Pediatric Formulations: What is Needed?

Shaping the Future of Pediatric Drug Development
John Alexander, MD, MPH, Deputy Director,
Division of Pediatrics and Maternal Health, CDER, FDA
June 24, 2026

Disclosures

- The views expressed in this talk represent my opinions and do not necessarily represent the views of FDA
- I have no financial relationships to disclose relating to this presentation

Welcome

- Shaping the Future of Pediatric Formulation Development

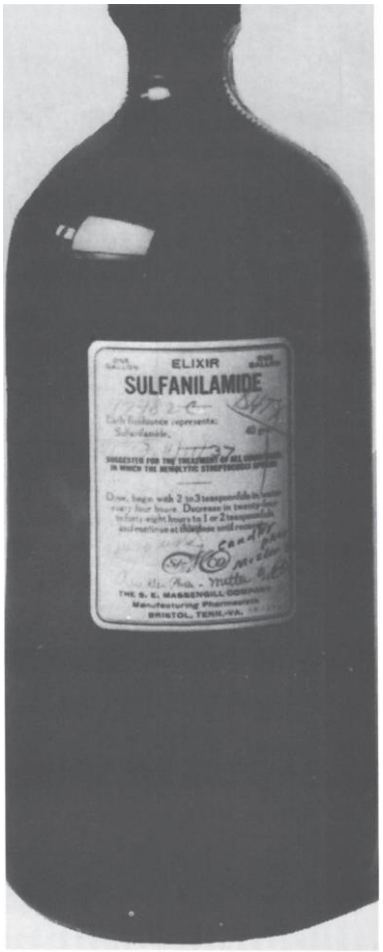
- 2019 Workshop

  Pediatric Formulation Development: Challenges of Today and Strategies for Tomorrow

- Considerations for pediatric formulations

  What is needed for pediatric patients?

A Moment in History



- In 1937, “elixir” of sulfanilamide
- 10% sulfanilamide, 72% diethylene glycol, 16% water
- 105 deaths (including 34 children)
  - Renal failure (vacuolar nephropathy)
  - Death in mean of 9.4 days (2-22 days)
- Led to passage of the 1938 Federal Food Drug and Cosmetics Act
  - New drug application showing safety

Annals of Internal Medicine, 122(6), 1995, 456-461

History Repeats

- 1990: 40 children in Nigeria died from renal failure (acetaminophen syrup)
  - 1969: seven children in Cape Town (sedative)
  - 1985: five burn patients in Spain (silver sulfadiazine)
  - 1986: 14 children in Bombay (glycerine)
- 2022-3: six alerts of DEG/EG contamination of OTC medicines in Gambia, Cameroon, Iraq, Pakistan and more
    - WHO: https://www.who.int/news/item/01-12-2023-diethylene-glycol-(deg)-and-ethylene-glycol-(eg)-contamination---analytical-methods-developed-for-testing-paediatric-medicines

What is needed? Safety first

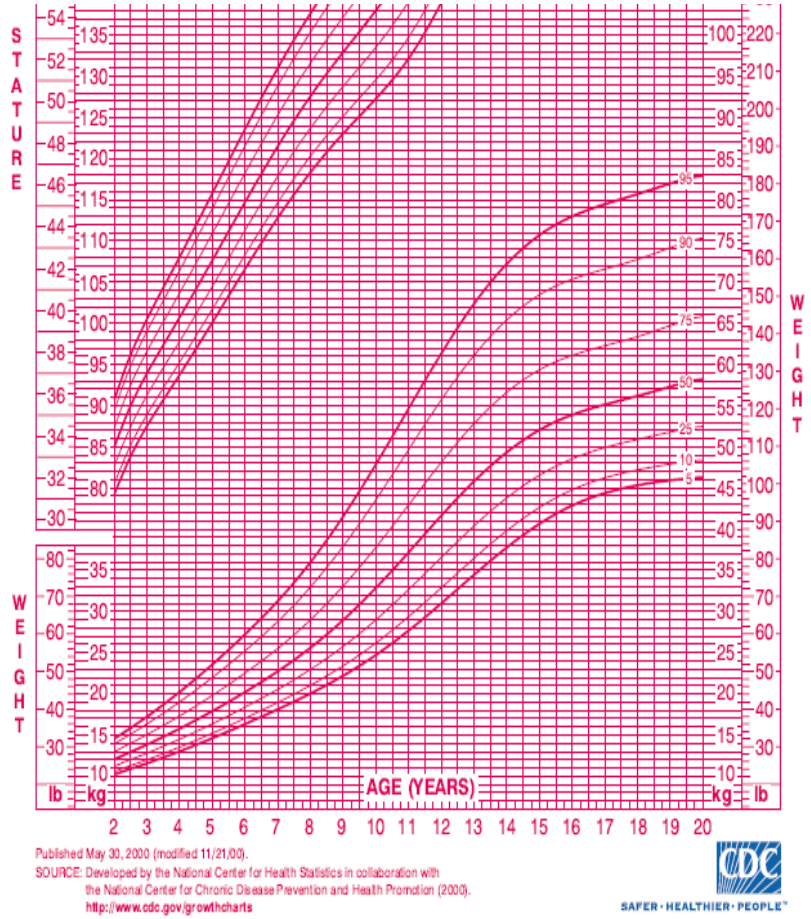
Pediatric Development

- Development is a factor in multiple ways
  - Ontogeny of metabolic pathways
    - Benzyl Alcohol as the classic example
  - Maturation of organ systems
    - Can contribute to risks from excipients
  - Children are not just small adults
    - More excipient concerns with younger age
    - Neonates as a protected population

What is needed?

Recognition of developmental effects

Pediatric Growth



- CDC growth charts
  - Girls 2 and older (shown)
- Adult range: 45-85 kg
- Pediatric range: 8-85 kg
  - Not counting < 2 years (separate growth charts for birth to 36 months)

What is needed?

Flexible dosing

Palatability/Acceptability

- The most effective medicines won't work in someone who won't take it
  - Most children's hospitals have websites addressing techniques for medication

    (e.g., https://www.seattlechildrens.org/conditions/a-z/medicine---refusal-to-take/)
  - Bitterness of active ingredients often worse in pediatric-friendly formulations (liquid, chewable)
  - Alternative strategies used for adults (e.g., coating) should signal need to rethink pediatric formulation

What is needed? Alternative formulations

Summary

There are many pediatric considerations that are important in pediatric formulation development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