

**AMENDMENT TO THE AMENDMENT OF MR. SMITH
OF TEXAS TO H.R. 1249, AS REPORTED
OFFERED BY MS. WASSERMAN SCHULTZ OF
FLORIDA**

[Amendment is to file SLS_150 of June 13, 2011]

Beginning on page [28], strike the section [27] inserted on page 139, after line 12, and insert the following:

1 SEC. [27]. STUDY ON GENETIC TESTING.

2 (a) IN GENERAL.—The Director shall conduct a
3 study on effective ways to provide independent, confirming
4 genetic diagnostic test activity where gene patents and ex-
5 clusive licensing for primary genetic diagnostic tests exist.

6 (b) ITEMS INCLUDED IN STUDY.—The study shall in-
7 clude an examination of at least the following:

8 (1) The impact that the current lack of inde-
9 pendent second opinion testing has had on the abil-
10 ity to provide the highest level of medical care to pa-
11 tients and recipients of genetic diagnostic testing,
12 and on inhibiting innovation to existing testing and
13 diagnoses.

14 (2) The effect that providing independent sec-
15 ond opinion genetic diagnostic testing would have on

1 the existing patent and license holders of an exclu-
2 sive genetic test.

3 (3) The impact that current exclusive licensing
4 and patents on genetic testing activity has on the
5 practice of medicine, including but not limited to:
6 the interpretation of testing results and performance
7 of testing procedures.

8 (4) The role that cost and insurance coverage
9 have on access to and provision of genetic diagnostic
10 tests.

11 (c) CONFIRMING GENETIC DIAGNOSTIC TEST ACTIV-
12 ITY DEFINED.—For purposes of this section, the term
13 “confirming genetic diagnostic test activity” means the
14 performance of a genetic diagnostic test, by a genetic diag-
15 nostic test provider, on an individual solely for the purpose
16 of providing the individual with an independent confirma-
17 tion of results obtained from another test provider’s prior
18 performance of the test on the individual.

19 (d) REPORT.—Not later than 9 months after the date
20 of enactment of this Act, the Director shall report to the
21 Committee on the Judiciary of the Senate and the Com-
22 mittee on the Judiciary of the House of Representatives
23 on the findings of the study and provide recommendations

- 1 for establishing the availability of such independent con-
- 2 firming genetic diagnostic test activity.

