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COMMENTS

"WAR ON CANCER": WHY DOES THE FDA DENY ACCESS TO ALTERNATIVE CANCER TREATMENTS?

*Michael E. Horwin**

*"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 two and a half years old.

In February 1994, two and a half year-old Dustin Kunnari was diagnosed with a deadly brain tumor called medulloblastoma,¹ which was the size of a golf ball.² The neurosurgeon skillfully removed 75% of the tumor,³

* J.D. Candidate, December 2001, California Western School of Law; M.A., International Business, Webster University, St. Louis 1990; B.A., Cultural Anthropology, University of California, Santa Barbara 1984. 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 two and a half years old and had his entire life before him.

1.

Medulloblastoma is a fast-growing tumor of the cerebellum, a part of the brain that is located in the posterior fossa—the lower, rear portion of the skull. It tends to spread (metastasize) throughout the brain and spine via the cerebrospinal fluid or directly into areas adjacent to the cerebellum . . . this tumor is most common in children between three and eight years of age.

AMERICAN BRAIN TUMOR ASS'N, ABOUT MEDULLOBLASTOMA 1 (1998).

2. *Patient Access to Alternative Treatments: Beyond the FDA Before the Government Reform Committee of the House of Representatives*, 105th Cong. (Feb. 4, 1998) [hereinafter *Patient Access to Alternative Treatments—Kunnari Testimony*] (statement of Mr. Jack Kunnari) available at http://www.house.gov/reform/hearings/healthcare/fda298/2_4jk.htm (last visited June 23, 2001).

3. *Id.*

but surgery alone was not an adequate treatment⁴ and Dustin's parents were referred to a chemotherapy trial.⁵ 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."⁶ "In addition, the doctors could not name a single child who had done well following any of these treatments."⁷ To Dustin and his family, this "cruel regimen with so little hope"⁸ was less than promising.⁹

In April 1994, the Kunnaris traveled to Houston to consult with Stanislaw Burzynski, M.D., Ph.D.¹⁰ Dr. Burzynski used an innovative and non-toxic therapy to treat brain tumors.¹¹ Because Dustin still had some tumor left in his brain, Dr. Burzynski explained that the efficacy of his therapy could be determined rapidly.¹² If, after six weeks, the remaining tumor had shrunk or disappeared then the treatment was working.¹³ 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.¹⁴ 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.¹⁵ The boy stayed on the antineoplastons, but a year later, a second tumor appeared approximately one inch in diameter.¹⁶ Dr. Burzynski increased the dose of his therapy and the second tumor dissolved.¹⁷ Today, over seven years from his initial diagnosis, Dustin is a normal, healthy, cancer-free boy with no side effects from the treatment.¹⁸

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.¹⁹ Alexander was a strong, handsome and

4. AMERICAN BRAIN TUMOR ASS'N, *supra* note 1, at 5.

5. *Patient Access to Alternative Treatments—Kunnari Testimony*, *supra* note 2.

6. *Id.*

7. *Id.*

8. *Id.*

9. *Id.*

10. *Id.*

11. Antineoplaston Therapy, at <http://www.burzynskipatientgroup.org/antineopl.htm> (last visited June 23, 2001).

12. *Patient Access to Alternative Treatments—Kunnari Testimony* *supra* note 2.

13. *Id.*

14. *Id.*

15. *Id.*

16. *Id.*

17. *Id.*

18. *Id.*

19. Physician Progress Note of Dr. Ronald Gabriel, Pediatric Neurologist (Aug. 10, 1998) (on file with author).

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.²⁰ 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.²¹ After extensively researching the medical treatment options, we also chose Dr. Burzynski's therapy for Alexander.²² 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.²³ 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.²⁴ Once the cancer returned on the standard treatment, then Burzynski could treat our son.²⁵

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.²⁶ We were devastated to learn that if our son was one of the "lucky ones" to survive, the side effects of chemotherapy could include:

20. *Hearings on Integrative Oncology—Cancer Care for the New Millennium—Before the Committee of Government Reform, House of Representatives, 106th Cong.* (June 7, 2000) [hereinafter *Hearings on Integrative Oncology—Horwin Testimony*] (statement of Michael and Raphael Horwin), available at <http://www.house.gov/reform/hearings/healthcare/00.06.07/horwin.htm> (last visited May 20, 2001).

21. *Id.*

22. *Id.*

23. *Id.*

24. *Id.*

25. *Id.*

26. *Id.*

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,²⁷ worsening of neurological symptoms, ineffectiveness, and death.

We continued to look for other options outside of the United States.²⁸ 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 head and spine.²⁹ 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.³⁰ Having endured chemotherapy and having the cancer return, Alexander now met the FDA requirements and qualified for Dr. Burzynski’s therapy.³¹ Our son was so sick that we chartered an air ambulance to fly him from Los Angeles to Houston.³² But the cancer was too widespread. My son, Alexander Horwin, died on January 31, 1999.³³ He was only two and a half years old.³⁴

Although Dr. Burzynski’s therapy has been in limited use since 1976³⁵ and has cured a significant number of people with malignant brain tumors when he has been permitted to do so;³⁶ his therapy is still not FDA ap-

27. *Id.* In fact, according to a major medical treatise the standard cancer therapies are “toxic,” and the “most common causes of death in patients with cancer are infection (leading to circulatory failure), respiratory failure, hepatic failure, and renal failure.” ANTHONY S. FAUCI ET AL., HARRISON’S PRINCIPLES OF INTERNAL MEDICINE 496, 499 (14th ed. 1998).

28. *Hearings on Integrative Oncology—Horwin Testimony*, *supra* note 20.

29. *Id.*

30. *Id.*

31. *Id.*

32. *Id.*

33. *Id.*

34. *Id.*

35. THOMAS D. ELIAS, THE BURZYNSKI BREAKTHROUGH 99-125 (1997). In the early 1970s, Burzynski was a research scientist at Baylor University in Houston, Texas. There, he isolated various peptides and tested them in cell cultures and animal models. The peptides stopped the growth of the cancers. He had also found that cancer patients have significant differences in peptide content compared to healthy people. Burzynski then proceeded to use the therapy on terminal cancer patients and had similar success. *Id.* See also *Phase II Study of Antineoplastons A10 and AS2-1 in Children with Primitive Neuroectodermal Tumors—Protocol BT-12*, at <http://catalog.com/bri/BT12RE.html> (last visited June 23, 2001).

36. Dr. Burzynski can only accept patients who meet a FDA approved clinical protocol See *Active Clinical Trials of Antineoplastons*, at <http://www.cancermed.com/clntrls.htm> (last visited Apr. 5, 2001). The overwhelming majority of these protocols require that children be

proved.³⁷ In 1983, Dr. Burzynski approached the FDA to initiate the approval process.³⁸ In 1993, Dr. Burzynski's Investigation New Drug application (IND) was finally accepted and clinical trials began.³⁹ Today, however, after eight years of trials, the therapy is still not FDA approved.⁴⁰ 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.⁴¹ 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.⁴² 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.⁴³ 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 non-toxic therapy.

The FDA is charged with determining what drugs are approved for interstate commerce and under what circumstances non-approved drugs may be accessed.⁴⁴ An examination of the FDA's position in relation to cancer sufferers, especially children, will reveal that this agency has consistently

administered chemotherapy and radiation first and the tumor must return. However when the tumor returns, most children only live a few weeks and do not meet the life expectancy requirements of the FDA approved protocol—a horrific catch-22. *See Phase II Study of Antineoplastons A10 and AS2-1 in Children with Primitive Neuroectodermal Tumors—Protocol BT-12* (§ 7.1.3, 7.1.2.4), at <http://catalog.com/bri/BT12RE.html> (last visited June 23, 2001). When permitted, Dr. Burzynski has cured children with astrocytomas (see, for example, Matthew Anderson), brainstem tumors (see, for example, Jessica Ressel), optic-hypothalamic gliomas (see, for example, Paul Michaels), medulloblastomas (see, for example, Dustin Kunnari), and other brain tumors (see, for example, Shontelle Hiron). *Our Stories: Burzynski Patient Group Directory*, at <http://www.burzynskipatientgroup.org/stories.htm> (last visited June 23, 2001).

37. *Active Clinical Trials of Antineoplastons*, at <http://catalog.com/bri/clntrls.htm> (last visited May 31, 2001).

38. *History Between Dr. Burzynski and FDA*, at <http://catalog.com/bri/summary.htm> (last visited May 29, 2001).

39. *Id.*

40. *Active Clinical Trials of Antineoplastons*, *supra* note 37.

41. Letter from Robert J. DeLap, M.D., Ph.D., Director of the Division of Oncology Drug Products, Center for Drug Evaluation and Research, Food and Drug Administration, to Dr. Burzynski, Burzynski Research Institute (paragraphs A.1., D.22.) (June 12, 1996) (on file with the author).

42. *Id.* *See also Phase II Study of Antineoplastons A10 and AS2-1 in Children with Primitive Neuroectodermal Tumors—Protocol BT-12* (§ 7.1.3, 7.1.2.4), at <http://catalog.com/bri/BT12RE.html> (last visited June 23, 2001).

43. *Patient Access to Alternative Treatments: Beyond the FDA Before the Government Reform Committee of the House of Representatives*, 105th Cong. (Feb. 4, 1998) [hereinafter *Patient Access to Alternative Treatments—Emord Testimony*] (statement of Jonathan W. Emord, Attorney), available at http://www.house.gov/reform/hearings/healthcare/fda298/2_4je.htm (last visited June 23, 2001).

44. 21 U.S.C. § 312 (2001), 24 C.F.R. § 312 (2001).

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.⁴⁵ 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.

I. THE WAR ON CANCER

On January 22, 1971, during President Nixon's State of the Union Address, the President declared a "war on cancer."⁴⁶ He stated, "The time has come in America when the same kind of concentrated effort that split the atom and took man to the moon should be turned toward conquering this dread disease. Let us make a total national commitment to achieve this goal."⁴⁷

In the thirty years that have elapsed since this declaration, we have unfortunately fallen far short of this goal and the "war" continues to take an

45. U. S. v. Rutherford, 442 U.S. 544, 550 (1979).

46. President Richard Nixon's Annual Message to Congress on the State of the Union (Jan. 22, 1971), http://www.nixonfoundation.org/Research_Center/PublicPapers.cfm?BookSelected=1971 (last visited May 20, 2001).

47. *Id.*

enormous number of casualties. According to the National Cancer Institute (NCI), between 1973 and 1991, the age-adjusted⁴⁸ cancer *death* rate increased.⁴⁹ From 1991 to 1998, the death rate began to decrease,⁵⁰ but the overall percentage of change between 1973 to 1998 was 0%.⁵¹ This year, cancer will kill an average of 1,500 Americans a *day*.⁵² In fact, according to the American Cancer Society "[c]ancer is [now] the second leading cause of death in the US [sic], exceeded only by heart disease."⁵³ And perhaps most disturbingly, cancer is now the leading cause of death by disease in children.⁵⁴

Like most wars fought by this country, this nation has not been hesitant to spend large sums of money in pursuit of its goals. Since 1971, the NCI has expended over 42 billion dollars for a cure.⁵⁵ Progress has been made in a minority of cancers,⁵⁶ albeit at a cost of terrible suffering, in some cases.⁵⁷

48. Age-adjusted means that the statistics are adjusted to reflect the change in the population's ages. For example, one would expect that an older population would have a higher cancer death rate than a younger population. As the American population ages this change is factored into the numbers so that the death rate is independent of this aging.

