

+ Sen.
Romney

AMENDMENT NO. _____

Calendar No. _____

Purpose: To require a public meeting on nonprofit manufacturers of prescription drugs.

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. ROSEN

Viz:

1 At the appropriate place in title IX, insert the following:
2

3 **SEC. 9 _____. FDA PUBLIC MEETING ON NONPROFIT PRE-**
4 **SCRIPTION DRUG MANUFACTURERS.**

5 (a) IN GENERAL.—Not later than 1 year after the
6 date of enactment of this Act, the Secretary of Health and
7 Human Services shall—

8 (1) hold a public meeting on nonprofit manu-
9 facturers of prescription drugs, which shall include
10 public testimony from relevant stakeholders and aca-
11 demics; and

1 (2) open a docket for public comment related to
2 such meeting.

3 (b) TOPICS.—The public meeting under subsection
4 (a) shall focus on the following topics:

5 (1) The extent to which growth in the nonprofit
6 prescription drug sector can help address patient ac-
7 cess challenges in the current prescription drug mar-
8 ketplace, such as drug shortages, limited medication
9 alternatives and competition, supply chain resiliency,
10 and specific products where there is insufficient
11 market demand to induce manufacturers to continue
12 to offer certain prescription drugs.

13 (2) Whether, and to what extent, the Secretary
14 of Health and Human Services should consider
15 changes to future user fee structures and processes
16 for nonprofit manufacturers of prescription drugs.