



THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C. 20201

NOV 3 1999

**MEMORANDUM FOR THE PRESIDENT**

I am pleased to enclose an important new report on access to child care for low-income families that HHS released last week. The report confirms the desperate need for additional investments in child care, and reinforces the critical importance of the Administration's efforts to secure additional child care subsidy funds in our on-going negotiations on the FY 2000 appropriations bills.

This report, titled *Access to Child Care for Low-Income Working Families*, finds that only 10 percent of the children eligible for Federal child care assistance are receiving the help they need. According to the report, which includes estimates done by the nonpartisan Urban Institute, 14.7 million children were eligible under Federal law last year for subsidies to help their parents pay the high cost of child care, but due to the limited funds available under the Child Care and Development Block Grant, only 1.5 million children actually received assistance. The percentage of eligible children who were served varied by state, from a high of just 24 percent in West Virginia to a low of 4 percent in Mississippi.

The report also finds that the price of child care is prohibitively high for low and moderate-income working families that do not receive assistance -- from \$3,500 to \$7,000 a year for a single preschool child. Child care costs consume one-quarter of the income of low income families that pay out of pocket for the care of at least one preschool child.

As you know, the Senate version of the Labor-HHS-Education appropriations bill included an additional \$818 million in discretionary funding for the Child Care and Development Block Grant (CCDBG). The Dodd-Jeffords amendment to add this funding passed the Senate by a margin of 54-41 -- the fourth time this year the Senate has voted to provide new money for child care assistance. Unfortunately, the Republican leadership did not include this funding increase for child care in the Labor-HHS-Education-DC appropriations bill passed this week.

I hope you will make this additional funding a top priority in Administration negotiations with the congressional leadership and appropriators. The additional \$818 million would help approximately 220,000 families pay for safe, reliable care for their children. Securing this funding would represent a major victory for the Administration. It would represent a significant down payment on the \$1.155 billion funding increase you requested for the CCDBG this year. Since the entire CCDBG program is forward funded every year, the additional \$818 million would not significantly complicate the outlay picture for FY 2000.

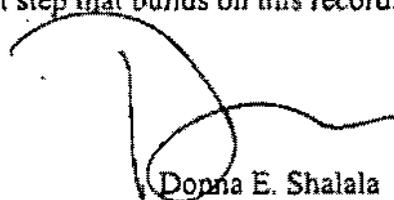
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Thanks in large part to your economic policies, the U.S. economy continues to be remarkably strong. Yet, as you noted in your speech on October 29, 1999, we as an Administration need to focus on helping parents balance work and family.

As you know, with the unemployment rate at a 30-year low, many employers are struggling to find workers. Even prior to this unprecedented economic expansion, the BLS predicted that women would make up 60 percent of new entrants to the labor force between 1994 and 2005. Welfare caseloads have experienced historic declines over the past few years, further increasing the number of women in the labor force. Unfortunately, parents cannot be productive employees when they cannot find affordable, safe care for their children. The HHS child care report finds that parents who do not receive child care subsidies are much more likely to be late for work, or miss it entirely, due to breakdowns in child care arrangements. Other parents, as you observed in your speech, are at work but are too worried about their children to concentrate on the job at hand.

Quality child care is necessary not only for parents to work productively, but for children's development and success in school. The overwhelming majority of children today are in child care at some point before entering school. New research from NIH reinforces the findings highlighted at your White House Conference on Early Learning and the Brain – children in higher quality child care programs develop stronger language, reading and math skills than do children in poor quality programs. The better the child care program, the better the child is prepared for school.

I am very proud of the progress your Administration has made so far to ensure that parents can succeed at home and at work, and in so doing help their children establish the foundation for a healthy and productive life. Securing additional child care funding in this budget cycle would be a tremendously important step that builds on this record. Thank you for your consideration.



Donna E. Shalala

# Access to Child Care for Low-Income Working Families



U.S. Department of Health and Human Services  
Administration for Children and Families

October 19, 1999



THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C. 20201

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MEMORANDUM FOR THE PRESIDENT

On behalf of Secretary Alexis Herman, my co-chair of the Quality Interagency Coordination Task Force (QuIC) and myself, I would like to update you on the progress of the QuIC. You directed us to convene the QuIC to further the recommendations of your Advisory Commission on Consumer Protection and Quality in the Health Care Industry. We are very pleased and proud to report that the QuIC – in existence only a little longer than a year – already has proven to be a valuable and successful means of coordinating Federal efforts to improve the quality of health care services provided in this Nation. We are very confident that the work of the QuIC and its extraordinary collaboration will serve as a model for the private sector.

As you noted in March 1998, Federal agencies with health care responsibilities exert significant power in the health care industry, and working together they could improve the quality of health care for all Americans. Since they first met in May 1998, the Cabinet Departments and Agencies participating in the QuIC --- Departments of Defense, Veterans Affairs, Labor, Commerce, and Health and Human Services, and the Office of Personnel Management, the Office of Management and Budget, the Coast Guard, the Bureau of Prisons, the Federal Trade Commission and the National Highway Traffic Safety Administration -- have proven to be deeply committed to ensuring that we provide or purchase high quality health care services. Dr. John Eisenberg, Administrator of the Agency for Health Care Policy and Research, serves as Operating Chair of the QuIC.

The QuIC has identified five areas that are common to the mission of each agency and that are of profound significance to improved health care quality: 1) providing patients and consumers with information to assist in their choices; 2) pursuing key opportunities for clinical quality improvement; 3) enhancing quality measurement; 4) developing the workforce; and 5) improving information systems. A multi-agency work group has been assigned to each of these areas to develop innovative projects that will achieve its goals. Health care leaders in each agency – and the QuIC as a full body – meet periodically to steer the actions of the work groups and ensure that participating agencies are aware of and contribute to the projects.

The QuIC can already boast a number of significant achievements. We would like to highlight a few:

- Diabetes Care: The QuIC has greatly enhanced Federal collaboration on the Diabetes Quality Improvement Project (DQIP). This is particularly evident in three areas:

Prepared by AHC/Cano

11/4/1999/0029

- Under the auspices of the QuIC, a number of Federal agencies are collaborating on the creation of a common clinical practice guideline to improve diabetes care. These agencies will use the guideline to improve the performance of providers.
  - A conference was held in August to share specific successful strategies for improving diabetes care. The attendees were organizations seeking to improve their current practices. The QuIC agencies brought their success stories and strategies to this conference.
  - The QuIC is seeking a broad agreement among Federal agencies to collect and report the performance of providers using diabetes measures developed by DQIP to judge the quality of clinical care.
- Reducing Medical Errors: The QuIC is working with the Institute for Healthcare Improvement (IHI) to create an initiative that will test several strategies for rapidly reducing the number of medical errors committed in "high-hazard" health care settings, including emergency rooms, intensive care units, and on-site rescue operations, around the country. Based on the results of previous IHI initiatives, we hope that some sites will be able to achieve reductions of 25% to 30% in the number of errors within 12 to 15 months.
  - Making Information Available to Consumers: The QuIC has aided the Federal Trade Commission in augmenting its Consumer.gov web site to include information on health care quality. Through this gateway, the QuIC now links to all of the Federal sites that provide information to assist people in making choices about their health care plans and providers, including information on the quality of health plans for Medicare beneficiaries, Federal employees, and participants in DoD's Tricare plans. There are also links to the Department of Labor's health benefits education campaign to help people understand what they are getting and what their rights are.
  - A Glossary of Commonly Used Terms. The QuIC agencies realized that there could be great benefit to the American people if we could agree to reduce the chance of confusion by using the same terms to mean the same things in our public communications. A set of terms has been developed and is being circulated to the Federal agencies to solicit their agreement to use the terms. We expect to have that agreement in October.

The enclosed report includes more detail on these and other accomplishments of the QuIC. We would be pleased to brief you on the work of QuIC to date and its plans for the future.



