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(Original Signature of Member)

119TH CONGRESS
2D SESSION

H. R. _____

To regulate human cadaveric islets for transplantation as organs.

IN THE HOUSE OF REPRESENTATIVES

Mr. NORMAN introduced the following bill; which was 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”.

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

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

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

10 (1) The term “drug”, as defined in section
11 201(g) of the Federal Food, Drug, and Cosmetic Act
12 (21 U.S.C. 321(g)).

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

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

20 (c) **REGULATIONS.**—

21 (1) **IN GENERAL.**—Not later than 1 year after
22 the date of enactment of this Act, the Secretary of
23 Health and Human Services (referred to in this sec-
24 tion as the “Secretary”) shall update regulations
25 promulgated under parts F, G, and H of title III of
26 the Public Health Service Act (42 U.S.C. 262 et

1 seq., 264 et seq., 273 et seq.) and the Federal Food,
2 Drug, and Cosmetic Act (21 U.S.C. 301 et seq.),
3 and such other regulations as the Secretary deter-
4 mines appropriate, to carry out the amendment
5 made by subsection (a).

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