

Separating
Science from Promotion
Evidence from Propaganda

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World Conference of Science Journalists
London
July 2, 2009

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:

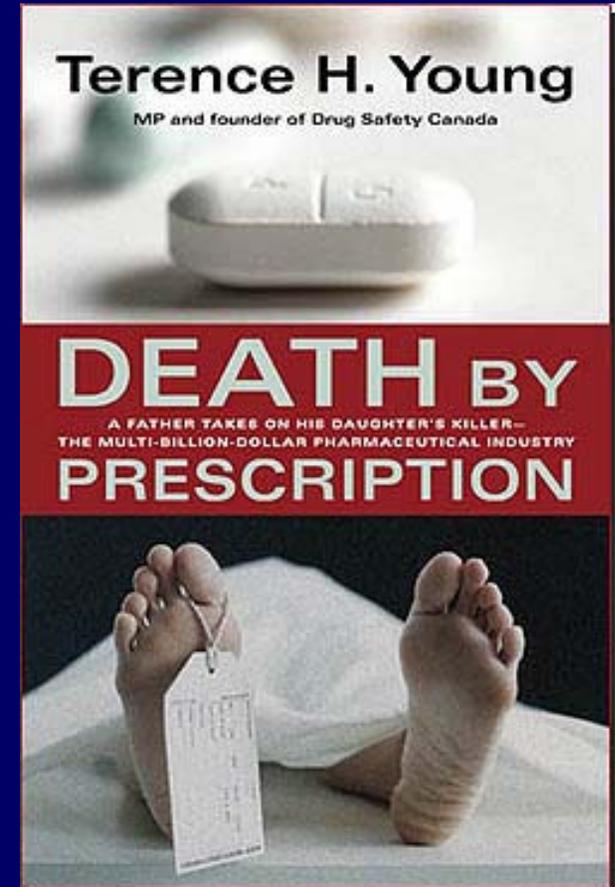
Pharma is driven by commercial expediency: promoting drugs of dubious benefit and **serious undisclosed risks** as “safe and effective.” **Patients suffer catastrophic harm.**

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negative data buried, unpublished.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

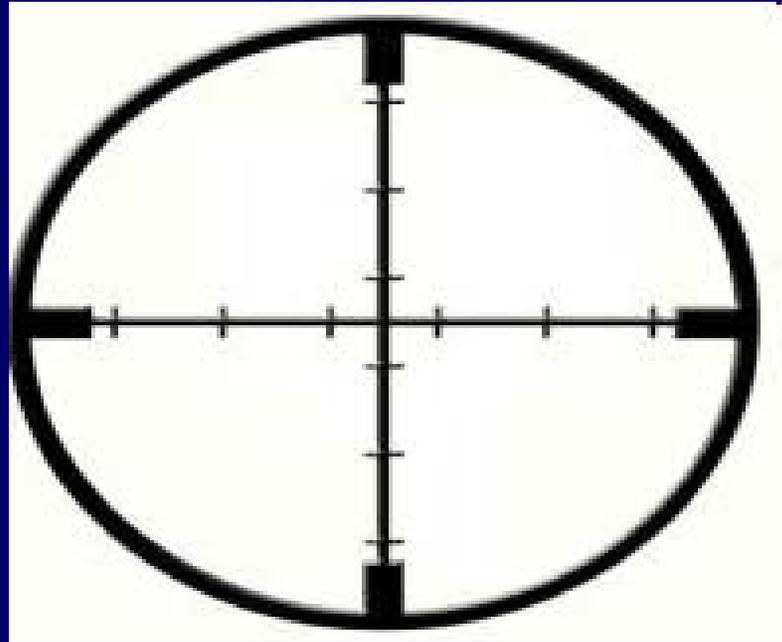
How industry tactics hide negative antipsychotic data.

