

114TH CONGRESS  
2D SESSION

# H. R. 5414

To amend the Federal Food, Drug, and Cosmetic Act to provide for establishment of one or more Intercenter Institutes within the Food and Drug Administration for a major disease area or areas, and for other purposes.

---

## IN THE HOUSE OF REPRESENTATIVES

JUNE 8, 2016

Mr. UPTON (for himself and Mr. PALLONE) introduced the following bill;  
which was referred to the Committee on Energy and Commerce

---

## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for establishment of one or more Intercenter Institutes within the Food and Drug Administration for a major disease area or areas, 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 “FDA Cross-Center  
5 Collaboration Act of 2016”.

1 **SEC. 2. ESTABLISHMENT OF FOOD AND DRUG ADMINISTRA-**  
2 **TION INTERCENTER INSTITUTES.**

3 (a) IN GENERAL.—Chapter X of the Federal Food,  
4 Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amend-  
5 ed by adding at the end the following:

6 **“SEC. 1014. ESTABLISHMENT OF FOOD AND DRUG ADMINIS-**  
7 **TRATION INTERCENTER INSTITUTES.**

8 “(a) IN GENERAL.—The Secretary shall establish one  
9 or more Intercenter Institutes within the Food and Drug  
10 Administration (referred to in this section as an ‘Insti-  
11 tute’) for a major disease area or areas. With respect to  
12 the major disease area of focus of an Institute, such Insti-  
13 tute shall develop and implement processes for coordina-  
14 tion of activities, as applicable to such major disease area  
15 or areas, between the Center for Drug Evaluation and Re-  
16 search, the Center for Biologics Evaluation and Research,  
17 and the Center for Devices and Radiological Health (re-  
18 ferred to in this section as the ‘Centers’). Such activities  
19 may include—

20 “(1) coordination of staff from the Centers with  
21 diverse product expertise in the diagnosis, cure, miti-  
22 gation, treatment, or prevention of the specific dis-  
23 eases relevant to the major disease area of focus of  
24 the Institute;

25 “(2) streamlining, where appropriate, of the  
26 processes for the review of medical products to diag-

1       nose, cure, mitigate, treat, or prevent the major dis-  
2       ease area of focus of the Institute applying relevant  
3       standards under sections 505, 510(k), 513(f)(2),  
4       and 515 of this Act, section 351 of the Public  
5       Health Service Act, and other applicable authorities;

6               “(3) promotion of scientific programs within  
7       the Centers related to the major disease area of  
8       focus of the Institute;

9               “(4) development of programs and enhancement  
10       of strategies to recruit, train, and provide continuing  
11       education opportunities for the personnel of the Cen-  
12       ters with expertise related to the major disease area  
13       of focus of the Institute;

14               “(5) enhancement of the interactions of the  
15       Centers with patients, sponsors, and the external  
16       biomedical community regarding the major disease  
17       area of focus of the Institute; and

18               “(6) facilitation of the collaborative relation-  
19       ships of the Centers with other agencies within the  
20       Department of Health and Human Services regard-  
21       ing the major disease area of focus of the Institute.

22       “(b) PUBLIC PROCESS.—Prior to establishing an In-  
23       stitute under subsection (a), the Secretary shall provide  
24       for a period of public comment on the proposed Institute.

1       “(c) TIMING.—The Secretary shall establish at least  
2 one Institute under subsection (a) before the date that is  
3 1 year after the date of enactment of the FDA Cross-Cen-  
4 ter Collaboration Act of 2016.

5       “(d) TERMINATION OF INSTITUTES.—The Secretary  
6 may terminate any Institute established pursuant to this  
7 section if the Secretary determines such Institute is no  
8 longer benefiting the public health. Not less than 60 days  
9 prior to terminating such Institute, the Secretary shall  
10 provide public notice of such termination, including the  
11 rationale for such termination.”.

12       (b) TECHNICAL AMENDMENTS.—Chapter X of the  
13 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391  
14 et seq.) is amended—

15           (1) by redesignating section 1012 as section  
16 1013; and

17           (2) by redesignating the second section 1011  
18 (with respect to improving the training of State,  
19 local, territorial, and tribal food safety officials), as  
20 added by section 209(a) of the FDA Food Safety  
21 Modernization Act (Public Law 111–353), as section  
22 1012.

○