"This is chilling the climate" for space research and "putting a burden on a lot of researchers," warns Claude Canizares, a Massachusetts Institute of Technology physicist and chair of the NRC's space studies board. In a 4 February letter to NRC chair Bruce Alberts, he warned of "serious repercussions in the university and industrial communities" that threaten to undermine international cooperation on space projects. Canizares urged Alberts to organize a workshop on the issue, and on 16 March he briefed NASA Administrator Dan Goldin during a meeting of the NASA Advisory Council, which named Canizares chair of a subcommittee to study the issue.

State Department managers maintain that the rules are no stricter than when the department was previously in charge of satellite-related licensing and should not hinder researchers. "We don't regulate fundamental and basic research at universities, and there is no intention by State to bring about a change in scientific research," says Lowell. There are exemptions in the rules for university researchers, he added, giving them more flexibility than industrial scientists and engineers.

NASA's Robert Tucker, who handles the issue for the space agency, notes that foreign scientists who are full-time employees at a U.S. university do not need licenses to be involved in satellite work. But given the continuing congressional interest in the issue—legislators held several hearings last year—and related judicial decisions, nervous university lawyers and companies such as Lockheed Martin are interpreting the rules strictly in cases like the one involving the Stanford payload, called Gravity Probe B. For example, some university teams were reluctant even to respond to a recent NASA request for proposals for scientific payloads in a small satellite program, Canizares says, out of concern that they would need export licenses to discuss technical details of the payload with foreign-born students. "People are so worried about this, there's a cascading of conservatism," Canizares told Goldin. Both Canizares and Parkinson, who chairs the NASA Advisory Council, urged Goldin to convey the community's concerns to Administration officials.

The controversy comes at an awkward time for Goldin, who just 2 months ago announced an initiative to improve and expand NASA's relationship with universities. But NASA officials are loath to risk antagonizing Congress in pressing their case. In February, the agency notified contractors that they are responsible for getting the necessary export licenses for hardware, software, technical data, or technical assistance, as well as for situations in which "the foreign person" has access to data or software.

"I would not like to see hearings [involving] NASA-funded researchers who face criminal prosecution," Goldin told Canizares at the advisory council meeting. But he nevertheless agreed to examine the issue and pledged to work cooperatively with universities.

The controversy doesn't stop with satellites. Other academic groups are fearful that congressional hostility to many types of international exchanges may spread to work in other areas. For example, Department of Energy (DOE) researchers must navigate much stricter rules than in the past when interacting with foreign colleagues and graduate students, part of the fallout from allegations of lax security at nuclear weapons labs. In response, Rachel Claus, counsel for the DOE-funded Stanford Linear Accelerator Center, has urged universities to stand united and to refuse to attend "U.S. citizens only" meetings held by timid hosts. The Washington-based Council on Government Relations and the Association of American Universities have also begun to raise the issue with Administration officials.

But most scientists seem to be talking to themselves. Lowell said last week that he has received no complaints from the scientific community about the rules regarding spacecraft. At the same time, he says the department is only a week or so away from revising those regulations based on vocal concerns from industry. "If scientists want to make changes," he says, "this is the time."

–ANDREW LAWLER

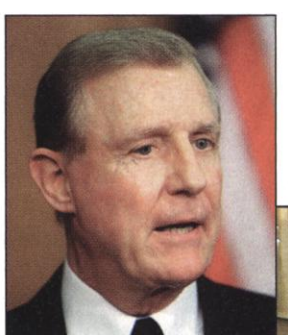
BIOMEDICAL POLITICS

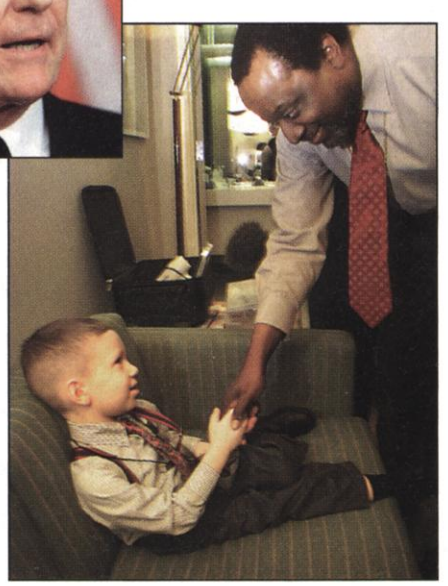
Controversial Cancer Therapy Finds Political Support

Some members of Congress and presidential hopefuls are lobbying the FDA to let a 4-year-old boy receive an unapproved treatment

For nearly 2 decades, Texas physician Stanislaw Burzynski has battled the medical establishment and federal officials over his controversial treatment for cancer. Many patients who have flocked to the Burzynski clinic outside Houston claim to be cured. But the Food and Drug Administration (FDA) maintains that his drugs, dubbed antineoplastons, have not been shown to be either effective or safe and has tried to shut him down. Burzynski prevailed in a key court battle in 1997 and continues to practice. But under FDA rules, he can only use these drugs in experimental trials monitored by the agency, and only on patients who have exhausted conventional therapies. Now Burzynski's powerful allies in Congress and on the presidential campaign trail have launched a major lobbying campaign and media blitz to overturn that rule. It is the latest saga in the long-running battle over who should control access to unorthodox medical treatments.

