PRESIDENTIAL CORRESPONDENCE
MAIL ANALYSIS
BOOK TWENTY = P-403 – P-412

P-403 FDA APPROVAL OF CANCELL
REVISIONS: OCTOBER 8, 1993

P-404 BREAST CANCER RESEARCH
REVISIONS: MAY 20, 1994
OCTOBER 11, 1994
SEPTEMBER 19, 1995
APRIL 16, 1997

P-404A BREAST CANCER RESEARCH/PERSONAL INVOLVEMENT
REVISIONS: MAY 20, 1994
OCTOBER 11, 1994
SEPTEMBER 25, 1995
APRIL 16, 1997

P-405 HEALTH CARE REFORM/CONCERN RE MEDICARE
REVISIONS: MAY 23, 1994

P-406 HEALTH CARE REFORM/PHYSICIANS' CONCERNS
REVISIONS: NONE

P-407 HEALTH CARE COVERAGE/CONCERNS ABOUT
INDEPENDENT CONTRACTOR
REVISIONS: MARCH 29, 1994

P-408 COVERAGE OF ABORTION IN HEALTH CARE ACT
REVISIONS: NONE

P-409 QUESTIONS REGARDING HEALTH CARE PLAN
REVISIONS: NONE

P-410 SERIOUS ILLNESS
REVISIONS: MAY 31, 1994

P-410A MEDICAL RESEARCH/CONCERNS RE SPECIFIC DISEASES
REVISIONS: JUNE 7, 1994

P-411 MARIJUANA/MEDICAL PURPOSES
REVISIONS: MAY 9, 1997

P-412 CLONING
REVISIONS: MAY 13, 1997

Clinton Presidential Records
Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a tabbed divider. Given our digitization capabilities, we are sometimes unable to adequately scan such dividers. The title from the original document is indicated below.

P403

Divider Title: _____

MAIL: 1037275
FROM: AMANDAD
T[redacted]:AMANDAD, ANNIES, BARBARAG, BOBBYH, CARMENF, CYRILJ, DAVIDB, DEBORAHP, DEBRAW, DICKA, ELLENB, ELLYS, EMILYC, GENEB, GEORGEB, GLORIAC, GREGGT, GUSL, ILEANAG, INT15, JANV, JEFFH, JEFFR, JENNYB, JENNYM, JIMD, JUDITHG, KAYM, KIRSTENW, KYLEB, LANAD, LARKP, LORIA, MARKK, MARKM, MARYB, MARYLOUM, MAUREENH, MIKES, MONICAM, PETERVR, PHILW, RAYG, ROGERG, SETHM, SHARONL, STEVEH, TONIAB
CC..:
DATE: 20 Jul 1994
TIME: 02:46PM
SUBJ: Obsolete letters

The following Presidential letters are now OBSOLETE:

P-300b -- Views re Abourtion and Gays in the Military
P-316 -- Pro & Con Executive Order re Gag Rule
P-602 -- Views re Executive Order 12818
P-706 -- Midwestern Flood
P-817 -- Edward Byrne Memorial State and Local Law Enforcement Assistance Grant Program/1995
P-901 -- Employee Educational Assistance Act H.R. 127

The following Presidential letters are now OBSOLETE (letters on these subjects are to be sent to AGLIAS):

P-[redacted]03 -- FDA Approval of Cancell
P-[redacted]3 -- Rehiring of Patco Air Traffic Controllers
P-612 -- American Airline Strike
P-616 -- Concerns re Canadian Wheat

The following Presidential letters are OBSOLETE (Letters to be coded as follows):

P-153a -- Personal Hardship/No Support (Code P-153)
P-150B -- Views w/Plans and Proposals (Code P-150)
P-161 -- Support for the President re Arkansas Troopers' Allegations (Code JD-303)
P-208d -- Sin Taxes, Health Care Finances (Code HCIC)
P-807 -- Execution of Gary Graham (Code P-150)

The Master Form Letter Index has been updated.

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background

P-901

MAIL: 179846
TO..: ALICEP, AMANDAD, ANDYH, ANNIES, BARBARAG, BETSYC, BOBBYH, CARMENF, CYRILJ, DAVIDB, DEBRAW, DICKA, ELLENB, ELLENS, ELLYS, EMILYC, EMMITM, ERICHV, GENEB, [redacted] GEORGEB, GLORIAC, GREGGT, GUSL, INT36, INT37, INT38, INT39, INT40, INT41, INT42, INT42B, INT43, INT44, INT44B, INT45, INT45B, JANV, JENNYB, JOHNNYB, JUDITHG, KYLEB, LANAD, LORIA, MARIAMA, MARIEK, MARKM, MARYB, MARYLOUM, MAUREENH, MIKES, MONICAM, PETERVR, PHILW, QUORUM, RAYG, ROBS, ROGERG, SANDYH, SETHM, SHARLEEN, SHARONL, SHIRLEYS, SLRV1, SLRV2, STEVEH, TOMMYT, TONIAB, VIOLAB, VOL14, VOL2, VOL4, VOL40, VOL9, WILLC, YPVOL1, YPVOL2, YPVOL3, YPVOL4, YPVOL5, YPVOL6
FROM: GLORIAC
DATE: 19 Oct 1993
TIME: 10:13AM
SUBJ: MS-206A; MS-206B; P-309; P-310; P-403

