


Critical Think Rx
A prescription for critical thinking about psychotropic medications

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Welcome to **CriticalThinkRx**, a project funded by the State Attorneys General Consumer and Prescriber Grant Program. The project is one of 28 in 19 states funded by a multi-state settlement of consumer fraud claims against a pharmaceutical company regarding the marketing of a psychotropic drug.

A Critical Curriculum on Psychotropic Medications



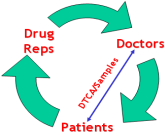
A Critical Curriculum on Psychotropic Medications

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www.CriticalThinkRx.org

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Module 4

Pharmaceutical Industry Influences on Prescribing



Part A



Expanding Drug Markets

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Pharmaceutical drugs = Big business



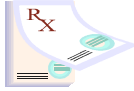
World sales:
\$643 billion in 2006
\$685 billion projected for 2008

(IMS Health, 2006, 2007; Pharmaceutical Executive, 2007; Los Angeles Times, 2007) 6

Brand-name drugs

Manufacturer holds an exclusive patent to market them for about 15 years

- 40% of prescription volume
- 90% of revenues

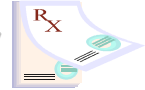


(IMS Health, 2007; Pharmaceutical Executive, 2007)

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Generic drugs

Once patent on marketing a brand-name drug expires, drug becomes a “generic,” and sells for much less, as other manufacturers may apply to market it



(IMS Health, 2007; Pharmaceutical Executive, 2007)

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“Blockbuster” drugs

Generate more than \$1 billion of revenue each year

Are heavily marketed, so their manufacturer can make profits during the marketing exclusivity period

7 of the top 10 companies have 1 psychotropic drug among their top 3 blockbusters



(Pharmaceutical Marketing, 2006)

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**Antidepressants,
antipsychotics,
anticonvulsants:
among top 6 drug classes
sold in U.S.**



(Pharmaceutical Executive, 2007; IMS Health, 2006)

Growing consensus:

Psychotropics are not popular because they are particularly effective

...“medicalization” and “disease mongering” also stimulate drug use

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“Medicalization”

- Defining or treating a problem as a *medical* disease, requiring *medical* treatments


(Conrad & Leiter, 2004; Mintzes, 2002)

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"Disease mongering"

- Turning ordinary ailments into diseases
- Framing conditions as being severe and widespread
- Seeing mild symptoms as serious
- Seeing risks as diseases

(Moynihan, Health, & Henry, 2002; Moynihan, 2002)



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Disorders Made to Order

Pharmaceutical companies have come up with a new strategy to market their drugs: First go out and find a new mental illness, then push the pills to cure it.

Brendan I. Koerner
July/August 2002 Issue

MotherJones

Disease awareness campaigns turn healthy people into patients


Owen Dyer London



DOI: 10.1371/journal.pmed.0030189.g001


Pills are often marketed as a solution to human anxieties and dissatisfactions

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Prescription Psychiatry

How big a dose?



Psychiatry by Prescription


Do psychotropic drugs blur the boundaries between illness and health?

PLOS MEDICINE

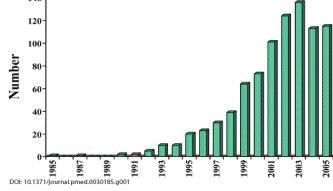
a peer-reviewed open-access journal published by the Public Library of Science

The Latest Mania: Selling Bipolar Disorder

David Healy



This is one of a series of articles on disease mongering in the April 2006 issue



One of the most famous direct-to-consumer television ads for a drug begins with a vibrant woman dancing late into the night. A background voice says, "Your doctor probably never sees you when you feel like this." The advert cuts to a shrunken and gaunt figure, and the voiceover now says, "This is who your doctor usually sees." Cutting again to the woman, in active shopping mode, clutching bags with the latest brand names, we hear: "That's why so many people with bipolar disorder are being treated for depression and not getting treated with antidepressants and the manias with antipsychotics or lithium."

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Part B




Marketing Expands Drug Markets

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Cost of marketing and promoting drugs in U.S.

