

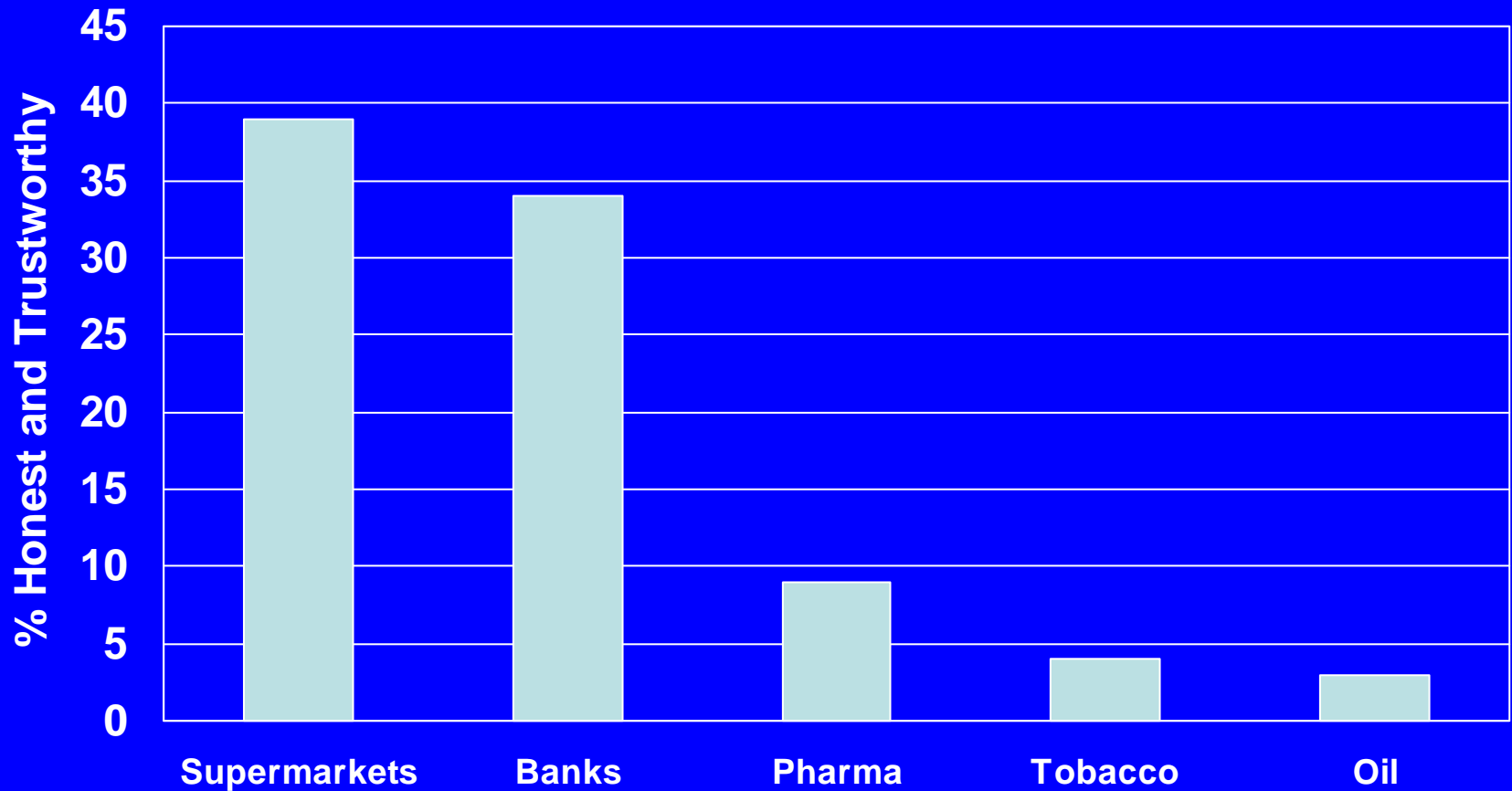
How Big Pharma Should Change

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Presented at

Eighth Annual Pharmaceutical Regulatory
and Compliance Congress and
Best Practices Forum
Washington, DC
November 7, 2007

