THE WHITE HOUSE

WASHINGTON
August 13, 1996

INFORMATION

MEMORANDUM FOR THE PRESIDENT

FROM: Carol H. Rasco, Assistant to the President for Domestic Policy
Patricia S. Fleming, Director, Office of National AIDS Policy

SUBJECT: HIV-related legislation

cc: The First Lady

Background:

The proposed HIV Prevention Act of 1996 (H.R. 3937), introduced August 1st by Rep. Tom Coburn (R-OK), has received some attention from conservative commentators recently. While it is unlikely to move this year, we thought it would be useful to summarize the Administration's position on the various issues this legislation raises.

As you know, Rep. Coburn was the author of legislation requiring mandatory HIV testing of newborns. This was opposed by most in the public health community, and a compromise was attached to the Ryan White CARE Act, which you signed in May, that would require mandatory testing of newborns in the year 2000 if states have not achieved a 95 percent acceptance rate of voluntary testing or have not reduced their rate of perinatal transmission by 50 percent. Reports from the International Conference on HIV/AIDS in Vancouver indicate that many health care providers are achieving high rates of voluntary testing and that the hoped for decline in perinatal transmission is beginning to be seen. (There already is a 10% decrease reported between 1994 and 1995.)

Key elements of H.R. 3937:

This new bill offered by Coburn would legislate in areas that have traditionally been left to public health professionals. In each area, the Centers for Disease Control and Prevention and state and local health departments already have the authority to act and in some cases they have. This is a case where rigidly legislated standards could result in inappropriate public health responses to a constantly evolving epidemic.

(1) *Requires reporting of the names of all individuals who test positive for HIV to state health departments.* This would be an intrusion on the discretion of the states to determine appropriate public health policies. Twenty-seven states already have names reporting policies and CDC provides additional funds to encourage states to adopt such a policy.

(2) *Requires states to have notification programs for sex and needle sharing partners of those*

who are HIV positive. This is unnecessary. The CDC already requires such programs as a condition of receipt of Federal prevention funds.

(3) *Permits the involuntary testing of defendants in sexual assault cases -- both to inform the victim and as relevant information in a prosecution.* Again, this is unnecessary. The Omnibus Crime Act of 1994 allows sexual assault victims to request HIV testing of an accused offender.

(4) *Allows health care professionals to make HIV testing of patients a pre-condition for performing invasive procedures.* This is counter to the current guidelines of the Public Health Service, which say it is critical that health professionals take universal precautions *for all invasive procedures regardless of the patient's HIV status.*

(5) *Requires HIV positive health care workers to notify patients before performing invasive procedures.* This policy already is reflected in PHS guidelines on HIV-infected health care workers; all states are required to adopt these policies.

(6) *Establishes the sense of Congress that it is a felony for HIV positive individuals to engage in behaviors that an individual knows places others at risk, even if no transmission occurs.* This is an issue for state criminal codes. There have already been numerous prosecutions under existing law in such cases.

Summary:

In summary, this legislation is unnecessary. Many of the provisions reflect existing policy while others would override the judgment of public health professionals and eliminate the flexibility they need to adapt policies based on new scientific knowledge.

None of Coburn's proposals would actually promote the behavior change necessary to reduce HIV transmission. Your Administration has made great strides in improving HIV prevention programs -- primarily through the introduction of a community planning process that gives states and localities much greater flexibility in their use of federal funds to target interventions based on the demographics of the epidemic in their jurisdiction. Funding has increased by $85.1 million (or 17 percent) since 1993, and you have requested another $33.5 million for FY 1997.

The legislation also fails to address the problem that far too many people with HIV do not know their status. The CDC estimates that only 62% of the 650,000-900,000 people with HIV in the U.S. do not know their status. With the growing consensus in the scientific community that the earliest possible intervention in the course of HIV infection is probably the most appropriate intervention, it will be critical to convince more people to take advantage of testing. This will require a combination of actions -- including stronger outreach to those at risk and a change in attitude toward testing by those most at risk to HIV. At the request of the Office of National AIDS Policy, the CDC and the Health Resources and Services Administration will be funding a project to examine how programs and policies related to encouraging people to seek HIV testing and care should be modified. This project is expected to be completed by the end of the year.

Jen Klein → Orig. has been sent to staff secretary

APR 5 1996

THE WHITE HOUSE

WASHINGTON

April 8, 1996

MEMORANDUM FOR THE PRESIDENT AND THE FIRST LADY

FROM: Carol H. Rasco, Assistant to the President for Domestic Policy CHR
Patricia S. Fleming, Director, Office of National AIDS Policy PSF

SUBJECT: Amendment regarding mandatory HIV testing of newborns

cc: Jennifer Klein

We are writing to bring you up to date on the status of congressional consideration of the issue of mandatory HIV testing of newborns. House-Senate conferees met last week to try to resolve differences regarding an amendment on HIV testing of newborns that was added to the Ryan White CARE Act reauthorization bill during House consideration. However, no final conclusion was reached.

