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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. list	re: patients and Antineoplaston Therapy (4 pages)	03/25/1996	b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Elizabeth Drye
OA/Box Number: 10452

FOLDER TITLE:
Daschle Access Bill

2014-0046-S
rc1373

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 advice 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]
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- Dr.'s allow Dr.'s to tell patients whatever they want.
- I had Lyme disease - cholostrom. -
  Defn. of a drug - ① intends to affect structure and/ function of the body
  ② therapeutic claims for product.
  ③
- No position on his bill. No hold. Have concerns w/this
- Press him -

MEMORANDUM TO CHRIS JENNINGS

FROM: MARILYN YAGER

RE: Meeting with Former Rep. Berkley Bedell

DATE/TIME: Monday, March 25
1:00pm

LOCATION: Room 212, OEOB (Your office)

BACKGROUND: Per our conversation last week, this meeting is to give Berkley a chance to pitch his alternative medicine bill, as sponsored by Senators Daschle and Harkin.

Status w/ Bill Schultz

As you may recall my saying, he believes the FDA has turned a deaf ear to the positives of their proposal and he believes the FDA's strong opposition kills any possibility of their bill moving. Berkley also believes it is the wrong thing politically for the President because it feeds people's view that the Administration is unwilling to lessen the regulatory, big government hold on healthcare.

I have already cautioned Berkley from getting his proposal caught up in the GOP efforts to reform FDA, especially since we might vetoing their legislation unless something more moderate could be worked out.

Following a conversation with Pete Rouse, Daschle's AA (and former Berkley Bedell AA), he thought it was reasonable to push a demonstration effort of the concepts in Berk's legislation. However, neither Daschle nor Harkin have made the demonstration proposal to Berkley. I raised it with Berkley and said I thought that is what he should be pushing this year. I also suggested that if there was a Democratic alternative FDA reform bill it would increase the likelihood of his proposal getting included (especially if is was a demonstration).

I have also told Berkley that although I know we would not support the bill in its current form, that I thought we might be able to bring FDA around to some sort of demonstration idea. I have since raised the idea with Jerry Mande at FDA who said he would review whether FDA might be willing to support a demonstration if it was attached to a FDA reform they could support.

And finally, you should know that you are meeting with Berkley in lieu of the Vice President. Berkley wanted to meet with the Vice President, who he obviously knows from their days in the House. The VP's wants to avoid meeting if possible. I advised Berkley that all FDA policy comes through you at the White House.

Thanks for taking the time to meet with Berkley, I appreciate it.

Here's an old summary of the Bill

Concept Paper
Access to Medical Treatment Act

Premise: The United States has the best medicine in the world, and the Food and Drug Administration plays an essential role in evaluating the safety and efficacy of medical treatments. However, the current health care delivery system effectively excludes the development and utilization of alternative medical treatments that may help patients *and* are not proven harmful. Therefore, it makes sense to consider opening up the system to such alternative treatments under certain carefully circumscribed conditions.

The Proposal: This legislation would allow an individual to be treated by any licensed health care practitioner with any method of medical treatment the individual desires, so long as:

1) there is no evidence that the treatment is dangerous;
2) the patient is fully informed of the risks and side effects of the treatment; and
3) no claims are made as to the efficacy of the treatment, except for truthful reporting that does not result from financial motives.

The bill also specifies that treatments administered under this legislation do not qualify for government reimbursement (such as Medicaid).

Rationale:

• FDA approval process discourages innovation.
The time and expense currently required to gain FDA approval of a treatment works to limit participation in this system to large pharmaceutical companies. It effectively precludes the potentially innovative contributions of individual practitioners, scientists, smaller companies and others who do not have the financial resources to complete the FDA approval process. It also serves to prevent low-cost treatments from gaining access to the market.

• Current practices are not making sufficient progress toward combatting degenerative diseases.
Pharmaceutical drugs have proven effective in treating many infectious communicable diseases (i.e. pneumonia, meningitis, smallpox, etc.). They have not proven nearly as effective in treating degenerative diseases, such as cancer, Alzheimer's and heart disease. Greater attention should be devoted to our dual responsibility to develop new and more effective ways to treat both infectious and degenerative diseases.