49. NATIONAL CANCER INSTITUTE SEER CANCER STATISTICS REVIEW 1973-1998 TABLE II-1 ALL SITES (INVASIVE) TRENDS IN SEER INCIDENCE AND US MORTALITY USING THE JOINPOINT REGRESSION PROGRAM, 1973-1998 WITH UP TO THREE JOINPOINTS BY RACE AND SEX, *available at* http://seer.cancer.gov/Publications/CSR1973_1998/allsites.pdf (last visited June 23, 2001).

50. *Id.*

51. NATIONAL CANCER INSTITUTE SEER CANCER STATISTICS REVIEW 1973-1998 TABLE I-10 SEER INCIDENCE AND U.S. MORTALITY TRENDS BY PRIMARY CANCER SITE AND SEX, ALL RACES 1973-1998, *available at* http://seer.cancer.gov/Publications/CSR1973_1998/overview/overview5.pdf (last visited June 23, 2001).

52. *American Cancer Society: Statistics*, at <http://www3.cancer.org/cancerinfo/sitecenter.asp?ctid=8&scdoc=40000&scs=0&scp=0&scss=0> (last visited Apr. 5, 2001).

53. *Id.*

54.

While cancer is only a minor cause of death in infancy (<1 year), it was the third most common cause of death between the ages of 1 and 19 in 1997, following unintentional injuries and homicides. It constitutes about 8% of deaths between age 1 and 19, and is the leading cause of death from disease at these ages.

American Cancer Society—Childhood Cancer, Introduction, at <http://www3.cancer.org/cancerinfo/sitecenter.asp?ct=1&ctid=8&scp=8.3.4.0032&scs=4&scss=1&scdoc=42014&pnt=2&language=english> (last visited Apr. 5, 2001).

55. NATIONAL CANCER INSTITUTE PLANS & PRIORITIES FOR CANCER RESEARCH—HISTORICAL BUDGET INFORMATION, *available at* http://2002.cancer.gov/search?NS-search-page=document&NS-rel-doc-name=/live/2002histbdgt.htm&NS-query=1989&NS-search-type=NS-boolean-query&NS-collection=Search_2002_Site&NS-docs-found=2&NS-doc-number=2 (last visited June 23, 2001).

56. NATIONAL CANCER INSTITUTE SEER CANCER STATISTICS REVIEW 1973-1998 TABLE I-15 TRENDS IN SEER INCIDENCE AND U.S. MORTALITY FOR SELECTED CANCER SITES, 1973-1998, ALL RACES, MALES AND FEMALES, *available at* http://seer.cancer.gov/Publications/CSR1973_1998/overview/overview5.pdf (last visited June 23, 2001). According to the National Cancer Institute, between 1973 and 1998 there has been a decrease in mortality for the following cancers: oral cavity and pharynx, stomach, colon and rectum, pancreas, larynx, cer-

Nonetheless, surgery, chemotherapy, radiation and hormone therapy are still the four main modalities to treat various forms of cancer.⁵⁸

Three of these four modalities—surgery, radiation, and chemotherapy—have been in use for decades. Surgery has been employed to excise tumors for at least 500 years.⁵⁹ Similarly, treating cancer with radiation has been practiced for nearly a century since the days of Madam Curie.⁶⁰ By the early 1900s, surgery and radiation (i.e. X-ray and radium) had already become the “orthodox” treatments for cancer.⁶¹ In the 1950s, chemotherapy was added to the orthodox arsenal.⁶² The fourth modality, hormone therapy, was added more recently but is only effective in specific cancers such as breast cancer and carcinoma of the prostate.⁶³

After 500 years of surgery, 100 years of radiation, 50 years of chemotherapy, the application of hormone therapy, and despite spending billions of dollars on research, cancer still took the lives of approximately two and a half million Americans in the last five years.⁶⁴ This figure is more than six times the total number of American Servicemen who died during World War II.⁶⁵

vix uteri, corpus and uterus, ovary, Hodgkin's disease, and leukemias. *Id.*

57. EWAN CAMERON & LINUS PAULING, *CANCER AND VITAMIN C* 47 (1979).

58. *American Cancer Society, Cancer Resource Center, Types of Treatment*, available at http://www3.cancer.org/cancerinfo/load_cont.asp?st=tr&ct=1&prevURL=load_cont.asp&language=ENGLISH (last visited Apr. 5, 2001). According to the American Cancer Society (ACS) the types of treatment for cancer include surgery, radiation therapy, chemotherapy, hormone therapy, and immunotherapy. However, according to the ACS, immunotherapy is “most often used as an adjuvant therapy (along with or after another therapy) to add to the anticancer effect of the main therapy.” *Id.*

59. RALPH W. MOSS, PH.D., *THE CANCER INDUSTRY* 43-45 (1999).

60. “Radiation therapy was introduced following the discovery of the radioactivity of uranium in 1896 by Becquerel and of radium in 1898 by Marie and Pierre Curie. Use of radiation therapy in the treatment of cancer first occurred in 1896....” MARGARET BARTON BURKE, R.N., M.S., O.C.N., ET AL., *CANCER CHEMOTHERAPY A NURSING PROCESS APPROACH* 5 (1991). In 1917, a prominent New York physician who treated cancer wrote, “I have seldom if ever come across a patient with cancer who had had any intelligent and prolonged attempt to check its development by dietary, hygienic, and medicinal means; invariably the knife, X-ray, and radium have been the only measures under consideration.” L. DUNCAN BULKLEY, A.M., M.D., *CANCER—ITS CAUSE AND TREATMENT VOLUME II* 31 (1917).

61. BULKLEY, *supra* note 60, at 31.

62. The chemotherapeutic approach to kill cancer cells with poisonous agents was inspired when the Allied Liberty Ship, the John E. Harvey exploded in the harbor of Bari, Italy in 1943. The ship was carrying mustard gas and many of the sailors on board suffered or died from the destruction of their white blood cells. This clinical reaction was noted by Navy doctor, Peter Alexander and inspired synthesis of some of the first chemotherapeutic agents. RALPH W. MOSS, PH.D., *QUESTIONING CHEMOTHERAPY* 16 (1995).

63. Androgen Deprivation is one example of hormone therapy. *See, e.g.*, HARRISON'S *PRINCIPLES OF INTERNAL MEDICINE* 601 (Anthony S. Fauci, M.D., et al. eds., 14th ed. 1998).

64. *American Cancer Society: Statistics*, at <http://www3.cancer.org/cancerinfo/sitecenter.asp?ctid=8&scdoc=40000&scs=0&scp=0&scss=0> (last visited Apr. 5, 2001).

65. *THE WORLD ALMANAC* 209 (1999). There were 407,316 battle deaths plus “other deaths” for American Servicemen in WWII (2,500,000 / 407,316 = 6.1). *Id.*

Some scientists have attributed this extraordinary death toll to a more carcinogenic environment⁶⁶ and an aging population.⁶⁷ Others believe the figure is independent of these factors.⁶⁸ Nonetheless, it would seem rational to allow terminal cancer patients for whom orthodox therapies are known to be ineffective or debilitating to exercise freedom in selecting other modalities to extend their lives or to alleviate their pain and suffering. Unfortunately, the law currently does not permit such an exercise of personal choice.

II. HOW THE LAW HAS LIMITED ACCESS TO CANCER THERAPIES

A. *The Federal Food, Drug, and Cosmetic Act*

The Federal Food, Drug, and Cosmetic Act (FDCA) requires "substantial evidence" of safety and efficacy of drugs before they are approved.⁶⁹ The FDCA authorizes the FDA⁷⁰ to approve new drugs for interstate commerce.⁷¹

66. *American Cancer Society Environmental Cancer Risks*, available at <http://www3.cancer.org/cancerinfo/sitecenter.asp?ctid=8&scp=8.2.1.40057&scs=3&scss=7&scdoc=40093&language=english> (last visited June 23, 2001). "Environmental factors, defined broadly to include smoking, diet, and infectious diseases as well as chemicals and radiation, cause an estimated three-quarters of all cancer deaths in the United States." *Id.*

67. "The increases in the crude mortality rates due primarily to the aging of the population." *U.S. Cancer Mortality Rates by Different Age Standards 1973-1996*, available at *North American Association of Central Cancer Registries—Education & Training/Online Education*, <http://www.naacr.org/Training/html/course2/M11thumbnails/Ries.12.html> (last visited June 23, 2001).

68. For example, in respect to prostate cancer, one medical doctor has reported, "There is no direct scientific proof that early detection of prostate cancer will decrease the mortality rate." See Richard J. Babaian, M.D., *Oncology Case Reports and Review, Prostate Cancer: A Diagnostic Dilemma* vol. 10, at <http://www.roxane.com/pain/library/Newsletters/MDA/v10n3.html> (last visited June 23, 2001). With respect to female lung cancer the NCI has stated, "Both the rate of new lung cancer cases and lung cancer deaths are rising for women." See *National Institute of Health: New Report on Declining Cancer Incidence and Death Rates*, available at <http://www.nih.gov/news/pr/mar98/nci-12.htm> (last visited June 23, 2001).

69. 21 U.S.C. § 355(d) (1994).

70. 21 C.F.R. § 5.10 (West 2001).

Originally, the FDA was organized under the Department of Agriculture. In 1940, it was shifted to the Federal Security Agency. Finally, in 1953, it was transferred to the Department of Health, Education and Welfare (HEW), which is now known as the HHS. The FDA is part of the Public Health Service (PHS) group, which is located within the HHS. The FDA is empowered to enforce the Federal Food, Drug and Cosmetic Act, but it does not receive its authority from Congress directly. Rather, the legislation delegated the authority to the Secretary of HHS, who is appointed by the President of the United States. The Secretary then delegates this authority to the Assistant Secretary of HHS who oversees the PHS. This delegation of authority is atypical for an important regulatory body. Review is complicated further because the Commissioner of the FDA is appointed by the Secretary of HHS, yet, the Commissioner reports to the Assistant Secretary of HHS. . . . While the FDA reviews NDAs [New Drug Applications] and gives labeling and marketing approval to qualified drugs, it does not conduct the actual investigation or clinical trial. Furthermore, the FDA receives NDAs not only from commercial

Drugs are defined very broadly as “articles (other than food) intended to affect the structure or any function of the body of man” and “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals.”⁷² “Substantial evidence” means that “well-controlled investigations” were undertaken “by experts qualified by scientific training and experience to evaluate... the drug.”⁷³ Violation of the FDCA by using drugs that are not FDA approved can lead to seizure and destruction of the drugs in question,⁷⁴ injunctions to restrain further violations,⁷⁵ and criminal penalties, including imprisonment.⁷⁶

B. FDA's Drug Approval Process

The process by which a new drug is approved is expensive, lengthy and is carried out by the drug's sponsor, not the FDA. The “well-controlled investigations” used to determine “substantial evidence” include animal testing and human testing.⁷⁷ Typically, after the drug is tested on animals, the drug's sponsor may submit an application for an investigational new drug

entities, but from governmental agencies as well, such as the NIH.

Lynne Kessler Lechter, *Regulatory Overkill and the AIDS Patient*, 1 ALB. L.J. SCI. & TECH. 131, 150 (1991).