Coburn-Waxman Amendment

The House amendment, sponsored by Reps. Coburn (R-OK) and Waxman (D-CA), would trigger mandatory HIV testing of newborns if certain conditions are not met. It would require the Secretary of Health and Human Services to determine, within two years, if HIV testing of newborns is the standard of care when the HIV status of the mother is unknown. If it is the standard of care, the Secretary must then determine, after another 18 months, that newborn testing is occurring voluntarily in 95 percent of the infants born to mothers who have not been tested. If the Secretary determines that 95 percent of such newborns have not been voluntarily tested, then mandatory HIV testing of newborns would be required in those states not in compliance. The states would have three-and-a-half years to reach the 95 percent level through voluntary testing.

Leading medical groups (such as the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, and the Pediatric AIDS Foundation) oppose this amendment and support voluntary HIV testing of pregnant women. In addition, AIDS advocacy organizations are nearly universally opposed to this amendment.

Testing of Pregnant Women

During Senate consideration of the Ryan White CARE Act, an amendment offered by Senator Kassebaum was approved that would require states to adopt the Public Health Service's guidelines making routine counseling and voluntary testing of all *pregnant women* the standard of care. The emphasis on the prenatal period, of course, has the greatest potential for preventing transmission to newborns. Newborn testing will have virtually no impact on HIV transmission to newborns. Prenatal HIV testing would permit HIV infected mothers to take AZT during pregnancy and childbirth, which has been demonstrated to

reduce the likelihood of transmission by as much as two-thirds.

It is worth noting that there are already encouraging results confirming that the combination of routine HIV counseling, voluntary testing, and AZT by choice is highly effective at reducing perinatal transmission. A study from North Carolina indicates that, after being counseled about HIV, most women choose to be tested and that, if positive, most choose to take AZT. The rate of perinatal transmission fell from 21 percent of all infants born to HIV-positive mothers in 1993 to just 8.5 percent in 1994, on a par with the original NIH study. Results from hospitals in major urban centers -- such as Miami, Atlanta, and Harlem, show similar high rates of testing and AZT use.

Current Status

Discussions in conference have focused on possible changes to the Coburn-Waxman amendment, such as changing the trigger for mandatory HIV testing of newborns to a failure to achieve a 50 percent reduction in perinatal transmission. But the underlying mandatory nature of the amendment remains.

The Administration has deliberately not taken a position on Coburn-Waxman. Instead, we have consistently emphasized the importance of implementing the PHS recommendations for voluntary prenatal testing as the most effective intervention and the various HHS agencies have taken major steps to assure that testing and treatment are readily available to those women who need it. At the White House Conference on HIV/AIDS on December 6th, you stated that this is an issue that should be left to the public health officials to resolve, not politicians.

It is not clear how the conferees will resolve this issue, but it is quite possible that the final bill will contain something along the lines of the Coburn-Waxman amendment. While all the AIDS groups oppose the amendment, it is quite likely that they will be very divided over the issue of whether the CARE Act should be vetoed if it comes with a mandatory testing amendment. Some will consider reauthorization of Ryan White to be a higher priority; others will be more concerned about the precedent of signing mandatory testing legislation. At this time, we are giving no indication of future action until it is clear what the conference will do.

THE WHITE HOUSE

WASHINGTON

September 15, 1995

MEMORANDUM FOR THE FIRST LADY

FROM: Carol Rasco and Patsy Fleming

SUBJECT: Amendment regarding mandatory HIV testing of newborns

On Monday, the House of Representatives is expected to take up the reauthorization of the Ryan White CARE Act. As part of the bill, the managers have added an amendment co-sponsored by Reps. Coburn and Waxman regarding HIV testing of newborns.

The amendment requires the Secretary of Health and Human Services to determine if HIV testing of newborns is the standard of care when the HIV status of the mother is unknown. If it is the standard of care, the Secretary must then determine that newborn testing is occurring voluntarily in 95 percent of the infants born to mothers who have not been tested. If the Secretary determines that 95 percent of such newborns have not been voluntarily tested, then mandatory HIV testing of newborns would be required in those states not in compliance. The states would have three-and-a half years to reach the 95 percent level through voluntary testing.

During Senate consideration of the Ryan White CARE Act, an amendment offered by Senator Kassebaum was approved that would require states to adopt the Public Health Service's guidelines making routine counseling and voluntary testing of all pregnant women the standard of care. The emphasis on the prenatal period, of course, has the greatest potential for preventing transmission to newborns. It is not clear how these two amendments will be reconciled in conference.

The AIDS Policy Office has been working closely with Jennifer Klein to encourage the Department of Health and Human Services to move as rapidly as possible to assure that all federally funded services reaching pregnant women are linked to counseling and testing programs for pregnant women. The most significant advance in that regard has been a decision by the Health Care Financing Administration to advise the states that counseling and testing of pregnant women is the standard of care and therefore should be part of basic coverage for Medicaid recipients. Until now, Medicaid only required coverage of the AZT therapy of those women who had already been identified as HIV infected.

cc: Melanne, Jen

AMENDMENT TO H.R. 1872, AS REPORTED

OFFERED BY MR. COBURN OF OKLAHOMA

Page *[21], after line *[19], insert the following section (and redesignate provisions and conform cross-references accordingly):

SEC. 204. ADDITIONAL REQUIREMENTS FOR GRANTS.

