S. 362

To amend the Public Health Service Act to provide for a Pancreatic Cancer Initiative, and for other purposes.

IN THE SENATE OF THE UNITED STATES

February 16, 2011

Mr. Whitehouse (for himself, Mr. Kerry, Mr. Begich, Mr. Lugar, Ms. Collins, Mr. Inouye, and Mr. Brown of Ohio) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Public Health Service Act to provide for a Pancreatic Cancer Initiative, and for other purposes.

- 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; FINDINGS.
- 4 (a) Short Title.—This Act may be cited as the
- 5 "Pancreatic Cancer Research and Education Act".
- 6 (b) FINDINGS.—The Congress finds the following:
- 7 (1) More than 43,000 Americans were expected
- 8 to be diagnosed with pancreatic cancer in 2010 and
- 9 36,800 were expected to die from the disease. The

- 1 incidence among African-Americans is 40 to 50 per-2 cent higher than other ethnic groups.
 - (2) Pancreatic cancer is one of the few cancers for which survival has not improved substantially over the past 40 years. As a result, in 2003, pancreatic cancer surpassed prostate cancer as the 4th leading cause of cancer-related death in the United States.
 - (3) Seventy-five percent of pancreatic cancer patients die within the first 12 months of the diagnosis. The 5-year survival rate is only 6 percent.
 - (4) Scientific understanding of pancreatic cancer—its etiology, pathogenesis, detection, and treatment—lags far behind that of most other forms of cancer. In fact, pancreatic cancer is the only of the top 10 cancer killers in the United States that still has a 5-year survival rate in the single digits.
 - (5) In 2001, the National Cancer Institute developed "Pancreatic Cancer: An Agenda for Action". As of 2010, only five of the report's 39 recommendations have been implemented because of a lack of funding, focus, and commitment. In the meantime, pancreatic cancer deaths have continued to increase. Further, according to the "Cancer Trends Progress Report–2009/2010 Update", death rates for pan-

- creatic cancer are increasing while death rates for all cancers combined, including the four most common cancers (prostate, breast, lung, and colorectal), continue to decline.
 - (6) Pancreatic cancer constitutes 2 percent of the National Cancer Institute's Federal research funding, a figure far too low given the severity of the disease, its mortality rate, and how little is known about how to arrest the disease.
 - (7) Of the more than 6,200 research grants awarded in fiscal year 2009 by the National Cancer Institute, only 272 (approximately 4 percent) were categorized by the Institute as at least 50 percent relevant to pancreatic cancer research.
 - (8) The future supply of scientists entering this field of study is in serious jeopardy. Training grant (F, K, and T awards) funding in pancreatic cancer decreased by 15 percent from 2008 to 2009, a decline larger than any of the other leading cancers experienced. Pancreatic cancer trainees were awarded between 2.4- and 6.5-fold less grant money in 2009 than young researchers studying the other four top cancer killers.
 - (9) In 2007, the Scientific Advisory Board of the Pancreatic Cancer Action Network reviewed the

1	current state of the science and the Federal Govern-
2	ment's efforts on pancreatic cancer research and
3	prepared "The National Plan to Advance Pancreatic
4	Cancer Research" to identify the highest research
5	priorities, scientific infrastructure needs, and work-
6	force training requirements that are needed to pro-
7	vide the answers that pancreatic cancer patients and
8	their families and loved ones so desperately need.
9	SEC. 2. PANCREATIC CANCER INITIATIVE.
10	Part B of title III of the Public Health Service Act
11	(42 U.S.C. 243 et seq.) is amended by adding at the end
12	the following:
13	"SEC. 320B. PANCREATIC CANCER INITIATIVE.
14	"(a) Pancreatic Cancer Initiative.—
15	"(1) Establishment.—The Secretary shall es-
16	tablish and implement a Pancreatic Cancer Initiative
17	to assist in coordinating activities to address the
18	high mortality rate associated with pancreatic can-
19	cer. Such Initiative shall focus on—
20	"(A) advancing research on the causes, di-
21	agnosis, and treatment of pancreatic cancer
22	with the goal of increasing the 5-year survival
23	rate;

