

## GENEROUS DONATION FUNDS NOVEL CANCER THERAPY



*Dr. Dornfeld, Douglas Spitz, Sr., Nellie Spitz, Dr. Buatti at gift presentation*

The department of Radiation Oncology has received a generous donation of \$10,000 from Dr. and Mrs. Douglas Spitz, Sr., for the initiation of a phase I clinical trial. The clinical trial, "A phase I non-randomized dose study of two deoxyglucose given currently with fractionated daily radiotherapy in the treatment of patients with high-risk cancer of the head and neck," has been approved by both the FDA and institutional oversight committees, yet lacked funding to move forward.

Based on benchmark research of the Free Radical and Radiation Biology Program within the Department of Radiation Oncology, the study seeks to determine the safest dose of 2-deoxyglucose when administered daily with fractionated radiation therapy for head and neck cancer. Two-deoxyglucose, an analog of glucose, was chosen

based upon the hypothesis that cancer cells have dysfunctional antioxidant enzymes. To compensate for this, cancer cells use glucose as an antioxidant, thereby neutralizing any free radicals. This mechanism explains the increased glucose uptake observed in most cancer cells.

To kill cancer cells, radiation generates free radicals within the cancer cell. Research completed by the Free Radical and Radiation Biology Program indicated preventing the cancer cell from using glucose would sensitize cancer cells to radiation, increasing the efficacy of the radiation and the amount of tumor cell killing.

Before this groundbreaking work can be used as a therapy, however, it must go through rigorous phased clinical trials. The first step, a phase I trial, determines the maximum

tolerable dose of the new drug. To study a drug in a phase I clinical trial, an investigator must submit an investigational new drug application to the FDA. Ken Dornfeld, a physician scientist within the department of Radiation Oncology, generated the appropriate protocol and worked with the FDA to obtain approval for the use of 2DG with fractionated daily radiotherapy for head and neck cancer.

After this investigator initiated trial was approved, the application to the clinic was delayed by a lack of funding. With budgetary cutbacks and grants becoming tighter, unfortunately cancer funding took a hit. It was for this reason Dr. and Mrs. Douglas Spitz, Sr., stepped forward to supply needed money to the trial. Having lost two family members to head and neck cancer, the Spitzs understood how debilitating not only the cancer, but the treatment, can be. It was for this reason they are anxious to see a treatment come forward that will not sacrifice the quality of life for patients.

With their generous donation, the accrual of the first few subjects can begin, generating the needed preliminary data to prove to the funding agencies that the trial can work. After passing through the phase I trial, the clinical trial will move on to a phase II, to determine the most effective dose of 2-deoxyglucose when combined with fractionated radiotherapy for head and neck cancer.