



The Path to This Meeting

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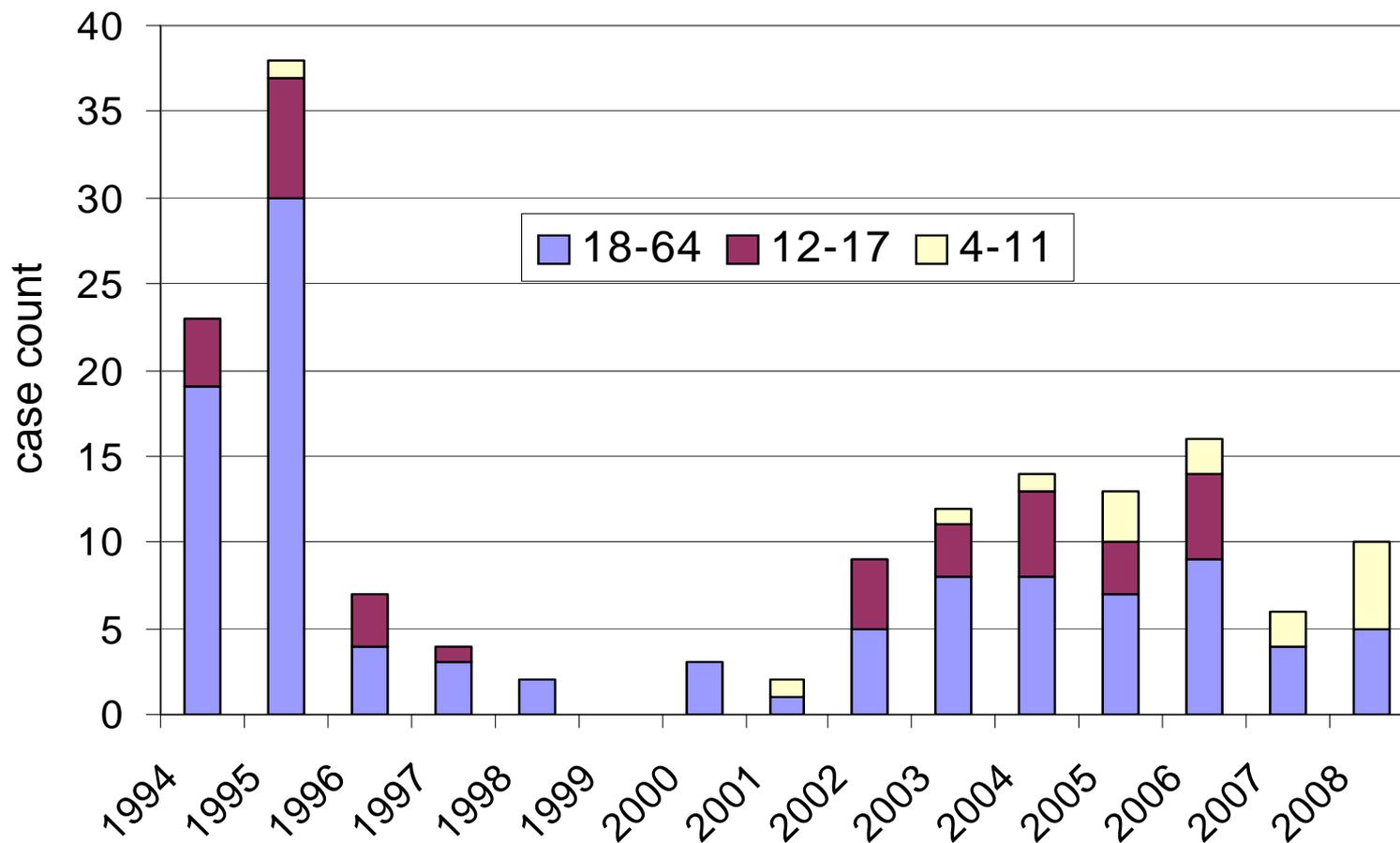
BPCA Exclusivity through June 2008

