111TH CONGRESS 2D SESSION

# S. 3320

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

May 6, 2010

Mr. Whitehouse 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) Nearly 42,500 Americans were expected to
- 8 be diagnosed with pancreatic cancer in 2009 and
- 9 nearly 35,250 were expected to die from the disease.

- The incidence among African-Americans is 40 to 50 percent 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-six percent of pancreatic cancer patients die within the first 12 months of the diagnosis. The 5-year survival rate is 5 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 research is where breast cancer research was in the 1930s—little understanding of the causes, no early detection, few effective treatments, and single-digit survival rates.
    - (5) In 2001, the National Cancer Institute developed "Pancreatic Cancer: An Agenda for Action". Nine years later, 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 death rates have continued to increase. Further, according to the Cancer

- Trends Progress Report—2009/2010 Update, death rates for pancreatic 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 research constitutes less than 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 5,000 research grants awarded annually by the Nations Cancer Institute in 2006, only 134 (approximately 3 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. Out of the researchers who received National Cancer Institute funding specifically for pancreatic cancer research in 2008, only 38 received funding totaling \$500,000 or more, a level appropriate for senior scientists. By comparison, this level of funding was awarded to 273 breast cancer researchers, 129 prostate cancer researchers, and 121 colorectal cancer researchers. Further, in the last 3 years, the National Cancer In-

- stitute has awarded only 5 grants for training and supporting new principal investigators in pancreatic cancer.
- (9) In 2007, the Scientific Advisory Board of the Pancreatic Cancer Action Network reviewed the 5 6 current state of the science and the Federal Govern-7 ment's efforts on pancreatic cancer research and prepared "The National Plan to Advance Pancreatic 8 9 Cancer Research" to identify the highest research 10 priorities, scientific infrastructure needs, and work-11 force training requirements that are needed to pro-12 vide the answers that pancreatic cancer patients and 13 their families and loved ones so desperately need.

#### 14 SEC. 2. PANCREATIC CANCER INITIATIVE.

- Part B of title III of the Public Health Service Act 16 (42 U.S.C. 243 et seq.) is amended by adding at the end 17 the following:
- 18 "SEC. 320B. PANCREATIC CANCER INITIATIVE.
- "(a) PANCREATIC CANCER INITIATIVE.—
- "(1) ESTABLISHMENT.—The Secretary shall establish and implement a Pancreatic Cancer Initiative to assist in coordinating activities to address the high mortality rate associated with pancreatic cancer. Such Initiative shall focus on—

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

1	"(2) Membership.—
2	"(A) In general.—The members of the
3	Committee shall be appointed by the Secretary,
4	in consultation with the Director of the Na-
5	tional Institutes of Health, and shall consist of
6	13 individuals as follows:
7	"(i) Nine experts in pancreatic cancer
8	research, who are each a full professor at
9	a major academic research institution and
10	who have each received multiple grants
11	from the National Cancer Institute or
12	other entities of the National Institutes of
13	Health with a primary focus on pancreatic
14	cancer research.
15	"(ii) Two young principal investiga-
16	tors in pancreatic cancer, who are each an
17	assistant-level professor in a major aca-
18	demic research institution and who have
19	each received at least one grant from the
20	National Cancer Institute or another entity
21	of the National Institutes of Health with a
22	primary focus in pancreatic cancer re-
23	search.
24	"(iii) One pancreatic cancer advocate.