The following Marsha Scott Letters have been RELEASED:

MS-206A -- Money Mail Acknowledgement/Greetings Request

MS-206B -- Money Mail Acknowledgement/Photo Request

The following Presidential Letters have been RELEASED:

P-309 -- Animal Rights

P-310 -- Gays in the Military

[redacted]03 -- FDA Approval of CanCell

The Master Form Letter Index has been updated.

THE WHITE HOUSE

WASHINGTON

October 19, 1993

Mr. John M. Doe
Title
Organization
Business Adr1
Business Adr2
Business City, BState BZip-BZip9

Dear John:

Thank you for writing to me with your views on CanCell.

I understand your interest in new drugs to combat serious diseases. Americans deserve access to quality health care. However, the safety of our citizens is equally important, and that is why drug treatments for any disease must be approved prior to public distribution.

The Food and Drug Administration reviews new drugs based on scientific studies for safety and effectiveness. This approval process protects the American people from possibly harmful effects.

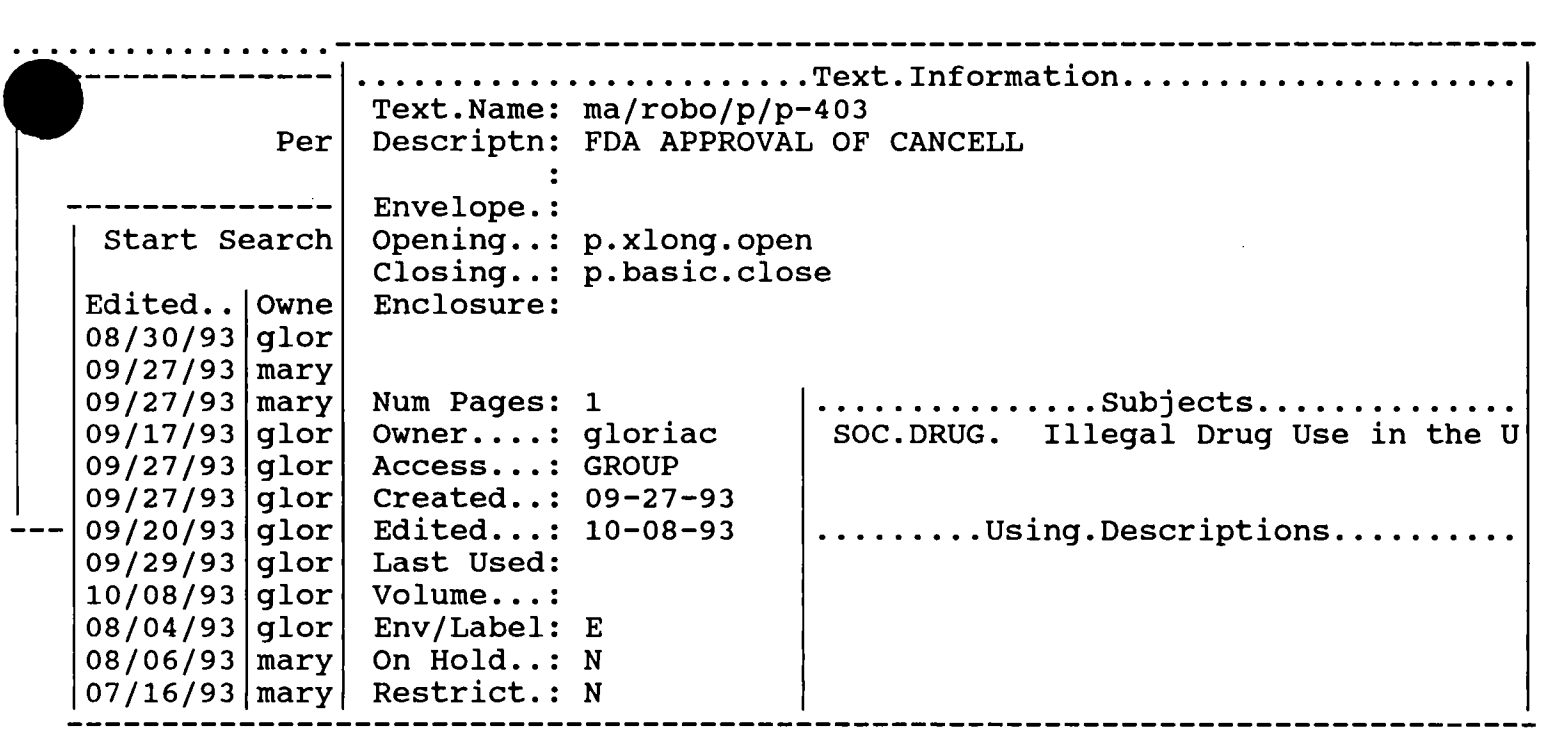
At this time there has been no adequate documentation that it is safe and effective. The sponsors of CanCell have not submitted the necessary data to allow the FDA to take action, and the testimonials about the favorable effects of CanCell cannot establish the product as safe and effective. The National Cancer Institute evaluated CanCell in 1990 and reached the same conclusion.

