

116TH CONGRESS
1ST SESSION

H. R. 2155

To provide for certain requirements with respect to the treatment of personally identifiable information by genetic testing services.

IN THE HOUSE OF REPRESENTATIVES

APRIL 9, 2019

Mr. RUSH introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To provide for certain requirements with respect to the treatment of personally identifiable information by genetic testing services.

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 “Genetic Information
5 Privacy Act of 2019”.

6 **SEC. 2. TREATMENT OF PERSONALLY IDENTIFIABLE IN-**
7 **FORMATION BY GENETIC TESTING SERVICES.**

8 (a) CONSENT REQUIRED.—

9 (1) EXPRESS CONSENT FOR DISCLOSURE.—

1 (A) IN GENERAL.—A genetic testing serv-
2 ice may not disclose personally identifiable in-
3 formation of a customer to a third party unless
4 the service obtains the express consent of the
5 customer.

6 (B) RELATIONSHIP TO INFORMED CON-
7 SENT REQUIREMENT.—In the case of the discolo-
8 sure of genetic information for medical re-
9 search, paragraph (2) applies instead of sub-
10 paragraph (A).

11 (2) INFORMED CONSENT FOR USE OR DISCLO-
12 SURE OF GENETIC INFORMATION FOR MEDICAL RE-
13 SEARCH.—A genetic testing service may not use ge-
14 netic information of a customer for medical research,
15 or disclose such information to a third party for
16 medical research, unless the service—

17 (A) obtains the informed consent of the
18 customer in accordance with section 46.116 of
19 title 45, Code of Federal Regulations, as in ef-
20 fect on the date of the enactment of this Act;
21 and

22 (B) documents the consent of the customer
23 in accordance with section 46.117 of title 45,
24 Code of Federal Regulations, as in effect on the
25 date of the enactment of this Act.

1 (3) OPTION REGARDING GENETIC INFORMA-
2 TION.—In seeking the consent of a customer under
3 paragraph (1) or (2) for the disclosure of personally
4 identifiable information, a genetic testing service
5 shall give the customer the option of providing con-
6 sent for the disclosure of the genetic information of
7 the customer while withholding consent for the dis-
8 closure of any other personally identifiable informa-
9 tion of the customer.

10 (4) PROHIBITION ON CONDITIONING SERVICE
11 ON CONSENT.—A genetic testing service may not
12 condition the provision of service to a customer on
13 obtaining the consent of the customer required by
14 paragraph (1) or (2), except to the extent that dis-
15 closure of personally identifiable information is nec-
16 essary to provide the service.

17 (b) NOTIFICATION.—

18 (1) NEW CUSTOMERS.—In the case of an agree-
19 ment for service entered into between a genetic test-
20 ing service and a customer on or after the effective
21 date described in section 6, the genetic testing serv-
22 ice shall notify the customer of the rights of the cus-
23 tomer under subsection (a)—

24 (A) at the time when the agreement is en-
25 tered into;

(B) using the same method of communication by which the agreement is entered into; and

(C) in a manner that is—

(i) clear and conspicuous; and

(ii) separate from any privacy policy, data use policy, or other similar document.

(2) EXISTING CUSTOMERS.—

(A) IN GENERAL.—In the case of an agreement for service entered into between a genetic testing service and a customer before the effective date described in section 6, the genetic testing service shall notify the customer of the rights of the customer under subsection (a)—

(i) not later than the date that is 1 year after such effective date;

(ii) using the primary method of communication of the genetic testing service with the customer; and

(iii) in a manner that is—

(I) clear and conspicuous; and

(II) separate from any privacy policy, data use policy, or other similar document.

1 (B) INABILITY TO CONTACT.—A genetic
2 testing service may not be considered to be in
3 violation of subparagraph (A) by reason of
4 being unable to contact a customer, if the serv-
5 ice sends the notification required by such sub-
6 paragraph—

7 (i) if the primary method of commu-
8 nication of the service with the customer is
9 in writing, to the last known home mailing
10 address of the customer in the records of
11 the service; and

12 (ii) if the primary method of commu-
13 nication of the service with the customer is
14 email or other electronic means, to the last
15 known email address, or using the last
16 known other electronic contact informa-
17 tion, as the case may be, of the customer
18 in the records of the service.

19 (3) WEBSITE NOTIFICATION.—In addition to
20 the notifications required by paragraphs (1) and (2),
21 a genetic testing service shall provide clear and con-
22 spicuous notification of the rights of customers
23 under subsection (a) on the internet website of the
24 service (if the service maintains such a website).

1 Such notification shall be separate from any privacy
2 policy, data use policy, or other similar document.

3 (4) CONTENTS.—The Commission shall include
4 in the regulations promulgated under subsection (d)
5 requirements for the contents of the notifications re-
6 quired by this subsection.

7 (c) INFORMATION SECURITY REQUIREMENTS.—The
8 Commission shall promulgate regulations that require a
9 genetic testing service to implement policies and proce-
10 dures to secure the personally identifiable information of
11 customers of the service against unauthorized access.

