BILL ANALYSIS

Senate Research Center
80R12187 UM-F

C.S.S.B. 450
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Health & Human Services
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Committee Report (Substituted)

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

The Associated Press reported that government-funded researchers have been testing AIDS drugs on hundreds of foster children for a little over two decades. There is no current law protecting foster children from being entered into clinical trials.

C.S.S.B. 450 prohibits a person from enrolling or consenting to the participation of a foster child in a clinical trial. The bill excepts from the prohibition certain studies including a study regarding the efficiency of an approved drug, a retrospective study based on certain data and medical records, a study based solely on medical records or certain data, or the treatment of a foster child with an investigational new drug that does not require the child's enrollment or participation in a research program. The bill also requires that information be reported to certain government and elected officials annually.

RULEMAKING AUTHORITY

This bill does not expressly grant any additional rulemaking authority to any state officer, institution, or agency

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Section 266.001, Family Code, as added by Chapter 268, Acts of the 79th Legislature, Regular Session, 2005, by adding Subdivisions (2-a) and (4-a), as follows:

(2-a) Defines "drug research program."

(4-a) Defines "investigational new drug."

SECTION 2. Amends Subchapter A, Chapter 266, Family Code, as added by Chapter 268, Acts of the 79th Legislature, Regular Session, 2005, by adding Section 266.0041, as follows:

Sec. 266.0041. ENROLLMENT AND PARTICIPATION IN CERTAIN RESEARCH PROGRAMS. (a) Prohibits a person from authorizing the enrollment of a foster child or consenting to the participation of a foster child in a drug research program (research program) without a court order as provided by this section, notwithstanding Section 266.004 (Consent for Medical Care).

(b) Requires the court, before issuing an order authorizing the enrollment or participation of a foster child in a research program, to appoint an independent medical advocate (advocate); review the report filed by the advocate regarding the advocate's opinion and recommendations concerning the foster child's enrollment and participation in the research program; consider whether the person conducting the research program provided the foster child, in a developmentally appropriate manner, certain information relating to potential side effects and any available alternative treatments and received the foster child's assent to enroll the child in the research program as required by the Code of Federal Regulations, 45 C.F.R. Section 46.408 or received informed consent in accordance with Subsection (h); and determine whether the enrollment and participation in the research program is in the foster child's best interest.

(c) Provides that an advocate appointed under Subsection (b) is not a party to the suit. Authorizes the advocate to conduct an investigation regarding the foster child's participation in a drug research program (investigation) to the extent that the advocate considers necessary to determine whether the foster child assented to or provided informed consent to the child's enrollment and participation in the research program, and the best interest of the child for whom the advocate is appointed, and to obtain and review copies of the foster child's relevant medical and psychological records and information describing the risks and benefits of the child's enrollment and participation in the research program.

(d) Requires an advocate, within a reasonable time after the appointment, to interview the foster child in a developmentally appropriate manner, if the child is four years of age or older; the foster child's parent if the parent is entitled to notification under Section 266.005; an advocate appointed by an institutional review board in accordance with the Code of Federal Regulations, 45 C.F.R. Section 46.409(b), if an advocate has been appointed; the medical team treating the foster child as well as the medical team conducting the research program; and each individual who has significant knowledge of the foster child's medical history and condition, including any foster parent of the child.

(e) Requires the advocate, after reviewing the information collected under Subsections (c) and (d), to submit a report to the court presenting the advocate's opinion and recommendation as it relates to information collected during the investigation. Requires the advocate, at the court's request, to testify regarding the advocate's opinion and recommendation.

(f) Authorizes the court to appoint any person eligible to serve as the foster child's guardian ad litem, as defined by Section 107.001, as the advocate. Prohibits certain persons from serving as the foster child's advocate.

(g) Authorizes a person otherwise authorized to consent to medical care for a foster child to petition the court for an order permitting the enrollment and participation of a foster child in a research program.

(h) Requires the person conducting the research program, in a developmentally appropriate manner, to provide certain information regarding expected benefits, side effects, and alternative treatments, if any, and to receive written informed consent to enroll the foster child for participation in the research program, before enrolling a foster child who is at least 16 years of age and has been determined to have the capacity to consent to medical care in accordance with Section 266.010 (Consent to Medical Care by Foster Child at Least 16 Years of Age) to participate in a research program.

(i) Authorizes the court to render an order approving the enrollment or participation of a foster child in a research program involving an investigational new drug before appointing an advocate if certain conditions exist, and upon a physician's recommendation.

(j) Requires the court, as soon as practicable after issuing an order under Subsection (i), to appoint an advocate to complete a full investigation.

(k) Provides this section does not apply to a drug research study regarding the efficiency of an approved drug that is based only on medical records, claims data, or outcome data, including outcome data gathered through interview with a child, caregiver of a child, or a child's treating professional, a retrospective drug research study based only on medical records, claims data, or outcome data, or the treatment of a foster child with an investigational new drug that does not require the child's enrollment or participation in a research program.

(l) Requires the department to annually submit to certain government officials and relevant committees in both houses of the legislature, a report regarding the

number of foster children who are enrolled or participated in a research program during the previous year, the purpose of each research program in which a foster child was enrolled or participated, and the number of foster children for whom an order was issued under Subsection (i).

SECTION 3. Amends Section 266.005(b), Family Code, as added by Chapter 268, Acts of the 79th Legislature, Regular Session, 2005, to require the Department of Family and Protective Services to make reasonable efforts to notify the child's parents within 24 hours of the enrollment or participation of a foster child in a research program under Section 266.0041.

SECTION 4. Makes application of this Act prospective.

SECTION 5. Effective date: September 1, 2007.