Withdrawal/Redaction Sheet
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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. letter	Letter from Carl T. Ott, M.D. (5 pages)	2/20/96	P6/b(6)
002. letter w/attach.	Mary K. Michaels to Hillary Clinton (4 pages)	9/16/96	P6/b(6)
003. letter w/attach.	Robert J. DeLap,M.D. to S.R. Burzynski, M.D. Re: Patients enrolled in CAN-1 Protocol (9 pages)	8/22/96	P6/b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Chris Jennings (Health Security Act)
OA/Box Number: 8993

FOLDER TITLE:
Correspondence-Burzynski [Stanislaw] [1]

gf69

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advise between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

FACT SHEET:

*DR. BURZYNSKI DISCOVERED ANTINEOPLASTONS IN 1967 IN POLAND WHERE HE GRADUATED FROM MEDICAL SCHOOL AT AGE 24, FIRST IN HIS CLASS.

*ANTINEOPLASTONS ARE NATURALLY OCCURRING (& Now Synthetically Made) NON-TOXIC, AMINO ACIDS & PROTEINS WHICH REPROGRAM CANCER CELLS.

*DR. BURZYNSKI HOLDS 40 PATENTS ON ANTINEOPLASTONS IN 24 COUNTRIES AND HAS WRITTEN 165 SCIENTIFIC PAPERS ON ANTINEOPLASTONS.

*OVER 110 INDEPENDENT SCIENTIFIC PAPERS ON ANTINEOPLASTONS HAVE BEEN PUBLISHED IN MEDICAL JOURNALS AROUND THE WORLD.

*A TEAM FROM THE NATIONAL CANCER INSTITUTE CONFIRMED THE ANTI-CANCER ACTIVITY OF ANTINEOPLASTONS IN 1991 AND VERIFIED FIVE COMPLETE REMISSIONS OUT OF SEVEN BRAIN TUMOR CASES EXAMINED.

*THE FDA AGREES ANTINEOPLASTONS ARE NON-TOXIC AND HAS APPROVED 68 PHASE 2 CLINICAL TRIALS FOR CANCER, HIV & OTHER AUTOIMMUNE DISEASES (ANTINEOPLASTON CLINICAL TRIALS ARE ALSO GOING ON IN JAPAN AND ISRAEL).

*DR. BURZYNSKI DOES NOT CLAIM TO HAVE A CURE FOR ALL CANCER, ONLY TO HAVE FOUND A SUBSTANCE THAT WORKS ON CERTAIN TYPES OF CANCER.

*SOME INSURANCE COMPANIES HAVE BEEN ORDERED TO PAY FOR ANTINEOPLASTON TREATMENT AFTER IT WAS PROVEN IN COURT BEYOND A REASONABLE DOUBT THAT THEIR TERMINAL PATIENTS HAD BEEN CURED.

*25 OTHER MD'S & PHD'S WORK AT DR. BURZYNSKI'S CLINIC & RESEARCH INSTITUTE WHICH HAS A MULTI-MILLION DOLLAR YEARLY OVERHEAD BUDGET.

*THE FDA HAS INSPECTED, CERTIFIED AND APPROVED DR. BURZYNSKI'S ANTINEOPLASTON MANUFACTURING FACILITY IN HOUSTON FOR 10 YEARS.

*IRONICALLY, DESPITE APPROVING HIS FACTORY & CLINICAL TESTS, THE FDA STILL WANTS TO JAIL DR. BURZYNSKI ON INTERSTATE COMMERCE CHARGES.

*FOUR GRAND JURIES HAVE CONSIDERED THE BURZYNSKI CASE - THREE OF THEM REFUSED TO INDICT BECAUSE OF LACK OF EVIDENCE.

*IN 18 YEARS AT LEAST 3000 PATIENTS HAVE RECEIVED DR. BURZYNSKI'S TREATMENTS & NOT ONE HAS EVER COMPLAINED TO THE FDA ABOUT HIM.

*THE WAR ON CANCER WAS DECLARED BY PRESIDENT NIXON 25 YEARS AGO IN 1971, 4 YEARS AFTER DR. BURZYNSKI DISCOVERED ANTINEOPLASTONS.

*DEATH RATES FROM ALL CANCERS HAVE ACTUALLY INCREASED IN THE PAST 25 YEARS; MEANWHILE, ANNUAL DRUG COMPANY CHEMOTHERAPY REVENUES HAVE RISEN FROM 3 BILLION IN 1989 TO 8 BILLION DOLLARS IN 1995 AND ARE PROJECTED TO REACH 13 BILLION BY THE YEAR 2000.

*TRADITIONAL CHEMOTHERAPY ROUTINELY CAUSES SEVERE SIDE EFFECTS INCLUDING HAIR LOSS, NAUSEA, AND DAMAGE TO THE IMMUNE SYSTEM.

U.S. House of Representatives
Committee on Commerce
Room 2125, Rayburn House Office Building
Washington, DC 20515–6115

September 7, 1995

The Honorable Janet Reno
Attorney General of the United States
Tenth Street and Constitution Avenue N.W.
Washington, D.C. 20530

Dear General Reno,

As Chairman of the Subcommittee on Oversight and Investigations, I am requesting a full investigation of very disturbing charges involving employees of the Department of Justice in Washington and the Office of the United States Attorney in Houston, Texas. I am enclosing copies of the written and oral testimony of Richard Jaffe, Esq., counsel to Dr. Stanislaw Burzynski. According to this testimony, Dr. Burzynski has been the victim of an extraordinary abuse of our legal system. The FDA together with its attorneys in the Office of Chief Counsel and the U.S. Department of Justice have brought his case before between three and four federal grand juries that have refused to indict him. All of this "criminal" investigation has occurred subsequent to a 1983 decision by a U. S. District Judge to deny the FDA an injunction against his practice of medicine. Currently, the government's allegations are before yet another federal grand jury in Houston.

It is extraordinarily rare for a grand jury to fail to indict at the request of the U.S. Attorney. As far as I know, a grand jury failing to indict some three to four times on essentially the same base of facts is virtually unprecedented. It would appear that the FDA and the Justice Department are abusing the grand jury process to harass and punish Dr. Burzynski for persuading a federal judge that he is not violating the law by practicing medicine within the State of Texas.

Regardless of the merits of their case, the transcript also suggests that other abuses of prosecutorial discretion have occurred. These include violations of Rule 6(e) relating to grand jury secrecy and the violation of statutes and rules designed to protect physician/patient confidentiality.

We expect that either the Inspector General or the Public Integrity Section of the Department of Justice, with the assistance of the FBI, will begin this investigation immediately. I would appreciate a report on its progress, no later that the close of business, Thursday September 21, 1995.

The Subcommittee will be conducting its own investigation of the role of the FDA and the Department of Health and Human Services in what appears to be an egregious violation of the rights of Dr. Burzynski. By copy of this letter, including the attachments, I am referring the matter to the Judiciary Committees of the Congress for their consideration of the role of the Department of Justice in this case.

In order to facilitate the Subcommittee's inquiry, we need the names and present locations and phone numbers of all HHS, DOJ and U.S. Attorney personnel who have been involved in the referral, preparation or presentation of any allegation involving Dr. Burzynski to federal grand juries from 1985 to the present. Please provide the Subcommittee with this information no later than the close of business, Thursday, September 21, 1995.

We are making no document requests of the Department of Justice at this time. However, the Subcommittee staff will be contacting some or all of the individuals whose names are requested above to pose questions or to request interviews. I would expect that you will instruct the DOJ personnel to cooperate fully with our investigation. I further request that you order that all documents relative to these investigations, including drafts and those recorded electronically, be maintained until all investigations into this matter are complete.

I look forward to working with you on this matter. Should you have any questions regarding this request, please contact Alan Slobodin of the Committee staff at (202) 225-2927. Thank you for your cooperation with the work of the Committee.

