

119TH CONGRESS  
1ST SESSION

**S.**

---

To regulate human cadaveric islets for transplantation as organs.

---

IN THE SENATE OF THE UNITED STATES

---

Mr. LEE (for himself and Mr. BUDD) introduced the following bill; which was read twice and referred to the Committee on \_\_\_\_\_

---

**A BILL**

To regulate human cadaveric islets for transplantation as organs.

1       *Be it enacted by the Senate and House of Representa-  
2 tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Increase Support for  
5 Life-saving Endocrine Transplantation Act” or the  
6 “ISLET Act”.

7 **SEC. 2. REGULATION OF HUMAN CADAVERIC ISLET TRANS-  
8 PLANTS.**

9       (a) IN GENERAL.—Section 374(d)(2) of the Public  
10 Health Service Act (42 U.S.C. 274b(d)(2)) is amended by

1 striking “pancreas,” and inserting “and pancreas, human  
2 cadaveric islets.”.

3 (b) CLARIFICATION.—Notwithstanding any other  
4 provision of law, none of the following terms includes  
5 human cadaveric islets:

6 (1) The term “drug”, as defined in section  
7 201(g) of the Federal Food, Drug, and Cosmetic Act  
8 (21 U.S.C. 321(g)).

9 (2) The term “biological product”, as defined in  
10 section 351(i) of the Public Health Service Act (42  
11 U.S.C. 262(i)).

12 (3) The term “human cells, tissues, or cellular  
13 or tissue-based products (HCT/Ps)”, as defined in  
14 section 1271.3 of title 21, Code of Federal Regula-  
15 tions (or any successor regulations).

16 (c) REGULATIONS.—

17 (1) IN GENERAL.—Not later than 1 year after  
18 the date of enactment of this Act, the Secretary of  
19 Health and Human Services (referred to in this sec-  
20 tion as the “Secretary”) shall update regulations  
21 promulgated under parts F, G, and H of title III of  
22 the Public Health Service Act (42 U.S.C. 262 et  
23 seq., 264 et seq., 273 et seq.) and the Federal Food,  
24 Drug, and Cosmetic Act (21 U.S.C. 301 et seq.),  
25 and such other regulations as the Secretary deter-

1       mines appropriate, to carry out the amendment  
2       made by subsection (a).

3                   (2) REPORT.—Not later than 6 months after  
4       the date of enactment of this Act, the Secretary  
5       shall report to Congress on the progress made in up-  
6       dating regulations as required under paragraph (1).