71. 21 U.S.C. § 321(b) (1994). “The term ‘interstate commerce’ means: (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.” *Id.* Interstate commerce also means drugs sold to patients who then transport them across state lines, or drugs whose components or packaging are produced in another state before sale to the patient. 21 U.S.C. § 355(a) (1994). *See also* U.S. v. Articles of Drug . . . Wans, 526 F. Supp. 703, 707 (D.P.R. 1981).

72. 21 U.S.C. § 321(g)(1) (1994). Psychological/metaphysical approaches are not considered drugs and are not subject to FDCA regulation. *Id.*

73. 21 U.S.C. § 355(d) (1994).

As used in this subsection and subsection (c) of this section, the term ‘substantial evidence’ means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. If the Secretary determines, based on relevant science, that data from one adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) are sufficient to establish effectiveness, the Secretary may consider such data and evidence to constitute substantial evidence for purposes of the preceding sentence.

Id.

74. 21 U.S.C. § 334 (1994).

75. *Id.* § 332.

76. *Id.* § 333.

77. *Id.* § 355.

exemption (IND).⁷⁸ Once an IND is granted (and as long as it is not revoked), the drug's sponsor can begin human trials.⁷⁹ An Investigational Review Board (IRB) is then appointed to oversee the three phases of human trials. Phase I is used to determine the safety and relative toxicity of the drug at various doses.⁸⁰ Phase II is used to determine efficacy as well as safety.⁸¹ In Phase III, the new drug is compared to a placebo or another similar drug.⁸² The test subjects for all three phases are usually patients who have not benefited from available drugs or treatments. After all three phases are complete, the FDA determines whether the drug is safe and effective for its intended use and whether it should be approved.⁸³

C. *The Rutherford Court*

FDA control over patients' access to cancer drugs was challenged in *Rutherford v. United States*.⁸⁴ In this case, terminally ill cancer patients sued to enjoin the FDA from stopping the interstate shipment and sale of laetrile on the grounds that it had not been approved for distribution under the FDCA.⁸⁵ Laetrile, also known as amygdalin, is a naturally occurring substance found in apricot kernels and hundreds of other plants.⁸⁶ Reportedly, it is has been used in the treatment of tumors for centuries beginning with the Chinese 3,500 years ago.⁸⁷ The FDA determined that distribution of laetrile in interstate commerce is illegal and subject to regulatory activity by the Food and Drug Administration. Such determination, the court pointed out, is reviewable by the district court under the Administrative Procedure Act, 5 U.S.C. section 701 et seq.⁸⁸

The district court held that the FDA's decision to stop the distribution of laetrile was "arbitrary [and] capricious [and] that it represents an abuse of discretion and is not in accordance with law."⁸⁹ The court stated, "[T]he individual must be given maximum latitude in determining his own personal destiny."⁹⁰ The court also described the destructive effects of orthodox treatment (radiation and chemotherapy) and held that individual decision-

78. 21 C.F.R. § 312 (2001).

79. *Id.*

80. *Id.*

81. *Id.*

82. *Id.*

83. For an overview of the FDA drug approval process see Lynne Kessler Lechter, *Regulatory Overkill and the AIDS Patient*, 1 ALB. L.J. SCI. & TECH. 131, 150 (1991)

84. *Rutherford v. U.S.*, 438 F. Supp. 1287, 1289-90 (W.D. Okla. 1977).

85. *Id.*

86. Laetrile is a benzaldehyde cyanophoric glycoside or nitriloside found in over 1,200 plants. ROBERT E. WILLNER, M.D., PH.D. THE CANCER SOLUTION 26 (1994)

87. *Id.* at 25.

88. *Id.*

89. *Rutherford*, 438 F. Supp. at 1291.

90. *Id.* at 1300.

making “is the sole prerogative of the person whose body is being ravaged. . . .”⁹¹ The court’s analysis focused on the constitutional rights of citizens; the right to privacy. The court held that by “denying the right to use a nontoxic substance in connection with one’s own personal health-care, [the] FDA has offended the constitutional right of privacy.”⁹² The court concluded:

Nonetheless, it appears uncontrovertible (sic) that a patient has the right to refuse cancer treatment altogether, and should he decide to forego conventional treatment does he not possess a further right to enlist such nontoxic treatments, however unconventional, as he finds to be of comfort, particularly where recommended by his physician?⁹³

The FDA appealed to the U.S. Supreme Court, which granted certiorari and reversed.⁹⁴ The Court based its analysis on deference to legislative intent and statutory construction.⁹⁵ According to the *Rutherford* Court, the FDCA “makes no express exception for drugs used by the terminally ill. . . .”⁹⁶ The Court explicitly held that “[e]xceptions to clearly delineated statutes will be implied only where essential to prevent ‘absurd results’ or consequences obviously at variance with the policy of the enactment as a whole.”⁹⁷ Apparently the Court found nothing absurd in preventing dying patients access to a non-toxic substance that might extend their lives or alleviate their suffering, even though these patients have been labeled “terminal” by orthodox medicine.

Furthermore, the *Rutherford* Court was sensitive to the authority of the FDA. The Court validated the FDA’s position that terminal cancer patients must be ensured a therapeutic gain and that only FDA approval can assure such a gain.⁹⁸ The opinion also stated that if FCDA standards do not apply to terminally ill patients, the FDA could ultimately lose its authority over all drugs.⁹⁹

91. *Id.*

92. *Id.* at 1301.

93. *Id.* at 1299-1300.

94. *U. S. v. Rutherford*, 442 U.S. 544, 551, 559 (1979).

95. *Id.* at 545.

96. *Id.* at 544.

97. *Id.* at 552.

98. *Id.* at 555-56.

Thus, the Commissioner generally considers a drug safe when the expected therapeutic gain justifies the risk entailed by its use. For the terminally ill, as for anyone else, a drug is unsafe if its potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit.

Id.

99. *Id.* at 557-58.

III. THE ACCESS TO MEDICAL TREATMENT ACT

Since 1993, an increasing number of members of Congress have recognized the inherent injustice in preventing cancer victims from having the medical freedom to try to save their lives. In the words of one Congressman:

I do not see how the FDA is serving the public when, by its actions it prevents a child with a brain tumor or a young woman with Non-Hodgkins Lymphoma from getting a treatment these individuals and their families have been informed about and have freely chosen to pursue. In essence, the FDA is telling someone battling a disease like cancer that they cannot have a potential life-saving treatment.¹⁰⁰

As a result, a bill has been repeatedly introduced in Congress entitled "The Access to Medical Treatment Act."¹⁰¹ This Act would allow a patient to be treated by any licensed health care practitioner with any method of medical treatment the individual desires, so long as a comprehensive list of requirements are met. These requirements mandate the petitioner to use "generally accepted principles and current information" to conclude that the unapproved drug will not cause a danger to the patient, to inform the patient that the drug is not approved, and to disclose any financial interest that the practitioner may have in the drug.¹⁰²

Senator Bob Dole, an original co-sponsor of the Access to Medical Treatment Act, has stated, "In a free market system, it seems to make sense to make available non-harmful alternative medical treatments to individuals who desire such treatments, without the Federal Government standing in the way."¹⁰³

Congress has attempted to pass the Act from 1993 to 1999.¹⁰⁴ Unfortunately, the FDA has maintained that this Act would jeopardize lives because it would not require clinical testing before prescribing a drug.¹⁰⁵ This position has convinced the majority of Congressmen and Senators that the risks outweigh the benefits in allowing patients the freedom to access the medical care of their choice. This position and the assumptions on which it rests will be discussed in detail *infra*.

100. 142 Cong. Rec. H4115 (daily ed. Apr. 29, 1996) (statement of Rep. Pallone).

101. S. 1955, 106th Cong. (1999); H.R. 746, 105th Cong. (1997); S. 578, 105th Cong. (1997); H.R. 2019, 104th Cong. (1995-96); S. 1035, 104th Cong. (1995-96); H.R. 4696, 103rd Cong. (1993-94); H.R. 4499, 103rd Cong. (1993-94) [hereinafter *Bills*].

102. S. 1955, 106th Cong. (1999).

103. *Natural Health Village Legislation: Access to Medical Treatment Act*, at <http://www.naturalhealthvillage.com/townhall/federal/access2med.html> (last visited Apr. 5, 2001).

104. See *Bills*, *supra* note 101.

105. *Patient Access to Alternative Treatments: Beyond the FDA Before the Government Reform Committee of the House of Representatives*, 105th Cong. (Apr. 22, 1998) [hereinafter *Patient Access to Alternative Treatments—Friedman Testimony*] (statement of Michael A. Friedman, M.D. Lead Deputy Commissioner Food and Drug Administration) available at <http://www.fda.gov/ola/therapy.htm> (last visited June 24, 2001).

A. *The Inherent Medical-Policy Position*

The FDA's policy objective is to ensure that cancer sufferers only employ the so-called "proven methods" and are not deceived into using non-approved therapies that can be ineffective and potentially dangerous. This concern is summarized in the *Rutherford* opinion:¹⁰⁶

Since the turn of the century, resourceful entrepreneurs have advertised a wide variety of purportedly simple and painless cures for cancer, including liniments of turpentine, mustard, oil, eggs, and ammonia; peat moss; arrangements of colored floodlamps; pastes made from glycerin and limburger cheese; mineral tablets; and 'Fountain of Youth' mixtures of spices, oil, and suet.¹⁰⁷

This policy is also reflected in the California Health and Safety Code: "It is established that accurate and early diagnosis of many forms of cancer, followed by prompt application of methods of treatment that are scientifically proven, either materially reduces the likelihood of death from cancer or may materially prolong the useful life of individuals suffering there from."¹⁰⁸ And finally, FDA representatives have testified that they must play a crucial role in determining what drugs are available so patients are "protected from untested and unproven products."¹⁰⁹

B. *Passing the Access to Medical Treatment Act*

The Access to Medical Treatment Act would allow cancer sufferers to choose the most appropriate medical treatment with the help of their physician. This Act, however, will not be passed unless the underlying medical-policy assumptions inherent in the Supreme Court's decision, state statutes, and the FDA's position are addressed. These assumptions are:

Standard therapies represent a patient's best chance for a cure;
Thorough clinical testing of cancer therapies is always necessary;
Bureaucrats should be placed in a position of trumping the medical decisions of a patient's own physician; and
Politics and economics play no role in determining what cancer treatments are labeled "proven" by the FDA, the pharmaceutical industry or the large institutional cancer centers.

Each one of these medical-policy assumptions will be discussed *infra*.

106. See *Rutherford*, 442 U.S. at 558.

107. *Id.*

108. CAL. HEALTH & SAFETY CODE § 109250 (West 1996).

109. *Patient Access to Alternative Treatments—Friedman Testimony*, *supra* note 105

IV. ARE STANDARD CANCER THERAPIES ALWAYS BEST?

Do standard cancer therapies represent a patient's best chance for a cure? The American Cancer Society statistics cited *supra* demonstrate that despite widespread use of the proven therapies of surgery, radiation, chemotherapy, and hormone therapy, 1,500 people will die of cancer today and every day.¹¹⁰ An example demonstrates this point.

