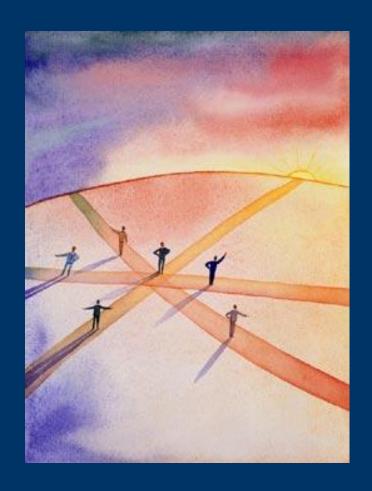
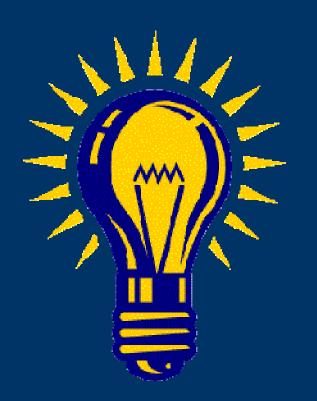
Psychiatry and the Drug Industry

(Health Care and the Drug Industry)

Tim Doty, R1
Rural Family Practice
July 27th, 2006











Outline (medicine is all about lists...)

Goals of physicians vs. goals of industry

Short history of Psychiatry and drugs

Relationship between the Drug Industry and...

- Physicians
- Patients
- Society

What needs to change?

The Drug Industry has...

- Transformed the lives of millions of psychiatric patients.
- Allowed many to live healthier, productive lives.
- Provided Medicine with some remarkable treatments for depression, bipolar, and schizophrenia.
- To some extent, destigmatized mental illness (as well as Psychiatrists..?)

This occurs when...

Physician goals = Industry goals



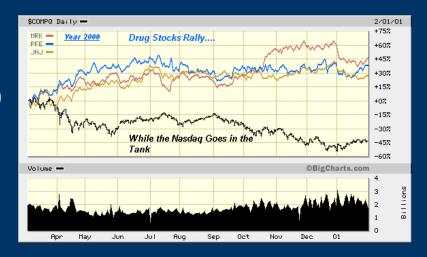
Better treatments for disease

However, when...

Physicians want the best for their patients



AND



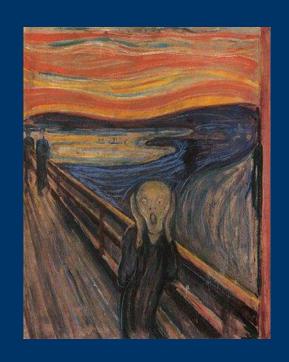
Drug Industry wants the best for their shareholders

(This is the absolute goal of any corporation)

Concern arises...

About the promotion or medicalization of normal variations in health as mental disorders...

(SAD, PMDD, and in medicine, Pre-HTN and hypercholesterolemia)



Patients being prescribed too many drugs, or even the wrong drugs.



Concerns...

- The encouragement, and even conscious creation (through marketing, advertising, etc...) of a "quick fix" society.
- Our subsequent over-reliance on drugs.
- Consequent drop in the use of psychotherapy (despite solid research that shows it is an effective strategy), as well as other non-drug therapies.
- Physicians as drug industry employees (Some work as actual employees, but others are more 'pseudo' employees)

We'll look at the drug industry and...

Physicians





Society



Patients

More specifically, we'll address the following questions...

The drug industry and...Physicians

Gifts

- What's wrong with gifts?
- Who pays for them?
- "Gifts don't influence me or my practice"

Continuing Medical Education

Who teaches us and whose message is it?

Research

- Who pays for the studies?
- Why do they always say "this drug is an effective choice..."

The drug industry and...Patients

DTCA

- Common goals or conflicting?
- Is DTCA balanced? fair?
- Why does the drug industry spend so much \$ on it?
- What is DTCA really for?

The drug industry and...Society

Promotion of illness

'Medicalization'

'Criminalization'

Is fraud simply the cost of doing business?

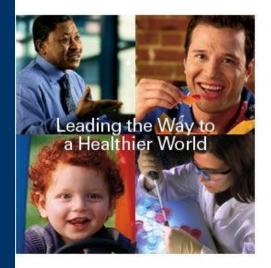
This seems to differ from what we hear about the drug industry...

How the drug industry wants us to see them





Site Map Site Search Contact Us



reality is...