12 (d) REGULATIONS.—

13 (1) IN GENERAL.—Not later than 1 year after
14 the date of the enactment of this Act, the Commis-
15 sion shall promulgate, under section 553 of title 5,
16 United States Code—

17 (A) regulations to implement subsections

18 (a) and (b); and

19 (B) the regulations required by subsection

20 (c).

21 (2) CONSIDERATIONS.—In promulgating regu-
22 lations under paragraph (1), the Commission shall
23 take into consideration—

24 (A) the size of, and the nature, scope, and

25 complexity of the activities engaged in by, dif-

1 ferent types or categories of genetic testing
2 services;

3 (B) the cost of implementing the require-
4 ments of subsections (a) and (b) and such regu-
5 lations; and

6 (C) in the case of the regulations required
7 by subsection (c), the current state of the art
8 in administrative, technical, and physical safe-
9 guards to secure information against unauthor-
10 ized access.

11 **SEC. 3. ENFORCEMENT.**

12 (a) **ENFORCEMENT BY FEDERAL TRADE COMMIS-**
13 **SION.—**

14 (1) **UNFAIR OR DECEPTIVE ACTS OR PRAC-**
15 **TICES.—**A violation of section 2 or a regulation pro-
16 mulgated under such section shall be treated as an
17 unfair or deceptive act or practice in violation of a
18 regulation under section 18(a)(1)(B) of the Federal
19 Trade Commission Act (15 U.S.C. 57a(a)(1)(B)) re-
20 garding unfair or deceptive acts or practices.

21 (2) **POWERS OF COMMISSION.—**The Commis-
22 sion shall enforce section 2 and the regulations pro-
23 mulgated under such section in the same manner, by
24 the same means, and with the same jurisdiction,
25 powers, and duties as though all applicable terms

1 and provisions of the Federal Trade Commission Act
2 (15 U.S.C. 41 et seq.) were incorporated into and
3 made a part of this Act. Any person who violates
4 such section or such a regulation shall be subject to
5 the penalties and entitled to the privileges and im-
6 munities provided in the Federal Trade Commission
7 Act.

8 (b) ENFORCEMENT BY STATE ATTORNEYS GEN-
9 ERAL.—

10 (1) CIVIL ACTION.—In any case in which the
11 attorney general of a State, or an official or agency
12 of a State, has reason to believe that an interest of
13 the residents of that State has been or is threatened
14 or adversely affected by any person who violates sec-
15 tion 2 or a regulation promulgated under such sec-
16 tion, the attorney general, official, or agency of the
17 State, as *parens patriae*, may bring a civil action on
18 behalf of the residents of the State in a district
19 court of the United States of appropriate jurisdic-
20 tion—

21 (A) to enjoin further violation of such sec-
22 tion or such regulation by the defendant;

23 (B) to compel compliance with such section
24 or such regulation; or

1 (C) to obtain civil penalties in the same
2 amount as the civil penalties that may be ob-
3 tained by the Commission under section 5(m) of
4 the Federal Trade Commission Act (15 U.S.C.
5 45(m)).

6 (2) INTERVENTION BY FTC.—

7 (A) NOTICE AND INTERVENTION.—The
8 State shall provide prior written notice of any
9 action under paragraph (1) to the Commission
10 and provide the Commission with a copy of its
11 complaint, except in any case in which such
12 prior notice is not feasible, in which case the
13 State shall serve such notice immediately upon
14 instituting such action. The Commission shall
15 have the right—

16 (i) to intervene in the action;

17 (ii) upon so intervening, to be heard
18 on all matters arising therein; and

19 (iii) to file petitions for appeal.

20 (B) LIMITATION ON STATE ACTION WHILE
21 FEDERAL ACTION IS PENDING.—If the Commis-
22 sion has instituted a civil action for violation of
23 section 2 or a regulation promulgated under
24 such section, no State attorney general, or offi-
25 cial or agency of a State, may bring an action

1 under paragraph (1) during the pendency of the
2 action of the Commission against any defendant
3 named in the complaint of the Commission for
4 any violation of such section or such regulation
5 alleged in the complaint.

6 (3) RULE OF CONSTRUCTION.—For purposes of
7 bringing any civil action under paragraph (1), noth-
8 ing in this Act or the regulations promulgated under
9 this Act shall be construed to prevent an attorney
10 general of a State from exercising the powers con-
11 ferred on the attorney general by the laws of that
12 State to—

13 (A) conduct investigations;

14 (B) administer oaths or affirmations; or

15 (C) compel the attendance of witnesses or
16 the production of documentary and other evi-
17 dence.

18 **SEC. 4. EFFECT ON OTHER LAWS.**

19 (a) PREEMPTION OF CERTAIN STATE LAWS RELAT-
20 ING TO GENETIC TESTING.—This Act and the regulations
21 promulgated under this Act supersede any provision of a
22 statute, regulation, or rule of a State or political subdivi-
23 sion of a State, with respect to an entity to the extent
24 this Act and the regulations promulgated under this Act
25 apply to such entity, that expressly provides for require-

1 ments relating to treatment of personal information by
2 services providing genetic testing that are similar to any
3 requirements contained in section 2 or a regulation pro-
4 mulgated under such section.

