THE RECALCITRANT CANCER RESEARCH ACT
AN IMPORTANT STEP TOWARD IMPROVING PANCREATIC CANCER SURVIVAL

PANCREATIC CANCER ACTION NETWORK®

Thanks to broad bipartisan and bicameral support, the Recalcitrant Cancer Research Act was signed into law on January 2, 2013, as part of the National Defense Authorization Act. The bill was originally introduced as the Pancreatic Cancer Research & Education Act by Representatives Anna Eshoo (D-CA), Leonard Lance (R-NJ) and Senator Sheldon Whitehouse (D-RI) and was co-sponsored by 59 senators and 295 representatives at the time of passage. The Act calls on the National Cancer Institute (NCI) to develop scientific frameworks, similar to strategic plans, for pancreatic and lung cancers and provides the NCI director with the authority to develop frameworks for other deadly cancers. These scientific frameworks will help provide the strategic direction and guidance needed to make true progress against recalcitrant, or deadliest cancers, which are defined by the statute as those with a five-year relative survival rate below 50 percent. In addition to pancreatic and lung cancers, some of the other cancers included in this definition include: brain, esophageal, liver, ovarian, and stomach. The NCI released the" Scientific Framework for Pancreatic Ductal Adenocarcinoma" in February 2014 and the scientific framework for small-cell lung cancer in July 2014.

THE SCIENTIFIC FRAMEWORKS PROVIDE CRITICAL STRATEGIC DIRECTION FOR RESEARCH ON OUR NATION'S DEADLIEST CANCERS

Until the Recalcitrant Cancer Research Act was passed, there was no national strategic plan for addressing our nation's deadliest cancers. However, when fully implemented, the statute will provide that much-needed strategic guidance and also provides the accountability and congressional oversight to ensure that the resulting research stays on target. Under the statute:

- Each scientific framework is required to include a review of the literature and promising advances, examine the number of researchers investigating the cancer, identify opportunities for coordinating NCI-funded research with research at other private and public entities, and identify public and private resources that can facilitate research into each particular recalcitrant cancer.
- The scientific frameworks are required to identify questions relating to basic, translational and clinical research that still need to be answered, to make "recommendations for appropriate actions" to address these questions, and to advance research in the prevention, diagnosis and treatment of each cancer. The statute also requires that the frameworks include "appropriate benchmarks to measure progress on achieving such actions," including ensuring adequate availability of researchers, promoting and developing initiatives and partnerships, and developing additional public and private resources.
- The steps taken to carry out the scientific frameworks are to be identified in the National Institutes of Health's (NIH) biennial report to Congress, including research grants awarded by the NIH, progress made in improving patient outcomes, such as relative survival rates, and updates on activities. The NIH's 2016 biennial report included a report on activities from FY2012-2013. Their 2018 report will show what progress has been made on the frameworks.
- The pancreatic and lung cancer frameworks are to be reviewed and updated by 2019. By July 2020, the NCI director must submit a report to Congress on the effectiveness of the frameworks on pancreatic and lung cancers in improving the prevention, detection, diagnosis and treatment of these cancers.
- The statute also requires the NCI director to consider the frameworks' recommendations when making decisions about exception funding.

WITH THIS ACT, CONGRESS HAS PROVIDED HOPE

The original underlying bill had overwhelming bipartisan support, acknowledging the need for a greater research focus on pancreatic cancer and other deadly cancers.

- Pancreatic cancer is one of the deadliest cancers. Of the major cancers, pancreatic cancer has the lowest five-year relative survival rate, currently 9 percent.[1,2]
- Pancreatic ductal adenocarcinoma, the subject of the 2014 scientific framework, accounts for 94 percent of pancreatic cancer cases.[1]
- In 2016, pancreatic cancer surpassed breast cancer as the third-leading cause of cancer death in the U.S.
- A report published in *Cancer Research* in 2014 predicted the shift mentioned above, and the authors further project that pancreatic cancer will surpass colorectal cancer to become the second leading cause of cancer-related death around 2020.[3]
- The same report predicts that by 2030, the top five cancer killers in the U.S. will be lung, pancreatic, liver, colorectal and breast – a significant shift from the ranking of lung, colorectal, breast, pancreatic and prostate at the time of publication.3 Lung, pancreatic and liver cancers are all considered to be deadly, or recalcitrant, cancers under the Recalcitrant Cancer Research Act. Their expected rise in the rankings of cancer killers underscores the need for a greater federal research investment to prevent these predictions from coming true.

Sources for statistics:
1. American Cancer Society. Cancer Facts & Figures 2017. Atlanta: American Cancer Society; 2017.
2. "Major cancer" is defined as one tracked by both the American Cancer Society and the National Cancer Institute.
3. Rahib L, Smith BD, Aizenberg R, Rosenzweig AB, Fleshman JM, Matrisian LM. Projecting Cancer Incidence and Deaths to 2030: The Unexpected Burden of Thyroid, Liver, and Pancreas Cancers in the United States. *Cancer Res.*, 2014; 74(11):2913-2921.