Sincerely,

Joe Barton

Joe Barton
Chairman
Subcommittee on Oversight
and Investigations

cc: Honorable Thomas J. Bliley, Jr., Chairman
Honorable John D. Dingell, Ranking Minority Member
Honorable Ron Wyden, Ranking Minority Member,
Subcommittee on Oversight and Investigations

Enclosures

DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
National Cancer Institute

Memorandum

Date October 31, 1991

From Associate Director, Cancer Therapy Evaluation Program

Subject Antineoplastons

To Bruce A. Chabner, M.D.
Director, Division of Cancer Treatment

I thought you would be interested in this for several reasons:

1. Our Unconventional Cancer Treatment approach seems to be working well (thanks to Mike Hawkins).

2. Our on-site review process is working well (thanks to Dorothy Macfarlane).

3. Antineoplastons deserve a closer look. It turns out that the agents are well defined, pure chemical entities. They are relatives of Thalidomide with presumed good CNS penetration. We are working with DTEP on them. The human brain tumor responses are real.

We will keep you informed.

Mike

Michael A. Friedman, M.D.

Mike
will you test them in a
phase II trial

CANCER FACTS
National Cancer Institute • National Institutes of Health

Antineoplastons/Dr. Stanislaw Burzynski

Dr. Stanislaw Burzynski of the Burzynski Research Institute in Houston, Texas, has identified a group of peptides produced by the body, which he calls "antineoplastons." Dr. Burzynski and his colleagues claim that these peptides are produced in individuals as part of a "biochemical defense system" that inhibits cancer cell growth. According to Dr. Burzynski, "The failure of the system and deficiency of antineoplastons will result in perpetuation of neoplastic growth and development of cancer." His treatment, therefore, consists of restoring this "cancer defense system" by giving antineoplastons to people with cancer.

The National Cancer Institute (NCI) reviewed seven cases of patients with primary brain tumors that were treated by Dr. Burzynski with antineoplastons A10 and AS2-1 and concluded that antitumor responses occurred. To evaluate further the effects of treatment with antineoplastons, NCI is conducting phase II clinical trials (treatment studies) using antineoplastons in adult patients with refractory brain tumors. One trial at Memorial Sloan-Kettering Cancer Center in New York City opened in late 1993. A second trial is to be carried out at Mayo Comprehensive Cancer Center in Rochester, Minnesota.

SPECIAL UPDATE

Dr. Julian Whitaker's

Health & Healing®

TOMORROW'S MEDICINE TODAY

Special Supplement to *Dr. Julian Whitaker's Health & Healing*
September 1996

The FDA's Latest Abuse of Power

In their efforts to destroy Dr. Burzynski and his antineoplaston therapy for cancer, the Food and Drug Administration (FDA) recently "ordered" that he must contact each one of his 300+ patients by telephone every day—no messages allowed. Dr. Burzynski has had to hire eight additional people, and his phone bill will be astronomical because he has patients all over the United States, Europe and the Far East.

The FDA has never made this a requirement of a scientific study before! Antineoplaston therapy, which Dr. Burzynski himself discovered, is essentially nontoxic, making this latest harassment indefensible.

It should frighten you that the US government is doing this. When it was founded 200 years ago, safeguards were written in to protect citizens not from each other, but from the arbitrary actions of government. When I tell people what the FDA has done and is doing to Dr. Burzynski and others, the most common response is, "but they can't do that, can they?" Very few people actually believe that our "guaranteed" personal freedoms are being violated. We are no longer governed by reasonable laws, we are ruled by people in power.

Congressman Richard M. Burr, after a public congressional hearing on FDA misconduct regarding Dr. Burzynski, noted that he was "not only horrified, but terrified. The (FDA's) abuse of power transcends regulatory misconduct. It constitutes nothing less than one of the worst abuses of the criminal justice system I have ever witnessed."

Attorney Nancy Lord in her successful defense of Rodger Sless who, like Dr. Burzynski, was indicted by the FDA with 17 felony counts, characterized the FDA as "so completely out of control—out of control of the people, out of control of Congress, that they are now no more than a band of armed terrorists."

We're familiar with the noble words at the beginning of the Declaration of Independence, but have forgotten that the document was a list of complaints about King George. It states that:

He has erected a multitude of new offices, and sent hither swarms of officers, to harass our people, and eat out their substance.

He has made judges dependent on his will alone, for the tenure of their offices, and the amount and payments of their salaries.

He has combined, with others, to subject us to a jurisdiction foreign to our constitution, and unacknowledged by our laws; giving his assent to their acts of pretended legislation.

For taking away our charters, abolishing our most valuable laws, and altering, fundamentally, the Forms of our governments.

For suspending our own legislatures, and declaring themselves invested with power to legislate for us in all cases whatsoever.

These words are as true today of the FDA as they were back then about King George—perhaps even more so. In Dr. Burzynski's case, it is not just that his "inalienable rights" are being violated by the FDA; the agency is determined to destroy an effective cancer therapy, then convince you that Dr. Burzynski is the villain, not them.

And they might succeed! This is not a movie script in which the courageous underdog rises up to prevail over the corrupt and powerful. Imagine, Dr. Burzynski goes to jail, and we lose a valid cancer therapy because a child from Michigan showed up for treatment of a deadly brain cancer and Dr. Burzynski saved that child's life with antineoplastons. What was criminal about that? The child was not a Texas resident!

Throughout history only a handful of people have been able to see the transgressions of their government, and even fewer have tried to do anything about it. Dr. Burzynski needs your help, and we all need to help ourselves. One of these days you will know a child or loved one with a fatal cancer, and the FDA will have eliminated antineoplastons as an option.

There are two ways you can help. **(1) Support the Burzynski Legal Defense Fund,** P.O. Box 1170, Pacific Palisades, CA 90272. This legal fight is expensive, and Dr. Burzynski's opponent has unlimited resources—your tax dollars. Imagine, the FDA is using your money to destroy a therapy that could one day save your life. King George was not nearly so nefarious.

(2) The second thing you can do is to get at least six signatures on the petition printed on the back of this supplement. The more, the better, but if you all got six and sent them in, we'd be able to present about **3 million names** to President Clinton in October. We must expose the FDA, and three million names will help show our elected officials that some of the appointed ones have spun out of control. My personal commitment is 150 names.

Julian Whitaker MD

Support Dr. Burzynski's Cancer Patients

Dr. S. R. Burzynski is facing prosecution by the Food and Drug Administration (FDA). If convicted, he could be sentenced to up to 290 years in prison. The charges derive from the fact that he treated non-Texas residents in his Houston clinic with a non-toxic experimental cancer drug he developed, antineoplastons.

The FDA does not allege that any patient was ever harmed. No patient has ever filed a complaint. FDA scientists have approved clinical trials of antineoplaston therapy.

A 1991 NCI (National Cancer Institute) study of brain tumor patients treated by Dr. Burzynski concluded that "anti-cancer activity [of antineoplastons] was documented." The NCI's Chief of Neuroradiology, Dr. Nicholas Patronas, testified under oath that Dr. Burzynski's patients would die if denied his treatment.

Clinical trials of antineoplastons are currently underway in Japan and are scheduled to begin soon in Israel. Dr. Burzynski himself is conducting 66 FDA-approved and supervised clinical trials and is currently in full compliance with FDA regulations. He will apply for FDA approval in the summer or fall of 1996.

We do not believe that any public interest is served by prosecuting Dr. Burzynski. With deaths from cancer on the increase and the current approaches to treating cancer clearly inadequate, public funds should be used to help Dr. Burzynski develop his drug, not to stop his research.

We the undersigned call on President Clinton to honor the spirit of his March 29, 1996 promise to cancer patients—improved access to promising cancer drugs—and to drop the senseless, wrongful, wasteful prosecution of Dr. Burzynski.

Name (print)	Street Address	City	State	Zip	Signature

Please return immediately to:
Dr. B. Petition, c/o Edward A. Reynolds, 2005 Muliner Ave., Bronx, NY 10462

(1) Please make copies of this petition and have others sign them.
(2) As soon as each sheet is completed, please send to the above address.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

EPN 718
(301) 496-0510
FAX: (301) 402-1584

October 30, 1991

Stanislaw R. Burzynski, M.D., Ph.D.
6221 Corporate Drive
Houston, TX 77036-3494

Dear Dr. Burzynski:

Enclosed is a copy of the report summarizing our review of the responses seen in seven brain tumor cases treated by you with Antineoplastons A10 and AS2-1. Dr. Michael Hawkins will be communicating with you at a later date with regard to the question of possibly conducting a confirmatory trial under Division of Cancer Treatment sponsorship.

