AMENDMENT TO RULES COMMITTEE PRINT 114-22

OFFERED BY MR. POLIS OF COLORADO

H.R. 6, 21st Century Cures Act

Page 235, insert after line 2 the following new subtitle:

Subtitle R—Other Provisions

SEC. 2321. STUDY ON TWO-TIERED APPROVAL PROCESS FOR DEVICES BY FDA.

(a) IN GENERAL.—Not later than one year after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report assessing the feasibility, benefits, and risks associated with establishing an expedited, two-tiered approval process for devices (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)) that would enable devices to be lawfully marketed as of the date on which the device has been shown to be safe—

(1) regardless of whether the device has been shown to be effective; and

(2) so long as the person submitting the application for approval of the device has made no false

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

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

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

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

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

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

(5) an analysis of the extent to which fraudulent or ineffective devices could be marketed to patients under such a process and how such risks could be successfully mitigated;

(6) proposals for providing device manufacturers with incentives to show the effectiveness of devices after the Secretary of Health and Human Services has approved such devices to be lawfully marketed under such a system, such as—

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

(B) by revoking approval of any device, the effectiveness of which has not been shown within a specified timeframe; and

(7) recommendations for whether such a process should be applicable to all devices or to only devices that have been granted specific designations by the Secretary or been determined eligible to be approved under specific approval programs under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).