(a) FINDINGS.—The Congress finds as follows:

(1) Research studies have demonstrated that administration of antiviral medication during pregnancy can significantly reduce the transmission of the human immunodeficiency virus (commonly known as HIV) from an infected mother to her baby.

(2) The Centers for Disease Control and Prevention have recommended that all pregnant women receive HIV counseling; voluntary, confidential HIV testing; and appropriate medical treatment (including antiviral therapy) and support services.

(3) The provision of such testing without access to such counseling, treatment, and services will not improve the health of the woman or the child.

(4) The provision of such counseling, testing, treatment, and services can reduce the number of pediatric cases of acquired immune deficiency syndrome, can improve access to and provision of medical care for the woman, and can provide opportunities for counseling to reduce transmission among adults.

(5) The provision of such counseling, testing, treatment, and services can reduce the overall cost of pediatric cases of acquired immune deficiency syndrome.

(6) The cancellation or limitation of health insurance or other health coverage on the basis of HIV status should be impermissible under applicable law. Such cancellation or limitation could result in disincentives for appropriate counseling, testing, treatment, and services.

(7) For the reasons specified in paragraphs (1) through (6)—

mandatory voluntary

(A) routine counseling and routine testing of pregnant women should be the standard of care; and

(B) the relevant medical organizations as well as public health officials should issue

guidelines making such counseling and testing the standard of care.

(b) ADDITIONAL REQUIREMENTS FOR GRANTS.—Part B (42 U.S.C. 300ff–21 et seq.) is amended—

(1) in section 2611, by adding at the end the following sentence: "The authority of the Secretary to provide grants under this part is subject to section 2673D (relating to the testing of pregnant women and newborn infants)."; and

(2) by inserting after section 2616 the following section:

"SEC. 2616A. REQUIREMENT REGARDING HEALTH INSURANCE.

"(a) IN GENERAL.—Subject to subsection (c), the Secretary shall not make a grant under this part to a State unless the State has in effect a statute or regulations regulating insurance that imposes the following requirements:

"(1) That, if health insurance is in effect for an individual, the insurer involved may not (without the consent of the individual) discontinue the insurance, or alter the terms of the insurance (except as provided in paragraph (3)), solely on the basis that the individual is infected with HIV disease or solely on

the basis that the individual has been tested for the disease.

"(2) That paragraph (1) does not apply to an individual who, in applying for the health insurance involved, knowingly misrepresented any of the following:

"(A) The HIV status of the individual.

"(B) Facts regarding whether the individual has been tested for HIV disease.

"(C) Facts regarding whether the individual has engaged in any behavior that places the individual at risk for the disease.

"(3) That paragraph (1) does not apply to any reasonable alteration in the terms of health insurance for an individual with HIV disease that would have been made if the individual had a serious disease other than HIV disease.

"(b) REGULATION OF HEALTH INSURANCE.—A statute or regulation shall be deemed to regulate insurance for purposes of this section only to the extent that it is treated as regulating insurance for purposes of section 514(b)(2) of the Employee Retirement Income Security Act of 1974.

"(c) APPLICABILITY OF REQUIREMENT.—

"(1) IN GENERAL.—Except as provided in paragraph (2), this section applies upon the expiration of the 120-day period beginning on the date of the enactment of the Ryan White CARE Act Amendments of 1995.

"(2) DELAYED APPLICABILITY FOR CERTAIN STATES.—In the case of the State involved, if the Secretary determines that a requirement of this section cannot be implemented in the State without the enactment of State legislation, then such requirement applies to the State on and after the first day of the first calendar quarter that begins after the close of the first regular session of the State legislature that begins after the date of the enactment of the Ryan White CARE Act Amendments of 1995. For purposes of the preceding sentence, in the case of a State that has a 2-year legislative session, each year of such session is deemed to be a separate regular session of the State legislature.".

(c) TESTING OF NEWBORNS; PRENATAL TESTING.—Part D (42 U.S.C. 300ff–71 et seq.) is amended by inserting before section 2674 the following sections:

"SEC. 2673C. TESTING OF PREGNANT WOMEN AND NEWBORN INFANTS; PROGRAM OF GRANTS.

"(a) PROGRAM OF GRANTS.—The Secretary may make grants to States described in subsection (b) for the following purposes:

"(1) Making available to pregnant women appropriate counseling on HIV disease.

"(2) Making available to such women testing for such disease.

"(3) Testing newborn infants for such disease.

"(4) In the case of newborn infants who test positive for such disease, making available counseling on such disease to the parents or other legal guardians of the infant.

"(5) Collecting data on the number of pregnant women and newborn infants in the State who have undergone testing for such disease.

"(b) ELIGIBLE STATES.—Subject to subsection (c), a State referred to in subsection (a) is a State that has in effect, in statute or through regulations, the following requirements:

"(1) In the case of newborn infants who are born in the State and whose biological mothers have not undergone prenatal testing for HIV disease, that each such infant undergo testing for such disease.

