H.R. ____, "The Fair Access to Clinical Trials Act"

BILL SUMMARY

- **Greatly increases public access to important safety information.** The database will build on the National Library of Medicine's www.clinicaltrials.gov. All sponsors of privately and publicly funded studies of drugs, biologics, or medical devices with safety or effectiveness endpoints must register. However, the registry will not include drug or biologic studies (1) designed solely to detect major toxicity (phase 1 studies), and (2) pharmacokinetic studies other than those in special populations.
- **Provides timely and detailed information on clinical studies at their outset.** Studies must be registered as a condition of obtaining Institutional Review Board ("IRB") approval before the trial begins. The initial registration must include detailed information about the trial, including:
    - Disease or condition with which the trial is concerned;
    - Hypothesis being tested;
    - Study design, methods, primary and secondary outcomes;
    - Eligibility criteria and total number of subjects;
    - Sponsor and principal investigator (with contact information); and
    - Sources of funding.
- **Requires the reporting of extensive data on study results.** Within 12 months from the last data collection, the sponsor must provide a summary of the clinical study results. The Secretary has authority to add any disclaimers necessary to help ensure that submitted data are not misinterpreted. The following types of data on study results must be submitted:
    - Results on primary and secondary outcomes, presented succinctly as quantitative data and as tests of hypotheses;
    - Basic demographic information on subjects;
    - Number of drop-outs and reasons for dropping out; and
    - Significant adverse events.
- **Creates an enforcement mechanism for non-compliance.** If a sponsor fails to submit required information to the database, or submits false or misleading information, the Secretary has authority to impose several penalties for noncompliance, including:
    - Revoking a sponsor's eligibility for further federal funding;
    - Refusing to grant future Investigational New Drug applications ("IND") to sponsors; and
    - Imposing civil money penalties of up to a total of $15,000 for individuals or non-profit institutions and $10,000 per day for for-profit companies. These fines are to be used by the Secretary to fund studies of comparative safety and effectiveness carried out by AHRQ.