

110TH CONGRESS
1ST SESSION

S. 736

To provide for the regulation and oversight of laboratory tests.

IN THE SENATE OF THE UNITED STATES

MARCH 1, 2007

Mr. KENNEDY (for himself and Mr. SMITH) introduced the following bill;
which was read twice and referred to the Committee on Health, Edu-
cation, Labor, and Pensions

A BILL

To provide for the regulation and oversight of laboratory
tests.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Laboratory Test Im-
5 provement Act”.

6 **SEC. 2. DEFINITIONS.**

7 (a) IN GENERAL.—

8 (1) FEDERAL FOOD, DRUG, AND COSMETIC
9 ACT.—Section 201 of the Federal Food, Drug, and
10 Cosmetic Act (referred to in this Act as the

1 “FFDCA”) (21 U.S.C. 321) is amended by adding
2 at the end the following:

3 “(rr) DEFINITIONS RELATED TO LABORATORY-DE-
4 VELOPED TESTS.—

5 “(1) ANALYTICAL VALIDITY.—The term ‘ana-
6 lytical validity’, with respect to a laboratory-devel-
7 oped test, means the extent to which the test can be
8 used to measure accurately and reliably the property
9 or characteristic that the test is intended to meas-
10 ure.

11 “(2) CLINICAL VALIDITY.—The term ‘clinical
12 validity’, with respect to a laboratory-developed test,
13 means the extent to which the test can be used for
14 its intended use.

15 “(3) DIRECT-TO-CONSUMER TEST.—The term
16 ‘direct-to-consumer test’ means a laboratory-devel-
17 oped test that is not a prescription test.

18 “(4) INTENDED USE.—The term ‘intended use’,
19 with respect to a laboratory-developed test, in-
20 cludes—

21 “(A) determining predisposition of an indi-
22 vidual to a disease or condition;

23 “(B) aiding diagnosis of a disease or con-
24 dition of an individual;

1 “(C) aiding decision-making on how to
2 treat a disease or condition of an individual;

3 “(D) aiding preimplantation genetic diag-
4 nosis;

5 “(E) determining a characteristic of a
6 human embryo or a human fetus;

7 “(F) determining whether an individual is
8 a carrier of an allele associated with a disease
9 or condition; or

10 “(G) otherwise obtaining information re-
11 lated to health or disease prevention (including
12 nutrition) for an individual.

13 “(5) IN VITRO DIAGNOSTIC PRODUCT.—The
14 term ‘in vitro diagnostic product’ shall have the
15 meaning given the term in section 809.3(a) of title
16 21, Code of Federal Regulations (or successor regu-
17 lation).

18 “(6) LABORATORY-DEVELOPED TEST.—

19 “(A) IN GENERAL.—The term ‘laboratory-
20 developed test’ means—

21 “(i) the use of analytical methods de-
22 veloped by a laboratory to process a bio-
23 logical specimen, whether at 1 laboratory
24 site or multiple sites, to report a test result

to a health care practitioner, a patient, or
a consumer; and

“(ii) includes an in vitro diagnostic
product that the laboratory has modified,
unless such modification requires
preclearance or preapproval of such modi-
fied in vitro diagnostic product under this
Act.

“(B) EXCEPTION.—The term ‘laboratory-
developed test’ does not include—

“(i) the processing of a biological
specimen to—

“(I) determine paternity;

“(II) aid in forensics; or

“(III) conduct research if the re-
sult of the test is not reported to a
health care provider, a patient, or a
consumer;

“(ii) an in vitro diagnostic product; or

“(iii) an analyte specific reagent, as
defined in section 864.4020 of title 21,
Code of Federal Regulations (or successor
regulation).

“(7) MANUFACTURER.—The term ‘manufac-
turer’, with respect to a laboratory-developed test,

1 means the laboratory that performs the test to proc-
2 ess a biological specimen.

3 “(8) PRESCRIPTION TEST.—The term ‘prescrip-
4 tion test’ means a laboratory-developed test that is
5 used to process a biological specimen only upon the
6 written or oral authorization, based on a practi-
7 tioner-patient relationship that is valid under appli-
8 cable Federal and State laws, of a practitioner li-
9 censed by law to administer or use such test.

