



AMENDMENT NO. _____

Calendar No. _____

Purpose: To require the Government Accountability Office to issue a report on nonprofit pharmaceutical organizations.

+ Sen. Romney

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 fol-
2 lowing:

3 **SEC. 9 ____ . GAO REPORT ON NONPROFIT PHARMA-**
4 **CEUTICAL ORGANIZATIONS.**

5 (a) GAO REVIEW.—The Comptroller General of the
6 United States (referred to in this section as the “Comp-
7 troller General”) shall prepare a report on—

8 (1) what is known about nonprofit pharma-
9 ceutical manufacturing organizations, including the
10 impact of such organizations on the development,

1 availability, and cost of prescription drugs in the
2 United States, which may include information with
3 respect to the capacity and capability to help prevent
4 or mitigate shortages of such drugs, and any chal-
5 lenges to manufacturing or other operations; and
6 (2) recommendations to address such chal-
7 lenges.

8 (b) REPORT.—Not later than 2 years after the date
9 of enactment of this Act, the Comptroller General shall
10 submit the report described in subsection (a) to the Com-
11 mittee on Health, Education, Labor, and Pensions of the
12 Senate and the Committee on Energy and Commerce of
13 the House of Representatives.