

"War on Cancer":

Why Does The FDA Deny Access To Alternative Cancer Treatments?

by Michael Horwin

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(The following is the introductory section of the article without the original footnotes; to read the entire article with footnotes, download this Word document.)

Dedicated to my son Alexander Roy Horwin. He was denied a potentially life saving treatment by the FDA on September 21, 1998. He died on January 31, 1999. He was 2 1/2 years old and had his entire life before him.

"I love purple.
I love yellow.
I love red.
Daddy, I love everything."

Alexander Horwin walking the halls of the Hematology-Oncology floor of Children's Hospital Los Angeles, looking at the brightly colored paintings on the walls while undergoing his second chemotherapy session in November, 1998. He would die in his mother's arms three months later at the age of 2 1/2 years old.

In February 1994, two and a half year-old Dustin Kunnari was diagnosed with a deadly brain tumor called medulloblastoma, which was the size of a golf ball. The neurosurgeon skillfully removed 75% of the tumor, but surgery alone was not an adequate treatment and Dustin's parents were referred to a chemotherapy trial. The doctors informed the Kunnaris that the side effects of the chemotherapy could include "bone pain, hearing loss, irreversible damage to the kidney and bladder, destruction of the immune system, learning disabilities, sterility, and, leukemia." "In addition, the doctors could not name a single child who had done well following any of these treatments." To Dustin and his family, this "cruel regimen with so little hope" was less than promising.

In April 1994, the Kunnaris traveled to Houston to consult with Stanislaw Burzynski, M.D., Ph.D. Dr. Burzynski used an innovative and nontoxic therapy to treat brain tumors. Because Dustin still had some tumor left in his brain, Dr. Burzynski explained that the efficacy of his therapy could be determined rapidly. If, after six weeks, the remaining tumor had shrunk or disappeared then the treatment was working. If the treatment failed, the Kunnaris could have the orthodox oncologists administer the more toxic therapies—chemo and radiation. For six weeks Burzynski's treatment, called "antineoplastons," was administered to Dustin. After this trial period was over, Dustin had a MRI (magnetic resonance imaging) of the brain at a local hospital. Consequently, the Kunnaris were rewarded with good news: the remaining tumor in Dustin's brain was gone. The boy stayed on the antineoplastons, but a year later, a second tumor appeared approximately one inch in diameter. Dr. Burzynski increased the dose of his therapy and the second tumor dissolved. Today, over seven years from his initial diagnosis, Dustin is a normal,

healthy, cancer-free boy with no side effects from the treatment.

In August 1998, four years after Dustin was originally diagnosed, my son, two-year-old Alexander Horwin was diagnosed with medulloblastoma, the same tumor as Dustin Kunnari. Alexander was a strong, handsome and intelligent child with curly brown hair and big brown eyes who could already speak English and French. He loved exploring the ocean and its mysterious tide pool animals with his Daddy. And he loved riding fast in his stroller along the boardwalk as his Mommy roller-bladed behind him.

Surgeons removed the entire tumor, but told us that without further treatment, this cancer would return and take Alexander's life. Like the Kunnaris, we looked for the best treatment for our son, one that was the least toxic and offered the greatest potential for survival and quality of life. After extensively researching the medical treatment options, we also chose Dr. Burzynski's therapy for Alexander. This time, however, the outcome would be different.

After bringing Alexander to Dr. Burzynski in Houston on September 21, 1998, we were stunned to learn that the FDA would not allow us to use this therapy. Dr. Burzynski explained that the FDA controlled his protocols and required children like Alexander to first undergo the "standard treatment" of chemotherapy and/or radiation. Once the cancer returned on the standard treatment, then Burzynski could treat our son.

This news seemed inconceivable to us. After enduring two brain surgeries, Alexander was now tumor-free and ready for the best cancer therapy that would stop the disease from reoccurring. There we sat before Dr. Burzynski in a brightly lit examination room in his clinic. In that clinic was the medicine that could potentially save our son's life. The doctor was willing to treat Alexander. We, Alexander's parents, wanted the treatment. Alexander wanted to be well again. But even though all of the parties in interest were willing, our decision had no weight or value. Instead, a decision made by a bureaucrat two thousand miles away would trump the determination of the parents and the doctor. This bureaucrat had never met Alexander, and did not know anything about our son's medical history. He did not love Alexander and yet his decision was final.