• FDA's role would not be changed.
The Access to Medical Treatment Act would not dismantle or appreciably change the current operations of the FDA or the conventional medical community. The FDA would still have responsibility for certifying treatments as safe and effective. This legislation merely attempts to open up the system to the utilization of new alternative treatments. The strict claims restriction in the bill is designed to ensure that little incentive exists for major marketing efforts of non-FDA approved treatments, and should address the legitimate concern that this legislation merely establishes a "bypass" for the FDA approval process.

• Consumer protections are an essential element of the bill.
The bill contains several important protections to address the issue of consumer safety. In addition to a strict claims restriction, these protections include a prohibition on financial reimbursement by any government health program, a strict definition of who qualifies as a health care practitioner, and a stipulation that treatments administered under this legislation may not pose a danger to the patient. [It bears noting that many conventional treatments, such as chemotherapy, would not qualify for utilization under this provision.]

• This is a freedom of choice issue.
Freedom of choice is one of the bedrock principles upon which our nation rests. Permitting administration of alternative medical treatments, provided that individuals are not misled or misinformed, extends freedom of choice to the realm of medicine. This legislation stems from the conviction that an individual suffering from a life-threatening or otherwise serious disease for which conventional medicine offers limited hope should not be denied access to a non-conventional treatment if there is reason to believe that it might be beneficial.

Section-by-Section Analysis:

Section 1. Short title

Section 2. Definitions

Section 3. An individual shall be permitted to be treated with any method of medical treatment that he or she desires, so long as the following conditions are met:

- administration of the treatment falls within the expertise of the health care practitioner (defined under Section 2 as any properly licensed medical doctor, osteopath, chiropractor or naturopath)
- there is no evidence that the treatment is a danger to the patient
- the patient has been informed of the nature of the treatment (including risks and side effects) and that the treatment has not been approved by the FDA
- no advertising or labeling claims have been made with respect to the efficacy of the treatment
- with the exception of accurate and documented claims made by the health care practitioner administering the treatment, no claims have been made with respect to the efficacy of the treatment by any individual with a financial interest in the supply or administration of the treatment

Section 4. An imported method of treatment shall not be prohibited solely because an advertising or labeling claim with respect to its efficacy has been made in a foreign country.

Section 5. Treatments may be imported into the United States or introduced into interstate commerce for use in accordance with this Act.

Section 6. No licensing board shall deny, suspend or revoke the license of a health care practitioner solely because the practitioner administers a treatment according to the provisions of this Act.

Section 7. No health care practitioner shall be eligible for financial reimbursement for a treatment under any government health program unless so authorized by the Secretary of Health and Human Services.

Section 8. A health care practitioner who violates any provisions of this Act shall not be covered by the protections of this Act and shall be subject to all other applicable laws and regulations.

Access to Medical Treatment Act
Cosponsors as of October 16, 1995

House of Representatives (HR 2019) 26 Total:

Joe Barton (R-6-TX)*
Brian Bilbray (R-49-CA)*
Christopher Cox (R-47-CA)
Peter DeFazio (D-4-OR)
Rosa DeLauro (D-3-CT)
Tom DeLay (R-22- TX)
Ronald Dellums (D-9-CA)
Peter Deutsch (D-20-FL)
Lane Evans (D-17-IL)
Thomas M. Foglietta (D-1-PA)
Victor Frazer (I-VT)
Martin Frost (D-24-TX)
Elizabeth Furse (D-1-OR)
Earl Hilliard (D-7-AL)
Maurice Hinchey (D-26-NY)
Andrew Jacobs Jr. (D-10-IN)
Jack Kingston (R-1-GA)
William Lipinski (D-3-IL)
James P. Moran (D-8-VA)
Owen B. Pickett (D-2-VA)
Eleanor Holmes Norton (D-DC)
Major R. Owens (D-11-NY)
Frank Pallone, Jr. (D-6-NJ)*
Lewis F. Payne (D-5-VA)
Christopher Smith (R-4-NJ)
Nydia Velazquez (D-12-NY).

