



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

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) and 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 deadly, cancers, which are defined by the statute as those with a five-year relative survival rate below 50 percent. Under the statute, the NCI is required to release scientific frameworks for pancreatic and lung cancers by July 2014. We applaud the NCI for releasing the "Scientific Framework for Pancreatic Ductal Adenocarcinoma" in February 2014, ahead of the statutory deadline. NCI is reportedly working on a similar framework for lung cancer, as required by the statute.

The scientific frameworks required by the new statute 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. 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 NCI Director must publish the frameworks on the Institute's website and submit them to the House Energy and Commerce Committee, the Senate HELP Committee and the House and Senate Appropriations Committees within 30 days of completion.
- The steps taken to carry out the scientific frameworks are to be identified in NIH's biennial report to Congress, including research grants awarded by NIH; progress made in improving patient outcomes, such as relative survival rates; and updates on activities.
- 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 NCI Director will consider the frameworks' recommendations when making decisions about exception funding.

The new statute has the potential to provide 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 and 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.^{1, 2}
- Pancreatic ductal adenocarcinoma, the subject of the Framework released in February 2014, accounts for approximately 95 percent of all pancreatic cancer cases.
- A recent report published in *Cancer Research* predicts that pancreatic cancer will surpass breast and colorectal cancer to become the second leading cause of cancer-related death by 2020.³
- The same report also predicts that by 2030, the top five cancer killers in the U.S. will be lung, pancreatic, liver, colorectal and breast – a dramatic shift from the current ranking of lung, colorectal, breast, pancreatic and prostate. Lung, pancreatic and liver cancers are all considered to be deadly, or recalcitrant, cancers. Their rise in the rankings of cancer killers underscores the need for a greater federal research investment to prevent these predictions from coming true.
- Examples of other cancers that are considered "recalcitrant," according to the statutory definition, include brain, esophageal, ovarian and stomach cancers, as well as multiple myeloma.



The statute has created a path for progress in pancreatic cancer research.

The scientific framework for pancreatic cancer built upon a report 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 scientific framework expands on these recommendations by providing specific suggestions for moving forward for each one.

1. Understanding the biological relationship between pancreatic cancer and diabetes

As an initial step toward this initiative, the NCI and the National Institute of Diabetes and Digestive and Kidney Diseases, with support from the Pancreatic Cancer Action Network, sponsored a meeting in June 2013 that explored the links between diabetes, pancreatitis and pancreatic cancer. The scientific framework notes plans to develop a funding opportunity announcement for expanding research in this area.

2. Evaluating screening protocols for biomarkers for early detection of pancreatic cancer and its precursors

The scientific framework indicates that the NCI will issue a Program Announcement by March 2015 to focus on the development of novel methods to obtain and interrogate pancreatic tissues containing pre-cancerous lesions.

3. Studying new therapeutic strategies in immunotherapy

The scientific framework states that the Cancer Immunotherapy Trials Network (CITN), which employs the collective expertise of expert academic immunologists, together with the NCI and foundation and industry partners, will design and conduct cancer therapy trials with the most promising immunotherapy agents in pancreatic cancer.

4. Developing new treatment approaches that interfere with RAS oncogene-dependent signaling pathways

The framework describes a recently launched major NCI initiative to develop drugs that target KRAS, a gene that is mutated in the vast majority of pancreatic cancer cases. Discovering how to defeat KRAS can lead to advances in pancreatic cancer treatment.

What we are asking from CONGRESS

The *Recalcitrant Cancer Research Act* and the NCI’s scientific framework on pancreatic ductal adenocarcinoma are important steps toward improving survival rates for pancreatic cancer. While NCI is still working on the specific details for the implementation of each initiative, we are looking forward to working with them on the next steps. Further, while the NCI noted in the pancreatic cancer framework that the Pancreatic Cancer Action Planning Group (PCAPG) will “continue to monitor the progress of the initiatives,” specific benchmarks have yet to be defined as outlined in the statute. We look forward to updating Congress on the full implementation of the statute. We believe that this has been a positive step forward for pancreatic cancer and hope that NCI will create frameworks for additional deadly cancers.

We are deeply concerned that NCI funding is falling dangerously behind where it needs to be. 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 more than 5 percent last year, largely as a result of sequestration. The FY 2014 Omnibus appropriations bill added back some of those cuts, but NCI funding is still far behind where it needs to be, and it faces more cuts in FY 2016. 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 overall NCI funding levels do not improve.

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

- Providing \$5.26 billion for the National Cancer Institute for FY 2015
- Continuing to include pancreatic cancer in the Department of Defense (DoD) Peer-Reviewed Cancer Research Program (PRCRP) and providing continued funding of at least \$25 million for the program
- Ensuring that the provisions of the *Recalcitrant Cancer Research Act* are fully implemented
- Joining the Congressional Caucus on the Deadliest Cancers

¹ American Cancer Society. *Cancer Facts & Figures 2014*. Atlanta: American Cancer Society; 2014.

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, and Matrisian LM: *Projecting Cancer Incidence and Deaths to 2030: The Unexpected Burden of Thyroid, Liver, and Pancreas Cancers in the United States*. *Cancer Research*, 2014. 74(11): p. 2913-2921.

⁴ NCI Funded Research Portfolio <http://fundedresearch.cancer.gov/>. Accessed May 2011, May 2012, and May 2013.