A. Example—Pediatric Brain Cancer

According to the FDA, radiation and chemotherapy are considered the "standard" therapy for treating pediatric brain cancers such as medulloblastoma.¹¹¹ That is why the FDA refused to allow Dr. Burzynski to treat our son, Alexander Horwin, introduced *supra*. But, according to oncologists, these "proven" or standard therapies are ineffective. Their medical journals contain admissions like the following: "[In] medulloblastoma, the most common primary tumor of the CNS [central nervous system] in childhood . . . [t]he role of adjuvant chemotherapy is unclear . . . virtually no cures are reported."¹¹² "Aggressive treatment of medulloblastoma, the most common pediatric brain tumor, has not improved survival."¹¹³ "[T]he absolute benefit of chemotherapy for the treatment of medulloblastoma in childhood is, as yet, not proven."¹¹⁴ "The median time to progression [return of the tumor] was 6 months."¹¹⁵ "For many years, chemotherapy has been utilized for the treatment of malignant brain tumors with minimal success."¹¹⁶ "The outcome for the majority of children with malignant brain tumors remains poor, despite surgery, irradiation and conventional chemotherapy."¹¹⁷

In comparison, Dr. Burzynski's innovative, non-toxic, but non-FDA-approved cancer therapy for brain tumors has been described as significantly

110. See *American Cancer Society Statistics*, *supra* note 52.

111. Chairman Dan Burton Introduces the "Thomas Navarro FDA Patient Rights Act," at <http://www.house.gov/reform/FDAPatientRightsAct.htm> [hereinafter *Thomas Navarro FDA Patient Rights Act*] (last visited Apr. 5, 2001).

112. H.S. Friedman & S.C. Schold Jr. *Rational Approaches to the Chemotherapy of Medulloblastom*, 4 *NEUROL CLIN.* 843-53 (1985).

113. M.D. Weil, et al., *Influence of a Child's Sex on Medulloblastoma Outcome*, 279 *JAMA* 1474-76 (1998).

114. S. Attard-Montalto, et al., *Is There a Danger in Delaying Radiotherapy in Childhood Medulloblastoma?*, 789 *BR. J. RADIOL.* 807-13 (1993).

115. J. R. Geyer, et al., *Survival of Infants with Primitive Neuroectodermal Tumors or Malignant Ependymomas of the CNS Treated with Eight Drugs in 1 Day: A Report from the Childrens Cancer Group*, 12 (8) *J. CLINICAL ONCOL.* 1607-15 (1994).

116. M.D. Prados & C. Russo, *Chemotherapy of Brain Tumors*, 14(1) *SEMIN. SURG ONCOL.* 88-95 (1998).

117. J. L. Finlay, *The Role of High-Dose Chemotherapy and Stem Cell Rescue in the Treatment of Malignant Brain Tumors*, *BONE MARROW TRANSPLANT* (1996 & Supp 3, 18:S1-5).

more successful than the “proven” therapies.¹¹⁸ In 1997, Robert E. Burdick, M.D., a Seattle oncologist and faculty member of the University of Washington Medical School, wrote:

It is very rare, currently, to ever get a complete remission or cure in a patient who has a malignant brain tumor using our standard modalities of surgery, radiation and chemotherapy. . . . As a rough estimate, neurosurgeons do well to cure 1 in every 1,000 brain cancer patients they operate on. Radiation therapy slows the growth of adult tumors gaining perhaps one month of life and again may result in a cure in only 1 in 500-1,000 patients. . . . Similarly, chemotherapy research, despite 30 years of clinical trials, has not resulted in the development of a single drug or drug combination that elicits more than an occasional transient response in primary brain tumors. . . . The responses [with Burzynski’s treatment] are far in excess of any prior series of patients published in the medical literature . . . a response rate here is an astounding 33%. Such remission rates are far in excess . . . of anything that I or anyone else has seen since research work on brain tumors began.¹¹⁹

Even the National Cancer Institute (NCI) agrees that Burzynski’s therapy works.¹²⁰ In a 1991 internal memo from Dr. Michael Friedman, Associate Director of Cancer Therapy Evaluation Programs, to Dr. Bruce Chabner, Director of the Division of Cancer Treatment, Friedman wrote that Burzynski’s treatment is comprised of “well defined, pure chemical entities . . . [and] [t]he human brain tumor responses are real.”¹²¹

Despite these findings by oncologists and the NCI, Dr. Burzynski’s therapy is not accessible. Surgery, radiation and chemotherapy are still the only therapies the FDA allows children to use until their cancers return, but by then it is often too late.¹²² Thus, to represent these approved therapies as a cancer victim’s only hope is disingenuous.

B. Is the Cancer Paradigm of Mainstream Medicine Infallible?

For decades, orthodox medicine has opined that an aberrant cell causes cancer.¹²³ Those who believe that the competence of an individual’s immune system is the more decisive factor in cancer have challenged this view.¹²⁴

118. *The Burdick Report* (Feb. 19, 1997), available at <http://www.burzynskipatientgroup.org/burdickreport.htm> (last visited June 24, 2001).

119. *Id.*

120. Memorandum from Dr. Michael Friedman, Associate Director, Cancer Therapy Evaluation Programs, to Dr. Bruce Chabner, Director, Division of Cancer Treatment (Oct. 31, 1999), available at <http://www.cancermed.com/friedman.html> (last visited Apr. 5, 2001).

121. *Id.*

122. *Thomas Navarro FDA Patient Rights Act*, *supra* note 111.

123. Professor Robert A. Weinberg describes cancer cells as “deaf to the usual controls on proliferation” and able to “follow their own internal agenda for reproduction.” Robert A. Weinberg, *How Cancer Arises*, 275 *SCI. AM.* 62, 63 (1996).

124. For example, according to Dr. Robert Millner, “[T]he repair and support of our immune system with natural remedies that do not interfere with normal processes is the best ra-

Today, this controversial perspective is becoming more mainstream as orthodox medicine has begun testing immune and "biological therapies."¹²⁵ Nonetheless, for many years such therapies were summarily rejected and those practitioners who used corresponding approaches were ostracized. The following example illustrates this point.

C. Professor Andrew C. Ivy, M.D.

Professor Andrew C. Ivy, M.D. enjoyed an impeccable reputation as a researcher, scientist and physician.¹²⁶ He taught thousands of medical students, had been involved in over 1,300 medical studies, and had discovered several of the body's hormones.¹²⁷ In 1946, he was appointed as the sole Medical Scientific Consultant to the U.S. Military Tribunal No. 1 at Nuremberg to serve as "an expert witness on scientific and ethical subjects."¹²⁸ Af-

tional and scientific approach (for the cure of cancer and degenerative diseases)." ROBERT E. WILLNER, M.D., PH.D. *THE CANCER SOLUTION* 11 (1994).

125. *NCI Fact Sheet: Biological Therapies: Using the Immune System To Treat Cancer*, available at http://cancer.med.upenn.edu/pdq_html/6/engl/600072.html (updated Apr 2000)

126. *The American Physiological Society, 17th APS President (1939-1941), Andrew C Ivy, (1893-1978)*, at <http://www.the-aps.org/about/presidents/introaci.htm> (last visited Apr. 5, 2001). The following comes from the American Physiological Society's biography of Dr. Ivy.

Andrew Conway Ivy served as president of the Society for the two-year term just before the dislocations caused by World War II. He had previously been secretary for five years. Born in Farmington, Missouri, he was educated primarily at the University of Chicago, where he received his Ph.D. degree in 1918 under A. J. Carlson. He received an M.D. degree from Rush Medical College in 1922 while associate professor of physiology at Loyola University School of Medicine (1919-23). Other academic positions were at the University of Chicago (associate professor, 1923-25), Northwestern University Medical School (head of the Division of Physiology and Pharmacology, 1926-45), the University of Illinois (vice-president, 1946-53; and distinguished professor of physiology, 1953-62), and Roosevelt University (research professor of biochemistry, 1962-66). He also served as scientific director of the Naval Medical Research Institute (1942-43), executive director of the National Advisory Cancer Council (1947-51), and director of the Ivy Cancer Research Foundation. Author of approximately 2,000 scientific articles (over 1,500 by 1955), his contributions were primarily in gastrointestinal physiology and pharmacology but also included the physiology of reproduction, applied physiology (aviation medicine), and physiological resistance to cancer. His interest in cancer increasingly dominated his career after 1946. This included work on a highly controversial drug, 'krebiozen,' which led to a temporary estrangement from his colleagues at APS. During the mid 1970s, however, he began attending Society meetings again and displayed the same vigor characteristic of him in former years. After his term as president, Ivy continued to serve the Society on the Board of Publication Trustees (1945-48), and in this capacity he is credited with recruiting Milton O. Lee, who in 1947 became the first employed executive secretary-treasurer of the Society as well as managing editor of the publications

Id.

127. HERBERT BAILEY, *A MATTER OF LIFE OR DEATH* 28-29 (1958)

128. ALEXANDER MITSCHERLICH & FRED MIELKE, *DOCTORS OF INFAMY, THE STORY OF THE NAZI MEDICAL CRIMES IX* (1949). "[T]he [U.S.] Secretary of War[] asked the Board of

ter the war, Ivy became the vice-president of the University of Illinois where he ran that university's large medical school.¹²⁹ He was also named Executive Director of the National Advisory Cancer Council and a director of the American Cancer Society.¹³⁰ Dr. Ivy's name can also be found in most standard medical dictionaries.¹³¹

For over twenty years, Ivy taught his medical students that rare spontaneous remissions of cancer found in the medical literature indicated the existence of some chemical substance produced in the body which acts as a defender against this disease.¹³² In 1949, Ivy began testing a cancer treatment called krebiozen.¹³³ Invented by Dr. Stevan Durovic,¹³⁴ krebiozen was made from a hormone that horses generated when they had been exposed to a fungus (*Actinomyces bovis*) that caused a cancer-like disease called "lumpy jaw."¹³⁵ The results of the therapy were very encouraging. Reportedly, the first terminal cancer patients found their tumors disintegrating after being administered the experimental drug.¹³⁶ In 1954, Dr. Ivy collated, analyzed and evaluated the various reports from physicians who had used krebiozen on terminal cancer patients. A summary of this medical report indicated, "In 111 of 226 externally measurable cases, or in about 50% of these cases, the tumors decreased in size."¹³⁷

The FDA never approved krebiozen.¹³⁸ In April 1965, a cancer victim named Geraldine Ray sued the federal government on the grounds that its prohibition of krebiozen was unlawful and unconstitutional.¹³⁹ Her amended complaint was dismissed, and following her death in October 1965, her estate appealed. The Court of Appeals for the Seventh Circuit affirmed the decision, holding that the doctrine of primary jurisdiction applied and the FDA was in the best position to decide whether krebiozen should be accessible or not.¹⁴⁰

In 1967, Dr. Allen Rutherford and a number of cancer patients who had been treated with krebiozen appealed a district court's decision to dismiss

Trustees of the American Medical Association [AMA] to nominate a medical scientist to serve as a consultant to the Nuremberg trial of Nazi physicians." *Id.* at ix. From the tens of thousands of AMA physicians, this organization chose Dr. Ivy.

129. BAILEY, *supra* note 127, at 28-29.

130. *Id.* at 30.

131. DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1611 (25th ed. 1974). Ivy invented a test he used to measure platelet and capillary function. *Id.*

132. BAILEY, *supra* note 127, at 31.

133. The word "Krebiozen" was compounded from Greek terms meaning "that which regulates growth." BAILEY, *supra* note 127, at 38-39.

