

FDA Law Renews Provisions to Improve Pediatric Drug Development

The Food and Drug Administration Amendments Act of 2007 (HR 3580) was passed in September 2007 to reauthorize until 2012 the FDA's prescription drug and medical device approval program which is primarily funded through fees paid to the agency by drug and device companies. It would also provide the agency broad new authority to regulate postmarket drug safety. The bill also reauthorizes the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Improvement Act (PRIA).

Title IV reauthorizes for five years the FDA's authority under PRIA to require a manufacturer who submits an application to market an approved drug or biologic with a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration to also submit a pediatric assessment. Title IV grants the Secretary of the Department of Health and Human Services (HHS) authority to require pediatric tests in appropriate circumstances.

Title V reauthorizes, also for five years, FDA's authority under BPCA to grant an additional six months of marketing exclusivity to a manufacturer of a drug in return for FDA-requested pediatric use studies and reports. Title V also includes provisions to encourage pediatric research for products that are off-patent, or for products whose manufacturer declines to conduct FDA-related studies. Title V increases to 180 days the time limit that the Secretary has to make exclusivity decisions. This title also strengthens labeling requirements to reflect study results in a "timely and consistent manner."

Other key provisions of the bill establish two clinical trials databases -- a clinical trials registry and a database for clinical trials results. All clinical trials conducted to test the safety and efficacy of either drugs or devices are subject to the database reporting requirements. The databases would apply to both privately and publicly-funded clinical trials. The statute requires that both databases be disclosed to the public through the Internet and there are civil monetary penalties for noncompliance.

The law also includes provisions related to enhancing drug safety. It codifies FDA's authority to require additional studies of medical products once they have reached the market. This can be in the form of either observational or clinical studies if new safety information is detected. In addition, the bill creates a "Risk Evaluation and Mitigation Strategy" (REMS) process. If the FDA determines a REMS is necessary to ensure that the drug's benefits outweigh its risks such a strategy would be applied. The REMS process could include elements such as package inserts, enhanced communication efforts, or certain restrictions on distribution and use. In an attempt to balance risk and benefit REMS could be used for new drug or biologic license applications, drugs and biologics that have already been approved, drugs and biologics seeking accelerated approval, and supplemental applications seeking approval of a new indication for use of the drug. If product sponsors violate the required studies or REMS, FDA has the authority to apply civil monetary penalties to the company.