

7. AN AMENDMENT TO BE OFFERED BY REPRESENTATIVE POLIS OF COLORADO OR HIS DESIGNEE, DEBATABLE FOR 10 MINUTES

1 claims with respect to whether the device is safe or
2 effective.

3 (b) INCLUDED ELEMENTS OF REPORT.—The report
4 described in subsection (a) shall include—

5 (1) an analysis of the impact of such a process
6 on survival rates and quality of life measures for
7 seniors and individuals with disabilities;

8 (2) an analysis of the impact of such a process
9 on survival rates and quality of life measures of indi-
10 viduals suffering from life-threatening or irreversibly
11 debilitating human diseases or conditions;

12 (3) an estimation of the impact such a process
13 would have on national health care costs;

14 (4) an analysis of the extent to which such a
15 process could be designed so as to guarantee that
16 patient safety is not compromised;

17 (5) an analysis of the extent to which fraudu-
18 lent or ineffective devices could be marketed to pa-
19 tients under such a process and how such risks
20 could be successfully mitigated;

21 (6) proposals for providing device manufactur-
22 ers with incentives to show the effectiveness of de-
23 vices after the Secretary of Health and Human
24 Services has approved such devices to be lawfully
25 marketed under such a system, such as—

1 (A) by permitting only limited marketing
2 of a device, the effectiveness of which has not
3 yet been shown; or

4 (B) by revoking approval of any device, the
5 effectiveness of which has not been shown with-
6 in a specified timeframe; and

7 (7) recommendations for whether such a proc-
8 ess should be applicable to all devices or to only de-
9 vices that have been granted specific designations by
10 the Secretary or been determined eligible to be ap-
11 proved under specific approval programs under the
12 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
13 301 et seq.).