I hope you realize the need for this approval process to protect our citizens from potentially harmful, unapproved drugs. I appreciate your taking the time to let me have your thoughts.

Sincerely,

(10/08/93)

SCREEN COPY FOR USER GLORIAC PRINTED ON 10:12:27 Oct 19 1993



THE WHITE HOUSE

WASHINGTON

October 8, 1993

FILE

Mr. John M. Doe
Title
Organization
Business Adr1
Business Adr2
Business City, BState BZip-BZip9

Dear John:

Thank you for writing to me with your views on CanCell.

I understand your interest in new drugs to combat serious diseases. Americans deserve access to quality health care. However, the safety of our citizens is equally important, and that is why drug treatments for any disease must be approved prior to public distribution.

The Food and Drug Administration reviews new drugs based on scientific studies for safety and effectiveness. This approval process protects the American people from possibly harmful effects.

At this time there has been no adequate documentation that it is safe and effective. The sponsors of CanCell have not submitted the necessary data to allow the FDA to take action, and the testimonials about the favorable effects of CanCell cannot establish the product as safe and effective. The National Cancer Institute evaluated CanCell in 1990 and reached the same conclusion.

No CHANGES

I hope you realize the need for this approval process to protect our citizens from potentially harmful, unapproved drugs. I appreciate your taking the time to let me have your thoughts.

Sincerely,

(10/08/93)

THE WHITE HOUSE

WASHINGTON

October 5, 1993

Mr. John M. Doe
Title
Organization
Business Adr1
Business Adr2
Business City, BState BZip-BZip9

Dear John:

Thank you for writing to me with your views on CanCell.

I understand your interest in new drugs to combat serious diseases. Americans deserve access to quality health care. However, the safety of our citizens is equally important, and that is why drug treatments for any disease must be approved prior to public distribution.

The Food and Drug Administration reviews new drugs based on scientific studies for safety and effectiveness. This approval process protects the American people from possibly harmful effects.

At this time there has been no adequate documentation that it is safe and effective. The National Cancer Institute evaluated CanCell in 1990 and reached the same conclusion. The sponsors of CanCell have not submitted the necessary data to allow the FDA to take action, and the testimonials about the favorable effects of CanCell cannot establish the product as safe and effective.

I hope you realize the need for this approval process to protect our citizens from potentially harmful, unapproved drugs. I appreciate your taking the time to let me have your thoughts.

Sincerely,

(10/05/93)

THE WHITE HOUSE

WASHINGTON

September 29, 1993

Mr. John M. Doe
Title
Organization
Business Adr1
Business Adr2
Business City, BState BZip-BZip9

Dear John:

Thank you for writing to me with your views on CanCell.

I understand your interest in new drugs ~~for~~ to combat serious diseases. Americans deserve access to quality health care. However, the safety of our citizens is equally important, and that is why drug treatments for any disease must be approved prior to public distribution.

The Food and Drug Administration reviews new drugs based on scientific studies for safety and effectiveness. This approval process protects the American people from possibly harmful effects. ~~and is not meant to inhibit or slow recovery from any disease.~~

~~The drug CanCell has been distributed illegally, and~~ ~~To~~ At this time ~~this point~~ there has been no adequate documentation that it is safe and effective. The sponsors of CanCell have not submitted the necessary data ~~to allow~~ the FDA to take action, and the testimonials about the favorable effects of CanCell ~~cannot establish the product as safe and effective.~~ The National Cancer Institute evaluated CanCell in 1990 and reached the same conclusion.

I hope you realize the need for this approval process to protect our citizens from potentially harmful, unapproved drugs. I appreciate your taking the time to let me have your thoughts.

Sincerely,

(09/29/93)

P-403. FDA APPROVAL OF CANCELL

THE WHITE HOUSE

WASHINGTON

September 27, 1993

Mr. John M. Doe
Title
Organization
Business Adr1
Business Adr2
Business City, BState BZip-BZip9

Dear John:

Thank you for writing to me with your views on CanCell.

I understand your interest in new drugs for serious diseases. Americans deserve access to quality health care. However, the safety of our citizens is equally important, and that is why drug treatments for any disease must be approved prior to public distribution.

The Food and Drug Administration reviews new drugs based on scientific studies for safety and effectiveness. This approval process protects the American people from possibly harmful effects and is not meant to inhibit or slow recovery from any disease.

