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Doctor's lifesaving effort could land him in prison

FDA ignores cancer drug's success

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HOUSTON - Federal prosecutors concede that a cancer doctor they will put on trial here in January for using an innovative but unapproved drug has been "saving lives." The admission is a landmark in the Food and Drug Administration's 13-year campaign against Dr. Stanislaw **Burzynski**, whose patients have raised more than \$700,000 for his legal defense.

The prosecution marks the first time the FDA has tried to jail a scientist for using a drug on which he is conducting FDA-authorized clinical trials.

In a pretrial motion, Assistant U.S. Attorney Mike Clark objected to a defense request for the jury to visit the chemical plant where Dr. **Burzynski** manufactures antineoplaston.

The jury visit request, said Mr. Clark, is "a thinly veiled effort to expose the jury to the specter of Dr. **Burzynski** in his act of saving lives."

A Polish immigrant formerly on the faculty of the Baylor College of Medicine in Houston, Dr. **Burzynski** claims success in treating brain tumors, breast cancers, prostate cancer, lung cancer and pancreatic cancer.

His medication is composed of chemicals that occur in significant quantities in the blood and urine of healthy people but are almost absent from cancer patients.

His patients have been convinced for almost 20 years that he has been saving their lives. Through four grand jury investigations and numerous disagreements with the FDA, hundreds of patients whose conventional physicians gave them only weeks or months to live have trooped into Dr. **Burzynski**'s Houston clinic.

The doctor claims that more than 60 percent of those who come see either a

reduction of their tumors or a stabilization of their disease.

"I know he saved my life," says Mary Jo Siegel, 46, a resident of Pacific Palisades, Calif., who sought the treatment from Dr. **Burzynski** in 1991 for non-Hodgkins lymphoma. "And he did it without any toxic side effects."

Pamela Wunningham, a Princeton, N.J., psychologist, was given six weeks to live in 1987 when radiation and chemotherapy failed to slow the growth of her Stage 4 astrocytoma brain tumor.

"There cannot be any other reason than **Burzynski's** treatment for my being alive and healthy and without any tumor," she says. "It's such a wonderful feeling to be alive these many years after they told me I'd be dead."

Conventional physicians who treated both women confirm their recoveries but refuse to credit Dr. **Burzynski**.

"It is unclear what caused Mrs. Siegel's improvement," Dr. Peter Rosen of the Jonsson Cancer Center in Los Angeles said in an interview. "Yes, she is perfectly well clinically. We don't know why she's improved. There's a scoundrel and a charlatan treating her."

Doctors who treated Mrs. Wunningham speculated she may have had a spontaneous remission. But these occur so rarely in brain tumors that the American Cancer Society doesn't even bother keeping statistics on them.

When the National Cancer Institute (NCI) in 1991 sent a six-person team to review some of Dr. **Burzynski's** brain cancer cases, they concluded that five of the seven tumors they inspected had vanished completely, with the other two substantially reduced.

"The basic conclusion was that in five of the seven patients whose cases we analyzed, the tumor disappeared. It's amazing and it's impressive," testified team member Dr. Nicholas Patronas in a 1994 hearing before the Texas Board of Medical Examiners.

Yet federal officials never stopped investigating Dr. **Burzynski** after first questioning him before a grand jury in 1985.

Government prosecutors, who on their fourth try obtained an indictment against Dr. **Burzynski** in November 1995, are fighting to keep the entire issue of whether the drug works out of the upcoming trial.

"Whether antineoplaston does or does not work is not an issue . . . and the jury should not be asked to decide the question," Mr. Clark said in an Oct. 11 court filing. He added that if the issue comes up at trial, it would be an "irrelevant, emotional, prejudicial and misleading concern."

The indictment against Dr. **Burzynski** charges him with 42 counts of selling an unapproved drug over state lines. This was done, the indictment says, when Dr. **Burzynski**'s patients from outside Texas carried the drug home with them after acquiring it in Texas.

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