

Separating  
Science from Promotion  
Evidence from Propaganda

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A body of **evidence** contained in pharmaceutical company documents, mostly uncovered during **civil and criminal legal proceedings**, leaves little doubt, but that Pharma has fully earned its plummeting reputation.

Merck—Vioxx

Eli Lilly— Zyprexa

Janssen (J & J)--Risperdal

GlaxoSmithKline—Paxil / Paroxetine

Pfizer—Neurontin—Trovan—Celebrex—Bextra

## Propaganda:

The pharma industry promotes itself as dedicated to bringing “**life-saving**” medicines to patients through “innovative research and development.”

## Evidence:

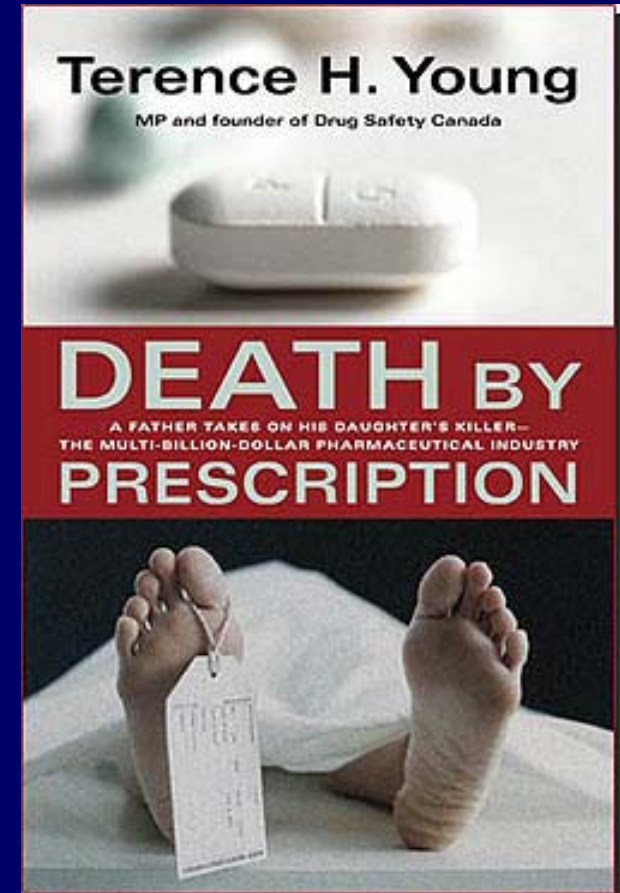
Pharma is driven by commercial expediency: promoting drugs of dubious benefit and **serious undisclosed risks** as “safe and effective.” **Patients suffer catastrophic harm.**

# Adverse drug reactions: 4th leading cause of death in the U.S.

*Each year:*

*1.5 Million Americans are hospitalized due to ADR*  
*106,000 hospitalized pts die of ADR*

*JAMA, 1998*



## Serious ADR reported to FDA MedWatch:

- 1998: ADR: 34,966; Deaths: 5,519
- 2005: ADR: 89,842; Deaths: 15,107

*Archives Internal Med, 200*

**Most drug-induced deaths** reported to the FDA were linked to **pain killers** (opiates and analgesics) and **Atypical antipsychotics**.

1998 – 2005: the deaths of 6,225 Americans were linked to Zyprexa, Risperdal, Clozaril.

*Archives of Internal Medicine, 2007*

Drug safety problems are due to **inadequate testing and false marketing claims** widely misrepresented as “*science-based evidence.*”

Pharma funds 80% of clinical trials turning science into a marketing tool designed to create an illusion: “*safe and effective.*”

Underpowered, minimal duration;  
clinically insignificant end points;  
cherry picked subjects;  
unreported injured dropouts;  
negative data buried, unpublished.

## Placebo is industry's *EasyPass*

*“...without placebo-controlled trials, industry would be forced to find better drugs rather than just more drugs.”*

*“Why risk trying to prove you're better than something, when all you need to show is that you're better than nothing?”*

*Robert Misbin, MD, FDA, Div. Endocrinology, 2001*

*“4 of every 28 new drugs are clinically superior—and 1 is also safe.”*

*Dr. Donald Light, Facts & Myths About Drug Development, 2007*

# Clinically insignificant, toxic drugs become blockbuster sellers.

Worst drugs are the most advertised

Merck: Fosamax, Vioxx

Pfizer: Neurontin, Bextra, Zoloft,  
Chantix, Geodon

GlaxoSmithKline: Paxil, Avandia

Lilly: Oraflex, Prozac, Cymbalta, Zyprexa

Janssen (J & J): Prepulsid, Risperdal

AstraZeneca: Seroquel

Wyeth: Prempro, Redux (Fen-Phen)