The Problem



Source: Harris Poll, October 2005 (n=1833)

How Big Pharma Should Change

- Follow the law
- Report trial results honestly
- Innovate
- Back off on DTC
- Stop the doctor bribing
- Call off the lobbyists
- Stop price gouging
- Don't forget the developing world

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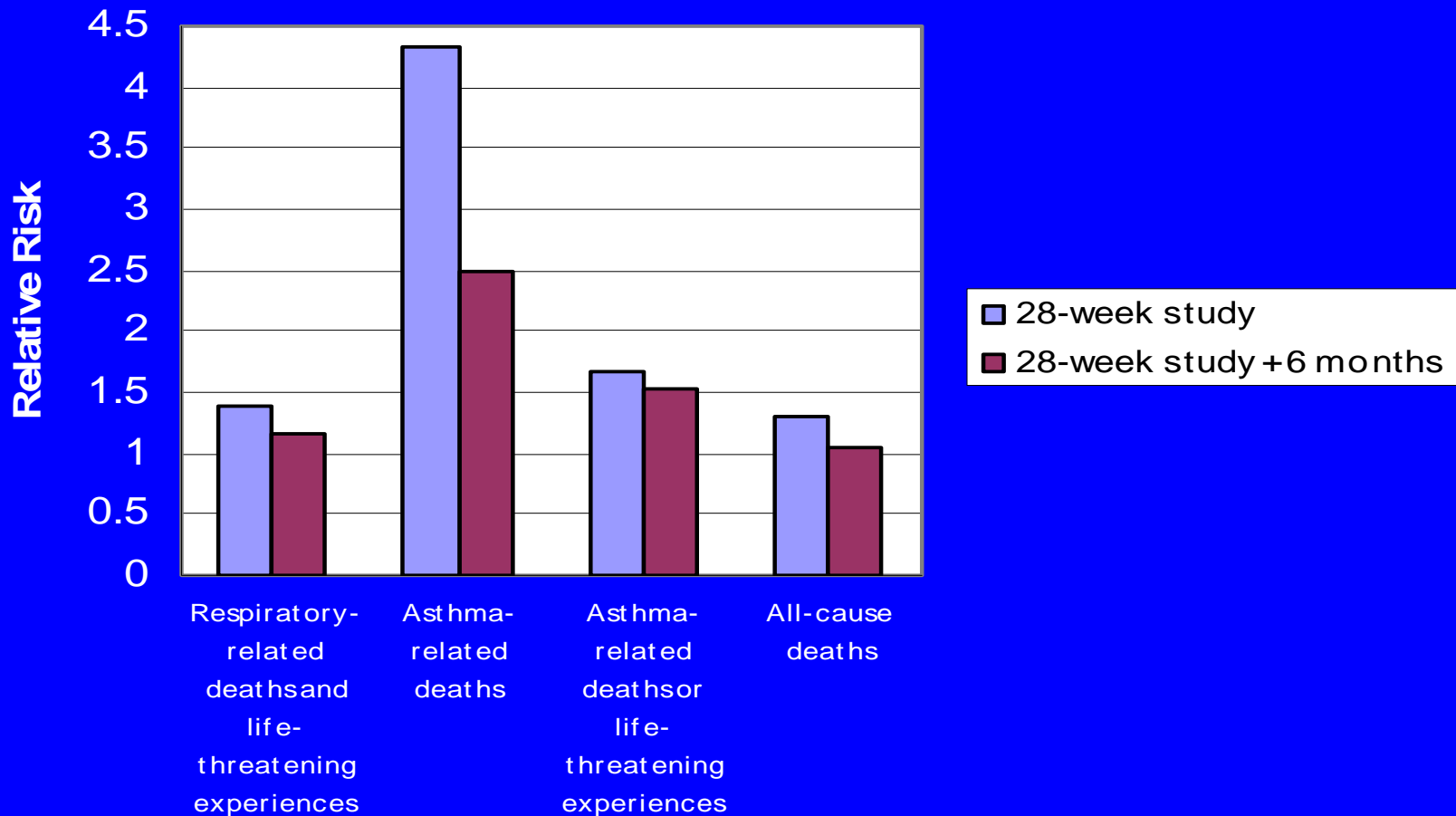
Top Pharmaceutical Company False Claims Act Cases as of January 2006

