State of Minnesota
HOUSE OF REPRESENTATIVES

EIGHTY-FIFTH
SESSION

HOUSE FILE NO. 21

January 8, 2007
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The bill was read for the first time and referred to the Committee on Health and Human Services
January 25, 2007
By motion, recalled and re-referred to the Committee on Biosciences and Emerging Technology

A bill for an act

relating to health; providing for clinical trial registration; providing civil penalties; proposing coding for new law in Minnesota Statutes, chapter 144.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. **[144.6601] CLINICAL TRIALS REGISTRATION.**

Subdivision 1. **Definitions.** For purposes of this section:

(1) "clinical trial" means a clinical investigation as defined by the federal Food and Drug Administration that involves any experiment to test the safety or efficacy of a drug or biological product with one or more human subjects;

(2) "clinical trial registry" means a publicly available data bank;

(3) "institutional review board" means an independent body constituted of medical, scientific, and nonscientific members, whose responsibility it is to ensure the protection of the rights, safety, and well-being of the human subjects involved in a clinical trial; and

(4) "sponsor" means:

(i) the manufacturer of a drug or biological product;

(ii) if the manufacturer provides no monetary support for the clinical trial, the person who provides the majority of monetary support; or

(iii) when the majority of monetary support comes from a state or federal agency, the principal investigator.

Subd. 2. **Requirements for institutional review board approval.** An institutional review board shall not approve any clinical trial unless the sponsor certifies in writing that:

(1) the clinical trial will be registered in a clinical trial registry at or before the time that patient enrollment begins;

(2) the clinical trial registry includes, at a minimum:

(i) a unique identifying number for each registered trial;

(ii) a statement of the interventions and comparisons studied;

(iii) a statement of the study hypothesis;

(iv) definitions of the primary and secondary outcome measures;

(v) eligibility criteria;

(vi) key trial dates;

(vii) the target number of subjects;

(viii) identification of the funding source; and

(ix) contact information for the sponsor;

(3) the clinical trial registry is accessible to the public at no charge, open to all prospective registrants, managed by a not-for-profit organization, and electronically searchable and contains a mechanism to ensure the validity of the registration data; and

(4) upon conclusion of the clinical trial, the results of the clinical trial will be published in a clinical trial registry that meets the requirements of clauses (2) and (3).

Subd. 3. **Review of prior approvals.** An institutional review board shall not approve any clinical trial if the sponsor failed to comply with subdivision 2 for a prior clinical trial that was approved by the same or another institutional review board under this section. Prior to approval, the institutional review board shall review the sponsor's record of compliance with subdivision 2 for prior clinical trials approved by the same or another institutional review board.

Subd. 4. **Penalties.** A sponsor in violation of this section is liable for a civil penalty of $20,000 per violation. Each day a sponsor is in violation is considered a separate violation. The attorney general or a district attorney, county attorney, or city attorney may bring an action against a sponsor for a violation of this section.