

AMENDMENT to HR 3692  
OFFERED BY MR. FORBES OF VIRGINIA  
[AHCAA\_001]

At the end of subtitle E of title V of division C (relating to public health and workforce development), insert the following new section:

1 **SEC. 2593. HUMAN STEM CELL RESEARCH AND THERAPY.**

2 (a) AUTHORIZATION.—Part B of title IV of the Pub-  
3 lic Health Service Act (42 U.S.C. 284 et seq.) is amended  
4 by inserting after section 409I the following:

5 **“SEC. 409J. HUMAN STEM CELL RESEARCH AND THERAPY.**

6 “(a) IN GENERAL.—The Secretary shall conduct and  
7 support basic and applied research to develop techniques  
8 for the isolation, derivation, production, testing, and  
9 human clinical use of stem cells that may result in im-  
10 proved understanding of or treatments for diseases and  
11 other adverse health conditions, including pluripotent stem  
12 cells that have the flexibility of embryonic stem cells  
13 (whether or not such pluripotent stem cells have an embry-  
14 onic source), prioritizing research with the greatest poten-  
15 tial for near-term clinical benefit in human patients, pro-  
16 vided that such isolation, derivation, production, testing,  
17 or use will not involve—

1           “(1) the creation of a human embryo for re-  
2 search purposes;

3           “(2) the destruction of or discarding of, or risk  
4 of injury to, a living human embryo; or

5           “(3) the use of any stem cell, the derivation or  
6 provision of which would be inconsistent with the  
7 standards established in paragraph (1) or (2).

8           “(b) GUIDELINES.—Not later than 90 days after the  
9 date of the enactment of this section, the Secretary, after  
10 consultation with the Director of NIH, shall issue final  
11 guidelines implementing subsection (a) to ensure that any  
12 research (including any clinical trial) supported under  
13 subsection (a)—

14           “(1) is clearly consistent with the standards es-  
15 tablished in subsection (a) if conducted using human  
16 cells, as demonstrated by animal trials or other sub-  
17 stantial evidence;

18           “(2) is prioritized in terms of potential for  
19 near-term clinical benefit in human patients, as indi-  
20 cated by substantial evidence from basic research or  
21 by substantial clinical evidence which may include  
22 but is not limited to—

23           “(A) evidence of improvement in one or  
24 more human patients suffering from illness or  
25 injury, as documented in reports by professional

1 medical or scientific associations or in peer-re-  
2 viewed medical or scientific literature; or

3 “(B) approval for use in human trials by  
4 the Food and Drug Administration; and

5 “(3) consistent with the standards established  
6 in subsection (a), may take into account techniques  
7 outlined by the President’s Council on Bioethics and  
8 any other appropriate techniques and research.

9 “(c) DEFINITIONS.—In this section:

10 “(1) HUMAN EMBRYO.—The term ‘human em-  
11 bryo’ includes any organism, not protected as a  
12 human subject under part 46 of title 45, Code of  
13 Federal Regulations, as of the date of the enactment  
14 of this section, that is derived by fertilization, par-  
15 thenogenesis, cloning, or any other means from one  
16 or more human gametes or human diploid cells.

17 “(2) RISK OF INJURY.—The term ‘risk of in-  
18 jury’ means subjecting a human embryo to risk of  
19 injury or death greater than that allowed for re-  
20 search on fetuses in utero under section 46.204(b)  
21 of title 45, Code of Federal Regulations (or any suc-  
22 cessor regulation), or section 498(b) of this Act.”

23 (b) PRIORITY SETTING; REPORTS.—Section 492 of  
24 the Public Health Service Act (42 U.S.C. 289a) is amend-  
25 ed by adding at the end the following:

1       “(d)(1) With respect to human stem cell research, the  
2 Secretary, acting through the Director of NIH, shall give  
3 priority to conducting or supporting research in accord-  
4 ance with section 409J.

5       “(2) At the end of fiscal year 2010 and each subse-  
6 quent fiscal year, the Secretary shall submit to the Con-  
7 gress a report outlining the number of research proposals  
8 under section 409J that were peer reviewed, a summary  
9 and detailed list of all such research proposals that were  
10 not funded, and an explanation of why the proposals did  
11 not merit funding. The reports under this paragraph shall  
12 be in addition to the reporting on stem cell research in-  
13 cluded in the biennial report required by section 403.”.

14       (c) BIENNIAL REPORTS.—Section 403(a)(5) of the  
15 Public Health Service Act (42 U.S.C. 283(a)(5)) is  
16 amended—

17             (1) by redesignating subparagraph (L) as sub-  
18       paragraph (M); and

19             (2) by inserting after subparagraph (K) the fol-  
20       lowing:

21                     “(L) Stem cells.”.

22       (a) STUDY TO EXPAND ACCESS TO THERAPEUTIC  
23 STEM CELL PRODUCTS.—Not later than 6 months after  
24 the date of the enactment of this Act, the Secretary of  
25 Health and Human Services shall study and submit rec-

1 ommendations to the Congress on any structural changes  
2 to the C.W. Bill Young Cell Transplantation Program es-  
3 tablished under 379 of the Public Health Service Act (42  
4 U.S.C. 274k) that would help to expand access to new and  
5 future stem cell therapeutic products, including stem cells  
6 derived from amniotic fluid as well as other sources such  
7 as dental pulp, nasal tissue, and fat that may benefit from  
8 inclusion in the coordinated distribution of bone marrow  
9 and cord blood stem cells.