134. Durovic was a Yugoslav refugee who had been living in Buenos Aires. *Id.* at 10. He had worked at the Pasteur Institute in Paris prior to WWII. *Id.* at 16.

135. *Id.* at 22.

136. *Id.* at 39-43.

137. HERBERT BAILEY, KREBIOZEN—KEY TO CANCER? 300 (1955).

138. *Tutoki v. Celebrezze*, 375 F.2d 105, 107 (7th Cir. 1967)

139. *Id.* at 106.

140. *Id.* at 107.

their suit against the American Medical Association (AMA).¹⁴¹ The suit alleged that the AMA had taken an active role in working with the FDA to interfere with the approval and national distribution of krebiozen.¹⁴² The court affirmed the lower court's decision on the grounds that the court had no jurisdiction to decide whether the FDA had placed unreasonable conditions on approval of the product.¹⁴³

At the time the United States government was outlawing the interstate shipment of krebiozen, it was widely accepted amongst orthodox medicine that human beings possessed no specific resistance to cancer in their blood. Hence, the notions that a substance from the blood of horses could arrest or cure cancer in people sounded like quackery to government scientists.

Today, Drs. Ivy and Durovic's insights may be better appreciated. In the last fifteen years, mainstream science has caught up with the wisdom of these two innovative physicians. According to a leading medical treatise, "Animal studies have conclusively shown that the immune system can recognize and eliminate malignant tumors *in vivo*."¹⁴⁴ In recent years, billions of dollars have been invested in isolating and synthesizing interleukin, interferon, and other cytokines—all natural immune-related substances which can kill or arrest cancer and that are found in the blood of mammals including horses and man.¹⁴⁵

D. Stanislaw Burzynski M.D. Ph.D.

The Burzynski therapy is also based on substances that naturally exist in healthy people.¹⁴⁶ As a research scientist at Baylor University of Medicine in the 1970's, Dr. Burzynski observed that people without cancer carry specific peptides in their blood and cancer patients are often missing these pep-

141. *Rutherford v. AMA*, 379 F.2d 641, 642 (7th Cir. 1967).

142. *Id.*

143. *Id.* at 643.

144. HARRISON'S PRINCIPLES OF INTERNAL MEDICINE 535 (Anthony S Fauci, et al eds., 14th ed. 1998).

145. For examples of immune related substances found in man, see *NCI Fact Sheet Biological Therapies: Using the Immune System To Treat Cancer*, available at http://cancer.med.upenn.edu/pdq_html/6/engl/600072.html (Updated Apr 2000) For examples of immune related substances found in horses, see B. Von Rechenberg, et al., *Upregulation of mRNA of Interleukin-1 and -6 in Subchondral Cystic Lesions of Four Horses*, 33 EQUINE VETERINARY J. 143-49 (2001) and G. Grunig and D.F. Antczak, *Horse Trophoblasts Produce Tumor Necrosis Factor Alpha But Not Interleukin 2, Interleukin 4, or Interferon Gamma*, 52 BIOLOGICAL REPRODUCTION 531-39 (1995). "Messenger RNA for interleukin 2 (IL-2), interleukin 4 (IL-4), and interferon gamma (IFN gamma) was detected in endometrial tissues, unstimulated peripheral blood lymphocytes, and control kidney tissue, but not in trophoblasts." *Id.* For an example where a horse blood product was used in the treatment of human disease see K.F. Mangan, *Interferon-induced Aplasia: Evidence for T-cell-Mediated Suppression of Hematopoiesis and Recovery after Treatment with Horse Antihuman Thymocyte Globulin*, 19 AM. J. HEMATOLOGY 401-13 (1985).

146. RALPH W. MOSS, PH.D., *THE CANCER INDUSTRY* 289-92 (1999)

tides.¹⁴⁷ By synthesizing these peptides and administering them to cancer patients, many cancers are dissolved or halted from growing.¹⁴⁸ Perhaps this idea sounded ludicrous in 1976, but today, the value of these peptides in destroying cancer cells has been proven in pathology laboratories throughout the world.¹⁴⁹ Nonetheless, mainstream oncologists still challenge Dr. Burzynski's approach and, as such, his non-toxic cancer treatment is still not approved for use even though the FDA has accelerated its approval of chemotherapy to treat brain tumors.¹⁵⁰

E. The Ramifications for Changing Paradigms

Mainstream medicine's paradigm of cancer as a disease of an aberrant cell is slowly being challenged. Today, orthodox researchers are learning how an individual's immune system can regulate cancer. Unfortunately, for the last one hundred years, orthodox science has made a monumental assumption that its aberrant cell paradigm was the only correct one. Millions of people may have died of cancer due to this presumption. Is it appropriate to assume that the paradigm embraced by government scientists today is accurate, thereby giving them unrestrained power to act on their supposition?

V. RELEVANCE OF CLINICAL TESTING

The FDA states that one reason why the Access to Medical Treatment Act is dangerous to patients is because it would not require clinical testing for carcinogenicity, toxicity or efficacy.¹⁵¹ Each one of these arguments will be analyzed *infra*.

147. *Id.* For a thorough discussion of Burzynski's treatment, see the 209 medical articles written by independent scientists listed in *Publications on Antineoplastons and their Active Ingredients by Scientists Independent of the Burzynski Research Institute*, available at <http://catalog.com/bri/pubsi.htm> (last visited June 24, 2001). Dr. Burzynski's 107 journal articles are referenced in *Publications by Stanislaw R. Burzynski, M.D., Ph.D.*, available at <http://catalog.com/bri/pub.htm> (last visited June 24, 2001).

148. When permitted, Dr. Burzynski has cured children with astrocytomas (Matthew Anderson), brainstem tumors (Jessica Ressel), optic-hypothalamic gliomas (Paul Michaels), medulloblastomas (Dustin Kunnari), and other brain tumors (Shontelle Hiron). *Our Stories Burzynski Patient Group Directory*, at <http://www.burzynskipatientgroup.org/stories.htm> (last visited June 23, 2001).

149. See also T.E. Witzig et al., *Induction of Apoptosis in Malignant B Cells by Phenylbutyrate or Phenylacetate in Combination with Chemotherapeutic Agents* 2 CLINICAL CANCER RESEARCH 681-92 (2000) and J.A. DiGiuseppe et al., *Phenylbutyrate-Induced G1 Arrest and Apoptosis in Myeloid Leukemia Cells: Structure-Function Analysis*, 8 LEUKEMIA 1243-53 (1999).

150. *Schering-Plough Announces FDA Approval of Temodar (Temozolomide) Capsules for patients with Refractory Anaplastic Astrocytoma*, available at <http://www.schering-plough.com/news/business/1999/8-11-99.html> (last visited Apr. 5, 2001).

151. *Patient Access to Alternative Treatments—Friedman Testimony*, *supra* note 105.

A. Testing for Carcinogenicity

No one wants to take a drug that can or may cause cancer. However, requiring carcinogenicity testing in the context of cancer is disingenuous for at least three reasons.

First, there is no logic in stopping cancer patients from accessing a therapy because they could get cancer from it in five, ten or twenty years. A small theoretical risk of developing cancer in the future carries little significance compared to the reality that the individual is dying of cancer now.

Second, the requirement for carcinogenicity testing suggests that all the products that are approved by the FDA are tested for carcinogenicity. This is not true. For example, none of the thirty vaccines that millions of children are administered before they are eighteen months old have been tested for carcinogenicity.¹⁵² In fact, these vaccines contain known and suspected carcinogens such as mercury and formaldehyde, but are not tested.¹⁵³ Despite cancer being the leading cause of death by disease in children,¹⁵⁴ the FDA permits healthy children to be injected with untested products that contain known and potential carcinogens, yet prohibits cancer victims with little time left to take a similar risk.

Third, the FDA admits "[M]any conventional drugs 'routinely used' to treat cancer patients can have serious or life-threatening effects."¹⁵⁵ In fact, many chemotherapy drugs are listed as known or suspected human carcinogens with the National Toxicology Program,¹⁵⁶ whose participating agencies include the FDA, NIH, and CDC.¹⁵⁷ The FDA's position, therefore, is that a

152. PHYSICIANS' DESK REFERENCE 1510, 1520, 1528, 1819, 1737, 1740, 1833, 1843, 1908, 2316, 2320, 2333, 3048 (53rd ed. 1999) [hereinafter P.D.R.]. For a list of the 30 vaccines, see *Center's for Disease Control Recommended Childhood Immunization Schedule United States, January-December 2001*. The 30 vaccines are administered in 20 injections. *Id.*

153. P.D.R., *supra* note 152.

154.

While cancer is only a minor cause of death in infancy (<1 year), it was the third most common cause of death between the ages of 1 and 19 in 1997, following unintentional injuries and homicides. It constitutes about 8% of deaths between age 1 and 19, and is the leading cause of death from disease at these ages

American Cancer Society,—*Childhood Cancer, Introduction*, at <http://www.cancer.org/cancerinfo/sitecenter.asp?ct=1&ctid8&scp=8.3.4.40032&scs=4&scss=1&scdoc=42014&pnt=2&language=english> (last visited Apr. 5, 2001).

155. *Patient Access to Alternative Treatments—Friedman Testimony*, *supra* note 105.

156. National Toxicology Program "Known to be Human Carcinogens, 8th Report on Carcinogens," at http://ntp-server.niehs.nih.gov/htdocs/8_RoC/Known_list.html (last visited Apr. 5, 2001). Examples of chemotherapy drugs that are listed as "Known to be Human Carcinogens" include Busulfan, Cyclophosphamide, Melphalan, and Thiotepa. *Id.* See also Department of Health and Human Services, National Toxicology Program "Reasonably Anticipated To Be a Human Carcinogen, 8th Report on Carcinogens," at http://ntp-server.niehs.nih.gov/htdocs/8_RoC/RAHC_list.html (last visited June 24, 2001). Examples of chemotherapy drugs that are listed as "Reasonably Anticipated To Be a Human Carcinogens" include BCNU and Cisplatin. *Id.*

157. National Toxicology Program—*NTP Mission*, available at <http://ntp>

cancer patient may be poisoned with a known carcinogen (i.e. chemotherapy), but it is too dangerous for the patient to take a drug that is only theoretically carcinogenic. In fact, therapies like Drs. Burzynski and Ivy's are comprised of natural substances. Unlike chemotherapy, they are not listed as carcinogens and no scientist has ever suggested that they are carcinogenic.¹⁵⁸

B. Testing for Toxicity

Besides carcinogenicity, the FDA argues that because people can be injured or killed from the toxicity of unapproved drugs, physicians and patients should not have the freedom to use these drugs.¹⁵⁹ Apparently the FDA believes that the same risk-benefit equation applies to every drug and every disease. Such logic is sophistry.

For example, the FDA cites the thalidomide disaster as a reason to clinically test every single drug.¹⁶⁰ Thalidomide was a sedative that was prescribed to pregnant women to combat many of the symptoms associated with morning sickness.¹⁶¹ This drug killed or produced catastrophic birth defects in many children.¹⁶² However, thalidomide was a sleeping pill and no one dies from insomnia. The modest benefits of a good night sleep are outweighed by almost any risk. Therefore, requiring thorough and meticulous clinical testing of a sleeping pill is appropriate and legitimate.

