

recalcitrant cancers. Pancreatic cancer has a 5-year relative survival rate of 6% and lung cancer, 16%. According to estimates, they will kill more than 37,000 and 160,000 people, respectively, this year.

“If the bill does nothing other than rivet our attention on these difficult malignancies, it will be great,” says Margaret Tempero, MD, director of the University of California, San Francisco (UCSF), Pancreas Center at the UCSF Helen Diller Family Comprehensive Cancer Center, and a member of the scientific advisory board of the Pancreatic Cancer Action Network in Manhattan Beach, CA.

Creating a comprehensive plan—called a scientific framework in the bill—would help narrow survival gaps and address difficult issues, Tempero says. For example, surgical resection is often not an option for patients with pancreatic cancer because their tumors are too advanced by the time the disease is diagnosed. As a result, researchers lack the tissue they need to study the biology of the disease.

The scientific framework for each recalcitrant cancer, says Julie Fleshman, president and CEO of the Pancreatic Cancer Action Network, will summarize the current status of the disease, identify research questions that have not been adequately addressed, and make recommendations to advance research, such as coordinating various initiatives and setting benchmarks to measure progress.

First filed 5 years ago and named the Pancreatic Cancer Research and Education Act, the bill grew out of the Pancreatic Cancer Action Network’s advocacy efforts. Attention to it swelled this past summer when the group released a report stating that pancreatic cancer is “anticipated to

move from the fourth to the second leading cause of cancer death in the U.S. by 2020.”

Although the bill initially had strong support from legislators, cancer researchers and others in the scientific community voiced considerable opposition to certain provisions. They expressed concern that the bill’s authorization of additional funds solely for pancreatic cancer research would pull money away from other worthy projects. Many also feared that a mandated 13-member advisory panel would usurp the authority of NCI’s peer-review committees.

In response to the criticism, the bill’s sponsors, advocates, and a bipartisan House subcommittee overhauled it, eliminating the advisory panel and the financial obligation, and changing the name to the Recalcitrant Cancer Research Act to allow for the inclusion of other types of cancers.

However, Senator Tom Coburn, MD, expressed opposition to the revised bill in a letter to the Senate’s minority leader. “I do not believe there is any demonstrated need for Congress to micromanage NIH how to better perform, organize, and disseminate the work being done in these fields,” he wrote. He also questioned taking “an outdated disease-by-disease approach” when cancer research now largely “focuses on broader, interdisciplinary questions.”

If the bill doesn’t pass the Senate by year’s end, supporters must reintroduce it next year. ■

FDA Approves Ultrasound Tool

The U.S. Food and Drug Administration (FDA) has approved a new adjunct screening tool to be combined with mammography for asymptomatic women with dense breast tissue who

have not had prior clinical breast intervention.

About 40% of women who are screened by mammography have dense breast tissue. These women have a higher proportion of dense fibroglandular tissue, which can obscure smaller tumors, and mammography fails to detect about 35% of their breast cancers. Although a recent paper (*J Natl Cancer Inst* 2012;104:1218–27) indicates that high breast density does not increase risk of death from breast cancer in women once diagnosed, it has been associated with an increased risk of developing the disease.

The sono-v Automated Breast Ultrasound System (ABUS) from U-Systems of Sunnyvale, CA, was initially approved in a premarket notification program in 2005 for adjunct diagnostic purposes, which involves the assessment of tumors already identified or suspected.

The FDA’s new approval for its use as a screening tool was based on a clinical reader study in which radiologists looked at 200 cases of asymptomatic women with dense breast tissue from a prospective multicenter registry. The study found that using sono-v ABUS in addition to mammography improved the detection of cancerous tumors by about 30% compared to mammography alone.

“What was very exciting in this reader study was that a majority of the cancers, which had not been seen on the screening mammograms during the prospective registry study, were invasive cancers that had not spread to the lymph nodes,” says Maryellen Giger, PhD, principal investigator of the study and professor of radiology at the University of Chicago. “If we were to wait for these to grow and become visible on a mammogram, there’s the chance the cancers would become lymph node positive.” ■

CORRECTION NOTE: In “Focusing on Recalcitrant Cancers,” 2 sentences in the second paragraph have been changed from the OnlineFirst version published October 4, 2012. The October 4, 2012, version included the following sentences: “The bill defines recalcitrant cancers as those having a 5-year relative survival rate of less than 20% and estimated to kill at least 30,000 Americans a year. Supporters hope it will raise public awareness of particularly intractable malignancies, notably pancreatic and lung cancers, the only 2 diseases that currently fit this definition of recalcitrant cancers.” These sentences have been replaced with the following: “While the bill defines recalcitrant cancers as those having a 5-year relative survival rate of less than 50%, it directs the NCI to initially develop a scientific framework for 2 or more cancers having a 5-year relative survival rate of less than 20% and estimated to kill at least 30,000 Americans a year. Supporters hope it will raise public awareness of particularly intractable malignancies, notably pancreatic and lung cancers, the only 2 diseases that currently meet this more limited definition of recalcitrant cancers.” A correction has been issued for the OnlineFirst version. The publisher regrets the error.

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