

ALLERGIC TO PEOPLE?

**The Manipulation of Information by Pharmaceutical
Companies
Case Study: Paxil**

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OVERVIEW: PAXIL

- Background Information.
- Marketing.
- Paxil Advertising.
- Paxil and the Law.



Questions: How have advances in information technology changed public awareness of pharmaceuticals and prescription medication?



Since the beginning pharmaceutical advertising, how have prescription drug companies controlled the public's available information on prescription drugs? And what effect has this had on the quality of the public's healthcare?



BAYH-DOLE ACT

- Passed in 1980.
- Academic institutions allowed to patent NIH funded inventions.
 - Can license drugs to private companies.
- Intended to accelerate transfer of technology to market.
- Requires invention to be available to the public on reasonable terms.
- Allows government to intervene and reassign patents.
- Led to collaboration between academic institutions and the pharmaceutical industry.



DRUG TRIALS

- Multibillion dollar business.
- Often controlled by sponsoring companies.
 - Design own trials.
 - Control publication of results.
- Academic institutions were replaced by for-profit testers (Contract Research Organizations).
- Start only after obtaining patent(20 years).
- Human subjects.
 - Some recruited through media.
 - Doctors are paid per enrolled subject.
 - Often not eligible.
- Deadlines created by companies
 - Problems arising near the deadline are often ignored



THE FDA

- Became increasingly friendly with pharmaceutical industry.
- Prescription Drug User Fee Act in 1992.
 - Requires drug companies to pay fee for each drug the FDA reviews.
 - Currently over half of FDA drug review center budget.
 - From 1992 to 2002, doubled the number of drugs reviewed annually and cut in halved the time spent on each.



PATENTS

- 20 years of exclusive rights.
- Protect from competitors during development and testing.
- Once approved by FDA, can be sold for rest of patent period without competitors.
- Intended to be incentive for developing innovative drugs.



“ME-TOO” DRUGS

- Variation on existing products
- FDA approved drugs 1998-2004
 - 14% New and Improved
 - 53 in 1990 to 27 in 2000
 - 8% Slightly Improved
 - 78% No Improvement
- Not tested against other drugs, only placebos.
- Not especially useful.
- Require extensive marketing.