1	"(B) promoting a cadre of new investiga-
2	tors in the field of pancreatic cancer research;
3	and
4	"(C) increasing physician and public
5	awareness of pancreatic cancer.
6	"(2) Consultation.—In carrying out this sub-
7	section, the Secretary shall consult with the Director
8	of the National Institutes of Health, the Director of
9	the National Cancer Institute, the Director of the
10	Centers of Disease Control and Prevention, and the
11	Interdisciplinary Pancreatic Cancer Coordinating
12	Committee established under subsection (b).
13	"(b) Interdisciplinary Pancreatic Cancer Co-
14	ORDINATING COMMITTEE.—
15	"(1) Establishment.—Not later than 60 days
16	after the date of the enactment of this section, the
17	Secretary, in consultation with the Director of the
18	National Institutes of Health, shall establish a com-
19	mittee to be known as the Interdisciplinary Pan-
20	creatic Cancer Coordinating Committee (in this sub-
21	section referred to as the 'Committee').
22	"(2) Membership.—
23	"(A) IN GENERAL.—The members of the
24	Committee shall be appointed by the Secretary,
25	in consultation with the Director of the Na-

1	tional Institutes of Health, and shall consist of
2	13 individuals as follows:
3	"(i) Nine experts in pancreatic cancer
4	research, who are each a full professor at
5	a major academic research institution and
6	who have each received multiple grants
7	from the National Cancer Institute or
8	other entities of the National Institutes of
9	Health with a primary focus on pancreatic
10	cancer research.
11	"(ii) Two new principal investigators
12	in pancreatic cancer, who are each an as-
13	sistant-level professor in a major academic
14	research institution and who have each re-
15	ceived at least one grant from the National
16	Cancer Institute or another entity of the
17	National Institutes of Health with a pri-
18	mary focus in pancreatic cancer research.
19	"(iii) One pancreatic cancer advocate.
20	"(iv) The Director of the National
21	Cancer Institute (or the Director's des-
22	ignee).
23	"(B) Chair.—The Secretary shall des-
24	ignate the Chair of the Committee from among
25	its members.

1	"(C) Duplication of Market
1	"(C) Publication of Names.—Not later
2	than 30 days after the establishment of the
3	Committee, the Secretary shall publish the
4	names of the Chair and members of the Com-
5	mittee on the Web site of the Department of
6	Health and Human Services.
7	"(D) Terms.—The members of the Com-
8	mittee shall each be appointed for a 3-year term
9	and, at the end of each such term, may be re-
10	appointed.
11	"(E) VACANCIES.—A vacancy on the Com-
12	mittee shall be filled by the Secretary in the
13	same manner in which the original appointment
14	was made.
15	"(3) Responsibilities.—The Committee
16	shall—
17	"(A) provide advice on overall research ob-
18	jectives and benchmarks for pancreatic cancer
19	research;
20	"(B) not later than 6 months after the es-
21	tablishment of the Committee, and every 5
22	years thereafter, develop a strategic plan in ac-
23	cordance with paragraph (4) for the conduct
24	and support of pancreatic cancer research and

1	awareness during the upcoming 5-year period;
2	and
3	"(C) conduct evaluations and make rec-
4	ommendations to the Secretary, the Director of
5	the National Institutes of Health, and the Di-
6	rector of the National Cancer Institute in ac-
7	cordance with paragraph (5) regarding the
8	prioritization and award of National Institutes
9	of Health research grants relating to pancreatic
10	cancer.
11	"(4) Strategic plan.—
12	"(A) DEVELOPMENT.—Not later than 6
13	months after the establishment of the Com-
14	mittee, and every 5 years thereafter, the Com-
15	mittee shall develop a strategic plan for the
16	conduct and support of pancreatic cancer re-
17	search and awareness during the upcoming 5-
18	year period.
19	"(B) Submission.—The Committee
20	shall—
21	"(i) submit to the Secretary each stra-
22	tegic plan developed under subparagraph
23	(A) for the upcoming 5-year period; and
24	"(ii) publish each such plan on the
25	Web site of the Department of Health and

1	Human Services within 30 days after the
2	date of submission of the plan to the Sec-
3	retary under clause (i).
4	"(C) Contents.—Each strategic plan de-
5	veloped under subparagraph (A) shall include—
6	"(i) recommended budgetary require-
7	ments for pancreatic cancer research, in-
8	cluding research grants awarded through
9	the National Cancer Institute, funding for
10	Specialized Programs of Research Excel-
11	lence (SPORE) that are focused on pan-
12	creatic cancer, and funding for the portion
13	of the cancer research incubator pilot
14	project established by section 409J(a) that
15	is focused on pancreatic cancer;
16	"(ii) recommendations on the coordi-
17	nation of extramural and intramural pan-
18	creatic cancer research initiatives and pos-
19	sibilities for partnerships among the na-
20	tional research institutes, including the
21	National Cancer Institute, the National In-
22	stitute of Diabetes and Digestive and Kid-
23	ney Diseases, the National Institute of En-
24	vironmental Health Sciences, the National
25	Center for Complementary and Alternative