Donna E. Shalala

Enclosure:

Progress of the Quality Interagency Task Force as of September 21, 1999

## **Progress of the Quality Interagency Coordination Task Force As of September 21, 1999**

In March 1998, your Advisory Commission on Consumer Protection and Quality in the Health Care Industry reported that one of the critical steps in advancing the quality of health care in this country was to unify providers, purchasers, quality oversight and improvement organizations, and the American people in their aims to improve health care quality. The President noted that the Federal agencies with health care responsibilities exert significant power in the health care industry, and could improve the quality of health care for Americans if they had common aims and better coordination. He asked Secretary Donna Shalala to bring these Agencies together in the Quality Interagency Coordination (QuIC) Task Force to work to improve health care quality. The QuIC has provided a significant opportunity for the Agencies to discuss issues of mutual concern. It has made substantial progress on specific projects to improve health care since it first met in May 1998.

Briefly, the Agencies that have been working together in the QuIC are the Departments of Defense, Veterans Affairs, Labor, Commerce, and Health and Human Services, and the Office of Personnel Management, the Office of Management and Budget, the Coast Guard, the Bureau of Prisons, the Federal Trade Commission and the National Highway Transportation and Safety Administration. Dr. John Eisenberg, Administrator of the Agency for Health Care Policy and Research, serves as Operating Chair of the QuIC.

In its initial meetings, the QuIC identified five areas of shared interest: 1) providing patients and consumers with information to assist in their choices; 2) pursuing key opportunities for clinical quality improvement, 3) enhancing quality measurement; 4) developing the workforce to provide higher quality care, and 5) improving information systems.

The QuIC appointed multi-agency work groups in each of these areas and asked them to develop specific projects that would move toward these goals. Key staff were appointed from each of the participating agencies and are working hard to bring these projects to fruition. The health care leaders in each agency meet periodically to steer the actions of the work groups and to ensure appropriate support is available. Its projects include:

### **QuIC Efforts to Improve Current Patient Care Practices**

The Work Groups identified several key opportunities to improve the care that is delivered. Some are areas in which there is scientific evidence demonstrating what should be done to diagnose and treat patients, but where common practice does not conform to those scientifically proven methods. Others are areas where research is needed to inform the choices that health care providers and managers make when determining what to do. The QuIC has undertaken efforts in these four specific areas:

- **Diabetes Care.** In 1997, you launched the Diabetes Quality Improvement Project (DQIP) which brought together the Health Care Financing Administration, The Department of Veterans Affairs (DVA), and private sector partners to identify ways in which diabetes care could be improved. Working from research sponsored by the Agency for Health Care Policy and Research that identified what is most important and effective in treating patients with diabetes, DQIP created a small set of measures to use in judging clinical performance and determining where improvement was needed. The DQIP efforts led to three specific actions under the QuIC.

  - First, before the QuIC was created, the DVA and the Department of Defense (DoD) had created a common guideline for care of diabetes and had planned to use the DQIP measures to assess performance. Under the auspices of the QuIC, other Federal Agencies were invited to participate in the creation of the guideline and to use the guideline to improve the performance of their providers.
  - Second, the DQIP group held a conference aimed at helping providers and community organization to identify successful strategies to improve the quality of diabetes care. The QuIC was able to enrich this conference by bringing to it the Federal Agencies and care teams with successful strategies to share and by bringing together teams who were seeking new ideas that could be tried in their own communities. The conference was highly successful, and its success will be extended through efforts to compile and disseminate the "best practices" that were described at the conference to other providers and community representatives who were unable to attend.
  - Third, the QuIC is seeking a broad agreement among Federal agencies to collect and report the performance of providers on the DQIP measures. The QuIC discussed the importance of Federal Agencies agreeing to use this common set of measures for patients with diabetes, and concluded that it would significantly help to improve patient care. The QuIC has endorsed the idea of asking the Federal Agencies to agree to use the DQIP measures. We are in the process of making that request of all of the participating Federal Agencies and expect to know by mid-October how they have responded and what it will mean to use the DQIP measures in their programs.
- **Depression Diagnosis and Care.** As with diabetes, there is substantial research showing that the diagnosis and treatment of people with mild to moderate depression could be greatly improved. The DVA and DoD identified this as an area in which they wished to create a guideline to improve the care of their populations. Through the QuIC, their efforts were expanded in two significant ways. First, other Federal agencies were invited to participate in developing and using the guideline. Second, the research agencies, such as the National Institutes of Health, the Agency for Health Care Policy and Research, and the Substance Abuse and Mental Health Administration, were involved and able to bring the latest and most compelling evidence from their research to the effort. A guideline that will enhance the care of depressed individuals will be completed by the end of October and disseminated to

Federal providers and made available to the public. One of the final steps needed is to marry performance measures to the guideline to ensure that the care for people with depression is getting better. Unfortunately, there is no clearly generally accepted superior set of depression care measures like the DQIP measures were for diabetes. Therefore, the QuIC organized a conference of experts in depression and measurement at the end of September and will produce not only the best measures available currently for monitoring performance, but also a research agenda for creating a more enduring set of critical measures.

- **Reducing Errors.** As indicated in the Advisory Commission's report to you, there is currently an unacceptable level of errors in health care. The QuIC is working with the Institute for Healthcare Improvement (IHI) to create an initiative that will test several strategies for rapidly reducing the number of errors committed. Our effort will be targeted specifically at health care delivery settings where patients are in need of urgent assistance and decisions have to be made rapidly, which we are calling "high hazard environments." These would include emergency rooms, operating rooms, intensive care units, and on-site rescue operations. This is the first such initiative targeted at error reduction in these high hazard environments. Based on the results of previous IHI initiatives, we hope that some sites will be able to achieve reductions of 25% to 30% in the number of errors within 12 to 15 months. The QuIC endorsed this effort at its meeting on September 21, and we are in the process of asking the agencies to decide if they wish to participate and how many teams they would like to have participate in the effort. Whatever is learned through this Federal effort will be shared broadly to help others reduce errors in their own health care delivery settings.
- **Effect of Working Conditions on Quality of Care.** From studies in other industries, we know that the conditions under which people work can dramatically affect their productivity and the quality of work that they do, but little research has been done on this issue in health care. Recent changes occurring nationwide in the levels of staffing in hospitals and nursing homes, as well as questions about how the organizational structure and physical environment affect the quality of care delivered, have made this an important topic in health care quality. These questions prompted the QuIC to look for research that could inform provider organizations about working conditions within their control that could influence the quality of care they deliver, but little research was available. Therefore, the QuIC elected to organize an expert meeting that will identify what is known about how working conditions affect the quality of care in health care and, more importantly, to identify the critical questions to be explored about the effect of working conditions on quality of care. We are collaborating in this effort with health care provider organizations, unions and other representatives of health care workers, and experts in facility design, art, organizational design, and quality improvement. This conference will provide a framework for Federal and private research efforts.

Future efforts to improve patient care will be developed based on the priorities of the Agencies involved and are likely to continue to expand on efforts to improve mental

health care and move into cardiac disease, cancer, and other major diseases. For example, the QuIC can take advantage of the National Cancer Institute's Quality of Cancer Care Initiative to affect the quality of cancer care delivered in ways that the NCI can not do solely through research efforts.

### QuIC Efforts to Create Quality Improvement Tools

One of the major benefits of the collaboration occurring under the QuIC is the ability to develop and share tools that enable the Federal agencies and others to improve the quality of care. The QuIC Work Groups identified several tools that were needed. By ensuring collective use of these tools, the QuIC will help to minimize the confusion that health care providers encounter in dealing with the various Federal agencies and improve the efficiency of the agencies' work. These include:

- " **A Common Credentialing Effort.** Currently, each Federal agency separately credentials the health care professionals who work for them. When professionals seek joint appointments from more than one agency, move from one agency to the other, or are called upon in times of national need, such as the Gulf War, to fill in for their colleagues who are serving abroad, the credentialing effort must begin again at the new agency. To prevent such duplication of effort and to improve the rigor of the initial credentialing process, the Federal agencies are working on a joint credentialing program that would allow electronic sharing of information across the agencies. This process began with an effort between the DVA and the Health Resources and Services Administration to test the feasibility of creating such a credentialing process for physicians and dentists. It has been judged successful, and the QuIC is working to expand both the number of Federal agencies that will use the process and the types of professionals who can be credentialed through the program. We expect this effort will take many more months of effort, but it is progressing.
- \* **Information on Measures.** A goal of the QuIC is to ensure that the Federal agencies are using common measures and risk adjustment methods when possible. These steps will help to reduce reporting burden for health care providers and increase our ability to compare performance across providers. Initial steps have been taken to enable us to move toward this goal.

