Opportunities for the Future of Monograph Reform

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Increasing access to safe and effective drugs can improve personal and public health

Role of the monograph and monograph reform?

- Facilitate use of ingredients recognized as safe and effective
- Ensure consumers receive information through labeling needed to use products with monograph ingredient
- Promote innovation in improving access to safe and effective drugs by the public

How should OMUFA be used evolve the monograph?

Establish clear priorities: Changes with largest opportunity to impact personal and public health

Examples: The challenge of pediatric overdoses involving monograph ingredients

- Experience with voluntary actions (CDC-led PROTECT initiative)
- Data-driven identification of possible interventions

Using data to inform public health priorities: Pediatric unsupervised ingestions of acetaminophen

- Problem identified using data on emergency department visits
- Liquid formulations identified as major contributor
- Laboratory research shows flow restrictors can limit access to container liquid contents
- 2011 initiative to use flow restrictors on liquid acetaminophen products
- Assess trends using National Poison Data System (Rocky Mountain Poison and Drug Center)

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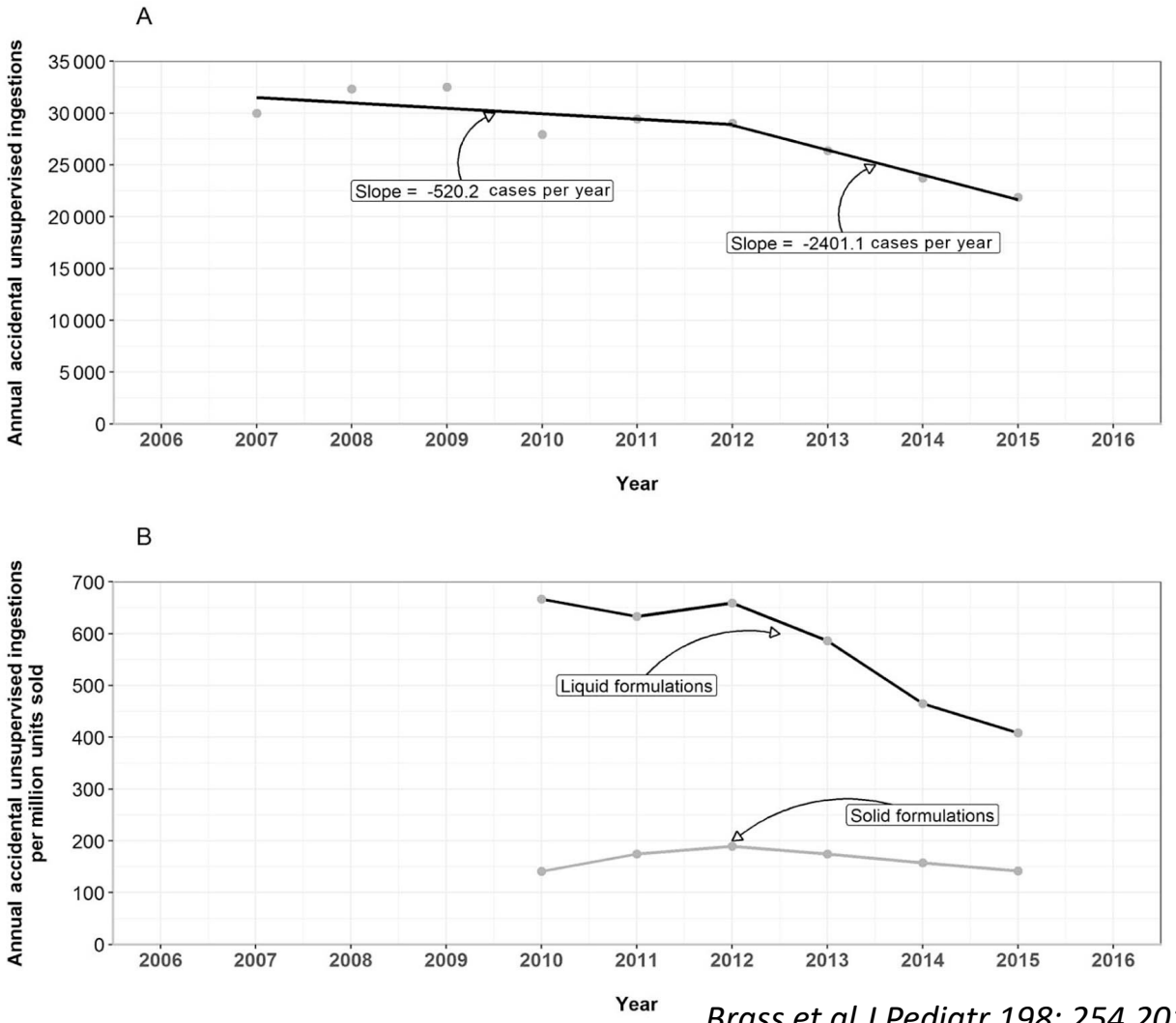