Senate (S. 1035) 6 Total

Tom Daschle (D-SD)
Robert Dole (R-KS)
Charles Grassley (R-IA)
Tom Harkin (D-IA)*
Mark Hatfield (R-OR)
Claiborne Pell (D-RI)*

HATCH (R UT)
SIMON (D IL)*
REID (D NV)
SIMPSON (R WY)
ABRAHAM (R MI)*

Jeffords

*Asterisk indicates members of the Health and Environment Subcommittee of the House Commerce Committee, or the Senate Labor and Human Resources Committee.

1051 Paulison Ave
Clifton NJ 07011-3628
Tel. 201 772 2000
Fax 201 772 2055

E-MAIL:
75162.341@compuserve.com

TO BERKLEY BEDELL
8 PAGES
202 547 2608

MarCal Associates Inc.

PRESS AND MEDIA ADVISORY-

3/21/96

HEALTH/MEDICINE/HUMAN INTEREST/FDA/CONGRESS

For More Information Contact:
Tony Martinez 201 772 2000, Fax 201 772 2055

EVENT: "BURZYNSKI'S LIST" CANCER PATIENTS TO HOLD CAPITOL HILL PRESS CONFERENCE WITH MEMBERS OF CONGRESS

DATE, TIME, AND LOCATION: TUESDAY MARCH 26, 1996 10:30 AM-12:00 NOON IN ROOM 2123, RAYBURN HOUSE OFFICE BUILDING, WASHINGTON DC

Washington DC-
On Tuesday, March 26, 1996 at 10:30 AM, the cancer patients of Dr. Stanislaw Burzynski MD, Ph.D., will hold a news conference to discuss their plight and battle with the Food and Drug Administration and the urgent need for legislative reform. A vehicle for that reform is passage of the Access to Medical Treatment Act, HR 2019, S. 1035. The bill is one of several legislative FDA reform measures under consideration by the Congress. The FDA has come under heavy scrutiny by the House Commerce Oversight and Investigations Subcommittee concerning the agency's actions against Dr. Burzynski and his patients. After more than a decade and three unsuccessful attempts before a federal grand jury, the FDA obtained an indictment last year against Dr Burzynski for providing his nontoxic experimental cancer therapy, called antineoplastons. In the government's pretrial order, the FDA has sought to block the patients' access to Dr. Burzynksi's cancer therapy by demanding the closing of his clinic. Dr. Burzynski's trial is scheduled for October, 1996. Legal maneuvers have stayed the order closing Dr. Burzynski's clinic until March 27th.

For Burzynski's patients, the government's order is tantamount to a death sentence. "The FDA violated the rights of the patients when they first acted to deny the patients their medical treatment, even though it is an experimental treatment. It is time for the US Congress and the Courts to act so that the rights of all Americans to choose and have access to the medical treatment of their choice be protected. The actions by the FDA in the Burzynski matter have harmed the patients, not protected them. Denying access to a life saving and life enhancing therapy while seeking to jail their physician providing it is not consumer protection. Our physician and his treatment are saving lives!" stated Steven Seigel, head of the Burzynski Patients Group. Seigel's wife MaryJo is recovering

from Non Hodgkin's Lymphoma with Burzynski's Antineoplaston. Many patients were, or are diagnosed with terminal or untreatable forms of cancer. For many patients, Dr. Burzynski's treatment has brought them back from the brink of death and provided them with a normal quality of life. The press and media will have an opportunity to hear their stories up close and personal.

After first seeking to block the patients' access to Burzynski's antineoplaston cancer therapy, the FDA then declared they would modify their actions after Members of Congress prevailed upon FDA Commissioner David Kessler to allow patients access to Burzynski's therapy. However, assurances made by the agency are turning out to be disingenuine. Cancer patients seeking his therapy are still being denied access. Patients in this predicament will also be at the press conference. Like a modern day Oskar Schindler, Burzynski is frantically working in an attempt to get his patients onto an approved trial list in order that his patients can continue to be treated. In a Kafkaesque twist, while Dr. Burzynski is under indictment for providing his experimental therapy to cancer patients seeking his therapy, the government has approved a few phase II clinical trials for him to conduct his treatment.

