Before the
U.S. HOUSE OF REPRESENTATIVES
House Commerce Committee
Subcommittee on Oversight and Investigations

February 4, 1998
Testimony of
Jonathan W. Emord, Esq.

Mr. Chairman and subcommittee members, I am an attorney who practices constitutional and administrative law before the federal courts and agencies. Among my clients are terminally ill cancer patients for whom FDA-approved treatments have failed. To understand their plight and what to do about it, you must put yourselves in their shoes.

Imagine for a moment a horrible circumstance. Imagine that you, Mr. Chairman, and you, members of this subcommittee, are stricken with an incurable brain tumor. Imagine that you have undergone surgery and several rounds of chemo and radiation therapy to no avail. Your doctors have told you they can do nothing more. They predict you will not live past six months to a year. In so many words they tell you that barring a miracle, your fate is sealed. What on earth can you do?

You are left with two very basic choices. You can accept the conventional wisdom and prepare to die, or you can fight for life against all odds and on your own terms. If you are like my clients, you will fight with every ounce of strength you can muster. You will race against time and the ravages of disease to find and try every promising experimental drug available for your condition.

Unfortunately, although it is your life, your body, your cancer, and your future, the decision of whether you may try an experimental drug is not yours. In the very last analysis, that decision is the FDA's. The FDA will second guess your physicians' judgment and your own.

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.

It is a cruel, inhumane government, Mr. Chairman, that robs even one terminally ill patient of a potential cure and of the freedom to fight for life on his or her own terms. Yet, from time to time, the FDA has done just that. Indeed, premature deaths have no doubt occurred because of FDA decisions not to allow access to experimental treatments. Every day this Congress fails to change FDA law and policy to afford the terminally ill access to experimental treatments--free of FDA interference--is another day that this Congress condones a loss of hope, of life's promise, for terminally ill patients. The Access to Medical Treatment Act is before you. The time has come to move it out of committee and pass it.

Consider my client, Zachary McConnell, a boy of 8, diagnosed at 5 with a Primitive Neural Ectodermal Tumor (PNET), a nearly fatal cancer that spreads its murderous tendrils through the brain with rapidity. At age 5 Zachary had to muster more courage and strength than most adults ever have. He suffered through brain surgery, rounds of chemotherapy, a radiation treatment, seven blood transfusions, eight hospitalizations, nausea, vomiting, deep bone aches, high fevers, severe gastrointestinal stress, and a loss of almost one-half of his body weight.

Faced with conventional treatments not curative for Zachary's tumor and treatments that produced effects worse than did the disease, Shaun and Desiree McConnell (Zachary's parents) decided to fight for their child's life with a promising, experimental alternative. On March 19, 1996, the experimental treatments began. On May 23, 1996, the FDA ordered Zachary off those treatments, sending him back to the failed conventional drugs.

The McConnells were devastated. They could not believe that their government had either the authority or the gall to deny them the right to fight for their boy's life. They vowed to oppose the decision through legal means with all the money and clout they and their friends could marshall. They 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. With the McConnells' blessing, we have supplied the relevant documents to you, Mr. Chairman, for inclusion in the record of these proceedings.

The McConnells' remarkable campaign is beyond the finances of most terminally ill patients. Few have either the means or the strength to wage such a campaign. For them when FDA says no, the answer is final. For them, the FDA is an omnipotent force that has the power to deny freedom to fight for life and to consign innocent victims of disease to a near certain death.

This system must change. The FDA Modernization Act makes no change to correct the basic flaws in the current system. We must protect patients from a force second only, in its lethality, to incurable disease, the FDA's denial of a terminally ill patient's access to promising, experimental drugs. Thank you. I am available for questions.