THE PANCREATIC CANCER ACTION NETWORK CALLS ON THE 114TH CONGRESS TO WAGE HOPE BY:

• Supporting a budget agreement or other legislation that provides the National Institutes of Health (NIH) with $33 billion for FY 2016, including a proportional $5.4 billion for the National Cancer Institute (NCI), and puts the NIH on a sustainable path for long-term growth

• Continuing to include pancreatic cancer in the Department of Defense Peer Reviewed Cancer Research Program and providing at least the FY 2015 funding level of $50 million

• Joining the bicameral Congressional Caucus on the Deadliest Cancers

PANCREATIC CANCER IS ONE OF THE DEADLIEST CANCERS

• Pancreatic cancer is the 4th leading cause of cancer-related death for both men and women in the United States, and it is the 11th most commonly diagnosed cancer in men and the 8th in women.*

• It is estimated that in 2015, 48,960 Americans will be diagnosed with pancreatic cancer, and 40,560 will die from the disease. Seventy-two percent of patients will die within the first year of diagnosis.

• Pancreatic cancer is the only major cancer with a 5-year relative survival rate in the single digits, at just 7 percent.

• African-Americans have the highest incidence rate of pancreatic cancer, between 31 percent and 65 percent higher than the incidence rates for other racial/ethnic groups.

• While overall cancer incidence and death rates are declining, the incidence and death rates for pancreatic cancer are increasing. Pancreatic cancer is projected to move past breast and colorectal cancer to become the 2nd leading cause of cancer-related death in the United States around 2020.

PANCREATIC CANCER IS VERY AGGRESSIVE; THERE ARE NO EARLY DETECTION METHODS

• Because the pancreas is located deep within the abdomen, where tumors are hard to detect, and because pancreatic cancer can progress very quickly from stage I (localized within the pancreas) to stage IV (metastatic disease) in an average of only 1.3 years, it is critical to develop early detection tools.

• At this time, there are no proven biomarkers, or clues detectable in the blood or other bodily fluids, that could indicate the presence of a pancreatic tumor.

• The vast majority of pancreatic cancer cases are diagnosed in late stage. More than half of patients are diagnosed once the disease has metastasized, or spread, elsewhere in the body. Only about 9 percent of pancreatic cancer cases are diagnosed when the disease is still confined within the pancreas.

• Symptoms — including abdominal or back pain, weight loss, jaundice, loss of appetite, nausea, diabetes and changes in stool — are often subtle and are generally initially attributed to other less serious and more common conditions.

• The cause of the majority of pancreatic cancer cases is unknown. For the few known risk factors (e.g., familial history, smoking, obesity), more research is needed to understand their direct relationship to the disease. The known behavioral factors only impact a minority of pancreatic cancer cases.

TREATMENT OPTIONS ARE EXTREMELY LIMITED; PATIENTS ARE UNDERTREATED

• While surgery (often the Whipple procedure) offers the best chance for survival, fewer than 20 percent of pancreatic cancer cases are diagnosed early enough for surgical intervention. Even with surgery, the disease recurs in approximately 80 percent of these patients, who die within 5 years of recurrence.

• For nonsurgical candidates, chemotherapy, possibly with radiation, is typically offered but is not considered curative.

• Since 1974, only three drugs have been approved by the U.S. Food & Drug Administration (FDA) to treat pancreatic cancer: gemcitabine (Gemzar®) in 1996, erlotinib (Tarceva®) in 2005, and albumin-bound paclitaxel (Abraxane®) in 2013 (the latter two in combination with gemcitabine). In 2011, a combination chemotherapy regimen called FOLFIRINOX was found to improve survival of metastatic pancreatic cancer patients. While gemcitabine plus Abraxane and FOLFIRINOX have recently been shown to extend the lives of pancreatic cancer patients, the improvement is small, and most patients still rapidly succumb to their disease.
Many pancreatic cancer patients go untreated or undertreated by standard therapies. A study showed that 38 percent of the patients received no treatment at all within 1 year of diagnosis. Even among patients diagnosed with early stage disease, 27 percent received no treatment, and only 47 percent underwent surgery. African-Americans have similar rates of diagnosis but undergo fewer surgical resections than other racial groups.

Although enrolling in a clinical trial is often the best option for pancreatic cancer patients, only about 4.6 percent of patients participate in clinical trials. While this percentage is within the national average for adult cancer patients (3-5 percent), it is not high enough, since the standard treatment options have limited effectiveness in fighting the disease. A complicating factor is that according to a recent survey, nearly half of pancreatic cancer patients’ treating physicians did not tell them about clinical trial options. This indicates that far more must be done to educate physicians about clinical trials and other available treatment options.

