

Overview of New Legislation: Food and Drug Administration Amendments Act of September 2007



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History of USA Pediatric Regulations/Legislation

- FDA Modernization Act: Pediatric Exclusivity 1997
- Pediatric Rule Regulation: 1998 (enjoined 2002)
- January 2002
 - FDAMA Exclusivity Sunsets
- January 2002
 - Best Pharmaceuticals for Children Act (BPCA)
- December 2003
 - Pediatric Research Equity Act (PREA)
- October 2007: Sunset for BPCA & PREA
- Food and Drug Administration Amendments Act
September 2007: FDAAA

RESULTS: February 2008

N= 144 Labels under BPCA

- Specific Dosing change/adjustment N=26*
- New or enhanced safety data N=42
- Efficacy and Safety NOT established N=32
- Expanded age to younger pediatric population N=92

* Pediatrics, Vol. 121, Number 3, March 2008 William Rodriguez

RESULTS: September 2007

N= 64 Labels under PREA

FDAAA 2007 & Pediatrics: How Congress Doubled Your Work!

- FDAAA reauthorized the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act. FDAAA also enacted new pediatric medical device provisions.
 - Title III, Pediatric Medical Device Safety and Improvement Act of 2007
 - Title IV, Pediatric Research Equity Act of 2007
 - Title V, Best Pharmaceuticals for Children Act of 2007

Important Components of FDAAA

- Mandated labeling for almost all submitted pediatric studies (Drugs and Biologics)
- Transparency enhanced by increasing the data being posted from the studies and requiring posting of the Written Request
- Expansion of the focused pediatric safety reviews
- Extending reach to Devices
- Requiring Pediatric input into all components

Title III: Devices

■ Humanitarian Device Exceptions: HDEs

- Adverse Events: FDA is to forward adverse event reports, for HDE devices with a pediatric indication for which profit-making is allowed, to the Office of Pediatric Therapeutics, who shall provide for periodic review of the adverse events by the Pediatric Advisory Committee (PAC)
- Annual Review: The PAC shall annually review all HDEs with a pediatric indication for which profit-making is allowed to determine whether the exemption remains appropriate for the pediatric populations for which it is granted
 - CDRH and OPT have established SOP for tracking HDEs and need for review by PAC
- GAO Report: GAO must report to Congress on the effects of permitting profits on the sale of pediatric devices marketed under an HDE by Jan. 2012

Title IV: PREA

- Products subject to PREA will now have their pediatric plans reviewed by a Pediatric Committee.
- Submitted Studies will now result in labeling irrespective of regulatory decision
- Labeling will trigger a mandatory pediatric safety review which will be brought to the PAC
- Biologics are now included

Title V: BPCA

Pediatric Advisory Committee

- ISSUE: Capability of OPT, PAC members, CDER, and CBER review staff to prepare, analyze, present, and review data in a timely manner
 - Between the end of 2003-2007: there were over 70 products brought for review by the PAC
 - Present projections: approximately 40 products should be brought to the PAC in 2009 alone. This will require a PAC meeting every 3-4 months.
 - This Committee is also utilized for a number of other Advisory Committee issues and in joint meetings, including Dispute Resolution

Legislation encouraging pediatric studies and availability of quality pediatric data IS resulting in new product labeling. Our job is to ensure those products are safe and labeled to reflect emerging safety signals that occur once the product is used in larger numbers of the pediatric population.



