

By: Uresti, et al.

S.B. No. 450

A BILL TO BE ENTITLED

AN ACT

relating to enrollment and participation in certain research programs of certain children in foster care.

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

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

(2-a) "Drug research program" means any clinical trial, clinical investigation, drug study, or active medical or clinical research that has been approved by an institutional review board in accordance with the standards provided in the Code of Federal Regulations, 45 C.F.R. Sections 46.404 through 46.407, regarding:

(A) an investigational new drug; or

(B) the efficacy of an approved drug.

(4-a) "Investigational new drug" has the meaning assigned by 21 C.F.R. Section 312.3(b).

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

Sec. 266.0041. ENROLLMENT AND PARTICIPATION IN CERTAIN RESEARCH PROGRAMS. (a) Notwithstanding Section 266.004, a person may not authorize the enrollment of a foster child or consent to the

1 participation of a foster child in a drug research program without a  
2 court order as provided by this section, unless the person is the  
3 foster child's parent and the person has been authorized by the  
4 court to make medical decisions for the foster child in accordance  
5 with Section 266.004.

6 (b) Before issuing an order authorizing the enrollment or  
7 participation of a foster child in a drug research program, the  
8 court must:

9 (1) appoint an independent medical advocate;

10 (2) review the report filed by the independent medical  
11 advocate regarding the advocate's opinion and recommendations  
12 concerning the foster child's enrollment and participation in the  
13 drug research program;

14 (3) consider whether the person conducting the drug  
15 research program:

16 (A) informed the foster child in a  
17 developmentally appropriate manner of the expected benefits of the  
18 drug research program, any potential side effects, and any  
19 available alternative treatments and received the foster child's  
20 assent to enroll the child to participate in the drug research  
21 program as required by the Code of Federal Regulations, 45 C.F.R.  
22 Section 46.408; or

23 (B) received informed consent in accordance with  
24 Subsection (h); and

25 (4) determine whether enrollment and participation in  
26 the drug research program is in the foster child's best interest and  
27 determine that the enrollment and participation in the drug

1 research program will not interfere with the appropriate medical  
2 care of the foster child.

3 (c) An independent medical advocate appointed under  
4 Subsection (b) is not a party to the suit but may:

5 (1) conduct an investigation regarding the foster  
6 child's participation in a drug research program to the extent that  
7 the advocate considers necessary to determine:

8 (A) whether the foster child assented to or  
9 provided informed consent to the child's enrollment and  
10 participation in the drug research program; and

11 (B) the best interest of the child for whom the  
12 advocate is appointed; and

13 (2) obtain and review copies of the foster child's  
14 relevant medical and psychological records and information  
15 describing the risks and benefits of the child's enrollment and  
16 participation in the drug research program.

17 (d) An independent medical advocate shall, within a  
18 reasonable time after the appointment, interview:

19 (1) the foster child in a developmentally appropriate  
20 manner, if the child is four years of age or older;

21 (2) the foster child's parent, if the parent is  
22 entitled to notification under Section 266.005;

23 (3) an advocate appointed by an institutional review  
24 board in accordance with the Code of Federal Regulations, 45 C.F.R.  
25 Section 46.409(b), if an advocate has been appointed;

26 (4) the medical team treating the foster child as well  
27 as the medical team conducting the drug research program; and

1           (5) each individual who has significant knowledge of  
2 the foster child's medical history and condition, including any  
3 foster parent of the child.

4           (e) After reviewing the information collected under  
5 Subsections (c) and (d), the independent medical advocate shall:

6           (1) submit a report to the court presenting the  
7 advocate's opinion and recommendation regarding whether:

8           (A) the foster child assented to or provided  
9 informed consent to the child's enrollment and participation in the  
10 drug research program; and

11           (B) the foster child's best interest is served by  
12 enrollment and participation in the drug research program; and

13           (2) at the request of the court, testify regarding the  
14 basis for the advocate's opinion and recommendation concerning the  
15 foster child's enrollment and participation in a drug research  
16 program.

