

AMENDMENT TO COMMITTEE PRINT
OFFERED BY MR. STUPAK

At the appropriate place in the bill, insert the following (and make such technical and conforming changes as may be necessary):

1 **SEC. ____ . AUTHORITY OF THE OFFICE OF SURVEILLANCE**
2 **AND EPIDEMIOLOGY.**

3 With respect to actions of the Food and Drug Admin-
4 istration related to postmarketing drug safety, including
5 labeling changes, postapproval studies, and restrictions on
6 distribution or use of drugs with serious risks, covered
7 under an amendment made by this Act, the Office of Sur-
8 veillance and Epidemiology (or any successor office) of
9 such Administration and the Office of New Drugs (or any
10 successor office) of such Administration shall make deci-
11 sions jointly. In the event of a disagreement with respect
12 to such an action related to postmarketing drug safety,
13 including labeling changes, postapproval studies, and re-
14 strictions on distribution or use of drugs with serious
15 risks, between such 2 offices, the 2 offices shall submit
16 the disagreement to the Commissioner of Food and Drugs,
17 and within 7 days after submission the Commissioner shall
18 make the decision with respect to such action.