The QuIC has created a compendium of all of the measures currently in use by Federal agencies. It is available to all who are seeking information on the measures currently available for use in assessing quality. The information also will be available through a National Measures Clearinghouse web site that is under development by the Agency for Health Care Policy and Research. The QuIC members are sharing and testing the most advanced risk adjustment methods available. Comparisons will be made on the results, the relative costs of each method, and their effectiveness. A workshop is planned to discuss which measures and risk adjustment methods work best for particular purposes, and to agree on which are best.

- **Formulary Guidance.** Several Federal organizations maintain formularies for their beneficiaries. Others, such as the Health Care Financing Administration, must oversee organizations that provide care to their beneficiaries and need a method by which they can ensure that the formularies of provider organizations are adequate to meet the expected needs of the populations they serve. A team of individuals is working to determine how to provide guidance based on scientific evidence that will help provider organizations determine what a formulary must contain to be adequate to meeting these expected needs.
- **A Taxonomy of Quality Improvement Methods.** A tool that is essential if the nation is to learn which quality improvement strategies work best in various situations is a common method and language for identifying and describing quality improvement interventions. The QuIC Agencies conducted an expert meeting and are in the process of finalizing a taxonomy that will allow us to describe and compare the quality improvement strategies used in Federally sponsored research, and in projects of the DVA, DoD and HCFA's peer review organizations. This taxonomy will be published in a professional journal for broad use, and will be put to work immediately upon completion by the Federal agencies in their solicitations for research proposals, descriptions of on-going projects, and instructions to their provider organizations.
- **Improved Information Exchange across Agencies.** Common information is used by the Federal agencies, but much of it is not exchanged electronically in a format that can be used by all agencies. The information systems experts have been studying methods to improve the efficiency and completeness of the data that are used in many agencies. They have started with the "exclusions list," which is the list of individuals and organizations to which the Federal agencies can not make health care payments. Individuals and organizations appear on this list after they have committed fraud or other similar actions in the delivery of health care goods and services. Agencies have noted that they are not sure they have accurate and up to date information on this list, or that they are missing information, such as the individual's or organization's unique identifier code, and must make inquiries to verify identities before paying for services. Work is underway to determine if a single, searchable list that has the complete information needed by the agencies can be maintained and shared electronically. Further projects to explore the impact that information systems improvement can have on quality are being discussed.
- **Strategies for Ensuring Patients' Rights.** In November 1997, the President directed the Federal agencies to bring their programs into compliance with the Patients' Bill of Rights that was developed by the Advisory Commission. As part of the efforts to bring our programs into compliance, key agency staff have been discussing their approaches and the challenges. They have been able to share ideas and strategies for bringing about compliance with the Bill of Rights to the extent that current legislation permits. These discussions have proven useful for all of the agencies.

## QuIC Efforts to Help Inform Americans About Health Care

The QuIC agencies share responsibility for communicating with the American people about their health care choices and are developing three products that will greatly enhance our ability to do so. These are:

- **A Gateway to Consumer Information Available from Federal Agencies.** The QuIC has aided the Federal Trade Commission in augmenting its Consumer.gov web site to include information on health care quality. Through this gateway, the QuIC now links to all of the Federal sites that provide information to assist people in making choices about their health care plans and providers, including information on the quality of health plans for Medicare beneficiaries, Federal employees, and participants in the DoD Tricare plans. There are also links to the Department of Labor's health benefits education campaign to help people understand what they are getting and what their rights are.
- **A Glossary of Commonly Used Terms.** The QuIC agencies realized that there could be great benefit to the American people if we could agree to reduce the chance of confusion by using the same terms to mean the same things in our public communications. A set of terms has been developed and is being circulated to the Federal Agencies to solicit their agreement to use the terms. We expect to have that agreement in October.
- **Guidance for Producing Report Cards.** Many organizations, including several Federal agencies, large purchasers, and employers, are attempting to help patients make better choices about their health care by providing "report cards" on provider and plan performance to the American people. There are scientific studies that show what is effective in providing these report cards to various types of people, and there are many organizations with experiences that can help others who are attempting to provide high quality report cards. To inform report card producers, the QuIC agencies have brought together researchers and report card producers to develop guidance based on the science and reported experiences. This information will be made available through a web site that is currently under development. It is expected to be available this spring.



Agency for Health Care Policy  
and Research  
2101 East Jefferson Street  
Rockville MD 20852

SEP 30 1999

To: The Secretary  
Through:

DS  
COS  
ES



From: Administrator

Subject: Report to the White House on QuIC - ACTION

ISSUE

You indicated that you wanted to send a report to the White House on the progress of the Quality Interagency Coordination (QuIC) Task Force. A memo to the President is enclosed for your signature.

DISCUSSION

At the QuIC meeting on September 21, you heard about the substantial activities of the QuIC. Several of these activities are nearing completion, or are at a stage where there is information that should be made available to the public. You asked that we draft a report for you to use in reporting to the President on the progress that the QuIC has made. The memo for your signature and an attachment providing additional detail on the project are attached.

OPTIONS AND DISCUSSION

You indicated that the memo to the President should come from you and Secretary Herman. Since Secretary Herman was unable to attend the last QuIC meeting and is not cognizant of all of the activities underway, it may be best for you to forward this memorandum to the White House yourself.

You asked that the memo be directed to the President. It has been drafted in that format. Given that the Advisory Commission reported through the Vice President to the President, and given the Vice President's continuing interest in health care quality, would you prefer that this memo be sent through the Vice President to the President? Or should we send it to the Vice President, asking that he share it with the President?

This memo indicates your enthusiasm for the progress that the Departments have made in advancing health care quality. It does not suggest the possibility that the White House provide appropriate recognition for these multi-agency accomplishments. Would you like to suggest that some sort of recognition be given to the staff who have worked so hard on these projects?

99-0775

RECOMMENDATION

Send the enclosed memo forward to the President.

DECISION

Option 1. Send the memo as written.

Approved ✓

Disapproved \_\_\_\_\_

Date \_\_\_\_\_

OCT 28 1999

Option 2. Amend the memo for your signature and Secretary Herman's signature.

Approved \_\_\_\_\_

Disapproved \_\_\_\_\_

Date \_\_\_\_\_

Option 3. Send the memo via the Vice President.

Approved \_\_\_\_\_

Disapproved \_\_\_\_\_

Date \_\_\_\_\_

Option 4. Amend the memo to suggest some recognition for staff.

Approved \_\_\_\_\_

Disapproved \_\_\_\_\_

Date \_\_\_\_\_

  
John M. Eisenberg, M.D.

Attachment:

Memo to the President



THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C. 20201

OCT 27 1999

MEMORANDUM FOR THE PRESIDENT

As you know, the Department of Health and Human Services has been working for a number of years toward improving the Nation's system of organ procurement and transplantation. Our goal is to make the system operate for the greatest possible benefit of patients. We believe improvements in the organ transplant system could result in saving hundreds more lives each year.

Toward the goal of saving more lives, we have moved in two areas. With the Vice President's leadership, we have undertaken a National Initiative to increase organ donation. This effort has produced successful results in its first year. At the same time, HHS developed regulations to carry out the purposes of the National Organ Transplant Act of 1984. These provisions, developed over a period of years with extensive opportunities for comment, were published as a Final Rule on April 2, 1998.