The drug CanCell has been distributed illegally, and to this point there has been no adequate documentation that it is safe and effective. The sponsors of CanCell have not submitted the necessary data to allow the FDA to take action, and the testimonials about the favorable effects of CanCell cannot establish the product as safe and effective. The National Cancer Institute evaluated CanCell in 1990 and reached the same conclusion.

I hope you realize the need for this approval process to protect our citizens from potentially harmful, unapproved drugs. I appreciate your taking the time to let me have your thoughts.

Sincerely,

(9/27/93)

THE WHITE HOUSE

WASHINGTON

September 27, 1993

Mr. John M. Doe
Title
Organization
Business Adr1
Business Adr2
Business City, BState BZip-BZip9

Dear John:

Thank you for writing to me with your views on CanCell.

I understand your interest in new drugs for serious diseases. Americans deserve access to quality health care. However, the safety of our citizens is equally important, and that is why drug treatments for any disease must be approved prior to public distribution.

The Food and Drug Administration reviews new drugs based on scientific studies for safety and effectiveness. This approval process protects the American people from possibly harmful effects and is not meant to inhibit or slow ~~the~~ recovery FROM ANY DISEASE.

The drug CanCell has been distributed illegally and to this point there has been no adequate documentation that it is safe and effective. The sponsors of CanCell have not submitted the necessary data to allow the FDA to take action, and the testimonials about the favorable effects of CanCell cannot establish the product as safe and effective. The National Cancer Institute evaluated CanCell in 1990 and reached the same conclusion.

I hope you realize the need for this approval process to protect our citizens from potentially harmful, unapproved drugs. I appreciate your taking the time to let me have your thoughts.

Sincerely,

(9/27/93)

SLR/draft/cancell P.403

Monica Mullens
Form Letter--CanCell
9/2/93

Thank you for writing to me with your views on CanCell.

I understand your interest in new drugs for serious ~~incurable~~ diseases. ~~The health of the~~ American~~people is my top priority~~ ~~and the availability of~~ quality care~~and treatment is essential to improvement~~. However, the safety of our citizens is equally important, and that is why drug treatments for any disease must be approved prior to public distribution.

The Food and Drug Administration reviews new drugs based on scientific studies for safety and effectiveness. This approval process protects the American people from ~~a~~ possibly harmful ~~experience~~ and ~~does~~ not inhibit or slow the recovery~~of a serious or life-threatening disease.~~

CanCell~~which~~ has been distributed illegally~~to treat debilitating diseases, has not been proven as~~ safe and effective~~due to a lack of adequate scientific data.~~ The sponsors of CanCell have not submitted the necessary data to allow the FDA to take action, and the testimonials about the favorable effects of CanCell cannot establish the product as safe and effective. The National Cancer Institute evaluated CanCell in 1990 and reached the same conclusion.

I hope you realize the ~~necessity of~~ need for this approval process to protect our citizens from potentially harmful, unapproved drugs. I appreciate your taking the time to let me ~~know how you feel.~~ have your thoughts.

August 3, 1993

Ms. Tammy Falcone
4 Mason Drive
Hazlet, New Jersey 07730

Dear Ms. Falcone:

Your June 29, 1993, letter to President Clinton concerning CanCell was referred to the Food and Drug Administration (FDA) on July 28 for a response. First of all, please understand that we sympathize with your very serious health condition and can well appreciate the pain and suffering you are experiencing as a result of AIDS and Lyme Disease. The clinical data on AZT point to side effects in many patients, but I would strongly recommend that you discuss alternate medical therapies with your physician. May I also suggest that you discuss with him or her possible support/counseling groups for Lyme disease and AIDS sufferers.

FDA has the responsibility to review new drug applications and to determine whether the information submitted by a sponsor establishes a drug's safety and effectiveness. Although CanCell has been promoted as a treatment for cancer, AIDS, multiple sclerosis, muscular dystrophy, Parkinson's disease, Alzheimer's disease, scleroderma, and other serious diseases, its safety and effectiveness in treating these disorders has never been established.

Also known as Entelev, CanCell was developed by James V. Sheridan, a former researcher at the Michigan Cancer Center. CanCell is an unapproved drug, and its distribution has been in violation of the Federal Food, Drug, and Cosmetic Act. This statute requires a drug to be approved before marketing or before distributing in interstate commerce. Before a drug can be approved for general availability, interstate distribution, and marketing, it must be tested in a scientific manner to establish safety and effectiveness in treating a specific disease or disorder. Unfortunately, testimonials about the favorable effects of the use of CanCell cannot be used to establish whether the product CanCell is safe and effective.

In separate actions in 1989 and 1990, Mr. Sheridan and Mr. Edward J. Sopcak were ordered to stop distributing CanCell into interstate commerce unless they first obtain an approved new drug application. On November 13, 1992, Mr. Sopcak was found in civil contempt of the Decree by Judge Friedman for continuing to ship CanCell. In addition, Judge Friedman ordered Mr. Sopcak to cease taking orders for CanCell and to notify all patients he has ever supplied of the injunction and that he cannot supply the drug. The Judge also warned Mr. Sopcak that he risks further sanctions, including incarceration if he continues to violate the Court's order. Mr. Sopcak's formal appeal was just recently denied.