- 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

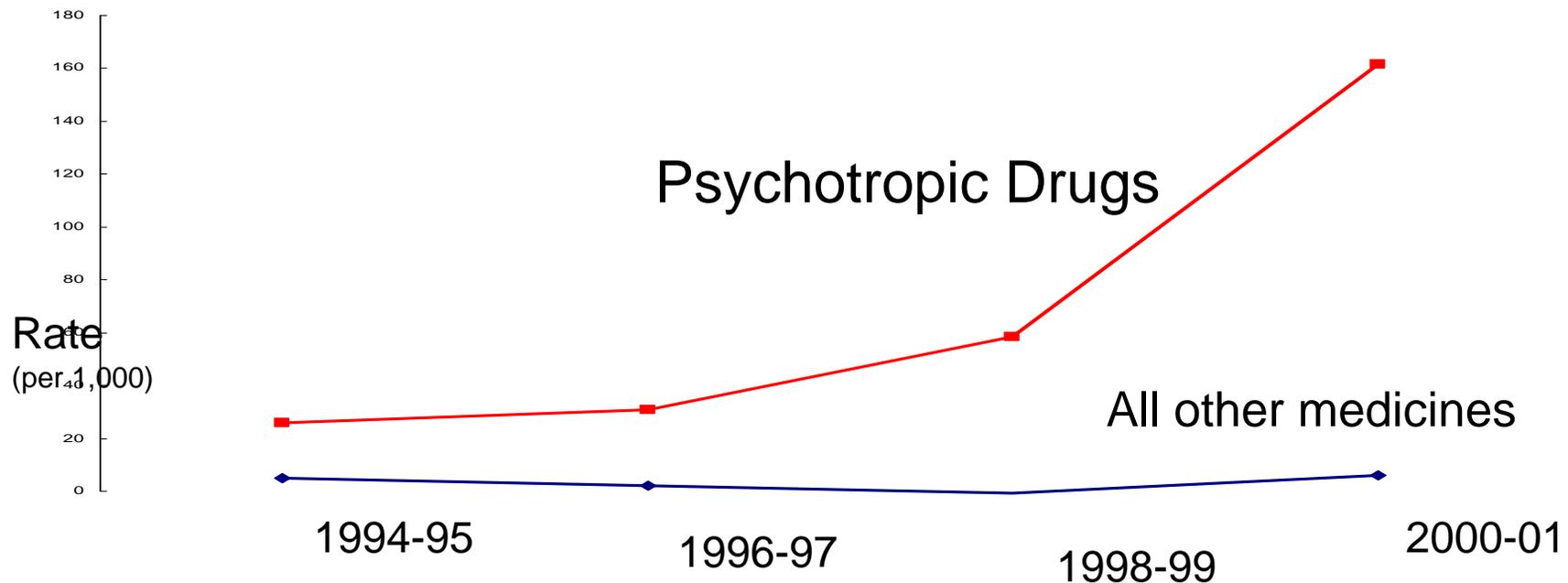
- Both marketed harm-producing products.
- Both engaged in corrupt corporate practices.
- Both concealed hazards & launched deceptive marketing / advert campaigns.

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

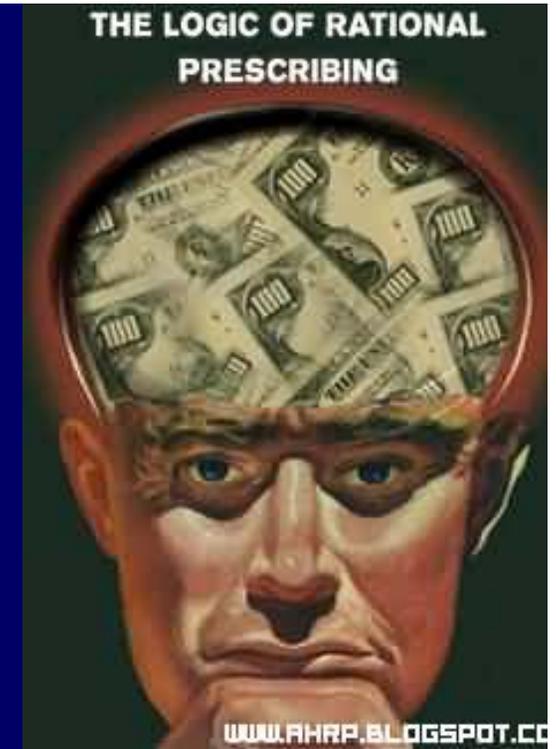
Birth of pediatric market:
contrived disease rationale
promotes antipsychotic use.

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.”