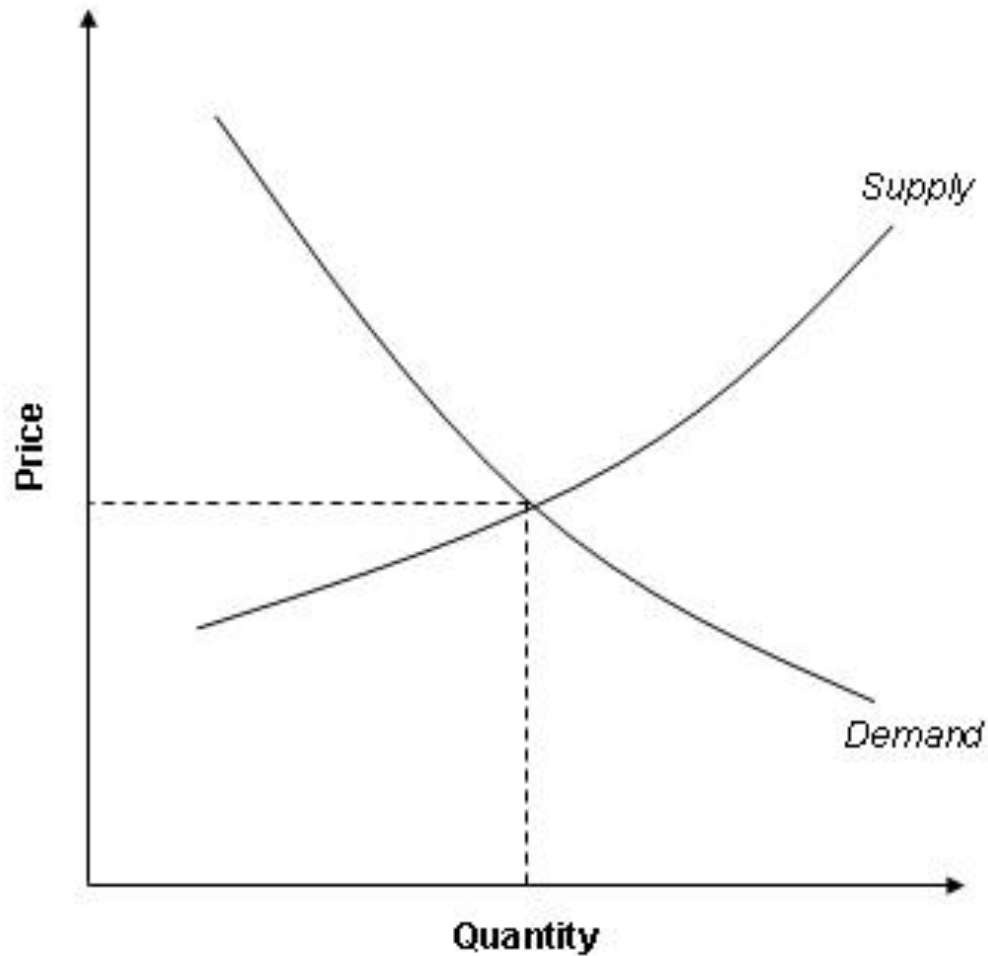
FOOD FOR THOUGHT

- From 1996 to 2004: Dollars spent by Big Pharma increased by 500%
- Today, the Drug Industry spends roughly twice as much money on marketing than R&D.
- The number of pharmaceutical drug lobbyists on Capital Hill are greater than the numbers sent by the tobacco industry, oil industry and banking industry.
- The world's best-selling prescription drug generates \$8 billion per year. Roughly \$1 million per hour.
- 10 years ago the average American probably could not name 10 prescription drugs off the top of their head.



ECONOMICS 101

Supply and Demand



HOW TO CREATE DEMAND

Increase Supply

- "Market Saturation" - the result of lax government regulation
 - The exploding number of allergy meds
 - How many SSRIs (Selective Serotonin Reuptake Inhibitors)?
Paxil, Prozac, Zoloft
- Me-Too Drugs
 - In 2004, 78% of pharmaceutical drugs produced that had "No improvement over existing drugs."
- "Branding"



HOW TO CREATE DEMAND

Increase Demand: Turn Consumers Into Patients

- The "Worried Well": Manipulating the Public Impression
 - Big Pharma and "Disease Mongering"
 - Redefining sickness
 - Creating new diseases
 - Changing the bar
 - A marked increase in the medicalization of society
 - Redefining medication
 - Pharmaceuticals as the cutting-edge of science
- Addiction: Make Patients Dependent



HOW TO CREATE DEMAND

- Multiple Diagnosis for Multiple Drugs

“Generalized Anxiety Disorder”

“Major Depressive Disorder”

“Obsessive Compulsive Disorder”

“Panic Disorder”

“Post Traumatic Stress Disorder”

“Premenstrual Dysphoric Disorder”

“Social Anxiety Disorder”

Xanax
alprazolam tablets 

Celexa
citalopram HBr 

PAXIL
PAROXETINE HCl


Sarafem
fluoxetine hydrochloride

Zoloft
(sertraline HCl)

PROZAC
fluoxetine hydrochloride

BuSpar
buspirone HCl, USP

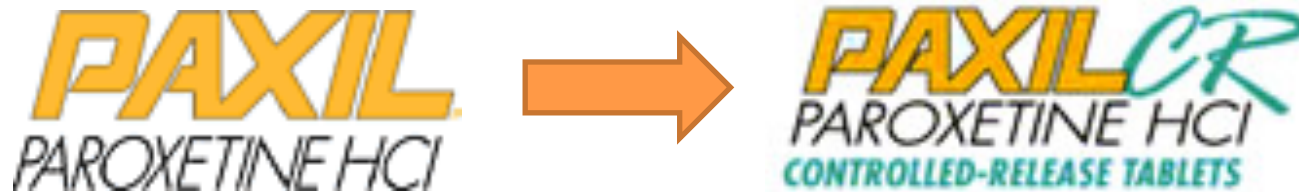
ONCE-DAILY
Wellbutrin XL
bupropion hydrochloride
extended-release tablets 



PATENTS

Milking Exclusive Rights

Economic Strategy: Recolor it, Rename it, and Remarket it as a "new-and-improved" drug



"ASK YOUR DOCTOR"