FDA encourages and works with sponsors to speed up the approval of promising new drugs, especially those for life-threatening and seriously debilitating diseases for which there are no known treatments. However, Mr. Sopcak and Mr. Sheridan have not submitted adequate scientific studies that establish the product CanCell as a promising treatment for any disease or disorder. The National Cancer Institute reached the same conclusion when it evaluated CanCell in 1990. Until the CanCell sponsors submit such additional data, FDA cannot take any action to allow the product to be distributed, nor does the Agency or the President have any legal mechanism in place to overturn a Court order.

We hope this information provides you with the understanding of how drugs must be scientifically proven to be safe and effective before we can have them distributed to the public. These actions were taken to protect people like you, not to inhibit or slow the recovery of a seriously debilitating disease. If you are interested in a clinical drug trial program, I encourage you to contact the Nationwide Clinical Trials Information Telephone Line, which is 1-800-874-2572.

I regret that this response is not more favorable, but at least I hope that the information has been useful.

Sincerely,

Walter D. Osborne
Supervisory Policy Analyst
Office of the Executive Secretariat

SCREEN COPY FOR USER GLORIAC PRINTED ON 08:30:08 Oct 12 1993

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.............. ----------------------------------------------------------------
 -------------| ........................Text.Information....................
              | Text.Name: ma/robo/p/p-403
          Per | Descriptn: FDA APPROVAL OF CANCELL
              |          :
 -------------| Envelope.:
  Start Search| Opening..: p.xlong.open
              | Closing..: p.basic.close
 Edited..|Owne| Enclosure:
 07/22/93|mary|
 07/16/93|mary|
 10/08/93|glor| Num Pages: 1          |...............Subjects.............
 08/30/93|glor| Owner....: gloriac    | SOC.DRUG.  Illegal Drug Use in the U
 09/27/93|mary| Access...: GROUP      |
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 09/17/93|glor| Edited...: 10-08-93   |.........Using.Descriptions..........
 09/27/93|glor| Last Used:            |
 09/27/93|glor| Volume...:            |
 09/20/93|glor| Env/Label: E          |
 09/29/93|glor| On Hold..: Y 10/08/19 |
 10/08/93|glor| Restrict.: N          |
 ----------------------------------------------------------------------------
```

MAIL: 179372
TO..: ALICEP, AMANDAD, ANDYH, ANNIES, BARBARAG, BETSYC, BOBBYH,
CARMENF, CYRILJ, DAVIDB, DEBRAW, DICKA, ELLENB,
[redacted]
ELLENS, ELLYS, EMILYC, EMMITM, ERICHV, GENEB,
GEORGEB, GLORIAC, GREGGT, GUSL, INT36, INT37,
INT38, INT39, INT40, INT41, INT42, INT42B, INT43,
INT44, INT44B, INT45, INT45B, JANV, JEFFR, JENNYB,
JOHNNYB, JUDITHG, KYLEB, LANAD, LORIA, LYNDAR,
MARIAMA, MARIEK, MARKM, MARSHAS, MARYB, MARYLOUM,
MAUREENH, MIKES, MONICAM, PETERVR, PHILW, QUORUM,
RAYG, ROBS, ROGERG, SANDYH, SETHM, SHARLEEN,
SHARONL, SHIRLEYS, SLRV1, SLRV2, STEVEH, TOMMYT,
TONIAB, VIOLAB, VOL14, VOL2, VOL4, VOL40, VOL9,
WILLC, YPVOL1, YPVOL2, YPVOL3, YPVOL4, YPVOL5,
YPVOL6
FROM: DICKA
DATE: 08 Oct 1993
TIME: 05:31PM
SUBJ: The following Presidential Letters have been RELEASED:

P-001B - SUPPORT/THOUGHTFUL ARTICLE
P-001C - SUPPORT/THOUGHTFUL ENCLOSURE
P-208F - SMALL BUSINESS CONCERNS
P-208G - NEED FOR ECONOMIC STIMULUS/JOBS
P-216A - SUGGESTIONS FOR REINVENTING GOVERNMENT
P-401 - MENTAL HEALTH IN HEALTH CARE PACKAGE
P-403 - FDA APPROVAL OF CANCELL
P-503B - ARAB/ISRAELI PEACE PROCESS
P-603 - REHIRING OF PATCO AIR CONTROLLERS
P-[redacted]00 - GUN CONTRL/BRADY BILL

Hold

[redacted] form letter Master Index has been updated to reflect
these changes

[redacted]

To Jeff on 5/3/93
for WW approval

Now obsolete

Maureen:
OK
-MM

P-403 CHILDHOOD IMMUNIZATION PROGRAM

THE WHITE HOUSE

WASHINGTON

April 23, 1993

Mr. John M. Doe
Title
Organization
Business Adr1
Business Adr2
Business City, BState BZip-BZip9

Dear John:

Thank you for expressing your thoughts on childhood immunizations. Because too many families are deterred by outrageously high costs from having their children immunized, the United States has the third worst immunization record in this hemisphere.

The Comprehensive Child Immunization Act of 1993 will ensure that all children in the United States will be immunized against vaccine-preventable diseases by their second birthday, during the period when they are most vulnerable to illness. It will provide an additional $300 million to strengthen the public service delivery infrastructure. The funds will be directed to nonprofit and public clinics in underprivileged rural and urban communities. It would also institute a new information and tracking system that would establish, through grants to the states, state immunization registries. This would permit public health agencies to follow up on children who have not been adequately immunized. I also intend to challenge the manufacturers of these vaccines to work with us.

We will continue in our efforts until preventable childhood diseases no longer threaten our families and our children. I appreciate your ideas on this vital issue.

Sincerely,

4/22/93

P-403 CHILDHOOD IMMUNIZATION PROGRAM

It would also institute a new information and tracking system that would establish, through grants to the states, state immunization registries.

(PARAGRAPH 2, SENTENCE 4)

OR WAS MY ORIGINAL RIGHT! ?

April 7, 1993

Mr. John M. Doe
Title
Organization
Business Adr1
Business Adr2
Business City, BState BZip-BZip9

Dear John:

Because Thank you for expressing your ~~concerns~~ thoughts on childhood immunizations. Too many families are deterred by outrageously high costs from having their children immunized, ~~Remarkably~~ the United States has the third worst immunization record in this hemisphere.

