Compassionate
Oncology Medical Group

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**AREDIA MONOTHERAPY TO CONTROL METASTATIC,
HORMONE REFRACTORY PROSTATE CANCER
FOR MORE THAN SIX YEARS**

In May of 1997, I consulted on Bernie S. He initially presented in 1983 at the age of 57 with an abnormal digital rectal exam. Biopsy revealed prostate cancer. Unfortunately, we were never able to get a copy of that pathology report since it was done 14 years before my consultation with him. The records referred to moderately differentiated prostate cancer.

He initially elected no therapy until 1988. At that time, his PSA was elevated to 170. His prostatic acid phosphatase was increased to 4. He initially was treated with Lupron and flutamide. Later that year, he underwent orchiectomy, and continued on flutamide. His PSA dropped to 0.15, and remained at that level through 1991.

In March of 1993, a bone scan was read as stable findings with respect to this patient's known bony metastatic disease. The bone scan identified that the right eighth rib focus had cleared, but a new focus was identified in the left fourth costochondral junction. There was some decrease in activity at C6 and T1. The previously noted increased activity in the lower thoracic spine had resolved.

A bone scan in 1994 was read as normal, and the report stated, "Previously noted abnormalities have cleared, presumably representing a response to orchiectomy."

Bernie's PSA first began to increase in 1992 when it was 0.46. His flutamide should have been discontinued at this time, but was not. By early 1997, his PSA was 4.85. When he consulted with me in May of 1997, his PSA was 5.78. He obviously had hormone resistant prostate cancer since his PSA had risen in spite of orchiectomy and flutamide. Bernie was told to discontinue his flutamide.

He demonstrated a classical flutamide withdrawal response since his PSA dropped to 1.51, and remained at that level until August of 1997. I then added Proscar 5 mg per day, and his PSA dropped to 0.99 in early September 1997. However, one week later, his PSA had risen to 1.1. At that point, he was started

on monthly infusions of Aredia. His PSA remained stable at 1.05 in September and October of 1997, but by November, it dropped to 0.92.

In January of 1998, his PSA was 0.67, and by May of 1998, PSA was 0.37. The only therapy Bernie was receiving for prostate cancer was Proscar 5 mg once each day, and monthly infusions of Aredia.

In July of 1998, PSA dropped to 0.2, and remained there for the next two months. However, in October 1998, PSA fell to 0.14. In November, it dropped to 0.1, and in December 1998, to 0.07. In February of 1999, PSA was unmeasurable at less than 0.05.

As of February 1999, Bernie had been on Aredia for 17 months, and his PSA had dropped from 1.05 to unmeasurable. In March of 1999, PSA was 0.11, and by September of 1999, PSA was 0.2. Nevertheless, this meant that in two years, his PSA had declined by 80%, just from Aredia.

In February 2000, PSA was 0.16; in May, 0.17. In September 2000, PSA was 0.19. Thus, three years after starting Aredia, his PSA was still more than 80% lower than it was prior to starting Aredia.

In October 2000, he received his forty-first dose of Aredia, and his PSA was 0.18. We discontinued Aredia at that point because he had developed a mild abnormality in kidney function. Over time, his kidney function essentially normalized.
In spite of discontinuing Aredia, as of June 2001, his PSA was 0.24, and in October 2001, 0.26. At that point in time, four years after starting Aredia, his PSA had still declined by over 75%.

In April 2002, PSA was 0.249, and in August 2003, 0.334. At that point in time, it was almost six years since we had initiated Aredia, and Bernie's PSA was still less than one-third its initial value prior to starting Aredia.

Aredia as a single agent had reduced Bernie's PSA by two-thirds, six years after starting treatment, and he had not received any additional Aredia since October 2000.

In August 2003, Bernie was found to have rectal carcinoma, and was treated with chemotherapy and radiation therapy. In

November 2003, his PSA was 0.083; in December, 0.043, and in January 2004, 0.014.

In March 2004, PSA was 0.008, and by May 2004, his PSA had become unmeasurable at less than 0.003. In February 2005, Bernie's PSA remained unmeasurable at less than 0.003.

In April 2005, at the age of 79, Bernie died from coronary artery disease. His PSA was unmeasurable.

Prior to consulting with me in 1997, Bernie had been told by his Kaiser physicians that there was nothing more to be done for him, and that he was not expected to survive much longer. Eight years later, his PSA was unmeasurable, and he died of cardiovascular disease, not cancer. I have had other patients demonstrate PSA declines just from Aredia, but Bernie's response was the most dramatic.

If anyone ever tells you that Aredia does not have the ability to control PSA (and, by inference, prostate cancer) in anyone with metastatic, hormone refractory prostate cancer, just tell them that Bernie S. proved otherwise.

As always —

Be happy,
Be well,
Live long and prosper,

DR. BOB

P.S. In spite of the fact that Bernie received monthly Aredia, and usually 120 mg per month for approximately three years, he never had any signs or symptoms of osteonecrosis, or any other jawbone/dental problems.