



## **The Recalcitrant Cancer Research Act: An important step toward improving pancreatic cancer survival**

Thanks to broad bi-partisan and bi-cameral 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) and Leonard Lance (R-NJ) and Senator Sheldon Whitehouse (D-RI) and was co-sponsored by 59 Senators and 295 Representatives.

As passed, it calls on the National Cancer Institute (NCI) to develop scientific frameworks that will help provide the strategic direction and guidance needed to make true progress against recalcitrant or deadly cancers.

### **The new statute will provide strategic direction for the nation's deadliest cancers.**

The law calls for the scientific frameworks, or strategic plans, for pancreatic and lung cancers to be created under the direction of the NCI Director by July 2014 and to be updated within five years. Under the statute, the NCI Director may also develop scientific frameworks for other deadly or recalcitrant cancers, defined as those with a five-year relative survival rate below 50 percent.

- Each scientific framework will 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 help facilitate research into each particular recalcitrant cancer.
- The scientific frameworks will also identify questions relating to basic, translational, and clinical research that still need to be answered and make recommendations for advancing research.
- To improve accountability, within 30 days of completion, the NCI Director must publish the frameworks on their website and submit them to the House Energy and Commerce Committee and Appropriations Committee and to the Senate HELP Committee and Appropriations Committee.
- The steps taken to carry out the scientific frameworks will be identified in the biennial report to Congress, including: research grants awarded by NIH for pancreatic and lung cancer; progress made in improving outcomes for people diagnosed with pancreatic and lung cancer, such as relative survival rates; and updates on activities pertaining to pancreatic and lung cancer.
- By July 2020, the NCI Director must submit a report to Congress on the effectiveness of the frameworks in improving the prevention, detection, diagnosis, and treatment of pancreatic and lung cancer.
- The NCI Director will use the frameworks' recommendations when making decisions about exception funding.

### **The statute addresses a specific need.**

The underlying bill, the *Pancreatic Cancer Research & Education Act*, was first introduced because we are not making scientific progress on pancreatic cancer and the consequences are deadly.

- Pancreatic cancer is one of the deadliest cancers and is one of the few cancers for which survival has not improved substantially in more than 40 years. Of the major cancers, pancreatic cancer has the lowest five-year relative survival rate.<sup>1,2</sup>
- A recent report issued by the Pancreatic Cancer Action Network, found that by 2020, pancreatic cancer is expected to become the second leading cause of cancer death in the United States.<sup>3</sup>
- We need to step up investment in this disease. In 2011, the Pancreatic Cancer Action Network issued its report "Pancreatic Cancer: A trickle of federal funding for a river of need" that demonstrates a serious lack of federal resources allocated to pancreatic cancer research. Among the report findings was that two to almost five times as many individual investigator (R) grants were awarded to the other top-five cancer killers over pancreatic cancer. An analysis of the FY2010 and FY2011 funding showed little change.<sup>4</sup>
- Given the research discovery timeline and the significant projected increase in pancreatic cancer cases, nothing less than dramatic and urgent action is required to tackle pancreatic cancer. Yet, until the *Recalcitrant Cancer Research Act* was passed, there was no national strategic plan addressing this disease. However, if fully implemented, the *Recalcitrant Cancer Research Act* will provide that strategic plan.
- Examples of other cancers that are considered "recalcitrant" according to the statutory definition include lung, brain, esophageal, liver, ovarian, and stomach cancers as well as multiple myeloma.



### Progress is being made as a result of the statute.

NCI is currently working on drafting the report called for in the *Recalcitrant Cancer Research Act* that is due in July 2014. As a step in addressing the provisions outlined in the bill, NCI held a “horizon scan” meeting in the fall 2012, during which KRAS was identified as a priority area for pancreatic cancer. Since the passage of the bill, they are now taking steps to draft the report based on the findings from the “horizon scan” meeting and implement several of the priority areas identified in that meeting.

- NCI has taken steps to implement the RAS Therapeutics project that will thoroughly study the RAS family of proteins found in cancer. KRAS, a member of the RAS family, plays a critical role in nearly all pancreatic tumors. The KRAS mutation is associated with especially aggressive tumors and with resistance to chemotherapy and targeted cancer therapies; major advances in pancreatic cancer can be made once scientists discover how to defeat KRAS. Therefore, this project has the potential to make a real impact on survival rates, particularly if it is well funded.
- In June 2013, NCI and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), with additional support from the Pancreatic Cancer Action Network, hosted a workshop “Pancreatitis-Diabetes-Pancreatic Cancer.” The workshop explored the mechanisms behind the increased risk for pancreatic cancer associated with chronic pancreatitis and diabetes, and looked for ways to use this knowledge to optimize the detection and treatment of pancreatic cancer. Again, important areas of research for pancreatic cancer were identified but NCI needs adequate funding to move new projects forward.

### What we are asking from CONGRESS

The Pancreatic Cancer Action Network has long advocated for ensuring that there is a national strategic plan and accountability for making progress on pancreatic cancer and therefore applauds Congress for passing the *Recalcitrant Cancer Research Act* in December 2012. We look forward to updating Congress on the implementation of this important first step in improving pancreatic cancer survival.

While we commend Congress and President Obama for enacting this legislation, our work is far from complete. The pancreatic cancer statistics call for aggressive measures to develop early detection and treatment tools before incidence dramatically increases, but NCI funding is falling dangerously behind. In fact, over the last decade, NIH has lost approximately 20 percent of its purchasing power because funding has not kept pace with the rate of biomedical inflation. Added to that, the NCI budget was cut by 5.8 percent, largely as a result of sequestration. We cannot hope to have success in diseases like pancreatic cancer if this situation continues. Further, it will be very difficult to leverage the opportunities that come out of the scientific framework developed as a result of the *Recalcitrant Cancer Research Act* if the funding levels do not improve.

### The Pancreatic Cancer Action Network calls on the 113<sup>th</sup> Congress to give current and future pancreatic cancer patients a fighting chance by:

- Ensuring that the provisions of the *Recalcitrant Cancer Research Act* are fully implemented.
- Supporting a permanent fix to sequestration and providing sustained adequate funding for the NIH and NCI.

<sup>1</sup> American Cancer Society. *Cancer Facts & Figures 2013*. Atlanta: American Cancer Society; 2013.

<sup>2</sup> Major cancer” is defined as one tracked by both the American Cancer Society and the National Cancer Institute,

<sup>3</sup> Matrisian LM, Aizenberg R, Rosenzweig A: The alarming rise of pancreatic cancer deaths in the United States: why we need to stem the tide today, Manhattan Beach, CA, Pancreatic Cancer Action Network, 2012, [www.pancan.org/section\\_research/reports/pdf/incidence\\_report\\_2012.pdf](http://www.pancan.org/section_research/reports/pdf/incidence_report_2012.pdf).

<sup>4</sup> NCI Funded Research Portfolio <http://fundedresearch.cancer.gov/>. Accessed May 2011 and May 2012.