biological causation. These sources:

a. Provided fairly strong supporting evidence.
b. Provided evidence to the contrary
c. Took no position on the topic of bio-causation.

ASR #5

The American Psychiatric Association concluded its involvement in the MindFreedom episode by:

a. Issuing what may be described as a “blind faith” position paper in support of bio-causation.
b. Directing MindFreedom to additional sources that tended to bolster APA’s position.
Q: In the absence of empirical evidence, what has caused changes in the direction of bio-causation among both the public and professional cultures?

Q: And what does that mean for our behavioral treatment efforts?

Objective 3: List important events in the history of the bio-causation movement in the U.S.

30 years ago...

- Henry Gadsden, CEO of Merck

Merck should be like “Wrigley’s chewing gum…Merck should be able to sell to everyone…”

Moynihan & Cassels, 2005, *Selling Sickness*

Today, it has come to this...

Sleep med Ambian (print advertisement)

Ad consists of a tear-out card, showing:

A sleep mask, bright red, with this message:

“Bring the FREE 7-night trial offer certificate to your prescriber today.”

- Take the ad to your doctor, who may write the prescription, which...
- ...you then take to the pharmacy for the free Rx of Ambien.

The Ambian Ad’s small print warns

- Ambian could cause you to get up, while asleep or not fully awake, and:
  - Drive a car
  - Make and eat food
  - Talk on the phone
  - Have sex

The Ambian ad’s small print goes on:

Taking Ambian may cause you to experience:

- outgoing or aggressive behavior
- confusion
- agitation
- hallucinations
- worsening depression
- suicidal thoughts, memory loss, anxiety
- severe allergic reactions
“Psychiatry’s Anxious Years”

NY Times (Nelson, 1982)

- Residency drop from 1970-1980, 11% to 5% of medical school grads.
  - 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

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 non-science based factors including:
  - Protection of its turf from “outsider” professionals
  - Re-establishing its esteem

Objective 4: List evidence that shows the impact of Big Pharma on mental health treatment practices:

Psychiatry finds a more-than-willing partner:

Big Pharma

Pharmaceutical Company Financial Interests

- Question: How to 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

- Top ten revenue producing drugs included:
  - Zyprexa
  - Zoloft
  - Paxil
  - $7.5 billion in sales in the U.S.

Vaczek, 2003

2001-2002:

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

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 on anti-psychotic drugs.

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


ASR #7

Since 2000, the number of U.S. children on anti-psychotic medications has:

a. Declined slightly
b. Remained stable, due to intervention by the FDA
c. Doubled.
d. Quadrupled.
Objective 5: Describe one study that demonstrates the effectiveness of direct-to-consumer advertising on physicians’ prescribing practices.

Direct-to-Consumer advertising was legalized in 1995

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

Does direct-to-consumer advertising influence physicians’ Rx’ing?

Journal of the American Medical Association

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.

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

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.

ASR #8

When actors role-played depressed patients to unsuspecting physicians, mention of a specific drug by the actor caused the doctor to:

a. Be far more likely to prescribe that specific drug.
b. Be far more likely to prescribe an antidepressant, but not necessarily that one.
c. Be no more likely to prescribe an antidepressant.
Objective 6: Describe Big Pharma’s impact on the American Psychiatric Association, the Congress and on several high profile psychiatrists.

The Pharmaceutical Industry Work$ its Magic on Psychiatrists

- Support of the American Psychiatric Association.
- Lobbying the Congress.
- Direct payments to 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*

More on Pharma and the American Psychiatric Association annual conference...

Example: Pfizer®
at the 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.).

Pharma lobbied the congress...

- 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 2005
PublicIntegrity.org*
By 2006, the American Psychiatric Association was receiving about ____ of its financial support from the pharmaceutical industry.

a. 30%
b. 50%
c. 80%

Working as lobbyists for the drug industry are more than ___ former U.S. Senators and more than ___ former members of the U.S. House of Representatives.

a. 12; 50
b. 20; 80

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

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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, continued

- 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, continued...

- 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, continued

- 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,” wrote 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—”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, continued

- 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
- Failed to report most of it to Harvard.

One more on Dr. Biederman

- “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.

ASR #11

The activities of Drs. Frederick Goodwin, Joseph Biederman and others illustrate the likelihood that the pharmaceutical industry has gained influence by _____.

a. Close monitoring of research protocols
b. Close monitoring of university-drug industry ethical codes.
c. Co-opting doctors, with cash.

