

108TH CONGRESS  
2D SESSION

# H. R. 4258

To promote technological advancements that will dramatically reduce the timeframe for the development of new medical countermeasures to treat or prevent disease caused by infectious disease agents or toxins that, through natural processes or intentional introduction, may pose a significant risk to public health now or in the future.

---

## IN THE HOUSE OF REPRESENTATIVES

MAY 4, 2004

Mr. TURNER of Texas (for himself, Mr. ANDREWS, Mrs. CHRISTENSEN, Mr. DICKS, Ms. HARMAN, Mr. HOYER, Ms. JACKSON-LEE of Texas, Mr. LANGEVIN, Ms. LOFGREN, Mr. LUCAS of Kentucky, Mr. MEEK of Florida, Ms. NORTON, Mrs. LOWEY, Ms. MILLENDER-MCDONALD, Mr. PALLONE, and Ms. EDDIE BERNICE JOHNSON of Texas) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Armed Services and Select Homeland Security, 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

---

## A BILL

To promote technological advancements that will dramatically reduce the timeframe for the development of new medical countermeasures to treat or prevent disease caused by infectious disease agents or toxins that, through natural processes or intentional introduction, may pose a significant risk to public health now or in the future.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Rapid Pathogen Iden-  
3 tification to Delivery of Cures Act”.

4 **SEC. 2. FINDINGS AND POLICY.**

5 (a) FINDINGS.—The Congress finds as follows:

6 (1) The possibility exists today that terrorists  
7 or others who intend harm to United States forces  
8 deployed abroad or to the homeland will use tech-  
9 niques in biotechnology to enhance the trans-  
10 missibility, stability, virulence, or host range of a bi-  
11 ological agent, or to render existing diagnostic,  
12 therapeutic, and vaccine strategies or innate immune  
13 responses against a biological agent less effective.

14 (2) This possibility will likely grow over time as  
15 such techniques develop, improve, and spread as an  
16 inevitable result of biotechnology innovation.

17 (3) Natural processes can also lead to the emer-  
18 gence of previously unknown and harmful pathogens  
19 or render known pathogens resistant to existing di-  
20 agnostic, therapeutic, or adaptive immune ap-  
21 proaches.

22 (4) Long delays in developing new and effective  
23 responses to pathogens are typical. The discovery,  
24 development, and approval process for new drugs  
25 and vaccines typically requires 10 to 20 years and  
26 costs an average of \$800 million. These constraints

1 reflect the long, costly research and development  
2 process, including the failure of most drug or vac-  
3 cine candidates to demonstrate favorable characteris-  
4 tics in pre-clinical testing, as well as the expensive,  
5 time-consuming clinical trials required to prove the  
6 safety and effectiveness of new treatments.

7 (5) Congress has already authorized the  
8 abridgement of the long testing and approval process  
9 required to ensure safety and efficacy under the  
10 emergency conditions of a severe outbreak of a  
11 harmful pathogen. However, it will likely still take  
12 years for even an experimental treatment or vaccine  
13 to become available.

14 (6) There is no coordinated, focused research  
15 and development program or overall national strat-  
16 egy to achieve significant and dramatic reductions in  
17 the timeframe from the identification of a pathogen  
18 to the development and emergency approval for  
19 human use of reasonably safe and effective new bio-  
20 defense medical countermeasures against a pre-  
21 viously unknown or engineered pathogen or toxin.

22 (7) Even utilizing existing technologies, there is  
23 no organized capability in the public or private sec-  
24 tor to rapidly screen drug candidates for potential  
25 therapeutic activity against pathogens, develop and

1 manufacture drug, biological, or medical device prod-  
2 ucts, or test already approved treatments for efficacy  
3 against a previously unknown or engineered biologi-  
4 cal threat that puts our deployed armed forces or  
5 the homeland at risk.

6 (8) In the area of infectious disease in par-  
7 ticular, private sector firms are abandoning all types  
8 of innovation and research and development in favor  
9 of investments in more profitable medical markets.