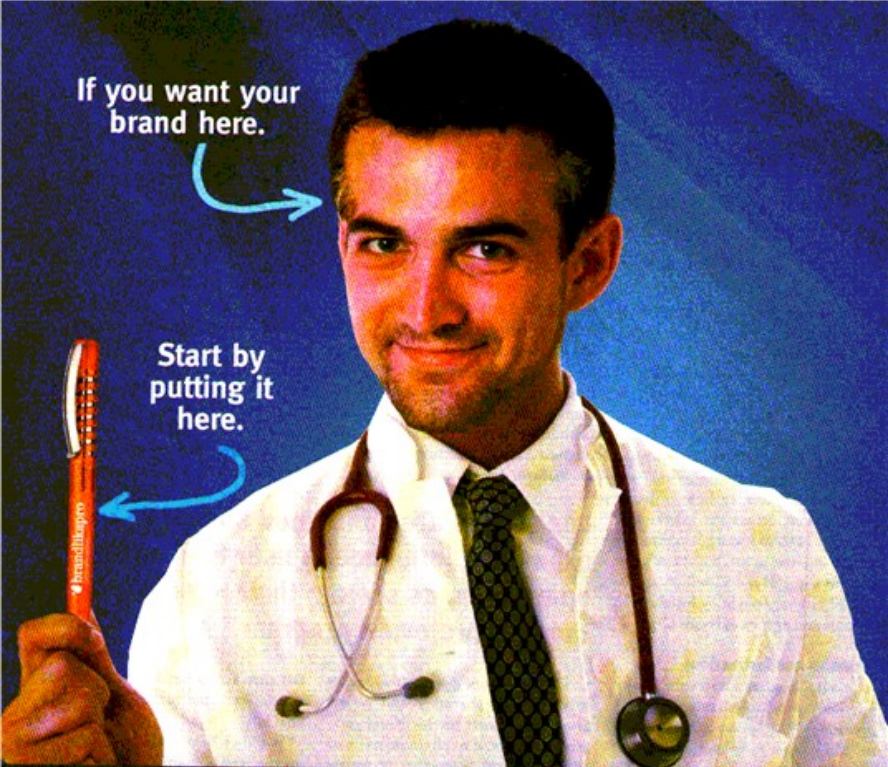
The Free Lunch and the "Education Fund"

- Free stuff: pens, clocks, alcohol, meals, golf, sports tickets.
 - In essence: Bribery
 - Doctors become walking advertisements
- Catering to the Doctor... since medical school?
- Free samples
 - In 2004, \$16 Billion
- \$15 billion/year spent on doctors
 - Fund Continuous Medical Education
 - Offer free meals and gifts
 - Salesmen pitch their own drugs



THE BEAUTY AND THE PHYSICIAN

- Usually the case that drug reps are educated in finance or business administration
- Doctors should not trust Drug Reps as educators of drugs.
- The medical in-joke
- Doctors' prescribing patterns
 - Name recognition
 - Subconscious subscription



If you want your brand here.

Start by putting it here.

Put your brand in their hands.

At Senator, we understand how difficult it is to get your product in front of the ones who write the prescriptions. That is why our unique line of writing instruments is designed as much for aesthetics as for function. These award-winning designs provide an elegant, yet useful way to keep your brand in their hands, and on their minds.

