

107TH CONGRESS  
2D SESSION

# H. R. 3966

To direct the Director of the Office of Science and Technology Policy to conduct a study of the impact of Federal policies on the innovation process for genomic technologies, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

MARCH 14, 2002

Ms. RIVERS (for herself and Mr. WELDON of Florida) introduced the following bill; which was referred to the Committee on Science, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To direct the Director of the Office of Science and Technology Policy to conduct a study of the impact of Federal policies on the innovation process for genomic technologies, and for other purposes.

1       *Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Genomic Science and  
5 Technology Innovation Act of 2002”.

6 **SEC. 2. FINDINGS.**

7       The Congress finds the following:

1 (1) Genomic science promises a revolution in  
2 the development of new and effective genomic tech-  
3 nologies and other innovations, and it is in the na-  
4 tional interest to speed the development and deploy-  
5 ment of these new technologies through policies that  
6 promote innovation in the field of genomic science  
7 and technology.

14 (3) Intellectual property policies for genomic  
15 science and technology products are being imple-  
16 mented without an adequate understanding and con-  
17 sideration of the net impact of such policies on the  
18 innovation process.

19 (4) Decisions about intellectual property policy  
20 being made now are likely to have significant im-  
21 pacts on basic research and the development of  
22 genomic technology for decades to come.

23 (5) The Office of Science and Technology Pol-  
24 icy is uniquely positioned to lead the development of  
25 a coordinated, interagency policy to promote innova-

1       tion in genomic science and technology. A definitive  
2       study coordinated by the Office of Science and Tech-  
3       nology Policy that identifies the impacts of Federal  
4       innovation policy on the innovation pipeline for  
5       genomic technology and includes recommendations  
6       for policies, including any statutory changes needed  
7       to optimize the genomic technology innovation pipe-  
8       line, would contribute significantly to the develop-  
9       ment of the policy.

10 **SEC. 3. STUDY.**

11       (a) REQUIREMENT.—The Director of the Office of  
12 Science and Technology Policy shall conduct, or may con-  
13 tract with the National Academy of Sciences to conduct,  
14 a study that assesses the impact of Federal policies, in-  
15 cluding intellectual property policies, on the innovation  
16 process for genomic technologies.

17       (b) CONSULTATION.—In conducting the study, the  
18 Director of the Office of Science and Technology Policy  
19 shall consult with the National Science and Technology  
20 Council, the National Science Foundation, the Secretary  
21 of Energy, the Secretary of Commerce, the Secretary of  
22 Health and Human Services, and other agencies or divi-  
23 sions of agencies the Director considers appropriate.

24       (c) ADVISORY COMMITTEE.—In conducting the  
25 study, the Director of the Office of Science and Tech-

1 nology Policy shall consult with an advisory committee, or-  
2 ganized as a subcommittee of the President's Committee  
3 of Advisors on Science and Technology, that shall include  
4 balanced membership from research universities and other  
5 nonprofit research institutions, industry, economists, legal  
6 experts, bioethicists, clinicians and clinical scientists, ge-  
7 netic practitioners, and advocacy groups.

8 (d) CONTENTS.—The study shall—

9 (1) identify and quantify, to extent possible, the  
10 actual and reasonably expected effects of innovation  
11 policy on genomic science and technology innovation;

12 (2) explicitly consider various alternative levels  
13 of intellectual property protection genomic materials  
14 may receive and the likely impact of the various lev-  
15 els of protection on each element of the innovation  
16 pipeline, including—

17 (A) fundamental genomic research carried  
18 out at universities and other nonprofit research  
19 institutions;

20 (B) commercial genomic research at uni-  
21 versities, nonprofit research institutions, and  
22 for-profit institutions, including the expected ef-  
23 fects on intracompany investment and external  
24 private capital;

(C) development of commercial genomic technologies, including the expected effects on investment capital; and

(D) access to genomic technologies and processes; and

(3) include an assessment of the net impact of

Federal innovation policies on innovation for genomic technologies, including an assessment of—

(A) researchers' access to genomic mate-

rials;

(B) the rate of innovation;

(C) the quality of innovation;

(D) the cost of new genomic technologies

brought to market;

(E) the impact of restricted access to genomic diagnostics on evaluation, improvement, and clinical utilization;

(F) the cost and availability of innovative technology;

(G) whether Federal innovation policies create barriers to research through denial of use of a research tool, increased costs of licensing, legal and litigation costs, transaction costs, or the perception of increased legal liability, or hinder the access of researchers to genomic ma-

1           terials and to databases of genomic sequence in-  
2           formation;

3           (H) whether Federal innovation policies af-  
4           fect the choice of area of research conducted by  
5           researchers or institutions or provide positive  
6           benefits to such research, including additional  
7           funding from private sector partners; and

8           (I) the range of incentives providing moti-  
9           vation for genetics research and technology de-  
10           velopment other than intellectual property pro-  
11           tection.

12 **SEC. 4. REPORT.**

13           The Director of the Office of Science and Technology  
14           Policy shall, within 270 days after the date of the enact-  
15           ment of this Act, transmit a report to Congress that—

16           (1) contains the findings of the study conducted  
17           under section 3; and

18           (2) makes recommendations for policies, includ-  
19           ing legislative changes, needed to optimize the  
20           genomic technology innovation pipeline.

21 **SEC. 5. COORDINATED POLICY.**

22           After the report is transmitted to Congress under sec-  
23           tion 4, the Director of the Office of Science and Tech-  
24           nology Policy shall incorporate the policy recommenda-  
25           tions into a coordinated interagency policy to promote in-

1 novation in genomic science and technology, including the  
2 sound use of intellectual property policy.

3 **SEC. 6. DEFINITIONS.**

4 For the purposes of this Act—

5 (1) the term “genomic materials” means any  
6 material containing a human or human pathogen  
7 polynucleotide sequence other than genetic probes  
8 and markers and transgenic organisms;

9 (2) the term “genomic technology” means any  
10 genetic diagnostic methods or kits, tools, probes, or  
11 markers, and any pharmaceutical or therapy that  
12 uses or incorporates genomic materials; and

13 (3) the term “innovation policy” includes intel-  
14 lectual property protection and policies.

