

**AMENDMENT TO H.R.**  
**OFFERED BY MR. PALLONE**

**(Page & line nos. refer to Committee Print of 6/13/03)**

At the end of section 1860D-3(d) of the Social Security Act (as proposed to be inserted by section 101) [page 35, after line 2] add the following new paragraph:

1           “(6) NEGOTIATING FAIR PRICES WITH PHARMA-  
2           CEUTICAL MANUFACTURERS.—

3           “(A) IN GENERAL.—The Administrator shall, con-  
4           sistent with the goals of providing quality care and con-  
5           taining costs under this part, negotiate contracts with  
6           manufacturers of covered outpatient drugs that provide  
7           for the maximum prices that may be charged to indi-  
8           viduals enrolled in a prescription drug plan, a MA-  
9           EFFS Rx plan that provides coverage of covered out-  
10          patient drugs, or a qualified retiree prescription drug  
11          plan, by participating pharmacies for dispensing such  
12          drugs to such individuals.

13          “(B) PROMOTION OF BREAKTHROUGH DRUGS.—

14          “(i) IN GENERAL.—In conducting negotiations  
15          with manufacturers under this paragraph, the Ad-  
16          ministrator shall take into account the goal of pro-  
17          moting the development of breakthrough drugs.

18          “(ii) DEFINITION.—For purposes of this para-  
19          graph, a drug is a ‘breakthrough drug’ if the Ad-  
20          ministrator determines it is a new product that will  
21          make a significant and major improvement by re-  
22          ducing physical or mental illness, reducing mor-  
23          tality, or reducing disability, and that no other  
24          product is available to enrollees that achieves simi-  
25          lar results for the same condition.