

## **Pharma Lecture**

Would it be ok for me to take \$500 from Shering-Plough to begin lecture with plug for Clarinex?

Are Ray etc – the crack dealers in Bourgois' In Search of Respect any worse than Pharmaceutical industry?

All pushers

& interesting overlap in techniques (cheap introductory offers to get hooked)

**Marcia Angell** wrote polemic, and I'm sure we'd find nice people work for Pfizer etc...

But...

Angell (former editor, New England Journal of Medicine) shows...

### 1) **Clinical Trials**

a) *Rigged through all sorts of tricks:*

(i) compare new drugs with placebos, not real rivals

(ii) compare v rigged dose of rival

(iii) use partial data – cf Celebrex 6 months instead of full year of data they had

VIOXX the same

(iv) Use young subjects with few side effects

new drugs may actually be worse than old cheaper ones – as with diuretics for hypertension

b) *Clinical trials not really run by doctors anymore*

Doctors often paid bounty on subjects they recruit – so incentive to cut corners

CROs (Contract Research Organizations) subcontract to doctors & control study design, analysis etc

See **Le Carre's** The Constant Gardener on CROs

Often written up by drug Companies & doctors paid to sign, edit

**Adriana Petryna** studies CROs

Looking at techniques for manipulation

Many find subjects in Ukraine & E. Europe – drug trials have become kind of surrogate health care

Go there for lax regulations

What owed to these subjects once trials over?

“professional Guinea pigs”

c) *Contract clauses to prevent publication*

**Betty Dong (UCSF) & synthroid** (hyperthyroidism) Boots invoked confidentiality clause to prevent her from publishing her finding that synthroid no more effective than cheaper generic

**Nancy Olivieri, L1 & Apotex** – similar situation

See Rachel Schuchman, *The Drug Trial*

Scientific authority invoked in drug studies, but actual practice of science being hollowed out

d) *Only convenient trials declared*

medical journals now asking for trials to be registered at outset, so can't be hidden

## 2) **FDA**

a) *Underfunded* to look at drug ads, safety issues

b) *Reliance on user fees* from drug companies to review clinical trial data. (New since mid-90s).

Is Angell right that “he who pays the piper...”?

c) *Many on FDA panels also consult for Drug Companies*

Similar issue for NIH employees, many of whom consult for pharmaceutical companies

NIH used to be public service. Now danger its mainly route to stock options, consulting fees – real source of wealth

Cf. Congressional staffers who endure long hours and low wages so they can get to work for lobbying firms

Hijacking of meaning of public service: regulatory job now avenue to private wealth

### 3) Medical Journals

a) Have had *weak conflict of interest policies*

until recently, didn't know interests of authors

**Sheldon Krimsky** found often still undeclared

b) Don't ask who *really wrote articles*

c) Hard to find *unbiased referees & editorialists* because everyone funded by some corner of the pharmaceutical industry

**Krimsky** (Science in the Private Interest) found clear effects of sponsorship on judgment

DSM: 56% authors have financial ties to Pharmaceutical industry, 80% for psychiatric disorders like PMDD, anxiety disorders etc<sup>1</sup>

d) *Ad revenue* from Pharmaceutical companies vital to medical journals

### 4) Marketing

a) According to Angell, *30% costs* – added to sticker price

b) US one of only 2 countries with *Direct To Consumer ads*

really about disease construction, not informing public

1997 provision about advertising side effects watered down –  
now just direct public to a website.

(Note much of the evisceration of regulations done by  
**Clinton** – this isn't a Republican v Democratic issue)

Direct to Consumer ads increased by three times 1997-2001

c) *corruption of Doctors*

detailers (salespeople)– often former cheerleaders

free mugs, lunches, vacations, conferences etc for doctors

pharmaceutical companies give free seminars for doctors'  
required continuing education

**Marcel Mauss** & gift theory: “no gift is given but in  
the expectation of a return.”

free samples for doctors & patients til hooked

prescription tracking to test doctor compliance

recent direct mail episode re antidepressants (patients getting direct mail solicitation to change anti-depressant brand).