Their ultimate objective is to make \$\$\$





Most profitable industry...

In 2005, global sales of pharmaceuticals reached over \$ 600 billion (N. America over \$ 265 billion) (More than all but the 18 top GDP countries)

This represented a 7% growth from 2004 (slightly less than previous years, but the industry is forecasting solid, consistent growth for yrs.)

Averages a return of ~17% on revenue every year (highest profit margin of any industry)

Leading psychotropic medications...

Antidepressants and mood stabilizers rank 4th in global drug sales, with \$19.8 billion in sales in 2005 (-3.9% from 2004, only class in top 10 to drop)

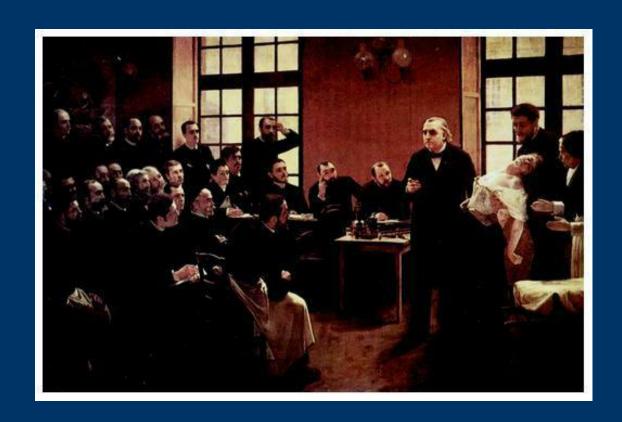
Antipsychotics ranked 5th at \$16.2 billion in 2005 (+10.7% from 2004).

Overall highest global sales (how do psychotropics fit in?)

- Zyprexa (olanzapine) 7th at \$ 4.7 billion
- Risperdal (risperidone) 8th at \$ 4.0 billion
- Effexor (venlafaxine) 10th at \$ 3.8 billion

But how did we get here?

The History of Psychiatry (and drugs)



19th century Psychiatry

Physical restraint

• There is no doubt that psychiatry has come a long way since the days of the insane asylum, where alienists (as psychiatrists used to be called because they dealt with the 'aliens' of society) treated their

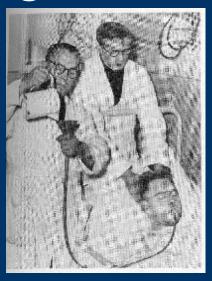
guests to the -

Utica crib (19th century)

Treatment for schizophrenia

or with electric shocks and chemically induced convulsions using insulin or metrazol -







Metrazol induced such powerful convulsions that it caused fractures in almost half of the patients they administered it to.

(20)

Early 1900's...

- Drugs consisted mostly of barbiturates, sedatives and some stimulants.
- Drugs were rarely given much attention, and they were generally seen as a form of chemical restraint.
- Not used as specific treatments like they are today.
- Almost all drugs currently used in Psychiatry have been introduced since the 1950's.

Since the 1950's...

- Drugs began to gain more importance.
- Most discoveries occurred serendipitously

The Drug Industry...

- Fostered the "psychopharmacological era"
- Described as the "ultimate force behind the adoption of new drugs such as chlorpromazine"
- Credited with transforming Psychiatry into a genuine and modern medical specialism.

Drugs in Psychiatry...

- Specific drugs began to be used for specific conditions, and this led to speculations about the etiology of these diseases.
- These trends can be epitomized by the well-known dopamine theory of schizophrenia and the monoamine theory of depression.

This way of thinking...

Transforming psychiatry from a more comprehensive view of mental illness as part of the...

Biopsychosocial model

To the more 'Pharma-friendly'...

"Bio-Bio" model

This is where illness exists as a product of a deficiency or an imbalance of neurotransmitter levels.

The helps convince us that a drug is the best solution.

we'll start with...

The drug industry and physicians...

The drug industry and physicians

In today's medical world, the giving of gifts from industry to physicians is common and pervasive.

Question...

In the US, the drug industry spends _____ per year on marketing to each physician?

- (a) \$ 500
- (b) \$ 1,500
- (c) \$ 5,000
- (d) \$ 10,000

What do you mean by gifts?

These gifts come in all shapes and sizes, from the small and inexpensive pen, coffee mug or notepad, to the lavish weekend conference in a warm, holiday hot spot.