10 (9) Tremendous potential exists for benefits to  
11 health by concerted, targeted public-private invest-  
12 ment to dramatically reduce the timeframe for the  
13 development of new countermeasures. The pharma-  
14 ceutical and biotechnology industries are fundamen-  
15 tally innovative and are quick to integrate new tech-  
16 nologies. Useful and important discoveries and tech-  
17 nological advances will be rapidly absorbed by the  
18 private sector, leading to faster delivery of new  
19 medicines and reductions in the costs of drug devel-  
20 opment.

21 (b) POLICY.—The Congress hereby declares it to be  
22 the national policy of the United States to promote techno-  
23 logical advancements that will dramatically reduce the  
24 timeframe for the development of new medical counter-  
25 measures to treat or prevent disease caused by infectious

1 disease agents or toxins that, through natural processes  
2 or intentional introduction, may pose a significant risk to  
3 public health now or in the future.

4 **SEC. 3. RAPID BIODEFENSE COUNTERMEASURES DEVELOP-**  
5 **MENT NATIONAL STRATEGY.**

6 Title III of the Homeland Security Act of 2002 (6  
7 U.S.C. 181 et seq.) (Public Law 107–296) is amended by  
8 inserting after section 304 the following section:

9 **“SEC. 304A. RAPID BIODEFENSE COUNTERMEASURES DE-**  
10 **VELOPMENT NATIONAL STRATEGY.**

11 “(a) NATIONAL STRATEGY FOR SHORTENING THE  
12 MEDICAL COUNTERMEASURE DEVELOPMENT TIME-  
13 FRAME.—Not later than 180 days after the date of the  
14 enactment of the Rapid Pathogen Identification to Deliv-  
15 ery of Cures Act, the Secretaries of Homeland Security,  
16 Health and Human Services, and Defense shall submit to  
17 Congress a report setting forth a strategy to achieve dra-  
18 matic reductions in the timeframe from pathogen identi-  
19 fication to the development and emergency approval for  
20 human use of reasonably safe and effective priority coun-  
21 termeasure against a novel or unknown pathogen or toxin.

22 “(b) ELEMENTS.—The report under subsection (a)  
23 shall include the following:

24 “(1) The identification of the technical impedi-  
25 ments to reductions in the timeframe from pathogen

1 identification to priority countermeasure develop-  
2 ment and approval under emergency conditions.

3 “(2) The identification of the research, develop-  
4 ment, and technology needs and clinical research  
5 needs to address these impediments.

6 “(3) The identification of existing research and  
7 development efforts in Federal agencies, academia  
8 and industry that are addressing the needs identified  
9 in subsection (c)(2).

10 “(4) The identification of facilities, programs  
11 and resources that can be utilized to address these  
12 research, development, and technology needs and  
13 clinical research needs among—

14 “(A) Federal agencies;

15 “(B) colleges and universities;

16 “(C) not-for-profit institutions;

17 “(D) industry, including information tech-  
18 nology, software, robotics, pharmaceutical and  
19 biotechnology companies and their consortia;  
20 and

21 “(E) foreign research and technological in-  
22 stitutions.

23 “(5) A proposal for the establishment of a co-  
24 ordinated and integrated federal program to address

1 these research, development, and technology needs,  
2 including—

3 “(A) the application of Federal Govern-  
4 ment resources, including recommendations for  
5 the allocation and prioritization of Federal  
6 funds;

7 “(B) interagency management and coordi-  
8 nation mechanisms;

9 “(C) the establishment of partnerships be-  
10 tween private corporations and Federal agencies  
11 or Federally funded entities;

12 “(D) information and technology sharing  
13 and coordination mechanisms among public,  
14 private, academic, not-for-profit, and inter-  
15 national institutions;

16 “(E) the use of incentives to promote pri-  
17 vate sector participation; and

18 “(F) the adjustment of Federal regulatory  
19 requirements to promote private sector innova-  
20 tion.

