

# Union Calendar No. 129

113TH CONGRESS  
1ST SESSION

# H. R. 698

**[Report No. 113–181, Part I]**

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).

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## IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 14, 2013

Mrs. CAPPS introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

JULY 30, 2013

Additional sponsors: Mr. HARRIS, Mr. CUMMINGS, Mr. GRIJALVA, Ms. LEE of California, Mr. BURGESS, Ms. WILSON of Florida, Ms. MOORE, Mr. PAYNE, Mr. CLAY, Mr. RANGEL, Mr. SCHIFF, Mr. GRIFFIN of Arkansas, Mr. BRALEY of Iowa, Mr. HUFFMAN, Mr. LOEBSACK, Mr. POLIS, Mr. WITTMAN, Ms. NORTON, Mr. RADEL, Mr. COSTA, Mr. MICHAUD, Mr. RUIZ, Mr. CICILLINE, Ms. SCHAKOWSKY, Mrs. CAROLYN B. MALONEY of New York, Mr. RUSH, Mrs. MILLER of Michigan, Mr. TAKANO, Ms. PINGREE of Maine, Mr. PETRI, Mr. BRADY of Pennsylvania, Ms. SHEA-PORTER, Ms. SPEIER, Mr. HASTINGS of Florida, Mr. McDERMOTT, Mr. SEAN PATRICK MALONEY of New York, Mr. CARTWRIGHT, Ms. JACKSON LEE, Mr. YOUNG of Florida, Ms. TITUS, Mr. CARSON of Indiana, Mr. MCKINLEY, Mr. BENISHEK, Mr. LEVIN, Ms. ROS-LEHTINEN, Mr. COHEN, Mr. POCAN, Mrs. CHRISTENSEN, Ms. SCHWARTZ, Mr. HIMES, Ms. CHU, Mr. HARPER, and Mr. LIPINSKI

JULY 30, 2013

Reported from the Committee on Energy and Commerce

JULY 30, 2013

The Committee on the Judiciary discharged; committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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## **A BILL**

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).

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 “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.—

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

13 (A) in paragraph (2)(E), by striking “, in-  
14 cluding standards for preventing the acquisition  
15 of organs that are infected with the etiologic  
16 agent for acquired immune deficiency syn-  
17 drome”; and

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

19 “(3) CLARIFICATION.—In adopting and using  
20 standards of quality under paragraph (2)(E), the  
21 Organ Procurement and Transplantation Network  
22 may adopt and use such standards with respect to  
23 organs infected with human immunodeficiency virus  
24 (HIV), provided that any such standards ensure that  
25 organs infected with human immunodeficiency virus

1 may be transplanted only into individuals who are  
2 infected with such virus before receiving such  
3 organ.”.

4 (2) CONFORMING AMENDMENT.—Section  
5 371(b)(3)(C) of the Public Health Service Act (42  
6 U.S.C. 273(b)(3)(C); relating to organ procurement  
7 organizations) is amended by striking “including ar-  
8 ranging for testing with respect to preventing the  
9 acquisition of organs that are infected with the etio-  
10 logic agent for acquired immune deficiency syn-  
11 drome” and inserting “including arranging for test-  
12 ing with respect to identifying organs that are in-  
13 fected with human immunodeficiency virus (HIV)”.

14 (b) PUBLICATION OF RESEARCH GUIDELINES.—Part  
15 H of title III of the Public Health Service Act (42 U.S.C.  
16 273 et seq.) is amended by inserting after section 377D  
17 the following:

18 **“SEC. 377E. GUIDELINES, STANDARDS, AND REGULATIONS**  
19 **WITH RESPECT TO ORGANS INFECTED WITH**  
20 **HIV.**

21 “(a) IN GENERAL.—Not later than 1 year after the  
22 date of the enactment of the HIV Organ Policy Equity  
23 Act, the Secretary shall develop and publish guidelines for  
24 the conduct of research relating to transplantation of or-

1 gans from donors infected with human immunodeficiency  
2 virus (in this section referred to as ‘HIV’).

3 “(b) CORRESPONDING CHANGES TO STANDARDS AND  
4 REGULATIONS APPLICABLE TO RESEARCH.—Not later  
5 than 1 year after the date of the enactment of the HIV  
6 Organ Policy Equity Act, to the extent determined by the  
7 Secretary to be necessary to allow the conduct of research  
8 in accordance with the guidelines developed under sub-  
9 section (a)—

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

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

16 “(c) REVISION OF STANDARDS AND REGULATIONS  
17 GENERALLY.—Not later than 2 years after the date of  
18 the enactment of the HIV Organ Policy Equity Act, and  
19 annually thereafter, the Secretary, shall—

20 “(1) review the results of scientific research in  
21 conjunction with the Organ Procurement and Trans-  
22 plantation Network to determine whether the results  
23 warrant revision of the standards of quality adopted  
24 under section 372(b)(2)(E) with respect to donated

1 organs infected with HIV and with respect to the  
2 safety of cross-strain transplantation;

3 “(2) if the Secretary determines under para-  
4 graph (1) that such results warrant revision of the  
5 standards of quality adopted under section  
6 372(b)(2)(E) with respect to donated organs in-  
7 fected with HIV and with respect to cross-strain  
8 transplantation, direct the Organ Procurement and  
9 Transplantation Network to revise such standards,  
10 consistent with section 372 and in a way that en-  
11 sures the changes will not reduce the safety of organ  
12 transplantation; and

13 “(3) in conjunction with any revision of such  
14 standards under paragraph (2), shall revise section  
15 121.6 of title 42, Code of Federal Regulations (or  
16 any successor regulations) for consistency with such  
17 standards.”.

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

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

22 “(d) EXCEPTION.—An organ donation does not vio-  
23 late this section if the donation is in accordance with all  
24 applicable guidelines and regulations of the Secretary

1 made under section 377E of the Public Health Service  
2 Act.”.

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113<sup>TH</sup> CONGRESS  
1<sup>ST</sup> Session

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