However, cancer is not insomnia. In the context of a cancer patient who has been sent home to die or for whom orthodox therapies are ineffective, the potential benefits of an unapproved treatment is not dying or not dying in tremendous pain. The hypothetical risks that many cancer patients are willing to endure for such benefits are enormous. Nonetheless, the FDA insists

server.niehs.nih.gov/main_pages/about_NTP.html (last visited June 24, 2001).

The NTP is an interagency program consisting of relevant toxicology activities of the National Institutes of Health's National Institute of Environmental Health Sciences (NIH/NIEHS), the Centers for Disease Control and Prevention's National Institute for Occupational Safety and Health (CDC/NIOSH), and the Food and Drug Administration's National Center for Toxicological Research (FDA/NC'IR)

Id.

158. National Toxicology Program "Known to be Human Carcinogens, 8th Report on Carcinogens," at http://ntp-server.niehs.nih.gov/htdocs/8_RoC/Known_list.html (last visited Apr. 5, 2001). There is no listing for Burzynski's therapy or its constituent agents. *Id.* See also Department of Health and Human Services, National Toxicology Program "Reasonably Anticipated To Be a Human Carcinogen, 8th Report on Carcinogens," at http://ntp-server.niehs.nih.gov/htdocs/8_RoC/RAHC_list.html (last visited June 24, 2001). There is no listing for Burzynski's therapy or its constituent agents. *Id.*

159. *Patient Access to Alternative Treatments—Friedman Testimony*, *supra* note 105

160. *Id.*

161. Thalidomide Victims Ass'n of Can.—Home Page, available at <http://www.thalidomide.ca/wit.html> (last visited June 24, 2001).

162. *Id.*

that treatments for insomnia and cancer must be subject to similar procedures for clinical testing and approval.¹⁶³

In addition, clinical testing under the auspices of FDA approval does not guarantee a drug's safety. For example, according to the *New England Journal of Medicine*, "the results of clinical trials submitted with an application to the FDA to market a drug, cannot provide comprehensive information on possible adverse events."¹⁶⁴

C. Off-Label Use

Ironically, while most chemotherapy drugs are FDA-approved, many are not approved for the specific cancers for which they are used.¹⁶⁵ Over time, and often with the urging of drug companies, these "off-label" uses become part of the standard of care. In fact, *none* of the chemotherapy drugs that are routinely used to treat childhood brain cancers are FDA approved for children or for brain cancer.¹⁶⁶

D. Testing Naturally Occurring Substances

In addition to treating cancer like insomnia, the FDA treats laboratory drugs the same as natural agents. The FDA states "[I]t does not matter to FDA (sic) whether a product is characterized as 'mainstream' or 'alternative'; it does not matter whether the product was synthesized in a state-of-the-art laboratory or was found in the Brazilian rain forest."¹⁶⁷ Even herbs,

163. This criticism was inspired by the Congressional Testimony of Dr. Arnold Eggers According to Dr. Eggers,

Cancer kills 500,000 people a year in the U.S. A one-year bureaucratic delay in releasing a cure for cancer would necessarily kill 500,000. These are the people who would still be alive if the government hadn't blocked their access to treatment in their lifetime. These days, toxic side effects of drugs are quickly discovered and publicized, or else extremely rare, and it is inconceivable that 500,000 people could be killed by a dangerous new treatment before the alarm was called. I believe this arithmetic or statistical argument shows the error of the current system, which guarantees that there will be a vast unnecessary loss of life if ever cancer is cured.

Patient Access to Alternative Treatments: Beyond the FDA Before the Government Reform Committee of the House of Representatives, 105th Cong. (Feb. 4, 1998) (statement of Arnold Eggers, M.D.) available at <http://www.house.gov/reform/hearings/healthcare/fda288/4ac.htm> 2_ (last visited Oct. 11, 2001).

164. G. A. Faich, *Adverse-Drug-Reaction Monitoring*, 314 *NEW ENG J MED* 1589-92 (1986).

165. See, e.g., the chemotherapy drugs vincristine, cytoxan (i.e. cyclophosphamide), etoposide, and cisplatin. PDR, *supra* note 152, at 773, 779, 1624.

166. *Id.*

167. *Patient Access to Alternative Treatments—Friedman Testimony*, *supra* note 105

the FDA points out, can “pose serious risks.”¹⁶⁸ This argument ignores two critical points.

First, a substance that is part of human biology that cancer victims may be missing (like Burzynski’s peptides) is not the same as a synthetic laboratory formulation that has never existed before on the earth and has never been introduced into the human body. The natural agent that a sick body is missing does not pose the same variety of risks as a synthetic drug.

Secondly, the FDA ignores the hundreds of years of history and the wealth of information regarding the application of herbs and other naturally occurring agents to human disease.¹⁶⁹ While many naturally occurring substances can be dangerous or deadly, it is pure arrogance to insist that the existing, extensive knowledge regarding the safety and efficacy of certain natural agents in the treatment of cancer should be ignored.

E. Testing to Provide for Informed Decisions

The FDA maintains that without clinical testing, physicians and patients cannot make informed choices regarding a treatment’s benefits (i.e. efficacy).¹⁷⁰ In the cancer context, this is a hypocritical argument. Under the rubric of standard clinical testing, thousands of cancer patients are administered drugs whose biological effects are not yet known.¹⁷¹ In other words, it is acceptable for patients to use their bodies as a living laboratory to test a synthetic drug from a major pharmaceutical company, but it is not acceptable for those same patients to try a naturally occurring agent prescribed by their physician. In both scenarios, data can be collected on patient outcomes and compared to the figures of patients who use orthodox treatments. In this way, the results of using non-approved therapies can be calculated and compared to standard treatments.

Finally, the FDA ignores the fact that a physician who has used a particular treatment is the expert on its application and use. While the treatment may be new, and thus not routinely used, a small minority of physicians will always be ahead of the rest. Such is the nature of medicine. Nonetheless, for the FDA, this physician’s experience, knowledge and expertise is trumped by uninformed FDA bureaucrats. According to attorney Jonathan W. Emord, “Your physician may recommend an experimental drug, the corporate sponsor of that drug may agree to supply it, and the clinical investigator may agree to administer it, but if the FDA disagrees, you are out of luck.”¹⁷²

168. *Id.*

169. See, e.g., HILDEGARD VON BINGEN, *PHYSICA* (Priscilla Throop trans., Healing Arts Press 1998).

170. *Patient Access to Alternative Treatments—Friedman Testimony*, *supra* note 105

171. See NCI Clinical Trials—*Understanding Trials*, available at <http://cancertrials.nci.nih.gov/understanding/basics/index.html#why> (last visited June 24, 2001).

172. *Patient Access to Alternative Treatments: Beyond the FDA Before the Government*

VI. DO BUREAUCRATS MAKE BETTER MEDICAL DECISION MAKERS THAN A PATIENT'S PHYSICIAN?

All cancer sufferers are not the same. Age, state of health, type of cancer, type of cancer cell, spread of the cancer, and the spirit to live are different for every individual.¹⁷³ As the eminent cancer surgeon William Osler said, "Variability is the law of life, and as no two faces are the same, so no two bodies are alike, and no two individuals react alike and behave alike under the abnormal conditions which we know as disease."¹⁷⁴ Is it, therefore, fair to assume that the appropriate people to choose an optimum cancer therapy for an individual are FDA bureaucrats, judges or politically appointed "cancer commissions"—people who have never met the patient, read his medical history, or looked at his blood test, pathology report or x-ray? Many patients and doctors argue that the individuals who are in the best position to select a cancer therapy are the patient and their physician. Nonetheless, the law currently favors the opinion of the bureaucrat or judge over that of the patient's medical doctor.

For example, the California Health & Safety Code has been used to permit the state to disapprove treatments for cancer by exercising its police powers even "[w]here there is a genuine difference of medical opinion among the experts on the question of whether a drug is generally recognized as safe for the treatment of a particular disease."¹⁷⁵ In other words, when there is a disagreement as to the safety of a specific therapy for a specific patient, the position of a lawmaker trumps the opinion of the patient's doctor.

Why is this the law? The California Court of Appeal cited a 1969 California Supreme Court case where a *chiropractor* treated a child with cancer and the child died.¹⁷⁶ The court argued that this was an "example of the kind of tragedy which the state has a compelling interest to prevent."¹⁷⁷ This argument resonates with the familiar theme that gullible cancer patients will mistakenly choose the wrong therapy and, therefore, they must be protected from their own naiveté by a paternalistic government. However, this case does not address the factual issue of how a bureaucrat can be a better medical decision maker than a patient's own *medical doctor*. For California to cite as precedent a case where a *chiropractor* treated a patient for cancer

Reform Committee of the House of Representatives, 105th Cong. (Feb. 4, 1998) [hereinafter *Patient Access to Alternative Treatments—Emord Testimony*] (statement of Jonathan W. Emord, Attorney).

173. HARRISON'S PRINCIPLES OF INTERNAL MEDICINE 493-99 (Anthony S. Fauci, M.D., et al., eds., 1998).

174. William Osler Addresses: *The Clinical Years*, at <http://www.shim.org/~munhan/osler-homepage/clinical-years.htm> (last visited Apr. 5, 2001).

175. *People v. Privitera*, 128 Cal. Rptr. 151, 158 (1976) (citing U.S. v. Article of Drug Labeled (Box) Furestrol Vaginal Suppositories, 294 F. Supp. 1307, 1311 (D.C. Ga. 1968)); See CAL. HEALTH & SAFETY § 109345 (West 1996).

176. *Privitera*, 128 Cal. Rptr. at 159 (citing *People v. Phillips*, 75 Cal. Rptr. 720 (1969)).

177. *Privitera*, 128 Cal. Rptr. at 159.

clearly misses the point. Chiropractors are not medical doctors. In fact, according to the California Labor Code, a chiropractor does not have any right “to represent, advertise, or hold himself out as a physician.”¹⁷⁸ Furthermore, under the California Business & Professional Code, a chiropractor is not authorized to practice “medicine, surgery, osteopathy, dentistry or optometry, nor the use of any drug or medicine now or hereafter included in materia medica.”¹⁷⁹

The U.S. Supreme Court has confused the same issue. The *Rutherford* court noted that “resourceful entrepreneurs” advertise a variety of “simple and painless cures for cancer,” designed to trick cancer victims.¹⁸⁰ If medical doctors are “resourceful entrepreneurs” then why are they given a license to practice medicine? If they are not “resourceful entrepreneurs,” then this concern does not apply to medical decisions made by patients with the help of their medical doctor.

Is the U.S. Supreme Court challenging the competence of the medical profession? Presumably, medical doctors are uniquely trained to render diagnostic and therapeutic assistance to their patients. Patients should therefore be allowed to choose their medical doctor and expect that their doctor will exercise sound judgment in selecting an appropriate treatment for their disease. There is no data to suggest that patients and doctors are more likely to make mistakes if their list of cancer options is allowed to expand beyond surgery, radiation, chemotherapy and hormone therapy. No such study has ever been undertaken. This is especially ironic because the FDA continuously purports the importance of using data in driving decisions.¹⁸¹

It is also useful to note that the federal government, not patients, has filed nearly every lawsuit brought against physicians who used non-approved cancer therapies.¹⁸² Surely, if patients thought they had been conned or exploited by “resourceful entrepreneurs” they or their estates would have filed complaints.

