

*Domestic Policymaking in the Clinton-Gore White House 1993-2001:
Selected Memoranda and Documents*

Health and Health Care Documents (Annex II)

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THE WHITE HOUSE
WASHINGTON

January 31, 1997

MEMORANDUM FOR THE PRESIDENT

FROM: Bruce Reed, Assistant to the President for Domestic Policy *BR*
Patricia S. Fleming, Director, Office of National AIDS Policy *PSF*

SUBJECT: Follow up to the December meeting of the Presidential HIV/AIDS Advisory Council

We are pleased to transmit to you the most recent recommendations of the Presidential Advisory Council on HIV and AIDS following its meeting of December 15-17.

A copy of the Council's recommendations is attached. These recommendations, in summary, ask for the following:

- Continued leadership by the Administration for funding for AIDS research, prevention, treatment, and housing as well as protection of Medicare and Medicaid.
- Continued advocacy for funding for AIDS Drug Assistance Programs and HUD's Housing Opportunities for People with AIDS program.
- Greater focus by the Federal Bureau of Prisons on the needs and rights of federal prisoners living with HIV/AIDS.
- Greater support for AIDS treatment programs focused on Native American communities.
- Administration leadership in working with states and the private sector on reducing the cost of AIDS drugs.

The Council also approved a resolution commending you and the Office of National AIDS Policy for formulating the first-ever National AIDS Strategy, which you received from Patsy Fleming on December 17. The Council also sent a letter to Secretary Shalala urging her to support Federal funding for needle exchange programs to reduce the spread of HIV among intravenous drug users, their sexual partners, and their children.

The steps we will take in the coming months to address these concerns are as follows:

- Your fiscal 1998 budget includes across-the-board increases in funding for AIDS research, prevention, treatment, and housing. While these increases are smaller than in previous years, they are significant in the context of your balanced budget proposal.

- Your budget maintains the Federal guarantee of Medicare and Medicaid coverage for people with disabilities including people living with HIV/AIDS. However, the proposed per capita cap concerns many AIDS advocates because of its potential to reduce benefits to costly patients.
- The Federal Bureau of Prisons and the Department of Defense are working on addressing the inclusion of HIV/AIDS issues in all services of the Federal Bureau of prisons and Department of Defense prisons and briggs (including D.C. jails).
- The Office of National AIDS Policy is convening a roundtable discussion of AIDS issues related to the Native American community on February 11.
- The Department of Health and Human Services is working with the states and others to find ways to reduce the cost of AIDS drugs to government programs.
- The Department of Health and Human Services will report to Congress on or about February 15 on Federally-sponsored research into the effectiveness of needle exchange programs to reduce HIV transmission without encouraging use of illegal drugs.

**Presidential Advisory Council on HIV/AIDS
Fifth Full Council Meeting
December 15 - 17, 1996**

REPORT FOUR

RECOMMENDATIONS

•National AIDS Strategy Resolution

The Council commends the President and the Office of National AIDS Policy for demonstrating leadership in developing the Federal Government's first national comprehensive strategy for dealing with the HIV/AIDS epidemic. While there are clearly significant issues regarding the epidemic which still must be addressed, the National AIDS Strategy provides a foundation for the Federal Government's response to HIV/AIDS in the year ahead. Specific implementation tactics and strategies must be developed.

The Council believes that in order to have any realistic chance of achieving the President's stated goals of finding a cure, developing a vaccine, and reducing annual new infections to zero, other important issues such as how to decrease infections among intravenous drug users must be addressed more comprehensively.

The Council intends to continue to ensure that all crucial issues are dealt with and to ensure that the actions of relevant Federal Agencies are consistent with the National AIDS Strategy and with the recommendations of this Council.

IV.A. Leadership Recommendation

Background

During the debate over the FY1997 budget, President Clinton exercised leadership critical to the lives of people living with HIV and at risk for HIV by protecting Medicaid and Medicare, holding out for increases in funding for research, prevention and care, and by seeking budget amendments for the AIDS Drug Assistance Program and HOPWA as the need for increased funding became apparent.

The FY 1998 budget debate will require the same level of leadership from the President and his Administration. Our nation faces the continuing challenge of assuring access to new and promising treatments for HIV, the opportunity that new avenues of treatment and vaccine research offer, the need to expand prevention efforts to more Americans at risk, and the need to assure that people with HIV have housing that addresses their needs.

Recommendation IV.A.1.

That in his FY 1998 budget request, the President continue to protect Medicaid and Medicare, and seek increases in funding for research, prevention, care and services — including the Ryan White Care Act and HOPWA. In particular, because of the availability of new drug therapies, ADAP funding must be increased, and not in competition with funding for the care system. Increased funding will be essential until new financing systems can be developed among private and public health payers to cover the cost of the new therapies.

In the international arena, the President should seek increases in funding for USAID programs relating to the global epidemic.

Recommendation IV.A.2.

That the Vice-President continue the dialogue which he has established with the major manufacturers of HIV/AIDS drugs and that the issue of international provision of basic medications for the prevention and treatment of opportunistic infections and other HIV/AIDS associated medical conditions be added to their agenda.

IV.B. AIDS/Prison Issues

Background

Citizens incarcerated in the United States prisons system have a constitutional right to quality health care appropriated social services, and humane living conditions.

This issue was first addressed in the 1991 NCOA report in the Federal Bureau of Prisons. In 1995 the ONAP revisited this issue so that the needs of the HIV-infected prison population were not neglected.

"HIV infected prisoners who are not provided adequate medical care while incarcerated become sicker and can impose an unnecessary burden on the health care delivery system upon release. Moreover, without proper prevention education, prisoners and formerly incarcerated persons will continue to engage in risky behavior and thereby increase the possibility of new transmissions. People of Color have been particularly hard hit by the expanding HIV/AIDS epidemic and they also experience high rates of incarceration.¹

"For prisoners with HIV/AIDS locked away in federal, state, and local prisons and jails, a short prison term can become a death sentence because of lack of medical care, little

¹ 1996, Policy Statement, NORA Working Group on Incarcerated Populations.

psychosocial support, discrimination, stigmatization, and harassment from both corrections staff and other prisoners. Studies have shown that prisoners with HIV/AIDS live half as long as similar IDU populations on the outside. Women prisoners with HIV/AIDS are the fastest growing and most medically underserved prison population. Compassionate release or medical parole is out of reach for most prisoners with full-blown AIDS (and other life threatening illnesses).²

Historically, prison infirmaries have not been equipped to deal with the specialized needs of inmates with HIV/AIDS and infections associated with HIV disease such as multiple-drug-resistant tuberculosis. In an effort to address these concerns, we recommend the following:

Recommendation IV.B.1.

The Council requests a comprehensive and specific report be from the Federal Bureau of Prisons, and the Department of Defense, within 90 days, addressing the inclusion of HIV/AIDS issues in all services of the Federal Bureau of Prisons and DoD prisons and briggs (including D. C. Jails). This should minimally include the following:

- a. Content and frequency of prison staff educational efforts paying particular attention to issues of; women at-risk for HIV, substance use, prevention, and the medical management of HIV disease.
- b. Accessibility of all FDA approved HIV/AIDS therapeutic modalities for prison inmates with HIV/AIDS, and numbers of prisoners availing themselves of these therapies.
- c. Availability of mainstream clinical drug trials for prison inmates, the nature of any access barriers -- and means to remove such barriers, and numbers, sites and principal investigators of these programs.
- d. The status of quality assurance criteria and certifications, (including nondiscrimination guidelines) with a demonstrable high level of compassionate care available for the ill and dying.
- e. Description of case management for prison inmates with HIV/AIDS.
- f. Availability of voluntary peer education opportunities for HIV+ inmates. (Please include curriculum participation, site, and frequency statistics.)
- g. Accessibility of condoms and barrier protection against HIV transmission to prison

² 1996, HIV/AIDS in Prison Project, Catholic Charities, Judy Greenspan, author.

- Your budget maintains the Federal guarantee of Medicare and Medicaid coverage for people with disabilities including people living with HIV/AIDS. However, the proposed per capita cap concerns many AIDS advocates because of its potential to reduce benefits to costly patients.
- The Federal Bureau of Prisons and the Department of Defense are working on addressing the inclusion of HIV/AIDS issues in all services of the Federal Bureau of prisons and Department of Defense prisons and briggs (including D.C. jails).
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The Council believes that in order to have any realistic chance of achieving the President's stated goals of finding a cure, developing a vaccine, and reducing annual new infections to zero, other important issues such as how to decrease infections among intravenous drug users must be addressed more comprehensively.

The Council intends to continue to ensure that all crucial issues are dealt with and to ensure that the actions of relevant Federal Agencies are consistent with the National AIDS Strategy and with the recommendations of this Council.

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The FY 1998 budget debate will require the same level of leadership from the President and his Administration. Our nation faces the continuing challenge of assuring access to new and promising treatments for HIV, the opportunity that new avenues of treatment and vaccine research offer, the need to expand prevention efforts to more Americans at risk, and the need to assure that people with HIV have housing that addresses their needs.

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In the international arena, the President should seek increases in funding for USAID programs relating to the global epidemic.

Recommendation IV.A.2.

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psychosocial support, discrimination, stigmatization, and harassment from both corrections staff and other prisoners. Studies have shown that prisoners with HIV/AIDS live half as long as similar IDU populations on the outside. Women prisoners with HIV/AIDS are the fastest growing and most medically underserved prison population. Compassionate release or medical parole is out of reach for most prisoners with full-blown AIDS (and other life threatening illnesses).²

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- d. The status of quality assurance criteria and certifications, (including nondiscrimination guidelines) with a demonstrable high level of compassionate care available for the ill and dying.
- e. Description of case management for prison inmates with HIV/AIDS.
- f. Availability of voluntary peer education opportunities for HIV+ inmates. (Please include curriculum participation, site, and frequency statistics.)
- g. Accessibility of condoms and barrier protection against HIV transmission to prison

² 1996, HIV/AIDS in Prison Project, Catholic Charities, Judy Greenspan, author.

inmates.

- h. Specific details concerning the availability of ongoing (at least every 6 months) educational programs for incarcerated individuals regarding all aspects of HIV, including substance abuse issues and sexuality.
- I. Definition of the limits of jurisdiction which differentiate the authority of the federal government in all correctional facilities; District of Columbia, military, federal, state, and local correctional institutions, including federal funding streams.
- j. The scope of implementation of the seven major recommendations of the National Commission on AIDS (March, 1991).

Recommendation IV.B.2.

The Administration should direct the Secretary of Health and Human Services to develop oversight language appropriate for discharge planning (including accessing benefits) for ex-offenders with HIV/AIDS designed to assure their continuity of care through Probation Departments in various locales as well as the accessibility of appropriate linkages within the community.

IV.C. AIDS/Native American Issues

Background

During 1994 - 1995, extensive efforts were made in the public and private sector to insure and preserve HRSA assistance to special populations. Under the reauthorization, it appears to be discretionary for the Secretary to determine allocations to specific communities and projects.

Recommendation IV.C.1.

Therefore, the Council requests that the President instruct the Secretary of Health and Human Services to reassess the legislative intent of the reauthorized Ryan White CARE Act regarding needs of the Native American community to insure appropriate support for Native American care, infrastructure development, and coordination *on a national level*.

Background

Agreements ensuring the fulfillment of Native American health care needs are part of the traditional government-tribal relationship. In the instance of alcohol and substance abuse programs, IHS was instructed to develop memorandums of agreement with tribal

governments and the BIA to ensure that these three entities work together to reduce the effects of addiction in tribal communities. Memorandums of agreement include a specific tribal plan describing needs, availability of services, and prevention efforts. Similar memorandums are needed in dealing with HIV/AIDS. Local tribes have need to have ownership of direct client services for HIV case management on their Reservations; Native Case Management Programs need a commitment from IHS that they will work cooperatively with these programs, which are located on and off Reservations.

Recommendation IV.C.2.

Therefore, the Council requests that the Secretary of Health and Human Services instruct the Director of Indian Health Services to demonstrate within ninety-days the adequacy of *HIV* prevention, care, and treatment including access to needed drugs, for American Indians and Alaska Natives living on or near reservations. This should include documentation of needs assessments completed, barriers, and gaps identified and proposed solutions. It should also include a discussion of how IHS plans to work with the private non-profit sector to improve AIDS-related services.

Background

Programs providing Case Management Services to Native Americans need to ensure that the services are culturally relevant for this population. Criteria to evaluate the cultural relevancy of services may include such things as: Native Americans seated on the governing or policy-making body, insuring that 50% of the staff are native Americans, insuring that traditional tribal healing services are available onsite by referral. IHS needs to commit to complying with the *Buy Indian Act* for training IHS personnel in HIV/AIDS Case Management Services.

Recommendation IV.C.3.

Therefore, the Council requests that the Secretary of Health and Human Services instruct the Director of IHS to develop Case Management oversight guidelines which are appropriately oriented to the specific needs of Native American people with HIV/AIDS and assure the provision of health care and in a safe and culturally appropriate manner.

IV.D. AIDS/Service Issues

Recommendation IV.D.1

That the Administration take leadership in working with the states and the private sector to reduce the cost of pharmaceuticals to ADAP and Medicaid programs.

Recommendation IV.D.2

That the federal government working with the states expeditiously finance, and evaluate new demonstration projects that 1) enable funds to be used for very early access to HIV care services, and 2) assess the resulting impact on health status, life expectancy, client return to work and earned income, and net health care costs (new expenditures offset by lowered costs), on a lifetime and annual cost-of-care basis. These demonstrations should be financed with new funds, so as not to diminish access to care and treatment under current funding.

Recommendation IV.D.3

That the Office of National AIDS Policy create a mechanism for the public sector, the private sector, and the community to engage in a formal, facilitated dialogue process on how to set priorities for HIV care and services that assures the best use of resources and recognizes a context of shifting demands for services. This dialogue should be completed within six to eight months.

Recommendation IV.D.4

That the Office of National AIDS Policy work with the Secretary of HHS and the Secretary of Labor, the co-chairs of the Advisory Council on Consumer Protection and Quality in Health, to assure inclusion of the concerns of people living with HIV and their recommendations.

THE WHITE HOUSE

WASHINGTON

March 12, 1997

MEMORANDUM FOR THE PRESIDENT

FROM: Bruce Reed, Assistant to the President for Domestic Policy
Eric Goosby, Interim Director, ONAP

RE: Update on Status of Needle Exchange Programs

There have been a number of recent events involving needle exchange programs. On February 13, a National Institutes of Health Consensus Conference Statement recommended lifting the ban on use of federal funds for needle exchange programs. On February 18, HHS sent a Congressionally requested report to the Senate Appropriations Committee reviewing the scientific data on needle exchange programs to date. This memo provides background to put the issue in context, with a discussion of these recent events.

Current Statute. There are three statutory restrictions on the use of federal funds for needle exchange programs. (1) The Substance Abuse and Mental Health (SAMHSA) block grant prohibits use of federal funds for needle exchange unless the Surgeon General determines that they are effective in reducing the spread of HIV and the use of illegal drugs. The statute does permit federal research and evaluation of existing needle exchange programs. (2) The 1996 Ryan White CARE Act reauthorization places a flat prohibition on the use of Ryan White funds for needle exchange. (3) The Labor/HHS Appropriations bill prohibits funding of needle exchange unless the Secretary determines that such programs are effective in preventing the spread of HIV and do not encourage the use of illegal drugs.

Epidemiology of HIV Infection. Thirty six percent of AIDS cases are directly or indirectly caused by IV drug use. Up to fifty percent of new HIV infections may be related to IV drug use. The effects of IV drug use have become a driving force in the HIV epidemic.

Number of Needle Exchange Programs. There are over 100 needle exchange programs in the US, with most programs distributing through two or more sites. As of 1996, twenty-eight States had local needle exchange programs.

Federally Sponsored Research. The National Institute on Drug Abuse (NIDA) at NIH has funded 15 demonstration projects to evaluate the impact of needle exchange programs on rates of HIV infection and patterns of drug use (including the effectiveness of these programs as gateways to substance abuse treatment). Only two of the 15 studies are completed at this time. There has also been a significant amount of privately funded research on needle exchange programs through foundations and other nonprofit groups.

State and Local Government. At their recent winter meeting, the National Governors Association passed a resolution stating: "Federal restrictions or requirements on the use of available funding interfere with the ability of States to develop comprehensive prevention strategies." The Association of State and Territorial Health Officers (ASTHO) passed the following resolution in December 1995: "The federal government should repeal the ban on the use of federal funds for needle exchange services to allow interested States and localities the financial flexibility to support successful prevention and treatment initiatives within their jurisdictions." The US Conference of Mayors also supports lifting the ban on use of federal funds for needle exchange.

HHS Report to Senate Appropriations. Report language was included in the September 1996 Senate L/HHS Appropriations bill requesting that HHS provide a report on the status of current research projects, an itemization of previously funded research, and findings-to-date regarding the efficacy of needle exchange programs for reducing HIV transmission and not encouraging illegal drug use. The report prepared by HHS reviewed all published studies of US needle exchange programs, including one by the Institute of Medicine; it did not attempt to determine if the Congressional standard has been met for lifting the ban on federal funding. The summary section of the report contains the following: "Overall these studies indicate that needle exchange programs can have an impact on bringing difficult to reach populations into systems of care that offer drug dependency services, mental health, medical and support services. These studies also indicate that needle exchange programs can be an effective component of a comprehensive strategy to prevent HIV and other blood borne infectious diseases in communities that choose to include them."