Gifts, con't

They can be of a more professional nature, such as drug samples, copies of research papers, reimbursements for referring patients to clinical trials or sponsorships for educational activities.

However, they can also be of a more personal nature as well, such as when conferences have social events attached to them, or if these activities include travel expenses, golf balls, coffee makers, or other personal gifts.

Gifts, con't...

• Occasionally these interactions result in criminal investigation.



- Drug giant GlaxoSmithKline was accused in 2003 of using World Cup soccer tickets, cash, stereos, and holidays to bribe Italian and German doctors into prescribing their drugs.
- In the same year, Astra-Zeneca was required to pay a \$355 million settlement for their part in a scheme in which US doctors billed insurance providers for drugs provided free by the company.....and this is just the tip of the iceberg.

Why are they given?





- Gifts are primarily designed to foster goodwill, familiarity and recognition of a company's product.
- Gift giving also forms the beginnings of a social contract in which some form of reciprocity is desired, or even expected.
- In many cases this may not be outwardly expressed, but social science research consistently demonstrates that -

"the obligation to directly reciprocate, whether or not the recipient is conscious of it, tends to influence behaviour."

Why are they given?

• In Medicine,

"the reciprocity rule is often exploited in that the giver (ie: drug rep) is not only able to decide the form of the initial favour, but also the form of the return favour as well. In other words, if physicians are to reciprocate for small gifts, they cannot do so in any form they please, as they are essentially compelled to reciprocate by supporting their benefactor's products."

• "Foot-in-the-door" marketing...brownies make people happy...and more willing to listen to you.

Why are they accepted?

- Some may feel it is a professional right/privilege.
- Time pressures It's an easy way to stay up-to-date on new treatments.
- Students are socialized into accepting them.
- Many physicians feel that accepting gifts poses little problem.

In fact...

- One study of medical residents showed that 61% felt that "promotions don't influence my practice," while only 16% believed the same about other physicians.
- Bias is recognizable, but only in others.
- Studies also show that the more gifts a physician receives, the more likely he or she believes they don't influence their behaviour.

So what's the problem?

- There is solid evidence that gift giving directly influences the behaviour of physicians in ways that benefit the drug industry (Wazana and others)
- <u>Knowledge</u> (inability to identify wrong claims about medication)
- <u>Attitude</u> (positive attitude toward pharmaceutical representatives; awareness, preference, and rapid prescription of a new drug)
- <u>Behaviour</u> (requests for medications that rarely held advantages over existing ones; non-rational prescribing behaviour; increasing prescription rate; prescribing fewer generic but more expensive, newer medications at no demonstrated advantage)

Conflict of interest...

- COI "arises when a primary ethical or professional interest clashes with financial self-interest."
- When a physician (whose primary interest is the patient) makes a decision that puts the interest of industry ahead of that of his/her patient....then there is conflict.
- Since bias is unconscious, this conflict of interest often goes unrecognized.

How do patients feel about gifts?

- Patients don't want physician's decisions about their care influenced by the interests of others who stand to gain financially.
- When researchers attempt to find out just how patients feel about these relationships, they often have difficulty locating physicians willing to take part in the studies.
- This lack of willingness suggests that physicians are justifiably conflicted about this behaviour.

Continuing Medical Education, or "education"

- Physicians have a professional obligation to stay current.
- CME is often sponsored and supported, sometimes even organized by industry.

Keep in mind ...

- For physicians, CME means learning how to provide better care, whereas for industry it is merely a required step in selling their products.
- Funding from industry depends on marketing potential.
- \$ comes from the marketing budget.

CME considerations...

- Who is the speaker (how were they selected and by whom?)
- Does the speaker have competing interests?
- Have they made them known?
- What is the topic (Depression vs. SSRI's in Depression)
- Is the presentation balanced?
- Who made the slides (presenter or drug company)
- How much presence/advertising is there from industry?

What about the research?

- Years ago research was largely publicly funded.
- Today approx. 70% of research on drug treatments is funded by industry.
- In the US, Contract Research Organizations hire out their services to drug companies.
- Future contracts depend on positive results.
- = Pressure to make things look good.

Borison and Diamond case

- Psychiatrists who set up a CRO in the US.
- Investigation revealed huge personal wealth
- Bonuses to staff who enrolled the most patients
- Cash incentives to test subjects
- Convicted of fraud

* Borison was the lead investigator in two key trials that led to the approval of risperidone in the US.

Exaggeration of drug benefits...

