

H.R. _____, Food and Drug Administration Amendments Act of 2007

Differences Between H.R. 2900 and H.R. _____

Title I. Prescription Drug User Fee Amendments of 2007

- Technical and Conforming Changes

Title II. Medical Device User Fee Amendments of 2007

- Technical and Conforming Changes

Title III. Pediatric Medical Device Safety and Improvement Act of 2007

- Technical and Conforming Changes

Title IV. Pediatric Research Equity Act of 2007

- H.R. _____ provides that, if the Secretary requires a pediatric test, the Secretary must certify whether the Foundation for the National Institutes of Health has sufficient funding to initiate and fund all of the studies required. H.R. _____ authorizes this program through 2012.

Title V. Best Pharmaceuticals for Children Act of 2007

- Technical and Conforming Changes

Title VI. Reagan-Udall Foundation

- Technical and Conforming Changes

Title VII. Conflicts of Interest

- H.R. 2900 allowed the Secretary to grant one conflict of interest waiver from voting per advisory committee meeting. H.R. _____ limits both participation and voting waivers. It requires the Secretary to determine the aggregate percentage of waivers provided in fiscal year 2007. The Secretary will then be required to decrease the number of waivers by 5 percent for each of fiscal years 2008 through 2012.

Title VIII. Clinical Trial Databases

- H.R. _____ requires that a rulemaking be completed to decide on the format of a few data elements in the clinical trial results database. This rulemaking will also consider whether to include results for unapproved drugs.

Title IX. Enhanced Authorities Regarding Postmarket Safety of Drugs

- H.R. 2900 subjects an applicant who violates a Risk Evaluation and Mitigation Strategy (REMS) requirement to a civil monetary penalty of not more than \$250,000 per violation, and not to exceed \$1 million for all such violations adjudicated in a single proceeding. If a violation continues after the Secretary provides notice of such violation to the applicant, authorizes the Secretary to impose a civil penalty of not more than \$10 million per violation, and not to exceed \$50 million for all such violations adjudicated in a single proceeding. For a violation that is continuing in nature and poses a substantial threat to the public health, authorizes the Secretary to impose a civil penalty not to exceed \$1 million for each day that such person is in violation.
- H.R.____ makes an applicant who violates a REMS requirement subject to a civil monetary penalty of \$250,000 per violation, and not to exceed \$1 million for all such violations adjudicated in a single proceeding. In the case of a violation that continues after the Secretary provides written notice to the responsible person, the responsible person shall be subject to a civil monetary penalty of \$250,000 for the first 30-day period (or any portion thereof), and such amount shall double for every 30-day period thereafter that the violation continues, not to exceed \$1 million for any 30-day period, and not to exceed \$10 million for all such violations adjudicated in a single proceeding.

Title X. Food Safety

- H.R.____ requires the Secretary to establish an Adulterated Food Registry and improves standards for pet food. H.R.____ also includes provisions to improve communication requirements during an ongoing recall of human or pet food. These provisions are modeled on language contained in the Senate bill, S. 1082.

Title XI. Other Provisions

- H.R.____ includes provisions regarding clearance of articles written by the Food and Drug Administration (FDA) employees, and among other things, the treatment of tropical and neglected diseases. These provisions are modeled on language contained in the Senate bill, S. 1082.