We thank you for your help and cooperation in making these cases available for our review, and for your kind hospitality during our visit.

Sincerely,

Dorothy K. Macfarlane, M.D.
Head, Quality Assurance and
Compliance Section
Regulatory Affairs Branch
Cancer Therapy Evaluation Program

cc: Dr. Michael Hawkins

DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
National Cancer Institute

Memorandum

Date October 30, 1991

From Head, Quality Assurance and Compliance Section, RAB, CTEP

Subject Review of Brain Tumor Cases Treated With Antineoplastons

To See Distribution

On October 4, 1991, CTEP staff (Dr. Michael Hawkins, Dr. Michael Hamilton, Dr. Dorothy Macfarlane) and invited consultants (Dr. Nicholas Patronas, neuroradiologist, NIH Clinical Center, and Dr. James Nelson, neuropathologist, AFIP) visited the offices of Dr. Stanislaw Burzynski in Houston, Texas to review seven selected brain tumor cases which Dr. Burzynski felt represented the best responses achieved with Antineoplastons A-10 and AS2-1 treatment. Following is a summary of each case history, as described by Dr. Burzynski, and the assessment of slides and scans by the review team.

Patient #1 (E.L.)

46 year old white female who experience Jacksonian seizures and was diagnosed as having right parietal lobe glioblastoma multiforme in October 1987. Resected 11/10/87 at University of Maryland Hospital, and received radiation therapy following surgery. Tumor recurred in February 1988.

Presented to Dr. Burzynski in March 1988. Treated initially with Antineoplaston A10 capsules, AS2-1 injections and oral low dose methotrexate. Received only 8 days of MTX. Received intermittent steroids from 4/6/88 through 6/1/88. Considered a CR by 11/28/88 CT scan. Continued on full-dose treatment (0.5 to 1.0 gm A10 capsules daily, plus 2 gm AS2-1 IV daily) until 4/3/89. At that time, she was placed on AS2-1 capsules for maintenance therapy. In summer of 1989 patient discontinued treatment and in 8/89 recurrence was documented on MRI scan. Resection for recurrent glioblastoma multiforme at Johns Hopkins 11/28/89. Died 4/90.

Pathology review: Slides from 11/10/87 resection confirm glioblastoma multiforme.

Radiology review: Marked decrease in tumor size, possible complete response from 11/28/88 through 3/28/89 by CT. Recurrence possibly as early as 5/30/89 CT.

Patient #2 (P.W.)

36 year old female who first presented in 1974 with Bell's palsy. It is not clear that this event was related to the

later tumor which was first suspected in summer 1987. A stereotactic biopsy of the brain stem on 7/27/87 revealed anaplastic astrocytoma, stage IV, Grade 3. Received radiation therapy at UCSF (total 73Gy) until October 1987. Progression noted on scans of 2/88 and 4/88.

Presented to Dr. Burzynski in May 1988 with paralysis of right side of face, diplopia, decreased strength in right upper extremity, right ear hearing loss, headaches and problems with balance and memory. Started on Antineoplaston A10 capsules, AS2-1 IV and low dose oral methotrexate from 5/25/88 until 7/12/88, when she was switched to IV A10 (30 gm/day) and IV AS2-1 (15 gm/day) given overnight. This dose and schedule was continued until 8/10/89 when patient was switched to maintenance doses of oral A10 and AS2-1. Received IV Decadron 2mg/day from 5/29/88 through 9/7/88. No steroids given since that date. Called CR at 1/23/89 MRI. All treatment discontinued on 1/21/90 and patient remains in CR (last MRI 1/29/91). Residual facial nerve palsy, no other symptoms.

Pathology review: Slides from 7/21/87 stereotactic biopsy: consistent with anaplastic astrocytoma--small specimen (1 mm fragment) artifact distorts nuclei. Could be lower or higher grade astrocytoma.

Radiology review: From 1/23/89 MRI through latest MRI on 1/29/91 there is only a small cavity (1 cm or less) at the former tumor site which probably represents the site of biopsy. The previously seen tumor parenchyma is no longer present. Possible CR.

Patient #3 (J.K.)

47 year old white male who presented in April 1897 with deafness, progressive weakness and occasional seizures. Subtotal resection at UCSF April 24, 1987. Diagnosed as anaplastic astrocytoma close to the Foramen of Monroe. Patient treated at UCSF with radiation therapy + BUdR, which was stopped because of an exfoliative dermatitis. Patient next treated with combination of Procarbazine, CCNU, and vincristine which led to prolonged leukopenia and peripheral neuropathy. Progressed on treatment and switched to beta interferon (12/87 to spring 88). In June, 1988 started chemotherapy with DFMO and MGBG, but no response.

Presented to Dr. Burzynski 7/13/88 and started daily IV A10 and AS2-1 (overnight infusions). Showed slow progression initially, then stabilization by spring/summer 1989. On 5/22/89, antineoplaston dose was decreased and patient placed on AS2-1 capsules. By spring 1990, CTs showed progression of former tumor and appearance of new lesions. Restarted 4/12/90 on daily IV A10 (1 gm/kg/day) and AS2-1 (0.17 gm/kg/day) by continuous infusion pump. In June dose of AS2-1 was increased to 0.23 gm/kg/day and decadron was added from 6/27/90 to

7/25/90. In September 1991, decreased A10 dose by 60% and AS2-1 dose by 25%. Called PR in 10/91; approaching CR. Telephone follow up on the day of our visit; patient reported some memory deficit, but otherwise fine.

Pathology review: Slides from original subtotal resection showed infiltrating glioma (astrocytoma or mixed astrocytoma/oligodendroglioma), borderline anaplastic glioma.

Radiology review: Very aggressive tumor. Original tumor showed "fleshy" component of 4.5 cm on 8/24/88. Latest CT on 9/6/91 shows cavity of 4.0 cm with "fleshy" component of 1.3 cm, which may be residual tumor or calcium deposit. Numerous new lesions appeared starting with 11/88 CT, but all had disappeared by 12/19/90 CT. Good PR, possible CR.

Patient #4 (P.M.)

7 year old white male who presented with diplopia, nausea and vomiting in 11/85. CT on 11/7/85 showed suprasellar mass and hydrocephalus. Shunt placed 11/8/85. On 11/11/85 underwent craniotomy and biopsy at Mayo Clinic. Diagnosed as Stage IV astrocytoma, histologic Grade 1, inoperable. Treated with vitamins and laetrile originally. At the beginning of 1988, the patient experienced headaches and tumor progression was noted. A second shunt was placed.

Presented to Dr. Burzynski 4/18/88. Started on A10 capsules, AS2-1 IV and low dose methotrexate. In June 1988, a slight increase in tumor size was noted. On 6/23/88 patient was switched to overnight IV A10 (1 gm/kg/day) and IV AS2-1 (0.5 gm/kg/day). Progressive decrease in tumor size was noted; called a PR on basis of 4/17/90 MRI. Changed to continuous infusion A10 and AS2-1 at same doses on 5/29/90. Latest MRI on 8/2/91 shows further decrease in tumor size.

Pathology review: Slides from original biopsy. Well - differentiated astrocytoma, possibly juvenile pilocytic astrocytoma.

Radiology review: Pre-treatment scans show a hypothalamic mass plus trilocular cyst. Main component of cyst + tumor in hypothalamus followed through serial scans. There was a substantial decrease in size of both solid and cystic components, with the decrease in the cystic part more dramatic. Decrease in solid component of approximately 40-50%.

Patient #5 (H.E.)