"(2) That the results of such testing of a newborn infant be promptly disclosed in accordance with the following, as applicable to the infant involved:

"(A) To the biological mother of the infant (without regard to whether she is the legal guardian of the infant).

"(B) If the State is the legal guardian of the infant:

"(i) To the appropriate official of the State agency with responsibility for the care of the infant.

"(ii) To the appropriate official of each authorized agency providing assistance in the placement of the infant.

"(iii) If the authorized agency is giving significant consideration to approving an individual as a foster parent of the infant, to the prospective foster parent.

"(iv) If the authorized agency is giving significant consideration to approving an individual as an adoptive parent of the infant, to the prospective adoptive parent.

"(C) If neither the biological mother nor the State is the legal guardian of the infant, to another legal guardian of the infant.

"(3) That, in the case of prenatal testing for HIV disease that is conducted in the State, the results of such testing be promptly disclosed to the pregnant woman involved.

"(4) That, in disclosing the test results to an individual under paragraph (2) or (3), appropriate counseling on the human immunodeficiency virus be made available to the individual (except in the case of a disclosure to an official of a State or an authorized agency).

"(c) LIMITATION REGARDING AVAILABILITY OF GRANT FUNDS.—With respect to an activity described in any of paragraphs (1) through (4) of subsection (b), the requirement established by a State under such subsection that the activity be carried out applies only to the extent that the following sources of funds are available for carrying out the activity:

"(1) Federal funds provided to the State in grants under subsection (a).

"(2) Funds that the State or private entities have elected to provide, including through entering into contracts under which health benefits are provided. This section does not require any entity to expend non-Federal funds.

"(d) DEFINITIONS.—For purposes of this section, the term 'authorized agency', with respect to the placement of a child (including an infant) for whom a State is a legal guardian, means an entity licensed or otherwise approved by the State to assist in such placement.

"(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $10,000,000 for each of the fiscal years 1996 through 2000.

"SEC. 2673D. TESTING OF PREGNANT WOMEN AND NEWBORN INFANTS; CONTINGENT REQUIREMENT REGARDING STATE GRANTS UNDER PART B.

"(a) DETERMINATION BY SECRETARY.—During the first 30 days following the expiration of the 2-year period beginning on the date of the enactment of the Ryan White CARE Act Amendments of 1995, the Secretary shall publish in the Federal Register a determination of whether it has become the standard of care a routine practice in the provision of health care in the United States to carry out each of the activities described in paragraphs (1) through (4) of section 2673C(b). In making the determination, the Secretary shall consult with the States and with other public or private entities that have knowledge or expertise relevant to the determination.

"(b) CONTINGENT APPLICABILITY.—

"(1) IN GENERAL.—If the determination published in the Federal Register under subsection (a) is that (for purposes of such subsection) the activities involved have become routine practices, paragraph (2) applies to a State on and after the date applicable to the State under subsection (d).

"(2) REQUIREMENT.—Subject to subsection (c), the Secretary shall not make a grant under part B to a State unless the State meets not less than one of the following requirements:

"(A) The State has in effect, in statute or through regulations, the requirements specified in paragraphs (1) through (4) of section 2673C(b).

"(B) The State demonstrates that, of the newborn infants born in the State for the most recent 1-year period for which the data are available, the HIV status of 95 percent of the infants is known.

"(c) LIMITATION REGARDING AVAILABILITY OF FUNDS.—With respect to an activity described in any of paragraphs (1) through (4) of section 2673C(b), the requirements established by a State under subsection (a)(2)(A) that the activity be carried out applies only to

the extent that the following sources of funds are available for carrying out the activity:

"(1) Federal funds provided to the State in grants under part B.

"(2) Federal funds provided to the State in grants under section 2673C.

"(3) Funds that the State or private entities have elected to provide, including through entering into contracts under which health benefits are provided. This section does not require any entity to expend non-Federal funds.

"(d) APPLICABILITY OF REQUIREMENT.—

"(1) IN GENERAL.—Except as provided in paragraph (2), the date applicable to a State for purposes of subsection (b)(1) is the expiration of the 120-day period beginning on the date on which the determination referred to in such subsection is published.

"(2) DELAYED APPLICABILITY FOR CERTAIN STATES.—In the case of the State involved, if the Secretary determines that the State has not met the requirement described in subsection (b)(2)(B), and that a requirement under subsection (b)(2)(A) cannot be implemented in the State without the enactment of State legislation, then the date applicable to

a State for purposes of subsection (b)(1) regarding the requirement is the first day of the first calendar quarter that begins after the close of the first regular session of the State legislature that begins after the date on which the determination referred to in subsection (b)(1) is published. For purposes of the preceding sentence, in the case of a State that has a 2-year legislative session, each year of such session is deemed to be a separate regular session of the State legislature.".