The "Comprehensive Child Immunization Act of 1993" will ensure that all children in the United States ~~are~~ will be immunized against vaccine-preventable diseases by their second birthday, during the period when they are most vulnerable to illness. It will provide an additional $300 million to strengthen the public service delivery infrastructure. The funds will be directed to nonprofit and public clinics in underprivileged rural and urban communities. It ~~The bill~~ would also institute a new information and tracking system through grants to the states to establish state immunization registries. This would permit public health agencies to follow up on children who have not been adequately immunized. I also intend to challenge the manufacturers of these vaccines to work with us.

We will ~~not stop~~ continue our efforts until preventable childhood diseases no longer threaten our families and our children. I appreciate your ~~thoughts~~ ideas on this vital issue.

Sincerely,

(4/7/93)

That would

APR 22 1993

pw

Are we instituting a system, or grants, or registries? Or establishing one through other? Or?

P/403

Thank you for expressing your concerns on childhood immunizations.

Too many families are deterred by outrageously high costs from having their children immunized. Remarkably, the United States has the third worst immunization record in this hemisphere. The "Comprehensive Child Immunization Act of 1993" will ensure that all children in the United States are immunized against vaccine-preventable diseases by their second birthday during the period when they are most vulnerable.

It will provide an additional $300 million to strengthen the public service delivery infrastructure. The funds will be directed to non-profit and public clinics in underprivileged rural and urban communities. The bill would also institute a new information and tracking system through grants to the States to establish State immunization registries. This would permit public health agencies to follow up on children who have not been adequately immunized. I intend to challenge the manufacturers of these vaccines to work with us. We will not stop until preventable childhood diseases no longer threaten our families and our children. I am appreciate your thought on this vital issue.

monica mullens
draft/childimmunization
April 6, 1993 (slightly updated)

Thank you for expressing your concerns on childhood immunizations.

Too many families are deterred by outrageously high costs from having their children immunized. Remarkably, the United States has the third worst immunization record in this hemisphere. The plan I proposed to Congress will lead to the immunization of one million more infants and children beginning this summer.

It will provide an additional $300 million to strengthen the public service delivery infrastructure. The funds will be directed to non-profit and public clinics in underprivileged rural and urban communities.

I also want to establish a new information and tracking system to permit public health agencies to follow up on children who have not been adequately immunized. I intend to challenge the manufacturers of these vaccines to work with us. We will not stop until preventable childhood diseases no longer threaten our families and our children.

FING

monica mullens
draft/childimmunization
March 15, 1993

SLR PRESIDENTIAL FORM LETTER APPROVAL

MAIL ANALYSIS CODE: P-403

SUBJECT: Child Immunization

SLR STAFF ASSIGNEE: Monica Mullens **Ext. 2276**

(SLR Staff: Circle all the necessary White House departments which should review the letter)

==========

DEPARTMENT APPROVAL

This form is used to document who has approved drafts of form letters to be signed by the President. Please read the accompanying draft, and make any changes you think are appropriate. **Print your name and the date of approval** in the blank for your department, initial the right approval blank, and make any substantive comments directly on the response draft.

	Name/Date/Initials	Approved As Is	Approved With Changes
Domestic Policy:			✓
Environmental Policy:			
~~Health Care Task Force:~~			
Intergovernmental Affairs:			
Legislative Affairs:			
National Economic Council:			
National Security Council:			
Political Affairs:			
Public Liaison:			
Science and Technology:			
White House Counsel:			
Other:			
Other:			

==========

QUALITY CONTROL FINAL APPROVAL: K.W. (initials) **DATE:** 4/5/93

==========

Remarkably,

Thank you for expressing your concerns on childhood immunizations. It Too many families are deterred by outrageously high costs from having their children immunized. ~~The~~ the United States has the third worst immunization record in this hemisphere. ~~My plan~~ It will lead to the immunization of one million more infants and children beginning this summer. It will provide ~~I will seek~~ an additional $300 million to strengthen the public service delivery infrastructure. The funds will be directed to non-profit and public clinics in underprivileged rural and urban communities. It I also want to establish a new information and tracking system to permit public health agencies to follow up on children who have not been adequately immunized. I intend to ~~want to~~ challenge the manufacturers of these vaccines to work with us, ~~for we cannot have profits at the expense of our children.~~ We will not stop until preventable childhood diseases no longer threaten our families and our children.

The plan I proposed to Congress

monica mullens
draft/childimmunization
March 4, 1993

allocated to schools with concentrations of poor children. About 14,000 full-year equivalent jobs would be created.