Our Final Rule was supported by patients' groups and many prominent transplant centers and professionals, but was opposed by the HHS contractor which operates the Organ Procurement and Transplantation Network (OPTN) and by others in the transplant community. Last Fall, Congress imposed a one-year moratorium on implementation of the Final Rule, and mandated that a study of the issue be carried out by the National Academy of Science's Institute of Medicine (IOM). Congress also asked for further consultation between HHS and the transplant community. Both of these actions have been completed.

The IOM published its study in July. Its findings strongly validated the concerns and the approach of the HHS Final Rule. In particular, the study reinforced the need for Federal oversight of the Nation's organ procurement and transplantation system -- not to impose government in medical decision-making, but to ensure that the policies of the OPTN were operating fairly and effectively in the public interest. Throughout this year, HHS also continued meeting with the various elements of the transplant community, listening to concerns about the Final Rule and identifying common goals.

On October 20, HHS published amendments to the Final Rule which reflect the findings of the IOM report as well as our discussions with the transplant community. These amendments especially benefit from the input provided by the IOM, and they represent improvements in the

Prepared by APA/Fishback

11/2/1999/0028

Final Rule. But at the same time, we have preserved the core features of our Final Rule, which are the foundation for improving our system for patients. In particular, this means using standard medical criteria, developed by transplant professionals themselves, to decide which patients will receive organs. This is the only way to ensure that organs will reach patients who need them most.

Opponents of our Final Rule are once again seeking to use the Appropriations process to impose a renewed moratorium on the Final Rule. The Administration is on record as strongly opposing any new moratorium. I want to urge that we remain strong in defending our current position and insist that the regulation go forward as scheduled. Our approach has been validated by the IOM study that Congress ordered, we have listened to the concerns of all elements in the organ transplant community, and we must remain committed to an organ transplant system that saves more lives by serving patients in the fairest and most medically effective way possible.

In addition, both Congress and the Executive Branch should be concerned about the integrity of Federal spending for transplants. Medicare and Medicaid alone pay for more than half of transplant costs in the United States. However, without the Final Rule to define the Federal role in our transplant system, the government has little useable authority to assure that these Federal dollars are being used in a fair and effective manner.

Our goal is to work cooperatively with the transplant community to ensure the best possible transplant system for Americans. We have been careful not to inject government into decisions which must be left to medical professionals. Instead, we have designed a carefully balanced approach in which the Federal Government can carry out the oversight role which the IOM so clearly reaffirmed.

For these reasons, I would urge you to reject any actions by Congress that would further delay implementation of the Final Rule.



Donna E. Shalala

Attachments

THE Wash. Post, 10-23-91

## An End to Organ Games?

**T**HE FIGHT between the federal government and local organ transplant centers over how better to allocate scarce organs has been a strikingly unswerving application of territorial politics to an area where politics should play no role. This week the Department of Health and Human Services (HHS) published a final regulation—to go into effect in 30 days—intended to make organ distribution more equitable. The idea is to even out disparities among the many geographical areas served by the nation's 272 transplant centers, most of which grew up in an era when "harvested" organs needed, for technical reasons, to be used close to home. The varying populations of these regions mean uneven distribution, which, given the shortage of organs, spells death for some 4,000 patients a year for whom an organ cannot be found in time.

Enter HHS, which last year issued a draft regulation calling for the network's contractor, United Network for Organ Sharing, to come up with more equitable criteria based on medical, rather than geographical, status. The organ transplant network, though, fiercely opposed the regulation and persuaded Congress to delay its implementation a year. The network fears the changes would force local transplant centers to close, which in turn would dissuade families from donating loved ones' organs; it also warned of organ wastage

because of failed procedures if the sickest patients were invariably transplanted first.

Behind these concerns—for which a congressionally mandated report from the National Academy of Sciences' Institute of Medicine found no evidence—is the fear that local centers would close, eliminating the substantial income source they represent for the hospitals that house them. That may explain the otherwise remarkable fact that 10 states responded to the proposed rule by passing laws making it more difficult to send organs out of state. The Institute of Medicine report even cites cases where grieving families willing to donate were urged to sign contracts requiring that organs go only to in-state recipients.

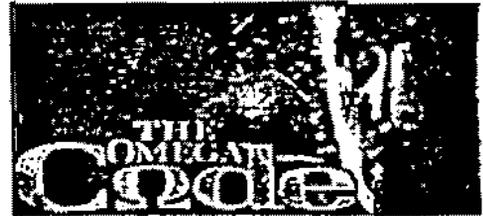
In fact, the report's researchers found no evidence that families care whether organs are used nearby; on the contrary, surveys showed they cared most whether the organs would be fairly used. The report recommends that geographical regions be made larger but that any new system make use of existing transplant networks rather than closing them down, a goal HHS Secretary Donna Shalala says could be achieved under the rule. Opponents of the reforms could still hobble and delay the regulation further as part of the budget appropriation for HHS. Such an action would be an extension of a cynical battle that costs patients' lives as it drags on.

# USA TODAY

NO. 1 IN THE USA... FIRST IN DAILY READERS

## THE HIT HOLLYWOOD OVERLOOKED 1D

TUESDAY



Top 10 sleeper: Grass-roots marketing vaulted biblical 'Omega Code' into a weekend box office hit.

Tuesday, October 19, 1999

# Fairer' transplant rules set

## HHS policies would reduce inequities in organ cases

By Robert Davis  
USA TODAY

Years of debate over how organs are allocated for transplants ended Monday with government rules that will require strict accountability from doctors and establish more uniform criteria for deciding which patients get organs.

The Department of Health and Human Services, which has been concerned about unfairness in patient selection and large regional variations in availability of organs, is requiring a new set of "core policies" that will change the medical community's handling of transplant cases.

The policies are intended to lessen the importance of waiting lists, force hospitals to share more information about more patients and minimize inequities that can lead to heart-breaking medical choices.

Government officials have been concerned that doctors sometimes pick their own relatively healthy patients over very sick patients in a hospital across town or in another state.

The rules are intended to ensure more protection for sicker patients and establish a series of criteria that treat all patients by one set of rules, including survivability.

"We think that this is going to improve (patient) survival overall," said Claude Earl Fox, administrator of the Health Resources and Services Administration.

"We think it is going to be a fairer system."

The transplant community, which has expressed concern about loss of medical independence, reacted cautiously.

"We absolutely believe (Secretary of Human Services Donna Shalala) should exercise oversight, but we do not believe the secretary should be making medical decisions," said a statement from Ronald Busuttil, president of the American Society of Transplant Surgeons.

The private group that runs the transplant system, the United Network for Organ Sharing (UNOS), said it was still reviewing the rules, which take effect in about 90 days.

The rules call for UNOS to establish policies that would:

- ▶ Establish the same basic criteria to decide which patients get transplants and when.

- ▶ Expand organ-sharing regions to ensure that organs reach patients who need them most. A recent report found that the wait for organs was 45 days in Iowa but 721 days in western Pennsylvania.

- ▶ Release information to the public to allow physicians and patients to identify the most

B-B

# THE PLAIN DEALER

MONDAY, OCTOBER 25, 1989

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President and Publisher

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Editor

**ROBERT M. LONG**  
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Editorial Page Director

**THOMAS H. GREER**  
Senior Vice President

## Ensuring a healthy system

By keeping the details open to doctors' suggestions, feds may produce a better organ donation network

The Clinton administration continues to push for a more regional system of allocating donated organs. That's good for sick people.

But the push leaves a lot of room for input from hospitals and doctors involved in transplant surgery. That's good for all concerned.

Whether the United Network for Organ Sharing, the hospital organization that set up the current system of allocating transplants, can recognize the common good remains to be seen. Thus far, UNOS has been much too intent on defending its methods to acknowledge that patients might be better served by a few changes.

Donna Shalala, secretary of Health and Human Services, has expressed a willingness to lay down the law if UNOS balks at doing its work the way its employer, the federal government, wants it done. But Shalala cleverly has stopped well short of dictating precisely what UNOS must do.

Instead, her department has set forth broad administrative requirements and left the details for the medical professionals at UNOS to decide.