NIH Consensus Conference. A NIH Consensus Development Conference on Interventions to Prevent HIV Risk Behaviors was held February 11-13, 1997. This conference was developed and directed by a non-Federal panel of experts, predating the Congressional request for an HHS report. The resulting Consensus Conference Statement is an independent report of an expert panel, not a policy statement of the NIH. This Statement, released on February 13, concluded that needle exchange programs are effective in reducing both HIV transmission and IV drug use and recommended lifting the legislative restrictions on needle exchange programs.

Analysis of Evidence on Needle Exchange Programs and IV Drug Use. The preponderance of data collected so far suggests a stable or declining level of drug use among needle exchange participants. About half of the studies on the effects of needle exchange show a decline in drug use. Two studies show an increase in drug use, but these studies have been discounted by expert panel as outliers. In addition, almost all studies indicate that needle exchange program participants tend to be older (median age 33 to 41 years old) and tend to be long-term users (duration of use 7 to 20 years). There is no data to suggest needle exchange programs increase new initiates into drug use, and the age of participants often increases over time.

It is important to note, however, that most studies have methodological weaknesses, inherent to the population and subject, that are nearly impossible to overcome. These methodological problems include: 1) reliance upon individuals' self-reporting of drug use; 2) the difficulties of creating a control group that does not receive clean needles yet continues participating in the

study; and 3) the difficulties of isolating the effects of needle exchange programs from the many other factors that may influence drug use in a given population.

The Administration's Response. HHS, ONDCP, and the White House jointly developed a response to questions about the HHS report and NIH Conference Statement. This response states that data on the effect of needle exchange programs in reducing HIV seroprevalence is solid, but that data on the effect of these programs on drug use patterns is less clear. The response further states that HHS will continue research efforts to evaluate new data on needle exchange programs and will work with the Congress on effective HIV prevention strategies. General McCaffrey strongly believes that the Administration should not challenge or raise questions about the current legislative restrictions on needle exchange programs.

Next Steps for HHS in Evaluating Effects on Drug Use. HHS will conduct a scientific review of the data presented at the NIH Consensus Conference. The data has not yet been through the peer review process required for publication and needs close examination. A second step will be an analysis of data already collected through the NIDA demonstration projects, which have not yet been specifically studied for effect on drug utilization patterns.

Congressional Climate and Community Expectations. The HHS report was released during the Congressional recess, and Hill reaction has been muted to date. Harold Varmus, Director of the NIH, received direct questions on needle exchange from Reps. Dickey (R-AR) and Wicker (R-MS) during an NIH Appropriations hearing. Secretary Shalala also received one question on lifting the federal funding ban prior to release of the report.

Both the House and Senate generally have punted the issue of needle exchange programs to HHS. The exception is last year's prohibition on use of Ryan White treatment funds for needle exchange programs, which passed unanimously. The Congressional response to any attempt to lift restrictions on funding likely would be hostile. The climate, however, may be softening somewhat. Senator Specter, Chair of the L/HHS Appropriations Subcommittee, has come to support needle exchange programs (Philadelphia has one of the largest); Rep. Rangel, once adamantly opposed to needle exchange programs, is reported to be shifting in his stance; and the state flexibility arguments advanced by NGA and ASTHO may also start to have an effect.

The AIDS community is united in seeking an end to the ban on federal funding of needle exchange programs. With some exceptions, however, the national AIDS organizations understand the downside of demanding that the ban be lifted before the necessary educational and political groundwork is laid. What the community wants from the Administration at this point is not so much an immediate lifting of the restrictions as a strong indication that the Administration generally will let science guide policy in combating HIV transmission.

THE WHITE HOUSE
WASHINGTON

May 6, 1997

MEMORANDUM FOR THE PRESIDENT

FROM: Bruce Reed, Assistant to the President for Domestic Policy
Dr. Eric Goosby, Acting Director, Office of National AIDS Policy.

SUBJECT: Follow up to the April meeting of the Presidential HIV/AIDS Advisory Council

We are pleased to transmit to you the most recent recommendations of the Presidential Advisory Council on HIV and AIDS following its meeting of April 5 - 8.

A copy of the Council's recommendations is attached. These recommendations, in summary, ask for the following:

- Opposition of the HIV Prevention Act of 1997;

- Work to eliminate all regulations and requirements for mandated reviews by citizen review panels of the content of HIV prevention materials;

- Continued leadership and highest priority by our government on development of a successful HIV/AIDS vaccine within a decade;

- Encourage scientific research on the potential benefits and/or risks of medical marijuana and pending results of such research, the government refrain from any efforts to prosecute doctors, who in good faith, discuss the use of medical marijuana or recommend it for their patients;

- Continued advocacy for prison issues relating to compassionate release, discharge planning, standards of care, protective barriers, and substance use; and

- Continued leadership by the Administration on providing the science in a report to Congress on the efficacy of syringe exchange programs to reduce the transmission of HIV and the certification of such syringe exchange programs as effective in reducing the incidence of new HIV infections while not increasing substance abuse.

The Council also sent a letter to you regarding the elimination of discrimination against those infected with HIV by certain Federal agencies (copy attached).

Presidential Advisory Council on HIV and AIDS

Stephen N. Abel, D.D.S.
Mr. Terje Anderson
Ms. Judith Billings
Mr. Nicholas Bollman
Mr. Tonio Burgos
Jerry Cade, M.D.
Rabbi Joseph Edelheit
Mr. Robert Fogel
Ms. Debra Fraser-Howze
Ms. Kathleen Gerus
Ms. Phyllis Greenberger
Mr. Bob Hattoy
Mr. B. Thomas Henderson
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Mr. Ronald Johnson
Mr. Jeremy Landau
Alexandra Mary Levine, M.D.
Mr. Steve Lew
Ms. Helen H. Miramontes
Rev. Altagracia Perez
Michael Rankin, M.D.
Mr. H. Alexander Robinson
Ms. Debbie Runions
Mr. Benjamin Schatz
Mr. Richard W. Stafford
Ms. Denise Stokes
Ms. Sandra Thurman
Bruce Weniger, M.D.

THE WHITE HOUSE
WASHINGTON

May 16, 1997

MEMORANDUM FOR THE PRESIDENT

FROM: Bruce Reed, Assistant to the President for Domestic Policy
Sandra Thurman, Coordinator for National AIDS Policy

SUBJECT: International Studies on Reducing Maternal-Infant HIV Transmission

This memorandum will provide background on the controversy over an ongoing group of U.S.-supported international clinical trials studying options to reduce maternal transmission of HIV in developing countries. A brief overview of current knowledge, the rationale for further research, the World Health Organization position, concerns of domestic public interest groups, and the Department of Health and Human Services' position will be covered. Attached separately are talking points and Q&A's prepared by HHS on the issue.

Perinatal Transmission The World Health Organization (WHO) estimates over 1,000 HIV+ infants are born each day. Women with HIV disease have a 15%-40% risk of transmitting HIV to their baby with each pregnancy. The National Institutes of Health demonstrated that this transmission risk can be lowered to 8.3% by the administration of the drug AZT to women orally during pregnancy and intravenously during labor, and to their newborn infants orally for 6 weeks. This NIH study, known as ACTG 076 - comparing AZT with a placebo - was halted and published in 1994 when these dramatic results were evident. It has become the standard of care to offer all HIV+ pregnant women AZT therapy in the U.S.

An important unanswered research question is at what point during pregnancy or birth do women transmit HIV to their babies -- and if it is necessary to administer AZT over many months to prevent HIV infection in infants. Because many developing countries cannot afford expensive drug therapies for their citizens, pinpointing the critical period in which to administer AZT to prevent perinatal transmission is important so that the greatest number of women could be offered treatment.

Research Study Design Issues The public health leadership of several WHO member countries collaborated with the NIH and Centers for Disease Control and Prevention (CDC) to design and develop research studies to prevent perinatal HIV transmission in countries with limited health care infrastructure and resources. Each research study included an informed consent document outlining the research question, the randomization to an AZT or placebo group, and a detailed description of potential risks study participants may incur. All study protocols were reviewed and approved by the NIH and CDC Institutional Review Boards (IRBs) and the host countries. The political leadership of each host country were also fully informed of the study methodologies and concurred with their implementation. The first studies proposed by this international collaborative group began in 1993 with funding support from the U.S. (NIH, CDC) and France.

World Health Organization Activity In June 1994, the WHO hosted a meeting of researchers and public health practitioners from the U.S., Europe, and countries in Africa, Asia and the Caribbean which have a high incidence of HIV disease. The purpose of the meeting was to examine the results of the NIH ACTG 076 trial in terms of their applicability internationally. The following recommendations were issued from this meeting:

- 1) Encourage the use of AZT as outlined by the NIH ACTG 076 study in industrialized countries; and
- 2) Immediate exploration of alternative regimens that could be used to achieve prevention of perinatal HIV prevention in the developing world.

WHO participants established parameters for the conduct of research studies in developing countries. The studies supported by the U.S. and France were consistent with these parameters.

Concerns of Some U.S. Public Interest Groups Dr. Sidney Wolfe of the Public Citizen Health Research Group wrote a long critique of U.S. involvement and support for these international perinatal HIV prevention studies in a letter to Secretary Shalala. The letter was broadly distributed to the media. Key concerns raised were:

- o Some research designs include a placebo arm when AZT has proven benefit. Such a research design would never be allowed in the U.S.
- o The studies violate major international ethical guidelines, specifically: the World Medical Association's 1975 Declaration of Helsinki; four of the Nuremberg codes for human experimentation; and the International Ethical Guidelines for Biomedical Research Involving Human Subjects designed to address ethical issues in developing countries
- o There is no guarantee that women and infants in host countries will benefit from the research knowledge gained
- o The lack of appropriate care in host countries does not justify study designs with placebo arms that have no benefit. The standard of care in many countries does not include access to prenatal care, medications, hospital births or intravenous infusions
- o Comparison of these studies to the Tuskegee syphilis study; criticism that IRBs should ensure that risks to subjects are minimized and subjects are not unnecessarily exposed to risk; this is colonialism at its worst

Senator Carol Moseley-Braun (D-IL) has also voiced her concern regarding study designs with a placebo arm when there is a known effective treatment for HIV prevention. She is alarmed that such studies are supported with U.S. funds, and thinks it is inappropriate to continue such funding in face of the apology being offered to the Tuskegee survivors this Friday.

Department of Health and Human Services The Department of Health and Human Services has conducted a review of the U.S.-funded studies in question and continues to support both the study designs and public health importance of completing them. They are ongoing as of this date. HHS testified to this effect before the House Government Reform and Oversight Committee last week. There was very little discussion of the issue among Representatives present.

In brief, the HHS position maintains:

- o The studies address a pressing need in the global control of the spread of HIV, defining interventions that will result in reductions in maternal-infant transmission which can be safely and routinely implemented in the developing world;
- o The studies are based on the assumption that the NIH ACTG 076 regimen is not a feasible therapeutic intervention in developing countries due to lack of medical infrastructure and cost constraints; the research design examines options for treatment which are viable and affordable within the medical care delivery systems of the study countries
- o All ongoing studies are in full compliance with U.S. and in-country regulations and laws, have gone through extensive in-country and U.S. ethical review processes and an international ethical review, and all studies have strong in-country support; an independent Data and Safety Monitoring Board continues to provide oversight of research findings at regular intervals
- o Broadly accepted ethical principles for international research recognize a role for the local standard of care when testing the effectiveness of a new intervention. In the case of developing host countries, the local standard is minimal to no health care access. Studying new research options of AZT administration at specific times during pregnancy offers a new benefit to individuals who would not otherwise have had it, while defining research knowledge that may allow many individuals to benefit if shorter courses of AZT prove effective for HIV prevention. The placebo arm is equivalent to the local standard of care.

Attached are Q&As and talking points which support the HHS position on this issues.

THE WHITE HOUSE
WASHINGTON

QUESTIONS AND ANSWERS

Q. Did you know about the NIH supported clinical trials using AZT and placebos in HIV infected pregnant women in developing countries?

A. I am aware that NIH is funding some research into how to improve prevention of mother to infant transmission of HIV in some developing countries. I understand that AZT is the drug that is being used in these studies.

I have asked the Secretary of Health and Human Services to provide me with a report on these NIH studies. I also asked for an evaluation of how these studies will help the women and infants involved and how the studies are helping to curb maternal transmission of HIV in these countries.

Q. Some of the women in these studies are not receiving AZT, they are getting a placebo. How does this compare with the U.S. position that all HIV infected pregnant women and their infants should be offered AZT?

A. That question will be addressed in Secretary Shalala's report. Just let me say that in many developing countries no HIV treatment at all is available for pregnant women or their infants. It is totally different situation than what we have in this country where AZT is readily available.

Q. Some critics are saying that the NIH funded AZT studies in developing countries are not different from what happened in the Tuskegee study where treatment was withheld from some of the participants. How do you answer that?

A. Well, I will need to see the report from HHS before I can fully address that. But I must emphasize that in the Tuskegee study, treatment that was widely available in this country was deliberately withheld from some of the participants. In the AZT studies overseas, the only AZT treatment available is the treatment provided to participants in the study.

Q. Some critics are saying that there is an issue of violation of international ethical codes in the AZT studies. Is this true?

A. I will know more about the studies and the specific concerns surrounding it when I review Secretary Shalala's report. Until then, I can't say anything further on this. I can assure you that we will not support any studies where such violations occur.

TALKING POINTS

- * OUR GOAL IN SUPPORTING THESE STUDIES IS TO FIND EFFECTIVE WAYS TO PREVENT MOTHER-TO-CHILD TRANSMISSION OF HIV THAT CAN BE USED IN DEVELOPING COUNTRIES. THAT MEANS FINDING A REGIMEN THAT IS EFFECTIVE FOR THE SPECIFIC POPULATION AND AFFORDABLE IN THAT COUNTRY.
- * THE FULL AZT-076 REGIMEN, WHICH IS THE STANDARD OF CARE IN THE UNITED STATES, IS NOT FEASIBLE FOR THESE COUNTRIES. IT IS EXPENSIVE AND REQUIRES SOPHISTICATED MEDICAL MONITORING.
- * WE HAVE WORKED WITH THE WORLD HEALTH ORGANIZATION, UNAIDS AND THE HOST GOVERNMENTS TO DESIGN THESE TRIALS. THEY ARE FULLY SUPPORTED BY THE INTERNATIONAL BODIES AND BY THE HOST GOVERNMENTS
- * THESE TRIALS HAVE BEEN REVIEWED FROM AN ETHICAL STANDPOINT BY THE CDC AND NIH INSTITUTIONAL REVIEW BOARDS, AND BY REVIEW BOARDS IN THE HOST COUNTRIES. WE AGREE THAT THESE ARE DIFFICULT AND COMPLEX ISSUES, BUT THAT IS EXACTLY WHY WE WENT TO SOME LENGTHS TO ACHIEVE MEDICAL AND ETHICAL CONSENSUS ON THE RESEARCH NOT ONLY WITHIN HHS, BUT WITH INTERNATIONAL ORGANIZATIONS AND THE HOST COUNTRIES THEMSELVES.
- * WE ARE DEDICATED TO FINDING AN EFFECTIVE THERAPEUTIC INTERVENTION THAT CAN REALISTICALLY BE ADMINISTERED IN THE HOST COUNTRIES AND IS AFFORDABLE.

THE WHITE HOUSE
WASHINGTON

June 20, 1997

MEMORANDUM FOR THE PRESIDENT

FROM: Bruce Reed
Sandra Thurman

SUBJECT: U.S. Conference of Mayors Needle Exchange Resolution

This memorandum will provide you a quick overview of the U.S. Conference of Mayors resolution on needle exchange programs, and the politics of this issue in Congress, public health community and AIDS advocacy groups.

Mayors Resolution The FY 1997 Appropriations bill maintains the prohibition on federal funding of needle exchange unless the Secretary of HHS determines that such programs are effective in preventing the spread of HIV and do not encourage the use of illegal drugs. Mayor Willie Brown of San Francisco is sponsoring a resolution at the Mayors meeting (see attached) calling on Secretary Shalala to exercise her waiver authority and permit state and local public health officials to use federal funds for needle exchange as one component of a comprehensive HIV prevention strategy.

Other mainstream public health and state government groups (Nation Governor's Association, Association of State and Territorial Health Officers, National Black Caucus of State Legislatures) support removing the federal funding restrictions in favor of state/local flexibility to design HIV prevention strategies that respond to the characteristics of the HIV epidemic in their jurisdiction.

Department of Health and Human Services HHS sent a report to Congress in February 1997 concluding these needle exchange programs can have an impact on bringing difficult to reach populations into systems of care that offer drug dependency services, mental health, medical and support services. These studies also indicate that needle exchange programs can be an effective component of a comprehensive strategy to prevent HIV and other blood borne infectious diseases in communities that choose to include them. The Department has not acted on the funding restrictions, but is internally moving towards a position that would allow grantees to use federal funds if certain conditions are met.

Office of National Drug Control Policy General McCaffrey remains skeptical that needle exchange programs will not increase drug use. He has stated, however, that he remains open to reviewing the scientific findings for that issue. In that vein, he plans on talking with representatives from NIH on this issue next week. It remains clear, though, that in the absence of

General McCaffrey, congressional support for the program would be impossible to obtain. (Even with his support, it will be extremely difficult to achieve congressional support for the authority to use federal funds for needle exchange programs.)

Congress Six Republican members of the House Labor/HHS Appropriations Subcommittee have indicated their intent to offer an amendment repealing the authority of Secretary Shalala to waive the prohibition on federal funding for needle exchange. The House mark-up is scheduled for the week of July 7. Subcommittee Chair Porter (R-IL) has high regard for NIH's scientific position, but clearly would need tangible support from HHS and the public health community to defeat such an amendment. On the Senate side, Sen. Specter chairs the L/HHS Subcommittee and he has come to generally support needle exchange programs-- Philadelphia has one of the largest. Both he and Sen. Harkin (ranking Member) would be inclined to leave the waiver language as is and avoid difficult votes on this issue. If HHS were to lift the ban, staff are not sure how the votes would fall.