40 year old white female diagnosed in 12/89. Craniotomy and partial resection on 12/31/89; glioblastoma multiforme of left temporal lobe. Received 6000 rads from January 18 to March 7,

1990. MRI on 4/9/90 showed progression after radiation therapy. Biopsied 5/9/90.

Presented to Dr. Burzynski on 5/24/90 with headaches, right-sided weakness and slurring of speech. Started on continuous infusion A10 (1 gm/kg/day) and AS2-1 (0.33 gm/kg/day). Called PR by 7/25/90 MRI. Progressed and switched to antineoplastons + methotrexate + vincristine. Continued to progress and died 1/1/91.

Pathology review: Slides from 12/31/89 partial resection showed glioblastoma multiforme. Slides from biopsy of 5/9/90 show residual tumor with extensive necrosis, cell density less than original tumor and more giant cells present. These changes are associated with radiotherapy and/or chemotherapy.

Radiology review: Unusually large tumor in 4/90 which decreased in size (39%) after treatment with antineoplastons. Had progressed by next MRI two months later, with former cavity filled in by tumor.

Patient #6 (R.W.)

10 year old male who had a VP shunt on 12/27/87. On 8/18/89 a mass was identified in the region of the hypothalamus. Stereotactic biopsy on 8/28/89 revealed glioblastoma, Stage IV, Grade 3. Received radiation therapy from 10/4/89 to 11/15/89 (total 5500 rads). Progressed 1/2/90, with increased tumor size and enhancement, and new area of tumor in ependyma and lateral ventricle.

Presented to Dr. Burzynski on 4/12/90 with hearing and memory deficits. Started on continuous infusion A10 (1 gm/kg/day) and AS2-1 (0.34 gm/kg/day). Doses decreased 4/17/90 because of high uric acid and given decadron 4/17 and 4/18; returned to full dose antineoplastons 4/24/90. Received decadron for nausea and vomiting 5/2-23/90. Off treatment on 5/9 through 5/11 and again 5/16 through 5/20 because of elevated uric acid. Re-started on 50% original dose 5/21/90. Dose increased on 6/5/90 to A10 (45 gm/day) and AS2-1 (15 gm/day). Single IV dose of decadron on 6/7/90. Decreased antineoplaston doses on 11/1/90 to A10 30gm/day and AS2-1 12.5 gm/day. A10 dose decreased again on 1/2/91 to 24 gm/day. Received single dose IV decadron on 1/16/91; no decadron since. Called CR on 11/1/90 Antineoplaston dose decrease in 4/91; still on treatment and still in CR.

Pathology review: Slides from original stereotactic biopsy in 1989. Glioma consistent with anaplastic astrocytoma. Differential: anaplastic astrocytoma or spindle cell variant of oligodendroglioma.

Radiology review: Original pre-treatment MRI on 1/2/90 showed a hypothalamic mass with subependymal spread; measured main

tumor in hypothalamus only. By 8/22/90, enhancement of ventricle had disappeared. By 10/25/90, there is no enhancement seen. Abnormal, probably scar tissue, in the former tumor bed. CR, which remains unchanged through 7/1/91 MRI.

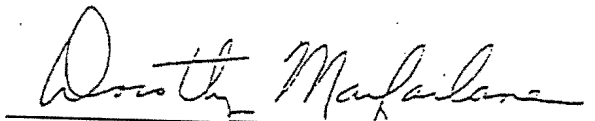
Patient #7 (H.M.)

30 year old white male who was diagnosed with astrocytoma Stage IIIB following craniotomy and biopsy of left frontal lesion in October 1987. Received radiation therapy during October-November 1987.

Presented to Dr. Burzynski on 7/8/88 with recent increase in right-sided weakness. Started on overnight infusions of A10 (135 gm/kg/day) and AS2-1. Received varying doses of steroids continually from beginning of treatment to present. IV antineoplastons discontinued 3/31/89. Started AS2-1 capsules 4/4/89 and added A10 capsules and low dose methotrexate on 5/17/89. On 11/3/89 progression was noted and intermittent IV bolus AS2-1 begun. Switched to continuous infusion A10 (90 gm/day) and AS2-1 (25 gm/day) on 5/1/90. A10 discontinued on 6/8/90. By August 1990, former tumor appeared calcified.

Pathology review: Infiltrating anaplastic astrocytoma.

Radiology Review: No pre-treatment scans available. A large cavitary mass is present in left frontal lobe on 8/22/88 CT. It demonstrates ring enhancement. A second component of this lesion invades the corpus callosum and crosses the midline invading the opposite frontal lobe. By 8/3/89 CT, no enhancement is seen. Areas of unusual tumor calcification appear. The calcifications increase over time extending into the entire tumor parenchyma and masking any possible enhancement on the CT scans. Remains stable until 9/19/91 when MRI shows definite enhancement. Question of whether difference seen is because 9/19/91 scan is an MRI compared to earlier scans which were all CT. Good response--possible CR?



Dorothy K. Macfarlane, M.D.

Distribution:

Dr. Michael Friedman
Dr. Michael Hawkins
Dr. Michael Hamilton
Dr. Nicholas Patronas
Dr. James Nelson
Dr. Michael Grever

Patient # 1 (E.L.)

	CT/MRI	Largest Diameter Measurement	Notes:
2/8/88	CT	2.3 cm	At recurrence
3/8/88	CT	2.3 cm	Started treatment 3/ /88
4/22/88	CT	2.3 cm	
6/6/88	CT	2 cm	
7/20/88	CT	1.5 cm	Ca deposit
9/28/88	CT	1.1 cm	Ca deposit
11/28/88	CT	0 ?	Edge blurred: artifact or shrunk area of enhancement
1/11/89	CT	same	Ca deposit - ? of small area of enhancement
3/28/89	CT	same	
5/30/89	CT	1.5cm	
6/2/89	CT	1.5cm?	No contrast - can't compare
7/5/89	MRI	1.8cm	
7/14/89	CT	1.5cm	
8/1/89	MRI	2.0 cm	
9/5/89	MRI	2.6 cm	
10/14/89	MRI	5 cm	

Impression: Marked decrease in tumor size - possible CR

Patient #2 (P.W.)

	Measurements of Greatest Diameter				
	Scan	T_1	T_2		
	CT/MRI	site	Tumor Only	Tumor + Edema	Notes:
2/25/88	MRI	UCSF	2.2 cm	2.8 cm	Contrast?
4/29/88	MRI	UCSF	3.0	3.5	Contrast?
7/11/88	MRI	Houston	2.2	2.6	No contrast — Started Tretmen 5/25/88?
9/17/88	MRI	Houston	1.9	2.5	No contrast
10/18/88	MRI	Houston	1.3	2.2	No contrast
1/23/89	MRI	Houston	1.0	1.0	small cavity seen - biopsy site?
4/10/89					incomplete films
1/15/90	MRI	Northridge Hosp.	1.0 ?	1.0 ?	small cavity - Siemens machine - no scale
2/29/91	MRI	Princeton	1.0	1.0	small cavity with hemosiderin - no edema

Impression: From 1/23/89 scan on, both T_1 and T_2 measurements represent a small cavity, probably the site of biopsy PR ± CE?

Patient #3 (J.K.)

		Lesions:					
					(R) Temporal		
	CT/MRI	(R) frontal	(R) temporal	(R) Parietal	horn	(L) frontal	(L) Temporal
3/18/88	CT	2.8 cm	0	0	0	0	0
6/29/88	CT	Film missing			Started treatment		7/13/88
8/24/88	CT	4.4 cm	0	0	0	0	0
11/28/88	CT	4.0 cm	8 mm	0	0	0	0
1/30/89	CT	4.0/4.2	1 cm	? dot	0	0	0
3/15/89	CT	4.2 cm	1.2 cm	? 2mm dot	0	0	0
5/15/89	CT	3.9/4.1	9-10 mm	? dot	1.8 cm	1.0 cm	8 mm
7/24/89	CT	3.9/4.0	0	0	0	9 mm	6 mm
11/6/89	CT	3.8/3.8	0	0	0	1.2 cm	3-4 mm
1/31/90	CT	3.5/3.7	0	0	0	1.1 cm	0
4/11/90	CT	3.5/3.6	0	0	0	7-8 mm	0
6/4/90	CT	3.9/3.9	0	0	0	0	0
8/6/90	CT	4.0/4.0	0	0	0	0	0
10/15/90	CT	4.0/4.0	0	0	0	0	0
12/19/90	CT	4.0 (cavity)	0	0	0	0	0
4/1/91	CT	4.0 (cavity)	0	0	0	0	0
6/28/91	CT	4.0 (cavity)	0	0	0	0	0
9/6/91	CT	* 1.3 cm	0	0	0	0	0
	* Note:	All CT's done at UCSF					

* 1.3 cm "fleshy" component, decreased from 4.5 cm "fleshy" component on 8/24/88. Question of whether 9/6/91 residual represents tumor or calcium.

