



AMENDMENT NO. _____

Calendar No. _____

Purpose: To exclude in vitro clinical tests developed by academic medical centers or components of such centers from the requirements with respect to in vitro clinical tests.

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 Mr. TUBERVILLE

Viz:

1 In section 587C of the Federal Food, Drug, and Cos-
2 metic Act, as added by section 823 of the bill, at the end
3 add the following:

4 “(j) ACADEMIC MEDICAL CENTERS.—

5 “(1) IN GENERAL.—The provisions of this sub-
6 chapter shall not apply to an in vitro clinical test for
7 which the developer is an academic medical center or
8 any component of such a center.

9 “(2) DEFINITIONS.—For purposes of this sub-
10 section:

1 “(A) ACADEMIC MEDICAL CENTER.—The
2 term ‘academic medical center’ means any of
3 the following:

4 “(i) An accredited medical school (in-
5 cluding a university).

6 “(ii) An accredited academic hospital.

7 “(iii) A faculty practice plan affiliated
8 with a hospital.

9 “(iv) A hospital in which a majority of
10 the physicians on the medical staff consists
11 of physicians who are faculty members.

12 “(B) ACCREDITED ACADEMIC HOSPITAL.—
13 The term ‘accredited academic hospital’ means
14 a hospital or health system that sponsors 4 or
15 more approved medical education programs.

16 “(C) APPROVED MEDICAL EDUCATION
17 PROGRAM.—The term ‘approved medical edu-
18 cation program’ includes an education program
19 that—

20 “(i) is approved or accredited by a na-
21 tionally recognized organization, which in-
22 cludes the Accreditation Council for Grad-
23 uate Medical Education, the American Os-
24 teopathic Association, and the Commission

1 on Accreditation of Allied Health Edu-
2 cation Programs; or

3 “(ii) provides credit to a participant
4 for certification in a specialty or sub-
5 specialty recognized by the American Med-
6 ical Association, the American Board of
7 Medical Specialties, or successor organiza-
8 tion.

9 “(D) COMPONENT.—The term ‘compo-
10 nent’, with respect to an academic medical cen-
11 ter, includes—

12 “(i) an entity affiliated with the aca-
13 demic medical center; and

14 “(ii) a nonprofit support organization
15 whose primary purpose is supporting the
16 mission of such center.”.