

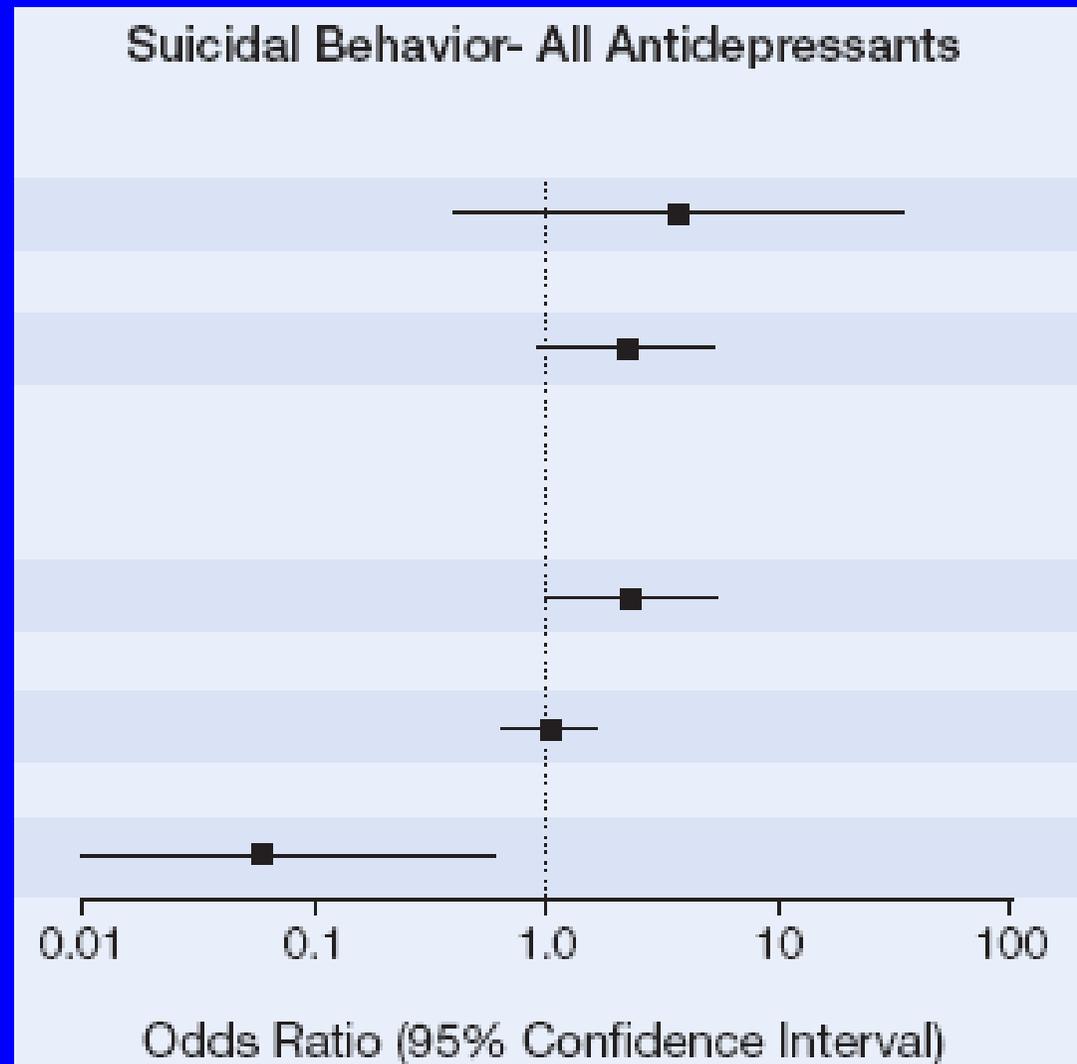


FDA meta-analyses of 372 placebo controlled trials of SSRIs and similar drugs involving 99,839 patients

www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4272b1-01-FDA.pdf

Kuehn
JAMA 2007

Pediatric Studies	
Age < 12 y	
Age ≥ 12 y	
Adult Studies	
Age < 25 y	
Age 25 to 65y	
Age ≥ 65 y	