We don't necessarily need a higher number of clinical trials, but we do need better designed clinical trials. Owing to the survival statistics and the fast progression of this disease, the number of pancreatic cancer patients available to participate in clinical trials is limited. In fact, an analysis showed that it would take an average of 6.7 years to fully accrue all the clinical trials that were open in 2011. One of the problems that must be addressed is that trials need to be designed to better match patient needs — for example, more trials should be available for patients who have already received some treatment.

### UNIQUE RESEARCH CHALLENGES REQUIRE SPECIFIC SOLUTIONS

- Around 95 percent of pancreatic tumors are driven by mutations in a gene called KRAS, which signifies a particularly aggressive and treatment-resistant tumor. Mutated KRAS has been dubbed “undruggable,” although efforts are underway to devise therapeutic strategies to target KRAS.
- Pancreatic tumors are surrounded by more dense fibrotic tissue, known as the stroma, than are most other solid tumors. More research is necessary to decipher the role of the stroma in cancer progression and response to treatment.
- Solving these and other challenges requires more researchers and more resources focused on the disease — but the solutions will spur scientific advances in the entire field of cancer research.

### THERE IS HOPE

In February 2014, the NCI released the “Scientific Framework on Pancreatic Adenocarcinoma,” the first report required under the Recalcitrant Cancer Research Act, which Congress passed in 2012.

This critical framework, as well as the scientific framework on small-cell lung cancer released in July 2014 and others that will hopefully follow for other deadly cancers, will help provide the strategic direction needed to change patient outcomes in the nation’s deadliest cancers, defined in the statute as those with a 5-year relative survival rate below 50 percent.

The pancreatic cancer framework outlines four key research topics for pancreatic cancer: the role the KRAS gene plays in this disease, the link between diabetes and pancreatic cancer, biomarkers for early detection of pancreatic cancer and immunotherapies.

One exciting project that the NCI has launched as part of this framework, the RAS Initiative, has the potential to increase the survival rate for pancreatic cancer as well as for the more than 30 percent of all other forms of cancer that are driven by KRAS.

The Pancreatic Cancer Action Network is doing its part to help foster these promising areas by awarding more than $28 million through our Research Grants Program since 2003. Grants have been awarded to 123 researchers at 50 institutions across the country. The organization also recently launched the Know Your Tumor℠ precision medicine initiative, aimed at translating research findings into clinical benefit by tailoring treatment options to the molecular profile of a patient’s tumor.

### WHAT WE ARE ASKING FROM CONGRESS

While we commend Congress and President Obama for enacting the Recalcitrant Cancer Research Act, and the NCI for beginning the implementation, our work is far from complete. The pancreatic cancer statistics call for aggressive measures now to develop early detection tools and more effective treatments before pancreatic cancer becomes the second leading cause of cancer-related death in the United States in just 5 years.

Approximately 80 percent of all pancreatic cancer research funding comes from the federal government, and the NCI is the largest federal source of funding. Therefore, the NCI is a critical resource in determining the future of this disease. We are encouraged by the increased support that Congress gave to the Department of Defense’s Peer Reviewed Cancer Research Program (PRCRP) in FY 2015 and by the continued inclusion of pancreatic cancer in the program. However, we are deeply concerned that NCI funding is falling dangerously behind where it needs to be and that there is no end in sight. When accounting for inflation, the NIH has lost approximately 22 percent of its purchasing power since 2003. Ten years ago, the NIH funded nearly one out of three grant applications. However, that number has now dropped to about one in seven.

We cannot hope to have success in diseases like pancreatic cancer if this situation continues. Furthermore, the funding situation will make it very difficult to leverage the opportunities that come out of the scientific framework developed as a result of the Recalcitrant Cancer Research Act. We recognize that setting federal spending priorities under the existing spending caps is challenging, but we strongly believe that to make progress on diseases like pancreatic cancer, expanding the funding opportunities available at the NCI must be made a national priority. **We therefore urge Congress to support a budget deal or other legislation that supports robust and sustainable increases now and in the future for the NCI and to provide at least level funding for the PRCRP in FY 2016.**

*The population-based statistics refer to all kinds of pancreatic cancer. Unless otherwise noted, all other facts refer to pancreatic adenocarcinoma as “pancreatic cancer.”*