As a result, comments like those of UNOS board member Ronald Ferguson of Ohio State University, couldn't possibly ring more hollow. "I support keeping medical decisions about transplant in the hands of the doctors that are caring for the patients. I oppose the intrusion of the government into the process," Ferguson says in a letter he has been asking his patients to mimic, sign and send to Congress (an actively intrusive arm of the government, last time we checked).

Good for you, Dr. Ferguson. Your argument in favor of keeping doctors in charge of curing patients is right in line with what Secretary Shalala wants, loath though you may be to admit it.

She is asking only that the criteria hospitals use to determine a patient's place on a transplant waiting list be standardized around the country, and that any donated organ be made available to the patient in most urgent need in a region larger than a single state. Further, HHS wants UNOS to establish performance measures so transplant centers' work can be evaluated.

Those broad requirements are fair, sensible and in line with advances in organ transplantation, preservation and transportation. The details of how to meet those requirements are the medical professionals' to decide, which is as it should be.

Unfortunately, the medical professionals at UNOS became used to lax HHS oversight over the years, and rare indeed is the hospital or doctor eager for performance evaluations. So it is no surprise that this government contractor has enlisted allies in Congress to help it become a law unto itself. That should not be allowed to happen.

The small burdens the Clinton administration is asking UNOS to take on hold great promise for improving the treatment of patients. But if the medical professionals best suited to do the job fail to do it, the government will have to step in and do its imperfect best.

# Editorial

The New York Times  
ON THE WEB

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July 26, 1999

## Improving Access to Organs

### Forum

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**F**or more than a year the Clinton Administration has been trying to improve the way human organs donated for transplants are distributed to patients around the country. But Congress, responding to intense opposition from transplant centers, has blocked the use of new Federal regulations that aim to broaden organ sharing across arbitrary local lines. A new report by the Institute of Medicine, a branch of the National Academy of Sciences, confirms that changes are needed to make the system more fair and effective.

The current system directs most organs to be used in the local area where they were donated. That can create unfair situations where patients who are less ill may get transplants while more severely ill individuals who happen to live outside the local organ procurement area are made to wait. This has become an increasingly important public health issue, since about 4,000 Americans die each year while waiting for transplants.

The Department of Health and Human Services tried to address the problem by issuing new regulations last year. These direct the United Network for Organ Sharing, a private organization that coordinates organ distribution nationally, to design a new allocation system that puts more emphasis on medical criteria and leaves less to geography. But Congress delayed that directive from going into effect until this October. The network insisted that the rules would force small transplant centers to close and discourage organ donations if donors knew organs would go outside their community.

The Institute of Medicine report, commissioned by Congress, found those fears to be overblown. The report, which focused on liver transplants, said waiting periods for the very sickest patients were actually comparable across the nation. But there were differences in waiting times for patients who were less ill. The report recommends improving distribution by requiring that organs be shared across

wider regions based on population, so long as the regions are not so geographically large as to pose problems in transporting the organs.

The report also affirmed the need for more active Federal oversight and greater scientific review of allocation principles. These recommendations are consistent with the Administration's approach. The transplant community should drop its resistance to Federal regulations that could make the system more equitable for patients everywhere.

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# THE LANCET

Volume 352, Number 9122

## Changing the US transplant system

In the USA, where you live can determine whether or not you receive an organ transplant. That is because the US organ allocation system is broken up into 11 regions and operates a "locals first" policy in which organs are first offered to patients in the area where the organs were obtained, then to patients in the surrounding region, and finally to patients in the rest of the nation. As a result, a patient living in one part of the country may receive a transplant before another patient with greater medical need living in another part of the country.

To try to reduce such geographical disparities, US Secretary of Health and Human Services, Donna Shalala, has proposed new regulations that will require the national Organ Procurement and Transplantation Network (OPTN), a private sector system of organ procurement organisations and transplant centres established by the 1984 National Organ Transplant Act, to revise its allocation policies so that eligible patients are not denied a transplant because of where they live.

Precisely how the OPTN is to attain this goal is left to the network to work out, but the policies must satisfy three performance goals. They must establish standardised criteria for determining which patients are medically eligible to be put on transplant waiting lists and for determining the medical status of patients, so that the medical needs of different patients can be compared; and they must set up allocation protocols that will reduce the influence of geographical factors so that organs will first go to those with the highest medical urgency. In pursuit of these goals, however, the regulations do not require the OPTN to adopt policies which, because they are impractical or are contrary to sound medical judgment, lead to futile transplants and organ wastage.

On the face of it, it is hard to see what is objectionable about Shalala's proposal, but the response of the United Network of Organ Sharing (UNOS), the DHHS contractor that operates OPTN, has been furious. In a letter sent to every US Senator last spring, the outgoing president of UNOS, L G Humstick, described the regulations as a "federalization of the current system which takes away control of the transplant system from doctors

and patients in almost 300 transplant centers and hands it over to Federal regulators" and forces doctors to give livers "to the very sickest patients", who are likely to require second or third transplants and thus use organs that could have gone to save other patients. Humstick predicts that the regulations will make it more difficult for most patients to receive a transplant because organs will be shunted towards a few large transplant centres with the longest waiting lists and the sickest patients.

But it is hard to see how the regulations amount to a "federalization" of the US transplant system, when they merely set performance goals and allow OPTN to develop the policies. The regulations also do not require that transplants be given to the "very sickest" patients but rather that preference be given to those who are "very ill but who, in the judgment of their physicians, have a reasonable likelihood of post-transplant survival" over those who are less medically urgent. Finally, it is hard to predict, before OPTN has formulated the final policies, what impact the regulations will have on smaller transplant centres. However, it can be argued that since where organs will go will depend on the needs of patients and not the size of the transplant centre smaller programmes could fare well under the new rules.

But what is clear is that the rhetoric adopted by UNOS and other opponents of the proposal is not helpful and has already caused mischief. Two states have passed legislation that gives state residents priority for organs donated within those states. Several other states are considering similar laws, which, if they survive court challenge, will further fragment the US organ allocation system.

The new regulations proposed by Secretary Shalala seem to give the network sufficient leeway to move closer to the desired goal without requiring it to adopt policies that will waste organs or force doctors to perform futile transplants. UNOS would better serve the transplant community if it abandoned its stance and began working with DHHS to draw up allocation policies that are practical and fair.

*The Lancet*



THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C. 20201

OCT 25 1999

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4/c

**MEMORANDUM FOR THE PRESIDENT**

I am writing to express my deep concern over discussions occurring in Congress that could result in creation of a new, independent Medicare board. As envisioned by its proponents, this board would operate as an independent entity designed to oversee the Medicare+Choice program, including the competition among private plans and between private plans and fee-for-service Medicare. The creation of such a board seriously undermines your authority over Medicare, the beneficiary protections that you have worked hard to establish for this program, and the significantly improved refocused management which has reduced the Medicare error rate by over fifty percent. This new board also sets the stage for capping government expenditures for Medicare, threatening Medicare beneficiaries' entitlement to first-class medical care.

The board's advocates say they want to bring private-sector expertise into the administration of the program and say they want to avoid conflicts of interest in running a competitive system. Their first goal is being accomplished without undermining the current strengths of Medicare and their second contention is a false promise. Not only will their proposals not achieve their goals, but, for the reasons stated below, they would substantially undercut our ability to serve beneficiaries and efficiently administer the program. At the end of this memorandum, I will describe the activities that we have already undertaken to garner additional private sector expertise in administering Medicare.

**Medicare Board Leads to Reduced Beneficiary Protections.** Under your leadership and through the hard work of this Department, we have ensured that Medicare includes the beneficiary protections outlined in your Patients' Bill of Rights. Medicare was one of the first programs in the country to incorporate these protections and remains a model program. This would not have been possible if the Medicare+Choice program were administered by an independent board.

Given the hostility we have seen in the private sector to even the modest proposals in the Patients' Bill of Rights, I do not believe that a board comprised of private sector health officials would have taken a strong, pro-beneficiary stance. It is not surprising that the strongest proponents of a Medicare board, including managed care interests, are among the most active opponents of strong patient rights legislation. I believe that we must maintain our ability to keep Medicare in the forefront of beneficiary protection. Creation of an independent Medicare board is not consistent with that imperative.