With no other treatment options available, we returned to Los Angeles and reluctantly agreed to have chemotherapy administered to Alexander. We were devastated to learn that if our son was one of the "lucky ones" to survive, the side effects of chemotherapy could include:

Low hemoglobin, low white blood cells, low platelets, infection, need for blood transfusion, need for platelet transfusion, pain, nausea, vomiting, hair loss, skin injury, heart damage, lung damage, liver damage, kidney damage, loss of hearing, small stature, hormonal problems such as low growth hormone or low thyroid hormone, infertility, second cancer, intellectual decline, worsening of neurological symptoms, ineffectiveness, and death.

We continued to look for other options outside of the United States. Three months after starting chemo, and while receiving the third "round" of this therapy, Alexander started complaining of pain. "Mommy, I have pain here and here," he repeated pointing to his head and back. On January 11, 1999, a CT scan of Alexander's head was done at Children's Hospital in Los Angeles. The doctors assured us that they could see "nothing" and sent us home. Alexander's pain persisted. Finally, on January 18, 1999, we demanded an MRI. To our horror it revealed thirty new tumors throughout Alexander's head and spine. We were told that Alexander had a "few days perhaps" to live and he was discharged home from the hospital with decadron, morphine and hospice care. Having endured chemotherapy and having the cancer return, Alexander now met the FDA requirements and qualified for Dr. Burzynski's therapy. Our son was so sick that we

charted an air ambulance to fly him from Los Angeles to Houston. But the cancer was too widespread. My son, Alexander Horwin, died on January 31, 1999. He was only two and a half years old.

Although Dr. Burzynski's therapy has been in limited use since 1976 and has cured a significant number of people with malignant brain tumors when he has been permitted to do so; his therapy is still not FDA approved. In 1983, Dr. Burzynski approached the FDA to initiate the approval process. In 1993, Burzynski's Investigation New Drug application (IND) was finally accepted and clinical trials began. Today, however, after eight years of trials, the therapy is still not FDA approved. In fact, between 1994 (when two and a half year-old Dustin Kunnari was diagnosed) and 1998 (when two year-old Alexander Horwin was diagnosed), the FDA tightened its criteria regarding which children can be treated with the non-approved protocol. Since 1996, these criteria have required that children with operable brain tumors must first undergo chemotherapy and/or radiation and have the cancer return before Dr. Burzynski can treat them. Even then, the FDA must personally accept the patient onto the protocol before the therapy can begin. If the FDA says "no," there is no appeal. Unfortunately, Alexander was diagnosed after 1997, and therefore, the FDA required that he first be treated with chemo and/or radiation before he could avail himself of Dr. Burzynski's nontoxic therapy.

The FDA is charged with determining what drugs are approved for interstate commerce and under what circumstances non-approved drugs may be accessed. An examination of the FDA's position in relation to cancer sufferers, especially children, will reveal that this agency has consistently and steadfastly come between patients and the non-FDA approved treatments recommended by the patient's medical doctor. The juxtaposition of the stories of the children introduced supra—Dustin Kunnari, who was fortunate enough to be treated and who is alive and healthy, and Alexander Horwin, who was not treated, allowed only orthodox therapy, and who died five months after being diagnosed—raises a number of disturbing legal issues that will be discussed in this note.

Part I will introduce our nation's war on cancer and discuss how well the war has been waged. Part II will survey how the law has consistently limited patient access to non-FDA approved cancer therapies. It will discuss the role of the FDA and the perspective of the U.S. Supreme Court. Part III will focus on the Access to Medical Treatment Act. Four Congresses have attempted to pass this legislation that would allow patients access to non-approved therapies, but the FDA has successfully argued against its passage each time. The agency's medical-policy positions will be identified and critiqued.

Parts IV through VII focus on solutions. Overcoming the FDA's policy arguments is essential to having the Access to Medical Treatment Act passed which would allow children to have access to the therapy that has the best chance of saving their lives. Therefore, these medical-policy suppositions will be critically examined. In Part IV, the assumption that standard cancer therapies are always best will be challenged. In Part V, the importance of requiring thorough clinical testing of new cancer drugs will be considered. Part VI will discuss whether bureaucrats should be placed in a position of trumping the medical decisions of a patient and their physician. Part VII will address the unsuspected role that economics may be playing in the multi-billion dollar cancer industry. Finally, Part VIII will conclude by arguing that the current state of the law in respect to cancer therapy is antithetical to our country's core values.