New lesions →

	(L) lateral ventricle wall A	(L) lateral ventricle wall B	(L) frontal horn	(L) parietal horn	(R) Temporal	medulla
1/31/90	4 mm	3 mm	0	0	0	0
4/11/90	0	1 cm	9 mm	1.2 cm	9 mm	0
6/4/90	0	6 mm	8 mm	1.0 cm	8 mm	8 mm suspicious
8/6/90	0	5 mm	0	5-6 mm	0	0
10/15/90	0	2 mm	0	0	0	0
12/19/90	0	0	0	0	0	0
4/1/91	0	0	0	0	0	0
6/28/91	0	0	0	0	0	0
9/6/91	0	0	0	0	0	0

Patient # 4 (P.M.)

Hypothalamic

	CT/MRI	Site	Cyst/Mass	Notes:
11/7/85	CT	Wn Beaumont Hosp	2.8 cm	Enhancing portion - can't measure two diameters
11/26/86	MRI	U. Mich.	5 x 3.0 cm	Measurement of main dicentral part; has also unmeasured lobes both sides
3/10/88	MRI	U. Mich.	5.5 x 3.3	
8/21/88	MRI	U. Mich.	5.0 x 2.8	Lobe on (R) has disappeared
10/26/88	MRI	U. Mich.	4.6 x 2.7	
1/29/89	MRI	U. Mich.	4.3 x 2.5	↑ protein, no hemorrhage
5/31/89	MRI	U. Mich.	4.0 x 2.2	Enhancing component = 2.2cm
9/26/89	MRI	U. Mich	3.6 x 2.2	Enhancing component = 1.9 cm.
4/17/90	MRI	U. Mich.	3.4 x 1.6	Enhancing component = 1.5 cm.
8/21/90	MRI	U. Mich.	3.4 x 1.6	Enhancing component = 1.5 cm. - spotty
1/12/91	MRI	U. Mich	3.4 x 1.6	
8/2/91	MRI	U. Mich	3.2 x 1.0	No contrast * see below

Note: Hypothalamic mass with tri-locular cyst. Measured main cystic component in hypothalamus

8/2/91 MRI Note: Cerebellar pontine angle cystic projections nearly completely gone. Brain stem free of compression

Impression: Substantial decrease in size; size of cystic components decrease greater than that of solid component. Overall about 40-50% decrease in size.

Patient #5 (H.E.)

	CT/MRI	Site	(L) Temporal			
5/18/90	MRI	Santa Fe	6.5 X 5cm			
7/25/90	MRI	Santa Fe	6.0 X 3.3cm		39% decrease in size	
9/19/90	MRI	Santa Fe	6.2 X 5.0		Progression with cavity + tumor	Filled in
10/31/90	MRI	Santa Fe	7.5 X 6.3			

All scans on Simmons MRI - no scale except 5cm

Impression: 39% decrease in tumor size from 5/18 to 7/25; progression by 9

Patient #6 (R.W.)

	CT/MRI	Site	Hypothalamus		
1/2/90	MRI	New Brunswick	5.1 X 2.2 cm		
5/15/90	MRI	same	1.0 X 0.6	Started treatment	4/12/90
6/21/90	MRI	Houston	1.2 X 0.8	Not including horn	
8/22/90	MRI	New Brunswick	0.4 X 0.2	Enhancement of ventricle dissappears	
10/25/90	MRI	same	0	No enhancement - abnormal tissue where tumor was	
1/7/91	MRI	same	0	same as above	
4/1/91	MRI	same	0	No enhancement - scar tissue	
7/1/91	MRI	same	0	No enhancement - same as above	

Impression: CR, 9+ months duration

Patient #7 (H. M.)

	CT/MRI	Site	(L) Frontal	Bifrontal	
* 8/22/88	CT	Bellaire	4.0 cm	4.8 cm	faint enhancement - highly necrotic
11/7/88	CT	Bellaire	3.9		
1/30/89	CT	Bellaire	3.2		very faint enhancement
3/2/89	CT	Butterworth	4.0		has crossed midline
6/5/89	CT	Bellaire	2.3 - calcium		calcified area 2.3 cm - no enhancement
8/3/89	CT	Bellaire	calcium	4.4 cm	calcium deposits - bilateral no enhancement
11/2/89	CT	Bellaire	calcium	4.5 cm	Calcium increased - (L) frontal and bifrontal
2/1/90	CT	Bellaire	3.0 cm	5.0 cm	No enhancement
3/5/90	CT	Bellaire	3.0 cm	5.0 cm	No enhancement
4/30/90	CT	Bellaire	3.0 cm	5.5 cm	No enhancement
6/7/90	CT	Bellaire	3.0 cm	5.5 cm	No enhancement - increased calcium bifrontal
7/16/90	CT	Butterworth	3.0 cm	5.5 cm	? area of new enhancement
8/16/90	MRI	Butterworth			No pre-contrast scan
9/19/90	MRI	Butterworth	3.1 cm	5.5 cm	Definite enhancement

* No pre-treatment scan

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001. letter	Letter from Carl T. Ott, M.D. (5 pages)	2/20/96	P6/b(6)

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gf69

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
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002. letter w/attach.	Mary K. Michaels to Hillary Clinton (4 pages)	9/16/96	P6/b(6)

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RESTRICTION CODES

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I, Mark Leroy Snyder

PROTEST

the FDA'S DESPICABLE USE OF POWER
and its willingness to destroy me
and one of the most promising cancer therapies ever discovered!

Is this DUE PROCESS?
To kill me and 300 other cancer patients,
while legally taking away their life support systems?

This is a civil dispute, NOT A CRIME --unless the FDA wins!
It then becomes a gross crime against humanity.

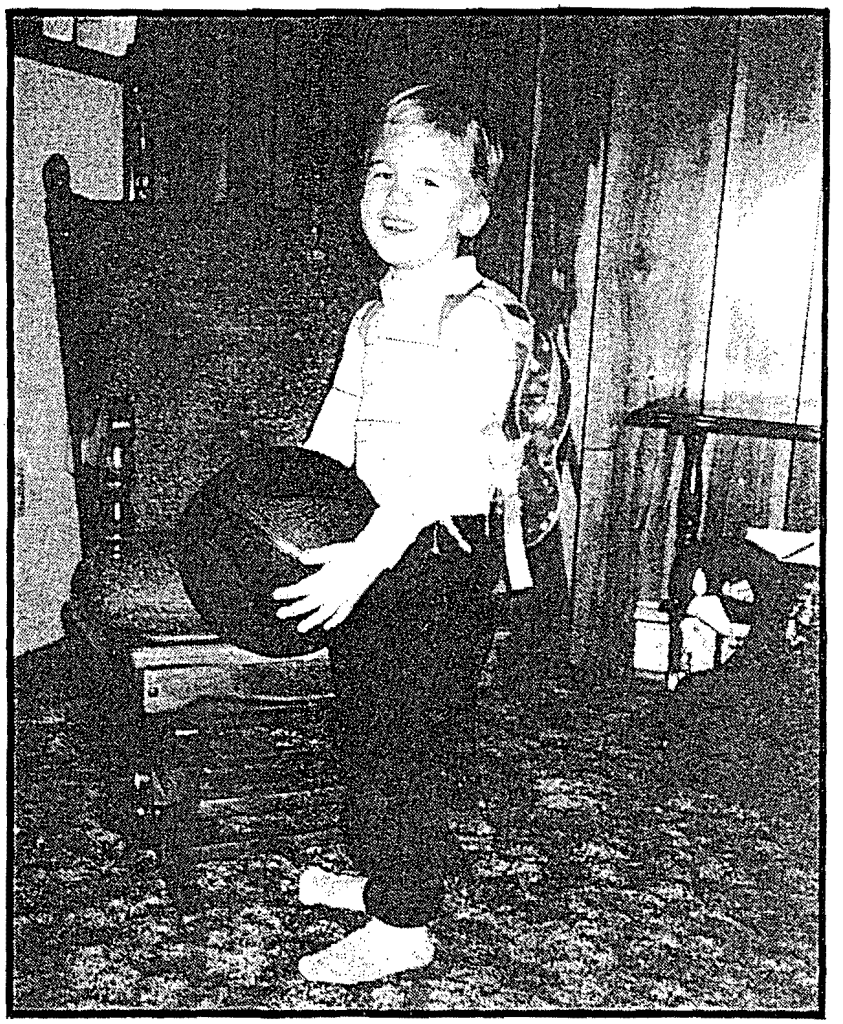
As a lifelong quadriplegic,
it will negate 43 years of struggle to live.

