

*M. F. B. J.*  
S.L.C.

AMENDMENT NO. Bennet Amendment #2 Calendar No. \_\_\_\_\_

Purpose: To provide for the development of a strategy and implementation plan with respect to appropriate interactions between medical device regulations and health information technology hardware and software, including medical mobile applications.

**IN THE SENATE OF THE UNITED STATES—112th Cong., 2d Sess.**

**S.** \_\_\_\_\_

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes.

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

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. Bennet + Mr. Hatch

Viz:

1 At the appropriate place, insert the following:

2 **SEC. \_\_\_\_ . MOBILE MEDICAL APPLICATIONS.**

3 (a) **LIMITATION.**—Notwithstanding any other provi-  
4 sion of law, the Food and Drug Administration Medical  
5 Mobile Applications Draft Guidance shall not have effect  
6 until September 30, 2013.

7 (b) **STRATEGY AND PLAN.**—Not later than March 1,  
8 2013, the Secretary of Health and Human Services (re-

1 ferred to in this section as the “Secretary”), in coordina-  
2 tion with the Commissioner of Food and Drugs and the  
3 National Coordinator of Health Information Technology,  
4 shall develop and submit to the appropriate committees  
5 of Congress, a strategy and implementation plan on the  
6 appropriate interaction between medical device regulation  
7 and health information technology hardware and software,  
8 including medical mobile applications.

9 (c) WORKING GROUP FOR STAKEHOLDER INPUT.—

10 In carrying out subsection (b), the Secretary shall—

11 (1) convene a working group of external stake-  
12 holders and experts, as determined appropriate by  
13 the Secretary, to provide appropriate input in the  
14 strategy and implementation plan required in this  
15 section; and

16 (2) conduct no fewer than 3 public meetings in  
17 diverse geographical areas of the United States to  
18 provide individuals in different regions an oppor-  
19 tunity to comment.