

AMENDMENT TO COMMITTEE PRINT
OFFERED BY MR. BURGESS OF TEXAS

[REMS_001, June 11, 2007]

Strike page 18, line 15, through page 21, line 21 (subsection (f) of section 505A of the Federal Food, Drug, and Cosmetic Act, as added by the bill; relating to restrictions on distribution or use) and insert the following:

1 “(f) PROVIDING SAFE ACCESS FOR PATIENTS TO
2 DRUGS WITH KNOWN SERIOUS RISKS THAT WOULD
3 OTHERWISE BE UNAVAILABLE.—

4 “(1) ALLOWING SAFE ACCESS TO DRUGS WITH
5 KNOWN SERIOUS RISKS.—The Secretary may require
6 that the risk evaluation and mitigation strategy for
7 a drug include such elements as are necessary to as-
8 sure safe use of the drug, because of its inherent
9 toxicity or potential harmfulness, if the Secretary
10 determines that—

11 “(A) the drug, which has been shown to be
12 effective, but is associated with a serious ad-
13 verse drug experience, can be approved only if,
14 or would be withdrawn unless, such elements
15 are required as part of such strategy to miti-

1 gate a specific serious risk listed in the labeling
2 of the drug; and

3 “(B) for a drug initially approved without
4 elements to assure safe use, other elements
5 under subsections (d) and (e) are not sufficient
6 to mitigate such serious risk.

7 “(2) ASSURING ACCESS AND MINIMIZING BUR-
8 DEN.—Such elements to assure safe use under sub-
9 paragraph (A) shall—

10 “(A) be commensurate with the specific se-
11 rious risk listed in the labeling of the drug;

12 “(B) within 30 days of the date on which
13 any element under subparagraph (A) is im-
14 posed, be posted publicly by the Secretary with
15 an explanation of how such elements will miti-
16 gate the observed safety risk;

17 “(C) considering such risk, not be unduly
18 burdensome on patient access to the drug, con-
19 sidering in particular—

20 “(i) patients with serious or life-
21 threatening diseases or conditions; and

22 “(ii) patients who have difficulty ac-
23 cessing health care (such as patients in
24 rural or medically underserved areas); and

1 “(D) to the extent practicable, so as to
2 minimize the burden on the health care delivery
3 system—

4 “(i) conform with elements to assure
5 safe use for other drugs with similar, seri-
6 ous risks; and

7 “(ii) be designed to be compatible
8 with established distribution, procurement,
9 and dispensing systems for drugs.”.