Rank	Company	Date	Settlement
5	TAP	2001	\$560m
6	Abbott	2003	\$400m
8	SmithKline	1997	\$325m
11	Schering-Plough	2004	\$293m
12	AstraZeneca	2003	\$266m
14	Bayer	2003	\$257m
20	Pfizer	2004	\$152m
	Bristol Myers	2007	\$328m

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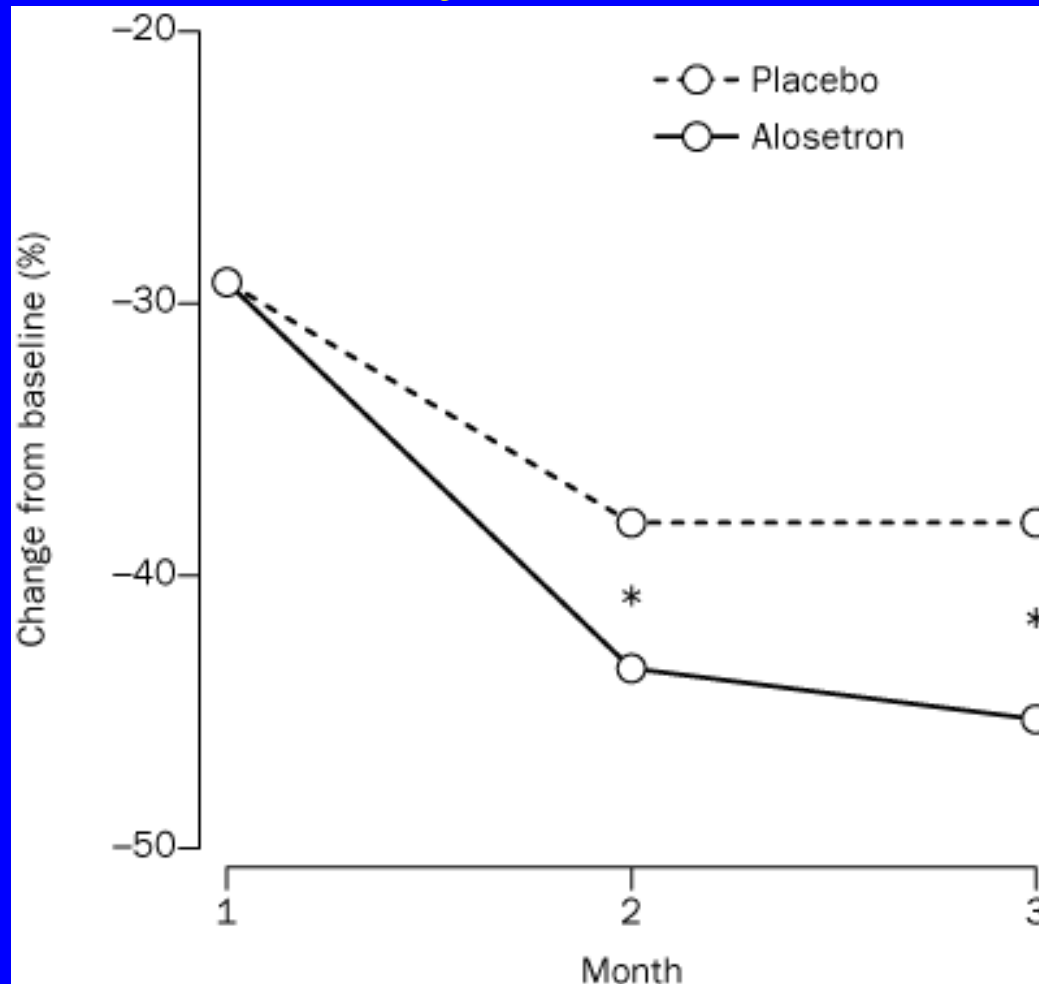
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Salmeterol Postmarketing Study (SMART)



