105TH CONGRESS 2D SESSION

H. R. 3815

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 HOUSE OF REPRESENTATIVES

May 7, 1998

Mr. Sam Johnson of Texas (for himself, Mr. Levin, Mr. English of Pennsylvania, Mr. Houghton, Mr. Price of North Carolina, Ms. Lofgren, Mr. Dooley of California, and Mr. Bentsen) introduced the following bill; which was referred to the Committee on Ways and Means

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) Charitable Research Hospital.—
4	A charitable research hospital which—
5	"(i) is owned by an organization de-
6	scribed in section $501(c)(3)$ and exempt
7	from taxation under section 501(a),
8	"(ii) is not a private foundation, and
9	"(iii) is designated as a cancer center
10	by the National Cancer Institute.
11	"(4) Exclusion for amounts funded by
12	GRANTS, ETC.—The term 'qualified medical innova-
13	tion expenses' shall not include any amount to the
14	extent such amount is funded by any grant, con-
15	tract, or otherwise by another person (or any gov-
16	ernmental entity).
17	"(c) Medical Innovation Base Period
18	Amount.—For purposes of this section, the term 'medical
19	innovation base period amount' means the average annual
20	qualified medical innovation expenses paid by the taxpayer
21	during the 3-taxable year period ending with the taxable
22	year immediately preceding the first taxable year of the
23	taxpayer beginning after December 31, 1997.
24	"(d) Special Rules.—

- 1 "(1) Limitation on foreign testing.—No 2 credit shall be allowed under this section with re-3 spect to any clinical testing research activities con-4 ducted outside the United States.
 - "(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 (at such time and in such manner as the Secretary may by regulation prescribe) to have this section apply for such taxable year.
- 13 "(4) Coordination with credit for in-14 CREASING RESEARCH EXPENDITURES AND WITH 15 CREDIT FOR CLINICAL TESTING EXPENSES FOR CER-16 TAIN DRUGS FOR RARE DISEASES.—Any qualified 17 medical innovation expense for a taxable year to 18 which an election under this section applies shall not 19 be taken into account for purposes of determining 20 the credit allowable under section 41 or 45C for 21 such taxable year."
- 22 (b) GENERAL BUSINESS CREDIT.—Section 38(b) of 23 the Internal Revenue Code of 1986 (relating to current 24 year business credit) is amended by striking "plus" at the 25 end of paragraph (11), by striking the period at the end

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- 1 of paragraph (12) and inserting ", plus", and by adding
- 2 at the end the following:
- 3 "(13) the medical innovation expenses credit
- 4 determined under section 41A(a)."
- 5 (c) Deduction for Unused Portion of Cred-
- 6 IT.—Section 196(c) of the Internal Revenue Code of 1986
- 7 (defining qualified business credits) is amended by strik-
- 8 ing "and" at the end of paragraph (6), by striking the
- 9 period at the end of paragraph (7) and inserting ", and",
- 10 and by adding at the end the following:
- 11 "(8) the medical innovation expenses credit de-
- termined under section 41A(a)."
- 13 (d) Conforming Amendment.—The table of sec-
- 14 tions for subpart D of part IV of subchapter A of chapter
- 15 1 of the Internal Revenue Code of 1986 is amended by
- 16 adding after the item relating to section 41 the following: "Sec. 41A. Credit for medical innovation expenses."
- 17 (e) Effective Date.—The amendments made by
- 18 this section shall apply to taxable years beginning after
- 19 December 31, 1997.

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