Industry estimates: \$29.9B



Independent estimates: \$57.5B

The NEW ENGLAND JOURNAL of MEDICINE
(Donohue, Cevasco & Rosenthal, 2007)

PLOS MEDICINE
a peer-reviewed open-access journal published by the Public Library of Science
(Gagnon & Lexchin, 2008)

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**Drug company
marketing targets
all players in the health
care system**



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**It influences physicians to
prescribe through:**

Gifts:

- *free lunches*
- *drug samples*
- *continuing medical education*
- *payments for lecturing, consulting and research*



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**It influences physicians to
prescribe by:**

- ✓ funding countless activities of professional organizations
- ✓ drug advertising in professional journals
- ✓ paying doctors to serve on “expert committees” that create and promote guidelines for drug treatments used by other doctors

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**It influences consumers
to seek drugs through:**

- ✓ direct-to-consumer-advertising (DTCA)
- ✓ “disease awareness” campaigns
- ✓ funding “patient advocacy” groups
- ✓ online medical information and promotions

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**It influences legislators and
government agencies to approve
drugs and create favorable
conditions for drugmakers through:**

- ✓ lobbying at all levels of government
- ✓ large donations to political parties
- ✓ payment of “user fees” to the FDA


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**It influences experts to evaluate
drugs positively by:**

- ✓ paying researchers to run clinical trials and develop treatment guidelines
- ✓ signing “secrecy agreements” with researchers to conceal negative drug information
- ✓ paying academics and researchers to lend their names to articles they have not written (“ghostwriting”)

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Drug Reps



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100,000 drug reps in the United States



~ 1 for every 6 doctors

(Oldani, 2004; Greene, 2004; Fugh-Berman & Ahari, 2007) 26

Doctors who meet frequently with reps:

- ✓ increase prescribing of newer, costlier drugs
- ✓ reduce prescribing of generics
- ✓ increase nonrational prescribing
- ✓ use rep as main information source

(Dana & Loewenstein, 2003; Reist & VandeCreek, 2004, Schwartz et al. 2001; Wazana, 2000) 27

Reps know just which doctors to target and how

Health Information Organizations combine purchased pharmacy data, AMA physician data, and patient data to determine which drugs individual physicians prefer for which diagnoses and which patient groups

This *prescription tracking* is used to tailor marketing to physicians and evaluate effects of promotions on their prescribing behavior

(Fugh-Berman, 2008) 28



Gift-giving

Very effective, even when
doctors don't think so



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The Boston Globe

Does a drug firm's free lunch influence doctors?

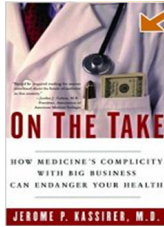
By Scott Lassman | May 18, 2007

Physicians and the Pharmaceutical Industry Is a Gift Ever Just a Gift?

JAMA
The Journal of the American Medical Association

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Are doctors “on the take”?



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The NEW ENGLAND JOURNAL of MEDICINE

A National Survey of Physician–Industry Relationships

Among a sample of 3,200 physicians:

- 83% received food at work
- 78% received drug samples
- 35% were reimbursed for CME
- 28% were paid to give lectures or recruit patients in trials

(Campbell et al., 2007)

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The New York Times

Psychiatrists Top List in Drug Maker Gifts

By GARDINER HARRIS
Published: June 27, 2007

1997- 2005: drug companies paid Minnesota doctors \$57 million

- psychiatrists received \$6.7 million

(Ross et al., 2007; The New York Times, 2007)

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1 in 3 Minnesota psychiatrists received money from drugmakers

“One in three Minnesota psychiatrists has received funding from drug manufacturers in the past five years, including seven past presidents of the Minnesota Psychiatric Society, two state drug policy advisers and 17 faculty psychiatrists at the University of Minnesota.”

(Olson, 2007)

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The New York Times

May 10, 2007

Psychiatrists, Children and Drug Industry’s Role

By GARDINER HARRIS, BENEDICT CAREY and JANET ROBERTS

Psychiatrists receiving money from drug companies more likely to prescribe “off-label” antipsychotics to children

Prescription for Influence Beyond the Label

Average number of prescriptions for atypical antipsychotics for children written by Minnesota psychiatrists who received the following amounts of money from the drug makers from 2000 to 2005:

PAYMENTS	PRESCRIPTIONS*
\$5,000 or more	223
Under \$5,000	67

* For children enrolled in Minnesota’s fee-for-service Medicaid program
Sources: Minnesota Board of Pharmacy; Minnesota Medicaid

The New York Times

“Free” samples...

- ✓introduce drug into doctor’s office
- ✓generate sales, influence brand choice
- ✓Mostly go to wealthy/insured patients
- ✓63% of total promotional spending

Return-on-investment:

\$10 in sales for every \$1 spent

(Adair & Holmgren, 2005; Backer et al. 2000; Chew et al. 2000; Cutrona et al. 2008; ugh-Berman & Ahari, 2007)

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Small gifts are powerful

Studies suggest that *the most powerful form of influence might be small gifts*

The more gifts a doctor received, the more he/she believed that they had no influence on prescribing

(Reist & VandeCreek, 2004; Dana & Loewenstein, 2003; Oldani, 2004) 37



The “gift cycle”

A three-way exchange of gifts between doctors, drug reps, and patients



(Reist & VandeCreek, 2004; Dana & Loewenstein, 2003; Oldani, 2004) 38

“Ask your doctor...”