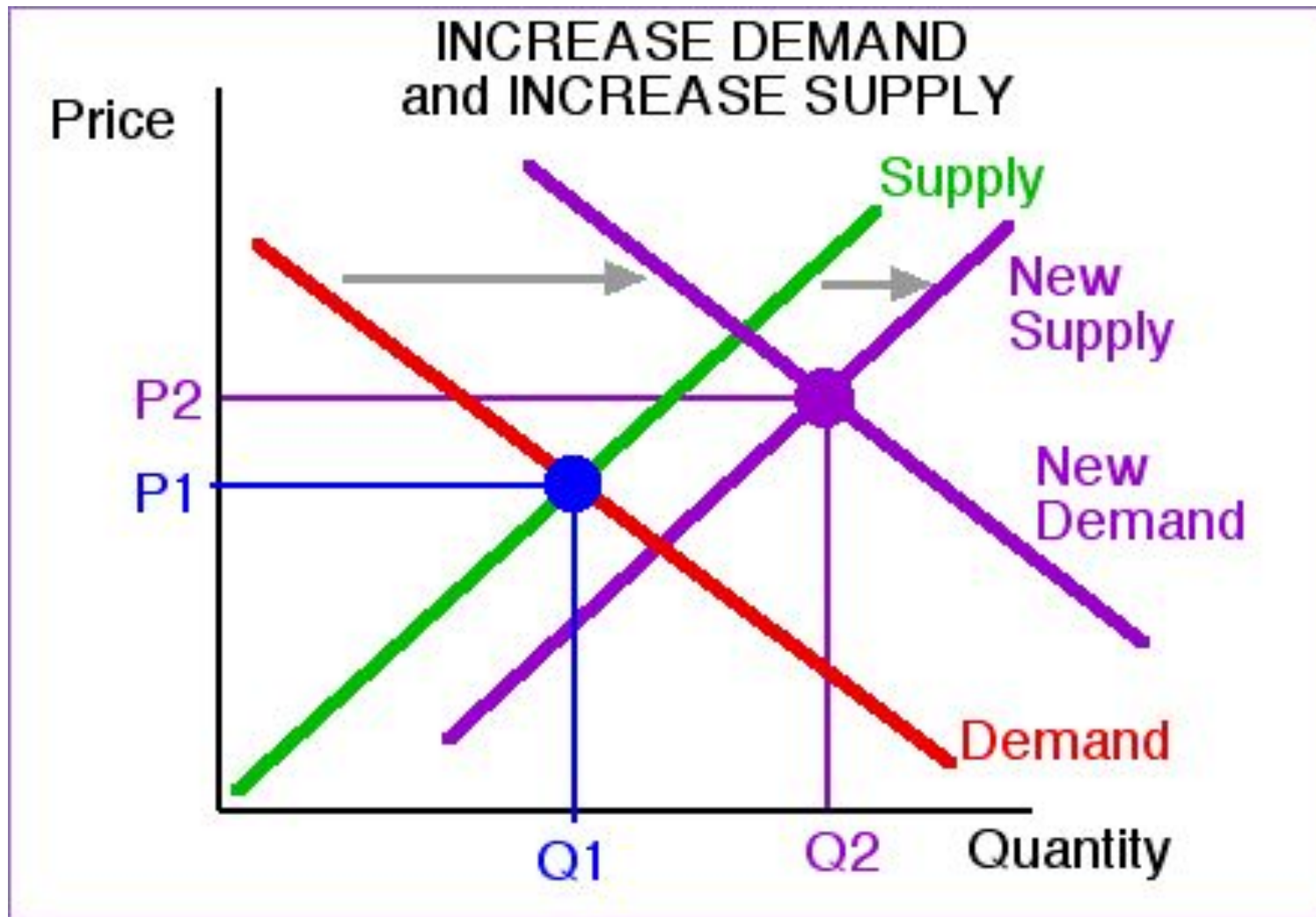
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brandlikapro
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red dot
2000 Winner
Best Design

THE BROKEN MARKET



CASE STUDY: PAXIL

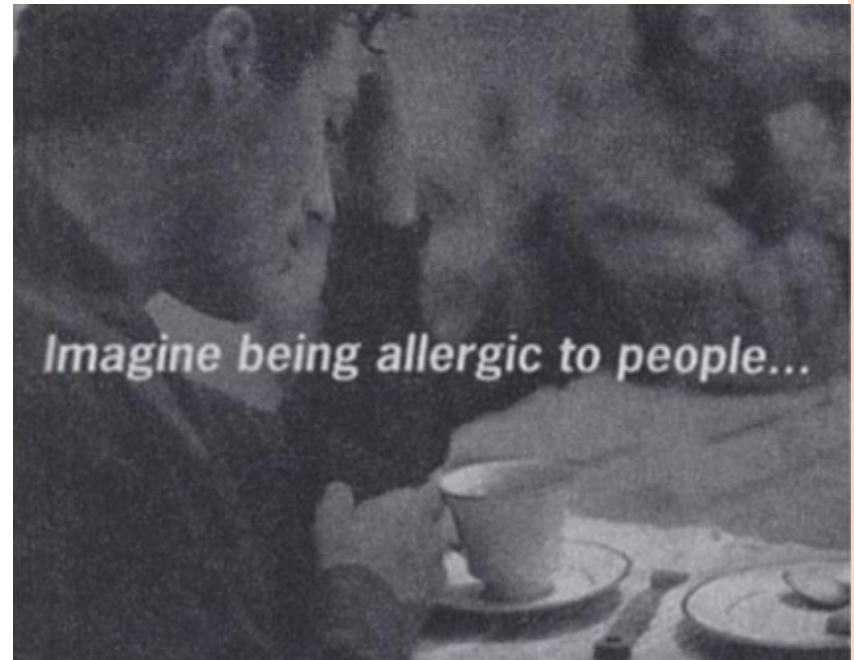
“Every marketer’s dream is to find an unidentified or unknown market and develop it. That’s what we were able to do with Social Anxiety Disorder.”

