Doctor accused of selling false hope to families

A QUESTIONABLE CANCER CURE

USA TODAY investigates Houston doctor Stanislaw Burzynski, who has been treating the terminally ill with unconventional treatments for 36 years. While supporters see him as a hero, critics say he exploits the vulnerable.

Liz Szabo, Rene Alston, Keith Carter, Karl Gelles, Tory Hargro and Jerry Mosemak, USA TODAY

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USA TODAY investigation finds experts questioning why Houston doctor is allowed to continue to offer his alternative cancer treatment with antineoplastons.

(Photo: Michael Stravato for USA TODAY)

LINDEN, N.J. — On the last day of his life, Josia Cotto's parents gave him a choice.

The 6-year-old boy had been fighting an inoperable brain tumor for 10 months. When his mother, Niasia Cotto, found him in his bed, unresponsive and unable to open his eyes, "we knew there was nothing else that we could do," she said.

An ambulance took Josia to a hospice room at a local hospital. His parents covered him in a soft, blue-and-white blanket, hugged him and held his small hand for the last time.

"We told him the choice was his, whether to keep fighting or be in peace with God," said his mother. "He chose."

Josia's parents would have paid any price to save him.

A Texas doctor, two months, earlier, had given them one: $25,000 upfront, by cash or check.

Clinging to hope, the Linden, N.J., couple took Josia to see Stanislaw Burzynski (https://www.documentcloud.org/documents/815622-josia-web-page.html), a Houston doctor claiming to be able to do what no one else can: cure inoperable pediatric brainstem tumors.

Virtually any other doctor might have recited the same sad statistics: Although doctors can now cure 83% of pediatric cancers in the U.S., there is usually no hope for kids with Josia's tumor. Perhaps 5% survive five years.

A look at a doctor's cancer claims.*(Photo: Jerry Mosemak, USA TODAY)*

Burzynski — an internist with no board certification or formal training in oncology — has said publicly that he can cure half (https://www.documentcloud.org/documents/815619-fda-letter-2012.html#document/p4/a130911) of the estimated 200 children a year diagnosed with brainstem tumors. The Cottos were told that treatment could cost over $100,000 (http://www.nydailynews.com/new-york/family-friends-school-pulling-brave-brooklyn-boy-josia-cotto-battling-rare-brain-tumor-article-1.1034309), mostly out of pocket, because insurance plans often refuse to cover (https://www.documentcloud.org/documents/816000-acs-on-antineoplastons.html#document/p1/a130900) Burzynski Clinic treatments.

Burzynski, 70, calls his drugs "antineoplastons" and says he has given them to more than 8,000 patients (https://www.documentcloud.org/documents/815608-burzynski-web-site-screen-capture-by-fda.html#document/p3/a131096) since 1977.

He originally synthesized these sodium-rich drugs from blood and urine — the urine collected from public parks, bars and penitentiaries. Although they've been made in a lab since 1980, they still carry a distinctive and unpleasant odor (https://www.documentcloud.org/documents/816000-acs-on-antineoplastons.html#document/p2/a130876). And while the experimental drugs have not been approved by the Food and Drug Administration,

Burzynski has described them like the holy grail of cancer therapy: safe, natural and highly effective. He has also prescribed them as a treatment for AIDS, lupus and other conditions.

STORY: Experts dismiss Burzynski's cancer claims (http://www.usatoday.com/story/news/nation/2013/11/15/burzynski-cancer-science/2994731/)

STORY: Families run out of hope, money after treatments (http://www.usatoday.com/story/news/nation/2013/11/15/jeanine-graf-cancer-children/2994675/)

Some patients are convinced that he saved their lives.

Mary Jo Siegel of Ventura, Calif., says she believes Burzynski cured her lymphoma. James Treadwell from Coronado, Calif., credits Burzynski with curing his brain tumor. Jenny Gettino of Syracuse, N.Y., says Burzynski cured her daughter of an infant brain tumor.

James Treadwell, of Coronado, Calif., is a proponent of alternative cancer treatments by doctor Stanislaw Burzynski. He was treated for a brain tumor.*(Photo: Robert Hanashiro, USA TODAY)*

Yet the National Cancer Institute (https://www.documentcloud.org/documents/816837-national-cancer-institute.html#document/p1/a130907) says there is no evidence that Burzynski has cured a single patient, or even helped one live longer. He has not backed up his claims by publishing results from a randomized, controlled trial (http://www.cancer.gov/dictionary?cdrid=45858) — considered the gold standard of medical evidence — in a respected, peer-reviewed journal.

