S. 470 -- The Fair Access to Clinical Trials Act of 2005
Summary of Major Provisions

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OVERVIEW

The Fair Access to Clinical Trials Act of 2005 will improve physician treatment decisions and enhance reliability of medical research by requiring that results of clinical drug studies be made publicly available to doctors, patients and medical researchers.

The FACT Act offers a meaningful solution to the problem of suppressed data on the safety and effectiveness of drugs. Currently, pharmaceutical companies conduct thousands of clinical trials annually. But few of those results are ever made public, preventing doctors from making fully informed treatment decisions, encouraging publication of only positive results while those that show a drug is useless or even harmful remain hidden, and hampering medical analyses of results from multiple trials (known as meta-analyses) that can reveal problems that single studies may not reveal on their own.

The bill also strikes a reasonable balance between the needs of the drug researchers and the public's right-to-know about study findings.

SPECIFIC PROVISIONS:

- **Clinical Trials Registry and Results Data Bank --** Requires the Department of Health and Human Services to create a public drug trial registry and results database in a format that is publicly accessible and easily understood
- **Registry:** Maintains the requirement that drug trials for serious or life-threatening conditions be registered before they begin, and specifies that the registry will include specific information on the type, purpose, recruitment and other data.
- **Results Database:** Requires that information on and summary results of ALL clinical drug trials (except very early investigational trials, known as Phase I trials) be submitted to the Secretary for inclusion in the results database. Information shall include **–**

    - A description of the outcomes to be measured;
    - The actual completion date of the trial and any reasons that date differed from the estimated completion date;
    - A summary of the results of the trial in a non-promotional format, including

        - Trial design and methodology;
        - Results of the clinical outcomes measured; and
        - Summary data tables with appropriate information on statistical significance of findings;
        - Safety data, including data on deaths and adverse events;
    - Published articles in medical journals that relate to the trial;
    - A description of the process used to review the trial results, including a statement as to whether the trial results have been reviewed by independent reviewers;
    - Whether the trial studied an unapproved use of a drug and if so, whether the potential new use is being reviewed by FDA has been rejected by FDA, or has been withdrawn by the pharmaceutical company; and
    - Whether the data has been submitted to the Food and Drug Administration

- **Transparency**:
    - Requires FDA to make public its reviews of trials submitted for new drug or supplemental applications. (Currently, FDA reviews of data submitted for supplemental applications are not made public) and
    - Requires FDA to make public safety consultations by the Office of Drug Safety

- **Deadlines:**
    - Trial results must be submitted with one year of the study's completion;
    - If investigators or drug sponsors cannot reasonably meet a deadline, they may notify the Secretary who will set a new deadline if appropriate.
    - Results are made public as soon as possible after their submission.
    - If investigators or drug sponsors are seeking publication of results in a peer-reviewed journal, the Secretary may delay posting of results for up to 2 years.

- **Penalties:** Failure to submit trial results on time will result in:
    - A notice to the public that results have not been submitted as required by law;
    - For drug companies, penalties of $10,000/day for each day of noncompliance;
    - For researchers conducting studies wholly funded by the federal government, ineligibility for future federal support for research

- **Other Provisions**
    - **Past Trial Results:** The Secretary may require submission to the databank of results of trials conducted prior to enactment of the FACT Act .
    - **Submission of False Information**: The Secretary may correct information submitted by drug companies that is inaccurate, false or misleading.