Prepared by ASP/Cano

11/19/99/0037

**Medicare Board Dilutes Presidential Authority.** Placing the Medicare+Choice program under the control of an independent board splits accountability for the program and substantially dilutes your authority over a substantial portion of Medicare. This is a significant loss given that Medicare serves 39 million beneficiaries and makes up 11 percent of the Federal budget.

The Administration's ability to make changes to Medicare in the context of the President's Budget would be limited. This is especially true since proposals for treating traditional fee-for-service Medicare as a health plan under the structure of Medicare+Choice would allow a new board to exercise substantial authority over the entire program. In particular, a board could be given substantial authority over what private health plans would be paid by Medicare. It could also be given authority to oversee aspects of traditional Medicare, including benefits and, under some proposals, total spending by traditional Medicare.

As a result, the presence of a board would have hampered our ability to exert strong budget discipline, such as the steps we have taken to extend the life of the Medicare Part A Trust Fund to 2015. Similarly, it would not have been possible to use Medicare changes to help finance key domestic initiatives to improve the health of the nation, such as the Children's Health Insurance Program.

Furthermore, creation of a board would limit the Administration's authority to make key program changes to address Medicare problems identified by beneficiaries, providers, or other segments of the American public.

**Medicare Board Diffuses Accountability for Medicare.** Authority over certain key functions would be unnecessarily complicated by bifurcating control of Medicare between a board and the Health Care Financing Administration (HCFA).

For example, Administration efforts to reduce fraud and abuse in Medicare have been successful because we have provided clear, consistent policy guidance and because we have been willing to take the political heat generated by our aggressive stance. I do not believe that an independent board (especially one that includes private sector health care executives, as would be likely with any congressionally created board) would have initiated or sustained such a controversial, yet productive, program. Specifically, the HCFA actuaries credit aggressive fraud control efforts with bringing down the Medicare baseline through reducing either the rate of growth or the actual level of spending on inpatient hospital services, home health, and lab services. Our efforts have also led to the first-ever decline in hospital upcoding since the inception of a prospective payment system in 1984. The bifurcation of authority under a board would threaten the significant advances made by this Administration by complicating the relationship between the program and the HHS Inspector General and between Medicare and the Department of Justice.

Similarly, this Administration has taken significant steps to measure and hold health plans and providers accountable for quality of care for seniors and other vulnerable populations. The diffusion of accountability threatens our ability to move aggressively in this area as we have on the Patients' Bill of Rights.

**Medicare Board Creates Potential Confusion of Authority That Would Be Detrimental to Beneficiaries.** HCFA is currently responsible for a wide range of activities that might become the responsibility of either the board or HCFA, or both. These functions include beneficiary education, procedures for appeals and grievances, provider enrollment, survey and certification of providers, and quality assurance. If these functions were assigned to HCFA, their applicability to private plans would become uncertain; if assigned to the board, more functions would be removed from the lines of public accountability. If assigned to both, there would be confusion and uncertainty among all parties involved.

**A Medicare Board Provides the Infrastructure for Ending the Medicare Entitlement.** Although the proponents of a board deny that they intend to fundamentally change Medicare, it is clear that creation of an independent board would establish the administrative framework for a defined contribution plan, which specifies the government's financial contribution toward beneficiaries' health care but does not specify the benefits to which beneficiaries are entitled. Creating an independent board is an ideal first step toward capping government contributions for Medicare, and beneficiary advocates will see it as such. It is not surprising that some of the strongest advocates in Congress for a board are the same Members who tried to cap Medicare spending in the 1995 budget bill that you vetoed.

**Claims About Current Conflicts of Interest in Managing Medicare Are Not Legitimate.** Advocates for a board argue that HCFA has an inherent conflict of interest in both managing the competition among private health plans and fee-for-service Medicare and operating the fee-for-service Medicare program. In fact, the risk of conflict of interest could be greater if managed care executives, hospital administrators, physicians, durable medical equipment suppliers, or any other individual who benefits from Medicare payments were given statutory powers through participation on the board.

Today, HCFA manages both original Medicare and Medicare+Choice, having successfully supervised the growth of Medicare+Choice to a program that enrolls about one of every six beneficiaries. HCFA's role is not unique - conflicts of interest are successfully avoided by CalPERS and many private employers that run self-insured plans while contracting with competing health plans.

The assertion that HCFA's dual role creates a conflict of interest may stem from certain decisions that private plans may find onerous, such as those in setting standards for consumer protection and quality assurance. Such decisions stem directly from HCFA's primary concern for serving the needs of beneficiaries, not from any desire to bias the competition. If a Medicare board also places serving the needs of beneficiaries as its core mission, it will inevitably make similar decisions. Thus, it will also be subject to the same charges of conflict of interest.

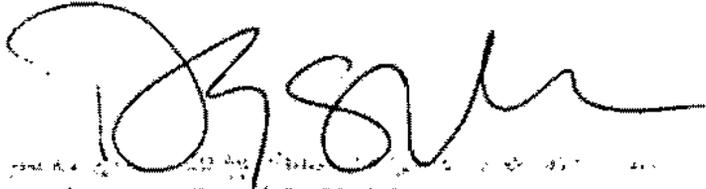
Under your proposal for a competitive defined benefit, traditional Medicare and private health plans would compete on an equal footing, allowing both Medicare and beneficiaries to save when beneficiaries choose efficient health plans. As discussed above, I believe that many board proponents are using the conflict of interest accusation as an excuse to take the first step toward ending the entitlement.

**Private Sector Involvement Can be Achieved Without a Medicare Board.** While I am deeply concerned about the proposals to create an independent board to administer a portion of Medicare, I am committed to expanding the program's access to private sector expertise. In September, we chartered a Management Advisory Committee for HCFA. This step was part of HCFA management modernizations contained in your budget. The committee allows HCFA to get expert advice from individuals in the public and private sector regarding innovations in management practices. It also will allow HCFA to maintain critical relationships with public and private sector experts in management, leadership, and purchasing strategies. The committee will address issues including how HCFA can better manage its private sector contractors and how it can be a more prudent purchaser of fee-for-service Medicare services. The committee need not make recommendations regarding payment or coverage policy, because the Medicare Payment Advisory Commission (MedPAC) and the recently established Medicare Coverage Advisory Committee already fulfill these functions.

I will chair the committee, which will include up to 11 additional members that I will appoint. The members will be selected from among nationally recognized authorities in academia, private consulting, public and private sector health purchasing entities, and private companies. The committee would not include provider or beneficiary representatives since they are already represented in many advisory committees to the Congress and the Department.

If Medicare reform is successful, this committee could also easily be adapted to serve as an advisory body for the implementation of the fee-for-service modernization reforms included in your Medicare plan. Experts from private and public sector organizations that purchase health care for their employees and beneficiaries, as well as experts in public administration, would provide recommendations to the Secretary on how to implement these reforms to purchase services more competitively. HCFA would benefit from the advice of these experts in a forum open to public participation.

**In Conclusion, Creation of a Medicare Board to Oversee a Portion of the Program Would Be a Grave Mistake.** It would be a disservice to our successors and to future generations of beneficiaries if we were to weaken the executive management of Medicare, not only because it is a substantial and growing proportion of federal outlays, but because older and disabled Americans are particularly vulnerable and need government protection. This Administration has strengthened Medicare in innumerable ways: extending solvency, increasing benefits, advancing new beneficiary protections, and strengthening program integrity. The Medicare program would most likely not be experiencing the benefits of the Administration's improvements had the Medicare board, as proposed, been in existence.

A handwritten signature in black ink, appearing to read 'Donna E. Shalala', is written over a faint, illegible background of text.

Donna E. Shalala



October 25, 1999

NOTE TO THURGOOD MARSHALL, JR.

A handwritten signature in black ink, appearing to be "Lambert".

I am forwarding herewith a Memorandum for the President, signed by Secretary Shalala. In her memorandum, the Secretary provides the President with background information regarding a new independent Medicare Board.