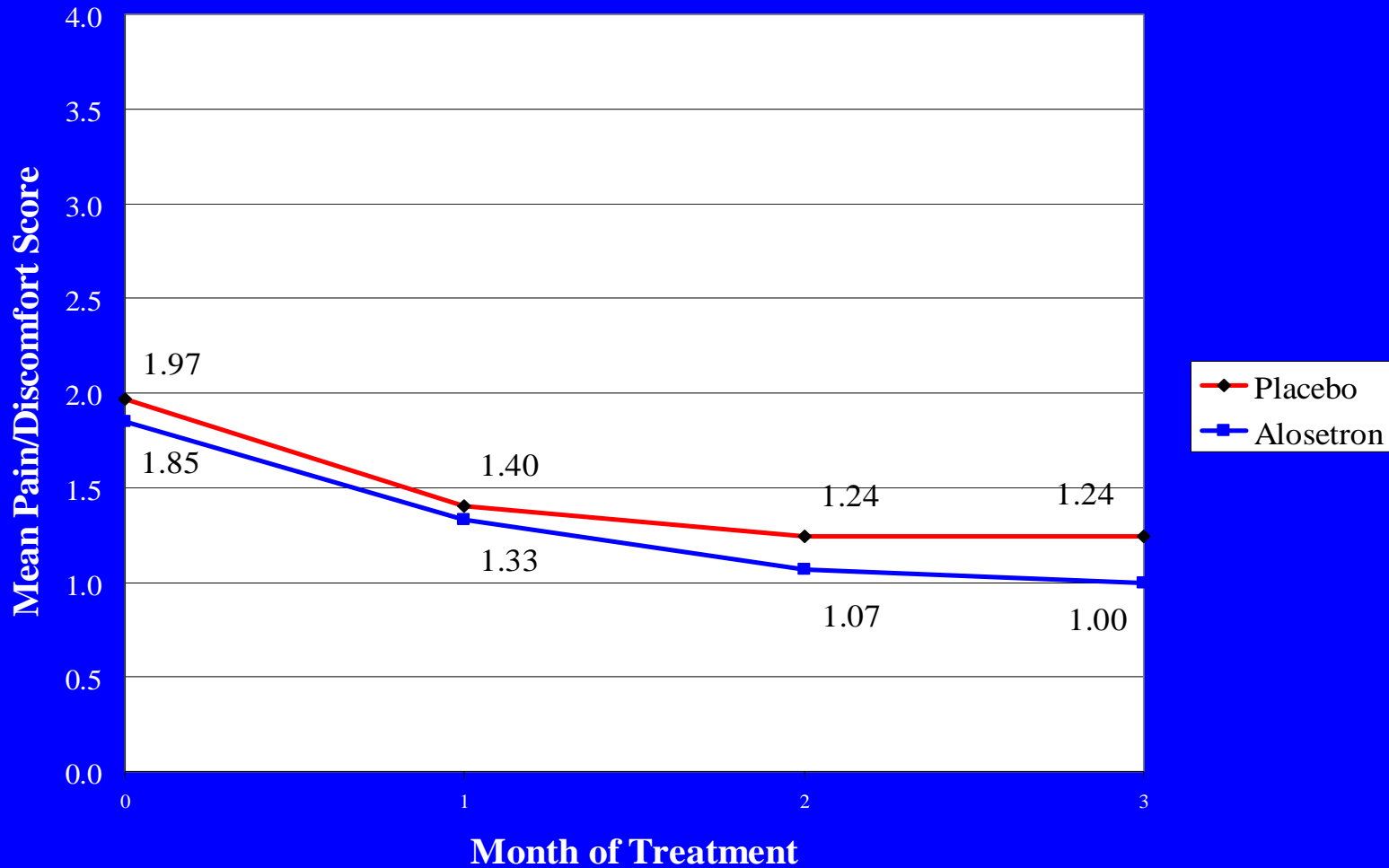
Source: Lancet 2005;366:1261-2

Depiction of Alosetron (Lotronex) Efficacy in Lancet



Source: Lancet 2000;355:1035-40

Public Citizen Depiction of Alosetron (Lotronex) Efficacy



Source: Lancet 2000;356:2009

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Drugs for Alzheimer's Disease

- Donepezil (Aricept), rivastigmine (Exelon), and galantamine (Reminyl)
- Review of 22 published RCTs
- Typical improvement: 1.5-3.9 points on 70-point scale
- Conclusion: “the scientific basis for recommendations of cholinesterase inhibitors for the treatment of Alzheimer's disease is questionable”
- 2004 retail sales: \$861 million

Smoke and Mirrors

- Nexium (esomeprazole)
- Xopenex (levalbuterol)
- Levaquin (levofloxacin)
- Focalin (dexmethylphenidate)
- Lexapro (escitalopram)
- Redux (dexfenfluramine)

Over-the-Counter Pediatric Cough/Cold Remedies

- 11 RCTs since the 1950s
 - Some without placebo groups
 - Some unclear if randomized or blinded
- No evidence of efficacy for 0-12 years
- Fewer than a dozen ingredients
- 800 individual products
- \$500 million in annual sales

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Zit 101 Offered at Acne High

Differin[®]
(adapalene cream) CREAM, 0.1%

Acne Info for Teens

GALDERMA

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Acne Basics True or False? Talking to Parents
Ask Your Doctor Skin Care The Right Routine for You

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Teen Survival Handbook.

the 3 levels of cool

Level	Requirement	#of Free Music Downloads
1	Sign Up	2
2	Get and Fill Differin® Prescription	7
