

AMENDMENT NO. \_\_\_\_\_ Calendar No. \_\_\_\_\_

Purpose: To improve human health and encourage biomedical innovation by accelerating efforts to improve protocols for testing and eventual implementation of vaccines for HIV/AIDS, tuberculosis, malaria, and other related infectious diseases in developing countries, and to promote advance market commitments to advance vaccine development.

IN THE SENATE OF THE UNITED STATES—110th Cong., 2d Sess.

**S. 2731**

To authorize appropriations for fiscal years 2009 through 2013 to provide assistance to foreign countries to combat HIV/AIDS, tuberculosis, and malaria, and for other purposes.

Referred to the Committee on \_\_\_\_\_ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENTS intended to be proposed by Mr. KERRY

Viz:

- 1 On page 44, line 9, strike "Section" and insert the
- 2 following:
- 3 (a) TUBERCULOSIS VACCINE DEVELOPMENT PRO-
- 4 GRAMS.—Section

1 ~~On page 45, between lines 6 and 7, insert the fol-~~  
2 ~~lowing:~~ **On page 58,<sup>2</sup> after line 22, insert the following:**

3 **SEC. 206 FACILITATING VACCINE DEVELOPMENT**

4 **(b) TECHNICAL ASSISTANCE FOR DEVELOPING**  
5 **COUNTRIES.**—The Administrator of the United States  
6 Agency for International Development, utilizing public-  
7 private partners, as appropriate, and working in coordina-  
8 tion with other international development agencies, is au-  
9 thorized to strengthen the capacity of developing coun-  
tries' governmental institutions to—

10 (1) collect evidence for informed decision-mak-  
11 ing and introduction of new vaccines, including po-  
12 tential HIV/AIDS, tuberculosis, and malaria vac-  
13 cines, if such vaccines are determined to be safe and  
14 effective;

15 (2) review protocols for clinical trials and im-  
16 pact studies and improve the implementation of clin-  
17 ical trials; and

18 (3) ensure adequate supply chain and delivery  
19 systems.

20 **(b) ADVANCED MARKET COMMITMENTS.**—

21 (1) **PURPOSE.**—The purpose of this subsection  
22 is to improve global health by requiring the United  
23 States to participate in negotiations for advance  
24 market commitments for the development of future

1 vaccines, including potential vaccines for HIV/AIDS,  
2 tuberculosis, and malaria.

3 (2) NEGOTIATION REQUIREMENT.—~~Not later~~  
4 ~~than 1 year after the date of the enactment of this~~  
5 ~~Act,~~ **T**he Secretary of the Treasury shall enter into  
6 negotiations with the appropriate officials of the  
7 International Bank of Reconstruction and Develop-  
8 ment (World Bank) and the GAVI Alliance, the  
9 member nations of such entities, and other inter-  
10 ested parties to establish advanced market commit-  
11 ments to purchase vaccines to combat HIV/AIDS,  
12 tuberculosis, malaria, and other related infectious  
13 diseases.

14 (3) REQUIREMENTS.—In negotiating the  
15 United States participation in programs for ad-  
16 vanced market commitments, the Secretary of the  
17 Treasury shall take into account whether programs  
18 for advance market commitments include—

19 (A) legally binding contracts for product  
20 purchase that include a fair market price for up  
21 to a maximum number of treatments, creating  
22 a strong market incentive;

23 (B) clearly defined and transparent rules  
24 of program participation for qualified devel-  
25 opers and suppliers of the product;

1 (C) clearly defined requirements for eligi-  
2 ble vaccines to ensure that they are safe and ef-  
3 fective and can be delivered in developing coun-  
4 try contexts;

5 (D) dispute settlement mechanisms; and

6 (E) sufficient flexibility to enable the con-  
7 tracts to be adjusted in accord with new infor-  
8 mation related to projected market size and  
9 other factors while still maintaining the pur-  
10 chase commitment at a fair price.

11 (4) REPORT.—Not later than 1 year after the  
12 date of the enactment of this Act—

13 (A) the Secretary of the Treasury shall  
14 submit a report to the appropriate congres-  
15 sional committees on the status of the United  
16 States negotiations to participate in programs  
17 for the advanced market commitments under  
18 this subsection; and

19 (B) the President shall produce a com-  
20 prehensive report, written by a study group of  
21 qualified professionals from relevant Federal  
22 agencies and initiatives, nongovernmental orga-  
23 nizations, and industry representatives, that  
24 sets forth a coordinated strategy to accelerate  
25 development of vaccines for infectious diseases,

1           such as HIV/AIDS, malaria, and tuberculosis,  
2           which includes—

3                   (i) initiatives to create economic in-  
4                   centives for the research, development, and  
5                   manufacturing of vaccines for HIV/AIDS,  
6                   tuberculosis, malaria, and other infectious  
7                   diseases;

8                   (ii) an expansion of public-private  
9                   partnerships and the leveraging of re-  
10                  sources from other countries and the pri-  
11                  vate sector; and

12                  (iii) efforts to maximize United States  
13                  capabilities to support clinical trials of vac-  
14                  cines in developing countries and to ad-  
15                  dress the challenges of delivering vaccines  
16                  in developing countries to minimize delays  
17                  in access once vaccines are available.

AMEND THE TABLE OF  
CONTENTS AS FOLLOWS

" SEC. 206. FACILITATING  
VACCINE DEVELOPMENT "