A handwritten signature in black ink, appearing to be "Mary Beth".  
Mary Beth Donahue

Attachment  
Memo to the President



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Office of the Assistant Secretary  
for Planning and Evaluation  
Washington, D.C. 20201

OCT 20 1999

TO: The Secretary  
Through: DS TZ  
COS 10/21  
ES LB  
FROM: Margaret A. Hamburg, M.D. MATT  
Assistant Secretary for Planning and Evaluation  
Gary Claxton Gary  
Deputy Assistant Secretary for Health Policy  
SUBJECT: Medicare Board

At your request, my staff has prepared the attached memorandum on the subject of an independent Medicare board. This memorandum states the case for why creation of a board would undermine the President's authority for running this program and threaten the consumer protections that have been established for Medicare beneficiaries. It also outlines activities that the Department has already taken to involve additional private sector expertise in administering Medicare.

The attached memorandum has been cleared by ASMB, ASL, ASPA, and HCFA, and their comments and suggestions have been included.

99-0841



THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C. 20261

OCT 8 1999

MEMORANDUM FOR THE PRESIDENT

On February 18, 1998, you issued an Executive Memorandum to the Departments of Agriculture, Education, Housing and Urban Development, Health and Human Services, Interior, Labor, Treasury, and the Social Security Administration requesting that they participate in your public-private initiative to enroll children in the Federal-State insurance programs. The Departments responded on June 26, 1998, with a list of over 150 strategies that (1) identified employees and grantees who work with families, (2) prepared strategies to ensure that employees and grantees are educated about the availability of CHIP and Medicaid, (3) developed an Agency-specific plan as part of the Administration-wide outreach plan and (4) identified any legislative or statutory barriers which affect the identification and enrollment of uninsured children in CHIP and Medicaid.

I am pleased to forward to you the Report of the Task Force on Children's Health Insurance Outreach. The Task Force has met quarterly throughout the past year to learn about children's health insurance programs (CHIP and Medicaid), discuss specific ideas and coordinate the implementation of new outreach efforts. Smaller Task Force workgroups have created outreach tools and materials, shared data and developed strategies to access hard-to-reach groups such as rural and migrant children.

The Task Force has accomplished much of its original work plan and proposes new strategies for reaching out to uninsured children and their families. In addition, there are three new partners in this effort, the Departments of Justice and Commerce and the Environmental Protection Agency.

The Task Force will continue to work to implement these new strategies, to add new partners and to sustain complementary and aggressive outreach efforts, consistent with the overall initiative to cover uninsured children.

Donna E. Shalala

Enclosure

9/30/1999 0021

**Report to the President  
Interagency Task Force on Children's Health Insurance Outreach**

Submitted by the  
Secretary of Health and Human Services

October 12, 1999

In Collaboration With

The Secretary of Agriculture  
The Attorney General  
The Secretary of Commerce  
The Secretary of Education  
The Administrator of the Environmental Protection Agency  
The Secretary of Housing and Urban Development  
The Secretary of the Interior  
The Secretary of Labor  
The Commissioner of Social Security  
The Secretary of Treasury



OCT 5 1999

PO-4  
L/C

MEMORANDUM FOR THE PRESIDENT

We in the Department of Health and Human Services (HHS) took note of your address to the Veterans of Foreign Wars, in Kansas City on August 17, where you noted that in Russia "the average salary of a highly trained weapons scientist is less than \$100 a month." I want to let you know where we stand with a new initiative, the HHS Biotechnology Engagement Program (BTEP), a program that grew out of requests we received last year from the Secretary of Defense and the Secretary of State.

We are now working with our colleagues in the Departments of Defense and State to engage former biologic weapons scientists from Russia and from the New Independent States in collaborative research on applied high-priority public health problems. We have just completed an initial assessment in Russia involving experts on the cutting edge of tuberculosis (TB) research and development. They have identified a number of good topics and pairings of former weapon scientists with U.S. counterparts to develop rapid diagnostic tests, conduct basic research on TB vaccines, and work on new drugs for the treatment of TB. This is particularly important given the dangerous emergence of multi-drug-resistant TB.

The Department of State has provided HHS with \$4.8 million in start-up funding not only to address TB but for similar activities in areas such as hepatitis, HIV/AIDS, and other infectious diseases. These projects will be implemented through the International Science and Technology Center, one of the State Department's very successful nonproliferation programs.

I want to assure you that we are taking steps to engage these weapons scientists in mutually productive public health work and that we have both the capacity and the need for the funding requested by the State Department to support this activity. We are ready to join with State in seeking Congressional approval for the full program proposed by the Administration.

Donna E. Shalala

10/5/1999/0000

Prepared by PHS/Bart



Assistant Secretary for Health  
Surgeon General  
Washington, D.C. 20201

SEP - 8 1999

TO: The Secretary  
Through: DS KTM  
COS HRD 9/29  
ES \_\_\_\_\_

FROM: Assistant Secretary for Health  
and Surgeon General

SUBJECT: Letter to the President of the United States Informing Him of the Status of  
DHHS Biotechnology Engagement Program (BTEP) -- DECISION

ISSUE

This memorandum is in follow-up to a discussion I had last week with Dr. Thomas Novotny, Deputy Assistant Secretary for International and Refugee Health, OIRH, concerning the President's speech to the Veterans of Foreign Wars in Kansas City on August 17 (Tab A). The President noted that in Russia "the average salary of a highly trained weapon scientist is less than \$100 a month," and expressed his concern about Congressional cuts to the multi-agency Expanded Threat Reduction Initiative, of which DHHS is a part, in the international affairs budget request. We agreed that a letter to the President should be drafted to inform him of the status of the new DHHS Biotechnology Engagement Program (BTEP) designed to encourage collaboration with former Soviet bioweapons experts in an effort to reduce the threat of technology transfer (Tab B).

BACKGROUND

At the request of the Secretary of Defense and the Secretary of State, DHHS has been asked to work with the United States Government (USG) security agencies to "engage" Russian and the New Independent States (NIS) former biologic weapons scientists in collaborative research on applied high-priority public health problems. The Assistant Secretary for Health and Surgeon General has created the Biotechnology Engagement Program and formed an interagency Advisory Group to oversee its operations. This program now has funding in place and DHHS has become a "partner" to the International Science and Technology Center (ISTC) funding mechanism which is also supported by the Japanese and the European Union. Exploratory missions this spring and summer have brought Russian and NIS scientists together with DHHS counterparts and project proposals for work on tuberculosis, plague, and other infectious diseases are now being developed.

DISCUSSION

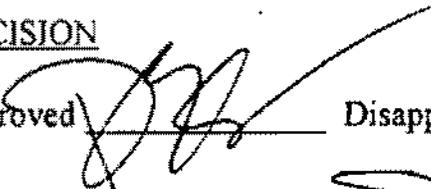
The timing of this letter may be slightly premature in that specific projects have yet to be approved, funded, and started. Nonetheless, the constructive engagement is underway including coordination with the Russian Ministry of Health to identify issues, such as Multi-Drug Resistant TB, (MDR-TB) where research on drugs, vaccines, and new diagnostics could be very helpful to long-term TB control efforts. We expect to complete a set of TB-related research proposals shortly, and proposals to address other infectious diseases are coming along nicely. We expect to have scientific merit reviews conducted in September/October and funding decisions for a first round of projects completed by the end of November at the latest. Each step of this process is being overseen by the BTEP Advisory Group you appointed.

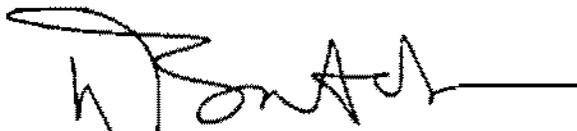
It would be most unfortunate to have funding for this program cut at this point. Thus, an early and timely message of progress may help to strengthen resolve that we are on the right track.

RECOMMENDATION

That you sign the attached memorandum to the President.

DECISION

Approved  Disapproved \_\_\_\_\_ Date OCT 5 1999



David Satcher, M.D., Ph.D.