Since the meeting with FDA and congressional committee members in early March, the FDA's response has not been encouraging. "The FDA is now seeking to make it virtually impossible for Dr. Burzynski to continue working through the endless bureaucracy and mindless paperwork they are now putting him through. The patients question whether our public servants at the FDA actually understand the harm they are doing to the patients and their families by the agency's conduct. If such conduct by our government is legal, then the laws must be and will be changed," implored Seigel.

The Burzynski matter highlights the need for appropriate legislative reform of the FDA. Rep. Peter DeFazio (D-Or) and other members of Congress will be joining the patients in rallying support for the Access to Medical Treatment Act, HR 2019 and S. 1085. This legislation would provide for a regulated procedure to allow patients access to the medical treatment of their choice from a licensed health care provider, as long as there is no evidence the treatment itself causes harm and they have been fully informed about the treatment and possible side effects. "Every patient, and all of Dr. Burzynski's patients have a right to decide what kind of treatment they want. We [the government] should not block access to a treatment that has clearly brought relief from suffering and a better quality of life to many people," stated Congressman DeFazio. The legislation is cosponsored by key congressional leaders including House Majority Whip Tom DeLay (R-TX), Commerce Investigations Subcommittee Chairman Joe Barton (R-TX), Senate Minority Leader Tom Daschle (D-SD), Senate Judiciary Committee Chairman Orrin Hatch (R-UT) and Senate Majority Leader and Republican Presidential Nominee Robert Dole (R-KS).

Boston Sunday Globe

NORTH WEEKLY

MARCH 24, 1996

NOTABLE

A new landscaping plan will give a new look to the Cushing House, home of the Newburyport Historical Society. Story, Page 15.

INSIDE

We're all with Stephen Johnson in the fight for his life

ANNE DRISCOLL

A friend went to the flower show recently where the dying and discontent of winter is thrown off with the hope of spring blossoms and in a package of seeds you can carry home in your pocket.

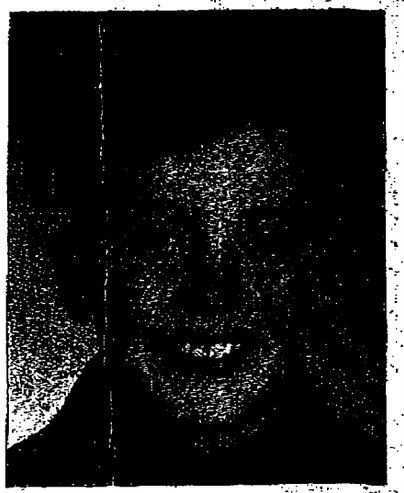
Last week the calendar gave us permission to enjoy what we've awaited for many weary months – the arrival of spring, but last weekend, even before March 20 – the equinox of days and nights equal to each other in stature and length and the harbinger of longer rays of light to come, there was a gathering of people who sat together in a posture of human hope.

The parking lot was full, the neighboring streets overflowing with cars and inside St. John the Baptist Sports Club donated for the night last Sunday about 100 people had come to find out how they might help Stephen Johnson, an 8-year-old Swampscott boy who has been diagnosed with a rare brain tumor that is inoperable, and comes with a 4 percent survival rate. But that diagnosis has not deterred the family's hope, for neither Stephen, nor his parents Tom and Mary, his 12-year-old brother, Tommy, his grandparents, many aunts and uncles, 22 cousins between ages 2 and 23, or any of the hundred who sat last Sunday ready and eager to volunteer their time, and hook their faith to the future of a little boy who could be their own.

Seven weeks ago, Stephen Johnson was a second-grade student at the Clarke School in Swampscott looking forward to the spring baseball season where his father is a Little League coach and where he excels as an athlete and as a team player. He's a popular student, works hard, plays fair, achieves well. Seven weeks ago, he was in the midst of the hockey season, scraping skates across the ice one Saturday like many other Saturdays before in his life when, try as he might, he couldn't help himself from falling to the frozen floor, again and again. All weekend, his worried parents called their parents, their brothers and sisters, consulting, discussing, confiding and ultimately pushing back a weighted drape of dread.