# Vioxx: just another pain pill with no therapeutic benefit.

- **Estimated 130,000 to 953,000 cardiac events**

*Donald Light, Institutional Foundations of Drug Disasters, 2008*

***55,000 estimated deaths***

*David Graham, FDA Whistleblower*

- **Merck Propaganda (2004)** *"really putting patient safety first..."*

- **Evidence:** 3-fold increased risk of death.  
Merck knew (2000) cardiac risk

*"is mechanism-based, as we worried it was..."*

*Edward Scolnick, chief scientist, Merck, 2000*

*"Drug disasters are literally built into the current system of drug testing and approvals... We are virtually defenseless against another Vioxx."*

*Dr. David Graham, Senate Testimony, 2004*

*"New drugs are twice as likely to cause harm compared to existing treatment."*

*Dr. Donald Light, Inst Foundations of Drug Disasters, 2008*

- How were hazardous drugs turned into high profit best sellers?

# “Cost of Pushing Pills”

Gagnon, Lexchin, PLoS Medicine, 2008

## Annual Expenditures:

- **Marketing (promotion)** **\$57.5 billion**
  - Influencing doctors (detailing) \$20.4 billion
- **Research & Development** **\$31.5 billion**
  - *Additional marketing expenditure:  
ghostwritten reports, fake journals  
lobbying, illegal off-label promotion*
- **2004 U.S. Pharma Sales** **\$235.4 billion**

# Pharma's pervasive influence has undermined prof / scientific integrity.

- Medical research / clinical trials
- Journals, scientific meetings
- Medical education / Grand rounds, CME
- Practice guidelines
- FDA review / approval process
- Public health policy
- Media mostly transcribe marketing hype as “scientific breakthroughs”

*“drug companies will do everything in their power to keep a drug on the market, especially their top money-makers.”*

*Terence Young, MP Canada, “Death by Prescription, 2009*

Pharma has paid hundreds of millions even billions of dollars in secret liability settlements —**to hide evidence.**

**But some secrets have come unsealed...**

# Unsealed secret company documents

- Lilly run a large and highly effective IIT program
- Significantly higher (x3 in some markets) investment than AZ
- They are perceived as open and flexible to receiving proposals but will often impose strict design changes before approval
- They impose few restrictions on the investigator once design changes are communicated and agreed
- They are fast and effective in turning studies around centrally and locally
- They offer significant financial support but want control of the data in return
- They are able to spin the same data in many different ways through an effective publications team
- Negative data usually remains well hidden
- Janssen have a well organised IIT plan
- Significant spend in some markets but variable in others
- Well structured, protocol-driven program that turns proposals around quickly through a very small approval team
- Local investment decisions are allowed on small IIT's
- No IIT data is allowed to be published without going through Janssen for approval, and communication is controlled by Janssen
- High expectations are set on investigators who publish favorable results but they are well rewarded for their involvement
- They seem less concerned than Lilly about negative data reaching the public domain
- BMS IIT program is growing very fast in launched markets



*AstraZeneca unsealed Seroquel document, 2003*

AstraZeneca documents reveal:  
Seroquel's safety was promoted with  
*“positive spin...smoke-and-mirrors.”* (1997)

But three Seroquel trials that showed a  
serious diabetes risk were buried.

*“Our objective is to neutralize customer  
objections to Seroquel's weight and diabetes  
profile.”* (2005) *Wall Street Journal, 2009*

*“drug companies will do everything...”*

# AstraZeneca: U.S. Medical Director used Sex to control Seroquel reports



*Martha Rosenberg, 2009*

**Dr. Wayne Macfadden**  
(now at J & J)  
acknowledged in  
sworn testimony...  
sexual relationships  
with several women  
who ghosted favorable  
**Seroquel** journal articles.

One woman was a researcher at the  
Institute of Psychiatry, King's College,  
London.

