

## **PEDIATRIC DRUG TESTING LEGISLATIVE AND REGULATORY HISTORY**

- 1992** The *Better Pharmaceuticals for Children Act* (BPCA) is introduced by Senator Nancy Kassebaum (R-KS).
- 1994** The *Better Pharmaceuticals for Children Act* is introduced by Senator Kassebaum and Representative Mike Kreidler (D-WA).
- 1996** The *Better Pharmaceuticals for Children Act* is introduced by Senator Kassebaum and Representative Jim Greenwood (R-PA).
- May 1997** Senators Mike DeWine (R-OH) and Chris Dodd (D-CT) and Representatives Greenwood and Henry Waxman (D-CA) introduce the *Better Pharmaceuticals for Children Act*.
- November 1997** BPCA is enacted as part of P.L. 105-115, the *Food and Drug Administration Modernization and Accountability Act* (FDAMA).
- December 1998** The Pediatric Rule is promulgated by the Food and Drug Administration.
- April 1999** The Pediatric Rule takes effect.
- 2000** A lawsuit is filed by Association of American Physicians and Surgeons, Competitive Enterprise Institute, and Consumer Alert challenging the authority of the Food and Drug Administration (FDA) to promulgate the Pediatric Rule.
- November 2001** The American Academy of Pediatrics (AAP), the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), and the Pediatric Academic Societies file an Amicus Brief in the lawsuit supporting the Pediatric Rule.
- January 2002** The *Best Pharmaceuticals for Children Act* is enacted, which renews and expands the 1997 law.
- March 2002** The Department of Health and Human Services (HHS) announces it intends to stay the Rule for two years while studying whether it is needed in light of passage of BPCA. The next month HHS reverses its position after strong objections from children's groups and members of Congress and announced it would continue to enforce Rule and defend it in court.
- October 2002** A federal district court strikes down the Pediatric Rule on the grounds that the FDA lacked the statutory authority to promulgate the Rule and that the Rule and the BPCA were incompatible.
- December 2002** EGPAF and AAP are granted the right to defend the Rule by the federal district court and file an appeal in US Court of Appeals. FDA decides not to appeal the decision.
- March 2003** Senators DeWine and Hillary Clinton (D-NY) introduce the *Pediatric Research Equity Act* (PREA), which codifies the Pediatric Rule.

- July 2003** The Senate unanimously passes PREA. Representatives Greenwood, Anna Eshoo (D-CA), and Deborah Pryce (R-OH) introduce the *Pediatric Research Equity Act* in the House.
- November 2003** The House passes PREA on a voice vote.
- December 2003** The President signs PREA into law (P.L. 108-155). EGPAF and AAP request that their appeal be dismissed.
- March 2007** Senator Clinton introduces the *Pediatric Research Improvement Act*, legislation to reauthorize and improve PREA.
- April 2007** Senator Dodd introduces the *Best Pharmaceuticals Amendments of 2007*, legislation to reauthorize and improve BPCA.
- June 2007** Representative Eshoo introduces the *Improving Pharmaceuticals for Children Act of 2007* to reauthorize BPCA and PREA.
- September 2007** The House and Senate pass the *Food and Drug Administration Amendments Act of 2007* (FDAAA), which includes the reauthorization of BPCA and PREA as part of a broader package of FDA reforms. The President signs FDAAA into law (P.L. 110-85).