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Medication errors with pediatric acetaminophen products during therapeutic use

- Voluntary actions in 2011:
  - Tabular format for dosing (weight and age)
  - Use only milliliter units
  - Use leading zeros
  - Include calibrated dosing device consistent with dosing instructions
  - Dosing device not significantly larger than highest dose
  - Standardize concentration 160 mg/5ml (FDA Guidance 2015)
- National Poison Data System exposure data

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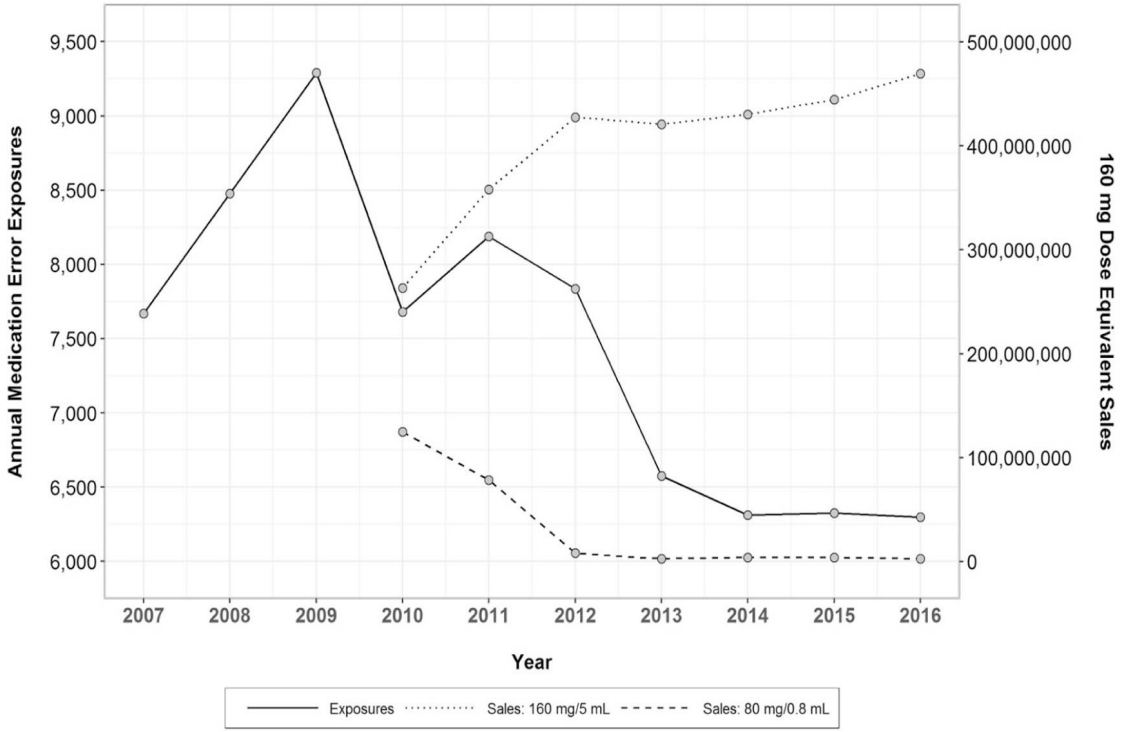

- Absolute number of exposures low
- **Children < 2 yo account for 66% of exposures!**
- No label dosing instructions – call healthcare professional

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Perspectives on monograph reform: Looking towards the future

- How to use the processes and authorities that have been put in place?
- Priorities should be based on personal and public health impacts of the specific issue under consideration
  - Data-driven to the degree possible
  - Example: reassess acetaminophen labeling for children under 2 yo
  - Consider opportunities for health benefits, not only risk reduction
- Original monograph created under necessity
  - Can advantages of monograph to stakeholders be leveraged?

Perspectives on monograph reform: Looking towards the future

- How incentivize innovation?
  - Can/should ingredients be added to the monograph?
    - Many NDA ingredients with well established records of safety and efficacy – monograph candidates?
    - Are the advantages and disadvantages to stakeholders understood?
    - Should monograph be viewed as alternative to NDA process? Why? Why not?
- Communication among stakeholders critical
  - In data-driven decision making the sources of data are outside of FDA
  - Cooperation critical to ensure that FDA has data it needs and stakeholders have the opportunity to provide that data
  - Transparency as to priorities/activities
    - Annual Forecast – excellent example – reassess if it is optimal

Thank you

for your

attention