Rough Draft

Talking Points for Secretary Shalala -- Senator Kassebaum

* I appreciate your hard work in bringing the Ryan White CARE Act reauthorization to the Senate floor. This bill has our full support and we hope the Senate will complete action on it quickly.

* I have heard of your interest in sponsoring an amendment to require mandatory prenatal HIV testing of women in certain states. This is an issue of concern to me, and I'd like to discuss it with you.

* As you know, the Public Health Service convened an extensive process through the CDC examining how best to address HIV prevention opportunities and treatment needs facing pregnant women. PHS recommendations were released earlier this month strongly supporting routine counseling and encouragement of voluntary testing for all pregnant women.

* It's clear that by helping women to learn their HIV status early in pregnancy, HIV transmission to their newborns can be reduced by two thirds if they follow a medical treatment plan.

* There's strong evidence that when routine HIV counseling is included in prenatal care, over 90% of women will accept HIV testing. I believe this is the way we ought to proceed.

* There is real concern that mandatory HIV testing of pregnant women may discourage them from seeking prenatal care. Many women at highest risk for HIV are mistrustful of health care systems to start with, and coercively requiring an HIV test may alienate them further. This way we lose the mother, and the opportunity for prevention.

* Should women avoid prenatal care, we face the potential of a double tragedy -- higher rates of low birthweight and birth defects among children never exposed to HIV, along with lost opportunities to prevent new HIV infection among infants.

* We have heard from many providers in both private practice and public health clinics that building a trusting doctor-patient relationship is essential in order for patients to follow a plan of care. Mandatory HIV testing would be a hollow step if women lose trust in their providers and refuse to accept their guidance.

* Across Public Health Service programs, our goal has been to encourage early and continuous prenatal care. We've come a long way, but we have a long way to go. I am very concerned that we not jeopardize our progress in bringing high risk women into care. Instead, we need creative, targeted efforts to reach them.

* I would look forward to working with you on alternative approaches to mandatory testing, and hope you will consider this.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

July 21, 1995
(Senate)

STATEMENT OF ADMINISTRATION POLICY

(THIS STATEMENT HAS BEEN COORDINATED BY OMB WITH THE CONCERNED AGENCIES.)

S. 641 -- Ryan White CARE Reauthorization Act of 1995
(Kassebaum (R) KS and 62 cosponsors)

The Administration strongly supports S. 641, consistent with the attached July 5th letter from the President to the Senate Majority Leader.

* * * * * * *

THE WHITE HOUSE

WASHINGTON

July 5, 1995

Dear Mr. Leader:

I am writing to urge you to lead the Congress in passing the reauthorization of the Ryan White CARE Act before the summer recess. We cannot allow this crucial program to lapse.

There is strong bipartisan support for the Ryan White CARE Act. The initial legislation was approved by overwhelming margins in both houses (95-4 in the Senate and 408-14 in the House) and signed into law by President Bush. Funding for this program has been endorsed from both sides of the aisle throughout the five years of the program and the reauthorization bill in the Senate has 60 co-sponsors. It is a program vital to the lives of Americans living with HIV and AIDS. Its existence has had a dramatic impact on the quality and length of their lives while helping to reduce the cost of their care.

The CARE Act provides direct services to people living with HIV and AIDS through grants to states, cities, community organizations, and local clinics. It emphasizes outpatient care in clinics and other facilities and is designed to relieve the burden on public hospitals and other more expensive inpatient facilities.

It has been a tremendous success in meeting this mandate. By lessening the demand on public hospitals and other facilities, valuable inpatient resources have been freed to care for patients with other diseases, and people with HIV and AIDS have been able to lead more productive lives in their communities. The CARE Act approach serves as a model for delivering more cost-effective health care for people with all diseases.

In 1994, the CARE Act provided care to more than 200,000 uninsured and underinsured people living with HIV or AIDS and early intervention services to another 85,000 people. The Act also funded HIV counseling and testing to nearly 100,000 Americans, provided pharmaceutical assistance to 75,000 individuals, and supported more than 15,000 women and children participating in AIDS-related clinical trials.

Let me share with you the story of one person who has been helped by this program -- one person whose experience with the CARE Act is typical of literally hundreds of thousands of other

Americans who have benefitted from this law. "Debbie" is a 27 year old woman living with AIDS in a rural part of South Carolina. Until recently, few doctors in Debbie's hometown were willing to treat AIDS patients in part because so many were uninsured. With funding from the Ryan White CARE Act, the County Health Department opened a clinic in the town of Orangeburg that operated six days a month with a rotating staff of five physicians and three nurses. The clinic's staff has taught Debbie's mother to care for her daughter at home. When Debbie is too sick to come to the clinic, the staff come to her. Not only has this prevented more costly hospitalizations, but it provides Debbie and her mother peace of mind. Debbie's Mom calls the clinic's staff her "guardian angels."

The Ryan White CARE Act is a model of compassionate caring for people in need. At a time when AIDS is the leading cause of death of young adults, we cannot let reauthorization of the CARE Act be held up by divisive arguments about how people contracted HIV. Nor should we be deterred by the false argument that people with HIV or AIDS are getting more help than those with other diseases. In fact, total federal spending in FY 1995 for research, treatment, prevention, Medicaid, Medicare, and income supplements for AIDS is less than one-third that for cancer and less than one-sixth that for heart disease. (AIDS spending is $6 billion, cancer is $17.5 billion, and heart disease is $38 billion.)

