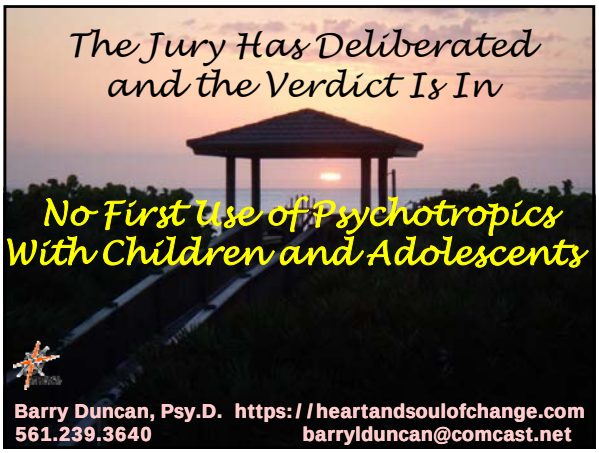
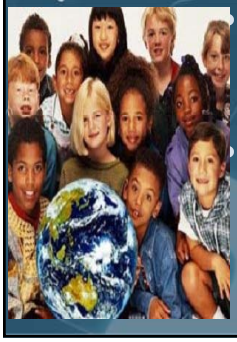


Disclosures

The presenter DOES have an interest in selling a technology, program, product and/or service to CME/CE professionals.

Dr. Duncan is a co-holder of the copyright of the Outcome Rating Scale/Session Rating Scale family of measures. The measures are free for individual use but Duncan receives royalties from licenses issued to groups and organizations. In addition, a Web-based system that uses the measures and analyzes the data is a commercial product and he receives royalties based on sales.

Youth Prescription Rates
Increasing Globally



- In the US, spending for meds for child behavior problems eclipsed any other drug category, including antibiotics
- While the US leads the world in psychotropic prescriptions to youth, global use of stimulants has significantly increased and antipsychotics have doubled across Europe

Study of poor children found that 26% on antipsychotics; Poor children 4 times more likely to be on antipsychotics

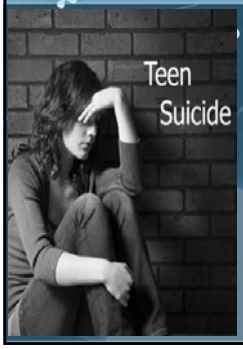
57% of foster children are taking 3 or more psychiatric drugs, 6 times national average

Apparently, children are vulnerable to psychotropics used as interventions of control rather than therapy.

The Questions
Children and Psychiatric Drugs

- Are the skyrocketing rates of prescription justified by clinical trial evidence?

SSRIs: Antidepressants
The Risks and the Black Box



- FDA study of 4400 youth revealed a risk of suicidality of 4% in SSRI patients, twice that of placebo; a follow up analysis of 22 RCTs reported similar findings; Finally, the FDA meta-analyzed 372 RCTs and reported that suicide risk increased as age under 25 decreased

SSRIs: Antidepressants
The Benefit

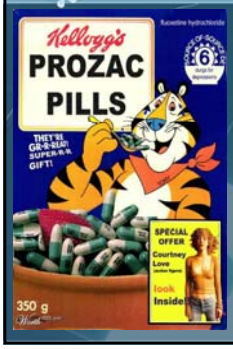
Of 15 published and unpublished clinical trials, only 3 show superiority to placebo on primary measures; none on patient or parent measures.

Antidepressants carry at least double the chance for suicidal ideation and behavior…Black box warning…Nicole

Risk/Benefit Analysis: TADS
(Treatment of Adolescent Depression Study)

- Multicenter, randomized, effectiveness trial funded by NIMH. N=432
- Short term (12-weeks) & long-term (36-weeks) of adols. diagnosed w/MDD
- 4 groups: Prozac, placebo, CBT, Prozac + CBT

SSRIs
TADS: The Benefit



- ✓CBT alone had comparable outcome at 30 weeks while the antidepressant treatment groups had significantly more psychiatric adverse events;
- ✓What about Suicide Risk?

Suicide Related Events (SREs) and Suicide Attempts (SAs) in TADS (Vitiello et al., 2009)

Treatment	N	SREs	%	SAs
Placebo	103	3	3	0
CBT	108	5	5	1
Fluoxetine alone	109	16	15	6
Combination	107	9	8	3
Placebo switched to fluoxetine or combination	9	9	100	6
CBT switched to fluoxetine or combination	3	2	67	2
Total Non-SSRI	211	8	4	1
Total SSRI	228	36	19	17


PSYCHOPHARMACOLOGY

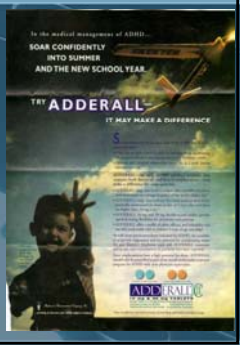
Outside the Black Box: Re-assessing Pediatric Antidepressant Prescription

Stimulants: The Multimodal Treatment Study of Children w/ADHD (MTA)

- Large 14 mo comparison of managed med v. BT v. combined v. TAU (medicated)
- 19 outcome measures
- All 4 groups improved
- Concluded that MM superior to BT & Combined brought no advantages

Stimulants
MTA: The Benefit

- Found advantage to med group on 3 of 19 measures
- At 36 months, groups did not differ.