Community The AIDS advocacy community is pushing vigorously to have the federal ban on needle exchange funding lifted. The community has recognized that a lot of political work needs to be done in Congress prior to removing the funding restrictions, so that a worse outcome is not realized with a flat ban on funding in lieu of the Secretary's waiver authority. Now that there's a clear sign that the House Subcommittee will consider an amendment for a flat ban, there is heightened interest in having HHS remove the funding restrictions and aggressively defend the science behind its action on the Hill.

To that end, some groups are trying to place press questions on needle exchange to you in conjunction with the USCM resolution on needle exchange.

Recommendation In the next month, we will give you an options memo that explores these issues in greater depth. You should not announce any new position at this time.

If you are asked about the issue in San Francisco, we recommend that you indicate support for local flexibility, and say that you have asked Secretary Shalala to review the science and make recommendations to you about how best to counter the dominant role intravenous drug use is playing in the transmission of HIV.

Bruce
Very good
This should be sent to make a 1st draft informed decision
THE WHITE HOUSE
WASHINGTON
 June 26, 1997
John D. [Signature]

MEMORANDUM FOR THE CHIEF OF STAFF

FROM: Bruce Reed

SUBJECT: Tobacco Settlement Review Process

This memo sets forth the process we will use to evaluate the proposed tobacco settlement and to present recommendations to the President. Our goal is to prepare an analysis for the President by late July that defines our public health and public interest objectives; weighs the settlement's strengths and weaknesses against those objectives; summarizes the views of the public health community, Congress, and other affected parties; and lays out positions the President could take on the settlement proposal.

Interagency Review

The review will be carried out by four major workgroups which have already begun to meet:

- I. **Regulatory Issues** (convened by Elena Kagan). This group will look at: (a) FDA regulation of product content, including nicotine; (b) FDA regulation of access, advertising, and labeling; and (c) restrictions on environmental tobacco smoke in public buildings and workplace settings. Participating White House offices are DPC, OMB, OVP, NEC, and OSTP. Participating agencies are HHS, DOI, DOL, GSA, EPA, and Treasury.
- II. **Program and Budget Issues** (convened by Chris Jennings). This group will examine proposed uses of settlement funds, including programs to reduce smoking and expand children's health care coverage. In particular, the group will consider the use of settlement funds for: (a) children's health care; (b) education efforts (including grass roots programs); (c) smoking cessation programs; and (d) investments in health research, including nicotine research. White House offices are DPC, OMB, NEC, OVP, and OSTP. Participating agencies are HHS, Treasury, DOL, USDA, Interior, VA, and DOD.
- III. **Legal Issues** (convened by Elena Kagan). This group will review the settlement's provisions on liability, damages, and document disclosure, and will consider constitutional, antitrust, and other legal issues raised by the settlement. White House offices are DPC, OVP, NEC, and Counsel. Participating agencies are DOJ, HHS, Treasury, EPA, and Interior.

IV. Industry Performance and Accountability (convened by Bruce Reed). This group will analyze the economic effects of a settlement. The group will assess: (a) the economics of the industry and the settlement's effects on industry performance, international markets, federal revenues, consumers, farmers, etc.; and (b) the set of incentives and penalties in the settlement to reduce tobacco use, especially by children. On a separate track, Dan Tarullo will oversee a look at Administration policy on tobacco-related trade and international issues, which the settlement does not directly address. White House offices are DPC, NEC, CEA, OVP, OMB, and OSTP; participating agencies are: HHS, Treasury, DOL, USDA, USTR, State, and DOD.

Public Outreach

We will work with OPL and HHS on a tightly focused public outreach effort designed to demonstrate that the President is conducting a thoughtful, thorough review focused on public health issues. Many groups covering a wide range of interests are affected by the proposed settlement. We will emphasize the President's focus on health by hosting 6-8 highly visible White House meetings with small, select groups of health experts. Working with OPL, we will encourage other interested groups (e.g., children's advocates, women's organizations, and farmers) to share their views through written comments and, where appropriate, meetings with agency and White House staff.

Donna and I will host the White House meetings over the next three weeks. We will convene experts from national health organizations; Koop-Kessler advisory group participants; experts on tobacco products and nicotine addiction; local grass-roots advocates; state and local tobacco control officials; and children's health advocates.

We will start by bringing in members of the Koop-Kessler advisory group, including the American Cancer Society, American Medical Association, and American Heart Association, the week of July 7. Future meetings will include: Action on Smoking and Health; American Academy of Pediatrics; American Public Health Association; Americans for Nonsmokers' Rights; and National Center for Tobacco-Free Kids, Joe Califano, and leading academics.

Congressional Outreach

We will need to take into account Congressional views on the settlement proposal. Multiple committees in both the House and Senate would have jurisdiction over legislation enacting an agreement. The goal of our Congressional outreach process will be to strengthen relationships on the issue with key members and to keep the debate bipartisan and balanced. We will consult with the leadership, anti-tobacco advocates, and representatives of tobacco states. Today and tomorrow HHS is making calls to key Republican and Democratic members to seek their input on how best to consult with the Hill in the coming weeks. We are working with Legislative Affairs and HHS on a detailed list of Congressional meetings to begin the week of July 7. There are many critical members, including Senators Lott, Daschle, Hatch, Kennedy, Lautenberg, Ford, and Durbin; and Congressmen Gephardt, Gingrich, Bliley, Waxman, Dingell, Hansen, Meehan, Gordon and others.

Press Plan

This issue is certain to attract considerable press attention throughout our review. Major news organizations have assigned entire teams to cover the tobacco settlement. After devoting so much coverage to the negotiations, the networks are determined to keep this issue alive. We should take advantage of that heightened interest to advance our public health message.

On Friday, Donna and I are prepared to brief the White House press corps on how we will conduct this review, who will be involved from within the Administration, and what groups and outside experts we plan to consult.

During the week of July 7, while the President is away, Donna and I will conduct the public health and Congressional meetings described above. This will give the press something to write about, and show that we are running an open process. During the week of July 14, we will continue public health and Congressional meetings and bring in two groups of attorneys general -- the enthusiasts and the skeptics. The Vice President is willing to hold a public hearing with us in mid-July if we need one.

Schedule

We have planned the following schedule. Some do not believe the review can be completed within 30 days, as the President suggested. But we will work as quickly as possible to preserve that option and ensure a decision by early August at the latest.

- Week of June 23: DPC convenes work groups and assigns analytic tasks to members. Donna and Bruce brief press on process and conduct.
- Week of June 30: Groups provide preliminary assessments of key issues.
- Week of July 7: Groups develop options for key issues. Bruce, Donna and others hold further meetings with public health groups and begin meetings with members of Congress.
- Week of July 14: Principals review workgroup assessments and meet to discuss options. Possible public hearing with the Vice President.
- Week of July 21: Initial meeting with the President.
- Late July/
early August: Presidential decision and announcement.

'97 SEP 5 PM7:34

THE WHITE HOUSE
WASHINGTON

FOR PRESIDENT'S FILE
12/10/97

September 5, 1997

Copied
Reed
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MEMORANDUM FOR THE PRESIDENT

FROM: Bruce Reed
SUBJECT: Tobacco Update

When you return next week, Secretary Shalala and I will give you detailed recommendations on how to proceed on tobacco. We are scheduled to meet with you on Friday, and you are scheduled to announce your position on Tuesday the 16th. This memo is a brief summary of what we are likely to recommend and what strategic and policy decisions you will need to make.

I. Overview

Although the industry was hoping for quick passage, some Republican leaders in both houses said this week that the tobacco settlement was too complicated for Congress to enact before they adjourn in late October. Lott would still like to get it done this year, but with the legislation being referred to six committees in the Senate alone, we need to stake out positions that can hold up over time.

Over the past two months, we have held extensive discussions with the public health community, attorneys general, members of Congress, and farmers. The public health community will welcome our recommendations on most issues: guaranteeing full authority for FDA to regulate nicotine; imposing tougher penalties on the industry if it fails to reduce teen smoking; demanding an additional \$50 billion to offset the credit in the budget agreement; making it somewhat easier to disclose industry documents; looking out for tobacco farmers; and so on. The only concerns of tobacco opponents that we cannot easily meet are dramatically increasing the overall price tag (Kennedy would like to see it doubled, to \$700 billion) and demanding to see all the documents before capping liability (Leahy, Waxman, and Skip Humphrey are pushing for "no immunity without disclosure").

The central strategic question is how far we want to push the industry for additional concessions, at the risk of losing this opportunity altogether. Bruce Lindsey and I have

repeatedly pressed the industry on the most important issues -- FDA, penalties, and documents -- with only modest progress. We met with them again today, and will continue to press them next week, but penalties remain a serious stumbling block.

Bruce believes we should not go forward unless we have the industry on board, because without an agreement on everything the industry will be free to use its considerable influence in Congress to undermine provisions it doesn't like -- for example, gutting the FDA provisions if it wins in the 4th Circuit. Secretary Shalala and the Vice President strongly believe we should not reach agreement with the industry, because any deal with tobacco companies will be suspect, and won't have enough congressional buy-in to withstand 6-12 months of debate in Congress.

This debate may become moot, if we can't get the industry to come around by next week on our bottom-line issues. In that case, I believe we should be both tough and reasonable, by demanding more than the industry can stomach right now (on FDA and penalties), but not more than they can possibly swallow in the end. I share Bruce's concerns about the industry's clout and penchant for mischief, but a little tension between us and the industry might actually help us during a drawn-out congressional debate. If we make this a fight over tougher penalties to reduce teen smoking (rather than how much money we want in return for capping liability), I believe we can beat the industry on a few points, even in this Congress -- especially in an election year.

II. Major Recommendations

A. FDA Authority

The first priority of the Administration in considering any tobacco legislation should be to confirm and protect the jurisdiction of the FDA to regulate tobacco products. The FDA must be able to regulate tobacco products, including by ordering the reduction or elimination of nicotine or other constituents, through its normal procedures in the furtherance of public health interests -- without any special procedural rules or requirements. We should call on Congress to pass legislation specifically empowering the FDA to require the modification of tobacco products based on a finding that this change would reduce the risk of the product to the public and is technologically feasible.

The industry still wants to put one hurdle in front of FDA, by saying the FDA may not go forward if a party affirmatively demonstrates that the action would create a significant contraband market in tobacco products. But we believe the FDA should only have to consider contraband as one of many relevant factors, including the number of addicted tobacco users and the availability of alternative products. We would eliminate two other weaknesses in the settlement -- the 12-year waiting period before FDA could ban nicotine, and the special procedural hurdles such as formal rulemakings.

THE SETTLEMENT HAS BEEN

12-10-97

B. Documents

For decades, the tobacco industry has failed to disclose essential facts in its possession about the dangers and addictiveness of tobacco products, and used attorney-client privilege to cloak scientific research and findings and possibly shield evidence of criminal or fraudulent behavior. It is therefore necessary to establish an effective and speedy mechanism to pierce fraudulent or otherwise improper claims of privilege and to force the disclosure of information that will advance public health interests. The documents issue has become a rallying cry for the most ardent opponents of a settlement, led by Skip Humphrey.

The settlement calls for a national documents depository and a three-judge panel to provide expedited rulings on whether documents should remain privileged. We recommend strengthening the document provisions by 1) allowing litigants to challenge privilege claims in individual lawsuits, even if the three-judge panel had already ruled, and 2) providing the FDA with access to all health-related documents, notwithstanding any claims of privilege. That will enable the FDA to put the industry's considerable expertise on nicotine to good use.

Even these steps will not go far enough to please Leahy, Waxman, and Humphrey, who want to break the companies' attorney-client privilege and insist that the tobacco companies disclose all privileged documents before any consideration of a settlement. But the Justice Department has expressed serious concerns about any broad abrogation of the privilege, arguing that such an approach would undermine the privilege generally and might enable a tobacco company official charged with criminal conduct to assert a violation of his Sixth Amendment right to effective assistance of counsel.

Handwritten notes:
4/11/97
Re: Leahy
@ Justice Dept
Public Health
in settlement

C. Penalties

The settlement sets ambitious targets to reduce youth smoking by 30% in 5 years, 50% in 7 years, and 60% in 10 years, and would require companies to pay \$80 million for each percentage point they fall short. Public health groups have praised the idea of targets and penalties, but complain that the current scheme does not give companies sufficient incentive to stop hooking teenagers. Our main problems with the current penalties are that they are tax-deductible, abatable, capped at \$2 billion, and too small to serve as a deterrent.

We can strengthen the penalties in a variety of ways -- all of which the industry has so far resisted -- but our current preferred option is a two-tier system, with graduated penalties that get stiffer if the industry misses the targets by a substantial margin. The first tier of penalties would require companies to pay \$80 million per point if the industry missed the targets by less than 5 points in year 5, less than 10 points in year 7, and less than 15 points in year 10. This penalty would be non-deductible, could not be abated, and would reflect a company's share of the youth market. If the industry missed by a greater margin, companies would pay the full first-tier penalty, and their settlement payment would be increased by a penny a pack for each additional

percentage point by which they missed the target. This second-tier penalty would cost companies about \$240 million a point, and has the additional virtue of locking in a permanent price increase that will help further reduce smoking by youth (and adults). Under this approach, if youth smoking went down by 30% over 10 years, instead of 60%, the industry would pay \$1.2 billion in financial penalties and be forced to raise prices another 15 cents a pack on top of that.

D. Farmers

We have made clear that tobacco farmers should receive protection in any legislative settlement, and that the Administration will work closely with members of Congress from tobacco states to forge a consensus. Secretary Glickman has traveled to tobacco markets in Virginia and North Carolina to express this commitment directly to farmers.

Farmers are primarily interested in continuation of the governmental tobacco program, guaranteed purchase at set levels of tobacco crops by cigarette companies, and some provision for buy out and transition to other crops, on a voluntary basis. Because farm groups and tobacco state members have not yet coalesced around a consensus proposal, we don't need to commit to a specific plan yet. The most discussed proposal is one released this month by Senators Ford and McConnell that would require companies to buy a minimum amount of domestic tobacco over 25 years and would install penalties on companies that do not meet the stated goals for tobacco buying. The proposal would also create a "Tobacco Community Revitalization Fund" administered by USDA, but not subject to the appropriation process, which could spend up to \$1 billion a year for 25 years from the settlement fund and would cover costs related to the tobacco program such as administration and crop insurance, make supplemental payments of up to \$300 million to producers whose income from tobacco drops substantially below the 1996 level, pay up to \$100 million in benefits for displaced cigarette factory workers, and provide up to \$250 million a year for rural economic development grants.

E. Funding

Although the settlement is advertised at \$368.5 billion, a variety of factors conspire to leave us with considerably less than that to spend on any new initiatives. The \$368 billion is a 25-year number, and must be adjusted downward to reflect a projected drop in cigarette consumption of about 15%. For scoring purposes, OMB adjusts the amount down still further to reflect lost business tax revenue and lost federal excise tax revenue from decreased consumption. Most of the rest of the money in the settlement is already spoken for, to pay for civil suits, cessation programs, counteradvertising, and the states' Medicaid claims. The main decision you will need to make is how best to spend the \$25 billion research trust fund, which most of us believe should be a 21st Century Research Fund dedicated to cancer and other tobacco-related research.

Some in the Administration (primarily the Treasury Department) and in Congress (led by Kennedy) believe the industry should be soaked for \$600-700 billion. This is probably a dealbreaker for the industry, but it would free up additional funds for new initiatives.

F: Other Issues

We will need to propose improvements in other, less prominent areas, which we will detail for you next week. These include limiting the industry's antitrust exemption to prevent unnecessary collusion and removing a little-noticed cap on punitives for future misconduct.

We will give you a more detailed memo on all these recommendations next week, and bring you up to date on our discussions with the industry, the Hill, and the public health community.

THE WHITE HOUSE
WASHINGTON

September 11, 1997

'97 SEP 12 AM 11:18

MEMORANDUM FOR THE PRESIDENT

FROM: Donna Shalala
Bruce Reed

SUBJECT: Tobacco

This memorandum (1) details the Administration process to review the proposed tobacco settlement; (2) describes the current context regarding tobacco; and (3) analyzes the substantive terms of the settlement and presents recommendations and options for an Administration proposal on tobacco.

I. ADMINISTRATION REVIEW OF SETTLEMENT

The Administration has engaged in an intensive review of the settlement on two fronts. Internally, four work groups were created and dozens of officials from across the Administration participated in their reviews. These work groups were: Regulatory Issues; Program and Budget Issues; Legal Issues; and, Industry Performance and Accountability Issues. They conducted a line-by-line analysis of the 68-page settlement document; in addition, they sought to explore alternative approaches to proposals contained in the settlement. This has not been done in an attempt to "fix" the settlement but rather to assess the adequacy of the settlement's provisions and to provide the Administration with the basis for articulating its positions and principles if a decision is made to encourage a legislative initiative.

Externally, the Vice President, Secretary Shalala and Bruce Reed met with individuals and groups representing a wide variety of views and interests to make certain that the Administration is aware of diverse viewpoints and has the benefit of expertise from outside the Administration. These consultations have been with public health and tobacco control organizations, state attorneys generals, tobacco industry lawyers, representatives of the smokeless and cigar industries, tobacco industry "whistle blowers," representatives of the retail, vending and the advertising industries, agricultural leaders from the Southeastern tobacco-growing states, and officials from the Brooke Group (Liggett). This broad range of viewpoints has informed the Administration's review and analysis. These consultations have made clear that any legislative proposal will be buffeted from many sides, several of which were not included in the negotiations among the state attorneys generals, plaintiffs' attorneys, and the tobacco industry.