Privacy issues

**Kaiser Permanente** has forbidden much of this to drs<sup>ii</sup>

## 5) Patents & Generics

### a) *Techniques to fend off generics*

test on kids – worth extra 6 months

challenge generic in court – worth 30-month delay

repeat above over & over for multiple patents

pay off generic manufacturer not to produce

1999 Abbott offered Zenith \$2 million/month not to make **hytrin** – blood pressure drug<sup>iii</sup>

repatent as new drug: **clarinex v Claritin**

**Prozac v Serafem**

repatent for new illness: PMDD, social anxiety disorder

**Trent Lott** has bill to reform system & speed generic approvals

Supported by many states, generic Companies & big Companies like GM (worried about health care costs of workers)

Opposed by Pharmaceutical companies

## 6) Overall dysfunctional situation

You'd think market system would unleash entrepreneurship & be best at meeting public health needs

Instead, we have these bizarre dysfunctions, many because we don't really have free market system but system where large Companies have used lobbying power to enter into alliance with state & use public resources against interests of consumers:

Incidentally, over 34,000 registered lobbyists in DC – doubled since 2000

65 for each Congressman

starting salaries can be \$300,000<sup>iv</sup>

a) *Companies pick up public research on cheap, don't do enough R&D of own*

taxpayer pays twice: through NIH, NCI, NSF

through medicare, Medicaid

Not getting many innovative new drugs, just “me-toos” for large chronic markets for statins, anti-arthritis drugs

b) *30% on marketing v 15% on R&D*

paying to be made to want drugs that may not work & may not need

c) *Wildly different prices for same drugs*

You're in trouble if no HMO to bargain for you

Those too poor to afford health insurance lack bargaining power: “poor pay more”

d) *Shortage of drugs we really need:*

few new antibiotics because they cure you quickly, so little profit to be made

kids' vaccines, flu vaccine (lasts one year)

malaria drugs (because malaria largely afflicts Third World where people can't afford drugs)

Bill Gates is the workaround solution: his foundation now funding research on malaria

e) Can't even get *cheaper drugs from Canada*

recent warning notes in parcels

lobbyists have blocked free trade with spurious safety arguments

These dysfunctions concealed by propagandistic rhetoric about amazing new drugs

**7) Public (or at least media) beginning to perceive problems re drugs & health care:**

**a) *Outcome problems***

U.S. ranks about 23 in life expectancy<sup>v</sup>

“Among 33 industrialized nations, the United States is tied with Hungary, Malta, Poland and Slovakia with a death rate of nearly 5 per 1,000 babies, according to a new report. Latvia's rate is 6 per 1,000.”<sup>vi</sup>

“In 2002 the United States spent \$5,267 per person on health care. Canada spent \$2,931; Germany spent \$2,817; Britain spent only \$2,160. Yet the United States has lower life expectancy and higher infant mortality than any of these countries.”<sup>vii</sup>

Yet pays 50-100% more per capita than other industrial countries for health care

40 million uninsured

bizarre insurance rules: will pay for diabetes amputations but not preventive care to forestall them!

**b) *Industrial competitiveness issues***

\$2,000 of your GM car for health insurance

not an issue in Japan, Germany etc, where there is universal health care

**Paul Krugman** arguing lack of single-payer health care dragging US industry down

Then, there are free riders: Walmart externalizes health care costs to taxpayer to maintain economic competitiveness

*c) Medicare drug benefit* largely written by pharma lobbyists

Congress told it would cost \$400 million, then news leaked that Admin deliberately concealed real price

& many seniors will be no better off because of “donut”

unpopular with seniors & deficit hawks

### **Possible Reforms**

Clinical trials that compare new with established drugs

Stricter rules for granting patents

Repeal Prescription Drug User Fee & strengthen FDA

No more industry shills on FDA committees

Independent clinical trials run by universities through NIH

Ban Direct To Consumer ads

Ban drug reps in operating rooms etc

Ban drug Company subventions of continuing education of doctors

Charge everyone the same for same drug – with subsidies for poor

Limit Companies to 1 30-month stay for patent litigation

Forbid generic Company collusion with big pharmaceutical companies – bribes not to produce.

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<sup>i</sup> Dan Vergano, “Study: medical manual’s authors often tied to drug makers” USA Today 4/20/06.

<sup>ii</sup> Gardiner Harris, “In Article, Doctors back ban on drug companies’ gifts” NYT 1/25/06:A11)

<sup>iii</sup> Sheryl Gay Stolberg & Jeff Gerth, “how companies stall generics and keep themselves healthy” NYT 7/23/00:A1).

<sup>iv</sup> **Restoring the Public Trust**

By Bill Moyers

TomPaine.com Friday 24 February 2006

<sup>v</sup> Christopher Shea, “Primary Paths.” BG 1/1/06 C4

<sup>vi</sup> **US Newborn Survival Rate Ranks Low**

By Lindsey Tanner

The Associated Press

Tuesday 09 May 2006

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vii **Pride, Prejudice, Insurance**

By Paul Krugman

The New York Times Monday 07 November 2005