17           (f) The court may appoint any person eligible to serve as  
18 the foster child's guardian ad litem, as defined by Section  
19 107.001, as the independent medical advocate, including a physician  
20 or nurse or an attorney who has experience in medical and health  
21 care, except that a foster parent, employee of a substitute care  
22 provider or child placing agency providing care for the foster  
23 child, representative of the department, medical professional  
24 affiliated with the drug research program, independent medical  
25 advocate appointed by an institutional review board, or any person  
26 the court determines has a conflict of interest may not serve as the  
27 foster child's independent medical advocate.

1       (g) A person otherwise authorized to consent to medical care  
2 for a foster child may petition the court for an order permitting  
3 the enrollment and participation of a foster child in a drug  
4 research program under this section.

5       (h) Before a foster child, who is at least 16 years of age  
6 and has been determined to have the capacity to consent to medical  
7 care in accordance with Section 266.010, may be enrolled to  
8 participate in a drug research program, the person conducting the  
9 drug research program must:

10       (1) inform the foster child in a developmentally  
11 appropriate manner of the expected benefits of participation in the  
12 drug research program, any potential side effects, and any  
13 available alternative treatments; and

14       (2) receive written informed consent to enroll the  
15 foster child for participation in the drug research program.

16       (i) A court may render an order approving the enrollment or  
17 participation of a foster child in a drug research program  
18 involving an investigational new drug before appointing an  
19 independent medical advocate if:

20       (1) a physician recommends the foster child's  
21 enrollment or participation in the drug research program to provide  
22 the foster child with treatment that will prevent the death or  
23 serious injury of the child; and

24       (2) the court determines that the foster child needs  
25 the treatment before an independent medical advocate could complete  
26 an investigation in accordance with this section.

27       (j) As soon as practicable after issuing an order under

1 Subsection (i), the court shall appoint an independent medical  
2 advocate to complete a full investigation of the foster child's  
3 enrollment and participation in the drug research program in  
4 accordance with this section.

5 (k) This section does not apply to:

6 (1) a drug research study regarding the efficacy of an  
7 approved drug that is based only on medical records, claims data, or  
8 outcome data, including outcome data gathered through interviews  
9 with a child, caregiver of a child, or a child's treating  
10 professional;

11 (2) a retrospective drug research study based only on  
12 medical records, claims data, or outcome data; or

13 (3) the treatment of a foster child with an  
14 investigational new drug that does not require the child's  
15 enrollment or participation in a drug research program.

16 (1) The department shall annually submit to the governor,  
17 lieutenant governor, speaker of the house of representatives, and  
18 the relevant committees in both houses of the legislature, a report  
19 regarding:

20 (1) the number of foster children who enrolled or  
21 participated in a drug research program during the previous year;

22 (2) the purpose of each drug research program in which  
23 a foster child was enrolled or participated; and

24 (3) the number of foster children for whom an order was  
25 issued under Subsection (i).

26 SECTION 3. Subsection (b), Section 266.005, Family Code, as  
27 added by Chapter 268, Acts of the 79th Legislature, Regular

1 Session, 2005, is amended to read as follows:

2 (b) Except as provided by Subsection (c), the department  
3 shall make reasonable efforts to notify the child's parents within  
4 24 hours of:

5 (1) a significant medical condition involving a foster  
6 child; and

7 (2) the enrollment or participation of a foster child  
8 in a drug research program under Section 266.0041.

9 SECTION 4. The change in law made by this Act by the  
10 enactment of Section 266.0041, Family Code, applies only to the  
11 enrollment and participation of a foster child in a drug research  
12 program on or after the effective date of this Act. A foster child  
13 enrolled or participating in a drug research program before the  
14 effective date of this Act is governed by the law in effect when the  
15 foster child was enrolled or began participating in the drug  
16 research program, and the former law is continued in effect for that  
17 purpose.

18 SECTION 5. This Act takes effect September 1, 2007.