

**The Food and Drug Administration Safety Act of 2005 – SUMMARY**  
**Senator Charles E. Grassley (R-IA) and Senator Christopher J. Dodd (D-CT)**  
**April 27, 2005**

The Food and Drug Administration Safety Act of 2005 (FDASA) will establish an independent Center within the Food and Drug Administration (FDA) – the Center for Post-market Drug Evaluation and Research (CPDER). The Director of the CPDER will report directly to the FDA Commissioner, and will be responsible for conducting risk assessment for approved drugs and biological products and ensuring their safety and effectiveness once they are on the market.

FDASA will:

- Authorize the Director to require manufacturers to conduct post-market clinical or observational studies if there are questions about the safety or efficacy of a drug or biological product.
- Authorize the Director to determine whether an approved drug or licensed biological product may present an unreasonable risk to the health of patients or the general public, given the known benefits.
- Authorize the Director to take corrective action if a drug or biological product presents an unreasonable risk to patients or the general public – including the authority to make changes to the label or approved indication, place restrictions on product distribution, require physician and consumer education, and require the use of other risk management tools.
- Allow the Director to withdraw approval of a drug or biological product if necessary to protect the public health.
- Require submission of advertising prior to dissemination, and certain advertising disclosures related to risks and benefits to patients, if one or more of the three following conditions is met: the Director has determined that the product may present an unreasonable risk to patients, the product is the subject of an outstanding post-market study requirement, or the product was approved within the last two years.
- Establish strong enforcement mechanisms, including civil monetary penalties, for those who fail to comply.
- Ensure that the Director benefits from all appropriate resources, including consultation with the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER), and makes all decisions based on a risk-benefit analysis.
- Ensure that all findings and decisions made by CPDER are transparent.
- Require a report and recommendations to Congress on post-market surveillance of medical devices.
- Authorize graduated appropriations totaling \$500 million over five years to ensure that CPDER has the resources to accomplish its goals.