Education: Chapter 1 Census Supplemental. The proposal would provide $235 million in 1993 to substantially mitigate the effects on distribution of Chapter 1 funds caused by changes in the location of poor children in the U.S. that occurred between the 1980 and 1990 censuses. The Chapter 1 compensatory education program will, for the first time, use 1990 census data to distribute 1993 appropriations used during the 1993–94 school year. The total number of poor children ages 5 to 17 increased between 1980 and 1990, and the distribution of those children shifted. Poor children are increasingly concentrated in the schools of the western States and less concentrated in the schools of the eastern States. The supplemental will ease the transition to a smaller compensatory education program in communities that would otherwise have the size of their Chapter 1 grants substantially reduced for the 1993–94 school year.

Agriculture/WIC Program. The Administration proposes to expand 1993 funding by $75 million for the Special Supplemental Food Program for Women, Infants, and Children (WIC), which pays for supplemental foods, health care referrals, and nutrition education for low-income pregnant and post-partum women, infants, and children under 5 years of age who are found to be at nutritional risk. The increase will permit the program to serve 300,000 additional participants, most of whom will be children ages 1–4. It is a down payment on the Administration's commitment in the long-term investment plan to provide full funding for WIC so that it serves all eligible children.

Agriculture/Emergency Food Assistance Program. The Administration proposes to provide $23 million worth of food to the States through The Emergency Food Assistance Program (TEFAP). This successful program provides surplus food to about 2.5 million needy households and has been an important weapon in the Nation's arsenal against hunger.

HHS/Childhood immunizations. The President's plan to increase childhood vaccinations will immunize one million children during the summer of 1993. The Administration proposes to award $300 million to support a community-based effort to finance vaccine purchases and education and outreach campaigns. This program will help to raise the Nation to the standards of child immunizations set by other advanced countries, which we have fallen far behind. Too many families are deterred by outrageously high costs from having their children immunized. The President intends to end that problem.

Labor/Summer Youth Employment and Training Program. Young Americans have an especially hard time finding jobs. The problem is worse for disadvantaged youth, and worse yet in the cities. The Summer Youth Employment and Training Program employs economically disadvantaged youth ages 14 to 21 to work at public and nonprofit agencies during the summer months. The Administration proposes to boost program funding by $1 billion in the summer of 1993. This will finance almost 700,000 summer jobs, bringing to

Today we must tell the drug companies to change those priorities. We cannot have profits at the expense of our children. These practices have got to stop.

But I want to make it clear: dealing with the cost of vaccines will not be enough; we also have to improve the delivery of preventive care. I want to say to the members of the press and to all the people who are here, we should be under no illusion that every family and every child in America has access to a health clinic as good as this one. (Applause.)

We should be under no illusion that every family and every child in America has access to a health clinic that opens at 7:00 a.m. in the morning and closes at 7:00 p.m. at night so that working families can bring their children. (Applause.)

And even here, where there has been a dramatic increase in the number of children immunized, we are still seeing rates of 70 percent immunization when the national goal, and what is necessary to assure that there will be no outbreak of communicable diseases, is 90 percent. Without an outreach program to go out and reach people where they are, in the languages they speak, in the homes and in the neighborhoods and in the organizations that they frequent, we will not be able to reach this goal.

So today, I am announcing a three-part policy to protect our children's future and to save the taxpayers millions of dollars. It will require changes on the part of all of us; and as I have in the last three weeks, I want to begin with the government so that we do our job first before we ask anyone else to change what they are doing.

I am pleased to announce that the job stimulus program that I will outline on Wednesday evening to the Congress will include $300 million to make vaccination services more widely available to all Americans. These funds will help public programs buy more vaccines, they will improve community services and personal outreach efforts. They will mean extended clinic hours all across America, more staff, and increased education efforts in conjunction with the Department of Education and the Department of Health and Human Services, and the resources necessary to create a national tracking system so we know what is happening to these children. These folks here are having a terrible time getting good and accurate records because we don't have a national tracking system.

These are the kinds of things that the national government owes the American people and owes these fine public health professionals if we're going to do what we should be doing to help protect our children. And we will begin with that. (Applause.)

