

withdrawn

AMENDMENT TO H.R. 1249
OFFERED BY MS. WASSERMAN SCHULTZ OF
FLORIDA

Page 134, after line 2, insert the following (and re-designate the succeeding sections and conform the table of contents accordingly):

1 **SEC. ____ . PERMITTING SECOND OPINIONS IN CERTAIN**
2 **GENETIC DIAGNOSTIC TESTING.**

3 (a) IN GENERAL.—Section 287 of title 35, United
4 States Code, is amended by adding at the end the fol-
5 lowing:

6 “(d)(1) With respect to a genetic diagnostic tester’s
7 performance of a confirming genetic diagnostic test activ-
8 ity that constitutes an infringement under section 271(a)
9 or (b) of this title, the provisions of sections 281, 283,
10 284, and 285 of this title shall not apply against the ge-
11 netic diagnostic tester or against a related health care en-
12 tity with respect to such confirming genetic diagnostic test
13 activity.

14 “(2) For the purposes of this subsection:

15 “(A) The term ‘confirming genetic diagnostic
16 test activity’ means any activity, commercial or non-
17 commercial, related to the analysis, development, im-

1 provement, modification, research, taking, perform-
2 ance, manufacture, marketing, sale, reporting, or
3 other use of any genetic diagnostic test, by a clinical
4 laboratory or other related health care entity, that is
5 conducted for the sole purpose of providing inde-
6 pendent confirmation as a second or further opinion
7 of results obtained from a prior test for an indi-
8 vidual confirming the presence or absence of a gene
9 mutation, but shall not include (i) the use of a pat-
10 ented machine or manufacture in violation of such
11 patent or (ii) the practice of a process in violation
12 of a biotechnology patent.

13 “(B) The term ‘genetic diagnostic tester’ means
14 any person who is administering a confirming ge-
15 netic diagnostic test activity.

16 “(C) The term ‘related health care entity’
17 means an entity with which a genetic diagnostic
18 tester has a professional affiliation under which the
19 genetic diagnostic tester performs the confirming ge-
20 netic diagnostic test activity, including, but not lim-
21 ited to, a clinical laboratory, nursing home, hospital,
22 university, medical school, health maintenance orga-
23 nization, group medical practice, or medical clinic.

24 “(D) The term ‘professional affiliation’ means
25 staff privileges, medical staff membership, employ-

1 ment or contractual relationship, partnership or
2 ownership interest, academic appointment, or other
3 affiliation under which a genetic diagnostic tester
4 performs the confirming genetic diagnostic test ac-
5 tivity on behalf of, or in association with, the health
6 care entity.”.

7 (b) EFFECTIVE DATE.—The amendment made by
8 subsection (a) shall take effect on the date of the enact-
9 ment of this Act and shall apply to diagnostic tests per-
10 formed on or after such date.

