

AMENDMENT TO COMMITTEE PRINT**OFFERED BY M__ . _____****(REAG-UDAL_003, June 19, 2007)**

Page 3, line 8, insert “, and including the incorporation of more sensitive and predictive tools and devices to measure safety” after “and cosmetics”.

At the end of the bill, add the following (and make such technical and conforming changes as may be necessary):

1 **SEC. ____ . CRITICAL PATH PUBLIC-PRIVATE PARTNER-**
2 **SHIPS.**

3 Subchapter E of chapter V of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is
5 amended by adding at the end the following:

6 **“SEC. 566. CRITICAL PATH PUBLIC-PRIVATE PARTNER-**
7 **SHIPS.**

8 “(a) ESTABLISHMENT.—The Secretary, acting
9 through the Commissioner of Food and Drugs, shall enter
10 into one or more collaborative agreements, to be known
11 as Critical Path Public-Private Partnerships, with one or
12 more eligible entities to implement the Critical Path Ini-
13 tiative of the Food and Drug Administration by developing

1 innovative, collaborative projects in research, education,
2 and outreach for the purpose of fostering medical product
3 innovation, enabling the acceleration of medical product
4 development, and enhancing medical product safety.

5 “(b) ELIGIBLE ENTITY.—In this section, the term
6 ‘eligible entity’ means an entity that meets each of the
7 following:

8 “(1) The entity is—

9 “(A) an institution of higher education (as
10 such term is defined in section 101 of the High-
11 er Education Act of 1965); or

12 “(B) an organization described in section
13 501(c)(3) of the Internal Revenue Code of 1986
14 and exempt from tax under section 501(a) of
15 such Code.

16 “(2) The entity has experienced personnel and
17 clinical and other technical expertise in the bio-
18 medical sciences.

19 “(3) The entity demonstrates to the Secretary’s
20 satisfaction that the entity is capable of—

21 “(A) developing and critically evaluating
22 tools, methods, and processes—

23 “(i) to increase efficiency, predict-
24 ability, and productivity of medical product
25 development; and

1 “(ii) to more accurately identify the
2 benefits and risks of new and existing med-
3 ical products;

4 “(B) establishing partnerships, consortia,
5 and collaborations with health care practitioners
6 and other providers of health care goods or
7 services; pharmacists; pharmacy benefit man-
8 agers and purchasers; health maintenance orga-
9 nizations and other managed health care orga-
10 nizations; health care insurers; government
11 agencies; patients and consumers; manufactur-
12 ers of prescription drugs, biological products,
13 diagnostic technologies, and devices; and aca-
14 demic scientists; and

15 “(C) securing funding for the projects of a
16 Critical Path Public-Private Partnership from
17 Federal and nonfederal governmental sources,
18 foundations, and private individuals.

19 “(c) FUNDING.—The Secretary may not enter into
20 a collaborative agreement under subsection (a) unless the
21 eligible entity involved provides an assurance that the enti-
22 ty will not accept funding for a Critical Path Public-Pri-
23 vate Partnership project from any organization that man-
24 ufactures or distributes products regulated by the Food
25 and Drug Administration unless—

1 “(1) the entity accepts such funding for such
2 project from 2 or more such organizations; and

3 “(2) the entity provides assurances in its agree-
4 ment with the Food and Drug Administration that
5 the results of the Critical Path Public-Private Part-
6 nership project will not be influenced by any source
7 of funding.

8 “(d) ANNUAL REPORT.—Not later than 18 months
9 after the date of the enactment of this section, and annu-
10 ally thereafter, the Secretary, in collaboration with the
11 parties to each Critical Path Public-Private Partnership,
12 shall submit a report to the Committee on Health, Edu-
13 cation, Labor, and Pensions of the Senate and the Com-
14 mittee on Energy and Commerce of the House of Rep-
15 resentatives—

16 “(1) reviewing the operations and activities of
17 the Partnerships in the previous year; and

18 “(2) addressing such other issues relating to
19 this section as the Secretary determines to be appro-
20 priate.

21 “(e) DEFINITION.—In this section, the term ‘medical
22 product’ includes a drug, a biological product, a device,
23 and any combination of such products.

24 “(f) AUTHORIZATION OF APPROPRIATIONS.—To
25 carry out this section, there are authorized to be appro-

1 priated \$5,000,000 for fiscal year 2008 and such sums
2 as may be necessary for each of fiscal years 2009 through
3 2012.”.