1	Medicine, and the National Center on Mi-
2	nority Health and Health Disparities;
3	"(iii) recommendations for improving
4	physician and public education about pan-
5	creatic cancer;
6	"(iv) recommendations for increasing
7	the number of scientists with doctorate de-
8	grees and clinician-scientists specializing in
9	pancreatic cancer research; and
10	"(v) guidelines for information gath-
11	ered by pancreatic cancer patient registries
12	and tissue banks to ensure uniformity and
13	accessibility to the research community.
14	"(5) Prioritization and award of Nih Re-
15	SEARCH GRANTS.—
16	"(A) In General.—The Committee shall
17	conduct evaluations and make recommendations
18	as needed to the Secretary, the Director of the
19	National Institutes of Health, and the Director
20	of the National Cancer Institute regarding the
21	prioritization and award of National Institutes
22	of Health research grants relating to pancreatic
23	cancer.
24	"(B) Peer review committee.—In car-
25	rying out subparagraph (A), the Committee

1	may appoint a peer review committee to assist
2	in the evaluation of pancreatic cancer grant ap-
3	plications to ensure that such applications are
4	reviewed by individuals with the appropriate ex-
5	pertise.
6	"(C) Evaluation.—In evaluating pan-
7	creatic cancer grant applications under sub-
8	paragraph (A), the Committee shall emphasize
9	grants that achieve at least one of the following
10	goals:
11	"(i) The grant is determined to be
12	predominantly relevant to pancreatic can-
13	cer research and has a primary focus on at
14	least one of the following areas:
15	"(I) Basic research to advance
16	the understanding of the biology of
17	pancreatic cancer, its natural history,
18	and the genetic and environmental
19	factors that contribute to its develop-
20	ment.
21	"(II) Research on more precise
22	diagnostic methods and screening to
23	detect pancreatic cancer in earlier
24	stages.

1	"(III) Advanced innovative clin-
2	ical trials testing targeted thera-
3	peutics and novel agents that will ex-
4	tend the survival of pancreatic cancer
5	patients and improve their quality of
6	life.
7	"(ii) The grant will increase the num-
8	ber of new pancreatic cancer investigators.
9	"(iii) The grant will meet identified
10	needs, criteria, or specific research goals
11	set forth in the strategic plan developed
12	under paragraph (3)(B).
13	"(D) RECOMMENDATIONS.—The Com-
14	mittee shall make recommendations for excep-
15	tion funding for grant applications that—
16	"(i) are predominantly relevant to
17	pancreatic cancer; and
18	"(ii) score within 10 points of the
19	payline.
20	"(c) Physician Awareness.—
21	"(1) Program.—The Secretary, in consultation
22	with the Director of the National Institutes of
23	Health, the Director of the Centers for Disease Con-
24	trol and Prevention, and relevant patient advocate
25	and physician organizations, shall develop a primary

1	care provider education program on pancreatic can-
2	cer. The Secretary may include in such program ac-
3	credited continuing medical education and such
4	other activities as the Secretary determines appro-
5	priate.
6	"(2) Definition.—The term 'relevant patient
7	advocate and physician organization' means a na-
8	tionwide organization that—
9	"(A) provides evidence-based disease infor-
10	mation to the public in a case management
11	style;
12	"(B) directly funds research in an unbi-
13	ased manner by working collaboratively with
14	health professionals at a variety of institutions
15	and using a peer-reviewed process;
16	"(C) advocates public policy outcomes that
17	reflect the needs of patients; and
18	"(D) provides information to patients,
19	families, and health professionals at the com-
20	munity level.
21	"(d) COMMUNICATION TOOL KIT.—The Director of
22	the National Cancer Institute and the Director of the Cen-
23	ters for Disease Control and Prevention, working collabo-
24	ratively with patient advocate organizations, shall develop
25	a communication tool kit for patients and their families