By Tuesday, the fear had become official. Stephen was diagnosed at Boston Children's Hospital as having brain stem pontime glioma, one of only 1,600 cases in the world. What followed was 21 days of radiation, twice a day, and finally, a conversation with the doctors in which the parents were told to take their son home. But that would have meant life without hope, and soon, Tom began searching in the most unlikely places for rays of light. He and his sister, Janet Bradley, began cruising the Internet for any information

Continued on next page



STEPHEN JOHNSON

All with Stephen in the fight for his life

Continued from preceding page

that might help them hold hope more firmly in their hands.

"Six weeks ago, I couldn't turn on the computer," said Janet. "Now I'm up until 4 o'clock in the morning on it, finding information it would have taken me months, years to find out without it. Information that is now right at my fingertips."

The information – the case histories of other brain tumor patients, available treatments, existing treatment centers, insurance coverages – have been crucial in helping the family navigate the terrifying terrain of a brain stem pontime glioma. Interestingly, the information highway with access ramps all over the world introduced Bradley to the blinking cursor of hope from a brain tumor survivor just minutes away – Samantha of Swampscott has a secret list on the Internet as a brain tumor survivor.

Through a friend and a Good Housekeeping article, the family also learned about the innovative work of Dr. Stanislaw Bruzynski in Houston, who has had encouraging success treating brain tumor patients with antineoplaston, a nontoxic alternative to other traditional – and insured – treatments. The treatment, which is not covered by Tom's veteran's insurance because it is considered experimental, is expected to cost $800,000 for a 21- to 22-month regimen. But health has no price tag and regardless of cost, Stephen is in Texas now with his parents, where he carries a 8-pound backpack on his 8-year-old back that infuses naturally-based neopeptides into his body 24 hours a day – at a cost of $400 a day.

"He's an angel. He's the sweetest. He's a little boy who has not complained once. He's a wonderful student, multitalented. He loves to read," said Stephen's aunt, Evelyn Greco, who cared for Stephen as a toddler at her family day care center and now has Stephen's older brother, Tommy, living with her while his family is in Texas. "When they had to put that pack on, his mother asked him if it was OK. He said, 'If this is how it has to be, this is how it has to be.'"

And in the meantime, while Mary, who took a leave from her job as a fourth-grade teacher at the Ford School in Lynn, and Tom, a disabled veteran who had just recovered from back surgery a month before his son began falling on the ice, stay by their son's side in a treatment center in Houston and try to snatch some sleep and peace from the nightmare that permeates their waking hours, hundreds of people are being mobilized on the North Shore and beyond.

Tom's sister, spends her days lobbying for passage of a federal bill that would make it easier, if not for Stephen, then for other families whose only hope rests with experimental or alternative treatments that are not FDA approved and therefore, generally, uninsured. The bill, which is in committee now, and will be discussed at a Washington press conference with Dr. Bruzynski's patients on Tuesday and Wednesday would increase access to nonconventional treatments that have no evidence of harm, but could provide help, as long as the patient is informed of the risks. When Bradley is not sending e-mail letters to members of Congress, telephoning or faxing them, she's working as a member on the steering committee that has joined rank behind the Johnson family.

"This is not something to be sad about. Listen, as long as there's some hope – and there is some hope – we want to try and support the family," said Joel Abramson, owner of Flagship Travel, who used his contacts to get Bobby Orr to host a fund-raiser for the family and is spearheading the April 30 benefit at the Danversport Yacht Club.

'He's an angel. He's the sweetest. He's a little boy who has not complained once. He's a wonderful student, multitalented. He loves to read.'

EVELYN GRECO
Stephen Johnson's aunt

The 100 people he was talking to last Sunday night included a member of the School Committee, the town clerk, neighbors, friends, coaches, teachers and co-workers. Martha Kellehan, the school's health educator, is heading up the celebrity committee for the benefit. Jack Dube, a local policeman who also is a hockey coach of Stephen's, is heading the committee contacting all the Swampscott youth sports players and their families.

