

GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2007

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HOUSE BILL 116
Senate Health Care Committee Substitute Adopted 7/19/07

Short Title: Tissue Bank Accreditation.

(Public)

Sponsors:

Referred to:

February 8, 2007

1 A BILL TO BE ENTITLED
2 AN ACT TO REQUIRE CERTAIN TISSUE BANKS OPERATING IN NORTH
3 CAROLINA TO BE ACCREDITED BY THE AMERICAN ASSOCIATION OF
4 TISSUE BANKS OR THE EYE BANK ASSOCIATION OF AMERICA.

5 The General Assembly of North Carolina enacts:

6 SECTION 1. Chapter 131E of the General Statutes is amended by adding a
7 new Article to read:

8 "Article 8A.

9 "Regulation of Tissue Banks.

10 "**§ 131E-171. Registration and accreditation requirements.**

11 (a) Any tissue bank that recovers human tissue at a location outside of a hospital,
12 when such tissue is intended for human transplantation, shall be registered with the
13 Food and Drug Administration and accredited by the American Association of Tissue
14 Banks (AATB), or accredited by the Eye Bank Association of America (EBAA), unless
15 the establishment is an organ procurement organization that has been designated by the
16 federal Secretary for Health and Human Services and is registered with the Food and
17 Drug Administration as a tissue bank.

18 (b) For purposes of this Article, 'human tissue' means musculoskeletal tissue,
19 including bone, tendons, ligaments, fascia, cartilage, and related soft tissues, skin,
20 cardiac tissue, dura mater, and ocular tissue. Human tissue in this Article shall not
21 include oocytes, semen, embryos, or stem cells from peripheral blood or umbilical cord
22 blood sources.

23 "**§ 131E-172. Inspection, enforcement, penalties.**

24 (a) The Department is authorized to inspect the records of any tissue bank
25 engaged in the recovery of human tissue for human transplantation in the State to
26 ascertain compliance with the registration and accreditation requirements of this Article.

27 (b) Notwithstanding the existence or pursuit of any other remedy, the Department
28 may maintain an action in the name of the State for injunctive relief or other process
29 against any tissue bank to restrain or prevent recovery of human tissue for human

1 transplantation without the required registration or accreditation or otherwise restrain or
2 prevent substantial noncompliance with this Article or the rules adopted pursuant to it.

3 (c) If any person hinders the proper performance of duty of the Department in
4 carrying out the provisions of this Article, the Department may institute an action in the
5 superior court of the county in which the hindrance occurred for injunctive relief against
6 the continued hindrance.

7 (d) Any person who knowingly and willfully engages in the recovery of human
8 tissue for human transplantation without registration with the Food and Drug
9 Administration or accreditation by the AATB or EBAA as required by this Article is
10 guilty of a Class 3 misdemeanor and upon conviction is liable only for a fine of not
11 more than five hundred dollars (\$500.00) for the first offense and not more than five
12 hundred dollars (\$500.00) for each subsequent offense."

13 **SECTION 2.** This act becomes effective October 1, 2007, and applies to
14 tissue banks engaged in the recovery of human tissue or cells for human transplantation
15 on or after that date.