

of surveys. Using mailed questionnaires we have learned about our patients' outcomes and the impact of some of our cancer therapies on survivors' lives. For example, we did a survey of patients with lymphedema and found that for those affected, there was significant impact on their feeling of well-being. This led to the formation of a clinical trial using Horsechestnut (an herb that is touted to reduce swelling and inflammation). We were not able to accrue the number of patients we had hoped to but we still learned a great deal about the psychosocial impact of this sequela. Out of the study grew our lymphedema support group.

Along the same lines, we did a survey of our estrogen-positive breast cancer patients around symptoms experienced with Tamoxifen and the Aromatase inhibitors. We found that significant numbers of those on aromatase inhibitors were experiencing joint and muscular side effects. In some it was enough to cause them to switch therapy or stop it all together. We reported our findings and there have since been additional studies confirming these findings. We are now in the process of designing a clinical trial using an herbal formula, Blue Citrus, that has anecdotally shown benefit in reducing the symptoms experienced with the aromatase inhibitors. More to come on that!

We have also done an active study to reduce side effects to the skin of those undergoing adjuvant whole breast radiation after lumpectomy. Raygel (reduced glutathione and anthocyanins) was anecdotally reported to reduce radiation dermatitis. In collaboration with a local naturopath, we designed a prospective study comparing Raygel to a placebo. The placebo was designed to look

and smell just like the Raygel but contained no active ingredients. On this study, all patients used traditional skin care but randomized to receive either placebo or Raygel. In a pilot study of 30 participants the Raygel outperformed the placebo by 24 percent. Since we had small numbers initially, this did not reach statistical significance. We have just completed a larger study of 130 participants which confirms our pilot with more convincing data. We are excited about sharing our findings. (See photos.)

We have had another exciting collaboration with the College of Oriental Medicine in the form of a clinical study on acupuncture after axillary node dissection. In the study, patients who undergo a formal axillary node dissection randomize to placebo (sham acupuncture) or acupuncture. The study is blinded and an independent observer records arm range of motion, pain indices, neurosensory changes and quality of life parameters. This study is currently ongoing and we look forward to what we hope will be exciting results.

And last but not least, we currently have opened a study on the Androgen Receptor and its role in Estrogen/Progesterone receptor negative breast cancer. This study grew out of work initiated by Dr. Pommier in their lab where they noted the demise of Estrogen/Progesterone negative breast cancer cell lines with the addition of DHEA-sulfate (a weak androgen). Further study showed this cell line to have an androgen receptor and that confirmed that this behavior was being mediated via the androgen receptor. Interestingly enough, Dr. Melaragno, our research chief, recalled a time when testosterone was used to treat metastatic breast cancer and

Placebo vs RayGel - Start



Placebo vs RayGel - Week #6



was successful in a small group of patients. In reviewing the literature, we found that the historical response rates would correspond with the expected numbers of Estrogen/Progesterone negative, androgen receptor positive patients by rough calculation. Based on this work we have designed a trial that places women with metastatic ER-/PR-/AR+

breast cancer on testosterone. We hope to show that we can manipulate this subgroup of breast cancer via the androgen receptor. If that proves to be the case then it opens the door to the possibility of adjuvant hormonal therapy for this group of patients with high risk breast cancer who currently only have chemotherapy as an option.

I could go on and on about the exciting programs that are homegrown at Legacy Cancer Services but I'll stop at this juncture. If you have questions or would like more detailed information about any of our studies, please call 503-413-8050.

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## Highlights of Legacy Cancer Services Studies 2006

### Title: Combined Glutathione And Anthocyanins An Improved Alternative For Skin Care During External Beam Radiation

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**Introduction:** Reduction in radiodermatitis during whole breast irradiation was seen in a pilot trial of Raygel (a combination of reduced glutathione and anthocyanins) but small sample size and short RayGel half-life precluded a statistically significant outcome. Results were promising and this prompted



a larger scale study of Raygel reformulated to an anhydrous base to improve stability and ease of application.

**Methods:** Patients undergoing whole breast irradiation were prospectively randomized to treatment with placebo or Raygel. Patients, physicians and staff were blinded. Skin reaction was documented by photographs and scored using the standard skin reaction severity scale. Patients were instructed to apply either topical Raygel or placebo cream 30-90 minutes prior to their radiation