Failure to publish negative results

• SSRI antidepressants, COX-II inhibitors

Multiple outcome measures, pick the best one

Statistically something will end up positive

Multiple publication of positive results

• 5 published papers, 3 trials

Exclusion of subjects from analysis

Drop a few ADR's and presto ** safe

Physicians as 'Brand Champions'

Physicians are often hired to provide expert opinion, sit on committees, or 'champion' their products.





COI and Clinical Practice Guidelines...

JAMA 2002,

- 81% of authors had at least some interaction with the drug industry.
- 59% had relationships with companies whose drugs were being considered in the guideline they authored.
- 96% had relationships that pre-dated the guideline creation process.

This is a concern since CPG's influence the practice of many, many physicians...

In 2000, NEJM

- Didn't have enough space to print all the financial interests of physicians authoring a paper on the antidepressant nefazadone.
- Difficulty finding an academic psychiatrist to write an editorial on the subject who did not have ties to companies making antidepressants.

Where is our professional integrity?

San Diego-based psychiatrist Loren Mosher, in his letter of resignation to the American Psychiatric Association, said:

"Psychiatrists have become the minions of drug company promotions." He blasted the drug-industry shaped definitions of mental disease: "No longer do we seek to understand whole persons in their social contexts – rather we are there to realign our patients' neurotransmitters."

next...

The drug industry and patients

DTCA of psychotropic medications...

Common goals (or conflicting goals?)

- Public 'education' about medical conditions
- Destigmatize mental illness
- 'Empowering consumers'

Conflicting goals

- Gain competitive advantage over existing products
- Maximize profits

The controversies of DTCA...

(fictional ads)

The Farnsworth Express, Monday Morning, April 54, 2007

Is Drug Advertising Balanced?

Georgia Richardson

The World Express, Saturday, September 32, 2004

Researchers say drug ads exaggerate benefits and minimize harms

Paul Francis, Health Reporter

The Daily Sun, January 5, 2003

Direct to consumer advertising misleads the public.

CMAJ, 2003 (Cassels)

- Newspaper coverage during 2000 of 5 intensely marketed prescription drugs...
- Of 193 articles that mentioned at least one benefit...
- 32% mentioned a possible side effect or harm
- 16% mentioned non-drug treatment options
- Benefits were mentioned nearly 5 times as often as harmful effects

However, DTCA increases sales, so...

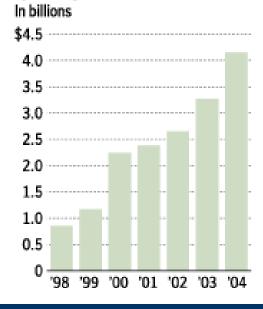
- From 1999-2000 drug companies poured millions more \$ into direct advertising...
- Merck upped DTCA spending by 117.7 %
- Eli Lilly boosted it by 554.9 %
- Bristol-Myers-Squibb upped it by 216.7 %
- Overall industry increase from \$ 791 million in 1996 to a staggering \$ 2.5 billion in 2001.
- (Remember, we pay for these costs through our drugs)

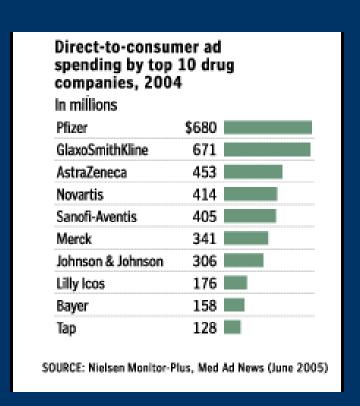
More recent DTCA spending...

Reeling in Customers

Spending on direct-to-consumer advertising for prescription drugs is nearly fivefold its level in 1998. Last year, Pfizer spent the most.

Total direct-to-consumer ad spending, 2004





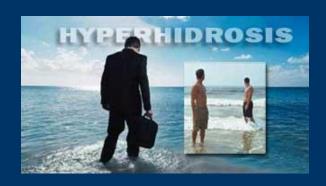
Industry knows very well that...

DTCA leads to more patient visits

DTCA leads to more direct requests for advertised drugs

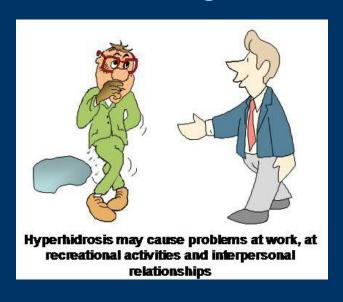
DTCA leads to more prescriptions for advertised drugs

Bottom lines of DTCA...