- 1 that focuses on specific pancreatic cancer issues related
- 2 to patient choices and patient care.
- 3 "(e) Report to Congress.—Not later than 1 year
- 4 after the date of the enactment of this section, and annu-
- 5 ally thereafter, the Secretary shall submit a report to the
- 6 Congress identifying the steps taken to implement the
- 7 Pancreatic Cancer Initiative under subsection (a). The re-
- 8 port shall include—
- 9 "(1) an assessment of the progress in improv-
- ing outcomes and reducing mortality rates for those
- diagnosed with pancreatic cancer;
- "(2) an explanation of how recommendations of
- the Interdisciplinary Pancreatic Cancer Coordinating
- 14 Committee in the strategic plan developed under
- subsection (b)(3)(B) for the preceding year have
- been implemented;
- 17 "(3) a summary of the recommendations that
- were made by the Interdisciplinary Pancreatic Can-
- cer Coordinating Committee for grant funding, in-
- cluding exception funding, the number of such rec-
- ommendations that were met, and the reasons why
- any recommendations were not met;
- 23 "(4) a breakdown of research grant award
- amounts by the National Institutes of Health during
- 25 the past year that are deemed relevant to pancreatic

1	cancer research along with a quantifiable measure as
2	to the relevancy of the grants to pancreatic cancer
3	"(5) the number of such grants awarded to new
4	principal investigators in pancreatic cancer described
5	in subsection (b)(2)(A)(ii); and
6	"(6) a summary of progress and deficiencies
7	that were noted in pancreatic cancer research during
8	the preceding year.
9	"(f) Authorization of Appropriations.—There
10	are authorized to be appropriated—
11	"(1) to carry out subsection (a), \$140,000,000
12	for fiscal year 2012 and such sums as may be nec-
13	essary for fiscal years 2013 through 2016;
14	"(2) to carry out subsection (c), \$2,000,000 for
15	fiscal year 2012 and such sums as may be necessary
16	for fiscal years 2013 through 2016; and
17	"(3) to carry out subsection (d), \$2,000,000 for
18	fiscal year 2012 and such sums as may be necessary
19	for fiscal years 2013 through 2016.".
20	SEC. 3. NATIONAL INSTITUTES OF HEALTH RESEARCH.
21	Part B of title IV of the Public Health Service Act
22	(42 U.S.C. 284 et seq.) is amended by adding at the end
23	the following:

1 "SEC. 409J. CANCER RESEARCH.

2	"(a) Cancer Research Incubator Pilot
3	Project.—
4	"(1) Grants.—
5	"(A) IN GENERAL.—The Secretary may
6	award grants to research institutions for use in
7	developing innovative compounds or tech-
8	nologies for the prevention, early detection, or
9	treatment of those cancers with 5-year survival
10	rates of less than 50 percent.
11	"(B) Relation to other nih grants.—
12	Subject to subparagraph (A), the Secretary
13	shall encourage each recipient of a grant under
14	this section to use the grant for research activi-
15	ties that may serve as a springboard for the re-
16	ceipt of other grants, including Specialized Pro-
17	grams of Research Excellence (SPORE) grants,
18	from the National Institutes of Health and its
19	national research institutes.
20	"(2) Grant Period.—The period of a grant
21	under this section shall be 5 years.
22	"(3) Focus.—During the initial 5 fiscal years
23	of carrying out this section, the Secretary shall focus
24	on awarding grants for use in developing innovative
25	compounds or technologies for the prevention, early
26	detection, or treatment of pancreatic cancer.

1 "(4) REPORT.—Not later than 5 years after the 2 date of the enactment of this section, the Secretary 3 shall submit a report to the Congress evaluating the 4 program under this section and making rec-5 ommendations for expansion of the program to other 6 cancers.

"(5) AUTHORIZATION OF APPROPRIATIONS.—
To carry out this subsection, there are authorized to be appropriated \$5,000,000 for fiscal year 2012 and such sums as may be necessary for fiscal years 2013 through 2016.

"(b) Centers of Excellence.—

- "(1) Designation.—The Secretary may designate two additional Specialized Programs of Research Excellence (SPOREs) focusing solely on pancreatic cancer research. In carrying out this paragraph, the Secretary may choose to designate one or more satellite centers that augment the work of a previously designated Specialized Program of Research Excellence.
- "(2) AUTHORIZATION OF APPROPRIATIONS.—
 To carry out this subsection, there are authorized to be appropriated \$20,000,000 for fiscal year 2012

- 1 and such sums as may be necessary for fiscal years
- 2 2013 through 2016.".

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