

**AMENDMENT TO COMMITTEE PRINT****OFFERED BY M\_\_.** \_\_\_\_\_**(REMS\_\_001, June 11, 2007)**

Strike page 41, line 15, through page 42, line 5, and  
insert the following:

1           “(3) Any person who introduces into interstate  
2           commerce or delivers for introduction into interstate  
3           commerce a new drug in violation of section 505(o)  
4           (relating to risk evaluation and mitigation strate-  
5           gies), shall be subject to a civil money penalty of not  
6           more than \$50,000 in the case of an individual and  
7           \$250,000 in the case of any other person for such  
8           introduction or delivery, not to exceed \$500,000 for  
9           all such violations adjudicated in a single pro-  
10          ceeding.”.

Page 42, after line 15, insert the following:

11          (c) ADDITION CIVIL PENALTIES.—Section 307 of the  
12          Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 335b)  
13          is amended by striking the term “application” each place  
14          such term appears and inserting “application or risk eval-  
15          uation and mitigation strategy under section 505A”.