I SUPPORT DR. BURZYNSKI

my only chance for life!

Call 313/668-7722 for further information.

DON'T LET THE FDA TAKE DUSTIN'S MEDICINE AWAY!



Dustin was 2½ years old when diagnosed with a brain tumor that could not be treated by conventional means. Dustin, now 4, has survived because of Dr. S. Burzynski's Alternative Treatment. Now the FDA is trying to imprison Dr. Burzynski for treating people without the FDA's approval.

Please give generously to:

Dr. Burzynski's
Legal Defense Fund
P.O. Box 1770
Pacific Palasades, CA 90272

LETTER FROM A PROSTATE CANCER PATIENT

To:
Subject: FDA's Unjustified War On Dr. Burzynski

Unknown to many people, a very successful pioneer in cancer research is facing persecution and criminal prosecution by the FDA. Also, unknown to many people, this very successful pioneer's medicine works. The FDA admits that it works. Who and what is this all about? Dr. Burzynski and Antineoplastons.

I was diagnosed with prostate cancer in 1994. I have been taking antineoplastons for 2 years with NO side effects. I have been in remission for 13 months. Yet at this very moment, Dr. Robert J. DeLap, FDA Director, Division of Oncology Drug Products is denying me the right and privilege as an American citizen to choose to continue an effective and non harmful treatment that has brought my cancer into remission. This is very difficult for me to understand how a man and organization who I support with my tax dollars is doing this to me. I also have trouble understanding why congress and our President can't stop this atrocity being committed against Dr. Burzynski and myself and the waste of tax dollars by the FDA persecuting a man whose only crime is violating some unwritten rules associated with the development and dispensing a medication that is providing a new lease on life for many people afflicted with the dreaded killer CANCER.

As an American citizen who contributes a significant sum of money to the tax coffers every year, I respectfully demand the following:
1. The FDA back off in their persecution and prosecution of Dr. Burzynski. Specifically, they should drop their criminal prosecution of Dr. Burzynski in Houston, Tx.
2. Dr. Robert J. DeLap, FDA Director, Division of Oncology Drug Products retract his request that Dr. Burzynski discontinue administration of antineoplastons to me, Dan Hockersmith.
3. That laws be adopted to prevent the government from prohibiting me from choosing the medical practitioner and effective non harmful medications of my choosing and not the FDA's choosing. The choice should be mine.
4. Reduction of FDA's far reaching powers and return them to an organization that recommends and advises, not dictates. They have become too powerful and unfortunately appear to have an incestuous relationship with the pharmaceutical companies and physicians.

I have great admiration and respect for 80% of what FDA has done for the American people, but they have become just like the cancer that I am fighting, OUT OF CONTROL. They must be brought under control quickly, or this country will be denied a great opportunity for an effective and nonharmful medication for the control and cure of cancer.

I implore you to get involved TODAY and help me and Dr. Burzynski.

Respectively,

Dan Hockersmith

P6/b(6)

Alternative-medicine doctor meets with pope

By Larry Witham
THE WASHINGTON TIMES

A doctor who works in alternative cures for cancer was summoned to the Vatican over the weekend and met yesterday with Pope John Paul II, fueling speculation that the 76-year-old pontiff may have cancer.

Dr. Stanislaw Burzynski, a Polish-born physician working in Houston, left Saturday for the Vatican, leaving no word with his associates of what the trip entailed.

"The simple fact is that he was summoned to Rome, and he did meet the pope today," Dean Mouscher, clinical trials director of the Burzynski Research Institute, said in a telephone interview yesterday.

Asked if the trip is cancer-related, Mr. Mouscher said: "It might be, but it might be for other reasons. He didn't know the reason, or said he didn't know. . . . Dr. Burzynski has some old friends in Poland who knew the pope."

The Vatican meeting took place a few days after John Paul returned from a pastoral visit to France, where he reportedly looked robust in comparison with other public appearances this year.

The pope, who was operated on in 1981 to remove a would-be assassin's bullet and in 1992 to remove an intestinal tumor, this year suffered three bouts of fever that doctors link to an inflamed appendix. It will be removed next month.

One source on Capitol Hill familiar with Dr. Burzynski's work said Vatican officials are saying he visited "to treat a cardinal." A Vatican spokesman could not be reached last night.

The trip is also unusual because Dr. Burzynski, who has 400 patients, was indicted in November by federal lawyers after a 12-year battle to certify his drug Antineoplastins with the Food and Drug Administration (FDA).

Dr. Burzynski said that, under approved clinical trials, the drug shrank malignant brain tumors.

After an FDA investigation, a grand jury in Texas issued a 75-count indictment charging the doctor and his clinic with contempt, mail fraud and putting an unapproved drug into interstate commerce. The trial may begin next month.

On Saturday at noon, supporters of the Burzynski Patient Group and some congressmen will demonstrate in Lafayette Park across from the White House for the administration reneging on fast-drug-approval rules and the FDA indictment.

"Cancer patients who are struggling to stay alive are having their treatments interrupted by FDA bureaucrats who sit behind a desk and play God," said Steven Siegel, director of the group. "Now, the FDA admits that its much-ballyhooed fast-track approval of promising new cancer drugs is a sham."

The FDA yesterday had no comment on the litigation. Its press release on the indictment emphasized that clinical trials of new drugs must be FDA supervised.

The Washington Times

Cancer doctor sees pope, but not about his health

By Larry Witham
THE WASHINGTON TIMES

Pope John Paul II has asked a Polish-American doctor about his alternative cure for cancer but has not discussed his own health, an associate of the doctor's said yesterday.

Dr. Stanislaw Burzynski, a Houston cancer expert who was summoned to the Vatican this week, could not be reached overseas to discuss details of his unusual visit with the pope.

But Dean Mouscher, clinical trials director of the Burzynski Research Institute in Houston, said Dr. Burzynski has called his associates since seeing the pope.

"He told me he did not discuss the pope's medical condition," Mr. Mouscher said in a telephone interview yesterday. "The pope was very interested in his cancer research."

He said nothing about the visit suggests the pope has cancer. "There was no reason to think that from Dr. Burzynski's trip. He did not say he [the pope] had cancer," he said.

A Vatican official said he had heard no rumors about the pope having cancer. "I've heard absolutely nothing," said Archbishop John Foley, a communications officer at the Holy See who was reached at his home in Rome last night. "I would be cautious. It's better to get confirmation from somewhere."

In November, a federal grand jury indicted Dr. Burzynski on charges of allowing his unapproved cancer treatment, a new drug called Antineoplastins, to cross state lines and to be sold by mail. His trial may begin next month.

The Vatican meeting took place Tuesday, a few days after John Paul returned from a pastoral visit to France, where he reportedly looked robust compared with other public appearances this year.

The pope, who was operated on in 1981 to remove a would-be assassin's bullet and in 1992 to remove an intestinal tumor, this year suffered three bouts of fever that doctors link to an inflamed appendix. It will be removed next month.