10 “(9) TYPE.—A laboratory-developed test shall
11 be considered of the same ‘type’ as an in vitro diag-
12 nostic product if the test and the product—

13 “(A) use similar analytical methods;

14 “(B) measure the same, or clinically com-
15 parable, properties or characteristics; and

16 “(C) have the same intended use.”.

17 (2) APPLICATION OF DEFINITIONS.—Any term
18 that is used in this Act that is defined in subsection
19 (rr) of such section 201 (as added by paragraph (1))
20 shall, for purposes of this Act, have the meaning
21 given such term in such subsection (rr).

22 (b) IMPLEMENTATION.—A laboratory-developed test
23 that is a direct-to-consumer test on the date of enactment
24 of this Act shall be deemed to be a prescription test if,
25 on the date that is 60 days after the date of enactment

1 of this Act and thereafter, such test satisfies the require-
 2 ments of this Act to be a prescription test.

3 **SEC. 3. LABORATORY-DEVELOPED TESTS DEEMED MED-**
 4 **ICAL DEVICES.**

5 Section 520 of the FFDCA (21 U.S.C. 360j) is
 6 amended by adding at the end the following:

7 “(o) LABORATORY-DEVELOPED TESTS.—Any labora-
 8 tory-developed test shall be deemed to be a device under
 9 section 201(h).”.

10 **SEC. 4. REPORTING ON AND PUBLIC DISCLOSURE ABOUT**
 11 **LABORATORY-DEVELOPED TESTS.**

12 (a) LABELING OF INTENDED USE AND REGULATORY
 13 STATUS OF LABORATORY-DEVELOPED TESTS AND TEST
 14 RESULTS.—

15 (1) IN GENERAL.—Section 520(o) of the
 16 FFDCA, as added by section 3, is amended by—

17 (A) striking “TESTS.—Any” and inserting
 18 the following: “TESTS.—

19 “(1) IN GENERAL.—Any”; and

20 (B) adding at the end the following:

21 “(2) TEST RESULTS; LABELING.—

22 “(A) IN GENERAL.—Any statement by the
 23 manufacturer of the result of a laboratory-de-
 24 veloped test reported to a health care practi-
 25 tioner, a patient, or a consumer, and any label-

ing for the test, shall prominently and conspicuously include—

“(i) the intended use of the test; and

“(ii) if the test has not been cleared or approved under this Act for such intended use, a statement that the test has not been cleared or approved under this Act for such intended use.

“(B) EFFECT.—The statement required under subparagraph (A) shall not include a statement that the test is investigational or not lawfully marketed.”.

(2) IMPLEMENTATION.—The requirements of paragraph (2) of such section 520(o) shall take effect on the date that is 60 days after the date of enactment of this Act.

(b) REGISTRATION OF MANUFACTURERS AND LISTING OF LABORATORY-DEVELOPED TESTS.—The requirements of section 510 of the FFDCA (21 U.S.C. 360) with respect to the registration of the manufacturer of a laboratory-developed test and the listing of a laboratory-developed test shall take effect on the date that is 270 days after the date of enactment of this Act.

(c) ADVERSE EVENT REPORTING FOR LABORATORY-DEVELOPED TESTS.—The requirements of section 519 of

1 the FFDCA (21 U.S.C. 360i) with respect to records and
 2 reports on a laboratory-developed test shall take effect on
 3 the date that is 1 year after the date of enactment of this
 4 Act.

5 (d) PUBLIC DATABASE OF INFORMATION ON VALID-
 6 ITY OF LABORATORY-DEVELOPED TESTS.—

7 (1) IN GENERAL.—Section 520(o) of the
 8 FFDCA, as amended by subsection (a), is amended
 9 by adding at the end the following:

10 “(3) DATABASE ON INFORMATION OF ANALYT-
 11 ICAL AND CLINICAL VALIDITY.—

12 “(A) IN GENERAL.—

13 “(i) SUBMISSION.—Unless a labora-
 14 tory-developed test is cleared under section
 15 510(k) or approved under section 515 or
 16 520(m) for its intended use, the manufac-
 17 turer of the test shall electronically submit
 18 to the Secretary information (in a form
 19 specified by the Secretary and certified as
 20 truthful and accurate) on the analytical
 21 and clinical validity of the test for its in-
 22 tended use.

