



Elizabeth Glaser Pediatric AIDS Foundation

Pediatric Perspectives on Improving Drug Safety

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of the U.S. Drug Safety System

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Elizabeth Glaser Pediatric AIDS Foundation

The mission of the Elizabeth Glaser Pediatric AIDS Foundation is to create a future of hope for children and families worldwide by accelerating the discovery of new treatments for HIV/AIDS and other serious and life-threatening pediatric illnesses.

Ensuring that drugs prescribed for pediatric patients are safe and effective is an important part of this charge.



Glaser Pediatric Research Network

- Texas Children's Hospital/Baylor College of Medicine
- Children's Hospital-Boston/Harvard Medical School
- Lucile Packard Children's Hospital at Stanford University
- Mattel Children's Hospital at the University of California Los Angeles
- UCSF Children's Hospital at the University of California San Francisco

Recent Improvements to Drug Safety for Children

- 1997: Better Pharmaceuticals for Children Act (enacted as part of the Food & Drug Administration Modernization Act)
- 1998: "Pediatric Rule" published in Federal Register by FDA
- 2002: Best Pharmaceuticals for Children Act (BPCA)
- 2003: Pediatric Research Equity Act (PREA)

Key Issues in Improving Drug Safety

- Continue commitment to timely access of patients to new therapies
- FDA authority to require post-market studies
- Flexible enforcement tools
- Mechanisms for sharing safety findings
- Sufficient resources to carry out any new responsibilities

Pediatric Issues

- Critical that any proposals for improving the current drug safety system recognize that children are not small adults
- Special needs of children must be addressed throughout the post-market safety continuum
- Pediatric expertise should be included in decision-making
- Any recommendations for changes to current system should recognize existing pediatric drug safety authorities – important to fill in gaps without undermining current protections



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