Dr. Burzynski, who has 400 patients, has said that, under clinical trials, his new drug shrunk malignant brain tumors.

"The FDA [Food and Drug Administration] are playing God," said Steven Siegel, director of the Burzynski Patient Group whose wife is a patient of Dr. Burzynski's. "They are keeping this successful treatment from people who depend upon it for their lives."

Mr. Siegel has been in Washington this week to lobby for passage of the Access to Medical Treatment Act.

Sun 3/24/96 60 CENTS

PRESIDENT ORDERS FASTER APPROVAL OF CANCER DRUGS

MOVE AIMED AT THE G.O.P.

F.D.A. Acknowledges Risk but Sees Increases in Survival and Comfort of Patients

By PHILIP J. HILTS

WASHINGTON, March 29 — The Clinton Administration announced today that it would take steps to streamline the Food and Drug Administration's rules to speed cancer drugs to patients.

President Clinton said the regulatory changes would apply to at least 100 drugs now under study. "Dozens of them will get to the market sooner and that means they can help Americans suffering from cancers of the breast, lung, ovary, prostate and colon, among others," he said at the White House.

The Administration hopes that the steps announced today will blunt a Republican drive to reduce the regulatory reach of the F.D.A. For some time Republicans have been pressing for changes at agencies like the Environmental Protection Agency and the F.D.A., arguing, for example, that delays in drug approval are bad for patients, drug companies and the nation's competitive position. The Administration has already taken steps to streamline or reduce some drug approval regulations.

The reforms will go into effect immediately, said Donna E. Shalala, Secretary of Health and Human Services.

But the agency acknowledged that the new approach ran the risk of sometimes making drugs available whose safety and effectiveness had not been as thoroughly tested as they might have been previously.

Until now, makers of cancer drugs had to show that they could lengthen the survival of cancer patients or improve the quality of their lives before the drugs would be approved for marketing. Under the new rules, however, all a company has to show is that the drug can measurably shrink the size of a tumor, even for only a short time.

In another significant change, the F.D.A. will accept evidence of a cancer drug's effectiveness from 26 other countries, essentially all those with some system for reviewing and approving drugs, rather than requiring lengthy testing in the United States. Drugs approved in the 26 countries could become widely available in the United States long before companies submit applications for approval to market them.

Under this so-called expanded-access program, which already covers AIDS drugs, any doctor can get one of these drugs from its maker by promising to provide information on the outcome of the treatment.

The F.D.A. said it would monitor the approval of drugs by the 26 countries so that the agency could quick-

Continued on Page 12, Column 1

President Planning to Quicken The Approval of Cancer Drugs

Continued from Page 1

ly review data and permit such expanded access to a drug if there was evidence that it worked.

The average approval time for so-called breakthrough therapies for life-threatening diseases is six months, but it is longer for drugs that are very similar to those already on the market.

"Science has matured to the point where we can actually make much earlier decisions," Dr. Shalala said. "This is a genuine reform, not just putting an artificial time frame on the F.D.A. We are reconceptualizing the drug-approval process based on science."

Vice President Al Gore called the new initiative a "common sense approach to approving promising new cancer therapies."

But the Commissioner of Food and Drugs, David A. Kessler, said in a telephone interview: "We are taking a risk here. We are going to make mistakes in this process. There will be some drug that comes along that is not as effective as it looked like or has much more severe side effects than we thought. But that risk is worthwhile when patients are facing life-threatening illnesses, we feel."

The Pharmaceutical Research and Manufacturers Association, the industry's trade group in Washington and a leading backer of Republican efforts to modify F.D.A. procedures, applauded today's announcement as "long overdue."

The statement said, "The Administration's effort is an acknowledgment that F.D.A. must be reformed, and it draws attention to the need to pass comprehensive legislation to improve drug development."

The main measure in Congress to streamline the agency's drug-approval process was approved by the Senate Labor and Human Resources Committee on Thursday, by a vote of 12 to 4. The bill, sponsored by Senator Nancy Landon Kassebaum, the Kansas Republican who is chairwoman of the committee, would require the F.D.A. to evaluate every drug or medical device within six months. The bill also takes the first steps to turn over drug approval to private groups paid for by the pharmaceutical industry.

The bill was attacked by Senator Edward M. Kennedy, Democrat of Massachusetts, as a giveaway to industry and a threat to public safety.

Senator Kassebaum said the bill would speed approval and give Americans access to any drugs available in Europe. In response to Mr. Kennedy, she said, "No one on this committee in any way wants to damage safety." She also said she would address some of Mr. Kennedy's concerns by suggesting changes to the bill before it reached the Senate floor.

Three bills were introduced in the House today in a package similar to the Senate measure. Representative James C. Greenwood, Republican of Pennsylvania, one of the sponsors of the package, said the legislation would not conflict with the President's action but enhance it.

Dr. Sidney Wolfe, director of Public Citizen's Health Research Group in Washington, said he was concerned about the Administration proposal, saying it was pressing the limits of what was possible. "These are extremely toxic drugs in cancer," he said. "You are fighting fire with fire, so if you just misestimate the benefits versus the risk by a little bit, you could end up doing more harm than good."

He noted that AIDS groups, which have had the benefit of rapid approval for some time, are now backing away from further shortcuts because the harm of early approval has become apparent for some patients.

"The agency will have to monitor these quick access drugs very carefully," he said.

Under the plan announced today, af-

A move to blunt efforts by the G.O.P. to fight regulation.

ter a drug is approved under the expanded-access program the companies will supply more detailed information on safety and effectiveness to insure that unexpected problems are discovered.

Moreover, the agency will add a patient advocate to each of its advisory boards, beyond the one consumer member already on the boards, which play a crucial role in determining if a drug is effective and safe enough to put on the market.

There are now about 300 cancer drugs in development at companies or waiting for approval of the F.D.A. All will be eligible for the expanded access, and probably 100 will be shown to be effective enough to gain expanded access quickly.

Dr. Kessler suggested three drugs that might be approved quickly under the rules, all for cases in which the first-line drug for the cancer fails. They are irinotecan, used for colorectal cancer; taxotere, used for breast cancer resistant to doxorubicin, and topotecan, used to treat ovarian cancer.

Dr. Shalala said that 1.3 million cases of cancer would be diagnosed in the United States this year.

More national news appears on page 24.

NY Times

3-30-96

Since 1989, Dr. Burzynski has had permission from the FDA to conduct studies of his investigational products (antineoplastons) in certain categories of cancer patients under the Investigational New Drug Exemptions (INDs).

In November 1995, a Federal grand jury in Houston, Texas, indicted Dr. Burzynski, for among other things, continuing to distribute his unapproved new drugs in violation of a 1984 Federal injunction and fraudulently billing insurance companies for his administration of those drugs. He is expected to go to trial October 15, 1996.

Judge Lake, in pre-trial proceedings on the pending criminal matter, issued an order on February 26, 1996, that all patients receiving antineoplastons must be enrolled in a clinical trial approved by the FDA. That order was stayed pending review by the Court of Appeals , and on April 12, 1996, the court affirmed Judge Lake's order.

Since Dr. Burzynski had a substantial number of cancer patients on antineoplastons at the time of the courts's ruling, the FDA permitted Dr. Burzynski to enroll under his IND all patients with refractory cancers who were receiving antineoplastons as of February 23, 1996. Any subsequent patients who met eligibility criteria would receive the product under clinical trials.

Prior to February 1996, Dr. Burzynski enrolled fewer than 20 patients in clinical trials conducted under an IND. In newspaper reports, however, Dr. Burzynski was quoted as saying that he has administered antineoplastons to more than 2500 patients. Since February 26, 1996, Dr. Burzynski has submitted over 60 new clinical trials to his IND. These protocols allow for the administration of antineoplastons for initial studies of effectiveness. The IND regulations require annual reporting of the status of the clinical trials and more frequent reporting of safety problems. FDA does not have current information regarding the number of patients he has enrolled in the clinical trials.

For patients who are not eligible to receive the antineoplastons under the clinical trials, the agency has granted over 125 "single patient exceptions." There have been a few cases where single patient exceptions have been denied, but those patients had not received recognized curative therapy.