In the United States, an average of 220 Americans are being diagnosed with AIDS every day and an average of 109 Americans are dying of this disease each day. Now is not the time to retreat in our national response to this terrible disease. We must move forward to meet the very real needs of Americans living with HIV and AIDS. We can certainly do more, we cannot do any less.

I hope you will join me in urging the Congress to move forward promptly with a five-year reauthorization of this vital program without complicated amendments so that we can once again show the American people that their government can provide the assistance they deserve.

Sincerely,

Bill Clinton

The Honorable Bob Dole
Majority Leader
United States Senate
Washington, D.C. 20510

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

10-Jul-1995 03:02pm

TO: (See Below)

FROM: Emily Bromberg
Intergovernmental Affairs

SUBJECT: mandatory testing

FYI, the NGA will send a letter tomorrow to Chairman Bliley and others stating that the NGA opposes mandatory AIDS testing for pregnant women because it is an umfunded mandate. The NGA is sending this letter because they heard rumors on the Hill that NGA had changed their position to support Coburn, and wanted to reiterate their opposition. The letter will be signed by Ray Scheppach.

Distribution:

TO: Carol H. Rasco
TO: George Stephanopoulos
TO: Jennifer L. Klein
TO: Barbara C. Chow
TO: Patsy Fleming

CC: Marcia L. Hale

HIV Testing Column

Two Decisions:

(1) Timing of article -- before or after Coburn comes up on floor in early August

- Need to consider reaction of groups

(2) Need to decide whether targeting makes sense

- Won't appease Coburn
- Won't appease groups that oppose testing

Notes on Column:

Everyone agrees that all pregnant women should know their HIV status. The good news is that we now know that treatment dramatically reduces the risk of transmission. Now that there is something we can do to reduce transmission, we owe to ourselves and our children to take whatever steps we can. That means getting prenatal care, getting tested and getting treated if a woman tests positive.

The complex issue that has been debated so passionately in newspapers, television reports, professional meetings and living rooms across the country is whether women should be required to be tested themselves or to have their newborns tested. I support the Coburn amendment that requires all states to test newborns for HIV infection in order to qualify for federal funding under the Ryan White Care Act. If a woman does not know her HIV status when she delivers her baby, the baby should be tested. We know that HIV positive babies can be treated with PCP prophylaxis to prevent deadly pneumonia in their first months of life and to keep them healthy longer.

But I also believe [may or may not yet be in Coburn] that we need to protect those women and children who test positive. We also know that women whose babies test positive are positive themselves -- in fact, the test result is a more accurate report of her status than her child's status (-- % of whom will actually test negative a few months later). Sadly, people who live with HIV today also continue to live with discrimination. We need to ensure that HIV results are confidential so that no woman whose baby tests positive risks losing her job or her home because of her HIV status. And we must ensure that no women whose baby tests positive risks losing her child, simply because she and her baby are HIV-infected. [Could get into medical neglect, but very controversial.]

However, waiting until a baby is born to find out that the child has been infected is too little too late. As guidelines recently published by the Centers for Disease Control recommend, we need aggressive counseling and voluntary testing of all pregnant women -- so that we can *prevent* infection during pregnancy rather than treat it after it happens. We've seen that

voluntary counseling and testing work. [Cite studies in Atlanta, Kaiser, Yale/New Haven] Women who have taken part in decisions about their medical care and consented to testing will trust their doctors and comply with treatment recommendations (many of which require cooperation over a period of months or years). For these reasons, the CDC guidelines are supported by the American Academy of Pediatrics, the Pediatric AIDS Foundation and the American College of Obstetrics and Gynecology [other groups]. In September, ACOG will release guidelines making it the standard of practice for all obstetricians to counsel and test their patients. [Statement about force of guidelines.]

That is why it is most important that all women get prenatal care. And that's why it is so important that:

- We preserve Medicaid as a safety net -- because for many HIV-positive women, Medicaid is the only chance they have to get prenatal care.

- Medicaid cover prenatal testing -- 40% of births in the United States are covered by Medicaid.

- Medicaid continue to cover AZT treatment for pregnant women and newborns, so that all women who know their HIV status can get treatment for themselves and their children.

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

13-Jul-1995 01:52pm

TO: Carol H. Rasco

FROM: Jeffrey Levi
AIDS Policy Council

CC: Jeremy D. Benami
CC: Jennifer L. Klein

SUBJECT: Newborn testing amendment

At this morning's Commerce Committee markup of Ryan White, Coburn withdrew with newborn testing amendment, with the understanding that he would try to work something out with Waxman before thebill goes to the floor. Waxman was prepared to offer a compromise amendment that would have created a discretionary fund for states to tap if they opt to require newborn screening when the mother's status is unknown.