II. EVENTS AND INTERESTS LIKELY TO SHAPE POLITICAL LANDSCAPE

While the proposed tobacco settlement presents the President with an opportunity to exercise again his leadership on this vital public health issue, there are many other factors beyond the settlement that shape the current landscape and will change it in the future. Some enhance the opportunity presented to the President; some limit it.

A. Public Health Community

Since the June announcement of the settlement, the public health community has become increasingly skeptical of the particular elements of the settlement and, more important, has become increasingly unified in their criticisms. At the same time, the public health community is willing to consider and back the possibility of a legislative solution. It should also be noted that the unity of the public health community can be easily fractured: While they generally agree on what's wrong with the settlement, they have different ideas on what good solutions would be.

The principal public health criticisms of the settlement are:

- Restricting FDA's authority in any fashion
- Proposing ineffective "look back" penalties on companies for not reducing underage smoking
- Limiting disclosure of industry documents
- Failing to increase the price of cigarettes sufficiently
- Preempting state and local restrictions that might be tougher than the settlement (the impact on additional state restrictions is unclear)
- Failing to address international tobacco control
- Limiting liability, i.e., eliminating past punitive damages and capping future punitive damages and eliminating class actions (The public health community will always have a lingering concern about limiting liability as the basis for a settlement. It is not only a desire to "punish" this industry, but also reflects a belief that the threat of litigation is needed to keep this industry in check.)

Moreover, there is a small but significant portion (American Lung Association, Stan Glantz, grass roots tobacco control groups like the state GASPS, and Public Citizen) of the public health community that believes the settlement should be scuttled entirely, not fixed. The public health community is well aware of all these tensions, and in fact, this community attempted to forge a consensus again in August. Representatives of 11 groups met August 8, and worked over the next two weeks to present the Administration with a consensus document. However, this "consensus" statement ended up saying little more than that the public health community would like to see a settlement reached and would be willing to work for it; they could not come to terms as to what the settlement should in fact look like. Also, this "consensus" statement does not preclude individual groups from identifying issues of particular

concern for them and actively seeking support in Congress for their viewpoint.

B. Lawsuits and Disclosure

A number of tobacco lawsuits are proceeding: the second-hand smoke lawsuit in Florida by the airline attendants; various private lawsuits, both individual suits and class-actions; and the Medicaid lawsuits by the states, most importantly those in Texas and Minnesota because of their timing. Any verdict against the tobacco industry will be widely viewed as another reason either not to negotiate with the industry or to take a stronger stance against the industry on several elements in the proposal. On the other hand, a verdict for the industry is likely to be seen as a reason to move forward with a legislative solution and weakening our position in any negotiations.

Just as important as the impact of any verdict is the disclosure issue raised by these lawsuits. Especially in the Medicaid lawsuit in Minnesota, state attorneys hold out the prospect of new industry documents coming to light that go far beyond any disclosed to date. In Florida and Minnesota, preliminary findings of fraud and criminal activity were made by either judges or special masters, and previously privileged documents are now being reviewed for public disclosure (in Florida, documents were disclosed in early August; in Minnesota, it is expected documents would become public by early 1998 when the case goes to trial). In addition, there is the possibility of indictments and trials because of ongoing DOJ criminal investigations and the resulting disclosure of secret documents in that process. Because no one really knows what is in the still secret documents, one concern is that they reveal activity that would generate such public outrage, that any accommodation with the industry would be seen as "selling out." In addition, some tie the disclosure issue to consideration of whether the immunity provisions of the settlement are adequate. Some Democrats, such as Sen. Patrick Leahy, take the position that any consideration of limiting liability has to be predicated on full disclosure of the documents.

Another factor on the legal front is the industry challenge to the FDA rule. Oral arguments on the appellate case were made in the Fourth Circuit on August 11, and two of the three judges voiced skepticism of the FDA rule. We do not know when the three-judge panel of the Fourth Circuit Court of Appeals will rule. Appeal to the en banc Fourth Circuit and the Supreme Court is available.

C. Congress

The Congressional horizon is receding into 1998 very quickly. In recent days, several Congressional leaders have said that legislative action on the settlement is unlikely in 1997. The Senate Republican leadership has made tentative plans to consider any tobacco legislation piecemeal, with at least six different committees having jurisdiction over parts of the settlement: Commerce, Judiciary, Labor, Agriculture, Environment and Public Works, and Finance. The

House Republican leadership has not indicated how it wants to proceed, although Rep. Richard Arney has said he expects similar divided consideration in the House. In the Senate and House, the Democratic leaderships are attempting to hold together tobacco-state and tobacco-control Democrats and present a united front. The potential of working with Congressional Democrats on this issue is very real and would give the Administration significant leverage in dealing with the GOP leadership.

D. Farmers

With regard to the Hill, the approach the Administration takes toward the issue of helping tobacco farmers may be the most significant. The settlement's failure to deal with tobacco farmers provides a significant opening for the Administration. Even some GOP members who have traditionally been supportive of the industry -- like Rep. Thomas Bliley -- are now saying their main concern will be helping their farm constituency. The farmers who in the past have provided substantial political cover to the industry can now be separated from the companies if they believe that will be in their best interest.

E. Affected Industries

In addition to the agricultural interests, several other segments of the economy are going to watch any settlement closely, e.g., hospitality industry with regard to environmental tobacco smoke (ETS), advertising and retail industries with regard to advertising and access restrictions, the asbestos industry and trial lawyers with regard to immunity. Each of these industries will have to make decisions on how a settlement affects its interests and when it wants to weigh in on the Hill. There is every indication that all of these industries will be very active and are already seeking to line up support for their cause on the Hill.

III. REVIEW OF SUBSTANTIVE ISSUES RAISED BY SETTLEMENT

The rest of this memorandum analyzes key aspects of the proposed settlement and highlights strengths and weaknesses. In providing this analysis, we do not mean to suggest that you should propose "fixes" to the settlement when you discuss tobacco legislation next week. To the contrary, we believe (though there are some strong arguments to the contrary) that you should set forth your own principles and plan for tobacco legislation. The following analysis, however, helps to illuminate some of the questions you will have to answer in deciding what to propose and communicating your views to the public.

One important note: This memorandum contains numerous representations as to what the tobacco industry is, or is not, willing to accept. These representations refer to what the tobacco industry is saying today. We have no reason to believe that these, in fact, are bottom line

positions of the industry.

A. FDA Authority

The first priority of the Administration in considering tobacco legislation should be to confirm and protect the jurisdiction of the FDA to regulate tobacco products -- including through the reduction or elimination of nicotine or other constituents.

Even as written, the settlement's provision on FDA jurisdiction had certain virtues. First, the provision specifically conferred jurisdiction to regulate tobacco products on the FDA, thereby removing the legal uncertainty now attending the FDA rule. Second, the provision established a "risk reduction" standard to guide the regulation of tobacco products in place of the "safety and efficacy" standard applicable to other drugs and devices. This change in standard could facilitate the FDA's regulation of tobacco products.

This provision of the settlement, however, also contained several glaring weaknesses. First, as you noted in your first comments on the settlement, the FDA would have to prove a negative in order to reduce or eliminate nicotine -- *i.e.*, that the action would not create a significant demand for contraband products. Second, the FDA could not eliminate nicotine for a period of 12 years. Third, the FDA could not take any action to modify tobacco products without surmounting a number of procedural hurdles -- *e.g.*, formal rulemakings -- not usually applicable to administrative action.

The public health community will demand -- and we believe the industry will grudgingly accept -- a legislative proposal that corrects these weaknesses. Any Administration proposal should eliminate the 12-year waiting period and the special procedural hurdles in the current settlement. It also should remove the necessity of the FDA's making a contraband finding. At one point, the industry proposed flipping the burden of proof on the contraband issue, so that the FDA could not take action if a party affirmatively demonstrated that doing so would create a significant contraband market. But even this approach puts too much weight on the contraband issue, which should be only one factor in the FDA's regulatory decisionmaking. To maintain maximum flexibility, one approach is to authorize the FDA to order changes to tobacco products based on a consideration of relevant factors, including relative risks to public health and technical feasibility.

Recommendation: Call for legislation preserving FDA authority over tobacco products, unencumbered by procedural or substantive criteria that may diminish that authority, and ensuring that FDA remains flexible to meet the future health challenges of tobacco.

B. Lookback Penalties

The settlement sets ambitious targets for reductions in teen smoking of 30% in 5 years.

50% in 7 years, and 60% in 10 years. The most recent data show underage prevalence at 18.2% in 1996, which means approximately 3.5 million youths aged 13-17 are daily smokers. Because the settlement targets are based on youth prevalence over the past decade, which has averaged 15.2%, the declines from current levels necessary to comply with the agreement would have to be 42% over 5 years, 58% over 7, and 67% over 10.

It is extremely difficult to predict how much teen smoking would decline under the settlement. While teen smokers are particularly sensitive to price -- Treasury has assumed that a price increase of 10% will reduce youth prevalence by 7% (compared to 2.6% for adults), and some studies suggest youth smoking will drop as much as 12% for every 10% increase in price -- we have never had a price shock of this magnitude. The Treasury Department estimates that the combined price rise from the current settlement and the 15-cent excise tax increase in the budget agreement would be about 80 cents by year 5, resulting in a 20% decrease from current youth smoking levels -- still well short of the settlement targets. Restrictions on access and advertising should reduce youth smoking still further, but no one can truly estimate the combined effect of price increases, access and advertising restrictions, and whatever activity the industry might undertake to counter these changes.

Under the settlement, companies would have to pay \$80 million for each percentage point they fall short, which is supposed to recapture the industry's projected profits from hooking that many young smokers. (The Treasury Department says a more accurate projection of profits would be \$60 million a point, which is roughly equal to \$80 million after taxes.) Public health groups have praised the idea of targets and penalties, but complain that the settlement does not give companies sufficient incentive to stop hooking teenagers. The major criticisms against the current penalties are that they are tax-deductible, abatable, capped at \$2 billion in a given year, not company-specific, and too small to serve as a deterrent.

The companies say that they could accept penalties of \$80 million a point that were not tax-deductible and could not be abated. They say they are unwilling to increase the price per point or to eliminate the \$2 billion annual cap.

One alternative approach would be to measure the number of teenagers who smoke a particular company's brands, and assess a company-by-company surcharge of \$1,000 (about 2 ½ times foregone profits) per teen smoker in excess of the youth reduction targets. A second approach would combine the company-by-company surcharge with a system of graduated penalties that get stiffer the more the industry misses the targets. For example, the industry could be required to pay \$200 million for each point missed between 0 and 30 percent, \$400 million for each point missed between 30 and 50 percent, and \$600 million for each point missed between 50 and 60 percent. Under this approach, the penalties could reach as high as \$1 a pack by year 10 if youth smoking failed to decline.

Recommendation: Call for legislation holding each tobacco company accountable for reducing the use of tobacco by youths and subjecting companies to serious financial loss for failing to

meet targets.

Alternative penalty schemes are outlined further in the charts on funding options attached to this memorandum.

C. Marketing, Advertising, and Labeling

The advertising and marketing restrictions in the settlement are very strong. They include all the restrictions in the FDA rule -- most notably, requirements of black-on-white advertising and bans on tobacco brand names in non-tobacco merchandise. The district court struck down these restrictions as inconsistent with the FDA's statutory authority, and the issue is not likely to be resolved quickly in court. The settlement also includes restrictions on advertising and marketing going far beyond the FDA rule, such as restrictions on point-of-sale advertising and bans on outdoor advertising, Internet advertising, the use of human images and cartoon characters, and payments for tobacco product placement in movies and other media. The Justice Department believes that all of these restrictions are highly vulnerable to constitutional challenge and that some flatly violate the First Amendment.

The Department of Justice believes that these additional restrictions on advertising should not be part of any legislation, but only of the consent decrees or other contracts entered into by the industry and Attorneys General. To the extent the restrictions are part of the legislation -- or seen as a condition of the legislation -- serious constitutional issues will arise. To the extent the restrictions are part only of the settlement agreements, their chance of being upheld would be significantly increased. (Larry Tribe, among others, believes that so long as the advertising restrictions are a function only of consent decrees and private agreements, they raise *no* constitutional issues. The Justice Department, by contrast, thinks that a court *might* strike down these advertising restrictions, even if included only in consent decrees or contracts, on the ground that the government coerced the companies to enter into these contracts in an effort to accomplish indirectly what it could not do directly.)

Assuming the advertising restrictions are included in consent decrees and agreements, serious questions relating to enforcement of the advertising restrictions arise. Each Attorney General settling a suit by consent would be able to enforce the restrictions in his or her state. But what of states in which there is no consent decree? Or what of states with inattentive Attorneys General? The proposed settlement agreement makes reference to a binding "national protocol" -- a contract designed to enhance enforcement of the advertising restrictions (and other provisions) in the consent decrees. But there is no consensus on precisely who will sign the protocol or how it will work in practice. As the legislative process unfolds, we must keep a close eye on this scheme -- and especially on any legislative references to it -- to ensure that it provides an effective mechanism for enforcing the advertising restrictions while not increasing the vulnerability of the restrictions to constitutional challenge (by making their enforcement something other than a matter of simple contract law).

We also should insist on statutory confirmation of FDA authority over the advertising and marketing of tobacco products, as part of our broader effort to secure legislation conferring full regulatory authority on the FDA. This grant of authority is valuable even though the settlement agreements will go further than the FDA could, precisely because the FDA probably will not have authority to enforce the contracts between the industry and the states. With a specific grant of authority, the FDA itself could enforce the restrictions contained in its 1996 rule, as well as any other constitutionally permissible restrictions it might wish to impose in the future.

In addition to including restrictions on advertising, the settlement contains provisions to require "Canadian-style" warning labels -- i.e., strengthened warnings (such as "cigarettes cause cancer" and "smoking can kill you") that appear on 25% of the front or display panel of tobacco products, printed in alternating black-on-white or white-on-black type. These provisions would strengthen significantly the existing warning labels, both in the starkness of the message and in its size and placement on tobacco products.

Recommendation: Call for legislation making explicit FDA authority to regulate the advertising of tobacco products and toughening warning labels on cigarette products. (Make limited reference to the tobacco industry's agreement to restrict advertising and do not say anything to suggest that this agreement is a condition of legislation.)

D. Access and Licensing

The access and licensing provisions of the settlement significantly enhance the ability of the government to prevent youth access to tobacco products. The current FDA rule establishes 18 as the federal minimum age of sale, requires retailers to check photo identification of anyone under 27, bans vending machines and self-service displays from actual establishments accessible to children, and eliminates free samples and the sale of single cigarettes. The proposed settlement incorporates these access restrictions while also banning all cigarette vending machines and requiring tobacco products to be placed out of reach of consumers in any facility that children may enter. Even more important, the settlement would establish a retail licensing scheme to enforce these access restrictions. FDA and Treasury agree that such a system will significantly further your goal of reducing youth access to tobacco. Assuming adequate funding, legislation creating a licensing system could count as one of the principal virtues of the settlement agreement.

As written, however, the licensing provision of the settlement contains some important ambiguities. Most critically, the settlement is vague as to who -- state authorities, federal authorities, or some combination of the two -- will administer the licensing scheme. We are not yet in a position to make a final recommendation on this question. FDA's current inclination is to give responsibility for running the scheme to the states, but to retain the power to revoke licenses. We are not yet sure whether such an approach would work as a practical matter; neither are we certain whether it could be accomplished consistently with the Constitution. Rather than

recommending a specific scheme, we should commit only to working with Congress and the Attorneys General on this question.

The settlement's licensing provision also now contains an inadequate penalty structure. Most troublesome, the settlement provides for permanent license revocation only after a licensee's tenth offense within two years. Because licensing officials are unlikely to conduct ten compliance checks on a single retailer in a two-year time frame, this provision is essentially meaningless. We should insist on strengthening the penalty scheme -- including by making mandatory revocation a real weapon -- without getting into a level of detail unsuitable at this stage of the process.

These provisions are not particularly high-profile. They have not attracted much attention, and nothing we say about them will alter the politics of the deal in either direction. But the provisions, if strengthened and clarified along the lines suggested, could prove one of the virtues of enacting tobacco legislation.

Recommendation: Call for legislation imposing strong access restrictions and establishing an effective retail licensing scheme with tough penalties.

E. Documents

For decades, the tobacco industry has failed to disclose essential facts in its possession about the dangers and addictiveness of tobacco products. In particular, the industry has used both the attorney-client and the work product privileges to cloak scientific research and findings -- and possibly to shield evidence of criminal or fraudulent behavior. The Attorneys General attempted to address this issue through creation of a special court to resolve all privilege claims made by the industry. Although the proposed system has certain virtues, it also suffers from serious defects. The industry is willing to make certain minor changes in the proposed scheme, but will not accept changes recommended by the Justice Department and FDA. Even these changes will not satisfy the harshest critics of the settlement, such as Skip Humphrey.

The settlement calls for a national document depository and a three-judge panel (appointed by the Judicial Conference of the United States) to provide expedited rulings on whether documents should remain privileged. The Attorneys General fought hard for this provision for two essential reasons. First, anyone -- not just a litigant, but any member of the public (including the New York Times or David Kessler) -- could ask the panel to review allegedly privileged documents. In this sense, the settlement establishes a Freedom of Information Act for tobacco documents. Second, the requester would not have to make the normal showing required in litigation for *in camera* review of a document: a *prima facie* case that the document is not privileged -- because, for example, it advanced a scheme of crime or fraud.