	Number
Written Requests issued:	360
Labeling changes:	149
Expanded age:	90
Safety and efficacy not established:	46
New/enhanced safety information:	43
Specific dosing change/adjustment:	26
Pediatric formulation:	15
Extemporaneous formulation:	7
PK differences (pediatrics vs. adults):	6
Products with safety reporting:	79

Assuring Pediatric Drug Safety

- BPCA 2002/2007 Legislation: Focused Pediatric Post-Marketing Safety Assessment following Exclusivity/Labeling
- Limited Pediatric Studies and Limited Number of Pediatric Patients in Clinical Trials may require Meta-Analysis
- Process: Set within the context of what is known about safety in adults

Trends in receipt of domestic, spontaneous cases of death in association with LABAs among reports with both age (4 - 64 years) and indication ("asthma"), 1994 through November 2008.

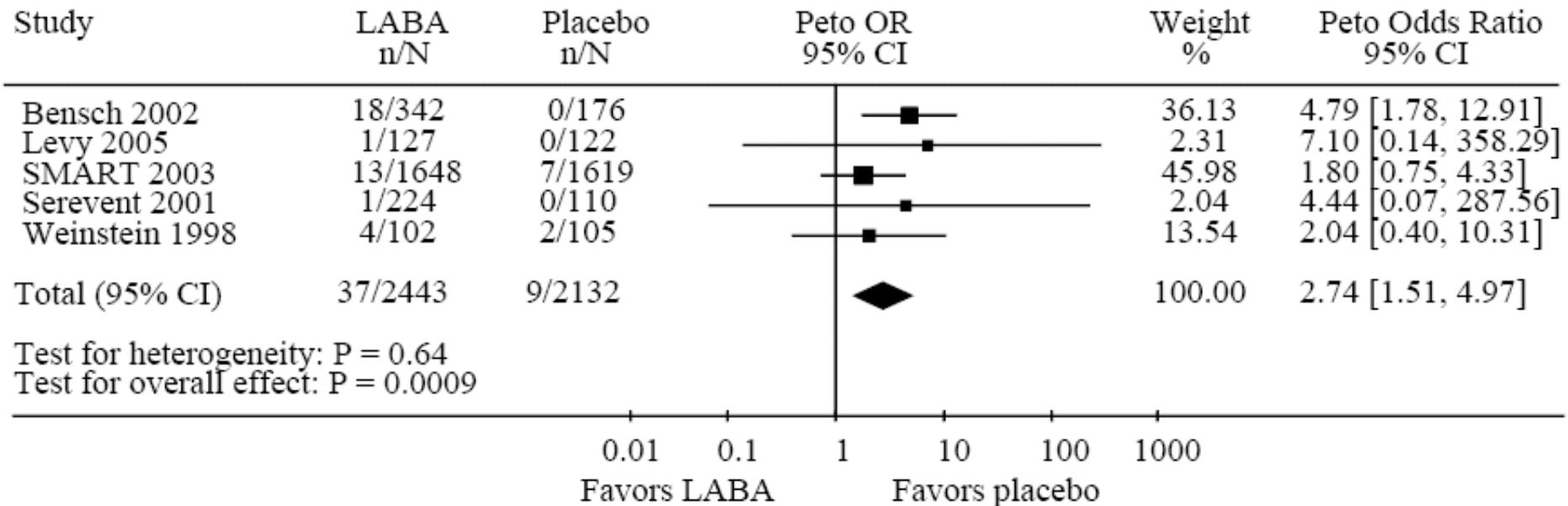


Salpeter et al.