'Educating the public'

- Connecting a list of symptoms to a disease in 15 seconds
- Connecting a disease to a drug in 30 seconds





Bottom lines of DTCA...

'Empowering consumers'

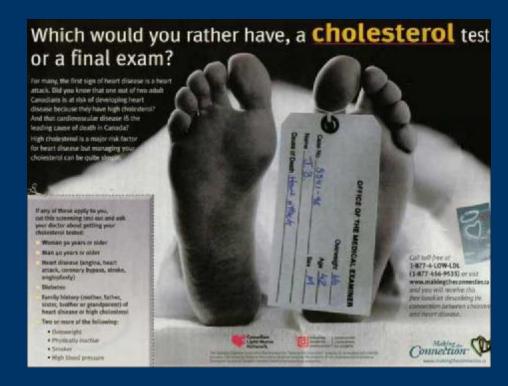
- Creating a demand for a drug (previous slide)
- Getting the patient (consumer) to see their doctor
- Getting the patient to ask for a drug

'Empowering' has a positive connotation

• Let's look at some examples of 'empowering'

'Empowering' through fear...

 Pfizer put together this ad which is designed to 'empower consumers' to see their doctor, unless they prefer to simply show up for their final exam.



'Empowering' by not empowering??

Weight loss drug orlistat (Xenical)

- Ad which shows a photo of a baby saying: "In the beginning, your weight was in the capable hands of your doctor. It still should be."



- Your weight is not your responsibility?
- Quick fix over long term solutions?
- Harm vs. Benefit



Mirtazapine (Remeron) ad...

The image of a couple dancing across the floor

"Are you sleepless, anxious, or depressed?"



"symptom relief in as little as 2 weeks"

The ad is saying "it doesn't matter why you're depressed or anxious...don't even think about it...just take this"

Trivializes depression...promoting a quick-fix

Remeron ad...

"Because your patients don't have time to wait"

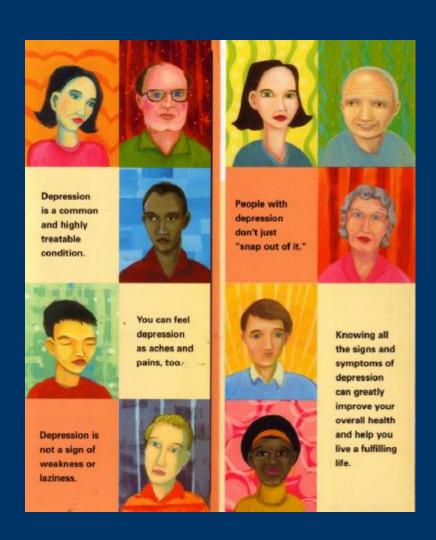
Telling doctors how to do their job

- Get on it, your patients don't have time for this.
- Don't try anything that'll take time.

What is wrong with society? Why are we so rushed?

- Stop for a minute and think about your life.
- No time taken to confront personal issues. Just take a pill and get on with it.

The drug industry and society





Promotion of illness, 'medicalization'

Depression

- 1950's Merck (launched amitriptyline) bought and distributed "Recognizing the Depressed Patient"
- Late 1980's, with SSRI's, Defeat Depression Campaigns
- Convince GP's of high rates of depression (5%, 20%, 10%)
- Convince Public that it's ok to take antidepressants (despite human nature to avoid reliance on a drug to be healthy)
- Results of all this?

Medicalizing depression...

- Long term disability due to depression has been increasing.
- Antidepressant use is increasing.
- Suicide rates (5-14 y/o) have doubled in last 20 years.
- Are we actually helping people, or harming them?
- Are we simply avoiding the real questions?
- It is thought that the drug industry pursued the antidepressant market after the benzodiazepine market dissolved following evidence of their addictive properties.

Real need, or marketing magic?

- Late 90's, antidepressant market dominated by Prozac (Lilly) and Zoloft (Pfizer).
- SmithKline needed to find a wider market for Paxil.
- SmithKline hired Cohn and Wolfe (PR firm)
- Press releases included, up to 13% pop'tn suffers from SAD
- Slogans like "imagine being allergic to people"
- Gained approval for use in Social Anxiety Disorder, or social phobia.
- Then they started marketing Paxil for SAD, and by the end of the year sales of Paxil was on par with Prozac... *presto.