1	"(iv) The Director of the National
2	Cancer Institute (or the Director's des-
3	ignee).
4	"(B) Chair.—The Secretary shall des-
5	ignate the Chair of the Committee from among
6	its members.
7	"(C) Publication of Names.—Not later
8	than 30 days after the establishment of the
9	Committee, the Secretary shall publish the
10	names of the Chair and members of the Com-
11	mittee on the Website of the Department of
12	Health and Human Services.
13	"(D) Terms.—The members of the Com-
14	mittee shall each be appointed for a 3-year term
15	and, at the end of each such term, may be re-
16	appointed.
17	"(E) VACANCIES.—A vacancy on the Com-
18	mittee shall be filled by the Secretary in the
19	same manner in which the original appointment
20	was made.
21	"(3) RESPONSIBILITIES.—The Committee
22	shall—
23	"(A) provide advice on overall research ob-
24	jectives and benchmarks for pancreatic cancer
25	research;

1	"(B) develop and annually update a stra-
2	tegic plan in accordance with paragraph (4) for
3	the conduct and support of pancreatic cancer
4	research awareness during the upcoming year
5	and
6	"(C) conduct evaluations and make rec-
7	ommendations to the Secretary, the Director of
8	the National Institutes of Health, and the Di-
9	rector of the National Cancer Institute in ac-
10	cordance with paragraph (5) regarding the
11	prioritization and award of National Institutes
12	of Health research grants relating to pancreation
13	cancer.
14	"(4) Strategic plan.—
15	"(A) DEVELOPMENT.—The Committee
16	shall develop and annually update a strategic
17	plan for the conduct and support of pancreation
18	cancer research and awareness during the up-
19	coming fiscal year.
20	"(B) Submission.—The Committee
21	shall—
22	"(i) submit to the Secretary each stra-
23	tegic plan developed under subparagraph
24	(A) for the upcoming fiscal year; and

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

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

1	prioritization and award of National Institutes
2	of Health research grants relating to pancreatic
3	cancer.
4	"(B) Peer review committee.—In car-
5	rying out subparagraph (A), the Committee
6	may appoint a peer review committee to assist
7	in the evaluation of pancreatic cancer grant ap-
8	plications to ensure that such applications are
9	reviewed by individuals with the appropriate ex-
10	pertise.
11	"(C) Evaluation.—In evaluating pan-
12	creatic cancer grant applications under sub-
13	paragraph (A), the Committee shall emphasize
14	grants that achieve at least one of the following
15	goals:
16	"(i) The grant is determined to be at
17	least 75 percent relevant to pancreatic can-
18	cer research and has a primary focus on at
19	least one of the following areas:
20	"(I) Basic research to advance
21	the understanding of the biology of
22	pancreatic cancer, its natural history,
23	and the genetic and environmental
24	factors that contribute to its develop-
25	ment.

1	"(II) Research on more precise
2	diagnostic methods and screening to
3	detect pancreatic cancer in earlier
4	stages.
5	"(III) Advanced innovative clin-
6	ical trials testing targeted thera-
7	peutics and novel agents that will ex-
8	tend the survival of pancreatic cancer
9	patients and improve their quality of
10	life.
11	"(ii) The grant will increase the num-
12	ber of young pancreatic cancer investiga-
13	tors.
14	"(iii) The grant will meet identified
15	needs, criteria, or specific research goals
16	set forth in the strategic plan developed
17	under paragraph (3)(B).
18	"(D) RECOMMENDATIONS.—The Com-
19	mittee shall make recommendations for excep-
20	tion funding for grant applications that—
21	"(i) have 75 percent or greater rel-
22	evance to pancreatic cancer; and
23	"(ii) score within 10 points of the
24	payline.
25	"(c) Physician Awareness.—

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

1	"(d) COMMUNICATION TOOL KIT.—The Director of
2	the National Institutes of Health and the Director of the
3	Centers for Disease Control and Prevention, working col-
4	laboratively with patient advocate organizations, shall de-
5	velop a communication tool kit for patients and their fami-
6	lies that focuses on specific pancreatic cancer issues re-
7	lated to patient choices and patient care.
8	"(e) Report to Congress.—Not later than 1 year
9	after the date of the enactment of this section, and annu-
10	ally thereafter, the Secretary shall submit a report to the
11	Congress identifying the steps taken to implement the
12	Pancreatic Cancer Initiative under subsection (a). The re-
13	port shall include—
14	"(1) an assessment of the progress in improv-
15	ing outcomes and reducing mortality rates for those
16	diagnosed with pancreatic cancer;
17	"(2) an explanation of how recommendations of
18	the Interdisciplinary Pancreatic Cancer Coordinating
19	Committee in the strategic plan developed under
20	subsection (b)(3)(B) for the preceding year have
21	been implemented;
22	"(3) a summary of the recommendations that
23	were made by the Interdisciplinary Pancreatic Can-
24	cer Coordinating Committee for grant funding, in-