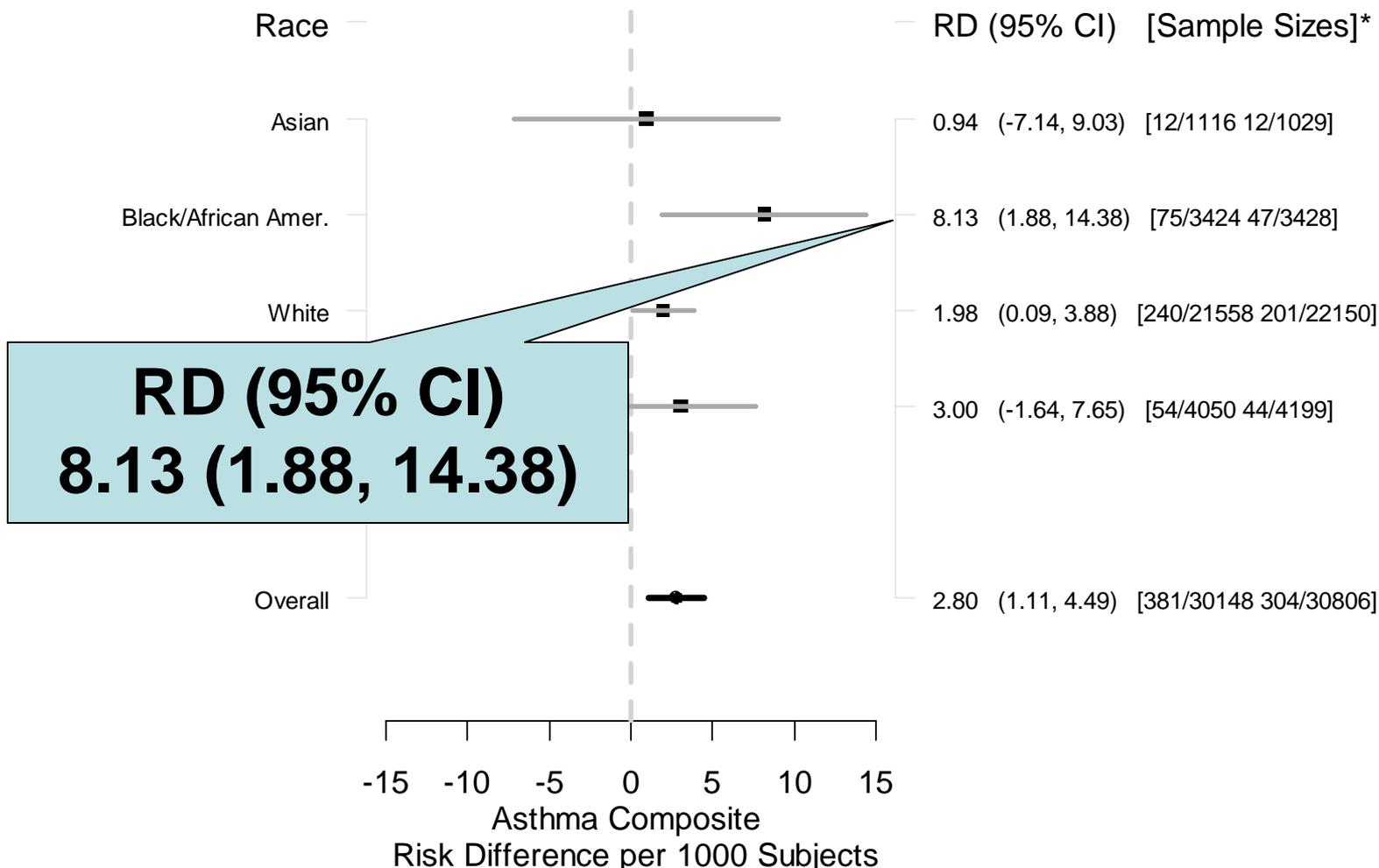
Meta-analysis of LABA pediatric trials which provided data on asthma hospitalizations

(All trials except SMART had mean subject ages between 8 and 10 y.o.)

