

AMENDMENT TO THE COMMITTEE PRINT**OFFERED BY _____****[Pediatric Rule]**

Page 1, line 3, redesignate section 1 as section 2 and insert after line 2 the following section:

1 SECTION 1. SHORT TITLE.

2 This Act may be cited as the “Pediatric Research Eq-
3 uity Act of 2007”.

Page 4, line 4, insert after “submit” the following:
“, on or after the date of enactment of the Pediatric Re-
search Equity Act of 2007,”.

Page 9, line 10, insert after “—” the following:
“Beginning on the date of enactment of the Pediatric Re-
search Equity Act of 2007,”.

Page 9, line 20, strike “and the written request, as
appropriate”.

Page 14, line 19, strike “assessments” and insert
“plans”.

Page 14, strike line 21 and all that follows through
page 16, line 4, and insert the following:

1 “(1) REVIEW.—The Secretary shall utilize an
2 internal committee to review all determinations that
3 a pediatric assessment is required under this section
4 and all deferral and waiver requests made pursuant
5 to this section. Such internal committee shall in-
6 clude, as appropriate, employees of the Food and
7 Drug Administration, with expertise such as pediat-
8 rics (including representation from the Office of Pe-
9 diatric Therapeutics), biopharmacology, statistics,
10 chemistry, legal issues, pediatric ethics, subject mat-
11 ter expertise pertaining to the pediatric product
12 under review, and other individuals as determined
13 appropriate by the Secretary.

14 “(2) ACTIVITY BY COMMITTEE.—The committee
15 referred to in paragraph (1) may operate using ap-
16 propriate members of such committee and need not
17 convene all members of the committee.

18 “(3) DOCUMENTATION OF COMMITTEE AC-
19 TION.—For each drug or biological product, the
20 committee referred to in paragraph (1) shall docu-
21 ment, for each activity described in paragraph (4),
22 which members of the committee participated in
23 such activity.

24 “(4) REVIEW OF REQUESTS FOR PEDIATRIC AS-
25 SESSMENTS, DEFERRALS AND WAIVERS.—All deter-

1 minations that a pediatric assessment required
2 under this section and all requests for deferrals and
3 waivers from the requirement to conduct a pediatric
4 assessment under this section shall be reviewed by
5 the committee referred to in paragraph (1).”.

Page 16, line 6, insert after “—” the following:
“Beginning on the date of enactment of the Pediatric Re-
search Equity Act of 2007,”.

Page 18, line 7, insert after “if” the following: “, on
or after the date of enactment of the Pediatric Research
Equity Act of 2007,”.

Page 21, line 7, insert after “—” the following:
“Beginning on the date of enactment of the Pediatric Re-
search Equity Act of 2007,”.

Page 21, line 18, insert after “—” the following:
“Beginning on the date of enactment of the Pediatric Re-
search Equity Act of 2007,”.

Page 23, lines 7 and 8, strike “Improving Pharma-
ceuticals for Children Act of 2007” and insert “Pediatric
Research Equity Act of 2007”.

Page 23, strike lines 15 through 17 (and remove the
subparagraph designation).

Page 24, after line 4, add the following:

1 **SEC. 2. GOVERNMENT ACCOUNTABILITY OFFICE REPORT.**

2 Not later than September 1, 2011, the Comptroller
3 General of the United States, in consultation with the Sec-
4 retary of Health and Human Services, shall submit to the
5 Congress a report that addresses the effectiveness of sec-
6 tions 505A and 505B of the Federal Food, Drug, and Cos-
7 metic Act (21 U.S.C. 355a) and section 409I of the Public
8 Health Service Act (42 U.S.C. 284m) in ensuring that
9 medicines used by children are tested and properly labeled.
10 Such report shall include—

11 (1) the number and importance of drugs and
12 biological products for children that are being tested
13 as a result of the amendments made by this Act and
14 the importance for children, health care providers,
15 parents, and others of labeling changes made as a
16 result of such testing;

17 (2) the number and importance of drugs and
18 biological products for children that are not being
19 tested for their use notwithstanding the provisions of
20 this Act and possible reasons for the lack of testing,
21 including whether the number of written requests
22 declined by sponsors or holders of drugs subject to
23 section 505A(g)(2) of the Federal Food, Drug, and
24 Cosmetic Act (21 U.S.C. 355a(g)(2)) has increased
25 or decreased as a result of the amendments made by
26 this Act;

- 1 (3) the number of drugs and biological products
2 for which testing is being done and labeling changes
3 required, including the date labeling changes are
4 made and which labeling changes required the use of
5 the dispute resolution process established pursuant
6 to the amendments made by this Act, together with
7 a description of the outcomes of such process, in-
8 cluding a description of the disputes and the rec-
9 ommendations of the Pediatric Advisory Committee;
- 10 (4) any recommendations for modifications to
11 the programs established under sections 505A and
12 505B of the Federal Food, Drug, and Cosmetic Act
13 (21 U.S.C. 355a) and section 409I of the Public
14 Health Service Act (42 U.S.C. 284m) that the Sec-
15 retary determines to be appropriate, including a de-
16 tailed rationale for each recommendation;
- 17 (5)(A) the efforts made by the Secretary to in-
18 crease the number of studies conducted in the
19 neonate population; and
- 20 (B) the results of those efforts, including efforts
21 made to encourage the conduct of appropriate stud-
22 ies in neonates by companies with products that
23 have sufficient safety and other information to make
24 the conduct of the studies ethical and safe; and

1 (6) pediatric studies conducted pursuant to this
2 section since 1997 and labeling changes made as a
3 result of such studies.