

1 **Subtitle F—Facilitating Respon-**  
2 **sible Manufacturer Communica-**  
3 **tions**

4 **[SEC. 2101. FACILITATING DISSEMINATION OF HEALTH**  
5 **CARE ECONOMIC INFORMATION.**

6 Section 502(a) of the Federal Food, Drug, and Cos-  
7 metic Act (21 U.S.C. 352(a)) is amended—**]**

8 **[(1) by striking “(a) If its” and inserting**  
9 **“(a)(1) If its”;**]

10 **[(2) by striking “a formulary committee, or**  
11 **other similar entity, in the course of the committee**  
12 **or the entity carrying out its responsibilities for the**  
13 **selection of drugs for managed care or other similar**  
14 **organizations” and inserting “a payor, formulary**  
15 **committee, or other similar entity, in the course of**  
16 **the payor, committee, or other similar entity car-**  
17 **rying out its responsibilities for the selection of**  
18 **drugs for managed care or other similar organiza-**  
19 **tions”;**]

20 **[(3) by striking “directly relates” and inserting**  
21 **“relates”;**]

22 **[(4) by striking “and is based on competent**  
23 **and reliable scientific evidence. The requirements set**  
24 **forth in section 505(a) or in section 351(a) of the**  
25 **Public Health Service Act shall not apply to health**

1 care economic information provided to such a com-  
2 mittee or entity in accordance with this paragraph”  
3 and inserting “, is based on competent and reliable  
4 scientific evidence, and includes, where applicable, a  
5 conspicuous and prominent statement describing any  
6 differences between the information and the indica-  
7 tion approved under section 505 or under section  
8 351 of the Public Health Service Act. The require-  
9 ments set forth in section 505(a) or in section 351  
10 of the Public Health Service Act shall not apply to  
11 health care economic information provided to such a  
12 payor, committee, or entity in accordance with this  
13 paragraph”; and】

14 【(5) by striking “In this paragraph, the term”  
15 and all that follows and inserting the following:】

16 【“(2) For purposes of this paragraph, the term  
17 ‘health care economic information’ means any analysis (in-  
18 cluding the data, inputs, clinical or other assumptions,  
19 methods, results, and other components comprising the  
20 analysis) that identifies, measures, or describes the con-  
21 sequences, including the separate or aggregated clinical  
22 consequences and costs of the represented health out-  
23 comes, of the use of a drug. Such analyses may be com-  
24 parative to the use of another drug, to another health care  
25 intervention, or to no intervention.”.】