

May 7, 2009

The Honorable Debbie Wasserman Schultz
118 Cannon House Office Building
United States House of Representatives
Washington, DC 20515

Dear Representative Wasserman Schultz:

Bravo for your efforts to improve the current approach to breast cancer in young women. Do not let anyone dissuade you from passage of the EARLY-Act — it is sorely needed. Despite massive spending, we have made almost no progress reducing morbidity and mortality in pre-menopausal women, largely because of a lack of awareness of their risk, which prevents them from being screened, coupled with the inaccessibility of screening methods that are effective in younger women. I am a two-time breast cancer survivor, diagnosed with a large and very aggressive tumor just a year after a “clean” mammogram. My late diagnosis led to a recurrence just eighteen months after the first, and ultimately necessitated nine surgeries, chemotherapy that damaged my heart and radiation that made an aesthetically-pleasing, post-mastectomy reconstruction impossible. Like you, my illness galvanized me to do something about this scourge. I have applied my 35 years of experience as a medical products executive to the cause of ending the early deaths and debilitating therapies that are so often the result of breast cancer in young women.

The biggest challenge we face in this fight is that over 70 percent of women have no risk factors prior to their diagnosis, and thus were never candidates for early screening. The widespread assumption that family history is the best predictor of breast cancer risk is probably responsible for hundreds of thousands of breast cancer deaths in young women. And there is virtually no utility of the standard method of mammographic screening in young women (as my experience so dramatically revealed to me). Young women do not have access to routine mammograms nor are they effective in this group because young, dense breast tissue tends to reflect the x-rays, resulting in a totally white film. That same dense tissue makes it virtually impossible to detect small (curable) tumors by physical examination. Since as with all cancers, early detection is the key to a cure, and late detection is responsible for most of the mortality. I realized we must find a way to change this equation, which started my quest for a better method of identifying women at risk.

What I found and have dedicated myself to since late 2006 is the HALO[®] Breast Pap Test. HALO is a risk assessment now being offered in >200 gynecology offices (including several in your district). HALO is non-invasive, well-tolerated, low-cost, and takes just five minutes. The HALO device collects nipple aspirate fluid (NAF) from the breast ducts (in an approach similar to a breast pump). The fluid is then analyzed in a laboratory for the presence of atypical ductal cells (also termed atypia); the early cellular changes that are thought to be precursors to breast cancer. The HALO test is very similar to the cervical Pap test, which tests for abnormal or

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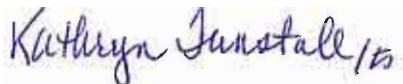
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atypical cervical cells, a known precursor to cervical cancer, and which has brought about a 15-fold decrease in cervical cancer deaths since its clinical adoption.

The HALO device makes practical the collection of nipple aspirate fluid, which has been clinically studied for over 30 years. In numerous large studies of nipple aspirate fluid, the presence of atypia in the fluid conferred a 400-500 percent increased risk of developing breast cancer. The simple fact is finding women at risk in order that they can be vectored to appropriate, higher levels of screening sensitivity and careful monitoring is the key to reducing breast cancer mortality. Said another way, we can change the fate of high-risk women if we know who they are — and HALO can help in the identification of them. High risk women are good candidates for chemoprevention, which has been shown in studies to prevent 86 percent of patients from ever developing breast cancer. By identifying high-risk women, HALO can also enable screening with technologies that are effective at finding early, tiny tumors in young tissue. These advanced screening methods, such as MRI, are generally inaccessible to asymptomatic women. Finding these small tumors on MRI can lead to a cure — Stage 0 and Stage 1 breast cancer have a nearly 100 percent cure rate.

The clinical foundation of the HALO technology is solid — a few key articles are attached. Our well-respected scientific advisors would be happy to join your battle as they, too, frequently speak out on the need to improve the breast healthcare of young women. Two great examples are Dr. Gail Lebovic, Director of Women's Services at the Cooper Clinic in McKinney, Texas, who is also President of the American Society of Breast Disease; and, Dr. Ernie Bodai, Director of Kaiser-Sacramento Breast Center and well-known as the inventor of the breast cancer stamp, which resulted from another great piece of Congressional legislation. NeoMatrix would very much like to be a part of the discussion and would be pleased to introduce some leading breast cancer specialists to Congress to help with the passage of your bill.

Sincerely,

A handwritten signature in blue ink that reads "Kathryn Tunstall" followed by a date "1/15". The signature is written in a cursive style.

Kathryn Tunstall
Chairman of the Board

Attachments