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 Life-saving Endocrine Transplantation Act” or the “ISLET Act”.

5 SEC. 2. REGULATION OF HUMAN CADAVERIC ISLET TRANS-

6 PLANTS.

7 (a) IN GENERAL.—Section 374(d)(2) of the Public Health Service Act (42 U.S.C. 274b(d)(2)) is amended by
striking “pancreas,” and inserting “and pancreas, human
cadaveric islets.”

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

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

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

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

(c) REGULATIONS.—

(1) IN GENERAL.—Not later than 1 year after
the date of enactment of this Act, the Secretary of
Health and Human Services (referred to in this sec-
tion as the “Secretary”) shall update regulations
promulgated under parts F, G, and H of title III of
the Public Health Service Act (42 U.S.C. 262 et
seq., 264 et seq., 273 et seq.) and the Federal Food,
Drug, and Cosmetic Act (21 U.S.C. 301 et seq.),
and such other regulations as the Secretary deter-
mines appropriate, to carry out the amendment made by subsection (a).

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