23 “(ii) ANALYTIC INTENDED USE.—If
 24 the intended use of a laboratory-developed
 25 test is limited solely to the measurement of

1 an analytical property or characteristic, the
2 manufacturer of the test shall not submit
3 any information with respect to the clinical
4 validity of the test under clause (i) other
5 than the following statement: ‘This test is
6 intended to measure only the property or
7 characteristic that is reported as a result
8 of use of the test. The test is not intended
9 to be used to diagnose or screen for any
10 disease or condition, or to otherwise aid in
11 decision-making with respect to health, and
12 this laboratory makes no representations
13 as to its usefulness for any such purpose.’.

14 “(B) INCLUSION.—The Secretary shall
15 provide for the automated inclusion of the in-
16 formation submitted under subparagraph (A) in
17 a database of such information on all labora-
18 tory-developed tests that shall be available to,
19 and searchable by, the public on the Internet
20 website of the Food and Drug Administration.

21 “(C) NOTICE.—The Secretary may give
22 written notice to the manufacturer of a labora-
23 tory-developed test that—

1 “(i) the information submitted by the
2 manufacturer for such test under subpara-
3 graph (A)—

4 “(I) does not adequately dem-
5 onstrate the analytical validity of the
6 test for its intended use;

7 “(II) does not adequately sum-
8 marize the peer-reviewed biomedical
9 literature about the clinical validity of
10 the test for its intended use;

11 “(III) relies on, or includes, in-
12 formation or data on the clinical valid-
13 ity of the test for its intended use that
14 has not been published in a peer-re-
15 viewed biomedical journal;

16 “(IV) does not adequately dem-
17 onstrate the clinical validity of the
18 test for its intended use; or

19 “(V) does not demonstrate that
20 the analytical validity or the clinical
21 validity of such test for its intended
22 use is comparable to the analytical va-
23 lidity or the clinical validity, as the
24 case may be, of an in vitro diagnostic
25 product of the same type that has

1 been cleared under section 510(k) or
2 approved under section 515 or section
3 520(m); and

4 “(ii) information about an intended
5 use that is not limited solely to the meas-
6 urement of an analytical property or char-
7 acteristic, as provided for in the statement
8 described under subparagraph (A)(ii), has
9 been included—

10 “(I) with a result of the test re-
11 ported by the manufacturer to a
12 health care practitioner, a patient, or
13 a consumer; or

14 “(II) in labeling for the test.

15 “(D) SECOND NOTICE.—The Secretary
16 shall provide to the manufacturer of a labora-
17 tory-developed test that has received a notice
18 under subparagraph (C) a second notice if—

19 “(i) the manufacturer has submitted
20 corrected information under subparagraph
21 (A) for such test within 90 days of having
22 received a notice under subparagraph (C);
23 and

1 “(ii)(I) 1 or more of subclauses (I)
 2 through (V) of subparagraph (C)(i) applies
 3 to such corrected information; or

4 “(II) the manufacturer has failed to
 5 include in such corrected information nec-
 6 essary information about the intended use
 7 referred to in subparagraph (C)(ii).”.

8 (2) IMPLEMENTATION.—

9 (A) ELECTRONIC SUBMISSION.—Not later
 10 than 1 year after the date of enactment of this
 11 Act, the Secretary of Health and Human Serv-
 12 ices (referred to in this Act as the “Secretary”)
 13 shall develop a portal on the Internet website of
 14 the Food and Drug Administration through
 15 which the information required by paragraph
 16 (3) of such section 520(o), as added by this
 17 subsection, shall be submitted to the Secretary.

18 (B) ELECTRONIC CERTIFICATION.—The
 19 Secretary shall require as a condition of submit-
 20 ting the information required by paragraph (3)
 21 of such section 520(o) that an individual sub-
 22 mitting such information certify electronically
 23 the truthfulness and accuracy of such informa-
 24 tion.

1 (C) PUBLICLY ACCESSIBLE DATABASE OF
2 INFORMATION.—Not later than 1 year after the
3 date of enactment of this Act, the Secretary
4 shall develop a database of the information sub-
5 mitted under paragraph (3) of such section
6 520(o) that shall be available to, and searchable
7 by, the public on the Internet website of the
8 Food and Drug Administration and to which
9 such information shall be automatically in-
10 cluded upon submission.