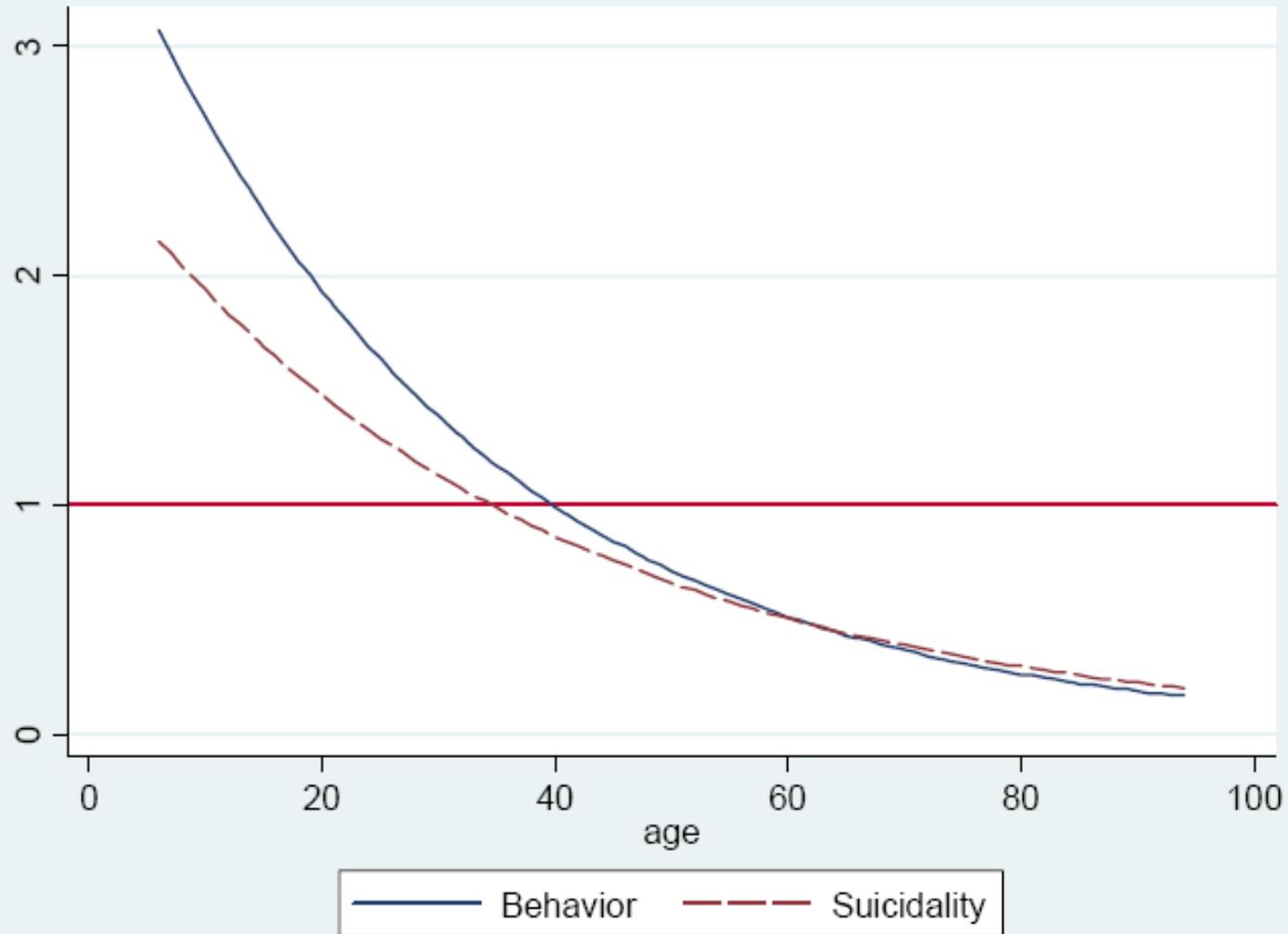


FDA meta-analyses of 372 placebo controlled trials of SSRIs and similar drugs involving 99,839 patients

www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4272b1-01-FDA.pdf

Odds ratios for suicidality and suicidal behavior for active drug relative to placebo by age.

Mean age 43 for the 99,839 patients



Publication bias, Eyding, IQWiG, BMJ 2010:c4737

Data on 74% (3033/4098) of patients were unpublished

	Reboxetine (n/N)	Placebo or selective serotonin reuptake inhibitor (n/N)	Odds ratio (95% CI)	Odds ratio (95% CI)	Ratio of odds ratios; published:unpublished (95% CI)	Publication bias (%)
Reboxetine v placebo						
Remission						
Published (1)	60/126	34/128		2.51 (1.49 to 4.25)		
Unpublished (6)	395/938	379/930		1.06 (0.88 to 1.28)	2.37 (1.36 to 4.13)	115
Total (7)	455/1064	413/1058		1.17 (0.91 to 1.51)		
Response						
Published (1)	70/126	43/128		2.47 (1.49 to 4.11)		
Unpublished (6)	469/938	439/930		1.12 (0.93 to 1.35)	2.21 (1.28 to 3.79)	99
Total (7)	539/1064	482/1058		1.24 (0.98 to 1.56)		
Patients with adverse events						
Published (2)	108/154	91/156		2.67 (0.52 to 13.79)		
Unpublished (6)	839/979	713/959		2.15 (1.66 to 2.80)	1.24 (0.24 to 6.53)	25
Total (8)	947/1133	804/1115		2.14 (1.59 to 2.88)		
Withdrawal owing to adverse events						
Published (2)	15/154	16/156		0.95 (0.45 to 1.99)		
Unpublished (6)	122/979	48/959		2.61 (1.79 to 3.80)	0.36 (0.16 to 0.84)	-57
Total (8)	137/1133	64/1115		2.21 (1.45 to 3.37)		

Internal industry documents

Quetiapine (Seroquel), AstraZeneca

Presentation at a congress and press release: Meta-analysis of four trials, quetiapine is significantly better than haloperidol.