The Justice Department, however, believes that this scheme, adopted without change, would pose serious dangers. DOJ points out that no one knows whether or how this panel will work -- whether the judges (or special masters appointed by them) will be competent; whether they will be so swamped with document requests as to create an enormous backlog; whether they will favor one side over the other. DOJ also notes that this panel will have sole authority to rule on claims of privilege. While under the current system many courts may adjudicate a claim of privilege (with a finding of privilege in one court often not precluding the opposite finding in another), the special three-judge panel's decisions would be binding in all courts in all litigation in the United States. On top of these Justice Department concerns, the FDA should have access to all documents -- even those rightfully privileged -- to determine whether they contain scientific or other health-related information (for example, reflecting the industry's extensive research on nicotine addiction) relevant to the regulation of tobacco products.

To meet these agency concerns, the Administration could offer alternative disclosure provisions. First, we could make any administrative disclosure process non-exclusive, so that a litigant could challenge a privilege claim in litigation even if the special panel had not completed review of the document in question or had ruled in favor of the company. (By contrast, a finding by the special panel that a document is not privileged would bind the company in all other proceedings.) Second, we could provide the FDA with access to all health-related documents, notwithstanding any claims of privilege.

The industry claims that it will not accept either of these changes, though it will accept a scheme allowing courts to rule on a privilege claim if the special panel has not yet done so. The industry also proposes adding a provision to the settlement to require each company to identify and disclose all health-related information contained in privileged documents, without turning over the documents themselves. Under this proposal, the special panel could find that a company had failed to disclose such information and levy substantial penalties. Finally, the industry has expressed a willingness to consider a different scheme for selecting the people to sit on the special panel.

On the other side, some in Congress and the public health community will find even the alternative provisions described above to be inadequate. These changes do not broadly abrogate the industry's attorney-client or work-product privileges. The Justice Department has expressed serious concerns about any such breach of the privilege, arguing that such an approach would undermine the privilege generally and would enable a tobacco company official charged with criminal conduct to assert a violation of his Sixth Amendment right to effective assistance of counsel. But some will demand the complete abrogation of the companies' attorney-client privilege as a term of the settlement -- or, even more broadly, insist (as Sen. Leahy, Rep. Waxman, and Attorney General Skip Humphrey already have done) that the tobacco companies disclose all privileged documents before any consideration of a settlement takes place.

Recommendation: Call for legislation ensuring broad disclosure of tobacco industry documents.

Options:

- A. Call for legislation creating exclusive document depository system and compelling release of scientific and other health-related information in allegedly privileged documents (but not documents themselves).
- B. Call for legislation creating non-exclusive document depository system, compelling release of scientific and other health-related information in allegedly privileged documents, and providing the FDA with access to all such documents.
- C. Call for legislation requiring full public disclosure of all allegedly privileged documents.

F. Environmental Tobacco Smoke

The best available scientific evidence indicates that environmental tobacco smoke (ETS) causes disease and death in non-smokers. The Environmental Protection Agency (EPA) classifies ETS as a Class A carcinogen and estimates that it is responsible for about 3,000 lung cancer deaths each year in non-smoking adults. The EPA also has found that ETS threatens the health of hundreds of thousands of children with asthma and other respiratory illnesses. Serious ETS restrictions, which ban smoking in public places or at work except in enclosed areas exhausted directly to the outside, reduce exposure to ETS and the harm it causes. At the same time, such restrictions lead many smokers to quit smoking entirely and many more to cut down. Indeed, among the many smoking cessation tools -- including substantial price increases -- ETS restrictions may well be the most effective.

All agree that the settlement's provision on ETS is extremely valuable. The proposed legislation would broadly prohibit smoking in public places, without preempting even stricter state or local laws. A remaining question is whether to exempt restaurants (but not fast food restaurants); bars, private clubs, hotel guest rooms, casinos, bingo parlors, and tobacco merchants from a broad ETS restriction. H.R. 3434, which the Administration supported, exempts restaurants (including fast food restaurants) and bars. The proposed rule on ETS that OSHA issued in 1994 does not include any exemption for the hospitality industry. HHS would prefer to cut back on the exception in the settlement, noting that many of the exempted work places pose the greatest threat to non-smokers. The Department of Labor (OSHA) would keep the exemption essentially as is on the ground that trying to include restaurants, casinos, etc. would make the whole provision politically unsalable.

Recommendation: Call for legislation imposing strict restrictions on smoking in public places.

Option: Include exception for some or all the hospitality industry (restaurants, casinos, etc.)

G. Liability and Other Legal Issues

The price of everything in the settlement agreement is, of course, protection from civil liability. The settlement limits total liability to \$5 billion each year (with any unspent portion of a base \$4 billion fund reverting to the government), prohibits class action and other joinder and consolidation devices, and eliminates punitive damage claims (but requires a payment of billions of dollars in punitive damages directly payable to the public). There is little doubt about the value of these provisions to the tobacco companies.

On the other hand, there is some debate about whether these provisions harm public health interests. The tort system, of course, generally serves to deter conduct that causes injury to health and safety. Many in the public health community believe that imposing caps on damages, eliminating punitive damages and barring class actions will diminish this deterrent effect and encourage the industry to cause still further harm. Others believe that these changes will not reduce deterrence (recall that \$5 billion in annual compensatory damages is \$5 billion more than the industry has ever paid before) — or at least that they are more than outweighed by provisions putting into effect a comprehensive regulatory scheme to regulate future behavior. They also argue that making the companies pay a punitive damage award for past misconduct to the public (for use in health research, etc.) makes far more sense from a public health perspective than allowing such funds to go as windfalls to individual plaintiffs.

The Justice Department believes that we would further advance public health interests by insisting on the removal of any limits on punitive damages for future misconduct. In DOJ's view, we should make clear that plaintiffs can seek such awards, and that these awards shall not count toward or be subject to yearly limits. The continued potential for unrestricted punitive damages will support the regulatory aspects of the legislation in deterring willful misconduct and otherwise changing corporate behavior. At the same time, this change will enable the legal system to punish the industry, over and above compensatory damages, for any future misbehavior.

DOJ also has urged us to consider some changes to the prohibition on class actions, joinder, consolidation, and other aggregation devices. The first point to make about this prohibition is that there is a substantial risk that it would be invalidated as applied to state courts for violating the Tenth Amendment. Any provision of this kind thus would have to be accompanied by explicit severance language. In addition, DOJ would like to define the ban on aggregation more narrowly — in particular, to allow some consolidation of cases prior to trial for purposes of conducting discovery and adjudicating pre-trial motions. This change, which would entail amendment of the current multidistrict litigation statute, would allow individual plaintiffs to share discovery materials and reduce discovery and other pre-trial costs. The industry apparently will resist any change to the provision on class actions, joinder, and consolidation. But given the cap on annual damages, it is hard to see why such changes matter so much to the industry. Moreover, the industry may see consolidation schemes of the kind DOJ would like to protect as less threatening than mechanisms (whether class actions or joinder rules) that

permanently tie many cases together, letting numerous "bad facts" cases ride in the wake of a couple of "good facts" cases all the way to judgment.

The FTC and Antitrust Division of the Justice Department are both concerned about the breadth of the antitrust exemption contained in the proposed settlement agreement, noting that it might protect such activities as price-fixing, mergers to monopoly, predatory pricing, and agreements not to produce reduced-risk products. The FTC and Antitrust Division note that they presumptively disfavor exemptions to the antitrust laws and that any exemption for tobacco companies must be limited to what is strictly necessary to serve the purposes of our tobacco proposal. Though we do not have specific language, the general idea would be to allow collusion only where strictly necessary to accomplish the purpose of reducing youth smoking.

We also must insist that neither the settlement nor any eventual legislation (including provisions relating to documents) will apply to or have preclusive effect on federal grand jury investigations or criminal prosecutions. In particular, the settlements and legislation should include a so-called "Halper provision," by which the participating companies waive any argument that the civil penalties in the settlement constitute a bar under the double jeopardy clause to criminal prosecution.

Finally, the preemption provisions of the proposed settlement are among its most baffling aspects — muddled, internally contradictory, and seemingly senseless. We should try to clarify them so that they preserve current FDA authority, while enabling states in appropriate circumstances to go beyond the provisions of the settlement agreement. More specifically, where existing law requires states to petition the FDA to regulate tobacco, states would remain under that obligation and the FDA would retain its current authority; where existing law allows states to regulate tobacco on their own, states could impose any regulations more stringent than the new federal standards. It is very difficult to know how much (if at all) this scheme deviates from what the drafters of the settlement intended. In any case, it is hard to imagine that the issue would drive any party from the table.

Recommendation: Condition limits on liability and aggregation (class actions, etc.) on complete satisfaction of all other demands. Make clear that federal legislation cannot in any way affect criminal prosecutions or more stringent state regulation.

H. Farmers

We have made clear that tobacco farmers should receive protection in any legislative settlement, and that the Administration will work closely with members of Congress from tobacco states to forge a consensus. Secretary Glickman has traveled to tobacco markets in Virginia and North Carolina to express this commitment directly to farmers.

Farmers are interested in continuation of the governmental tobacco program, guaranteed

purchase at set levels of tobacco crops by cigarette companies, and some provision for buy out and transition to other crops, on a voluntary basis. Farm groups and tobacco state members have not yet coalesced around a consensus proposal. One plan put forward this month by Senators Ford and McConnell would require companies to buy a minimum amount of domestic tobacco over 25 years and would install penalties on companies that do not meet the stated goals for tobacco buying. The proposal would also create a "Tobacco Community Revitalization Fund" administered by USDA, but not subject to the appropriation process, which could spend up to \$1 billion a year for 25 years from the settlement fund. This Revitalization Fund would cover costs related to the tobacco program such as administration and crop insurance, make supplemental payments of up to \$500 million to producers whose income from tobacco drops substantially below the 1996 level, pay up to \$100 million in benefits for displaced cigarette factory workers, and provide up to \$250 million a year for rural economic development grants.

Recommendation: Vow to protect tobacco farmers and communities in tobacco legislation.

I. International Issues

As you know, the settlement does not address international sale of tobacco products. Public health groups have criticized this aspect of the settlement; more broadly, they are pushing for the United States to take a leadership role in fighting tobacco's rapid global growth. Worldwide, there are 3 million tobacco-related deaths annually, and the World Health Organization expects that number to rise to 10 million by 2025, with 75% of annual deaths occurring in developing countries.

Some have suggested changes to normal trade policy as a response to the global spread of tobacco. USTR's current policy is to fight discriminatory barriers on behalf of all industries, including tobacco. One proposal is for USTR to stop providing such assistance to tobacco companies, on the ground that the entry of U.S. tobacco companies into foreign countries has arguably increased tobacco consumption. Your trade advisors, however, do not believe that we should take such action at this time.

As you noted just after announcement of the settlement, the United States can act by example in the area of tobacco control. That means, first and foremost, adopting policies to reduce smoking in this country. In addition, it means strengthening the Administration's leadership role in global and bilateral efforts to reduce smoking, including by providing assistance to international organizations. Finally, and at the very least, it means that U.S. embassies and missions act consistent with domestic policies by curtailing their involvement in tobacco marketing and export promotion activities. HHS is working with the Departments of State and Commerce on new guidelines on this issue.

Recommendation: Support efforts by other countries and international organizations to reduce smoking around the world.

J. Funding

Although the settlement is advertised at \$368.5 billion, a variety of factors conspire to leave us with considerably less than that to spend on any new initiatives. The \$368 billion is a 25-year number, and must be adjusted downward to reflect a projected drop in cigarette consumption of about 15%. For scoring purposes, OMB adjusts the amount down still further to reflect lost business tax revenue and lost federal excise tax revenue from decreased consumption. Most of the rest of the money in the settlement is already spoken for, to pay for civil suits, cessation programs, counteradvertising, and the states' Medicaid claims. No specific provision is made to reimburse the federal government for its Medicaid or Medicare expenses.

Options for How Much the Industry Should Pay

The attached charts outlines options on how much funding to seek and how to spend it. A chart attached to this memo suggests four options for how much the industry should pay:

1. **Current settlement:** This option assumes repeal of the \$50 billion tax credit in the budget agreement, restoring gross industry payments to the original level negotiated by the attorneys general -- \$368 billion over 25 years, with lookback penalties of up to \$32 billion over that period. This option would raise cigarette prices by approximately 60 cents a pack (on top of the 15-cent increase in the budget agreement).

2. **Tough penalties:** This option assumes the full level of base payments in Option 1 (\$368 billion), with dramatically tougher penalties on the industry if it fails to reduce teen smoking (which could raise up to \$303 billion over 25 years). These penalties would include a company-by-company surcharge, as well as stiff penalties of up to \$1 a pack. The entire option would raise cigarette prices between 60 cents and \$1.60 a pack, depending on the industry's success in reducing teen smoking.

3. **Restore promised investment revenues:** This option assumes the amount of payments necessary to fund additional public health investments at a level that reflects what some supporters of the original settlement said would be available. Under this option, the industry would make gross payments of \$620 billion over 25 years. This option includes the company-by-company surcharge, but not the steeper youth penalties. This option would raise cigarette prices by \$1 a pack.

4. **\$1.50 per pack:** This option assumes the level of industry payments necessary to increase cigarette prices by \$1.50 a pack right away, which David Kessler and Rep. Waxman have urged. Under this option, the industry would make gross payments of \$943 billion over 25 years.

Ways to Spend Additional Funding

The current settlement would fund a variety of public health initiatives, including a counteradvertising campaign; smoking cessation programs; FDA enforcement; other tobacco control efforts; and a \$4-billion-a-year trust fund that could serve as a 21st Century Research Fund dedicated to biomedical and tobacco-related research.

A chart attached to this memorandum outlines possible uses for additional funds, if any.

POTUS
Memo

THE WHITE HOUSE
WASHINGTON
October 8, 1997

MEMORANDUM TO THE PRESIDENT

cc: Vice President, Erskine Bowles, Bruce Reed, Gene Sperling
FROM: Chris Jennings
RE: **NEW YORK AND THE PROVIDER TAX ISSUE**

Tomorrow, DHHS will announce the results of its policy review of Medicaid provider taxes and its policy changes regarding New York. In brief, they will announce (1) policy clarifications that include clarify that certain provider taxes previously in question, including New York's regional tax, are permissible; and (2) support for legislation that expedites identifying impermissible taxes and ending their use. This is the culmination of an intensive process that involved HHS, OMB, DPC/NEC, Legislative and Intergovernmental Affairs, the Office of the Vice President and other senior staff. This memo provides you with detailed information on the policy review, subsequent actions, and the roll out plans.

BACKGROUND

Financing scheme and the law limiting it. During the late 1980s, many States established financing schemes that had the effect of increasing their Federal Medicaid funds without using additional State resources. Typically, States would raise funds from health care providers (through provider taxes or "donations"), then pay back those providers through increased Medicaid payments. Since the Federal government pays at least half of Medicaid payments, the provider taxes or donations would be repaid in large part by Federal matching payments. Using this mechanism, the State was left with a net gain because it only had to repay part of the provider tax or donation it originally received.

Because provider taxes and donations were effectively siphoning off potentially billions of dollars from the Federal Treasury, the Congress limited states' use of these schemes in a bill enacted by President Bush in 1991. The subsequent regulatory interpretation of these limits was, as you know, negotiated with the states and the National Governors' Association in 1993.

States' continued reliance on impermissible provider taxes and our enforcement record. Despite the new law and the regulations, many states continued to use provider taxes that at least appeared to be out of compliance. To date, these possibly impermissible taxes total an estimated \$2 to 4 billion and, in the future, could cost billions more. In response, HCFA issued letters and discussed its concerns about certain taxes with states, but -- for a variety of reasons -- never took any final action. Unfortunately, this has meant that a number of states continue using these taxes, believing that HCFA might never enforce the law, or that if they did, they could seek recourse through the White House or the Congress.

Consequently, we think that the best way to bring states to the negotiations is through reliance on a legislative strategy. By strengthening the Secretary's ability to negotiate, we avoid the uncertainty inherent in an ordinary administrative process. By stating what type of legislation we would support, we get ahead of the rifle shots and possibly prevent them, as well as to get the Congress invested in developing a mutual solution to the provider tax mess. And by offering to clarify our ways of identifying impermissible taxes, we may engage states that have concerns about our interpretation, thus possibly preventing suits. These incentives are reinforced by threat of a deadline for passage of such legislation (August 1998) that triggers an aggressive enforcement action by HCFA.

Reaction from New York. DHHS's review produces good news for New York. One of New York's major concerns have been that Medicaid regulations have not grandfathered the State's "regional" tax. Given evidence of Congressional intent for this tax treatment, the Administration has published a clarifying amendment to the regulation in today's *Federal Register*. This action relieves New York of over \$1 billion of provider tax liability.

However, there will be no final resolution on New York's other provider taxes. The New York delegation has already put us on notice that nothing less than a "hold harmless" solution is acceptable. They define this as meaning that they want us to waive all current taxes both retrospectively and prospectively; in other words, they want the provisions we line-item vetoed. Thus, even though there is good news for the state, it will almost certainly be viewed as insufficient.

Reaction from other states. Although nine other states benefit from the new policy clarifications, it is news of our support for legislation that will catch states' attention. The dozen or so states that have widely used provider taxes may view this positively. It is these states that we want to engage in discussion and eventually negotiations. However, the remaining states that either ended their provider tax use or who never used them to begin with may view our action as too conciliatory. We will make sure that we communicate to states that we have not -- and will not -- change our opposition to the use of provider taxes. We are simply looking for the most effective way to end states' reliance on impermissible taxes.

