

**AMENDMENT TO H.R. 4368, AS REPORTED  
OFFERED BY MR. MCCORMICK OF GEORGIA**

At the end of the bill (before the spending reduction account) insert the following:

1        SEC. \_\_\_\_\_. None of the funds made available by  
2 this Act may be used to implement the revised guidance  
3 entitled “Marketed Unapproved Drugs—Compliance Pol-  
4 icy Guide Sec. 440.100, Marketed New Drugs Without  
5 Approved NDAs or ANDAs”, published by the Food and  
6 Drug Administration in the Federal Register on Sep-  
7 tember 21, 2011 (76 Fed. Reg. 58398) (or any guidance  
8 of the same substance).