*Businessweek, 2009*



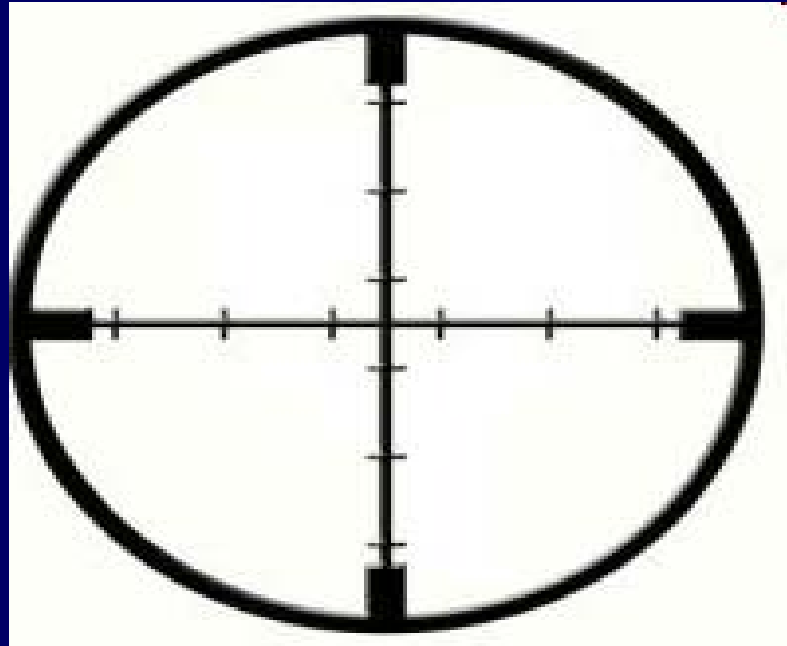
## How industry tactics hide negative antipsychotic data.

- Lilly “*spin* the same data in many different ways through an effective publications team. *Negative data usually remain well hidden.*”
- BristolMeyerSquibb “*Strategic focus is on unlicensed indications.*”
- J & J “*no data is allowed to be published without Janssen approval...investigators who publish favorable results are well rewarded.*”

*AZ Global Manager email, 2003*

# *Merck: Doctor Hit List*

***"Neutralize"***  
***"Discredit"***  
***"Destroy"***



***"We may need to seek them out and  
destroy them where they live ..."***

*Australian News, 2009*

# Commercial expediency trumps Ethics, Science, Safety

- **Pharma Corporate Ethics**
  - Exploitation, false claims
- **COI → Corrupted Science / Medicine**
  - biased trials, data manipulation, ghosted reports, fake journals, manufactured consensus
- **Corporate Crimes → Drug Disasters**
  - fraud, deception, concealed hazards, illegal promotion, threats / intimidation of critics

*Archive of drug industry documents, U of California, SF*

# Big Tobacco ~ Big Pharma

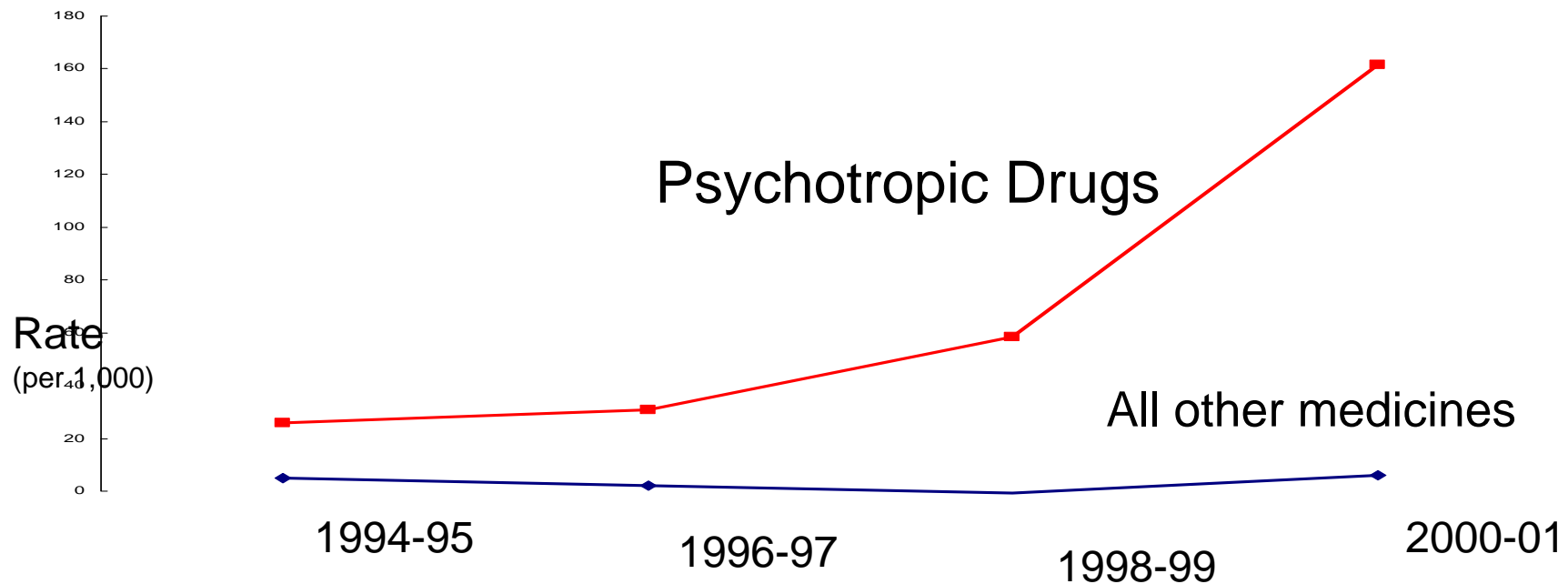
- Both marketed harm-producing products.
- Both engaged in corrupt corporate practices.
- Both concealed hazards & launched deceptive marketing / advert campaigns.