21 “(6) The identification of potential liability con-  
22 cerns stemming from distribution of rapidly-devel-  
23 oped priority countermeasures under emergency con-  
24 ditions and a proposal for regulatory or legislative  
25 approaches to eliminating these concerns.

1           “(7) A proposal for managing the transfer of  
2           new technologies and associated intellectual property  
3           rights.

4           “(c) CONSIDERATIONS.—In developing the national  
5           strategy under subsection (a), the Secretaries shall con-  
6           sider—

7           “(1) the research, development, and technology  
8           needs and clinical research needs of the entire  
9           pathogen identification to priority countermeasures  
10          discovery, development, production, and approval  
11          process, including—

12                   “(A) initial identification and characteriza-  
13                   tion of a pathogen or toxin, including the iden-  
14                   tification of any genetic or other manipulations;

15                   “(B) priority countermeasures discovery;

16                   “(C) pre-clinical testing and evaluation of  
17                   priority countermeasures;

18                   “(D) safety and efficacy animal testing, in-  
19                   cluding the needs for approval under emergency  
20                   conditions and accelerated approval of new pri-  
21                   ority countermeasure under the final rule ‘New  
22                   Drug and Biological Drug Products; Evidence  
23                   Needed to Demonstrate Effectiveness of New  
24                   Drugs When Human Efficacy Studies Are Not  
25                   Ethical or Feasible’ published in the Federal

1 Register on May 31, 2002 (67 Fed. Reg.  
2 37988);

3 “(E) safety and efficacy human testing, in-  
4 cluding mechanisms for the conduct of clinical  
5 trials under emergency conditions;

6 “(F) research-scale and full production-  
7 scale manufacturing, including biologics manu-  
8 facturing sciences; and

9 “(G) the approval of priority counter-  
10 measure under emergency conditions;

11 “(2) the potential importance of advanced tech-  
12 nologies such as automation, computer modeling and  
13 simulation, bioinformatics, pharmacogenomics, and  
14 bioengineering techniques for manufacturing;

15 “(3) the availability of sufficient manufacturing  
16 capacity for priority countermeasures production to  
17 meet potential public demand under emergency con-  
18 ditions; and

19 “(4) the current state of national and inter-  
20 national collaborative research networks and applica-  
21 tions to facilitate and encourage the rapid and co-  
22 ordinated development and sharing of laboratory and  
23 clinical research planning and results.

24 “(d) AUTHORITY TO CONTRACT.—The Secretary of  
25 Homeland Security, after consultation with the Secre-

1 taries of Health and Human Services and Defense and  
2 the working group established under section 319F(a) of  
3 the Public Health Service Act, may contract with any one  
4 or more for-profit or non-profit firm or institution to con-  
5 duct the necessary research and analysis needed to com-  
6 plete any one or more of the elements described in sub-  
7 section (b) of the report required in this section, provided  
8 the considerations described in subsection (c) are met.

9 “(e) DEFINITIONS.—In this section:

10 “(1) The term ‘emergency conditions’ refers to  
11 a declaration of emergency under section 564 of the  
12 Federal Food, Drug, and Cosmetic Act.

13 “(2) The term ‘pathogen identification’ means  
14 the point in time in which a specific agent that can  
15 be reasonably assumed to be the cause of (or has the  
16 potential to be the cause of) an infectious disease or  
17 toxin-induced syndrome has been identified and par-  
18 tially or wholly characterized scientifically.

19 “(3) The term ‘priority countermeasure’ has  
20 the same meaning given such term in section  
21 319F(h) of the Public Health Service Act.

22 “(f) AUTHORIZATION OF APPROPRIATIONS.—For the  
23 purpose of carrying out this section, there is authorized  
24 to be appropriated \$10,000,000 for fiscal year 2005.”.

