New breast cancer guidelines met with caution in western Pa.

By Christopher Cussat

In November, the U.S. Preventive Services Task Force (USPSTF) issued a controversial recommendation about breast cancer screening. The reaction to the group's official statement has been national, loud and mixed.

The statement released by the USPSTF on Nov. 17 was an update of its 2002 recommendation statement on screening for breast cancer in the general population. In short, the newest and most controversial part of recommendation states: "The USPSTF recommends against routine screening mammography in women aged 40 to 49 years. The decision to start regular, biennial screening mammography before the age of 50 years should be an individual one and take into account patient context, including the patient's values regarding specific benefits and harms."

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> *- Dr. Adam Brufsky of University of Pittsburgh Cancer Institute*

Adam Brufsky, M.D., Ph.D., provides a cautious voice representing the reaction of the Pittsburgh medical community. He is the associate director for clinical investigation at the University of Pittsburgh Cancer Institute.

According to Brufsky, the USPSTF had six computer models which all showed a benefit to annually screening women starting at age 40 and going up to age 84.

"Where there was a big difference in the six models was in whether you should start screening women over 50 and whether you should start screening women every other year instead of yearly," he says.

Four of the models suggested a small benefit to changing from twice a year to yearly, and the other two models showed a continued, substantial benefit to screening yearly and screening starting at age 40. The USPSTF decided to throw out the latter two models and keep former four, stating that it believes the harm of more frequent and earlier screening does not justify the additional small benefits.

Brufsky notes that when the USPSTF was pressed to define the "harm" mentioned in the statement, it explained that the "harm" was an increased anxiety of women over false positive tests. This is why there has been such criticism and controversy associated with the new recommendation.

"I think this is what really infuriated women because the USPSTF was basically saying, 'We know better than you and we don't want to expose you to the harm of increased anxiety,'" Brufsky says. He believes that most women would not mind the increased anxiety if it means that 1 out of 20 or 30 times cancer might be found.

He also notes that most medical professionals who have read the statement and reviewed its data respond with the following advice: "If you're a woman who doesn't want to be screened until age 50 and you want to be screened every other year, the model suggests that is OK. However, if you're a woman age 40 or 50 and you want to be screened every year, there's no reason why you shouldn't continue." Brufsky adds that if it were his relatives, he'd still recommend they be screened every year.

Another concern about the USPSTF statement is the fear that some insurance companies may want to stop paying for earlier or more frequent breast cancer screenings. Brufsky explains, "There's still enough uncertainty that insurance companies should not block women if they want to be screened yearly starting at age 40. That's what this is coming down to and that's what everybody is really afraid of. I think we're afraid that insurers and payers will use this to not support current screening practices."

Brufsky, who is also the director of the Women's Cancer Program at Magee-Womens Hospital of UPMC, is very confident that his views about the USPSTF recommendation are generally shared among his colleagues in Pittsburgh and even nationally.

"The USPSTF statement has not affected local screening or treatment policies. I tend to know the flavor in this town, and I think the vast majority of Pittsburgh medical professionals are still going to recommend annual mammograms for women starting at age 40," he says. He also believes that this is currently the general consensus of oncologists nationally.

Submitted photo

Dr. Adam Brufsky, University of Pittsburgh Cancer Institute associate director for clinical investigation.

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Bedford Memorial offers new incisionless procedure to eliminate heartburn

UPMC Bedford Memorial has announced that David C. Faber, M.D., of Bedford Surgical Associates Inc., is the first in the Bedford/Blair/Cambria county areas to offer the new Transoral Incisionless Fundoplication (TIF) using the EsophyX device for the treatment of gastroesophageal reflux disease.

Gastroesophageal reflux disease (GERD) is the flow of the stomach's contents and acid back up into the esophagus. This happens when the esophageal valve, part of the antireflux barrier, becomes weak or nonfunctional. GERD is also called heartburn, reflux and esophageal reflux.

Over the long term, persistent exposure of the delicate tissue of the esophagus to the acid contents of the stomach can cause chronic inflammation or esophagitis, which can lead to a potentially serious condition called Barrett's Esophagus. In some cases GERD sufferers may experience non-heartburn symptoms, such as hoarseness, persistent cough, dental erosions, sore throat, discomfort in the ears and nose and asthma-like symptoms. These symptoms cannot typically be resolved through drug therapy.

In addition to dietary controls, medications like non-prescription antacids, proton pump inhibitors and H2 blockers help prevent the acceleration of GERD. Over time, however, these medications may lose their effectiveness requiring increased dosage, increasing cost, and increasing the risk of long term side effects. Invasive surgical procedures such as the Nissen Fundoplication have long been known to be effective therapy for GERD. The risk of adverse events and the invasive nature of these procedures have made them lose popularity in recent years.

The EsophyX TIF procedure is performed safely, quickly and comfortably through the mouth, not through an incision. The procedure reconstructs the body's natural antireflux barrier to prevent the backflow of stomach acids into the esophagus. Most patients can return to work within a few days following this procedure.

Clinical results show that more than 85 percent of patients are completely off acid reflux pills 12 months after the procedure and report a significant reduction or elimination of heartburn symptoms.

For more information contact Faber at Bedford Surgical Associates Inc. at (814) 623-1002.

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Although the USPSTF recommendation statement may not necessarily change any current preventative care policies for breast cancer, there are many new and developing treatment options that will give additional hope to those who are afflicted by this disease. Brufsky explains, "In addition to better detection in general, we have actually greatly improved systemic therapy. For example, I think we've gotten a lot better with the kinds of anti-hormonal therapies that we give to people, like Tamoxifen or Arimidex. There are also up-and-coming therapies like Falsodex, and better chemotherapies that use milder drugs like Xeloda, Herceptin and Avastin."

He continues, "These things have really started to change the landscape for women who have early-stage breast cancer by preventing recurrences. Also, in women with later-stage breast cancer, their survival has increased dramatically – by at least a year or two if not more." Women who were diagnosed with metastatic breast cancer were often given only a year or two to live, according to Brufsky. With these new treatments, many of the same patients can survive three to five years and beyond.

"That's a direct result of these new treatments, and in fact, there are even more new ones coming," Brufsky says. "For example, there's a class of drugs called PARP inhibitors which inhibit a step in DNA repair in breast cancer."

Because of these advancements and a trend toward highly individualized therapy, his prognosis for survival rates is full of hope and optimism. "I would say that 80 to 90 percent of women who are diagnosed with breast cancer in 2010 will likely survive their disease."

University pharmaceutical, science consortium receives FDA contract

The U.S. Food and Drug Administration (FDA) has awarded the National Institute for Pharmaceutical Technology and Education Inc. (NIPTE) a $652,000, two-year contract to develop and deliver a professional development program to help to ensure that FDA reviewers are current in state-of-the-art pharmaceutical manufacturing and technology.

The implementation of this contract will require the design, development, delivery and assessment of an educational program based on the needs of the FDA's Office of Pharmaceutical Science (OPS) staff that review and evaluate the quality information for new drug applications. The program will increase the ability of reviewers to apply the newly acquired knowledge to practical issues associated with the review, research and policy-making activities.

In the initial period, NIPTE will work with the OPS on identifying the needs and developing recommendations on training areas. Once the assessment is complete, NIPTE will develop and deliver a scientific training program for the designated OPS staff.

The program will begin this year and is expected to be completed by September 2011.

Duquesne University is one of 11 leading pharmaceutical science and engineering schools nationwide to participate in NIPTE and has previously been involved in FDA reviewer training.