

AMENDMENT NO. _____ Calendar No. _____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—113th Cong., 1st Sess.

S. 330

To amend the Public Health Service Act to establish safeguards and standards of quality for research and transplantation of organs infected with human immunodeficiency virus (HIV).

Referred to the Committee on _____ and
ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended
to be proposed by _____

Viz:

1 Strike all after the enacting clause and insert the fol-
2 lowing:

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “HIV Organ Policy Eq-
5 uity Act”.

6 **SEC. 2. AMENDMENTS TO THE PUBLIC HEALTH SERVICE**
7 **ACT.**

8 (a) STANDARDS OF QUALITY FOR THE ACQUISITION
9 AND TRANSPORTATION OF DONATED ORGANS.—

1 (1) ORGAN PROCUREMENT AND TRANSPLAN-
2 TATION NETWORK.—Section 372(b) of the Public
3 Health Service Act (42 U.S.C. 274(b)) is amended—

4 (A) in paragraph (2)(E), by striking “, in-
5 cluding standards for preventing the acquisition
6 of organs that are infected with the etiologic
7 agent for acquired immune deficiency syn-
8 drome”; and

9 (B) by adding at the end the following:

10 “(3) CLARIFICATION.—In adopting and using
11 standards of quality under paragraph (2)(E), the
12 Organ Procurement and Transplantation Network
13 may adopt and use such standards with respect to
14 organs infected with human immunodeficiency virus
15 (in this paragraph referred to as ‘HIV’), provided
16 that any such standards ensure that organs infected
17 with HIV may be transplanted only into individuals
18 who—

19 “(A) are infected with HIV before receiv-
20 ing such organ; and

21 “(B)(i) are participating in clinical re-
22 search approved by an institutional review
23 board under the criteria, standards, and regula-
24 tions described in subsections (a) and (b) of
25 section 377E; or

1 “(ii) if the Secretary has determined under
2 section 377E(c) that participation in such clin-
3 ical research, as a requirement for such trans-
4 plants, is no longer warranted, are receiving a
5 transplant under the standards and regulations
6 under section 377E(c).”.

7 (2) TECHNICAL AND CONFORMING AMEND-
8 MENTS.—Section 371(b)(3)(C) of the Public Health
9 Service Act (42 U.S.C. 273(b)(3)(C); relating to
10 organ procurement organizations) is amended by
11 striking “including arranging for testing with re-
12 spect to preventing the acquisition of organs that
13 are infected with the etiologic agent for acquired im-
14 mune deficiency syndrome” and inserting “including
15 arranging for testing with respect to identifying or-
16 gans that are infected with human immunodeficiency
17 virus (HIV)”.

18 (b) PUBLICATION OF RESEARCH GUIDELINES.—Part
19 H of title III of the Public Health Service Act (42 U.S.C.
20 273 et seq.) is amended by inserting after section 377D
21 the following:

1 **“SEC. 377E. CRITERIA, STANDARDS, AND REGULATIONS**
2 **WITH RESPECT TO ORGANS INFECTED WITH**
3 **HIV.**

4 “(a) IN GENERAL.—Not later than 2 years after the
5 date of the enactment of the HIV Organ Policy Equity
6 Act, the Secretary shall develop and publish criteria for
7 the conduct of research relating to transplantation of or-
8 gans from donors infected with human immunodeficiency
9 virus (in this section referred to as ‘HIV’).

10 “(b) CORRESPONDING CHANGES TO STANDARDS AND
11 REGULATIONS APPLICABLE TO RESEARCH.—Not later
12 than 2 years after the date of enactment of the HIV
13 Organ Policy Equity Act, to the extent determined by the
14 Secretary to be necessary to allow the conduct of research
15 in accordance with the criteria developed under subsection
16 (a)—

17 “(1) the Organ Procurement and Transplan-
18 tation Network shall revise the standards of quality
19 adopted under section 372(b)(2)(E); and

20 “(2) the Secretary shall revise section 121.6 of
21 title 42, Code of Federal Regulations (or any suc-
22 cessor regulations).

23 “(c) REVISION OF STANDARDS AND REGULATIONS
24 GENERALLY.—Not later than 4 years after the date of
25 the enactment of the HIV Organ Policy Equity Act, and
26 annually thereafter, the Secretary, shall—

1 “(1) review the results of scientific research in
2 conjunction with the Organ Procurement and Trans-
3 plantation Network to determine whether the results
4 warrant revision of the standards of quality adopted
5 under section 372(b)(2)(E) with respect to donated
6 organs infected with HIV and with respect to the
7 safety of transplanting an organ with a particular
8 variant of HIV into a recipient with a different vari-
9 ant of HIV;

10 “(2) if the Secretary determines under para-
11 graph (1) that such results warrant revision of the
12 standards of quality adopted under section
13 372(b)(2)(E) with respect to donated organs in-
14 fected with HIV and with respect to transplanting
15 an organ with a particular variant of HIV into a re-
16 cipient with a different variant of HIV, direct the
17 Organ Procurement and Transplantation Network to
18 revise such standards, consistent with section 372
19 and in a way that ensures the changes will not re-
20 duce the safety of organ transplantation; and

21 “(3) in conjunction with any revision of such
22 standards under paragraph (2), shall revise section
23 121.6 of title 42, Code of Federal Regulations (or
24 any successor regulations) for consistency with such
25 standards.”.

1 **SEC. 3. CONFORMING AMENDMENT TO TITLE 18 OF THE**
2 **UNITED STATES CODE.**

3 Section 1122 of title 18, United States Code, is
4 amended by adding at the end the following:

5 “(d) EXCEPTION.—An organ donation does not vio-
6 late this section if the donation is in accordance with all
7 applicable criteria and regulations of the Secretary made
8 under section 377E of the Public Health Service Act.”.