Roll-out strategy. The timing of briefings on this tax issue is crucial given the political sensitivity in New York. Since the Vice President is in New York until 4pm that day, we are scheduling this briefing for 3:30 (tentatively). Donna called the Governor last night to tell him that we would meet with his staff on Thursday afternoon. Gene sent a similar message to Charlie Rangel last night with a consistent message and we have also notified other key members of the New York delegation. HHS has also planned briefings for committees of jurisdiction, the NGA, and other interested parties later in the afternoon.

Because of New York's media market, there is no question that tomorrow's announcement will attract significant coverage. We do believe, however, that the approach we are taking represents the best way to start a long-overdue process of eliminating impermissible provider taxes from the Medicaid program. We will keep you apprised of developments.

Quality Commission File

THE WHITE HOUSE
WASHINGTON

November 18, 1997

MEMORANDUM TO THE PRESIDENT

FROM: Chris Jennings

SUBJECT: Quality Commission's "Consumer Bill of Rights"

cc: Rahm Emanuel, Bruce Reed, Gene Sperling, Ann Lewis, Elena Kagan

On Thursday, you are scheduled to accept the Quality Commission's "consumer bill of rights." In preparation for the release of this much anticipated report, this memo provides background on the Commission, summarizes its key recommendations, and outlines how the Hill, influential interest groups and the elite validators are positioning themselves on the quality issue. It also summarizes our suggestions on how you might best respond to the Commission's first report.

Background. In response to growing concerns about quality shortcomings in the rapidly changing health care system, you pledged to establish a Quality Commission during the 1996 campaign. In March of this year, you unveiled the 34-Member Advisory Commission on Quality and Consumer Protection. This Commission has a broad-based membership of business, labor, provider, consumer, insurer/HMO, and state and local representatives, is co-chaired by Secretary Herman and Secretary Shalala, and is required to report to you through the Vice President.

At the Commission's inception, you asked the members to produce -- as their first order of business -- recommendations for a "consumer bill of rights." This week they are responding to that charge by releasing their final report on this issue. Their preliminary recommendations received widespread acclaim by the elites. They achieved this by balancing the desires of the consumer advocates and providers against the fears of the insurers and business community. Not surprisingly, the former generally felt the recommendations did not go far enough and the latter concluded they generally went too far.

The Commission was structured to end up to the middle/left of this debate from the beginning, as Donna and Alexis insisted that all final recommendations be done on a purely consensus basis. But what really assured that the business and insurer community would not make excessively loud complaints was the Commission's decision to push off making recommendations regarding how the "rights" would be enforced. It may or may not be able to resolve the Federal enforcement issue by the time the final report is released next March. (That report will also include recommendations that could have the most long-lasting impact on the health care delivery system; it will focus on how to measure and actually improve quality outcomes.)

Response to Cost/Coverage Loss Argument. In response to cost concerns raised by the business and insurer representatives, Lewin ICF (an analytical consulting firm) was commissioned by the Quality Commission to evaluate the cost impact of the two "consumer bill of rights" provisions that the Commission believed had the most potential to increase premiums -- the information disclosure and consumer appeals requirements. The study concluded, in a report that was released to the Commission members today, that the provisions would increase the cost of premiums by about 90 cents per month per beneficiary. While these numbers are preliminary and should not be used as the standard by which all consumer protection provisions are evaluated, they are extremely encouraging. Most important, these projections go a long way to undermining the HIAA/NFIB/Republican Leadership argument that consumer protections will increase premiums by "90 percent" and will reduce insurance coverage.

"Elites" Reaction to Quality Commission. To date, the elite validators have been quite impressed with the work of the Quality Commission. They perceive it to have made strong, but reasonable recommendations on the consumer protections front; interestingly, the experts view the Norwood bill as much more reckless, far-reaching, regulatory and costly. As you appropriately move to endorse a legislative approach, however, some of the validators will be quick to get nervous and will inevitably raise concerns. They, (and some Members of Congress), will also urge specificity on our position regarding enforcement and remedies. (These are the most divisive issues for the big business community.) While we will have to be responsive to some degree, we would be wise to not fall into the trap of sending legislative language to the Hill. Instead, we probably should work with the Hill to see where the consensus emerges and provide technical and political support to that end.

Thursday Event and Your Remarks. Your remarks on Thursday will culminate a very busy week on quality and consumer protections. Today, the Vice President joined the *Journal of the American Medical Association (JAMA)* in announcing their release of this month's edition, which is totally dedicated to the quality issue. Tomorrow, the Quality Commission will conclude the day with an expected final and unanimous approval of their well-received recommendations. And Thursday, we are designing a relatively brief ceremony marking the transmission of the Commission's "consumer bill of rights" and your reaction to it.

The Vice President will open the Thursday event by summarizing the Administration's accomplishments in this area. A consumer representative, who is disabled himself, will summarize the eight consumer rights and discuss their importance to all patients. His remarks will be followed by the actual presentation of the "consumer bill of rights" to you by Donna Shalala and Alexis Herman.

We will be suggesting that your remarks have a four-pronged message: First, you will accept the bill of rights and endorse them as an excellent framework for a long overdue national standard of consumer protections to help Americans navigate through a rapidly changing health care system; Second, you will challenge all private health plans to adopt and implement the Commission's bill of rights as soon as possible; Third, you will call on the Congress to pass -- before they adjourn next year -- appropriate Federal legislation to make certain the consumer protections are real for all Americans and to assure that the public's confidence in their health care system is restored; And fourth, you will direct all the agencies with jurisdiction over health care to exhaust every possible administrative action to assure that the programs they administer, and the plans they oversee, come into compliance with the bill of rights. You will also instruct them to report back to you by February what steps they have taken and plan to take in this regard, as well as to indicate what statutory limitations impede their ability to come into full compliance.

THE WHITE HOUSE
WASHINGTON

December 8, 1997

MEMORANDUM FOR THE PRESIDENT

FROM: BRUCE REED
CHRIS JENNINGS

SUBJECT: New AIDS Initiative

We have developed a \$115 million initiative for your FY 1999 budget to improve AIDS treatment and prevention programs. This increase would go to expand programs that are critical to preventing and treating this epidemic, including the AIDS Assistance Drugs Program (ADAP), which extends life-saving new treatment therapies to low-income and underserved populations.

Background on AIDS Funding

Since you came into office, AIDS programs that focus on treatment and prevention have improved dramatically. Medicaid, which provides coverage for half of all people with AIDS, now covers protease inhibitors. Funding for the Ryan White Program has increased by 200 percent since FY1993, funding for research at NIH has increased by 50 percent since that year, and funding for the ADAP program has increased 450 percent since 1996.

The AIDS community, however, has expressed disappointment with the Administration's recent efforts in this area. AIDS groups criticized the Administration for failing to propose major increases in discretionary spending in FY1998, which allowed Congress to outspend us in this area. And in just the last few weeks, the AIDS community reacted negatively to HCFA's conclusion that budget neutrality requirements prohibit establishing a Medicaid demonstration to provide early treatment to relatively healthy HIV-infected individuals. There is no doubt that the AIDS community will be examining the Administration's FY 1999 budget submission very closely.

Proposal

The AIDS office is recommending, and we agree, that you propose an \$115 million increase in your FY 1999 budget for AIDS treatment and prevention. (OMB is currently recommending \$100 million). All of this spending would go to existing discretionary programs that emphasize prevention and treatment. We would recommend that the majority of this increase go to the ADAP program, because new and effective treatments of this disease are currently not reaching many who need them. We also would recommend modest increases to CDC prevention education programs, as well as a range of programs providing funds to states,

cities, and community health centers.

Although the \$115 million that we are suggesting falls far short of the \$400 million the AIDS advocates are pushing, it is a significant investment that will improve AIDS treatment and prevention and soften criticism from the community.

Finally, in the wake of HCFA's decision on the Medicaid demonstration program discussed above, Nancy-Ann Min DeParle is looking into the possibility of a legislative proposal (which of course need not be budget neutral) for a model pilot project to expand eligibility to Medicaid for people with HIV earlier in the progression of their disease. As of this writing, we have significant questions about whether such a proposal is feasible and whether it could be done in time for the budget process. At the request of the Vice President, however, we are reviewing all options in this area closely.

THE WHITE HOUSE
WASHINGTON

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December 13, 1997

MEMORANDUM FOR THE PRESIDENT

FROM: BRUCE REED
GENE SPERLING
CHRIS JENNINGS

12-29-97

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SUBJECT: Health Insurance Coverage Initiatives

Throughout your Administration, you have worked to enact legislation to expand access to affordable health insurance. The Balanced Budget Act included an unprecedented \$24 billion investment for state-based children's health insurance programs. This historic initiative will clearly reduce the number of uninsured. However, there are other deserving populations whom we could target in our step-by-step reforms. These include the pre-65 year olds (referenced in the Medicare memo), workers between jobs, and workers in small businesses. In addition, we are working on possible proposals to expand Medicaid coverage to people with AIDS and disabilities through pilot programs. The policy development of these proposals is still underway, so we have not included them here.

Taken together, these initiatives total around \$10 billion over 5 years. This amount is less than half of the health investments enacted as part of the Balanced Budget Act and less than 4 percent of the premium assistance proposed in the Health Security Act. Having said this, none of your advisors believe the Medicare and Medicaid savings left after last year's deficit reduction effort are sufficient to fund these initiatives. There may be \$0.5 to 1 billion over 5 years in Medicaid savings, but those savings will be difficult to achieve and there may be other claims on them (e.g., child care, benefits to immigrants). Another possible source of funds is the tobacco settlement, given the natural link between tobacco and health care.

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Your advisors uniformly agree that we need to take all actions possible to achieve if not exceed your goal of increasing insurance coverage for 5 million children. A series of proposals are described in this memo to help accomplish that goal. There is less agreement on whether we should address a new group of uninsured people in this budget. The Department of Labor strongly supports the workers-between-jobs demonstration; of all health initiatives in the budget, it is their highest priority. OMB also supports that demonstration if sufficient funds are available. HHS believes that this proposal has merit, but is skeptical that it will attract any more support than it has in the past three years.

A. CHILDREN'S HEALTH OUTREACH

The Children's Health Insurance Program (CHIP) provides funds for coverage of millions of working families' uninsured children, a population that previously had trouble affording coverage. It also builds upon the Medicaid program, which covers nearly 20 million children. But important work remains to be done. In particular, we need to work with states to enroll the millions of uninsured children in these programs.

Medicaid eligible children are especially at risk of remaining uninsured. Over three million uninsured children are eligible for Medicaid. Educating families about their options and enrolling them in Medicaid has always been a problem, but it has recently become even more challenging. The number of children covered by Medicaid leveled off in 1995 and, according to the Census, dropped by 6 percent in 1996. While some of this decline may be due to the lower number of children in poverty, another part may result from families' misunderstanding of their children's continued eligibility for Medicaid in the wake of welfare reform.

Options to Increase Outreach for Medicaid and the Children's Health Insurance Program

To address the need for children's health outreach, we propose a series of policy options. Together, these initiatives could cost \$1 to 2 billion over five years (or more depending on policy choices about the enhanced match). Preliminary discussions with NGA and some children's advocates suggest they strongly support these efforts. In addition, the Administration is developing partnerships to encourage a complementary range of private outreach activities.

Enhanced match for outreach. One option for improving state outreach is to provide an enhanced match to enroll children who are eligible for but not previously enrolled in Medicaid. At the end of each year, if a state can document that it has increased its enrollment over its baseline, it would receive an increased matching amount per newly covered child (possibly through administrative payments). This policy rewards states only if they succeed in outreach, rather than matching activities that may or may not work. Depending on the amount of the incentive and the administrative design, this option could cost to \$0.5 to 1 billion over five years.

Moving outreach to schools and child care sites. We could build upon the "presumptive eligibility" provision in the Balanced Budget Act to make it easier to enroll children in Medicaid and CHIP. The BBA option allows limited sites (e.g., hospitals) to give low-income children temporary Medicaid coverage on the spot while they are formally enrolled in CHIP or Medicaid. This proposal would broaden these sites to include schools, appropriate child care sites, and Head Start sites, at the state's option. HCFA actuaries preliminarily estimate that this proposal would cost \$400 million over 5 years. Also, under the BBA, states that use presumptive eligibility must pay for its costs out of the CHIP allotment, reducing the amount available for other coverage. States have advised us that this requirement discourages them from taking advantage of the presumptive eligibility provision. HCFA actuaries preliminarily estimate that dropping this requirement would cost \$25 million over 5 years.

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Accessing 90 percent matching funds for outreach. A third way to increase funding for children's health outreach is to increase states' flexibility in using a special Medicaid fund set aside in TANF for outreach for children losing welfare. This \$500 million fund is currently allocated to states with a 90 percent matching rate for outreach activities to certain children. We could expand its use to all children, not just welfare children. HCFA actuaries preliminarily estimate that this policy would cost \$100 million over 5 years. NGA supports this change.

Simplifying enrollment. A simple, accessible enrollment process could encourage more families to enroll their children in Medicaid or CHIP. To help create such a process, we propose several actions, all of which are inexpensive. First, we could streamline the application process by simplifying Medicaid eligibility and by encouraging the use of simple, mail-in applications. HCFA has already developed a model single application form for both Medicaid and CHIP. We could condition some of the financial incentives described above on using a single or simple application. Second, we are reviewing the feasibility and cost of a nationwide 1-800 number that will link families with their state or local offices. Such a number could be placed in public service announcements, on the bottom of school lunch program applications, and on children's goods like diaper packages.

Discussion

There is unanimous support across agencies for focusing on children's health outreach. HHS, Treasury and CEA believe that such outreach should be the Administration's first priority. NEC/DPC and OMB believe that aggressive outreach will be needed to meet or exceed the Administration's goal of covering 5 million uninsured children. Although OMB is supportive, it points out that because some children may be impossible to reach and some states may not use these options, we are unlikely to enroll all 3 million children. NEC, also supportive, raises the concern that spending on an outreach initiative may be a communications challenge so soon after the enactment of the \$24 billion base children's health program. However, policy experts, Governors, and children's advocates alike will endorse this initiative.

One great challenge is the difficulty of finding savings from Medicaid to offset the costs of this initiative. With this in mind, your advisors are considering the tobacco settlement as a financing source. Specifically, we are exploring the advisability of allowing states to retain the Federal share of the tobacco funds if they dedicate those funds to high-priority Administration initiatives like child care, education, and health care. Governor Chiles would support such an approach if we dedicate the funds to children's health care, not just outreach.

12-29-97

B. WORKERS BETWEEN JOBS INITIATIVE

Families who lose health insurance while they are between jobs are a small but important group of uninsured Americans. These people pay for health insurance for most of their lives, but go through brief periods without coverage when they are temporarily unemployed. If they experience a catastrophic illness during this transition, the benefit of their years' worth of premium payments is lost. In addition, they could lose protection under the provisions of the Kassebaum-Kennedy legislation once they regain coverage.

Policy Options

There are two options. The first is that we include the same proposal that we have carried in our last two budgets. All states would receive grants to provide temporary premium assistance to eligible low-income families. States would use this money to partially subsidize families' premium payments for up to 6 months. This program costs \$10 billion over four years, or about \$2.5 billion per year. The same program could be scaled back by sunseting it in two or three years or possibly reducing the subsidy amount. It would still probably cost at least \$1 billion per year to have a nationwide program with enough funding per states to address this problem.

A second option is to propose the same policy but in a limited number of states. To test how best to address this population's needs, we would select states using a range of approaches like a COBRA-based subsidy, Medicaid, or covering the parents of children covered by CHIP. Since it is a grant program, we could make this program as large or small as we want. To give a sense of the options, last year's \$10 billion proposal over four years covered about 3.3 million people with incomes below 240 percent of poverty. If we assume the same set of policy parameters, a demonstration of \$1 billion over 5 years would cover about 230,000 people; a demonstration of \$2.5 billion would cover about 600,000; and a demonstration of about \$3.5 billion would cover about 800,000 people. OMB has suggested that we could limit the costs by only offering assistance to people below poverty. However, NEC/DPC are concerned about that this shifts the target away from the middle-class families we originally intended to help.

Discussion

On policy grounds, all of the agencies support this policy. It has been in our last two budgets because of its merits. Health coverage for workers changing jobs could also be important to a worker security theme in the State of the Union. This policy remains Labor's first priority because it targets a particularly vulnerable group and addresses the worker insecurity issues that played such a large role in the debate over Fast Track. OMB and CEA would support this initiative if there are sufficient funds. HHS believes that this policy is no more viable this year than it has been in the past; HHS would also object to using Medicare and Medicaid savings to fund this proposal. DPC/NEC are concerned about dropping this policy altogether and support a demonstration that is large enough to be viewed as improving coverage. If resources are limited, however, we would prefer the children's outreach initiative to this proposal.

C. VOLUNTARY PURCHASING COOPERATIVES

Workers in small firms are most likely to be uninsured. Over a quarter of workers in firms with fewer than 10 employees lack health insurance — almost twice the nationwide average. While 88 percent of workers in firms with 250 or more workers are offered health insurance, only 41 percent of workers in firms with less than 10 workers are offered coverage. This disparity reflects the poor functioning of the small group health insurance market. Studies have shown that administrative costs are higher and that small businesses pay more for the same benefits as larger firms.

Grants to States

Given the disadvantages faced by small firms, the question is: are there policies that can make insurance more affordable for small businesses and their employees? In the last two budgets, we have included a policy to provide seed money for states to establish voluntary purchasing cooperatives. These cooperatives would allow small employers to pool their purchasing power to try to negotiate better rates for their employees. This year, we propose both the original policy and a variation: a competitive grant approach so that a more limited number of states could receive a smaller, but more targeted, pool of funds. The total costs would be \$50 to \$100 million over 5 years.