1 **SEC. 4. CLINICAL RESEARCH UNDER EMERGENCY CONDI-**  
2 **TIONS.**

3 (a) IN GENERAL.—Not later than 180 days after the  
4 date of the enactment of this Act, the Secretary of Health  
5 and Human Services shall establish a system for the rapid  
6 establishment of clinical research programs to examine the  
7 safety and efficacy of new or existing treatments for novel,  
8 unknown, or bioengineered pathogens or toxins. The Sec-  
9 retary shall also provide the means for rapid dissemination  
10 of results and recommendations to clinicians nationwide.

11 (b) EMERGENCY FUND.—A fund is authorized to be  
12 established for use, at the discretion of the Secretary, sole-  
13 ly for the support of clinical research as described in sub-  
14 section (a).

15 **SEC. 5. INTERAGENCY WORKING GROUP.**

16 Section 319F(a) of the Public Health Service Act, as  
17 amended by Public Law 107–188, is amended—

18 (1) by inserting “the Secretary of Homeland  
19 Security,” after “in coordination with the”;

20 (2) by redesignating subparagraphs (D)  
21 through (L) as subparagraphs (E) through (M), re-  
22 spectively; and

23 (3) by inserting after subparagraph (C) the fol-  
24 lowing subparagraph:

25 “(D) development of a national strategy to  
26 achieve dramatic reductions in the timeframe

1 from the identification of a pathogen to the de-  
2 velopment and approval for human use under  
3 emergency conditions of priority counter-  
4 measures against a novel, unknown, or engi-  
5 neered pathogen or toxin;”.

6 **SEC. 6. DEVELOPING THE CAPABILITY FOR RAPID BIO-**  
7 **DEFENSE COUNTERMEASURE DEVELOP-**  
8 **MENT.**

9 (a) RESEARCH.—Section 319F(h)(1) of the Public  
10 Health Service Act, as amended by Public Law 107–188,  
11 is amended—

12 (1) in subparagraph (C), by striking “and”  
13 after the semicolon;

14 (2) by redesignating subparagraph (D) as sub-  
15 paragraph (E); and

16 (3) by inserting after subparagraph (C) the fol-  
17 lowing subparagraph:

18 “(D) the development of a capability to  
19 rapidly identify, develop, produce, and approve  
20 for human use under emergency conditions pri-  
21 ority countermeasures against a novel, un-  
22 known, or engineered pathogen or toxin; and”.

23 (b) RESEARCH AND DEVELOPMENT AT THE DEPART-  
24 MENT OF DEFENSE.—Section 1601(a) of the National  
25 Defense Authorization Act for Fiscal Year 2004 (Public

1 Law 108–136) is amended by adding at the end the fol-  
2 lowing: “The program shall also include research, develop-  
3 ment, and procurement to provide the Federal Govern-  
4 ment with the capability to rapidly identify, develop,  
5 produce, and approve for human use under emergency  
6 conditions priority countermeasures against a novel, un-  
7 known, or engineered pathogen or toxin, and for which no  
8 existing countermeasure has been determined to be safe  
9 or efficacious.”.

10 (c) RESEARCH AND DEVELOPMENT AT THE DEPART-  
11 MENT OF HOMELAND SECURITY.—Title III of the Home-  
12 land Security Act of 2002, as amended by section 3 of  
13 this Act, is amended by inserting after section 304A the  
14 following section:

15 **“SEC. 304B. DEVELOPING THE CAPABILITY FOR RAPID BIO-**  
16 **DEFENSE COUNTERMEASURE DEVELOP-**  
17 **MENT.**

18 “The Secretary, in collaboration with the Secretaries  
19 of Defense and Health and Human Services, shall carry  
20 out a program for research, development, and procure-  
21 ment to provide the Federal Government with the capa-  
22 bility to rapidly identify, develop, produce, and approve for  
23 human use under emergency conditions priority counter-  
24 measures against a novel, unknown, or engineered patho-

- 1 gen or toxin, and for which no existing countermeasure
- 2 has been determined to be safe or efficacious.”.

○