106TH CONGRESS 1ST SESSION

S. 1010

To amend the Internal Revenue Code of 1986 to provide for a medical innovation tax credit for clinical testing research expenses attributable to academic medical centers and other qualified hospital research organizations.

IN THE SENATE OF THE UNITED STATES

May 11, 1999

Mr. Jeffords (for himself, Mr. Rockefeller, Mrs. Hutchison, Mrs. Feinstein, and Mrs. Boxer) introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To amend the Internal Revenue Code of 1986 to provide for a medical innovation tax credit for clinical testing research expenses attributable to academic medical centers and other qualified hospital research organizations.

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

1	SECTION 1. CREDIT FOR CLINICAL TESTING RESEARCH EX-
2	PENSES ATTRIBUTABLE TO CERTAIN QUALI-
3	FIED ACADEMIC INSTITUTIONS INCLUDING
4	TEACHING HOSPITALS.
5	(a) In General.—Subpart D of part IV of sub-
6	chapter A of chapter 1 of the Internal Revenue Code of
7	1986 (relating to business related credits) is amended by
8	inserting after section 41 the following:
9	"SEC. 41A. CREDIT FOR MEDICAL INNOVATION EXPENSES.
10	"(a) General Rule.—For purposes of section 38,
11	the medical innovation credit determined under this sec-
12	tion for the taxable year shall be an amount equal to 20
13	percent of the excess (if any) of—
14	"(1) the qualified medical innovation expenses
15	for the taxable year, over
16	"(2) the medical innovation base period
17	amount.
18	"(b) Qualified Medical Innovation Ex-
19	PENSES.—For purposes of this section—
20	"(1) IN GENERAL.—The term 'qualified medical
21	innovation expenses' means the amounts which are
22	paid or incurred by the taxpayer during the taxable
23	year directly or indirectly to any qualified academic
24	institution for clinical testing research activities.
25	"(2) CLINICAL TESTING RESEARCH ACTIVI-
26	TIES.—

1	"(A) In General.—The term 'clinical
2	testing research activities' means human clinical
3	testing conducted at any qualified academic in-
4	stitution in the development of any product,
5	which occurs before—
6	"(i) the date on which an application
7	with respect to such product is approved
8	under section 505(b), 506, or 507 of the
9	Federal Food, Drug, and Cosmetic Act,
10	"(ii) the date on which a license for
11	such product is issued under section 351 of
12	the Public Health Service Act, or
13	"(iii) the date classification or ap-
14	proval of such product which is a device in-
15	tended for human use is given under sec-
16	tion 513, 514, or 515 of the Federal Food,
17	Drug, and Cosmetic Act.
18	"(B) PRODUCT.—The term 'product'
19	means any drug, biologic, or medical device.
20	"(3) QUALIFIED ACADEMIC INSTITUTION.—The
21	term 'qualified academic institution' means any of
22	the following institutions:
23	"(A) Educational institution.—A
24	qualified organization described in section
25	170(b)(1)(A)(iii) which is owned or affiliated

1	with an institution of higher education as de-
2	scribed in section 3304(f).
3	"(B) Teaching Hospital.—A teaching
4	hospital which—
5	"(i) is publicly supported or owned by
6	an organization described in section
7	501(c)(3), and
8	"(ii) is affiliated with an organization
9	meeting the requirements of subparagraph
10	(A).
11	"(C) FOUNDATION.—A medical research
12	organization described in section $501(c)(3)$
13	(other than a private foundation) which is affili-
14	ated with, or owned by—
15	"(i) an organization meeting the re-
16	quirements of subparagraph (A), or
17	"(ii) a teaching hospital meeting the
18	requirements of subparagraph (B).
19	"(D) Charitable Research Hos-
20	PITAL.—A hospital that is designated as a can-
21	cer center by the National Cancer Institute.
22	"(4) Exclusion for amounts funded by
23	GRANTS, ETC.—The term 'qualified medical innova-
24	tion expenses' shall not include any amount to the
25	extent such amount is funded by any grant, con-