—Barry Brand (Paxil Product Director)



REBRANDING PAXIL

- Compete with Prozac and Zoloft
- Paxil for Social Anxiety Disorder



Imagine being allergic to people...

You know what it's like to be allergic to cats, or dust, or pollen. You sneeze, you itch, you're physically ill. Now, imagine that you felt allergic to people. You blush, sweat, shake – even find it hard to breathe. That's what social anxiety disorder feels like.

Over ten million Americans suffer from **social anxiety disorder**, an excessive, persistent, disabling fear of embarrassment or humiliation in social, work, or performance situations.

The good news is that this disorder is treatable. People can overcome social anxiety disorder. So if you feel like you're "allergic to people," talk to your doctor or other health professional.

Learn more about **Social Anxiety Disorder**, call 1-800-934-6276
or visit www.allergictopeople.com

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FRAMING THE DISEASE

“an excessive, persistent, disabling fear of embarrassment or humiliation in social, work or performance situations”

- Social Anxiety Disorder as an "allergy"
- Not circumstantial/temporal
- Normal behavior becomes a disorder



I FEEL...

“Nervous”

“Fearful”

“Anxious”

“Self-conscious”

“Panicky”

“Afraid”



SELF-TESTS: AVAILABLE TO CONSUMERS ONLINE

Rate on a scale from 1 to 4:

- Being criticized scares me a lot.
- Talking to strangers scares me.
- Trembling and shaking in front of others is distressing to me.

(Quoted in Lane)

PAXIL SALES

- After rebranding, Paxil became the world's top selling antidepressant.
- \$4.97 billion in worldwide sales in 2003
- 11 million Americans currently taking antidepressants



PAXIL AND THE LAW

"The right to search for truth implies also a duty: one must not conceal any part of what one has recognized to be true."

-Albert Einstein

Duty of Candor- "full disclosure" rule; a duty to disclose to the [U.S. Patent Office] all information known to that individual to be material to patentability.

NSF: "...expects investigators to share with other researches...the data, samples, physical collections... in the course of the work."

NIH: "Data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health."



INDIVIDUAL RIGHTS TO ACCURATE RX INFORMATION

PATIENTS HAVE A FIFTH AMENDMENT FUNDAMENTAL RIGHT TO RECEIVE INFORMATION REGARDING THE POSSIBLE RISKS ASSOCIATED WITH THEIR TREATMENT

“[A] necessary corollary to the interest articulated in....*Cruzan* is the right of ...patients to information sufficient to reach an informed judgment on whether to consent to a particular treatment or to refuse it.” *Clarkson v. Coughlin*, 898 F.Supp. 1019 (S.D.N.Y.,1995) citing to (*White v. Napoleon*, 897 F.2d 103, 113 (3d Cir.1990)).

"...as part of the obligation to obtain “informed consent,” a doctor has a duty to disclose

“possible adverse side-effects of the drug.” *Calabrese*, 392 A.2d at 605; *see also SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc.*, 481 F.Supp. 1184, 1190 (D.N.J., 1979)



SCIENTIFIC MISCONDUCT IN THE RESEARCH AND DEVELOPMENT OF RX DRUGS

Scientific misconduct - "designing studies to ensure a desired result, making statements not justified by the evidence, publishing only part of the evidence, suppression of research findings, and -- worse -- outright fraud with fabrication of evidence."

Conflicts of interest increase the likelihood of scientific misconduct.