And Burzynski's drugs pose a risk of serious harm (https://www.documentcloud.org/documents/815592-antineoplastons-pdq-national-cancer-institute.html), including coma, swelling near the brain and death, according to the NCI and informed consent (https://www.documentcloud.org/documents/815617-informed-consent-form-given-to-abra-hall.html#document/p1/a131002) documents that patients sign before beginning treatment. While Burzynski has touted his treatments as an alternative to chemotherapy, a 1999 NCI study (https://www.documentcloud.org/documents/816819-mayo-clinic-1999-report.html)found that antineoplastons can cause many of the same side effects as conventional chemo: nausea, vomiting, headaches, muscle pain, confusion and seizures.

Many blame the system for failing to protect patients.

"He's a snake oil salesman," says pediatric oncologist Peter Adamson, a professor of pediatrics and pharmacology at Children's Hospital of Philadelphia. "This has gone on for so many years, it's really unbelievable."

For 36 years, critics say, Burzynski has been selling false hope to desperate families at the most vulnerable time of their lives.

"When you want so hard to believe something, you end up listening to your heart and not your head," says Lisa Merrit (http://burzynskiscam.com/)t of Armuchee, Ga., whose husband, Wayne, was treated (https://www.documentcloud.org/documents/815601-wayne-merritt-billing-sheet.html) briefly by Burzynski in 2009. The couple say that Burzynski misled them about the type of treatment that would be offered, as well as the cost. Burzynski, she says, is "the worst kind of predator."

There are many reasons why Burzynski has been able to stay in business so long. He has benefited from state laws that limit the Texas Medical Board's authority to remove his license, as well as the ability of terminally ill patients to collect damages. His devoted followers are willing to fight for him. He also has exploited the public's growing fascination with alternative medicine and suspicion of the medical establishment.

At times, Burzynski also has had an especially influential ally: the Food and Drug Administration.

FDA CHANGES COURSE

Although "there were some stormy relations with the FDA" in the past, Burzynski said in an interview, "now, we have a productive relationship."

For years, the FDA tried to prevent Burzynski from prescribing unapproved drugs.

In 1995, a federal grand jury indicted (https://www.documentcloud.org/documents/817440-federal-criminal-suit.html) Burzynski on 75 felony charges, including criminal contempt, mail fraud and violations of the Food, Drug and Cosmetic Act. As a condition of his bail, a judge ordered him to stop prescribing antineoplastons. For a time, it looked as if Burzynski might never treat another patient.

Dozens of Burzynski's patients flocked to Washington to defend him, arguing that taking away antineoplastons was akin to a death sentence. Siegel, who credits Burzynski with curing her lymphoma 22 years ago, has testified on his behalf five times — once at his criminal trial and four times at hearings on Capitol Hill.

Facing both a political and public relations firestorm, the FDA in 1996 abruptly changed course. It offered to allow Burzynski to continue treating patients, but only through an official trial. (http://clinicaltrials.gov/ct2/results?term=antineoplastons&Search=Search)

"With one stroke of the pen, the FDA made legal what it had previously said was illegal," says Burzynski's attorney, Richard Jaffe.

Yet even Jaffe has acknowledged that the trial — now in its 17th year — was more about politics than science. In his 2008 memoirs, *Galileo's Lawyer,* Jaffe called it "a joke."

"It was all an artifice, a vehicle we and the FDA created to legally give the patients Burzynski's treatment," Jaffe said.

"With political help, you can get the FDA to say yes," says Siegel, 63.

The indictments led to two trials. In 1997, one of Burzynski's criminal trials ended in a hung jury; the other, an acquittal.

Today, the FDA refuses to comment on Burzynski.

NO NEW DRUG APPLICATION

Even his staunchest supporters wonder why Burzynski's drugs are nowhere close (https://www.documentcloud.org/documents/817439-burzynski-sec-annual-filing-may-2013.html#document/p11/a131025) to receiving FDA approval.

"He's curing cancer," says Siegel, who co-founded the Burzynski Patient Group to spread the word about his therapies. "So why, why won't the FDA approve it?"