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1997: FDA allows full-scale, direct-to-consumer advertising (DTCA) of prescription drugs
- DTCA only allowed in the U. S. and New Zealand

(Gellad et al. 2007)

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DTCA increases drug use by

- ✓encouraging people to visit doctor
- ✓encouraging patients to request advertised drugs
- ✓influencing doctor’s behavior through patient requests

(Gellad et al., 2007; Donohue & Bernd, 2004; Wolfe, 2002; Consumer Reports, 2007)

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DTCA increases spending by

stimulating sales of newer, costlier drugs above older generics



(Gellad et al., 2007; Donohue & Bernd, 2004)

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Accuracy of DTC ads questioned

1995 to 2004: FDA sent 1,359 warning letters to drug companies for false or misleading advertising

Only 4 FDA staffers review thousands of ads

(Donohue et al., 2007; Zalesky, 2006)

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Example: 2007 Geodon ad “false and misleading”

2007 FDA letter: maker exaggerated claims of efficacy and did not mention risks of neuroleptic malignant syndrome, tardive dyskinesia, hyperglycemia and diabetes



GEODON “exaggerated claims, downplayed risks”

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Industry funds “patient advocacy” groups

2005-2006: \$29 million to 6 groups
- 7%-91% of the groups’ budgets
Groups rarely disclose funding
Funds decline when drugmakers don’t benefit

(Philadelphia Inquirer, 2006; Los Angeles Times, 2007)

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- o **National Alliance on Mental Illness** received \$11.7 million from 18 drugs firms in three years
- o **Children and Adults with Attention Deficit/Hyperactivity Disorder** is funded by Shire PLC, the #1 ADHD drugmaker
- o **Depression and Bipolar Support Alliance** receives more than half its funding from drug firms

(Philadelphia Inquirer, 2006; Los Angeles Times, 2007)

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NAMI, CHADD, and DPSA, among “patient advocacy” groups receiving most industry funding, promote view of distress as *chronic brain disease*, requiring latest drugs and neurobiological research

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Continuing Medical Education

“Educating” to expand markets?

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Medical Education Communication Companies (MECCs) earned over \$1 billion in 2004 to deliver industry-sponsored continuing medical education (CME)

(Relman, 2001; Elliott, 2004; Wazana, 2000) 49

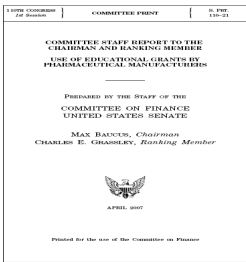
Industry-sponsored CME highlights sponsor’s drugs and is associated with increased prescriptions of those drugs

(Relman, 2001; Elliott, 2004; Wazana, 2000) 50

Concerns in U.S. Senate

APRIL 2007

Concern over drug firms’ influence on CME, and its impact on off-label drug use



(Report to Committee on Finance, US Senate, April 2007) 51

“Ghost” Marketing

Industry marketers and scientific journals

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“Ghostwriting”

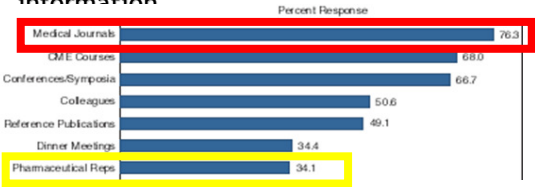
Pharmaceutical firms hire MECCs to write academic papers favorable to their products

MECCs then hire academics to publish the articles under their name without disclosure about the true source

(Moffat & Elliott, 2007) 53

“Ghostwriting” works because...

~ 76% of doctors consider medical journals their most important source of information



Source	Percent Response
Medical Journals	76.3
CME Courses	68.0
Conferences/Symposia	66.7
Colleagues	50.6
Reference Publications	49.1
Dinner Meetings	34.4
Pharmaceutical Reps	34.1

(Source: www.RxPromoROI.org; Fugh-Berman et al. 2006) 54

Even without ghost-writing...