Discussion

All agencies remain supportive of this policy and believe it should be included in this year's budget. In the past, we have failed to enact this proposal because Congressman Fawell has pushed an alternative approach more attractive to small businesses. Fawell's proposal would help small businesses to self-insure and in so doing escape all state regulation. Governors and consumer groups have consistently opposed the Fawell approach, fearing that it would leave the small group market with only the most risky and expensive groups, as low-risk groups move into the self-insured, non-regulated market. Our recent conversations with Fawell suggest that he may be open to compromise this year in a way that he has not been in the past.

good idea
to do more

THE WHITE HOUSE
WASHINGTON

December 13, 1997

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MEMORANDUM TO THE PRESIDENT

*THE BALANCED BUDGET ACT
12-29-97*

FROM: BRUCE REED
GENE SPERLING
CHRIS JENNINGS

SUBJECT: Reforms that Prepare Medicare for the Retirement of the Baby Boom Generation

The Balanced Budget Act (BBA) that you enacted took necessary steps to modernize the Medicare program and prepare it for the twenty-first century. It extended the life of the Trust Fund to 2010, invested in preventive benefits, provided more choice of plans for beneficiaries, strengthened our ongoing fraud activities, and lowered cost growth to slightly below the private sector rate through provider payment reforms and modest beneficiary payment increases. However, the BBA's policies were not intended to solve Medicare's long-term problems.

The Medicare Commission was established to address the demographic challenges posed by the retirement of the baby boom generation. The question is whether we should take action prior to the March 1999 Commission deadline to further strengthen the program and lay the groundwork for implementation of likely Commission recommendations.

The NEC and DPC have led an interagency examination of several policy options. This memo examines options to insure pre-65 year olds, to extend Medicare coverage of patient care costs associated with clinical trials, and to increase private long-term care insurance. Financing options to pay for these proposals follow this description.

Your advisors have differing views on whether to pursue any new proposals while the Medicare Commission is active and which proposals to pursue if you choose to do so. OMB and to some extent Treasury have concerns about a pre-65 option, because it may open the door to subsidies for a costly population and have the unintended effect of reducing employer coverage. Both OMB and Treasury oppose the clinical cancer trials proposal because it could set a precedent for every other disease group to ask for the same treatment.

*Should buy coverage
rather than
use the DPC
and make self-emplo*

Should you decide to pursue all of the options, traditional Medicare savings alone may not be sufficient to offset the costs and a Medicare income-related premium may be necessary. Such a premium will be politically contentious, although possibly more acceptable to our Democratic base if linked to a benefit expansion. Given the complexity of any decision to adopt an income-related premium, we outline here some of the issues, but defer a recommendation until we can meet with you on the subject.

A. PRE-65 HEALTH INSURANCE OPTIONS

Although people between 55 and 65 years old are more likely to have health insurance than others, they often face greater problems with access to affordable health insurance, especially when they are sick. Individuals in this age group are at greater risk of having health problems, with twice the probability of experiencing heart disease, strokes, and cancer as people ages 45 to 54. Yet their access to affordable employer coverage is often lower because of work and family transitions. Work transitions increase as people approach 65, with many retiring and shifting to part-time work or self-employment as a bridge to retirement. Some of this transition is involuntary. Nearly half of people 55 to 65 years old who lose their jobs when firms downsize or close do not get re-employed. At the same time, family transitions reduce access to employer-based health insurance, as individuals are widowed or divorced, or as their spouses become eligible for Medicare and retire.

As a result, the pre-65 year olds, more than any other age group, rely upon the individual health insurance market. Because their costs are not averaged with younger people's (as in employer-based insurance), the pre-65 year olds often face relatively high premiums and may face exorbitant premiums if they are sick. While the Kassebaum-Kennedy legislation improved access for people with pre-existing conditions, it did not restrict costs.

These access problems will increase because of two trends: the decline in retiree health coverage and the aging of the baby boom generation. Recently, firms have cut back on offering pre-65 retirees health coverage; in 1984, 67 percent of large and mid-sized firms offered retiree insurance but in 1997, only 37 percent did (although this decline may be slowing). In addition, in several small but notable cases (e.g., General Motors and Pabst Brewery), retirees' health benefits were dropped unilaterally, despite the firm's prior commitment. These "broken promise" retirees do not have access to COBRA continuation coverage and could have difficulty finding affordable individual insurance. An even more important trend is demographic. The number of people 55 to 65 years old will increase from 22 to 30 million by 2005 and to 35 million by 2010. Assuming current rates of uninsurance, this trend could raise the number of uninsured in this age group from 3 million today to 4 million by 2005, without even taking into account the decline in retiree health coverage.

The last reason for considering the coverage issues of this age group is the likelihood of proposals to raise Medicare eligibility age to 67, consistent with Social Security. The experience with covering a pre-65 age group now will teach us valuable lessons if we need to develop policy options for the 65 to 67 year olds.

Policy Questions

Two central questions determine the policy options for the pre-65 year olds: what is the target population, and what is the best way to cover these people.

Whom to Target. As with any incremental reform, targeting is essential to reduce the chance that the policy unintentionally offsets or reduces employer health coverage. While this policy will not affect employers' decisions to offer coverage to their current workers, it may affect employers' decisions to cover retirees, as well as employees' decisions to retire early. To protect against substitution, your advisors recommend limiting eligibility to a subset of the pre-65 year olds. There are two ways to limit eligibility.

The first approach is to limit eligibility to people ages 62 to 65. The 6 million people ages 62 to 65 work less than to people ages 55 to 59 (48 percent versus 74 percent), are more likely to have fair to poor health (26 versus 20 percent), and are more likely to be uninsured or buy individual insurance (28 versus 21 percent). In addition, 62 is the age at which Social Security benefits can be accessed. Within this 6 million, we could limit eligibility to the 2 million without access to employer or public insurance, and require that they exhaust COBRA coverage. These steps should reduce the likelihood that the policy will lead individuals to retire or drop retiree coverage.

A second approach is to limit eligibility within a broader age group — e.g., 55 to 65 year olds — to individuals who lack access to employer-based insurance for particular reasons:

- (1) Displaced workers: About 60,000 people ages 55 to 65 lost their employer insurance when they lost their job because a firm closed, downsized, or eliminated their position.
- (2) Medicare spouses: As many as 420,000 people lost employer-based family coverage when their spouses (almost all husbands) turned 65 and retired. This number could grow if employers drop retirees' dependent coverage for these spouses as a result of this policy.
- (3) "Broken promise" people: A small but visible and vulnerable group is the pre-65 retirees who lost retiree health coverage due to a "broken promise" (i.e., when the employer unexpectedly terminated coverage).

How to Provide Coverage. The second question is: what is the best way to increase access to affordable insurance? One approach is to extend COBRA continuation coverage for longer than 18 months. Currently, COBRA allows insured workers in firms with 20 or more employees to continue that coverage for 18 months by paying 102 percent of the premium. The major problems with extending COBRA are that (1) people in small firms are not eligible, (2) businesses will consider the policy an unfunded mandate, and (3) the policy could lead to discrimination against hiring older workers. In addition, firms could use this longer COBRA mandate as an excuse to not cover any employees.

A second approach is a Medicare "buy-in." Eligible people could buy into Medicare by paying a premium. Since Federal premium assistance for this group is prohibitively expensive, your advisors agree that participants should pay the full premium: the age-adjusted Medicare payment rate, plus an add-on for the extra risk of participants. This add-on could be high if, as the actuaries expect, most participants will be sicker than average. To attract healthier people and make it possible for more people to take advantage of the benefit, we could defer payment of part of the premium (e.g., this risk add-on) until age 65 by "amortizing" the payment. Under this option, Medicare would pay part of the premium as a loan up front, with repayment by the beneficiaries with their Part B premiums. This loan would be a Medicare cost in the short term.

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Option 1. "Broken Promise" People Only. The minimal option, with no Federal cost, is to require employers to offer COBRA coverage to retirees whose coverage they have dropped. This would allow retirees to buy into their active employer plan until age 65 at a premium (possibly 150 percent of the group rate, as has been done for other special COBRA populations). Even taking into account the premium payments, employers would bear some of the costs of their decision to terminate coverage, given the higher costs of people in this age group.

Option 2. Medicare Buy-In for Select Groups. The second option is to allow a Medicare buy-in for a subset of 55 to 65 year olds who have limited access to employer insurance. One group is the "Medicare spouses" — primarily uninsured women ages 55 to 65 whose husbands are already on Medicare. An alternative (or complement) is displaced workers. Since these groups are small, Medicare costs would be low.

Mr. Wrote body

Option 3. Medicare Buy-In for 62 to 65 Years Old Plus Selected Groups. The third option is to allow 62 to 65 year olds, plus a group like displaced workers, to buy into Medicare. This group is representative of the 65 to 67 year old population, giving a sense of what would happen if Medicare eligibility were postponed to 67 years old. The HCFA actuaries estimate that the Medicare cost of the worst-case scenario — 300,000 sick participants — is \$1.1 billion per year, not taking into account any beneficiary pay-back. Their initial estimate for the 62 to 65 year olds' costs, using more realistic assumptions, is about \$300 million per year. They assume that 160,000 people will participate: 70,000 currently uninsured and the remainder previously insured by expensive, individual insurance. Note that OMB has not yet cleared these estimates.

Discussion

Despite likely business opposition, your advisors all support a COBRA option for the "broken promise" retirees. Beyond this, your advisors have not yet reached a consensus. OMB and CEA are concerned that any unsubsidized entitlement for pre-65 year olds will not stay that way for long because pressure will build to lower the premiums. To test a buy-in for the pre-65 year olds, OMB and CEA would recommend covering only Medicare spouses, because doing so would probably have a smaller effect on the general trend in retiree health coverage and retirement. The Department of Labor supports a general Medicare buy-in. It feels strongest about covering displaced workers because of its broader goal of improving workers' security. Treasury shares OMB and CEA's concerns but would not object to a general Medicare buy-in if there were strong incentives for participants to enroll in managed care. This policy would make insurers, not Medicare, bear the risk, but could be politically difficult. HHS supports the broadest option and is concerned about only covering select groups since the enrollment may not be sufficient to justify the administrative effort.

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NEC/DPC recommend a package that includes (1) a Medicare buy-in for 62 to 65 year olds; (2) a Medicare buy-in for displaced workers; and (3) COBRA for the "broken promise" people. We think that this package is sufficiently narrow to limit effects on retiree health coverage or retirement. At the same time, the policy responds to the concerns of pre-65 year olds who feel vulnerable to losing employer coverage and/or facing unaffordable premiums.

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B. PRIVATE LONG-TERM CARE OPTIONS

12-29-97

A second idea to improve access to insurance focuses on long-term care. Unlike acute care, long-term care is not primarily financed by private insurance, which pays only 6 percent of its costs. Medicaid pays for 38 percent, Medicare pays for 21 percent, and families pay for 28 percent of the costs out of pocket. This large government role may not be sustainable as the baby boom generation retires. Today, one in four people over age 85 lives in a nursing home. This could increase substantially as the proportion of elderly living to age 90 is projected to increase from 25 percent to 42 percent by 2050. Thus, it is important to encourage the development of private insurance options. The Kassebaum-Kennedy legislation took a step in this direction by clarifying that certain long-term care insurance is tax deductible. But because many people incorrectly assume Medicare covers all of their long-term care needs and do not know about private long-term care insurance, more action is needed. This action could include providing information to Medicare beneficiaries about private insurance, funding a demonstration program to improve the quality and price of private insurance, or both. None of these options includes a new Medicare entitlement or subsidy.

Information on Quality Private Long-Term Care Insurance

We propose to leverage our role in Medicare to improve the quality of and access to private policies. HCFA would work with insurers, state regulators, and other interested parties to develop a set of minimum standards for private long-term care policies. If a plan met these standards, Medicare would approve its inclusion in the new managed care information system. (As a reminder, the BBA included provisions to provide annual information on managed care choices to beneficiaries.) This proposal would build upon that system and cost up to \$25 million in discretionary funds over 5 years (\$5 million in FY 1999), distinct from the user fees currently authorized for the managed care information system. We also could propose a demonstration that would test the feasibility of a partnership between Medicare and private long-term care insurance on a limited basis. Alternatively, we could experiment in providing more long-term care through Medicare managed care. The cost of a demonstration would depend on its size and policy parameters, but could be limited to \$100 to 300 million over 5 years.

Discussion

We believe this proposal has significant potential and is worth further development. There is some concern at HHS that coming to an agreement on a set of standards could be difficult and that insurers may argue that our standards drive up the cost of the policies, making them unaffordable. HHS also would prefer that any demonstration be funded through the mandatory budget. However, these concerns may not be insurmountable, especially since one objective of a demonstration could be to investigate high-quality private options that are affordable. Finally, we are still looking into the feasibility and advisability of using tax incentives to encourage the purchase of private long-term care policies and/or the use of IRAs for long-term care financing, although Treasury has strong concerns about the effectiveness of such options.

12-29-91

C. MEDICARE COVERAGE OF CANCER CLINICAL TRIALS

Medicare has not traditionally covered patient care costs associated with clinical trials. Scientists and advocates believe that we are not making sufficient progress in treating cancer, in part because the lack of Medicare coverage limits participation in these trials. HHS and DPC have been working on an approach that covers patient care for a limited number of these trials. Because of concerns about its cost, OMB and Treasury strongly oppose this option.

Nearly half of all cancer patients are covered by Medicare, yet Medicare does not cover patient care costs associated with these trials. This care can often be prohibitively expensive for cancer patients and their families. Expanding Medicare coverage could increase access to trials for the many beneficiaries with cancer. Historically most insurers have covered clinical trials for children. As a consequence, nearly 70 percent of children with cancer participate in clinical trials. Scientists agree that this participation rate has helped improve cancer treatments for children, and some argue that it is one reason for the dramatically higher survival rates for children cancer patients.

The lack of participation in trials, related to lack of Medicare coverage, has significant implications for research in all cancer areas, particularly for those cancers like prostate cancer where clinical trials are particularly undersubscribed. According to a former National Cancer Institute director, if 10 percent of all cancer patients participated in such trials, trials that currently take three to five years would take only one year. Additionally, as the nation's largest insurer, Medicare plays a significant role in setting the standard for the insurance companies. A commitment from Medicare to cover clinical trials would go a long way to encourage private insurance companies to cover these trials.

Proposal

We have developed a proposal to expand Medicare to cover patient care costs of cancer clinical trials conducted at the NCI and trials with comparable peer review. In addition, we would require a National Cancer Policy Board to make further coverage recommendations, and HHS to assess the incremental costs of such trials compared to conventional Medicare-covered therapies. Assuming the true incremental costs are substantially less than the actuaries project, as we believe, additional trial coverage as recommended by the Board could occur. The initial coverage would cost \$1.7 billion over five years. Senators Mack and Rockefeller have developed a more expansive and expensive proposal (co-sponsored by 26 Senators), which covers all FDA trials, many of which the experts believe do not meet a scientifically-meritorious standard.

A possible alternative way to cover clinical cancer trials' patient care costs is to dedicate resources from any significant increases that NIH / NCI receive in the upcoming budget. NCI could use these increases to simplify and centralize its clinical trials system, which has the potential to increase patient access. Although this option may be effective, the cancer community has clearly stated its preference for extending Medicare coverage. Another possibility is to require drug companies desiring Medicare coverage of additional clinical trials to contribute to part of the patient costs.

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Discussion

HHS is supportive of this policy and believes that it would not only give Medicare beneficiaries choices, but would encourage the private industry to cover clinical trials as well. HHS notes that this proposal is the highest priority for most of the cancer community as well as many in the women's community who believe it is an essential step to improve breast cancer treatment. The advocates have made it clear that they would strongly prefer the more expansive and expensive Rockefeller/Mack approach. But, the Senators might well support our proposal as an important first step and this would matter greatly to patient groups and the cancer community.

OMB and Treasury strongly oppose the Medicare coverage option. They note that Medicare would incur a large cost to provide medical services that are experimental and, therefore, unlikely to help the majority of beneficiaries. They also believe it will create enormous pressure to cover more types of cancer trials as well as non-cancer trials. Congress would likely expand the proposal beyond coverage of NCI trials, which will be very costly (up to \$3 billion over five years). Moreover, similar support will be demanded for trials of treatments for Alzheimer's, Parkinson's, and other maladies. OMB also believes drug companies — not Medicare — should take the lead in improving Medicare beneficiaries' access to clinical trials.

While recognizing the OMB and Treasury concerns, DPC/NEC believes that Medicare coverage has potential to contribute to expansions of clinical trials and possible break-throughs in cancer treatment. Our recommendation to include it in the FY 1999 budget depends on other decisions. If resources are limited, we would propose the pre-65 initiative instead of this one. In addition, a major increase in the NIH — and NCI — budgets could lessen the need for this policy. But, if sufficient resources are available, we would recommend that you support this benefit as a reinvestment in Medicare and an enhancement of our biomedical research package.

D. MEDICARE ANTI-FRAUD POLICIES AND INCOME-RELATED PREMIUM

Funding for Medicare initiatives will probably require Medicare offsets. One approach is to use Medicare anti-fraud initiatives. HHS and OMB believe that these offsets could total about \$2 billion over 5 years. This amount could fund some, but not all of the initiatives described above. To fund a more expansive series of initiatives, you may have to consider an income-related premium, which generates at least \$8 billion over 5 years.

ANTI-FRAUD PROVISIONS

could pay in 1998

In our ongoing efforts to reduce Medicare fraud, we have identified a number of small but important policies that could total about \$2 billion over five years. Several of them address problems identified by the HHS Inspector General, such as the overpayment by Medicare for certain cancer drugs, that you highlighted in your radio address today.