Comparison: Long-acting beta-agonists (LABA) and hospitalizations for asthma exacerbations - children

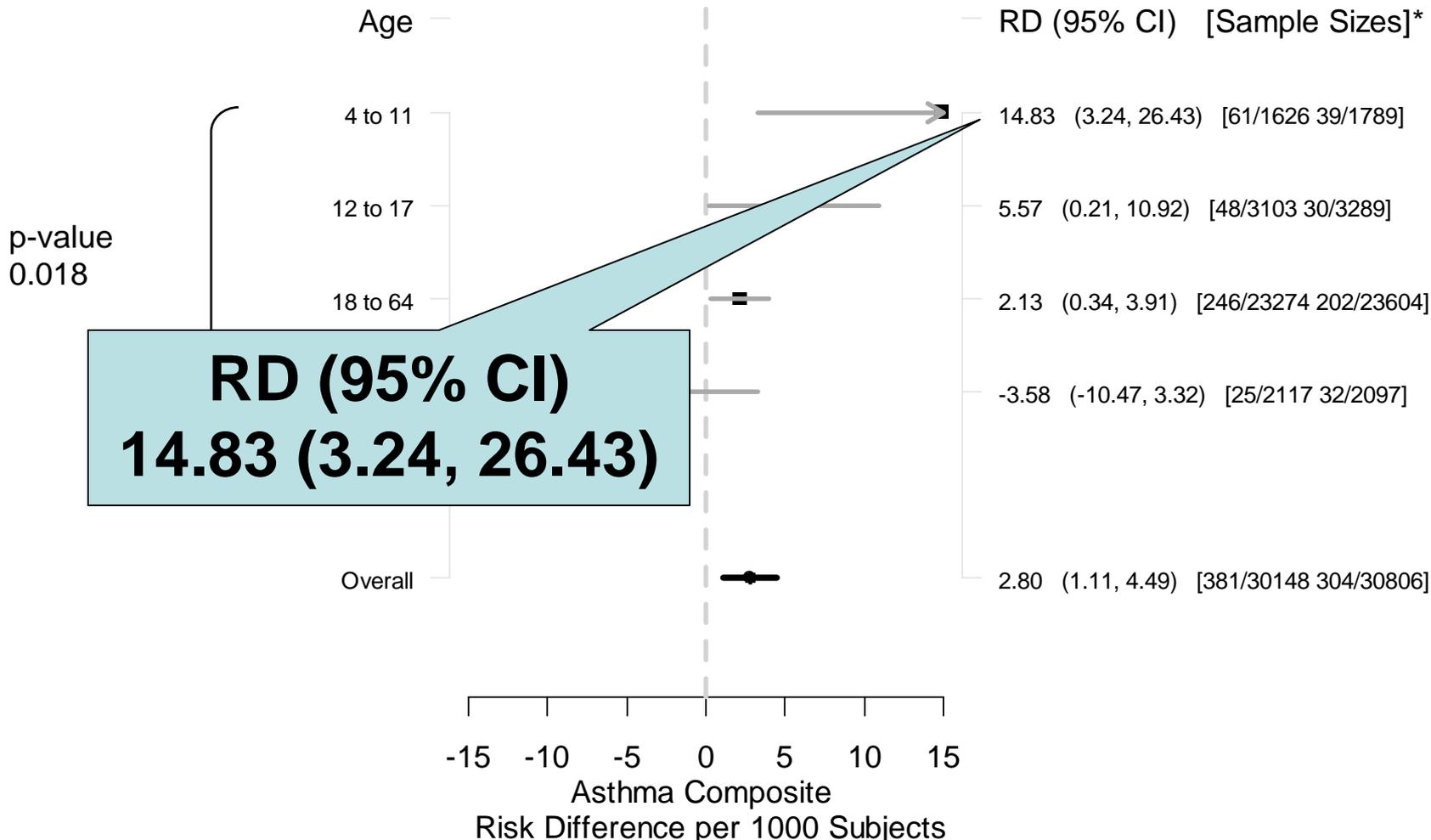


Asthma Composite by Race Subgroup Risk Difference Estimates



*RD = Risk Difference Per 1000 Subjects
[Treat. Events/Treat. n Plac. Events/Placebo n]

Asthma Composite by Age Subgroup Risk Difference Estimates



*RD = Risk Difference Per 1000 Subjects
[Treat. Events/Treat. n Plac. Events/Placebo n]

Three Advisory Committees

Therefore

- Three groups of experts...
- Bringing different perspectives to...
- Assist FDA in deciding how best to address the safety signals seen in the pediatric focused analysis.

