

110TH CONGRESS  
1ST SESSION

# H. R. 2592

To amend the Federal Food, Drug, and Cosmetic Act to provide for one or more Critical Path Public-Private Partnerships to implement the Critical Path Initiative of the Food and Drug Administration, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

JUNE 6, 2007

Ms. GIFFORDS (for herself, Mrs. BLACKBURN, and Mr. HALL of Texas) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for one or more Critical Path Public-Private Partnerships to implement the Critical Path Initiative of the Food and Drug Administration, and for other purposes.

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 “Safe and Effective  
5 Drug Development Act of 2007”.

1 **SEC. 2. PURPOSE.**

2       The purpose of this Act is to provide for one or more  
3 Critical Path Public-Private Partnerships to accelerate the  
4 translation of new scientific discoveries into new medical  
5 products that will cure and better treat disease, improve  
6 health care, prolong longevity and wellness, reduce health  
7 care costs, and enhance American competitiveness in the  
8 21st century.

9 **SEC. 3. FINDINGS.**

10       The Congress finds as follows:

11           (1) The Critical Path Initiative is the Food and  
12 Drug Administration's effort to stimulate and facili-  
13 tate a national effort to modernize the process of in-  
14 novation and commercialization through which fun-  
15 damental scientific discoveries are transformed from  
16 "proof of concept" and development into break-  
17 through medical products, therapies, and cures.

18           (2) On March 16, 2004, the Food and Drug  
19 Administration released a report entitled "Innova-  
20 tion/Stagnation: Challenge and Opportunity on the  
21 Critical Path to New Medical Products", addressing  
22 the recent slowdown in innovative medical therapies  
23 submitted to the Food and Drug Administration for  
24 approval. The report describes the urgent need to  
25 modernize the medical product development proc-

1        ess—the Critical Path—to make product develop-  
2        ment more predictable and efficient.

3            (3) The Food and Drug Administration has  
4        committed to working with companies, patient  
5        groups, academic researchers, and other stake-  
6        holders to coordinate, develop, and disseminate solu-  
7        tions to scientific hurdles that are impairing the effi-  
8        ciency of product development across the life science  
9        industries. For example, the Food and Drug Admin-  
10        istration has released a Critical Path Opportunities  
11        List of over 75 research priorities that, if accom-  
12        plished, would modernize the drug development proc-  
13        ess by 2010 and would help to make new medical  
14        discoveries available to Americans faster and at a  
15        lower cost.

16            (4) The Food and Drug Administration has al-  
17        ready initiated partnerships to share knowledge,  
18        streamline the cost and time of preclinical drug safe-  
19        ty evaluation, and better inform the use of “person-  
20        alized medicine”.

21            (5) However, much more must be done to foster  
22        the collaborative culture that must exist to mod-  
23        ernize the medical product development process. Col-  
24        lective sharing of scientific information and research  
25        methodology across the entire health care commu-

1 nity is crucial to igniting the medical innovation re-  
2 quired to keep pace with biomedical research.

3 (6) The power of public-private partnerships is  
4 vital to accomplish these tasks and to ensure that  
5 new scientific discoveries—in fields such as genomics  
6 and proteomics, imaging, and bioinformatics—can  
7 be more rapidly and effectively applied to cure dis-  
8 eases, enhance treatments, improve health care, pro-  
9 long longevity and wellness, reduce health care costs,  
10 and enhance American competitiveness in the 21st  
11 century.

12 **SEC. 4. CRITICAL PATH PUBLIC-PRIVATE PARTNERSHIPS.**

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

16 **“SEC. 566. CRITICAL PATH PUBLIC-PRIVATE PARTNER-**  
17 **SHIPS.**

18 “(a) ESTABLISHMENT.—The Secretary, acting  
19 through the Commissioner of Food and Drugs, shall enter  
20 into one or more collaborative agreements, to be known  
21 as Critical Path Public-Private Partnerships, with one or  
22 more eligible entities to implement the Critical Path Ini-  
23 tiative of the Food and Drug Administration by developing  
24 innovative, collaborative projects in research, education,  
25 and outreach for the purpose of fostering medical product

1 innovation, enabling the acceleration of medical product  
2 development, and enhancing medical product safety.

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

6 “(1) The entity is—

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

10 “(B) an organization described in section  
11 501(c)(3) of the Internal Revenue Code of 1986  
12 and exempt from tax under section 501(a) of  
13 such Code.

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

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

19 “(A) developing and critically evaluating  
20 tools, methods, and processes—

21 “(i) to increase efficiency, predict-  
22 ability, and productivity of medical product  
23 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 technical  
16                  programs of a Critical Path Public-Private  
17                  Partnership from Federal and nonfederal gov-  
18                  ernmental sources, foundations, and private in-  
19                  dividuals.

20                  “(c) FUNDING FROM CERTAIN INDIVIDUALS AND  
21 ORGANIZATIONS.—

22                  “(1) PROHIBITION.—The Secretary may not  
23                  enter into a collaborative agreement under sub-  
24                  section (a) unless the eligible entity involved provides  
25                  an assurance that the entity will not accept any

1 funding for the technical programs of a Critical  
2 Path Public-Private Partnership from any individual  
3 or organization that manufactures, distributes, or  
4 sells any product that is regulated by the Food and  
5 Drug Administration.

6 “(2) WAIVER.—Paragraph (1) (and any assur-  
7 ance provided thereunder) does not prohibit an eligi-  
8 ble entity from accepting funding from a consortium  
9 of companies whose products are regulated by the  
10 Food and Drug Administration if the Secretary—

11 “(A) determines that such acceptance  
12 would not result in any conflict of interest for  
13 the eligible entity, the Partnership, or the Gov-  
14 ernment; and

15 “(B) issues a waiver allowing such accept-  
16 ance.

17 “(d) ANNUAL REPORT.—Not later than 18 months  
18 after the date of the enactment of this section, and annu-  
19 ally thereafter, the Secretary, in collaboration with the  
20 parties to each Critical Path Public-Private Partnership,  
21 shall submit a report to the Committee on Health, Edu-  
22 cation, Labor, and Pensions of the Senate and the Com-  
23 mittee on Energy and Commerce of the House of Rep-  
24 resentatives—

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

3           “(2) addressing such other issues relating to  
4           this section as the Secretary determines to be appro-  
5           priate.

6           “(e) DEFINITION.—In this section, the term ‘medical  
7           product’ includes a drug, a diagnostic test, a biological  
8           product, a device, and any innovative combination of such  
9           products.

10          “(f) AUTHORIZATION OF APPROPRIATIONS.—To  
11          carry out this section, there are authorized to be appro-  
12          priated \$5,000,000 for fiscal year 2008 and such sums  
13          as may be necessary for each of fiscal years 2009 through  
14          2012.”.

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