What happened to Prozac?

More marketing magic -

Ely Lilly was facing the end of patent protection for Prozac.



- So they re-packaged it and gave it a new name Sarafem
- Obtained approval to market Sarafem for the treatment of severe PMS now called Premenstrual Dysphoric Disorder.
- In 2000, net sales of Prozac (and Sarafem) was \$2.57 billion
- Prozac (including Sarafem) accounted for 24 percent of Lilly's total net sales, down from 34 percent in 1996.
- Lilly is consistently lessening its reliance on sales of Prozac.

What happened to Paxil?

Several lawsuits filed against GSK

- One plaintiff, whose 17 y/o daughter took Paxil for SAD and then became agitated and aggressive. She later gouged a hole in her leg with a pair of scissors.... "No parent should ever have to go through what we did."
- Another 11 y/o boy, who was prescribed Paxil for Separation Anxiety Disorder, hung himself in the family laundry room with the dog leash the following month.

Many, many other similar stories.

Why did this happen?

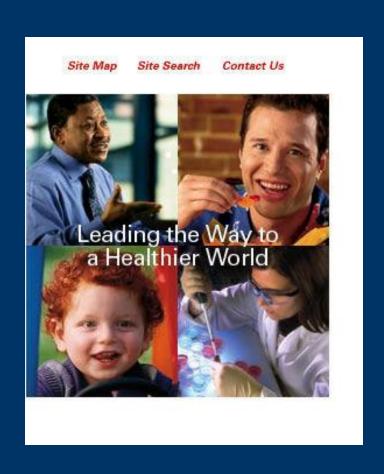
- No one was aware of the link between Paxil and akasthisia and increased suicidality because GSK deliberately hid this information.
- GSK also concealed years of information about serious withdrawal effects of Paxil.
- GSK's motive?
- If properly labelled, Paxil would lose its share of the SSRI market.

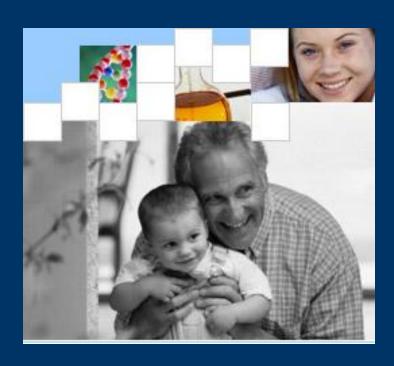
Attorney in GSK lawsuit...

"Through our Paxil litigation, we've obtained documents that show a seriously troubling mentality of profit over safety and a callous disregard for the welfare of children."

(Now I'm confused because...)

I thought the drug industry cares about us?





Not sure about us, but they care about these guys...

A PICTURE THAT'S WORTH \$14 MILLION

The total amount the health industry gave to these lawmakers who celebrated the signing of the drug/HMO industry-backed Medicare bill



CIAIM: "A lot of this happened - this bill happened because of grassroots work. A lot of our fellow citizens took it upon themselves to agitate for change, to lobby on behalf of what's right." - President George W. Bush, 12/08/03

FACT: "Drug companies and their trade associations deployed nearly 700 lobbyists to stamp out any proposals that would result in the federal government negotiating the cost of drugs or otherwise limiting the industry's astronomical profits. " - Public Citizen Report, June 2003

Millions paid out to deal with fraud...

"Is this simply the cost of doing business?"

With this in mind...

Costly Remedy Criminal or civil penalties already paid by selected drug companies to settle allegations of pricing fraud: COMPANY/ TOTAL PAID. DATE SETTLED IN MILLIONS PRODUCT(S) \$430 Neurontin Pfizer May 2004 AstraZeneca Zoladex 355 June 2003 Schering-Plough 345 Claritin July 2004 Bayer 257 Cipro, April 2003 Adalat GlaxoSmithKline 88 Paxil. April 2003 Flonase

Proposed DSM-V Diagnosis...

- At what point does an individual cross the line of earning a living, (even a decent living), and begin to negatively affect other people's lives?
- Just as a person may be diagnosed with various medical illnesses when they pose a risk to others, or to society, I propose a disorder for those whose pursuit of profit occurs despite any concern for the health of others.
- I believe this to be a serious disorder because it has been proven to negatively affect the health of millions of people.