THE STATUTE HAS CREATED A PATH FOR PROGRESS IN PANCREATIC CANCER RESEARCH

The scientific framework for pancreatic cancer was built upon a report that the NCI released in June 2013 called "Pancreatic Cancer: Scanning the Horizon for Focused Interventions." The Horizon Scan report proposed four specific initiatives for advancing pancreatic cancer research. The framework expands on these recommendations by providing specific suggestions for moving forward for each one. Over the last three years since the Framework was first released, the NCI has made important progress on the four key recommendations detailed below and has taken specific steps toward implementing them.

UNDERSTANDING THE BIOLOGICAL RELATIONSHIP BETWEEN PANCREATIC CANCER AND DIABETES

The NCI and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), with added support from the Pancreatic Cancer Action Network, sponsored a meeting in June 2013 that gave rise to a request for grant applications (RFA) to create a new research consortium. The NCI and NIDDK created the Consortium to Study Chronic Pancreatitis, Diabetes and Pancreatic Cancer (CPDPC) and in September 2015, 10 clinical centers were selected and approved for funding. The CPDPC is meeting regularly, and one of their major projects is the development of a cohort of new-onset diabetics for the purpose of validating assays for the early detection of pancreatic cancer.

EVALUATING SCREENING PROTOCOLS FOR BIOMARKERS FOR EARLY DETECTION

In June 2015, the NCI issued a Program Announcement inviting multidisciplinary teams to submit proposals aimed at establishing the Pancreatic Cancer Detection Consortium to improve early detection and characterization of precursor lesions. Applications are due between November 2015 and April 2018, and the first round of recipients have been announced. The NCI held a meeting in December 2016 to coordinate efforts between several NIH programs designed to identify biomarkers for the early detection of pancreatic cancer.

STUDYING NEW STRATEGIES IN IMMUNOTHERAPY

In December 2016, the NCI released a Request for Applications to support a consortium of up to five institutions to work collaboratively to advance this field and conduct clinical and pre-clinical research to identify new immunotherapies for the treatment of pancreatic cancer.

DEVELOPING NEW TREATMENT APPROACHES THAT INTERFERE WITH RAS ONCOGENE-DEPENDENT SIGNALING PATHWAYS

In 2013, the NCI launched the RAS Initiative with significant funding attached. The project has the potential to increase the survival rate for pancreatic cancer as well as for other forms of cancer that are driven by RAS. The initiative has boosted scientific momentum and collaboration. Since 2015, the Pancreatic Cancer Action Network has partnered with the NCI Frederick National Laboratory for Cancer Research, the hub of the RAS Initiative, to award fellowships to outstanding young scientists who are studying KRAS in pancreatic cancer. As part of this unique public-private partnership, our grantees travel to Frederick to conduct novel KRAS research, gaining unparalleled mentorship from experts and training on cutting-edge technologies.

WHAT WE ARE ASKING FROM CONGRESS

The Recalcitrant Cancer Research Act and the NCI's scientific framework on pancreatic ductal adenocarcinoma are important milestones toward improving survival rates. While the NCI continues its work to fully implement the original recommendations of the first scientific framework, there is significant urgency to build on this foundation to further accelerate progress and reach our goal to double patient survival by 2020. We therefore call on Congress to ensure that the NCI and the National Institutes of Health (NIH) have the necessary resources to aid in the discovery of better treatments and early detection tools that will improve pancreatic cancer survival. Further, we recognize that the five-year update to the framework required by the statute is due in 2019 and therefore call on the NCI to begin those discussions as soon as possible.

THE PANCREATIC CANCER ACTION NETWORK CALLS ON THE 115TH CONGRESS AND THE ADMINISTRATION TO WAGE HOPE BY:

- Supporting $36.2 billion for the National Institutes of Health (NIH) in FY2018, including $6 billion for the National Cancer Institute (NCI) and the funding provided from the 21st Century Cures Act.
- Continuing to include pancreatic cancer in the Department of Defense's Peer Reviewed Cancer Research Program (PRCRP) and providing a funding increase for the program above the FY2017 level.
- Supporting a strong federal commitment to those suffering from the deadliest cancers — defined by the Recalcitrant Cancer Research Act of 2012 as cancers with five-year survival rates below 50 percent — by joining the Congressional Caucus on the Deadliest Cancers, and by ensuring that there are no lapses or reductions in health coverage for this critical population.
- Continuing to monitor the implementation of the Recalcitrant Cancer Research Act — legislation that is opening new avenues of NCI-supported research for pancreatic cancer.

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