From the movie *The Fugitive* (1993)

CONFLICTS OF INTEREST: RX COMPANY PROFIT AND PUBLIC HEALTH

"Almost all clinical investigations of the comparative efficacy and safety of... medicinal agents require financial sponsorship, mainly by the pharmaceutical industry. Many, perhaps the majority, of such investigations are actually designed and initiated by medical or clinical pharmacology departments of pharmaceutical companies."


-Levy G. Publication bias: its implications for clinical pharmacology. *Clin Pharmacol Therap* 1992;52:115-119.

66%-Percentage of academic medical centers that hold equity interest in companies that sponsor research within the same institution.

-Justin E. Bekelman et al., "Scope and Impact of Financial Conflicts of Interest in Biomedical Research: A Systematic Review," *The Journal of the American Medical Association*, January 22, 2003.

3/5- Ratio of medical school department chairs receiving personal income from drug companies.

-Eric G. Campbell et al., "Institutional Academic-Industry Relationships," *The Journal of the American Medical Association*, October 17, 2007.



THE INFORMATION CRISIS: RX COMPANIES WITHHOLD/ MANIPULATE NEGATIVE RESEARCH FINDINGS

Publication Bias- Since 1948, 1 million controlled trials have been conducted, but the results from only half of them have been reported.

- Trials are (often) prematurely terminated and thus never have a chance of publication.

Manipulation of Trials to yield favorable Information:

"...the sponsor's drug may be compared with another drug administered at a dose so low that the sponsor's drug looks more powerful. Or a drug that is likely to be used by older people will be tested in young people, so that side effects are less likely to emerge. A common form of bias stems from the standard practice of comparing a new drug with a placebo, when the relevant question is how it compares with an existing drug."

-Angel, Marcia. Drug Companies and Doctors: A story of Corruption. NY Review of Books. January 15, 2009.



PEOPLE OF THE STATE OF NEW YORK V. GLAXOSMITHKLINE AND SMITHKLINE BEECHAM CORPORATION (2004)

1) GlaxoSmithKline withholding negative side-effect information on Paxil:

"GSK has allowed positive information about pediatric use of paroxetine to be disclosed publically, but has withheld and concealed negative information concerning the safety and effectiveness of the drug as a treatment for pediatric MDD."

Study 329-largest trial to date on using SSRIs in pediatric population.

- finds a 5x increase in suicidal ideation over placebo

329 eventually published withholding negative effects

- "generally well tolerated and effective for major depression in adolescents."

2) GSK manipulating language:

"Emotional Liability" = Suicidal Thinking



..

limited, derived from small open studies in adolescent depression (McConville et al; 1996; Tierney et al; 1995)

TARGET

To effectively manage the dissemination of these data in order to minimise any potential negative commercial impact.

PROPOSALS

- Based on the current data from Studies 377 and 329, and following consultation with SB country regulatory and marketing groups, no regulatory submissions will be made to obtain either efficacy or safety statements relating to adolescent depression at this time. However data (especially safety data) from these studies may be included in any future regulatory submissions, provided that we are able to go on and generate robust, approvable efficacy data. The rationale for not attempting to obtain a safety statement at this time is as follows;
 - i) regulatory agencies would not approve a statement indicating that there are no safety issues in adolescents, as this could be seen as promoting off-label use
 - ii) it would be commercially unacceptable to include a statement that efficacy had not been demonstrated, as this would undermine the profile of paroxetine.
- Positive data from Study 329 will be published in abstract form at the ECNP (Paris, November 1998) and a full manuscript of the 329 data will be progressed.
- The regulatory acceptability of Studies 511 and 453 and any other data in this patient population will continue to be investigated.



CONCLUSION

Commercialization of drugs has led to an increased informational disconnect between consumers, physicians, and the drug industry. This convoluted manipulation of information by the American Pharmaceutical Industry embodies the dangers of prioritizing monetary incentives over public welfare, all of which carries serious ethical ramifications.



FURTHER RESEARCH

- ☐ Research other pharmaceutical companies
- ☐ Further research into legal cases pertaining to pharmaceutical practices and ethics
- ☐ Challenge your doctor's understanding of these medications
- ☐ No "Free Lunch!"
- ☐ Meet with professionals who are continually fighting the pharmaceutical industry
- ☐ Combat the economical and legal corruption that Big Pharma practices



QUESTIONS?

