neoplastons. He publicly predicted the trial would not work. Burzynski was frustrated by the bureaucratic corruption but with his background, not too surprised, and he soldiered on.

When the National Cancer Institute's research trials failed, associate director Michael Freidman came back to Burzynski and offered to do trials with his antineoplastons, but only if he would agree to make major changes to the protocols that he'd spent decades developing. At first he refused, and Freidman threatened to find other sources for antineoplastons. Burzynski fired back that federal employees shouldn't contemplate patent infringement. The NCI finally agreed that Burzynski's protocols would be followed.

The protocols were simple and routine for cancer trials. Patients with very large tumors, multiple tumors, and metastases were to be excluded. These protocols are designed to rule out complicating factors that can skew results. When a year passed with no patients being enrolled, Burzynski suspected something was amiss. The NCI said it had trouble finding patients, and then altered the protocols to include the complex cancers behind the back of Burzynski, who could have changed the instructions for dosages to treat such advanced cancers if he had known. The dosages would have had to have been increased at least three times. As the conflict escalated the NCI quit sending information to Burzynski who had to resort to legal means to get access to the trial data about his own medications. He went on TV and said that he had gotten the distinct impression that the NCI wanted the patients to die so that the experimental trial would be over as soon as possible.

When Dr. Burzynski finally got the data for the trial, he learned that there were only nine patients enrolled and they had suffered from severe fluid retention, something that he monitored and was able to prevent with his patients. He suspected that the antineoplastons were being diluted. The FDA later added insult to injury by publishing in a medical journal that the antineoplastons did not have cancer treatment potential. Some researcher made the mistake of including figures that showed the antineoplastons in the patients' blood were three to 170 times less than the Burzynski clinic typically measured. The trial had been sabotaged.

The battles came to a head in the late 1990s when Texas congressmen Joe Barton organized an oversight committee to hold hearings about why the FDA continued to harass Burzynski. Jurors from previous hearings and throngs of former patients showed up to protest. By this time Burzynski had saved the lives of more than 300 people who were supposed to have been dead. Due to public pressure the FDA agreed to accept Burzynski patients into 72 different Phase II trials, but that wasn't the end of the conflict. A couple years later the FDA did manage to indict Burzynski on the interstate commerce charge, making it the first time in history that it was suing a doctor whose treatments it had approved. There were more rallies and press coverage, and the jury quickly voted to acquit.

After all of the dust had settled, even more corruption came to light from internal memos. Going back all the way to 1991 the U.S. Department of Health and Human Services had been filing patents on the one ingredient Burzynski had not patented, claiming that the rights to manufacture, use, and license it belonged solely to the government. Shortly after the patents were filed, Michael Freidman, who had obstructed Burzynski's trials at the National Cancer Institute, became deputy commissioner at the FDA, working directly under the commissioner who'd declared war on Burzynski. This breathtaking audacity did take Burzynski aback. Powerful government officials and the pharmaceutical industry had been conspiring to steal his invention.

Burzynski has survived and the threat of more lawsuits now seems to have gone away, with the last one now 13 years behind him. Recently he was quoted in the *Wall Street Journal* as saying he now has a good working relationship with the FDA that is getting better. He is now conducting Phase III trials on antineoplastons in the United States. There are also trials in progress in Japan and Europe, and he's even explored possibilities in China. Burzynski continues to put money made from treating patients back into research and development, which is very expensive. A single trial can cost as much as $25 million and the average cost for bringing a new pharmaceutical product to market is $1.5 billion. ♦

***For more information about Dr. Burzynski and antineoplaston therapy, visit the Web sites for The Burzynski Clinic (www.burzynskiclinic.com), The Burzynski Research Institute (www.burzynskiresearch.com), and*** Burzynski the Movie ***(www.burzynskimovie.com).***