Like many of Burzynski's supporters, Siegel suspects that the medical community and drug industry are aligned against him.

"Why does a doctor who can produce such extraordinary results continue to be attacked today?" Siegel asks. "The reason is because Dr. Burzynski and his patented discovery pose the greatest threat to an entrenched medical monopoly."

In fact, the FDA hasn't had a chance to approve Burzynski's drugs. He has never officially asked.

Although Burzynski said he has completed 14 intermediate-phase studies, he has yet to file a new drug application (https://www.documentcloud.org/documents/817439-burzynski-sec-annual-filing-may-2013.html#document/p11/a131025), the final step toward getting a drug approved.

That hasn't stopped Burzynski from using his relationship with the FDA to recruit patients.

Stacey Huntington says she took her daughter to see Burzynski last year partly because the FDA's oversight made his therapies seem safer and more promising. "My fear took us to Houston, and the hope he gave us made us proceed," says Huntington, of Chehalis, Wash.

In an interview, Burzynski said developing new drugs is complex and takes time.

Yet the FDA has approved (https://www.documentcloud.org/documents/816001-centerwatch-drug-approvals-in-oncology.html) 108 cancer drugs since Burzynski began his trial.

Cure rates for one type of pediatric brain tumor — medulloblastoma — are now 85%, according to St. Jude Children's Research Hospital in Memphis. Doctors can cure 95% of kids with Hodgkin lymphoma (a cancer of the lymph system), acute lymphoblastic leukemia (a blood cancer) and retinoblastoma (an eye tumor).

Fran Visco, president of the National Breast Cancer Coalition, describes the FDA's tolerance of Burzynski as "outrageous."

"They have put people at risk for a long time," says Visco, an attorney and breast cancer survivor. "That's completely unacceptable. How can anyone look at these facts and believe that there is a real clinical trial going on ... rather than just using the FDA and the clinical trial system to make money?"

Burzynski dismisses criticism of his work, referring to his detractors as "hooligans" and "hired assassins."

As for criticism from former patients, Burzynski says, "We see patients from various walks of life. We see great people. We see crooks. We have prostitutes. We have thieves. We have mafia bosses. We have Secret Service agents. Many people are coming to us, OK? Not all of them are the greatest people in the world. And many of them would like to get money from us. They pretend they got sick and they would like to extort money from us."

History will vindicate him, Burzynski says, just as it has vindicated other persecuted medical "pioneers," such as Louis Pasteur. In the future, Burzynski says, everyone will use his therapies, and the cancer treatments used today — such as surgery, chemotherapy and radiation — will be regarded as barbaric. "There will be a time when people will see the light," he says, "and our treatments will be used by everyone."

FDA IMPOSES NEW RESTRICTIONS

The FDA's patience with Burzynski apparently wore out after Josia died.

In a report sent to the FDA after the boy's death, Burzynski's staff acknowledged that his last blood sample, taken the day he passed away,showed a blood sodium level of 205 millimoles per liter, a level that is typically fatal. Burzynski's staff blamed that reading on a "false laboratory report based on a contaminated sample."

Yet hypernatremia is one of antineoplastons' most common side effects (http://www.cancerletter.com/downloads/20131111), known to doctors for two decades. (https://www.documentcloud.org/documents/817798-the-antineoplaston-anomaly-from-the-cancer-letter.html#document/p6/a131367)

One of Burzynski's own informed consent documents — the form that patients sign before they begin treatment — put the risk at 21% (https://www.documentcloud.org/documents/815617-informed-consent-form-given-to-abra-hall.html#document/p1/a131007).

On July 30, 2012 — six weeks after Josia's death — the FDA forbade Burzynski from giving antineoplastons to any new children.

Six months later, the FDA expanded its "partial clinical hold," (https://www.documentcloud.org/documents/817439-burzynski-sec-annual-filing-may-2013.html) forbidding Burzynski from giving the drugs to new adult patients, according to the Burzynski Research Institute's 2013 filing (https://www.documentcloud.org/documents/817439-burzynski-sec-annual-filing-may-2013.html#document/p12/a131019) to the Securities and Exchange

Commission (https://www.documentcloud.org/documents/817439-burzynski-sec-annual-filing-may-2013.html). About 10 patients who were already receiving antineoplastons were allowed to continue, to avoid interruption of care.