Second, I'm directing Secretary Shalala to begin negotiations with our drug manufacturers to assure that other states who do not have the arrangements that 10 do can buy the vaccines they need at affordable prices. There is no reason in the world why a child in Texas is unable to receive vaccination while a child in Massachusetts can. We can't stand this kind of inequality simply because of the economic priorities of the manufacturers of the vaccine. It's wrong. (Applause.)

Finally, the administration will prepare an initiative for my review in cooperation with key congressional health leaders, such as Senator Kennedy, Senator Riegle, Senator Bumpers, Senator

2/12/93

ELEMENTS OF THE PRESIDENT'S CHILDHOOD IMMUNIZATION INITIATIVE

I. Immediate infusion of funds into the non-profit and public delivery systems for vaccines.

For the remainder of Fiscal Year 1993, the President will seek an additional $300 million to strengthen the public service delivery infrastructure. Future legislation will include funding for FY 1994 and beyond.

The Office of Management and Budget estimates that the additional FY 1993 funding will lead to the immunization of one million more infants and children, starting this summer. The funds will be directed to non-profit and public clinics in underserved rural and urban communities. The clinics will be able to use the funds to hire additional nurses and outreach staff, keep facilities open longer, establish new service locations, expand informational and educational programs, improve vaccine safety and research, increase ties to family-based community organizations, and help establish a national tracking system.

II. Aggressive efforts by the Department of Health and Human Services to help assure adequate supply of vaccines at reasonable prices.

The President has directed the Secretary of HHS to enter into negotiations with the nation's vaccine manufacturers to develop agreements that will:

(1) Assure that any state can purchase any necessary or additional vaccines at reasonable prices.

(2) Assure an adequate supply of all necessary vaccines at economical prices for federally assisted programs, including those administered by the Centers for Disease Control, the Health Resources and Services Administration, the Indian Health Service, and the Health Care Financing Administration.

III. An initiative that will guarantee the immunization of every American child.

In cooperation with Congress, the Administration will prepare an initiative that aims to:

(1) Guarantee vaccination coverage for all children, regardless of whether they use public, non-profit or private health providers.

Hospital. He's there because he did not receive a meningitis vaccine that cost $21.48. The bill for his stay in the hospital has already topped $46,500.

In the health care policy that our national task force is developing, nothing will be more important than preventive care. Today, American taxpayers are being hit with $10 in avoidable health care costs -- avoidable health care costs -- for every $1 we could be spending on immunizing our young people. The recent resurgence of measles in our country afflicted over 55,000 people, most of whom were children. The epidemic cost this country $20 million in avoidable hospital costs alone.

Prevention would have cost $1 million. And those figures don't begin to take into account the terrible human cost, the agony of a young man like Rodney Miller with his joints swollen, with his ankles so swollen they have to be relieved with needling to get the pus out, that the pain and problems that he and many others will take throughout their lives simply because we don't immunize our children.

And lest you think that this is a problem that every country has, I want you to know in this beautiful health care building that the United States has the third worst immunization record in this hemisphere. Of all the nations in this hemisphere, only Bolivia and Haiti have lower immunization rates for their children than the United States of America.

Over the past 10 years, while immunization rates have been declining in many important areas, the price of vaccine has risen at six times the rate of inflation. Immunizing a child cost about $23 10 years ago; it costs more than $200 today. In a public clinic, the cost of fully immunizing a child has leapt from $7 to more than $90. Manufacturers of these vaccines cite the cost of research and development to defend the rising prices. Well, nobody wants research to slow down, but let's look at what's really happening.

The pharmaceutical industry is spending $1 billion more each year on advertising and lobbying than it does on developing new and better drugs. Meanwhile, its profits are rising at four times the rate of the average Fortune 500 company. Compared to other countries, our prices are shocking. Listen to this: The polio vaccine in the United States currently costs close to $10. In England, the same drug is available for $1.80. In Belgium, it costs 77 cents. The problems of having an adequate delivery system, plus the spiraling costs, are putting America's children and America's future in jeopardy.

To make matters worse, the makers of these vaccines have refused to make their products available to states at more affordable cost. I should tell you -- those of you who don't know -- that the federal government buys vaccines from the manufacturer and distributes it through the states and ultimately the people through the Center for Disease Control. We buy the vaccines at a much lower cost than a doctor can. The states often directly buy vaccines. They buy the vaccines at a higher cost than the federal government, but still at a lower cost than doctors. States can order large quantities and therefore should receive lower prices.

But listen to this: While 10 states have succeeded in negotiating agreements with the vaccine manufacturers that allow them to immunize all the children they can reach, manufactu[illegible] balking at starting [illegible]