Stimulants
MTA: The Risk—Adverse Events

- 64% of the children experienced ADRs; 11% were rated as moderate, and 3% as severe.
- Follow-up reveals sig. growth reduction with no rebound

Antipsychotics: Treatment of Early Onset Schiz. Spectrum Disorders (TEOSS)

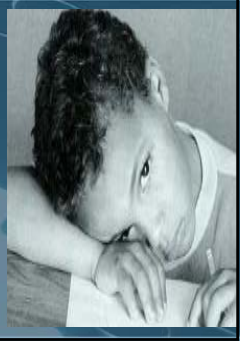
- TEOSS compared two SGAs (Risperdal & Zyprexa) to a FGA (Moban).
- At the end of eight weeks, the "response" rate was 50% for those treated with Moban, 46% for Risperdal, and 34% for Zyprexa; 41% didn't complete 8 weeks.

Antipsychotics
TEOSS: The Risks—Suicide

- 1 suicide & 8 (8%) were hospitalized for suicidality or worsening psychosis—at risk excluded.
- Weight gain resulted in suspension of Zyprexa arm.
- Adverse events "frequent." "May place many youth at risk for diabetes and cardiovascular problems."

Antipsychotics
TEOSS: Ultimate Risk and Benefit

- The 54 who "responded" during the initial 8 weeks entered into the 44-week maintenance study
- 40 of 54 dropped out for "adverse effects" or "inadequate response." Only 14 of 116 youth responded and stayed on the med for one year—only 12%.



Psychotropic Medications
The Risks That Don't Make the Ads

There is no informed consent with children. Parents and helpers need to know

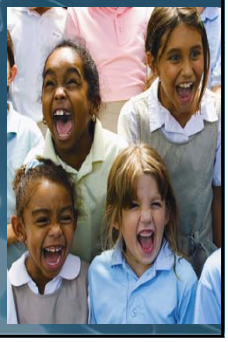
Antidepressant Risks: Mania—5 times the rate of placebo; 'Warning' for **suicidal** behavior—at least twice the rate of placebo; stunted growth

Stimulant Risks: 'Warnings' for suicide and cardiac risk; loss of 1 cm and 2.7 kg per yr; Mania, psychosis, cardiac sudden death; 64% report adverse reactions

Antipsychotic Risks: Diabetes, obesity; EPS, tardive dyskinesia, neuroleptic malignant syndrome, **suicide**, akathisia

Conclusions
A Risk Benefit Analyses

- Does not support meds as a first intervention;
- Offer alternatives: community, spiritual & counseling in concert w/values, culture, and preferences.
- Where there are no options, create them



Where Children Are Concerned
The Stakes Are Higher

Do not have a voice to say no and depend on adults to safeguard wellbeing; poor children have fewer adults watching over them and are vulnerable to dangerous drugs used for control rather than therapy. **It's up to us to ensure their safety.**

Now That You Know
The Risk/Benefit Analyses

Having heard this, you may choose to look the other way, but you can never say again that you did not know.
William Wilburforce, Address to the English Parliament regarding the Slave Trade

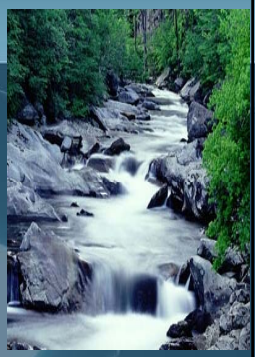
- I hope when you leave tomorrow you will take with you a skepticism of commercial interests with little conscience, a keen attention to the evidence, and a desire for ongoing study of broadening psychosocial options, including a follow up conference.

The Evidence and Ethics Demand
A Higher Standard of Care

Gabriel, foster care child, was on Vyvance , Lexapro, Zyprexa, Symbyax, and Adderal; died at age 7

1) Psychosocial intervention first—especially to the poor
2) No off label prescribing;
3) No polypharmacy
4) Separate pharmaceutical company influence from science and practice
5) Monitor treatment response with patient rated measures

"Children are like rivers: You can't step in the same river twice."



- Children change with changes in context
- Children change as they develop
- Children's identities are impressionable and mutable

Questions for the Presenters
Rules of Engagement

1. Appreciate your comments but please keep them brief, just a couple of sentences—then ask your question, identifying to whom it is addressed
2. Up to two additional panel members may respond. Please keep all responses under 3 minutes