According to FDA inspections performed after Josia's death, Burzynski has failed to report at least 18 hypernatremia cases (https://www.documentcloud.org/documents/817441-fda-march-inspection-of-burzynski-principal.html#document/p5/a131009).

The FDA publicly announced the restrictions on Burzynski's clinical trial for the first time in September.

According to the FDA, the Burzynski institutional review board — an outside body charged with protecting patients — failed that most basic duty. In a letter announcing the restrictions, the agency said it has "no assurance (https://www.documentcloud.org/documents/815620-fda-restriction-letter-on-irb-2013.html#document/p9/a131008)" that the board was "adequately protecting the rights and welfare of the human subjects."

The FDA based its decision on "objectionable conditions" and a "continuing pattern of deficiencies found during the last three inspections (https://www.documentcloud.org/documents/815634-march-2013.html)," the letter said.

FDA inspectors also faulted Burzynski personally, as principal investigator of the study, according to inspections (https://www.documentcloud.org/documents/817441-fda-march-inspection-of-burzynski-principal.html#document/p4/a131014) conducted from January to March. Copies of these reports were obtained through a Freedom of Information Act request. Addressing Burzynski, the inspectors wrote, "you failed to protect the rights, safety and welfare of subjects under your care."

Inspectors charged Burzynski, as principal investigator, with a variety of other serious offenses, some dating to 2001. (https://www.documentcloud.org/documents/815610-burzynski-fda-eir-20010810.html) Among them:

• Inflating success rates in 67% (https://www.documentcloud.org/documents/817441-fda-march-inspection-of-burzynski-principal.html) of cases, by inaccurately reporting how tumors responded to treatment.

• Destroying patients' original records (https://www.documentcloud.org/documents/817441-fda-march-inspection-of-burzynski-principal.html#document/p7/a131012).

• Failing to report "unanticipated problems (https://www.documentcloud.org/documents/817441-fda-march-inspection-of-burzynski-principal.html#document/p8/a131013)" to the institutional review board — sometimes for six or seven years.

In the inspections conducted this spring, officials noted four cases from 1998 or 1999 in which patients were hospitalized for serious issues — such as pneumonia, lack of consciousness or bleeding in the skull — that Burzynski researchers failed to report (https://www.documentcloud.org/documents/817441-fda-march-inspection-of-burzynski-principal.html#document/p5/a131009) until 2005. The FDA found similar problems in a 2001 inspection, when officials noted that Burzynski failed to report problems such as pneumonia, blood infections and pancreatitis, a life-threatening inflammation of the pancreas.

• Failing to protect patients from overdosing.

Forty-eight patients suffered a total of 102 drug overdoses (https://www.documentcloud.org/documents/817441-fda-march-inspection-of-burzynski-principal.html#document/p6/a131010) from 2005 to 2013.

While the overdoses made some of these patients excessively sleepy, one had a seizure and another was hospitalized (https://www.documentcloud.org/documents/817441-fda-march-inspection-of-burzynski-principal.html#document/p7/a131011) in intensive care (https://www.documentcloud.org/documents/815627-lawrence-fisher.html#document/p2/a131041) with a breathing tube.

This represents a continuing problem, dating to reports of overdoses in inspections as early as 2001.

Burzynski's review board also repeatedly rubber-stamped his requests to give patients antineoplastons outside of a clinical trial, the FDA's September letter suggests. In some cases, those decisions were made without consulting patients' medical records, or were made not by oncologists, but by a single member of the board, a "water rehabilitation" specialist with no medical training (https://www.documentcloud.org/documents/815620-fda-restriction-letter-on-irb-2013.html#document/p4/a131006).

Although researchers do sometimes provide experimental drugs outside of clinical trials, exceptions should be rare, with perhaps one or two cases per trial, Adamson says. In Burzynski's case, these "compassionate use" exceptions were common, FDA records show.

Enrolling patients for compassionate use can be lucrative. Although researchers cannot charge for experimental drugs, Burzynski does bill patients for related supplies and services.

In Burzynski's defense, Jaffe notes that inspection reports represent preliminary findings. The FDA has not yet issued final conclusions.

And Burzynski has taken issue with many of the FDA's findings.