"What impresses me about Stephen is his great enthusiasm. He's got a positive outlook and attitude that's just incredible. Even up to that last day on the ice he gave 100 percent," said Dube.

New life may be found in a pocket full of seeds, or, in Stephen's case, a backpack full of medicine to which he's giving 100 percent of his time and all of his positive attitude these days. If Stephen was here in his own hometown, instead of in Texas receiving that medicine, he would see the evidence of hope, recognize it readily in the faces of those who love him, and even in those who never met him but care deeply about him anyways. He would know that indeed, spring has sprung in Swampscott.

• • •

Two benefits have been organized for Stephen Johnson. Bobby Gaudet, owner of the Porthole Pub in Lynn has donated space for a fund-raiser April 6. Tickets are $15. Then on April 30, friends and family have organized a sports celebrity fund-raiser, A Tribute to Stephen Johnson, at the Danversport Yacht Club, emceed by Swampscott native Mike Lynch of Channel Tickets are $25 per person; there will be celebrity photos and autographs with Bobby Orr and others, as well as silent auction and raffle the night of the event. Anyone interested in making raffle or auction donations may contact Diane Smith at (617) 592-7297, or in purchasing tickets may call Cathy McLaughlin at (617) 581-0454. Financial contributions may be sent to the Stephen Johnson Fund, Account No. 77-103694-4, Salem Five Cents Savings Bank, 450 Paradise Road, Swampscott, MA, 01907. In addition, anyone interested in supporting the passage of HR2019 should contact their US representative and senators.

Anne Driscoll, who lives in Swampscott, writes a weekly column for North Weekly.

NORTH WEEKLY

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THE IMPLICATIONS OF BURZYNSKI'S LIST FOR FDA REFORM
by Maury Silverman

There is a drama going on in Washington that is a stark reminder of the need for substantive FDA reform. It is about a group of cancer patients struggling for their very lives; not particularly against that dreaded disease, as they have found problem solving in a nontoxic medication and therapy developed by a biological pioneer, a pathfinder to healing and humanity. Their struggle is with a wrongheaded bureaucracy, and with the United States government which wants to jail a modern day Oscar Schindler, in effect because he listened to his Oath of Hippocrates first, when he found that his talents, a rare combination of being a doctor, healer, and basic scientist conceived a way to bring advanced cancer cases back from the door of death. His only "sin" was to go out on his own in a quest to preserve his creativity and innovation in the effort to heal the terminally ill.

His name is Stanislaw Burzynski, M.D., Ph.D. He came to America believing in the American Dream, where society would honor him for his ideas, hard work, and the gift of healing. Instead, he has found more trouble with the FDA than with the Communist tyranny of the Poland he fled.

He developed a non-toxic biological therapy of peptides called antineoplastons that has fewer side effects and a better record of healing than the big business of the current cancer therapies that is prevalent.

The patients on Burzynski's list of cancer survivors have come to Washington to ask Congress to address FDA Reform in such a way that what they have gone through can never happen again. They are asking Congress to amend and revise the law so that the system will honor medical problem solving by removing the barriers that bureaucratic procedure and mentality has put in the way of innovation to develop second and third generation advancements in therapies for chronic, debilitating and terminal illness.

It is a story about creating a level playing field in pursuit of medical care based on complete information, informed decision making, and freedom of choice. Identifying and removing the record and realities of vested interests manipulating the system via federal regulatory agency and abuse of power and procedure is at the core of this dilemma.

On February 29, 1996, the House Commerce Oversight and Investigations Subcommittee held a hearing on cancer patients access to unapproved treatments. Very moving testimony by patients on antineoplastins and the Burzynski therapy; and those on Lymphokine-200. Many are cancer survivors that began with very progressively terminal prognoses. The LK 200 patients medicines have already been cut off by the FDA. To hear people tell of their experiences of improvement from cancer only to face certain deterioration and death after the FDA stopped access to a nontoxic

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