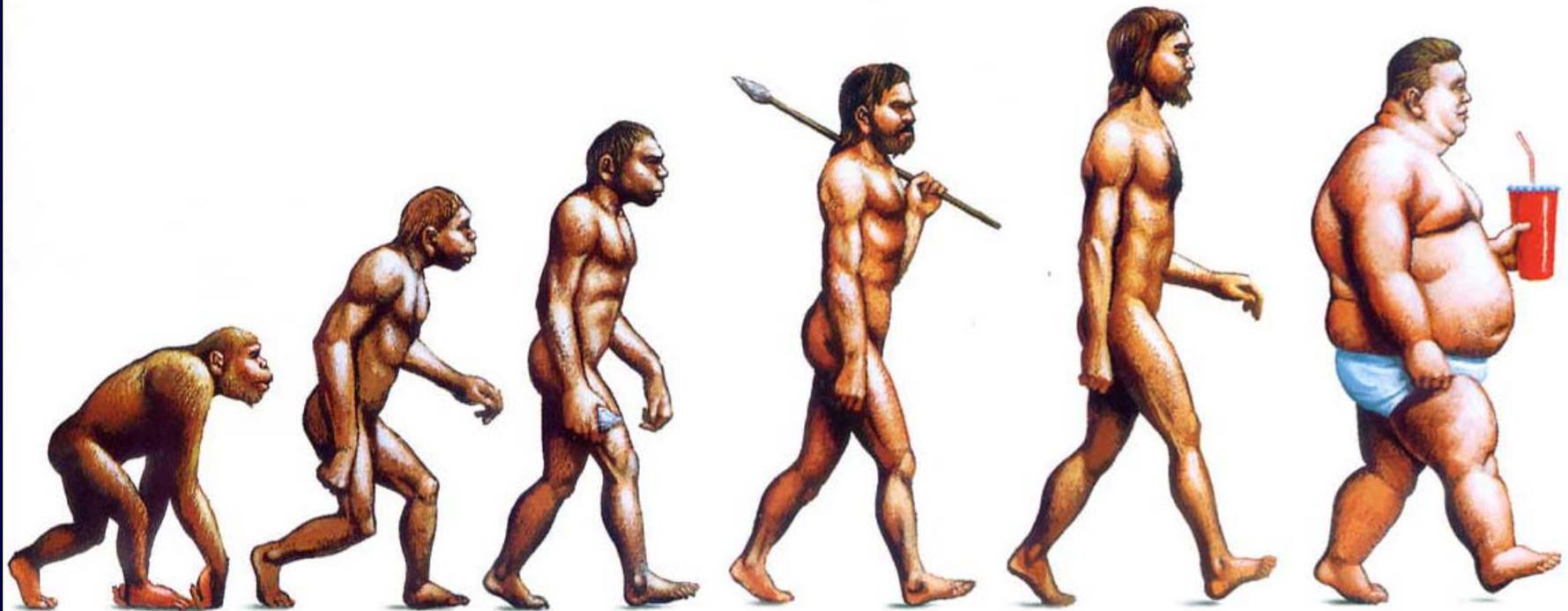
J Clinical Psychopharmacology, 1999

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.



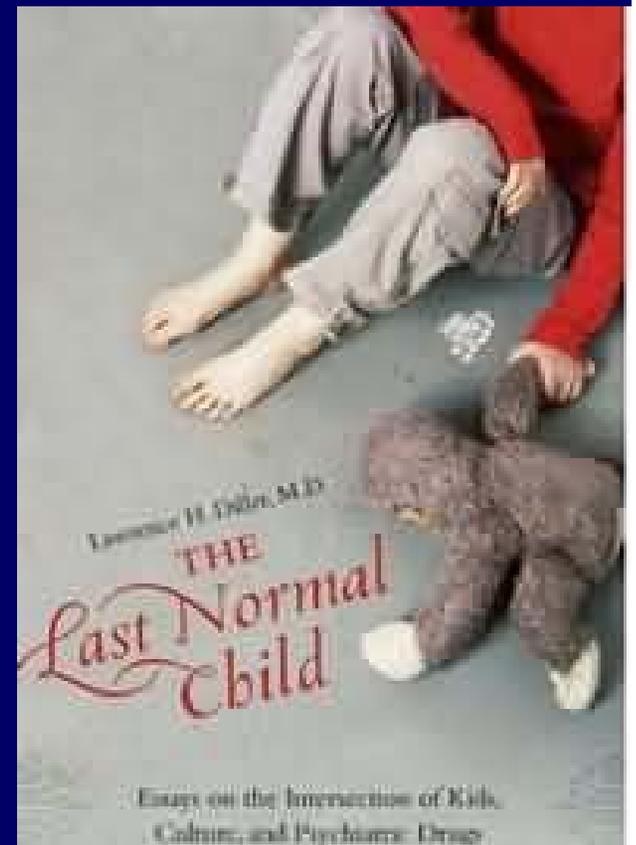
Boy Rx Risperdal
required double
mastectomy at age 13.

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

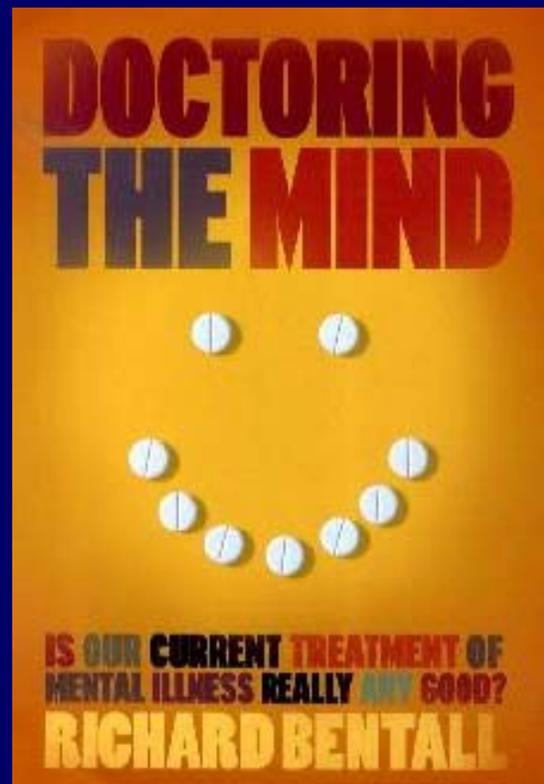
Despite staggering adverse effects...

*“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.