A drug firm may pay a journal \$1 million for reprints, creating enormous incentive for the journal to publish a favorable article

A former editor of *British Medical Journal* called journals “extensions of marketing arms” of drug firms and urged journals to *stop publishing all clinical trials*, and only evaluate them critically

(Moffat & Elliot, 2007; Smith, 2004; *The New York Times*, 2002)

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Government and the politics of influence

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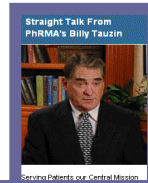
Pharmaceutical Researchers and Manufacturers of America (PhRMA) represents pharmaceutical and biotechnology companies in the U.S.



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PhRMA hired hundreds of lobbyists to help pass the Medicare Part D bill in 2004

Originally estimated to cost taxpayers \$534 billion, Medicare Part D forbids the government from negotiating drug prices



PhRMA head is Billy Tauzin, former Republican congressman from Louisiana

Drug industry lobbyists outnumber Congressmen 2:1

2006: Drug interests employed about **1,100** lobbyists, including **40** former members of Congress

CBS NEWS

Under The Influence
NEW YORK, APRIL 1, 2007

(Center for Public Integrity, 2007; *CBS News/60 Minutes*, 2007)

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Large investments in lobbying

2005 - 2006: \$182 million spent on federal lobbying

2005 - 2006: \$100 million spent on campaign contributions

Sales of top 20 lobbying spenders = 77% of the US drug market

(*CBS News/60 Minutes*, 2007; Center for Public Integrity, 2007)

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Defending industry interests

Main goal in 2007:

- Oppose laws that would strengthen FDA's ability to monitor drug safety
- Fight bills that would allow Medicare to negotiate drug prices, which could reduce government drug spending by 60%

(CBS News/60 Minutes, 2007; Center for Public Integrity, 2007)

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Part C

Conclusions and Recommendations

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Conclusions

Industry promotion of expensive drugs permeates all phases of the life-cycle of drugs

Deceptive drug marketing is "pervasive, dangerous and primarily aimed at doctors"

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Skepticism of industry grows

Previously "hidden" practices are increasingly exposed and scrutinized

Government hearings and legislative efforts highlight concerns over public health and public spending

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Some doctors call for limits

Asking for stringent regulation to eliminate conflicts of interest:

- no gifts, no speaking at industry-sponsored CME, no ghostwriting, disclose research and consulting contracts, replace free samples with vouchers for patients



(Troyn et al., 2006; Washington Post, 2006)

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Medical students take action

More Med Schools Show Pharma The Door

July 2nd, 2007 8:56 am By Ed Silverman

Last month, the American Medical Student Association ranked med schools based on their freebie policies, using a PharmFree scorecard. Since then, several schools reacted with embarrassment over their rankings.

- **Only 5 of 116 medical schools got an "A": for having a policy restricting drug industry access to students and faculty**

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But medical schools lag behind

- The International Committee of Medical Journal Editors (ICMJE) requires full disclosure of drug companies' role in research
- But even major journals still can't ensure transparency
- A study of 108 medical schools' agreements to conduct research for drug firms found that ICMJE guidelines were rarely followed
- Researchers have little access to data or power over publishing

(Rivera & Cummings, 2002)

(Schulman et al., 2002)

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States attempt legislation and sue drug firms

Most states have introduced bills or resolutions aimed at marketing

Several states are suing drugmakers for off-label promotion of antipsychotics and for hiding drug risks (see Module 5)

(Reist & Vandecreek, 2004; Zalesky, 2006)

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9 in 10 Americans favor reforms

Consumer Reports survey finds strong backing for drug reforms

As Congress prepares to vote on the most significant prescription drug safety legislation in 45 years, a new *Consumer Reports* poll finds that the American public strongly backs a number of reforms. Safety issues rose to the top, with 9 of every 10 Americans supporting reforms that would require warning labels and follow-up studies on drugs with safety problems, and public disclosure of all clinical drug trials.

ConsumerReports (2007)

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Recommended reforms to research

Create a public registry of all clinical trials

Fund clinical trials publicly, and cease drugmakers' ties to clinical research

Make raw clinical trial data accessible for independent analyses

(Antonuccio & Healy, 2008; NJPIRG Law & Policy Center, 2006)

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Researchers' commitment?

Because research participants expose themselves to risk, information derived from them should not be misused, suppressed, or distorted

Researchers should promise to make *all raw research data available publicly*, or forego approval from Institutional Review Boards

(Antonuccio & Healy, 2008)

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Teach prescribers, academics and consumers to:

- ✓critically evaluate drug marketing
- ✓rely on independent sources of information
- ✓implement best practices to minimize industry influence in schools, professional organizations, and mental health providers

(NJPIRG Law & Policy Center, 2006)

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A Critical Curriculum
on Psychotropic Medications

Module 4

The End



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