Interestingly, the NGA opposition to the Coburn amendment had not moved any members. Pay-go issues with Coburn's amendment are what caused him to withdraw it at this time.

Stay tuned.

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

13-Jul-1995 05:50pm

TO: Carol H. Rasco
TO: Jennifer L. Klein
TO: William G. White
TO: Gordon P. Agress

FROM: Jeffrey Levi
AIDS Policy Council

CC: Jeremy D. Benami

SUBJECT: Newborn screening--II

A compromise has been worked out between Coburn and Waxman (drafting still under way) that would (a) create a $10 million authorization (presumably from CDC funds) for two years that could be used by states to implement mandatory testing of newborns whose mother's status is not known -- if the states choose to implement such testing, in other words -- no federal mandate, but federal funds to assist those states that impose such a mandate; and (b) a requirement that the Secretary report back within two years her finding as to whether newborn screening should be the standard of care and, if yes, whether that standard of care is being implemented. If it is not being implemented as the standard of care, then there would be a requirement for mandatory testing across the nation, which would take effect 18 months after the Secretary's determination and which would be a condition of Ryan White funds. In other words, a federal mandate could not occur before 3-1/2 years from now.

The plan is that Coburn and Waxman would bring this to the Rules committee together, and that this would close off other floor amendments on this subject.

NATIONAL GOVERNORS' ASSOCIATION

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To Emily Bromley	From L2 Ryan
Co. White House	Co. Gov. Office
Dept.	Phone #
Fax # 456-2889	Fax #

July 12, 1995

Representative Thomas J. Bliley Jr.
Chairman, Committee on Commerce
Room 2125 Rayburn House Office Building
Washington, DC 20515-6065

Dear Chairman Bliley:

We are writing to you concerning the proposed amendment by Representative Coburn to H.R. 1872 the reauthorization of the Ryan White CARE Act. Versions of the amendment made available to us would make AIDS funding to states under the Act contingent upon passage of state laws requiring the mandatory testing of all newborns for HIV disease. While individual Governors may support the concept of such testing, the National Governors' Association (NGA) has no position on that part of the Coburn proposal. However, the NGA does have long standing policy and stands in opposition to the unfunded federal mandates provision of this amendment. These provisions are inconsistent with the spirit of recently enacted unfunded mandates legislation.

We also believe that the amendment has implication for state Medicaid programs. Medicaid now pays for about one-third of all births in the United States. While the amendment is silent on who pays, one can be sure that Medicaid will be billed for the testing required in this amendment. As such, it creates an unfunded Medicaid mandate at a time when the Congressional leadership has begun to acknowledge the adverse impact of such actions on states.

We are concerned that the costs resulting from this amendment may not be trivial. Attached, for your information, is a preliminary estimate of its financial impact that was developed by the National Alliance of State and Territorial AIDS Directors (NASTAD). While it may not be exact, it shows some of the operational details required for its implementation and gives a better understanding of the range of costs that would be incurred. They estimate that the amendment will cost more than $600 million over five years. With regard to Medicaid, state Medicaid programs currently pay for about one-third of all births in the nation. The NASTAD analysis would suggest an annual national cost to the Medicaid program of more than $40 million. Additional costs to states and local government would be incurred for uninsured and underinsured births.

We understand that as an alternative to an unfunded mandate, the committee may require the use of Title II dollars to fund this testing program. Since Title II provides a critical source of treatment funds in all states, such an action would seriously impair states' abilities to provide this much needed care.

Finally, we believe that an amendment may be offered that gives states with high incidence of pediatric AIDS, incentive funds to establish a mandatory program like the one proposed in Mr. Coburn's amendment. The NGA supports such incentive programs.

LIZ RYAN
STATE OF DELAWARE
SUITE 230

Thank you for your attention to our concerns and we look forward to working with you and the committee in the future on these and other issues.

Sincerely,

Governor Howard Dean M.D.
Chair

Tommy G. Thompson
Vice Chair

cc: Representative John D. Dingell
Members of the Commerce Committee

attachment

Fiscal Impact of Proposed Coburn Amendment to the Ryan White CARE Act

The Coburn Amendment would require, as a condition of Ryan White CARE Act funding, that states create laws mandating HIV antibody testing of all newborn infants. In order to implement the testing laws, substantial costs would be borne by states to conduct the following activities:

1. HIV testing of newborns (or in the case of prenatal testing, pregnant women);
2. Confirmatory laboratory tests for those testing HIV positive;
3. Disclosure of test results and appropriate HIV counseling to individuals tested;
4. Community outreach and follow-up for non-compliant or hard to reach patients;
5. State monitoring, assurance, surveillance and evaluation of testing, counseling and outreach programs.