cluding exception funding, the number of such rec-

1	ommendations that were met, and the reasons why
2	any recommendations were not met;
3	"(4) a breakdown of research grant award
4	amounts by the National Institutes of Health during
5	the past year that are deemed relevant to pancreatic
6	cancer research along with a quantifiable measure as
7	to the relevancy of the grants to pancreatic cancer;
8	"(5) the number of such grants awarded to
9	young principal investigators in pancreatic cancer
10	described in subsection (b)(2)(A)(ii); and
11	"(6) a summary of progress and deficiencies
12	that were made in pancreatic cancer research during
13	the preceding year.
14	"(f) AUTHORIZATION OF APPROPRIATIONS.—There
15	are authorized to be appropriated—
16	"(1) to carry out subsection (a), \$140,000,000
17	for fiscal year 2011 and such sums as may be nec-
18	essary for fiscal years 2012 through 2015;
19	"(2) to carry out subsection (c), \$2,000,000 for
20	fiscal year 2011 and such sums as may be necessary
21	for fiscal years 2012 through 2015; and
22	"(3) to carry out subsection (d), \$2,000,000 for
23	fiscal year 2011 and such sums as may be necessary
24	for fiscal years 2012 through 2015.".

#### 1 SEC. 3. NATIONAL INSTITUTES OF HEALTH RESEARCH.

- 2 Part B of title IV of the Public Health Service Act
- 3 (42 U.S.C. 284 et seq.) is amended by adding at the end
- 4 the following:
- 5 "SEC. 409J. CANCER RESEARCH.
- 6 "(a) Cancer Research Incubator Pilot
- 7 Project.—
- 8 "(1) Grants.—
- 9 "(A) IN GENERAL.—The Secretary may 10 award grants to research institutions for use in
- developing innovative compounds or tech-
- nologies for the prevention, early detection, or
- treatment of those cancers with 5-year survival
- rates of less than 50 percent.
- 15 "(B) Relation to other nih grants.—
- Subject to subparagraph (A), the Secretary
- shall encourage each recipient of a grant under
- this section to use the grant for research activi-
- ties that may serve as a springboard for the re-
- 20 ceipt of other grants, including Specialized Pro-
- 21 grams of Research Excellence (SPORE) grants,
- from the National Institutes of Health and its
- 23 national research institutes.
- 24 "(2) Grant Period.—The period of a grant
- under this section shall be 5 years.

- 1 "(3) Focus.—During the initial 5 fiscal years 2 of carrying out this section, the Secretary shall focus 3 on awarding grants for use in developing innovative 4 compounds or technologies for the prevention, early 5 detection, or treatment of pancreatic cancer.
  - "(4) Report.—Not later than 5 years after the date of the enactment of this section, the Secretary shall submit a report to the Congress evaluating the program under this section and making recommendations for expansion of the program to other cancers.
  - "(5) AUTHORIZATION OF APPROPRIATIONS.—
    To carry out this subsection, there are authorized to be appropriated \$5,000,000 for fiscal year 2011 and such sums as may be necessary for fiscal years 2012 through 2015.

### "(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.

1	"(2) Authorization of appropriations.—
2	To carry out this subsection, there are authorized to
3	be appropriated \$20,000,000 for fiscal year 2011
4	and such sums as may be necessary for fiscal years
5	2012 through 2015.".

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