SUBJECT: Participation and enrollment of foster children in drug research programs

COMMITTEE: Human Services — favorable, without amendment

VOTE: 8 ayes — Rose, S. King, J. Davis, Eissler, Herrero, Hughes, Naishtat, Parker

0 nays

1 absent — Pierson

SENATE VOTE: On final passage, April 17 — 30-0

WITNESSES: (*On House companion bill, HB 1112 by Turner:*)
For — Mazie Jamison, Children's Medical Center Dallas; Lee Spiller, Citizens Commission on Human Rights; Elizabeth Gallardo; Andrew Sabater; (*Registered, but did not testify:* Paula Littles, Texas AFL CIO; Elnita Gwin)

Against — None

On — Steve Bresnen, Federation of Texas Psychiatry

BACKGROUND: Code of Federal Regulations, 45 C.F.R. sec. 46.408 requires that a person attempting to enroll a child in a study should solicit the assent of the child to participate in the study if the child is capable of providing assent. The person must take into account the child's age, maturity, and psychological state when determining if the child is capable of giving assent.

DIGEST: SB 450 would define the circumstances under which it would be permissible to authorize a foster child to participate in a drug research program. A drug research program would be any clinical trial, investigation, drug study, or active medical research that had been approved by an institutional review board regarding an investigational new drug or the efficacy of an approved drug.

A person authorized to consent to medical care for a foster child could petition a court to enroll a foster child in a drug research program. A

person could not authorize a foster child to participate in a drug research program without a court order unless the person was the child's parent and had the right to make medical decisions for the foster child. Before issuing an order for a child to participate in a drug research program, the court would have to:

- appoint an independent medical advocate and review the report of the medical advocate's findings and recommendations;
- determine whether participation in the drug research program would be in the foster child's best interest and would not interfere with the medical care of the child; and
- determine whether the person conducting the research informed the child in a developmentally appropriate way about the study and received appropriate assent from the child to participate in the study as required by 45 C.F.R. sec. 46.408.

These requirements would not apply to retrospective studies or drug research studies that were based only on medical records, claims data, or outcome data. The court could order that a child be enrolled in a drug research program before appointing a medical advocate only if a physician recommended treatment to prevent the death or serious injury of a child and the treatment needed to occur before the advocate could complete an investigation. A foster child who was 16 or older would be informed of the expected benefits and possible side effects of a study and would have to consent to participate in a study.

With the exception of certain parties that the court determined could have a conflict of interest, the court could appoint any person eligible to serve as the foster child's guardian ad litem to be a child's medical advocate. The medical advocate would investigate whether the child assented to participate in the drug research program and if the program was in the best interest of the child. The advocate would review appropriate medical records and interview the child, child's parent, parties with knowledge of the child's medical history, and the medical teams treating the child and conducting the study. The medical advocate would submit a report to the court with opinions and recommendations as to whether the child assented to participation and if the study was in the child's best interest. The advocate also could testify before the court if requested to do so.

The Department of Family and Protective Services (DFPS) would submit an annual report to the governor, the lieutenant governor, the speaker of the House, and relevant House and Senate committees regarding:

- the number of foster children who participated in a drug research program during the previous year;
- the purpose of each drug research program in which a foster child was enrolled; and
- the number of court orders issued for a foster child to participate in a drug research program prior to a medical advocate being appointed.

The bill would take effect September 1, 2007, and would apply only to enrollment and participation of a foster child in a drug research program on or after this date.

SUPPORTERS SAY:

SB 450 would protect the health and prevent the exploitation of foster children. Foster children are a captive population that is vulnerable to the influence of many alternate caregivers. The bill would provide adequate legal safeguards that a foster child could participate in a drug research program only if a judge rendered an order determining that participation was in the child's best interest. The judge would make an informed decision facilitated by the research and recommendations of an independent medical advocate. An appropriate exception would be made for a judge to immediately issue a court order for a child to participate in a drug research program if a child's life was at risk. The reporting requirements of the bill would provide a final level of security for the foster child population because the state would oversee study participation and note any trends of concern that would require further changes to legislation.

OPPONENTS SAY:

SB 450 is a good bill that could be improved by adding one further safeguard. Certain drug research programs provide financial incentives for participation in a study. The bill should remove any financial incentive a foster family or other party could have to recommend that a foster child participate in a drug research study. Potential options would be to add provisions that any financial incentive from a drug research program would go either into a trust for the foster child or into a fund for the foster children's alumnae program.

NOTES: The companion bill, HB 1112 by Turner, was left pending in the Human Services Committee.