Profit seeking behaviour disorder (PSBD)

1. Must have 2 of the following –

- Desire to earn profit above all other goals.
- Willing to circumvent the needs of others in order to satisfy the above goal.

2. At least 3 of 5 of the following –

- Rationalizes behaviour through financial terms (increase efficiency, maximize profits)
- Indifference or absence of guilt
- Uses litigation to solve threats to profit
- Uses money to mitigate threats to profit
- Avoids apologizing or accepting responsibility for harm caused to others

Profit seeking behaviour disorder (PSBD)

3. PSBD is a medical diagnosis that can be ascribed not only to an individual, but to several individuals who collectively satisfy the criteria for diagnosis. (Diagnosing a corporation would be an example.)

Current treatment of PSBD consists of the 'ates'

- Regulate (behaviour)
- Litigate (actions)
- Confiscate (responsibility)
- Medicate (for serious cases)

- Be more skeptical
- Become more aware of corporate behaviour
- Bring your own lunch
- Buy your own dinner
- Know who's funding CME (public interest or private/profit)
- Know who's giving the talk (Dr. Smith is getting paid \$3,000 by ---- to give us a talk on a drug made by ----)

Report adverse events to Health Canada

- Serious underreporting of ADR's.
- Patients should benefit from information already known.

Don't let the results of one industry-funded research paper change your prescription habits, or the way you practice medicine.

• Wait for the 'brick' to land, not the 'feather.'

Incorporate patient values into treatment choices

- Tell them the evidence, let them make the decision
- Their body, their risk/benefit, not yours.

Prescribe one new drug at a time

- Less confusing for the patient
- Adverse reactions will have a known cause
- Side effects are easier to manage

Prescribe fewer drugs - Prescribe generics instead

• Lower costs substantially

Consider alternatives and other therapies

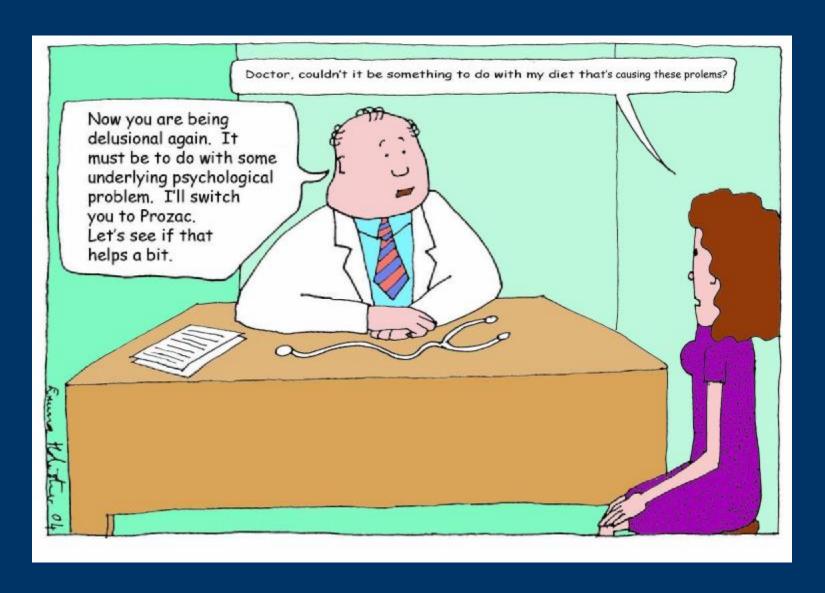
Take patients off drugs they don't need - perform "drug-ectomies"

- Patients have multiple prescriptions from multiple doctors and often there is no one keeping track.
- Increased chance of ADR, more difficult to sort out.
- Patients often appreciate it.
- They often feel better too.

What patients need to do...

- Be informed, seek out knowledge from different perspectives/opinions
- Realize you have a choice
- Realize you have values, (the care is for you)
- Ask your doctor when he/she last played golf.

The future of medicine?



If you become to skeptical, critical, don't fear...



The drug industry has described PharmAmorin as a "godsend" for sufferers of independent-thinking-related mental-health disorders.

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Part I: Physicians – Prescribing under the influence?

Part II: Patients – Do you feel unmotivated?

Part III: Society – Are there statins in the water?

Articles available at www.healthyskepticism.org/news.php click on the March 2006 edition

Any information contained in this presentation that is not referenced above can be found (with complete references) in the above papers written by Tim Doty, April 2004, and published online at the above web address.