In his written response (https://www.documentcloud.org/documents/817673-burzynski-response-to-fda-483-inspection.html) about the FDA's claims that he inflated his success rates, Burzynski said that he "complied with all criteria for evaluation of response and made accurate assessments for tumor response."

As for overdoses (https://www.documentcloud.org/documents/817674-burzynski-responses-to-overdoses.html), Burzynski said in an interview that his staff works hard to train patients and their families to administer antineoplastons correctly.

None of the overdoses was fatal, he said.

"The amount of medication that these patients receive is not dangerous," Burzynski said. "At worst, they would sleep for a few hours."

Visco, the breast cancer advocate, says she's encouraged to hear that the FDA has put Burzynski's trial on hold.

"It is about time that the FDA stepped in to stop Burzynski from subjecting more patients to harm," she says. "I do not know why it took so long."

BURZYNSKI STILL HAS OPTIONS

The FDA can't put Burzynski out of business. No matter what happens to his trial, Burzynski holds a license (http://www.tmb.state.tx.us/) to practice medicine in Texas.

So does his son, Gregory Burzynski, a doctor who's helping to carry on his father's business. As vice president of the Burzynski Clinic, his son, 34, works closely with his father and "oversees many operations" of the clinic, according to its website.

These days, doctors at the Burzynski Clinic are looking beyond antineoplastons. They mostly prescribe chemotherapy.

That's a huge shift. During Burzynski's criminal trial in the 1990s, patients who rallied to his defense carried signs reading, "Say No to Chemo."

But the Texas Medical Board, which has repeatedly tried and failed to put Burzynski out of business over the years, still questions Burzynski's care.

The board charged Burzynski (https://www.documentcloud.org/documents/815644-tmb-case-2010.html) in 2010 with violating state medical standards by prescribing legal cancer drugs in "random" and unapproved combinations, with no known benefits but clear harms.

Burzynski got those charges dropped (https://www.documentcloud.org/documents/815635-medical-board-motion-12.html) in 2012, by successfully arguing that he didn't sign any of the prescriptions in question.

Burzynski is scheduled to go before the medical board again in January (https://www.documentcloud.org/documents/815621-tmb-letter-to-huntington-about-january-hearing.html), based on a complaint filed by Stacey Huntington, whose daughter was treated with antineoplastons for a brain tumor. At the meeting, a board panel "will hear the case and make recommendation to the full board about what disciplinary action, if any, is appropriate."

Huntington, who paid Burzynski (https://www.documentcloud.org/documents/815591-abra-hall-billing-sheet.html) nearly $34,000 for about six weeks of care, says she's concerned about both billing irregularities and the quality of her daughter's treatment. Her daughter, Abra Hall (http://www.gofundme.com/AbraCancerFund), 27, developed a life-threatening blood infection called sepsis after leaving the clinic to continue treatment

at home. The infection developed in a catheter in Hall's chest, which was used to administer the antineoplastons, Huntington says. One month after developing sepsis, Hall was hospitalized again with a lung infection. Hall also developed serious complications from high doses of steroids, Huntington says.

Huntington says she decided to speak out to prevent other families from being taken advantage of.

"When you get a diagnosis of cancer, you are pretty vulnerable," she says. "I think they take advantage of that."

COTTOS NOT SURE WHAT TO THINK

Niasia and Jose Cotto hold a photo of son Josia in their Linden, N.J., home on Oct. 12. The boy died of a brain tumor.*(Photo: Todd Plitt, USA TODAY)*

No one told Josia's parents about any of this.

Not Burzynski. Not the FDA.

Jose and Niasia Cotto had no idea that their son's death prompted an investigation by the FDA, until they were contacted by USA TODAY.

The Cottos had long believed that Burzynski could have cured their son if only they had taken Josia to see him first, before giving him radiation and chemotherapy. They had even hoped to launch a non-profit, A Life for Josia Foundation, to help other children with cancer gain access to Burzynski's treatment.

Now, they don't know what to think.

Although more than a year has passed since they lost their son, the Cottos say they see reminders of him everywhere. Niasia, 32, says she feels his presence in simple things, such as the light of a bright star on a dark night.

"He's still with us," says Jose, 33. "I know God had his plan and his purpose for Josia."

Contact Szabo: lszabo@usatoday.com ()

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