## Important differences:

- **Doctors did not prescribe cigarettes**
  - promote tobacco or shield from liability
  - rely on tobacco for safety information
- Medical journals were not conduits for ghosted tobacco industry propaganda.

# Prescription for Disaster

## U.S. Rx Trends for Adolescents



*Used mostly for behavior control*

*Psych Services, 2006*

**Birth of pediatric market:**  
contrived disease rationale  
promotes antipsychotic use.

1994: Janssen (J & J) launched  
the antipsychotic, Risperdal.

1994: Psychiatry's Diagnostic Manual (DSM)  
broadly redefined pediatric bipolar disorder.

**1996-2004: "Bipolar" children increased 439%**

Blader, Carlson, *Biological Psychiatry* 2007



## Propaganda:

Leading journal reports signed by prominent academics claimed:

“Atypical antipsychotics are safe & effective...well tolerated...with a more favorable side-effect profile.”

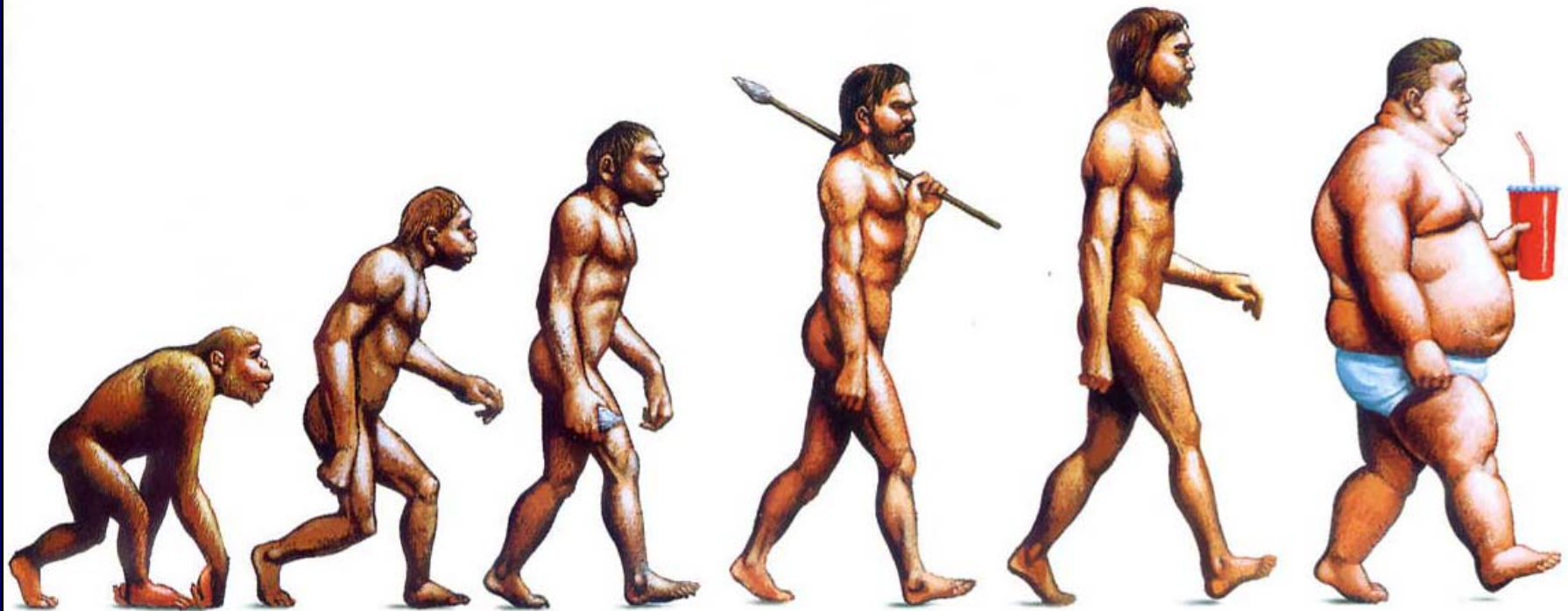
*J Clinical Psychopharmacology, 1999*

*Primary Care J Clinical Psychiatry, 2003*

They were silent about these drugs' staggering adverse effects and potentially lethal risks.

*Clozaril – Risperdal – Zyprexa – Seroquel – Abilify –  
Geodon*

## Evolution of Metabolic syndrome



No evidence the drugs help patients recover



# “Safe and effective?”

Severe adverse drug effects:

acute weight gain, diabetes mellitus,  
elevated prolactin—pituitary tumors

Metabolic Syndrome

Dangerously abnormal: liver function,  
cholesterol level, hyperglycemia, coronary  
heart disease—DEATH

Impair judgment, motor skills; sexual function

The new antipsychotics = worse than the old...