No data or results from well controlled clinical trials has been submitted to the agency for review. The FDA cannot accept anecdotal or testimonial information concerning drug effectiveness as the basis for marketing approval of new drugs.

On March 27, 1996, agency representatives (Dr. Friedman , Dr. DeLap, Theresa Toigo, Patty Delaney, and Nancy Stanisic) met with Mr. Schiff, and Mr. And Mrs. Siegel from the Burzynski Patient Group. The Burzynski Patient Group brought "48 Hours" staff and camera crew to the FDA without permission or knowledge of Broadcast Media.

OPTIONAL FORM 99 (7-90)

FAX TRANSMITTAL # of pages ► 1

To JENNINGS	From MANDE
Dept./Agency	P P6/b(6)
Fax # 456-7431	Fax #

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Food and Drug Administration
Rockville MD 20857

IND 43,742

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

SEP 15 1996

Burzynski Research Institute, Inc.
12000 Richmond Avenue, Suite 260
Houston, Texas 77082-2431

Attention: S. R. Burzynski, M.D., Ph.D.

Dear Dr. Burzynski:

Please refer to your Investigational New Drug Application (IND) submitted pursuant to section 505(i) of the Federal Food, Drug, and Cosmetic Act for Antineoplastons A10 & AS2-1 injections.

Please also refer to the September 10, 1996 letter that we received from Mr. Dean Mouscher of your staff. Mr. Mouscher had inquired about procedures for requesting a meeting with us to discuss your NDA development plans. FDA provided the information requested by Mr. Mouscher by facsimile transmission on September 12.

Enclosed are additional information and guidelines, regarding the format and content of a New Drug Application. Please note that the Federal Food, Drug, and Cosmetic Act provides, at 21 U.S.C. 355 (d), that FDA cannot approve a New Drug Application if there is a lack of substantial evidence consisting of adequate and well-controlled investigations showing that the drug product will have the effects it is purported or represented to have. Observations made in your clinical practice, or in CAN-1 protocol patients, could not be used as the basis for a new drug application, since these do not represent adequate and well-controlled investigations as defined in FDA regulations (21 CFR 314.126).

We also note that under our current regulations and practices, the Agency has never accepted data from a single investigator or clinic as the sole basis for approval of a new drug for cancer treatment. It is obviously important to know that the safety and effectiveness findings for a new drug can be replicated by more that one principal investigator.

The Cancer Initiatives announced in March of this year by President Clinton and Vice President Gore did not set aside any laws or regulations related to approval of new drugs for cancer treatment. In this regard, we have not changed or lowered our standards for the approval of such drugs.

IND 43,742
Page 2

I hope this information will be helpful to you. If you believe you have obtained promising data in patients enrolled on your currently ongoing IND protocols (other than CAN-1), we will be pleased to discuss those findings with you and give you our advice regarding further development of your investigational products.

Sincerely yours,

Robert J DeLap

Robert J. DeLap, M.D., Ph.D.
Director, Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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IND 43,742
Page 3

14. Guideline for the Format an Content of the Summary for New Drug and Antibiotic Applications

DR. BURZYNSKI PATIENT GROUP

P6/b(6)

September 23, 1996

Mr Chris Jennings,
Special Assistant To The President
Office Of Domestic Policy
Old Executive Office Building, Rm. 213
1700 Pennsylvania Ave, Wash. DC 20500

Dear Mr. Jennings,

As I am sure you will recall, I represent the Burzynski Patient's Group. We are an organization of persons who are patients and supporters of Dr. Stanislaw Burzynski and his clinic in Houston Texas.

A large contingency from our group will be coming to Washington this week to lobby and attend a rally in front of the White House. I want you to have this information in advance because I don't believe that you, or the President, have full knowledge of the issues at hand.

We have endeavored to open lines of communication with the President's administration with very little success. In fact, our lobbyist have told us that the President will have nothing to do with our issues, regardless of merit. If that is true, it would obviously be to the benefit of his opponents.

We are a group of mainstream professionals with no particular axe to grind. Dr. Burzynski is a compassionate and honest man who has finally developed a humane treatment for cancer. Since we have first hand knowledge that his medicine is effective, it is easy for us to support him.

It has been my personal experience in dealing with the F.D.A.'s administration that they have been less than forthright in their dealings with me, and Dr. Burzynski in particular. Given the blatant lies the F.D.A. has told, and the unconscionable acts they have committed against Dr. Burzynski's patients, I can't imagine that they represent our interest to you in an honest manner.

Dr. Burzynski has now completed the F.D.A. phase two study. The results prove that his treatment for cancer is both non harmful, and extremely successful against terminal cancers. No other current treatments can claim this.

When we contacted the F.D.A. to request information on expediting a new drug application, we received the attached response. They are unwilling to accept the data proving effectiveness, even though the results come from their own approved study.

Notice the last paragraph regarding President Clinton's March promise to expedite promising cancer cures. While that was an exciting and bold message, apparently it was meaningless to the F.D.A..

To clear up the main issues here, Dr. Burzynski's treatment was proven non harmful many years ago. The only legitimate question is one of efficacy. Since the F.D.A. refused to accept the testimony of hundreds of patients who received benefits from this medicine, he initiated phase two trials in record time.

These trials progressed in spite of overt acts committed by the F.D.A. to stall and divert the trials. Now that he has proven that the medicine is more effective than any other cancer trials ever submitted, we are told more proof is required. Please keep in mind that we are discussing terminal cancer! Standard alternatives to Dr. Burzynski's treatment are notoriously ineffective, always harmful and much more expensive in totality.

I and several members of our organization would like to meet with the President, you or another key member of the President's staff. While I am sure that all your schedules are very busy, the issues at hand affect the lives of every person in our country.

I am of the belief that common sense and communication could easily render our issues mute. The only other alternative open to us is to actively publicize and criticize, very possibly to the detriment of the President.

Please consider the merit of setting up a meeting. You have no reason not to trust me, and everything to gain from our information. I can be reached throughout today at P6/b(6) at home this evening P6/b(6) or on my pager at P6/b(6) P6/b(6) Tomorrow (Tuesday) evening I will arrive in Washington and be staying at the Belleveue Hotel (202) 638-0900.

Sincerely,

Ric Schiff

DR. BURZYNSKI PATIENT GROUP
P.O. Box 744
Clayton, CA 94517
(510) 672-8973

September 23, 1996

Ms. Maggie Williams
Chief Of Staff
Office Of the First Lady
1700 Pennsylvania Ave,
Wash. DC 20500

Dear Ms. Williams,

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Robert J DeLap

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AXE 9/20/96

14. Guideline for the Format an Content of the Summary for New Drug and Antibiotic Applications

DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
National Cancer Institute

Memorandum

Unconventional Therapy EV.

Date October 31, 1991

From Associate Director, Cancer Therapy Evaluation Program

Subject Antineoplastons

To Bruce A. Chabner, M.D.
Director, Division of Cancer Treatment

I thought you would be interested in this for several reasons:

1. Our Unconventional Cancer Treatment approach seems to be working well (thanks to Mike Hawkins).

2. Our on-site review process is working well (thanks to Dorothy Macfarlane).

3. Antineoplastons deserve a closer look. It turns out that the agents are well defined, pure chemical entities. They are relatives of Thalidomide with presumed good CNS penetration. We are working with DTEP on them. The human brain tumor responses are real.

We will keep you informed.

Mike

Michael A. Friedman, M.D.

Mike
will not test Memin C
phase II trial

Withdrawal/Redaction Marker
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
003. letter w/attach.	Robert J. DeLap,M.D. to S.R. Burzynski, M.D. Re: Patients enrolled in CAN-1 Protocol (9 pages)	8/22/96	P6/b(6)

This marker identifies the original location of the withdrawn item listed above. For a complete list of items withdrawn from this folder, see the Withdrawal/Redaction Sheet at the front of the folder.

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Chris Jennings (Health Security Act)
OA/Box Number: 8993

FOLDER TITLE:
Correspondence-Burzynski [Stanislaw] [1]

gf69

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advise between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]