A. *The Folly of Centralized Decision Making*

The folly of centralizing decision-making power becomes evident when considering the numbers of patients involved. Even if one were to assume that the FDA was in the best position to make medical decisions for everyone, the FDA cannot play the role of physician to the half million cancer patients who will die this year. The absurdity of such centralized decision-making is demonstrated with two examples.

178. CAL. LAB. § 3209.6 (West 2001).

179. CAL. BUS. & PROF. §§ 1000-1007 (West 2001).

180. U. S. v. Rutherford, 442 U.S. 544, 558 (1979).

181. *Patient Access to Alternative Treatments—Friedman Testimony*, *supra* note 105.

182. *See, e.g.*, *People v. Privitera*, 128 Cal. Rptr. 151 (1976), *U.S. v. Rutherford*, 442 U.S. 544 (1979), and *Koch v. Federal Trade Commission*, 206 F.2d 311 (6th Cir. 1953)

Zachary McConnell was in first grade when he was diagnosed with a malignant brain cancer.¹⁸³ He endured surgery, chemotherapy and radiation, but these highly toxic treatments made the boy dangerously sick.¹⁸⁴ Like the Kunnaris and the Horwins, Zachary's parents took their son to Dr. Burzynski's clinic in Houston, and his therapy appeared to be working.¹⁸⁵ However, on May 23, 1996, the FDA ordered Zachary off Burzynski's therapy, and sent him back to chemo and radiation.¹⁸⁶ The FDA asserted that the boy did not fit the criteria of the protocol and that he could only receive the non-approved therapy after the tumor returned.¹⁸⁷ Other Burzynski patients donated their own medicine to help Zachary¹⁸⁸ and the McConnells took their plight to the media.¹⁸⁹ The FDA finally reversed its decision and allowed the boy back on the therapy.¹⁹⁰ However, the two months that the child did not receive the proper dose of the treatment had its effect and the tumor returned in August 1996.¹⁹¹ Zachary McConnell died in 1998.¹⁹²

183. ELIAS, *supra* note 35, at 176-77. The cancer was a primitive neuroectodermal tumor (PNET), a cancer identical or similar to medulloblastoma depending on its location. *Id.*

184. *Id.* at 181.

185. *Id.* at 183. Prior to starting the Burzynski therapy, a small speck appeared on an MRI of Zachary's brain. The speck could have been scar tissue or a returning tumor. Within two months of starting Burzynski's therapy, the speck had disappeared. *Id.*

186. *Id.* at 184. See also *Patient Access to Alternative Treatments—Emord Testimony*, *supra* note 171.

187. ELIAS, *supra* note 35, at 184.

188. *Id.*

189. *Id.* at 185. According to their attorney, Jonathan W. Emord,

[The McConnells] hired Washington lawyers and a team of renowned scientific experts, and they pled their case to the media and before Congress, begging for help to reverse the FDA's decision. After a month and a half of constant, costly and time-consuming effort, the FDA buckled under the pressure, relented, and reversed its decision.

Patient Access to Alternative Treatments: Beyond the FDA Before the Government Reform Committee of the House of Representatives, 105th Cong. (Feb. 4, 1998) [hereinafter *Patient Access to Alternative Treatments—Emord Testimony*] (statement of Jonathan W. Emord, Attorney) available at http://www.house.gov/reform/hearings/healthcare/fda298/2_4jc.htm (last visited June 23, 2001).

190. The FDA wrote a letter to Burzynski, "We are now able to conclude that Zachary may have a very good prognosis. . . . We have determined that administration of antineoplastons to Zachary may continue." ELIAS, *supra* note 35, at 185. Between the time the FDA ordered eight-year-old Zachary off the medicine and the time they allowed him back on the medicine nothing had changed. According to Zachary's father, Shawn McConnell, "The only things that happened were political and media pressure. Now we know these decisions aren't based on science or the welfare of the patient. They're based on power and politics." *Id.* at 185-86.

191. *Id.* at 186.

192. Interview by Raphael Horwin with Shawn McConnell, Scottsdale Arizona (May 1999). Zachary was eventually taken off Burzynski's therapy by his parents because the tumor that reoccurred did not disappear after Burzynski was finally allowed to restart the therapy. Surgery and radiation therapy was used. ELIAS, *supra* note 35, at 187-88.

In the second example, Janet Isabella Cheadle was diagnosed with a malignant pediatric cancer called neuroblastoma when she was five years old.¹⁹³ She endured many months of high-dose chemotherapy and whole body radiation.¹⁹⁴ The treatments took a tremendous toll on the child and her parents sought to admit her to the Burzynski clinic.¹⁹⁵ The clinic told the parents that this required FDA approval.¹⁹⁶ The parents wrote a letter to the FDA's Consumer Safety Officer and they received no response.¹⁹⁷ Three weeks later, the parents contacted another FDA representative who told them that they required a copy of Burzynski's protocol.¹⁹⁸ The protocol, sent via Federal Express, was rejected within five hours of receipt.¹⁹⁹ Janet's parents called the FDA's Consumer Safety Officer at his home and the officer claimed he had no knowledge of the case.²⁰⁰ The parents were then referred to other FDA employees.²⁰¹ According to congressional testimony, Janet's father, Dr. Lyle Cheadle, "cried and begged" these bureaucrats to allow his daughter to be treated with this non-toxic therapy.²⁰² After fighting this bureaucracy for months, Janet Cheadle was ultimately allowed to be treated by Dr. Burzynski.²⁰³ Janet Isabella Cheadle is alive today.²⁰⁴ According to her father, all of the other conventionally treated children who were diagnosed with neuroblastoma with Janet have passed away.²⁰⁵ Dr. Cheadle continues to use a variety of non-FDA therapies to treat his child.²⁰⁶ "If I waited for the FDA, nothing would be done," Dr. Cheadle has stated.²⁰⁷

B. Can Terminal Patients Access Non-Approved Therapies?

The FDA contends that it is "committed to providing early access to promising, but unproven, medical treatments for seriously ill patients who might otherwise have no hope."²⁰⁸ However, the FDA also states, "As compelling as an individual case is, however, the cost of providing individual ac-

193. *Patient Access to Alternative Treatments: Beyond the FDA Before the Government Reform Committee of the House of Representatives*, 105th Cong. (Feb. 12, 1998) (statement of Dr. Lyle Cheadle).

194. *Id.*

195. *Id.*

196. *Id.*

197. *Id.*

198. *Id.*

199. *Id.*

200. *Id.*

201. *Id.*

202. *Id.*

203. Telephone Interview with Dr. Lyle Cheadle (July 19, 2001).

204. *Id.*

205. *Id.*

206. *Id.*

207. *Id.*

208. *Patient Access to Alternative Treatments—Friedman Testimony*, *supra* note 105.

cess cannot be to sacrifice the system that ultimately establishes whether therapies are safe and effective."²⁰⁹

There is no program to allow cancer patients to have access to non-approved therapies that are not undergoing clinical testing. The FDA, however, has two primary programs that theoretically allow a terminal cancer patient to have access to a non-approved therapy that is currently being tested. The first is called a "Treatment Investigational New Drug Application" (IND)²¹⁰ and the second has been termed a "Single Patient," "Emergency," or "Compassionate IND."²¹¹

Both IND's require that there must be no *comparable treatment alternative*.²¹² What does this mean? There is no case law on point, so currently it means whatever the FDA decides. For example, as discussed *supra*, the FDA has decided that chemotherapy is a comparable treatment alternative for malignant pediatric brain cancers even though oncologists admit it is ineffective and toxic. Therefore, children like Alexander Horwin and Zachary McConnell are not permitted access to an effective, non-toxic but unapproved therapy such as Dr. Burzynski's treatment.

How many patients are given access to non-orthodox agents through an IND? According to the Chairman of the House of Representatives Committee on Government Reform, "We know from the FDA's own records that in 1996, about 500 cancer patients were given access to an experimental drug through the FDA, compared to half a million [cancer victims] who died that year."²¹³ How many patients did the FDA turn down? The FDA claims that it

209. *Id.*

210. 21 C.F.R. § 312.34 (2001).

211. *Patient Access to Alternative Treatments—Friedman Testimony, supra* note 105.

212. 21 C.F.R. § 312.34(b) (2001).

Criteria. (1) FDA shall permit an investigational drug to be used for a treatment use under a treatment protocol or treatment IND if:

- (i) The drug is intended to treat a serious or immediately life-threatening disease;
- (ii) There is no comparable or satisfactory alternative drug or other therapy available to treat that stage of the disease in the intended patient population;
- (iii) The drug is under investigation in a controlled clinical trial under an IND in effect for the trial, or all clinical trials have been completed; and
- (iv) The sponsor of the controlled clinical trial is actively pursuing marketing approval of the investigational drug with due diligence.

21 C.F.R. § 312.34(b) (West 2001).

In respect to "Single Patient," "Emergency" or "Compassionate" IND's, the FDA's Michael A. Friedman, M.D. has testified that these IND exceptions may be permitted when "other options do not exist." See *Patient Access to Alternative Treatments—Friedman Testimony, supra* note 105.

213. *Patient Access to Alternative Treatments: Beyond the FDA Before the Government Reform Committee of the House of Representatives*, 105th Cong. (Feb. 4, 1998) (statement by Chairman Dan Burton).

does not keep any data or records on the patients it turns down for single patient or emergency IND requests.²¹⁴

VII. ADDRESSING THE ROLE OF ECONOMICS IN CANCER

Critically addressing the medical-policy arguments is crucial to creating a political atmosphere where current FDA policy can be responsibly challenged and changed. There is another controlling factor, however, that must also be addressed in order to inject integrity into lawmaking on this issue—the role of economics in cancer.

A. The Critic's Perspective

Over the last fifty years, critics, including scientists, congressmen, physicians, and journalists, have alleged that despite the conflicting scientific paradigms, economics plays a greater role than science in determining what cancer therapies are ultimately available to the public.²¹⁵ According to Robert E. Willner, M.D., Ph.D.²¹⁶ the pharmaceutical companies provide research grants, contracts and advertising support that “guarantees virtual control over scientific and medical direction and thought.”²¹⁷ Dr. Willner states:

There are many simple non-toxic effective treatments for cancer. The cost of providing them has been made impossible by the collusion between the FDA and the pharmaceutical industry. The establishment has deliberately used every imaginable and shameful tactic, some of which are even “strong arm,” to discredit, conceal[,] and destroy these therapies. The reasons are clear. The pharmaceutical industry, which profits in the countless billions from their infamous chemotherapy and all the drugs that usually have to be taken to deal with the horrible “side-effects” would lose an enormous income if the truth were known.²¹⁸

James P. Carter, M.S., M.D., agrees.²¹⁹ He has stated, “The FDA serves as the pharmaceutical industry’s watchdog which can be called upon to at-

214. *Patient Access to Alternative Treatments—Friedman Testimony, supra* note 105.

215. For an example of scientists: Dr. Linus Pauling and Dr. Samuel Epstein; for an example of congressmen: Mr. Berkley Biddel and Mr. Dan Burton; for an example of a physician: Dr. Robert Willner; for an example of journalists: Barry Lynes and G. Edward Griffin. See also BARRY LYNES, *THE HEALING OF CANCER: THE CURES—THE COVER-UPS AND THE SOLUTION NOW* (1989); and G. EDWARD GRIFFIN, *WORLD WITHOUT CANCER* (13th prtg. 1998).