3	Refill Differin® Prescription	10

sign up

Consumer Perceptions of DTC Advertisements

	1999	2002
Prompted them to talk to MD	27%	18%
Enough info to decide to talk to MD	70%	58%
Help make better decisions	47%	32%
Like seeing them	52%	32%



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Public Disclosure of Pharmaceutical Company Gifts to Physicians, 2002-2004

	Vermont	Minnesota
Threshold	\$25	\$100
Trade secret exemption?	Yes	No
Electronic submission?	Yes	No
Reporting period	2 years	3 years
Median physician gift >\$100 (maximum)	\$177 (\$20,000)	\$1000 (\$922,239)
Total physician gifts	\$1.01 million	\$22.4 million

Source: JAMA 2007;297:1216-23

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Pharmaceutical Company Lobbying, 1998-2005

- \$818 million in federal lobbying and state and federal campaign contributions
 - \$675 million in federal lobbying; largest for any industry in the nation
- 3009 lobbyists
 - 34% former officials
 - 75 former members of Congress

Source: <http://www.publicintegrity.org/rx/report.aspx?aid=723>

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Price Gouging

- False Claims Acts awards
- Anti-generic campaigns
 - Levothyroxine
 - 30-month challenges
 - Payments for non-production
- Price discrepancies with Europe

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What About the Developing World?

- Perinatal antiretrovirals received by only 10% of HIV+ pregnant women in Africa
- Aggressive stance at the TRIPS
- Abbott and Kaletra/Aluvia
 - Reaction to Thailand's issuance of compulsory license
 - Withdrawal of 7 NDAs

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