At the center of the furor is a 4-year-old boy with brain cancer, Thomas Navarro, whose parents want him to have access to Burzynski's unapproved treatment. The child's plight has been broadcast on NBC Nightly News and last week was the focus of a six-page spread in *People* magazine. Representative Dan Burton (R–IN), a longtime Burzynski supporter, has introduced a bill in Congress, named for the boy, that would strip FDA of its power to protect patients from clinical trials where safety is an issue. Some in the medical establishment fear this latest furor could open the floodgates for patients who want access to untested, and possibly dangerous, therapies. Burton's bill, in particular, is





Big guns. Both Rep. Dan Burton *(left)* and Alan Keyes *(right)* are championing the cause of Thomas Navarro (seated).

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drawing heavy criticism. A staffer for Henry Waxman (D–CA), the ranking Democrat on the House Government Reform and Oversight Committee, claims it would undo the FDA's system for protecting patients from the risks of experimental drugs. Thomas Moore, an expert on FDA policy at George Washington University, agrees. "This is like trying to abolish the criminal justice system because you disagreed with one decision made by a judge," he says.

The saga began in the early 1970s, when Burzynski, who had moved to Texas after earning medical and biochemistry degrees in Poland, first isolated what he called antineoplastons from blood and urine. Burzynski claims that these compounds, a mixture of peptides that he now produces synthetically, can reprogram cancer cells so that they die. In the late 1970s, Burzynski began treating cancer patients with this home-brewed cocktail, soon attracting a wide following.

The FDA took him to court in 1983, charging him with selling unapproved drugs across state lines. The legal wrangles dragged on for some 14 years, as various grand juries and U.S. attorneys investigated his practice. The 1983 FDA suit led to a decision that Burzynski could use the drugs only in Texas. In 1996 a U.S. District Court judge ruled that he could treat patients only in FDA-approved clinical trials. A year later, Burzynski was acquitted of charges of illegally shipping the unapproved drugs across state lines. Burzynski now has more than 70 protocols under way, phase II trials designed to test the efficacy of antineoplaston treatment for various tumors. Other researchers have also been evaluating the various compounds in Burzynski's mixture to determine whether any of them work. Evidence so far is inconclusive.

The Navarros, an Arizona family, found Burzynski on the Internet last October. Their son had just undergone surgery for an aggressive type of brain tumor known as a medulloblastoma. When treated with follow-up radiation and treatment, the survival rate for this type of cancer is at least 70%. But without those treatments, the tumor almost always reappears.

The Navarros were concerned about the side effects of those treatments. Radiation therapy, in particular, can be neurotoxic in children and can lead to a drop in IQ of up to 20 points. To the Navarros, Burzynski's course of treatment—as he describes it, a nontoxic medicine that is pumped into a patient's veins—promised a cure with no side effects. At the parents' urging, Burzynski asked the FDA to allow him to treat Thomas with antineoplastons. The agency refused, saying that the boy first had to receive standard treatments, which have a high likelihood of success.

Media blitz. The dispute over access to "antineoplaston" therapy has made network news and *People* magazine.

> **"This is like trying to abolish the criminal justice system because you disagreed with one decision made by a judge."**
>
> **—Thomas Moore**

The Navarros enlisted the help of Burton, chair of the House Government Reform Committee and a longtime supporter of alternative medicine and Burzynski himself. Burton wrote the FDA in December asking for "your assistance" in providing Thomas with the antineoplaston treatment and lamenting "personal and institutional bias against antineoplastons, Dr. Burzynski, and other unconventional cancer protocols." In a 14 January letter in response, FDA associate commissioner for legislation Melinda K. Plaisier said that "it would be unethical and medically inappropriate" to allow Burzynski to treat Thomas in lieu of standard therapy, which has been demonstrated to be beneficial. She cited "the absence of any clinical data to suggest that this [antineoplaston] treatment may be beneficial" and "the fact that it could be harmful." The harmful effects, say FDA officials, include reports of toxicity from the high sodium content of the drugs. FDA officials say the Navarros are risking their son's life by withholding conventional treatment. "We're standing behind this line. This should not be allowed," says Dianne Murphy, head of pediatrics at the FDA Center for Drug Evaluation and Research.

Many oncologists and medical experts back the FDA. Although the Navarros' concerns about the side effects of radiation and chemotherapy are understandable, they say, the risks have been blown out of proportion in the Navarros' minds. "Unfortunately there are [side effects], but not to the extreme it's being painted," says Archie Bleyer of the M. D. Anderson Cancer Center in Houston. Bleyer chairs the Children's Cancer Group, which includes experts across North America. "Leaving a child to die [without therapy] is worse than taking the risk of neurotoxicity from today's radiotherapy," says Bleyer, whose center has offered to treat Thomas.

That argument hasn't swayed the Navarros, whose message of the people versus the government has caught the attention of Republican big guns. In January, presidential candidate Alan Keyes gathered the signatures of then-candidates John McCain, Gary Bauer, Steve Forbes, and Orrin Hatch on a letter asking Health and Human Services Secretary Donna Shalala to "expedite a decision on allowing the medical treatment chosen" by the Navarros. (George W. Bush expressed support but did not sign the letter.) As *Science* went to press, the Navarros continued to press their case against FDA from a Houston hotel. (Thomas is "fine," and his last magnetic resonance imaging scan showed no tumor reappearance, says Donna Navarro.)

Meanwhile, Burton and 18 other sponsors have introduced a bill (HR 3677), the Thomas Navarro FDA Patient Rights Act, that would override the FDA's power to bar patients from participating in a protocol it deems unreasonably risky because an effective therapy already exists. The bill would prevent FDA from using that reason to stop a protocol as long as the patient or patient's parents acknowledged in writing that they were opting for an unapproved treatment. The bill is so sweeping that congressional experts say it is unlikely to go far in its current form. Even so, the publicity the case has generated could provide added fuel for those patients and congressional representatives seeking wider access to unapproved therapies.

–JOCELYN KAISER