5 (b) PRESERVATION OF CERTAIN STATE LAWS.—This
6 Act and the regulations promulgated under this Act may
7 not be construed to preempt the applicability of—

8 (1) State trespass, contract, or tort law; or

9 (2) other State laws to the extent that those
10 laws relate to acts of fraud.

11 (c) ADDITIONAL PREEMPTION.—

12 (1) IN GENERAL.—No person other than the at-
13 torney general of a State, or another official or
14 agency of a State, may bring a civil action under the
15 laws of any State if such action is premised in whole
16 or in part upon the defendant violating any provision
17 of this Act or a regulation promulgated under this
18 Act.

19 (2) PRESERVATION OF CONSUMER PROTECTION
20 LAWS.—This subsection may not be construed to
21 limit the enforcement of any State consumer protec-
22 tion law by an attorney general of a State, or an-
23 other official or agency of a State.

24 (d) PRESERVATION OF FTC AUTHORITY.—Nothing
25 in this Act may be construed in any way to limit the au-

1 thority of the Commission under any other provision of
2 law.

3 **SEC. 5. DEFINITIONS.**

4 In this Act:

5 (1) COMMISSION.—The term “Commission”
6 means the Federal Trade Commission.

7 (2) GENETIC INFORMATION.—The term “ge-
8 netic information”—

9 (A) has the meaning given such term in
10 section 201 of the Genetic Information Non-
11 discrimination Act of 2008 (42 U.S.C. 2000ff);
12 and

13 (B) includes a physical sample, such as
14 fluid or tissue, obtained from a customer for
15 purposes of performing a genetic test.

16 (3) GENETIC TEST.—The term “genetic test”
17 has the meaning given such term in section 201 of
18 the Genetic Information Nondiscrimination Act of
19 2008 (42 U.S.C. 2000ff).

20 (4) GENETIC TESTING SERVICE.—The term
21 “genetic testing service” means any entity that—

22 (A) offers genetic tests directly to con-
23 sumers; or

24 (B) analyzes genetic information obtained
25 from a genetic test offered directly to con-

1 sumers, except to the extent that the analysis is
2 performed by a medical professional for diag-
3 nosis or treatment of a medical condition.

4 (5) MEDICAL RESEARCH.—The term “medical
5 research” means the conduct of investigations, ex-
6 periments, and studies to discover, develop, or verify
7 knowledge relating to the causes, diagnosis, treat-
8 ment, prevention, or control of physical or mental
9 diseases and impairments of humans.

10 (6) PERSONALLY IDENTIFIABLE INFORMA-
11 TION.—

12 (A) DEFINITION.—The term “personally
13 identifiable information” means any of the fol-
14 lowing of an individual:

15 (i) Name.

16 (ii) Address.

17 (iii) Social Security number.

18 (iv) Phone number.

19 (v) Online identifier, such as an email
20 address or user ID.

21 (vi) Genetic information.

22 (vii) Information, other than genetic
23 information, that—

1 (I) relates to the past, present, or
2 future physical or mental health or
3 condition of the individual; and

4 (II) either—

5 (aa) identifies the individual;

6 or

7 (bb) there is a reasonable
8 basis to believe can be used to
9 identify the individual.

10 (B) MODIFIED DEFINITION BY RULE-
11 MAKING.—The Commission may, by regulation
12 promulgated under section 553 of title 5,
13 United States Code, modify the definition of
14 “personally identifiable information” under sub-
15 paragraph (A) to the extent that such modifica-
16 tion is necessary to accommodate changes in
17 technology or practices, will not unreasonably
18 impede interstate commerce, and will accom-
19 plish the purposes of this Act.

20 (7) STATE.—The term “State” means each
21 State of the United States, the District of Columbia,
22 each commonwealth, territory, or possession of the
23 United States, and each federally recognized Indian
24 Tribe.

1 (8) THIRD PARTY.—The term “third party”
2 means, with respect to a genetic testing service, an
3 entity (including an entity that controls, is controlled
4 by, or is under common control with the service)
5 that holds itself out to the public as separate from
6 the service such that a customer of the service act-
7 ing reasonably under the circumstances would not
8 expect the entity to be related to the service or to
9 have access to personally identifiable information
10 that the customer provides to the service.

11 **SEC. 6. EFFECTIVE DATE.**

12 Except for subsections (c) and (d) of section 2, sec-
13 tion 5(6)(B), this section, and section 7, this Act and the
14 regulations required by subsections (c) and (d) of section
15 2 shall apply beginning on the date that is 30 days after
16 the date on which the Commission promulgates such regu-
17 lations.

18 **SEC. 7. AUTHORIZATION OF APPROPRIATIONS.**

19 There is authorized to be appropriated to the Com-
20 mission \$5,000,000 for each of the fiscal years 2020
21 through 2029 to carry out this Act.

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