11 (D) LITERATURE REVIEWS AND CLINICAL
12 VALIDITY.—Not later than 270 days after the
13 date of enactment of this Act, the Secretary
14 shall issue a guidance document to facilitate the
15 use of reviews of the peer-reviewed biomedical
16 literature and other information and data about
17 the clinical validity of laboratory-developed tests
18 and in vitro diagnostic products when clearing
19 or approving such tests and products under the
20 FFDCA.

21 (E) MODIFICATIONS.—Not later than 18
22 months after the date of enactment of this Act,
23 the Secretary shall issue a guidance document
24 to clarify when modifications to a laboratory-de-
25 veloped test require updating of the information

submitted under paragraph (3) of such section 520(o). To the extent practicable, under such guidance, modifications to a laboratory-developed test under such paragraph (3) shall be required under the same circumstances as the submission of a report under section 510(k) of the FFDCA (21 U.S.C. 360(k)) or a supplemental premarket application under section 515 of the FFDCA (21 U.S.C. 360e) is required for modifications to a laboratory-developed test or an in vitro diagnostic product that is cleared or approved under the FFDCA.

(F) SUBMISSION OF INFORMATION.—The requirements of paragraph (3) of such section 520(o) shall take effect on the date that is 18 months after the date of enactment of this Act.

SEC. 5. CLASSIFICATION AND FDA REVIEW OF LABORATORY-DEVELOPED TESTS.

(a) CLASSIFICATION OF LABORATORY-DEVELOPED TESTS.—

(1) IN GENERAL.—Section 520(o) of the FFDCA, as amended by section 4, is amended by adding at the end the following:

“(4) CLASSIFICATION.—

1 “(A) IN GENERAL.—Notwithstanding sec-
2 tion 513(f)(1), a laboratory-developed test shall
3 be classified in class II, as defined in section
4 513(a)(1)(B), subject to both general and spe-
5 cial controls.

6 “(B) CLASS III.—Notwithstanding sub-
7 paragraph (A), a laboratory-developed test shall
8 be classified in class III if—

9 “(i) the Secretary gives notice to the
10 manufacturer of such test that such test
11 meets the requirements of section
12 513(a)(1)(C) to be in class III;

13 “(ii)(I) such test is intended for use in
14 the diagnosis of a contagious disease or
15 condition that is highly likely to result in
16 a fatal outcome; and

17 “(II) prompt, accurate diagnosis of
18 the disease or condition offers the oppor-
19 tunity to mitigate the public health impact
20 of the disease or condition; or

21 “(iii) such test is intended for use in
22 donor screening of a disease or condition
23 for which the Secretary has recommended
24 or required testing to—

25 “(I) safeguard the blood supply;

1 “(II) establish the safe use of
2 blood and blood products; or

3 “(III) establish the safe use of
4 tissue and tissue products.

5 “(C) CLASS I.—Notwithstanding subpara-
6 graph (A), the Secretary may classify a labora-
7 tory-developed test in class I if such test meets
8 the requirements of section 513(a)(1)(A) to be
9 in class I.”.

10 (2) IMPLEMENTATION.—

11 (A) CLASS III.—The Secretary may not
12 give notice under paragraph (4)(B)(i) of such
13 section 520(o) to the manufacturer of a labora-
14 tory-developed test that is not a direct-to-con-
15 sumer test before the date that is 2 years after
16 the date of enactment of this Act.

17 (B) CLASS I.—The Secretary may not clas-
18 sify a type of laboratory-developed test in class
19 I under paragraph (4)(C) of such section
20 520(o) before the date that is 18 months after
21 the date of enactment of this Act.

22 (C) SPECIAL CONTROLS.—Not later than 2
23 years after the date of enactment of this Act,
24 the Secretary shall identify in guidance docu-
25 ments whether there are special controls to

1 which all laboratory-developed tests, subcat-
 2 egories of such tests, or specific such tests shall
 3 be subject under section 514 of the FFDCA
 4 (21 U.S.C. 360d).