Internal document: quetiapine possesses *weaker* efficacy than haloperidol.

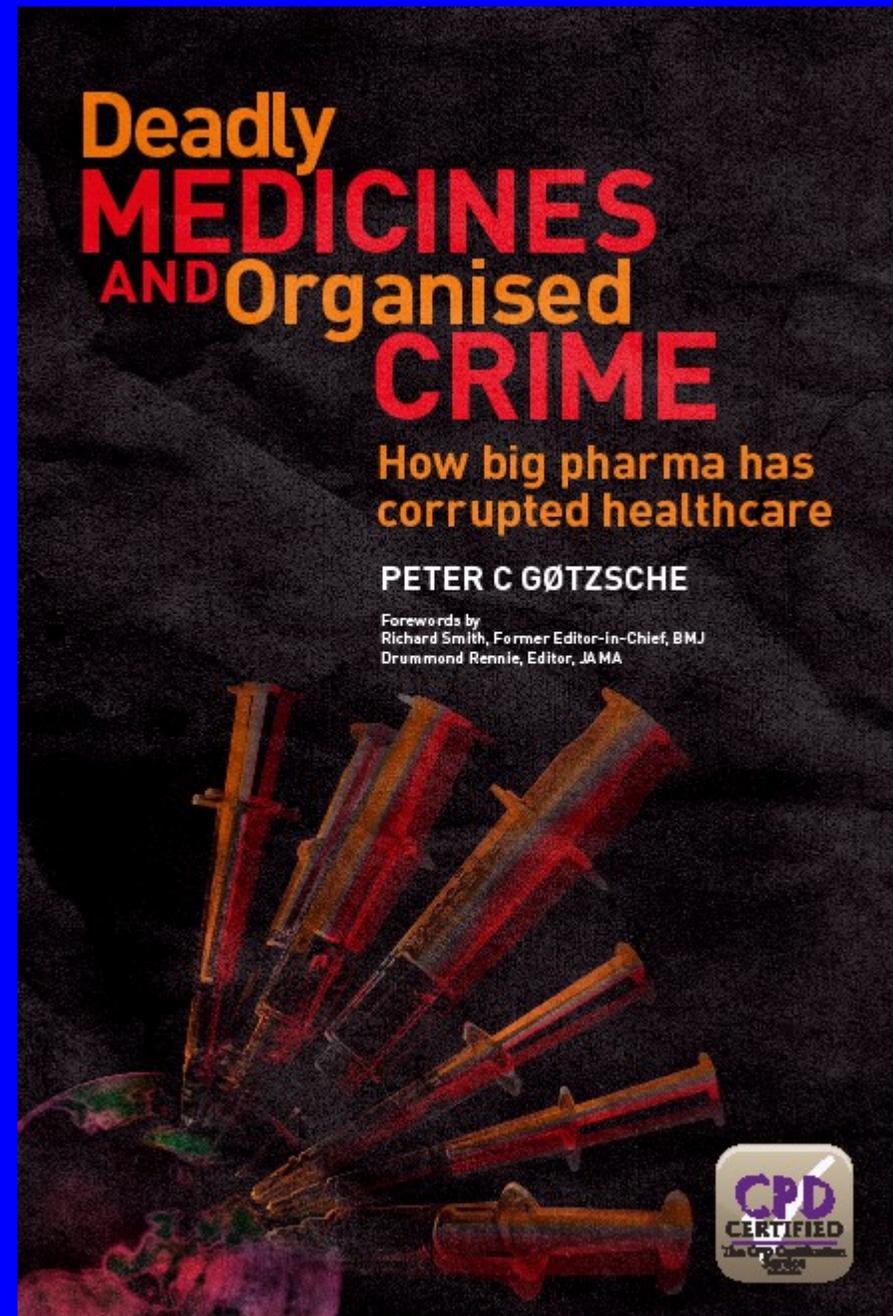
Negative trials called "buried trials" in internal emails.

Trial showing haloperidol was best published showing quetiapine was best.

In the United States and Europe,
*drugs are the third leading cause of
death after heart disease and cancer.*

Some major contributing causes:

- Highly impotent drug regulation
- Fake fixes, such as thousands of warnings and precautions
- Illegal marketing, kickbacks, fraudulent research and marketing
- Polypharmacy
- Unavailability of full study reports, protocols and the raw data



Sign a petition for access to data

2010: Nordic Cochrane Centre gets access at the EMA (after 3 years!)

2010: New openness policy at the EMA

2012: Workshop, how we can get access also to raw data at the EMA

2013: AbbVie and InterMune take legal action against the EMA

2013: AbbVie made it clear that a main reason to keep clinical trial data confidential was to hide adverse event data

2013: Openness policy stalled while court cases are unsettled

Sign a petition calling on Richard Gonzalez, the CEO of AbbVie to drop his legal action against the EMA's policy of open access to clinical trial data.

Boycott products from AbbVie, Abbott and InterMune

<http://chn.ge/13clTyF>
or Google: healy petition