INCOME-RELATED PREMIUM

Medicare subsidizes 75 percent of the Part B premium for all beneficiaries, including the wealthiest. Higher income beneficiaries, who actually receive more Medicare benefits than do poor beneficiaries, could afford premiums without subsidies. However, the addition of an income-related premium would make Medicare less of a social insurance program.

As you know, the Administration has publicly supported an income-related premium. It is not clear, however, that we should include this policy in our budget. Because this issue is very complicated, we will not make a recommendation until we meet with you on the subject.

Policy Options

Building from our position last summer, the income-related premium would be administered by the Treasury Department, not HCFA or the Social Security Administration. Eligible people would fill out each year a Medicare Premium Adjustment form (a separate form or a line on the 1040 form) and send a check to "The Medicare Trust Fund." Revenue from this premium, which is at least \$8 billion over 5 years, depends on who pays and how much they pay.

Who pays. The income thresholds determine how many people are paying the higher amount. We proposed thresholds of \$90,000 for singles and \$115,000 for couples in the Health Security Act. Last summer, the Senate, including most centrist Democrats, passed a policy that began the extra premium payment at \$50,000 for singles and \$65,000 for couples. During the budget debate, we did not express support for particular thresholds.

How much. The amount of the payment for the wealthiest beneficiaries is a second question. In the budget debate, we argued that a 100 percent premium (no subsidy) would cause some healthy and wealthy people to opt out of Medicare. However, an analysis by the Treasury Department this fall found that the effects of a 100 percent premium would be smaller. HHS would strongly object to changing our position to support an income-related premium that completely phases out the Part B subsidy. If we decide to change our past policy, we should have a strategic discussion about the timing of announcing such a change.

Discussion

The decision to propose an income-related premium is complicated, and your advisors have differing views about its timing and, to some extent, advisability. Some believe that we made a decision last summer to support this policy, regardless of circumstances. However, its introduction may provoke criticism. Many Democrats and possibly AARP will oppose the income-related premium (though this opposition may soften if the premium is linked to a Medicare investment). In addition, Republicans might label it a new tax and use our support for it as an issue during the 1998 campaign. The Medicare Commission almost certainly will recommend this policy if you do not in the spring of 1999. Leaving it to the Commission has the advantage of providing both Democrats and Republicans with political cover, but the disadvantage of decreasing your control over the structure of the premium and how it will be spent. DPC/NEC will prepare for a separate meeting to discuss this issue.

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THE WHITE HOUSE
WASHINGTON

April 9, 1998

4.9.98

MEMORANDUM FOR THE PRESIDENT

FROM: Bruce Reed
Elena Kagan

SUBJECT: McCain Legislation

With the overwhelming vote in favor of the McCain legislation in the Senate Commerce Committee and the subsequent announcement of the tobacco industry that it will fight this legislation, we have entered into a new phase of our effort to procure a comprehensive tobacco bill to reduce youth smoking. The Commerce Committee vote last week brought new momentum to this legislative effort. The industry's response should only add to that momentum, by making it even harder for Members of Congress to block legislation, lest they look as if they are doing the industry's bidding.

The broad consensus among your advisors is that we should aim for a strong, comprehensive bill that meets our core public health objectives and that the industry might reluctantly swallow in the end. Without industry consent, some provisions in comprehensive legislation (i.e., the most far-reaching advertising restrictions) would be impossible, while other provisions (e.g., narrower advertising restrictions and lookback penalties) would be in litigation for years. We should not compromise our objectives to secure that consent, but at the same time we should not ask for more than we need to achieve our public health goals and in the process destroy any chance of industry acquiescence. In any event, most of your advisors believe that efforts to push the price too far would be counterproductive, because tobacco-state Democrats will join with Republicans to derail a bill that goes as far as some in the public health community might like. Instead, we should try to address the aspects of the McCain bill that are most important to us and to securing broad Democratic support.

Your advisors also agree that the best way to get this kind of bill is to engage in negotiations with Senators Lott, Daschle, McCain, and Hollings that are designed to produce an agreed-upon bill to go to the Senate floor. The greatest danger we face is chaos on the Senate floor, in which some amendments roll back what we already have achieved (e.g., on FDA jurisdiction), while other amendments make the bill essentially unpassable (e.g., by stripping all liability protections while increasing the overall price of the deal).

We recommend against direct discussions with the industry at this stage; we doubt they would level with us anyway. Assuming Senator Hollings is in the room, we should have a decent sense of the industry's concerns, and of course we have more-than-adequate lines of communication to the public health community.

We list below several aspects of the McCain legislation in which we should seek changes during these negotiations. Note that FDA jurisdiction does not appear on this list; we were able to reach an agreement on this issue with Senators McCain and Frist, prior to the Commerce Committee vote, that satisfies all our regulatory needs and objectives.

I. Youth Lookback Penalties

We already have said that Congress must strengthen the lookback penalties in the McCain legislation, by incorporating some company-specific penalties and raising the cap on the industry surcharge. The incorporation of some company-specific penalties is a core demand of the public health community, and is strongly supported by HHS and Treasury. Such penalties, however, may be unacceptable to the industry, and especially to Phillip Morris because of its disproportionately large share of the youth market. (Unlike industrywide penalties, which can be passed on in the form of higher prices, company-specific penalties come straight out of a company's profits.) Bruce Lindsey has noted that even if we need to make demands in this area, we should not let the issue of company-specific penalties become grounds for vetoing the bill. We agree, but think it is important to try to find a way to address this issue.

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A number of approaches are available, and we should not now tie ourselves down to any of them. A company-specific penalty developed by Treasury and HHS would impose a \$500 fee for every child by which a company misses the targets (i.e., if a company misses the target by 10,000 children, it would pay a fee of \$5,000,000). This per-child surcharge represents the present value of the profits a company would gain from addicting a teenager over his lifetime. Treasury estimates that the total cost of this penalty -- i.e., across all companies -- could reach as much as \$500 million a year. Another approach, probably more acceptable to the industry, would be to allow suits between companies for redistribution of the industry-wide penalty. Such indemnification suits would create a potential for transforming the industry surcharge into a company-specific penalty scheme, without increasing the overall cost of the penalty provisions. We will continue to try to develop creative solutions in this area so that we can enter negotiations with a range of proposals.

Raising the cap on industry-wide penalties is obviously an easier matter. We would suggest proposing a change from the current \$3.5 billion to \$4 to \$5 billion if possible.

II. Price per Pack and Spending

Price per Pack

We should not demand any increase in the McCain bill's funding levels in the first five years, because McCain essentially adopted our own budget numbers (while adding a \$10 billion up-front payment). We recommend waiting until CBO scores the McCain bill before deciding whether to seek any increase in funding levels in later years. (McCain has asked CBO to score his bill by the time Congress returns.) Congressional scorekeepers may well estimate that the

yearly payments in the bill will increase the price of cigarettes not by the \$1.10 we estimated, but by the \$1.50 that the public health community has most often demanded. The higher figure may result from assumptions by CBO that (1) states will use the opportunity to increase state excise taxes, further reducing the number of packs sold and (2) the bill will significantly increase the black market for cigarettes, resulting in fewer than expected packs sold through the legitimate retail market. By reducing the number of expected packs sold, both of these changes would increase the per-pack price estimate, because the annual industry payment set in legislation would be spread among fewer packs. Once we know the actual per-pack price increase calculated by Congressional scorekeepers, we will be in a better position to determine whether we should push for a small increase in funding levels after the fifth year.

Spending

We hope for bipartisan consensus on much of the spending: we think Members could agree on approximately \$10 billion over 5 years for farmers; \$10 billion for prevention, cessation, counteradvertising, FDA enforcement, and other public health programs; \$10-15 billion for research (the Republicans may want to limit these funds to NIH); and \$20-25 billion for states. This distribution leaves about \$15 billion on the table, which Republicans will want to spend on Medicare or tax cuts and Democrats will want to spend on programs like child care and school construction.

One issue will concern the use of the state money. Our budget earmarked 57 percent of the state funding for child care, class size, and Medicaid outreach initiatives. As we go forward, we should argue at a minimum for a menu of state programs, such as child care and education, on which states would have to use a significant portion of their funds. For example, in the Harkin-Chafee bill, half of the state funds must be spent on one of 20 listed programs, which include child care, K-12 education, Medicaid, the Child Health Insurance Program, and Head Start.

Another issue, more important in the out-years, concerns the amount of money allocated to paying legal judgments. The June 20th settlement put only a few billion dollars into the tort fund in the first five years, on the theory that lawsuits against the industry would take some time to come to judgment. Congress may well use the same assumption, given competing spending priorities. But once this initial grace period is concluded, Congress must figure out how to fund legal judgments. The June 20th settlement placed a \$5 billion annual cap on judgments, with \$4 billion coming from the industry's base payments to the government and \$1 billion (a kind of copayment) from the defendant companies' coffers. The McCain bill establishes a \$6.5 billion cap; McCain contemplated that \$5.2 would come from the industry's base payments, with \$1.3 as a copayment, but his bill does not actually address this issue. Some in the public health world may begin to call for the entire amount to be paid by the companies, outside of their payments to the government. This change, however, would add an enormous amount to the total cost of the deal and could doom prospects for legislation. Room for a tort fund thus will have to be found in the out-years by squeezing some of the spending listed above.

III. Antitrust Exemption

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The McCain bill contains antitrust exemptions for the tobacco industry that are not necessary to achieve the goals of the legislation and may have serious anticompetitive effects. As written, the bill exempts any and all agreements designed to "reduce the use of tobacco products by underage individuals." This exemption could cover (among other things) price-fixing agreements of all sorts. The Department of Justice believes strongly, and we agree, that we should oppose all antitrust exemptions, except possibly for a narrowly-drawn exemption designed to allow companies to agree to restrict their advertising and marketing to children.

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IV. International Tobacco Control Efforts

As part of the public health spending noted above, we believe we should include significant funding (\$200 million a year) for international tobacco control efforts. These funds should be spent on both governmental and non-governmental efforts to promote public health and smoking prevention efforts abroad.

The McCain bill has several additional international provisions that we would like to change so that they do not interfere with our diplomatic and trade priorities. For example, although we support the bill's effort to prohibit U.S. government support for promotion of tobacco overseas, we need to ensure that the language does not interfere with USTR's ability to negotiate tariff reductions or interfere with treatment of other products. In addition, the McCain bill contains a provision that the State Department and HHS consider problematic and unenforceable, which would require U.S. companies to abide by the new labeling and advertising requirements when doing business in other countries. The industry strongly objects to these provisions for a different reason, because it views them as a real threat to its international operations.

V. Environmental Tobacco Smoke

The McCain bill would exempt the hospitality industry (restaurants, bars, casinos, etc.) from its environmental tobacco smoke provisions, which ban smoking, except in enclosed and specially ventilated areas, in public facilities. In addition, the bill would allow individual states to "opt out" of all of the provisions, even if the state had no ETS protections of its own.

Although HHS strongly opposes the hospitality exception (workers in the hospitality industry face grave risks from second-hand smoke), we doubt it is politically feasible to remove it. We should, however, try hard to eliminate the state opt-out provision, which could leave many of the nation's citizens without any protection from ETS. Alternatively, we might consider pushing the Harkin-Chafee approach to this issue, which rather than imposing a ban would provide funds to States that progressively reduce exposure to ETS.

VI. Liability Provisions

We believe we should adhere to the basic structure of the liability provisions in the McCain legislation. If we need to make these provisions a bit tougher, we can try to raise the cap from the current \$6.5 billion to the \$8 billion contained in Harkin-Chafee. Note, however, that doing so only compounds the budgetary issues surrounding the tort fund noted earlier in this memo: to the extent that money for tort judgments come from the industry's payments to the government, that money squeezes out funds for public health and other priorities; conversely, to the extent that money for tort judgments comes over and above the industry's payments to the government, the expected cost of the deal to the industry increases.

Finally, we may want to change the provisions in the McCain legislation that deny the liability cap to certain companies. The current provision, which has received almost no attention, lifts the cap for companies that miss the youth lookback target by more than 20 percentage points if they also have violated the Act or taken action to "undermine the achievement of youth smoking reductions." Because of the vagueness of this standard, the provision may have little or no effect. We should either tighten it (by linking the cap only to objective measures) or discard it entirely. Especially if we try to make the liability provisions tougher in other areas, agreeing to eliminate the provision may prove useful.

VII. Constitutional Issues

The Department of Justice is prepared to recommend changes to the advertising, marketing, and other speech-related provisions of the legislation in the event that the industry does not sign protocols agreeing to these restrictions. The Department also would like us to press for the elimination of all provisions regulating non-commercial speech, such as one that forbids companies from lobbying Congress, regardless whether the companies offer agreement.

Conclusion

In summary, we would recommend seeking these improvements:

Youth Lookback Penalties

- Incorporate some company-specific component in the penalty scheme
- Increase the industry-wide surcharge cap from \$3.5 billion to between \$4 and \$5 billion

Price and Spending

- No change in annual payment amounts in first five years; wait until CBO scores before deciding whether to seek later changes
- Ensure spending on research, public health, and farmers, press for spending on child care and education, or at least a menu including these programs

Antitrust Exemption

- Eliminate the antitrust exemption

International Tobacco Control

- Support funding for governmental and non-governmental organizations
- Narrow provision prohibiting U.S. support for promotion of tobacco overseas to ensure it does not interfere with USTR authority to negotiate treaties
- Remove requirement that companies must abide by new labeling and marketing requirements when operating overseas

Environmental Tobacco Smoke

- Eliminate "opt-out" provision that allows states to adopt weaker laws

Liability

- Retain basic structure of liability priorities
- Consider modifying level of cap and relation of cap to youth reduction targets

Constitutional Issues

- Recommend changes to minimize Constitutional difficulties

THE WHITE HOUSE
WASHINGTON

April 14, 1998

MEMORANDUM FOR THE PRESIDENT

FROM: Bruce Reed

SUBJECT: Needle Exchange Options

As we discussed last night, we have a couple of alternatives to Secretary Shalala's recommendation on needle exchange. You should try to make a decision on this issue before you leave for South America.

Under all these options, the government's top scientists would certify that needle exchange decreases HIV transmission and does not increase drug use. The central question is whether (and under what conditions) to release federal funds. The three possibilities are:

1. Release funds with HHS criteria (Shalala recommendation). Shalala recommended letting any community with a needle exchange program that meets specified criteria -- i.e., program cannot violate state paraphernalia laws, must refer participants to drug treatment, etc. -- exercise a local option to use federal AIDS prevention funds for that purpose. The HHS criteria would cut the number of eligible communities in half, because only 50-60 of the 110-120 programs nationwide operate legally. (Moreover, only six cities -- San Francisco, Los Angeles, New York, Chicago, Houston, and Philadelphia -- receive direct funding from CDC for HIV prevention. All other funds go to state health departments, so other cities would need the approval of the chief health official in the state.) Shalala and Sandy Thurman support this option because it will help the most communities. Most White House advisors oppose it because opening the door this wide will be easy for Congress to demagogue and quickly overturn.

2. Limit funds to areas where HIV transmission is at emergency levels. We could reduce the universe of needle exchange programs still further by only allowing a set number of communities with the most severe drug-related HIV problems to qualify -- for example, areas with 25-30% of total AIDS cases directly or indirectly related to injection drug use. (There probably aren't enough cases of infected babies born to drug addicts -- perhaps 500 a year nationwide -- to make that a separate criterion.) HHS estimates that only 10-15 programs (mostly in the largest cities) would meet these conditions in FY98. HHS could live with this option if the limitations only apply to FY98 funds. We could characterize it as a demonstration project and an emergency measure, not necessarily a moral endorsement of needle exchange. Some in the AIDS community believe this option is unethical, because it withholds a known

treatment from people in need. On the other hand, it might be easier to defend in the public arena and perhaps hold onto in Congress. This option would make it somewhat harder for Congressional leaders to force a tough vote for Democrats, although the far right might succeed in demanding a needle exchange ban anyway.

3. Withhold federal funds on the grounds that needle exchange is a local decision. The best way to prevent Congress from banning the use of federal funds is to take that issue off the table from the outset. Under this option, Shalala and government scientists would make a strong case for why communities with an HIV problem should consider needle exchange programs as a way to protect the public health. But we would make clear that because this is a contentious issue with nowhere near a national consensus, that decision and the money to pay for it must come at the local level. We would tell the AIDS community that this effort will do better over the long haul if we don't give Congress an opportunity to make political hay, and that the amount of federal money involved isn't worth the damage the right wing could do. Shalala, Thurman, and the AIDS community believe this option would make us look like cowards, because we'll never know whether we can win the Congressional battle unless we try. A number of White House advisors believe that battle is extraordinarily difficult to win in the short or long term, and this option is the only one that can withstand the Republicans' assault on the drug issue.

Obviously, there is no clear consensus on this issue. Shalala, Thurman, and others in the Administration closest to the AIDS community favor option 1 and could live with option 2, but oppose option 3. McCaffrey, Rahm, and others closest to the anti-drug community favor option 3 and oppose options 1 and 2. Most others in the White House oppose option 1 but could live with either option 2 or 3. If you believe we can hold onto a demonstration in Congress, you should probably go with option 2. If you believe Congress will ban this no matter what, needle exchange programs around the country would probably be better off if we went with option 3.

Erskine strongly recommends that you make up your mind before you leave tomorrow. The AIDS Council has another conference call tomorrow to decide whether to call for Shalala's resignation. No matter what you decide, it probably makes more sense to roll it out before Congress returns from recess.