Yearly cost estimates are based on 4,000,000 live births (based on 1994 provisional U.S. natality statistics provided by the National Center for Health Statistics). *The cost projection does not include estimated costs of health care and supportive services, AZT therapy, or clinical education for providers to conduct testing and counseling (which represent components of Ryan White CARE Act funded services germane to this issue).* The following is a preliminary estimate of cost:

1.	Elisa (HIV antibody) testing of all 4 million live births at average $10 per laboratory test:	$ 40,000,000
2.	Confirmatory (Elisa and Western Blot) testing of all HIV positives and false positives (estimated 7,000 HIV positives and 8,000 false positives at $75 per confirmatory test):	$ 1,125,000
3.	Disclosure of test results and counseling of all patients (based on national average of 60 FTE health care providers per every 100,000 patients tested and counseled x $25,000 average yearly salary):	$ 60,000,000
4.	Community outreach and follow-up for non-compliant patients: (based on cost of New York model program providing outreach to mothers and newborns, extrapolated nationally based on estimated cases of pediatric AIDS).	$ 8,000,000
5.	State monitoring, assurance, surveillance and evaluation: (based on an estimated 10% of projected cost of counseling, testing and follow-up implementation):	$ 10,912,500
	Estimated Cost for First Year:	$ 120,037,500

Source: The National Alliance of State and Territorial AIDS Directors

AMENDMENT TO H.R. 1872

OFFERED BY MR. COBURN

Page 21, after line 19, insert the following section (and redesignate provisions and conform cross-references accordingly):

SEC. 204. ADDITIONAL REQUIREMENTS FOR GRANTS.

(a) FINDINGS.—The Congress finds as follows:

(1) Research studies have demonstrated that administration of antiviral medication during pregnancy can significantly reduce the transmission of the human immunodeficiency virus (commonly known as HIV) from an infected mother to her baby.

(2) The Centers for Disease Control and Prevention have recommended that all pregnant women receive HIV counseling; voluntary, confidential HIV testing; and appropriate medical treatment (including antiviral therapy) and support services.

(3) The provision of such testing without access to such counseling, treatment, and services will not improve the health of the woman or the child.

(4) The provision of such counseling, testing, treatment, and services can reduce the number of pediatric cases of acquired immune deficiency syndrome, can improve access to and provision of medical care for the woman, and can provide opportunities for counseling to reduce transmission among adults.

(5) The provision of such counseling, testing, treatment, and services can reduce the overall cost of pediatric cases of acquired immune deficiency syndrome.

(6) The cancellation or limitation of health insurance or other health coverage on the basis of HIV status should be impermissible under applicable law. Such cancellation or limitation could result in disincentives for appropriate counseling, testing, treatment, and services.

(7) For the reasons specified in paragraphs (1) through (6)—

(A) mandatory counseling and voluntary testing of pregnant women should be the standard of care; and

(B) the relevant accredited medical organizations as well as public health officials should

issue guidelines making such counseling and testing the standard of care.

(b) ADDITIONAL REQUIREMENTS FOR GRANTS.—Part B (42 U.S.C. 300ff-21 et seq.) is amended by inserting after section 2616 the following section:

"SEC. 2616A. ADDITIONAL HIV-RELATED REQUIREMENTS.

"(a) TESTING OF NEWBORNS; PRENATAL TESTING.—Subject to subsection (d), the Secretary shall not make a grant under this part to a State unless the State has in effect a law establishing the following requirements:

"(1) That each newborn infant who is born in the State undergo testing for HIV disease (except that such requirement does not apply if the biological mother of the infant, while in the State, underwent prenatal testing for the disease).

"(2) That the results of such testing of a newborn infant be promptly disclosed in accordance with the following, as applicable to the infant involved:

"(A) To the biological mother of the infant (without regard to whether she is the legal guardian of the infant).

"(B) If the State is the legal guardian of the infant:

"(i) To the appropriate official of the State agency with responsibility for the care of the infant.

"(ii) To the appropriate official of each authorized agency providing assistance in the placement of the infant.

"(iii) If the authorized agency is giving significant consideration to approving an individual as a foster parent of the infant, to the prospective foster parent.

"(iv) If the authorized agency is giving significant consideration to approving an individual as an adoptive parent of the infant, to the prospective adoptive parent.

"(C) If neither the biological mother nor the State is the legal guardian of the infant, to another legal guardian of the infant.

"(3) That, in the case of prenatal testing for HIV disease, the results of such testing be promptly disclosed to the pregnant woman involved.

"(4) That, in disclosing the test results to an individual under paragraph (2) or (3), appropriate counseling on the human immunodeficiency virus be made available to the individual (except in the case

of a disclosure to an official of a State or an authorized agency).

"(b) HEALTH INSURANCE.—Subject to subsection (d), the Secretary shall not make a grant under this part to a State unless the State has in effect a law providing that, if health insurance is in effect for an individual, the insurer involved may not (without the consent of the individual) terminate the insurance, or alter the terms of the insurance, on the basis that the individual is infected with HIV disease or on the basis that the individual has been tested for the disease.

"(c) DEFINITIONS.—For purposes of this section:

"(1) The term 'authorized agency', with respect to the placement of a child (including an infant) for whom a State is a legal guardian, means an entity licensed or otherwise approved by the State to assist in such placement.

"(2) The term 'health insurance' includes a health plan.

"(d) APPLICABILITY OF REQUIREMENT.—This section applies on and after January 15, 1996.".