Another conclusion:

- The pharmaceutical industry’s marketing efforts (including direct-to-consumer advertising) have increased dramatically since 1995.
- 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

Objective 7: Provide evidence to show that the drug industry’s newest market segment target is... children.

- September 2007
- 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*

More Kids on Psychotropic Drugs

<table>
<thead>
<tr>
<th></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

U.S. Children?

- 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.

*Medicaid Review Panel finding, May 30, 2008*

ASR #12

Various studies show that, in recent years, the number of children taking psychotropic medications, including anti-psychotic medications, has:
- a. Increased dramatically
- b. Remained stable
- c. Decreased slightly

Objective 8: compare Pharmaceutical industry advertising to the findings of experts on one topic: The serotonin-depression “connection.”

Example:
Pharmaceutical companies routinely claim a Serotonin-depression connection.

…but, what do the experts say?

“A serotonin deficiency for depression has not been found”

Joseph Glenmullen(2000)
Harvard Medical School

Elliott Valenstein, 1998
“...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 Pharmaceuticals, April, 2010

ASR #13

Regarding a serotonin-depression connection, the drug industry has ______ this concept.

a. Initially promoted, then ceased promotion of
b. Never routinely promoted
c. Consistently promoted

ASR #14

Experts who have researched the possibility of a serotonin-depression connection have generally concluded that:

a. Evidence is mixed
b. Such a connection has never been proved.
c. Evidence is generally quite supportive of such a connection.

Conclusion:

Pharmaceutical Industry advertising is not to be believed.

Objective 9: List findings of studies of the effectiveness of anti-depressant and anti-psychotic medications.

Some studies are revealing.

Torfanil & 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*

Another review:
Sources: 19 studies of top-selling anti-depressants.
Primary result: Placebo accounted for 75% of improvement.

Kirsch & Saperstein, 1998
*Prevention & Treatment*

ASR #15
Studies of anti-depressant medications seem to show that these drugs:
- a. Are especially effective for milder depression, less so for severe depression.
- b. Are generally effective for all depression, regardless of severity.
- c. Are only marginally better than placebo.

ASR #16
Publication trends of studies of anti-depressants show that:
- a. Fewer studies are being published in the U.S. following the “publication explosion” of the 1990s.
- b. Studies are more frequent in European journals than in the U.S.
- c. Studies typically are not published, if they show that the drug was ineffective.
Mood med 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*

Who knew?

Study of 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:
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%.

**Objective 10: Discuss the likelihood that either the Congress or the FDA will intervene.**
- “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 antipsychotics.
  Review of eight studies

**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 antipsychotics.
The Congress?

- 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.

Q: Will the FDA save us?

A: 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

FDA, cont’d...

- 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) Forest swayed pediatricians with spa visits, fishing trips, tix to sports events & Broadway shows.
- Yet, April 2009--FDA approved Lexapro for adolescents.
Objective 11: List several efforts at pushback against the tide of pharma/psychiatry/bio-causation influence.

Some pushback begins.

- 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

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...

JAMA April 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 does not delay 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
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 biological causation.
- Organized psychiatry and the pharmaceutical industry have become symbiotic: Bio- causation = drug treatment.

Objective12: Describe several recommendations for behavioral practitioners as they work within the pharma/psychiatry/bio-causation U.S. zeitgeist.

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.”


ASR #17

Recent years have seen some “pushback” against the influence of the pharmaceutical industry on the medical profession. These efforts have come from:

a. Important individuals such as editors of major medical journals
b. “Fringe” sources such as homeopathy journals.
c. Low-circulation medical journals.
Objective 12: Describe several recommendations for behavioral practitioners as they work within the pharma/psychiatry/bio-causation U.S. zeitgeist.

Recommendation 1
Learn about the history of, and reinforcers for, adoption of the bio-causation model…
…Learn why pills trump skills.

Recommendation 2
Know about 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.

Recommendation 3
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 antidepressants.

Anti-depressants, continued...
- **Tri-cyclics:** Elavil, Tofranil, Sinequan, Pamelon, Vivactil, Norpramin
  
  **Side effects:** OD may be fatal; colenergic antagonists (dry mouth, urine & feces retention), poor bp accommodation, 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.