5 (b) CLEARANCE AND APPROVAL OF LABORATORY-
 6 DEVELOPED TESTS.—

7 (1) IN GENERAL.—Section 520(o) of the
 8 FFDCA, as amended by subsection (a), is amended
 9 by adding at the end the following:

10 “(5) APPLICATION OF SECTION 510(k), SEC-
 11 TION 515, OR SECTION 520(m).—A laboratory-devel-
 12 oped test shall be exempt from the requirements of
 13 section 510(k), section 515, and section 520(m), ex-
 14 cept that the manufacturer of a laboratory-developed
 15 test shall submit—

16 “(A) a report under section 510(k) if—

17 “(i) the test is classified in class II;

18 and

19 “(ii) the test is—

20 “(I) a direct-to-consumer test;

21 “(II) a test for which the manu-
 22 facturer has not submitted corrected
 23 information under paragraph (3)(A)
 24 within 90 days of having received a
 25 notice under paragraph (3)(C); or

1 “(III) a test for which the Sec-
2 retary has given second notice under
3 paragraph (3)(D) to the manufacturer
4 of such test; or

5 “(B) an application under section 515 or
6 section 520(m), as appropriate, if such test is
7 classified in class III.”.

8 (2) IMPLEMENTATION.—

9 (A) DIRECT-TO-CONSUMER TESTS.—The
10 requirement to submit a report under section
11 510(k) of the FFDCA (21 U.S.C. 360(k)) or an
12 application under section 515 or section 520(m)
13 of the FFDCA (21 U.S.C. 360e or 360j(m)), as
14 the case may be, under paragraph (5) of such
15 section 520(o), as added by this subsection, for
16 a direct-to-consumer test as provided in clause
17 (ii) of such paragraph shall take effect on the
18 date that is 180 days after the date of enact-
19 ment of this Act.

20 (B) CLASS II PRESCRIPTION TESTS.—The
21 requirement to submit a report under such sec-
22 tion 510(k) under paragraph (5) of such section
23 520(o) for a class II prescription device shall
24 take effect on the date that is 90 days after the
25 date of the notice to the manufacturer of such

1 test referred to in subclause (II) or (III) of
 2 paragraph (5)(A)(ii) of such section 520(o).

3 (C) CLASS III PRESCRIPTION TESTS.—The
 4 requirement to submit an application under
 5 such section 515 or such section 520(m) under
 6 paragraph (5) of such section 520(o) for a class
 7 III prescription device shall take effect on the
 8 date that is—

9 (i) 1 year after the date on which the
 10 Secretary gives notice to the manufacturer
 11 of such test that such test is classified in
 12 class III as provided under paragraph
 13 (4)(B)(i) of such section 520(o); or

14 (ii) 1 year after the date of enactment
 15 of this Act if such test is classified in class
 16 III as provided under clause (ii) or (iii) of
 17 paragraph (4)(B) of such section 520(o).

18 (c) REMOVAL OF LABORATORY-DEVELOPED TESTS
 19 FROM THE MARKET.—Section 520(o) of the FFDCA, as
 20 amended by subsection (b), is amended by adding at the
 21 end the following:

22 “(6) FAILURE TO MAKE SUBMISSION; NON-
 23 CLEARANCE OR DISAPPROVAL.—The manufacturer
 24 of a laboratory-developed test—

1 “(A) may commence and continue to re-
2 port, or offer to report, a result of such test to
3 any person until the date that—

4 “(i)(I) the manufacturer is required to
5 submit information under paragraph
6 (3)(A); and

7 “(II) the manufacturer fails to submit
8 such information;

9 “(ii)(I) the manufacturer has received
10 a notice under paragraph (3)(C); and

11 “(II) the manufacturer has failed to
12 submit corrected information under para-
13 graph (3)(A);

14 “(iii)(I) the manufacturer is required
15 to submit under paragraph (5)—

16 “(aa) a report with respect to
17 such test under section 510(k); or

18 “(bb) an application under sec-
19 tion 515 or 520(m); and

20 “(II) the manufacturer fails to submit
21 such report or application, as the case may
22 be;

23 “(iv) the report with respect to such
24 test under section 510(k) is not cleared by
25 the Secretary; or

1 “(v) approval of such application is
2 denied by the Secretary; and

3 “(B) shall immediately cease to report, or
4 offer to report, a result of such test to any per-
5 son on such date.”.