- tract, or otherwise by another person (or any governmental entity).
- 3 "(e) Medical Innovation Base Period
- 4 Amount.—For purposes of this section, the term 'medical
- 5 innovation base period amount' means the average annual
- 6 qualified medical innovation expenses paid by the taxpayer
- 7 during the 3-taxable year period ending with the taxable
- 8 year immediately preceding the first taxable year of the
- 9 taxpayer beginning after December 31, 1998.
- 10 "(d) Special Rules.—
- "(1) Limitation on foreign testing.—No credit shall be allowed under this section with respect to any clinical testing research activities conducted outside the United States.
- 16 "(2) CERTAIN RULES MADE APPLICABLE.—
 Rules similar to the rules of subsections (f) and (g)
 of section 41 shall apply for purposes of this section.
 - "(3) Election.—This section shall apply to any taxpayer for any taxable year only if such taxpayer elects to have this section apply for such taxable year.
- "(4) COORDINATION WITH CREDIT FOR IN CREASING RESEARCH EXPENDITURES AND WITH
 CREDIT FOR CLINICAL TESTING EXPENSES FOR CER TAIN DRUGS FOR RARE DISEASES.—Any qualified

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- 1 medical innovation expense for a taxable year to
- 2 which an election under this section applies shall not
- 3 be taken into account for purposes of determining
- 4 the credit allowable under section 41 or 45C for
- 5 such taxable year.
- 6 "(e) TERMINATION.—This section shall not apply to
- 7 any expense paid or incurred after the date specified in
- 8 section 41(h)(1)(B).".
- 9 (b) Credit To Be Part of General Business
- 10 Credit.—
- 11 (1) IN GENERAL.—Section 38(b) of such Code
- 12 (relating to current year business credits) is amend-
- ed by striking "plus" at the end of paragraph (11),
- by striking the period at the end of paragraph (12)
- and inserting ", plus", and by adding at the end the
- 16 following:
- 17 "(13) the medical innovation expenses credit
- determined under section 41A(a).".
- 19 (2) Transition rule.—Section 39(d) of such
- 20 Code is amended by adding at the end the following
- 21 new paragraph:
- 22 "(9) No carryback of section 41A credit
- 23 BEFORE ENACTMENT.—No portion of the unused
- business credit for any taxable year which is attrib-
- 25 utable to the medical innovation credit determined

- 1 under section 41A may be carried back to a taxable
- 2 year beginning before January 1, 1999.".
- 3 (c) Denial of Double Benefit.—Section 280C of
- 4 such Code is amended by adding at the end the following
- 5 new subsection:
- 6 "(d) Credit for Increasing Medical Innova-
- 7 TION EXPENSES.—
- 8 "(1) In general.—No deduction shall be al-
- 9 lowed for that portion of the qualified medical inno-
- vation expenses (as defined in section 41A(b)) other-
- 11 wise allowable as a deduction for the taxable year
- which is equal to the amount of the credit deter-
- mined for such taxable year under section 41A(a).
- 14 "(2) CERTAIN RULES TO APPLY.—Rules similar
- to the rules of paragraphs (2), (3), and (4) of sub-
- section (c) shall apply for purposes of this sub-
- 17 section.".
- 18 (d) Deduction for Unused Portion of Cred-
- 19 IT.—Section 196(c) of such Code (defining qualified busi-
- 20 ness credits) is amended by resdesignating paragraphs (5)
- 21 through (8) as paragraphs (6) through (9), respectively,
- 22 and by inserting after paragraph (4) the following new
- 23 paragraph:
- 24 "(5) the medical innovation expenses credit de-
- termined under section 41A(a) (other than such

- 1 credit determined under the rules of section
- 2 280C(d)(2)),".
- 3 (e) Clerical Amendment.—The table of sections
- 4 for subpart D of part IV of subchapter A of chapter 1
- 5 of such Code is amended by adding after the item relating
- 6 to section 41 the following:

"Sec. 41A. Credit for medical innovation expenses.".

- 7 (f) Effective Date.—The amendments made by
- 8 this section shall apply to taxable years beginning after
- 9 December 31, 1998.

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