# Risperdal linked to Gynecomastia

In 8-week clinical trials (2.3%) 43 children / adolescents on Risperdal grew breasts.



Boy Rx Risperdal  
required double  
mastectomy at age 13.

**70% of pediatric post-marketing gynecomastia cases linked to Risperdal.** *Doraiswamy, Pharmacotherapy, 2006*

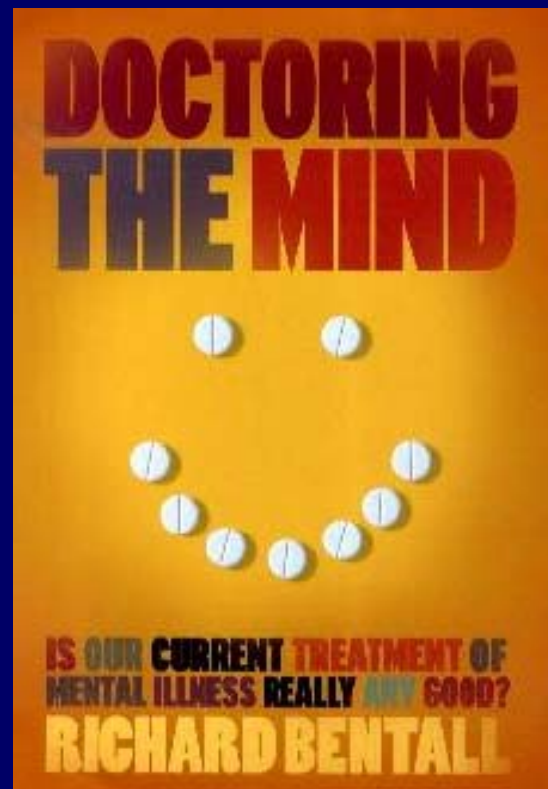
Despite staggering adverse effects...

*“nearly 1 in 5 psychiatric visits  
for children included  
a Rx for antipsychotics.”*

*Dr. Mark Olfson, Arch Gen Psych, 2006*



*“Drug companies are bribing American child psychiatrists with huge research grants to advocate [antipsychotic] treatment... to poison children...and it’s beginning to happen in the UK.”*



# Antipsychotic Use in Canadian Children: Up 1,000%

- *“University of British Columbia medical research suggests:*
- *“the number of children taking atypical antipsychotics has increased tenfold over the past decade.”*
- *“The drugs can have potentially serious side-effects, and are linked to increases in stroke and sudden death in adults.”*
- Health Canada has not approved atypical antipsychotics for children.

*CBS News, 2009*

*"Despite potential health consequences, the metabolic status of patients appears to have little bearing on clinicians' choices of an atypical antipsychotic agent."*

*Neil Osterweil, APA, 2007*

**2008 U.S. Antipsychotic sales: \$14.6 billion**

Zyprexa \$4.7

Seroquel \$4.5

Risperdal \$2.5

Abilify \$2.1

*IMS, Associated Press, 2009*





Public trust in the integrity of medicine and medical research will not be restored until:

1. A **firewall** is erected to curtail (if not eliminate) industry influence.
2. Pharma executives are held fully **accountable** for illegal practices.