A Critical Curriculum on Psychotropic Medications

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Module 4
Pharmaceutical Industry Influences on Prescribing

Part A
Expanding Drug Markets

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)
**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)

**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)

**“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)

**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

**“Medicalization”**

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

(Conrad & Letter, 2004; Mintzes, 2002)
“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)

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 treat it.


Part B
Marketing Expands Drug Markets

Cost of marketing and promoting drugs in U.S.

Industry estimates: $29.9B

Independent estimates: $57.5B

Donohue, Cevasco & Rosenthal, 2007

(Gagnon & Lexchin, 2008)
Drug company marketing targets all players in the health care system.

It influences physicians to prescribe through:

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

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

It influences consumers to seek drugs through:

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

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

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”)
Drug Reps

100,000 drug reps in the United States
~ 1 for every 6 doctors

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

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

(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

(Rens know just which doctors to target and how)

Gift-giving
Very effective, even when doctors don’t think so

(The Boston Globe)

Does a drug firm’s free lunch influence doctors?
By Scott Laessman | May 19, 2007

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

(JAMA)
Are doctors “on the take”? 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)

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

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

“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
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)

The “gift cycle”

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

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

“Ask your doctor…”

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)

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)

DTCA increases spending by

stimulating sales of newer, costlier drugs above older generics

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

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

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)

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

Continuing Medical Education
“Educating” to expand markets?

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

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

Industry-sponsored CME highlights sponsor’s drugs and is associated with increased prescriptions of those drugs (Relman, 2001; Elliott, 2004; Wazana, 2000).

Concerns in U.S. Senate

Concern over drug firms’ influence on CME, and its impact on off-label drug use (Report to Committee on Finance, US Senate, April 2007).

“Ghost” Marketing

Industry marketers and scientific journals

“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).

“Ghostwriting” works because...

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

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

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

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

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)
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)

Part C
Conclusions and Recommendations

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”

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

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 to patients

(Medical students take action
- On 5 of 116 medical schools got an A for having a policy restricting drug industry access to students and faculty

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

(Revera & Cummings, 2002)

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

(Schulman et al., 2002)

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)

(Rest & VandeCreek, 2004; Zalesky, 2006)

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 5 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.

(Consumer Reports, 2007)

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)

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)

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)
Module 4

The End