

*Maggie Hassan*  
Hassan S-4348 Amendment # 5

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

Purpose: To require public notification of waivers relating to organizational conflicts of interest.

IN THE SENATE OF THE UNITED STATES—117th Cong., 2d Sess.

**S. 4348**

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, 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 Ms. HASSAN

Viz:

1 At the appropriate place in title IX, insert the fol-  
2 lowing:

3 **SEC. 9\_\_\_\_. REQUIREMENTS REGARDING WAIVERS RELAT-**  
4 **ING TO ORGANIZATIONAL CONFLICTS OF IN-**  
5 **TEREST.**

6 (a) IN GENERAL.—The Secretary of Health and  
7 Human Services (referred to in this section as the “Sec-  
8 retary”) shall, not later than 14 days after awarding a  
9 contract relating to the Food and Drug Administration,  
10 publish, on the website of the Food and Drug Administra-  
11 tion, a notification of any waiver of any requirements re-

1   garding a potential or actual organizational conflict of in-  
2   terest granted to the contractor. Such notification shall  
3   be made publicly available in an easily accessible format,  
4   and shall include the name of the contract, the contractor  
5   receiving the waiver, the other contracts or clients that  
6   created the potential or actual organizational conflict of  
7   interest, and the efforts that the contractor plans to take  
8   to mitigate the potential or actual organizational conflict  
9   of interest.

10       (b) REGULATIONS.—Not later than 18 months after  
11   the date of enactment of this Act, the Secretary, in con-  
12   sultation with the Federal Acquisition Regulatory Council,  
13   shall issue regulations to carry out subsection (a).