

AMENDMENT TO COMMITTEE PRINT**OFFERED BY M__ . _____****(ped-Devices __002, June 20, 2007)**

Page 17, line 9, strike “to clearance of a premarket notification under section 510(k),” and insert “to clearance of a premarket notification under section 510(k), for a pediatric population or pediatric subpopulation,”.

Page 18, after line 11, insert the following (and make such technical and conforming changes as may be necessary):

1 “(c) DISPUTE RESOLUTION.—

2 “(1) IN GENERAL.—A manufacturer may re-
3 quest review under section 562 of any order or con-
4 dition requiring postmarket surveillance under this
5 section. During the pendency of such review, the de-
6 vice subject to such a postmarket surveillance order
7 or condition shall not be deemed misbranded under
8 section 502(t) or otherwise in violation of such order
9 or condition.

10 “(2) RELATION TO OTHER AUTHORITIES.—Not-
11 withstanding paragraph (1), the pendency of review
12 under section 562 shall not affect, delay, stay, or

1 preclude any ongoing or future seizure, recall, sus-
2 pension of marketing authority, or other regulatory
3 action that the Food and Drug Administration
4 deems necessary to protect the public health.”.

Beginning on page 18, strike line 12 and all that follows through the end of the bill (and make such technical and conforming changes as may be necessary).