216. The resume of Robert E. Willner, M.D., Ph.D. includes: Fellow of the American Board of Pain Management, Fellow of the American Academy of Neurologic and Orthopedic Medicine and Surgery, certified by the American Board of Family Physicians, Diplomat of the American Board of Family Medicine, member of the Board of Directors of the American Academy of Advancements in Medicine, Executive Secretary of the American Physicians Association. ROBERT E. WILLNER, M.D., PH.D., *THE CANCER SOLUTION* 299-303 (1994).

217. *Id.* at 5.

218. *Id.* at 19-20.

219. Dr. Carter has a medical degree from Northwestern University and a masters of science degree in Parasitology from Columbia University. He is a professor at Tulane University

tack and destroy a potential competitor, under the guise of protecting the public."²²⁰ A leading cancer expert, Samuel S. Epstein, M.D.,²²¹ concurs:

For decades, the war on cancer has been dominated by powerful groups of interlocking professional and financial interests, with the highly profitable drug development system at its hub. . . . The members of the generously funded cancer establishment include the NCI, ACS [American Cancer Society], the comprehensive cancer centers such as New York's prototypical Memorial Sloan-Kettering, whose annual budget exceeds \$350 million, NCI and ACS contractees and grantees at universities, and major pharmaceutical companies. Cancer care is big business, with annual cancer drug sales of approximately \$10 billion.²²²

Medical doctors are not alone in suggesting a link between the interests of the pharmaceutical industry and the cancer treatments that are accessible. Congressional Investigations have also reported that collusion may exist. For example, in 1953, United States Senator Charles Tobey, Chairman of the Interstate and Foreign Commerce Committee, directed Benedict F. Fitzgerald, Jr. to conduct an investigation to determine whether a conspiracy existed to suppress innovative cancer treatments. Fitzgerald was special counsel to the Senate Committee on Interstate and Foreign Commerce, a seasoned attorney and investigator with years of experience in uncovering price-fixing and monopolistic practices by major industries. On August 3, 1953, a summary of his report was entered into the Congressional Record Appendix. Fitzgerald stated:

My investigation to date should convince this committee that a conspiracy does exist to stop the free flow and use of drugs in interstate commerce which allegedly has solid therapeutic value. Public and private funds have been thrown around like confetti at a country fair to close up and destroy clinics, hospitals, and scientific research laboratories which do not conform to the viewpoint of medical associations.²²³

Forty-five years later, in 1998, Congressman Dan Burton testified:

The FDA dictates what treatments doctors can use in treating serious illnesses, but most of those are toxic and often dangerous to already weak-

School of Public Health and Tropical Medicine and has served as a consultant to the World Health Organization. JAMES P. CARTER, M.S., M.D., *RACKETEERING IN MEDICINE: THE SUPPRESSION OF ALTERNATIVES* (1993).

220. *Id.* at 179.

221. Samuel S. Epstein, M.D. is Professor of Occupational and Environmental Medicine at the School of Public Health, University of Illinois Medical Center at Chicago. Dr. Epstein is past chairman of the Air Pollution Control Association Committee on Biological Effects of Air Pollutants; President of the Society of Occupational and Environmental Health; and founder and secretary of the Environmental Mutagen Society. He has written over 250 scientific articles and ten books. SAMUEL S. EPSTEIN, M.D., *THE POLITICS OF CANCER REVISITED* (1998).

222. *Id.* at 367-69.

223. *A Report to the Senate Interstate Commerce Committee on the Need for Investigation of Cancer Research Organizations*, 83 CONG. REC. (1953).

ened patients. Meanwhile, our government agencies spend untold billions of dollars trying to find elusive cures [and] the FDA has harbored a culture of intimidation and sometimes harassment against those looking for alternative cures.²²⁴

B. Clinical Testing Translates Into Pharmaceutical Industry Control

While some type of collusion may exist to enable major drug companies to “corner the market” on cancer treatments, such a conspiracy is not necessary. Basic economics can produce the same results. For example, the FDA admits that “[m]ost new therapies today reach the market because a private commercial entity was willing to invest in the development and testing process necessary to bring a product to the market.”²²⁵ In fact, the cost of bringing a new drug to market has been estimated to be between \$250 to \$500 million²²⁶ with the average being \$313 million.²²⁷ Therefore, pharmaceutical companies have an incentive to finance, test, and market only those drugs that they can ultimately patent. To go to the expense to develop and market a drug they cannot patent, no matter how efficacious, would be a foolish expenditure of money that they could never recoup. In this way, the requirement to use clinical testing for all cancer therapies, and the great costs it entails, leads to eliminating from the market unprofitable, but potentially safe and effective therapies. According to Congressman Berkley Bedell, “It costs millions and millions of dollars to go through the FDA approval process. This freezes out anyone except giant corporations, and makes it utterly impossible for any low cost non-patentable medicines to get into the system.”²²⁸

For example, the NCI has stated that Dr. Burzynski’s therapy works for brain tumors.²²⁹ Other oncologists concur.²³⁰ In addition, the standard therapies for brain tumors (chemotherapy and radiation) are ineffective and catastrophically debilitating in young children.²³¹ Nonetheless, Burzynski’s therapy, comprised of administering specific polypeptides that most healthy people have in their blood, is still not FDA approved. One reason for this

224. *Patient Access to Alternative Treatments: Beyond the FDA Before the Government Reform Committee of the House of Representatives*, 105th Cong. (Feb. 4, 1998) (statement by Chairman Dan Burton).

225. *Patient Access to Alternative Treatments—Friedman Testimony*, *supra* note 105.

226. Barbara Sibbald, *Making a Case for a \$2700-a-Month Drug*, *CAN. MED. ASS’N J.*, available at <http://www.cma.ca/cmaj/vol-161/issue-9/1173.htm> (last visited Sept. 26, 2001).

227. Dennis Cauchon, *High Price, High Hopes for Cancer Drug*, *USA TODAY*, Nov. 24, 1999, available at <http://www.usatoday.com/life/health/drugs/lhdru075.htm> (last visited Sept. 26, 2001).

228. *Patient Access to Alternative Treatments: Beyond the FDA Before the Government Reform Committee of the House of Representatives*, 105th Cong. (Feb. 4, 1998) (statement of the Hon. Berkley Bedell).

229. Memorandum from Dr. Michael Friedman, *supra* note 120.

230. *The Burdick Report*, *supra* note 118.

231. See Friedman, *supra* note 112, Weil *supra* note 113, S. Attard-Montalto, *supra* note 114, Geyer, *supra* note 115, and Finlay, *supra* note 117.

may be that these peptides, which the NCI has called "well defined pure chemical entities,"²³² do not require genetic engineering or creative chemistry. And because they are naturally occurring substances, they cannot be patented to the same degree as novel synthetic drugs.²³³ As a result, pharmaceutical companies would not be able to control the market and pricing of these "pure chemical entities." Any profits they would gain would be dramatically less than the profit margins from the drugs that they can control through their patents. Increasing the accessibility of Dr. Burzynski's therapy would, therefore, translate into decreased market share for the treatments that enjoy higher profit margins (i.e. chemotherapy).

The figures involved in the cancer drug industry are not insubstantial. According to one estimate, treatment for brain tumors alone represents \$3.8 billion.²³⁴ Therefore, in the final economic analysis, the large drug companies would be financially justified to not finance the testing of therapies like Burzynski's, regardless of their safety and efficacy. In fact, in our free market economy, large drug companies would be justified to use their powerful lobbying resources to dissuade lawmakers from passing any law that would allow patients to access such non-patentable therapies that could cause them to lose substantial market share. Given these economic realities, even the FDA asserts that something must be done to create market incentives to test nonpatentable products.²³⁵

VIII. CONCLUSION

The FDA contends that their regulations in respect to cancer drugs, treatments and therapies exist to protect cancer patients from unscrupulous quacks. But such a position is incongruous when the issue is whether patients should be permitted to have therapies that their medical doctors recommend. Physicians are licensed professionals who should be allowed to treat patients as they see fit without government interference. And patients are already protected from quackery by medical malpractice laws that require professional competence and informed consent.

Why should terminal patients, who according to orthodox medicine will die, be prevented from accessing non-orthodox therapies through their medical doctor? The worst scenario is that the modality shortens their life. If, however, the patient is able to exercise informed consent, understand that the treatment is not FDA approved and that there are no guarantees in respect to

232. Memorandum from Dr. Michael Friedman, *supra* note 120.

233. A naturally occurring substance itself cannot be patented; only the process to manufacture it can be protected. However, in this case, the process to manufacture peptides is relatively simple, making this manufacturing aspect financially unattractive.

234. *KS Biomedix Brain Cancer Drug Wins Fast-Track Status*, *Reuters Medical News*, Aug. 6, 2001, available at <http://oncology.medscape.com/reuters/prof/2001/08/08.07/20010806rglt007.html> (last visited Aug. 11, 2001).

235. *Patient Access to Alternative Treatments—Friedman Testimony*, *supra* note 105.

the risks or benefits, why should the patient be prevented from exercising that choice?

A more plausible reason for the FDA's actions is that this bureaucracy has become unduly influenced by the multi-billion dollar drug industry. This industry stands to lose a great deal if the FDA would allow access to drugs that these manufacturers do not control. But whatever the reason, the FDA's position is unsupportable on medical policy grounds.

Dr. Benjamin Rush, physician and signer of the Declaration of Independence said:

Unless we put medical freedom into the Constitution, the time will come when medicine will organize itself into an undercover dictatorship. To restrict the art of healing to one class of men and deny equal privileges to others will constitute the Bastille of medical science. All such laws are un-American and despotic.²³⁶

Medical freedom was not written into the constitution, and today, there are a growing number of people, including physicians, who would argue that Dr. Rush's prophecy has been fulfilled.

My innocent son, Alexander, bore the brunt of that despotism. Like many other parents, my wife and I were not allowed to exercise the most fundamental right as mother and father—the right to try to save the life of our child. By interfering with this moral, ethical and legal right and obligation, our government demonstrated its despotism. Ironically, this country was founded to escape tyranny. Freedom has been America's hallmark and it is this freedom that has made our country grow and prosper. Our Declaration of Independence states "that all men are created equal, that they are endowed by their Creator with certain unalienable Rights, that among these are Life, Liberty, and the pursuit of Happiness."²³⁷ Because life is an unalienable right, individuals must be free to maintain their life when disease strikes them. Without the freedom to live, every other right our country bestows is meaningless.

"I say RIGHTS, for such [the people] have, undoubtedly, antecedent to all earthly government,—Rights, that cannot be repealed or restrained by human laws—Rights, derived from the great Legislator of the universe."

- John Adams²³⁸

236. *Future of Medicine: Medical Freedom and the Politics of Health Care* available at <http://www.alternativemedicine.com/digest/issue01/01015R00.html> (last visited July 4, 2001) citing BENJAMIN RUSH, *THE AUTOBIOGRAPHY OF BENJAMIN RUSH; HIS TRAVELS THROUGH LIFE TOGETHER WITH HIS COMMONPLACE BOOK FOR 1789-1813* (Greenwood Publishing Group, 1970) (1948).

237. THE DECLARATION OF INDEPENDENCE para. 2 (U.S. 1776).

238. JOHN ADAMS, *A DISSERTATION ON THE CANON AND FEUDAL LAW* (1765), available at <http://www.ashbrook.org/library/18/adams/canonlaw.html> (last visited Oct. 2, 2001).