ASR #18

An important side-effect of anti-depressant drugs is:

- a. They are addictive.
- b. They interfere with REM sleep
- c. They can be fatal, in overdose.

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.*
A side-effect of anti-psychotic medications is that they may cause:

- Addiction
- Tardive dyskinesia
- Euphoria.

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
- 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.

Recommendation 4

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

Recommendation 5

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

Recommendation 6

Stay in touch with the behavioral community:
- Journals
- On-line discussions
- Associations
- Attend conferences
- Develop a behavioral support network.
**Recommendation 7**

For each client problem, have ready a data-based description that shows how a behavioral method has worked with the same or a similar problem.

**Recommendation 8**

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

Some examples follow...

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**Jay Joseph and Johathan Leo Deconstruct Gottesman, 1991**

Gottesman’s 1991 table is reproduced in many textbooks, but never had been critically analyzed until 2006:


**From Gottesman’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 twins 48%
- Offspring of dual matings 46%

**Taking a closer look, there were problems with this study by Gottesman**

- 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.</td>
<td>4.3%</td>
</tr>
<tr>
<td>Pope, et. al.</td>
<td>0.0%</td>
</tr>
<tr>
<td>Abrams &amp; Taylor</td>
<td>2.9%</td>
</tr>
<tr>
<td>Guze, et. al.</td>
<td>3.6%</td>
</tr>
<tr>
<td>Baron, et. al.</td>
<td>5.1%</td>
</tr>
<tr>
<td>Kendler, et. al.</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

Gottesman used proband calculation method:

Example: 10 sib pairs, 3 of whom are concordant for schizophrenia.

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

Pairwise method (preferred).

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

Gottesman deconstructed, cont'd

The same-sex vs. opposite-sex puzzle:

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%

Gottesman deconstructed, cont'd

The equal environments assumption is wrong.

Recommendation 8, cont'd...

A conclusion regarding family studies, especially studies of MZ twins reared apart:

Such studies are rife with environmental-biological confounds, to the extent that…

…these studies are of little use in teasing out causes of behavior.

The equal environments assumption is wrong

- Relying on Gottesman, others, studies of MZ (identical) twins reared apart.
  - 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)
– 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.

ASR #20

Studies that are often presented as powerful evidence of bio-causation, such as family studies (including studies of identical twins reared apart) and studies of brain structure/function, have typically:
a. Been heavily critiqued in both popular literature and in the scholarly literature.
b. Been overrated as providing evidence of bio-causation.

Resources are available.

Here are some suggested sources:

Resources

Resources

Resources

Resources
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
Recommendation 9
Avoid overuse of behavioral jargon, present company excepted. “Speak so that the person sitting next to you on the bus would understand it.” (Paul Chance, personal communication, date long forgotten.)
A corollary: Avoid overuse of layperson terms.
In summary: Walk a fine line.

Recommendation 10
Quickly, and gently, refute common misunderstandings about behavioral methods and behavioral philosophy.

Myth: Behaviorists ignore genetic influences.

Reality:
Genes are important. Our genetic structure enables us to change our behavior based on its consequences.

Myth: Behaviorists discount or ignore thoughts and feelings.

Reality:
Thoughts and feelings are important, because we all have them. They are behaviors, things we do, subject to the laws of behavior (reinforcement, etc.).

Myth: Behaviorists favor punishment techniques.

Reality:
Positive reinforcement is the watchword of behaviorists.

Myth: Behaviorists ignore the uniqueness of the individual.

Reality:
All individuals are unique because they have unique learning histories and genetic structures.
Recommendation 11

Always keep before you the reinforcers for adoption of a bio-causation worldview.

**Reinforcers for:**
- The pharmaceutical industry: Money
- The psychiatric profession: Money, esteem, *raison d’etre.*
- The insurance industry: Money (short-term at least)
- The patient/client: Feeling less responsible, ease of taking medication vis-à-vis learning coping skills.

ASR #21

Which of the following is true of behaviorism:

- a. It tends to discount genetic influences on behavior
- b. It tends to disavow thoughts and feelings.
- c. It is oriented toward positive methods, rather than punishment.

A final comment

- More than three decades ago B. F. Skinner wrote, “...genetic sources sometimes become a kind of dumping ground: any aspect of behavior which at the moment escapes analysis in terms of contingencies of reinforcement is likely to be assigned to genetic endowment...” Skinner’s observation remains true today.

The End.

Thank you.