6 **SEC. 6. INSPECTION OF LABORATORIES; EXEMPTION FROM**
7 **REQUIREMENT FOR FDA TO INSPECT EVERY**
8 **2 YEARS.**

9 Section 520(o) of the FFDCA, as amended by section
10 4, is amended by adding at the end the following:

11 “(7) INSPECTION.—The requirement of section
12 510(h) with respect to the inspection of a registered
13 establishment at least once in every 2-year period
14 shall not apply to a manufacturer of a laboratory-
15 developed test that is classified in class II, unless
16 section 510(h) applies to such establishment because
17 of a drug or another device classified in class II or
18 III.”.

19 **SEC. 7. THE CLINICAL LABORATORY IMPROVEMENT**
20 **AMENDMENTS OF 1988.**

21 (a) COMPLIANCE WITH THIS ACT.—Compliance with
22 the requirements under this Act shall have no effect on
23 the obligation to comply with any requirement under sec-
24 tion 353 of the Public Health Service Act (42 U.S.C.
25 263a).

1 (b) COMPLIANCE WITH CLIA OF 1988.—Except as
 2 provided in subsection (c), compliance with the require-
 3 ments under section 353 of the Public Health Service Act
 4 (42 U.S.C. 263a) shall have no effect on the obligation
 5 to comply with any requirement of this Act.

6 (c) GOOD MANUFACTURING PRACTICE REQUIRE-
 7 MENTS AND CLIA OF 1988.—For a laboratory-developed
 8 test, compliance with the requirements under section 353
 9 of the Public Health Service Act (42 U.S.C. 263a) shall
 10 be deemed to satisfy the requirements under section
 11 520(f) of the FFDCA (21 U.S.C. 360j(f)) unless and
 12 until, after providing for public comment, the Secretary
 13 issues a final guidance document—

14 (1) in which the Secretary finds that—

15 (A) compliance with the requirements
 16 under such section 353 does not satisfy the re-
 17 quirements under such section 520(f); and

18 (B) compliance with the requirements of
 19 such section 520(f) are necessary to protect the
 20 public health;

21 (2) explaining the least burdensome approach
 22 for manufacturers of laboratory-developed tests to
 23 comply with the requirements of such section 520(f);
 24 and

1 (3) providing for coordination of inspection ef-
2 forts to ensure compliance with such section 353
3 and such section 520(f).

4 (d) RULEMAKING BY SECRETARY.—

5 (1) PROPOSED RULE.—Not later than 1 year
6 after the date of enactment of this Act, the Sec-
7 retary shall issue a proposed rule to establish a spe-
8 cialty area under section 353 of the Public Health
9 Service Act (42 U.S.C. 263a) for laboratory-devel-
10 oped tests to acquire genetic information, including
11 mutations, genotypes, gene expression, and chromo-
12 somal structure.

13 (2) FINAL RULE.—

14 (A) IN GENERAL.—The Secretary shall
15 issue a final rule not later than the date that
16 is 3 years after the date of enactment of this
17 Act, which shall be effective 1 year after the
18 date such rule is issued.

19 (B) CONTENT.—Such final rule shall in-
20 clude standards for proficiency testing of such
21 laboratory-developed tests, as provided under
22 section 353 of the Public Health Service Act
23 (42 U.S.C. 263a).

24 (3) EFFECT OF FAILURE TO ISSUE FINAL
25 RULE.—If the Secretary fails to issue the final rule

1 on or before the date that is 3 years after the date
2 of enactment of this Act, such laboratory-developed
3 tests shall be subject to the requirements of such
4 section 520(f) after such date and until such final
5 rule becomes effective.

6 **SEC. 8. ENHANCED REIMBURSEMENT UNDER FEDERAL**
7 **HEALTH PROGRAMS.**

8 The Secretary shall develop a mechanism to provide
9 enhanced reimbursement under Federal health programs
10 for in vitro diagnostic products and laboratory-developed
11 tests that are cleared under section 510(k) of the FFDCA
12 (21 U.S.C. 360(k)), or approved under section 515 or
13 520(m) of such Act (21 U.S.C. 360e or 21 U.S.C. 360j).

14 **SEC. 9. AUTHORIZATION OF APPROPRIATIONS.**

15 There are authorized to be appropriated such sums
16 as may be necessary for each of fiscal years 2007 through
17 2010 to carry out this Act.

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