Attachment



THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C. 20201

SEP 14 1999

MEMORANDUM FOR THE PRESIDENT

I encourage you to sign the attached proclamation which will declare October *Women's Health: Take Time To Care* (TTTC) month. Issuing this proclamation will heighten visibility for a superb program that educates women on the safe use of medicine. This program is run out of the Food and Drug Administration (FDA) and will sponsor events throughout October.

In the past two years, FDA's Office of Women's Health has reached more than 1.5 million Americans with this important message. TTTC has been so successful that this year, with the National Association of Chain Drug Stores (NACDS) as a co-sponsor, the program will reach at least 5 million women and their families about safe medicine use. To date, more than 20,000 drug stores across the country and more than 75 national women's, professional, religious, minority, and business groups have agreed to actively participate in the October effort.

As you have said, "Drugs are being constantly developed that help to improve the quality as well as the length of life, and if they are properly taken, they can actually reduce long term hospitalization and other medical costs." This is a program that directly addresses this issue.

I have worked with TTTC since its inception, and just this past May gave it my Distinguished Service Award. I strongly recommend that you sign the proclamation and encourage full White House support for this effort and related activities.

Donna E. Shalala

Attachment

Prepared by FOA/Friedberg

9/15/99 / 10/21

## **Women's Health: Take Time To Care Month, October 1999**

**By the President of the United States of America**

### **A Proclamation**

Thanks to the extraordinary success of modern medicine, Americans now live longer and healthier lives than at any time in our history. Today, more medicines are available than ever before, and we are continually discovering new drugs that successfully treat a wide range of diseases and conditions.

With many more prescriptions being written than in the past, the chance of misusing medications has increased. Indeed, between 30% and 50% of Americans who use medications don't use them as directed.

The consequences include increases in hospitalizations, nursing home admissions and deaths. In fact, adverse drug reactions are estimated to be responsible for 10% of all hospital admissions. Altogether, medication misuse costs the United States about \$76 billion each year.

These numbers are likely to increase in the new millennium. As the U.S. Food and Drug Administration (FDA) continues to make the drug approval process more efficient, more medicines will enter the marketplace. As the baby boomer population

ages, more prescriptions are likely to be dispensed. In 1998, 2.78 billion prescriptions were filled in retail pharmacies. By 2005, it is estimated that number will reach 4 billion. This unprecedented availability and demand for medicines is putting increasing pressure on our nation's health care system.

The FDA plays a crucial role in reducing Americans' risks by working to ensure that medicines are safe before they reach the marketplace. But once products are on the market, the responsibility for using them correctly falls primarily on the consumer. This is why all Americans must be told about safe medicine use—especially women. Women most often administer medications to family members and are also the leading users of medicines. However, today's women are often so busy with family, work and community responsibilities, that they lack the time to care for themselves and take medicines wisely.

During October 1999, the FDA's Office of Women's Health, in partnership with the National Association of Chain Drug Stores and other organizations throughout the country, will lead an important national public awareness campaign: *Women's Health: Take Time To Care*. It is targeting women with an urgent message to "Use Medicines Wisely" and is providing clear, concise information about medicine safety.

The *Take Time To Care* campaign is now in its third year. Because of extraordinary public response, what began as a grassroots effort is now national in scope and is expected to reach more than 5 million women and their families with the safe medicine use message.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim October 1999 as *Women's Health: Take Time To Care* month. I urge Government officials, business people, community leaders, educators, volunteers, women and all citizens of the United States to use this unique opportunity to take time to care about themselves, and those who need them, by learning to use medicines wisely.

IN WITNESS WHEREOF, I have hereunto set my hand this \_\_\_\_\_ day of \_\_\_\_\_, in the year of our Lord nineteen hundred and ninety-nine, and of the independence of the United States of America the two hundred and twenty-third.



September 8, 1999

TO: The Secretary  
Through: DS JZ  
COS MEJ 9/10  
ES LB

FROM: Commissioner of Food and Drugs

SUBJECT: Presidential Proclamation on *Women's Health: Take Time To Care* and Request for White House Participation -- DECISION

ISSUE

The purpose of this memo is to obtain your signature on the attached memorandum (Tab A) to the President requesting his signature on a national proclamation that would make October 1999 *Women's Health: Take Time To Care* (TTTC) month. I understand that since time is short, your personal support would greatly help us gain White House approval.

We would also like you to recommend that the White House take part in TTTC activities, following up on requests that have already been made to the First Lady and Mrs. Gore.

BACKGROUND

As you are aware, to help women lead healthier, longer lives, the Food and Drug Administration's (FDA) Office of Women's Health (OWH) developed *Women's Health: Take Time To Care*, a national public awareness campaign taking place this year in October 1999. The award-winning program aims to reach women with the theme, "Use Medicines Wisely." It makes women, who are the principal users of medications and who often administer them for family members, more aware of safe medication use with materials and interactive events led by pharmacists and other health professionals. This fall, the campaign will provide materials to over 5 million Americans about safe medicine use with the messages: Read the Label, Avoid Problems, Ask Questions and Keep a Record.

DISCUSSION

Since its beginning in 1997, TTTC has reached over 1.5 million people through more than 1,000 grassroots events across the country. In 1999, OWH is partnering with the National Association of Chain Drug Stores (NACDS) to make TTTC a major national campaign (Tab B). More than 70 NACDS member chains will participate, representing over 20,000 outlets nationwide.

99-0684

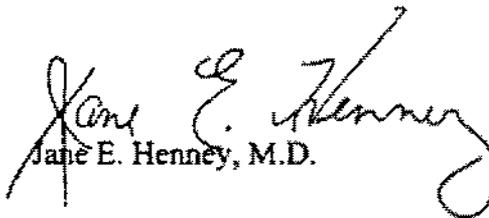
In addition to OWH and NACDS, the program will be led by businesses, health-service groups, nonprofit organizations, professional associations, other federal agencies, and state and local governments (see list of participating organizations and pharmacies at Tab C). These partners will distribute "My Medicines" brochures (Tab D) and hold interactive information sessions on safe medicine use. The campaign will also reach the public through television, radio, newspapers, magazines, newsletters, and the Internet.

Issuing a Presidential Proclamation and having an event at the White House would greatly heighten the visibility of the program and underscore the Administration's commitment to the importance of safe medicine use, especially as it relates to risk management.

The proposed proclamation has been reviewed and cleared at the Department by the Office of Women's Health, ASPA and AoA.

RECOMMENDATIONS

I recommend that you sign the attached memorandum to the President (Tab A) requesting that he sign the proclamation designating October 1999 as "Women's Health: Take Time To Care" month.

  
Jane E. Henney, M.D.

DECISION

Concur \_\_\_\_\_

Non-concur \_\_\_\_\_

Date \_\_\_\_\_

SEP 14 1999

Attachments:

- Tab A Memorandum to the President with National Proclamation
- Tab B October 1999 program summary
- Tab C Participating Organizations and Pharmacies
- Tab D "My Medicines" brochure

90-3-5  
L/C



THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C. 20253

APR 29 1998

MEMORANDUM FOR THE PRESIDENT

I am pleased to enclose a copy of the first Progress Report from the Home and Community Based Services Work Group. When you met with disability advocates, Administration appointees, and others interested in disability and long-term care issues in September 1997, you asked that HHS establish and lead this Work Group to take actions to expand and promote home and community based services. The enclosed Progress Report summarizes the Work Group's goals and activities to date.

I think you will agree that the group set for itself an ambitious agenda, and its leaders are to be commended for setting in motion an array of responses to the challenges they face. I am particularly pleased to note that the deliberations of the Work Group were helpful in developing several of your FY 2000 budget proposals. However, we know we still have much to do to achieve your key goal of expanding and promoting home and community based services and offering Americans of all ages with disabilities the opportunity to receive long-term supports in the settings of their choice.

*Donna E. Shalala*  
Donna E. Shalala

Enclosure

4/30/1998/0010

Prepared by NSO/Vanada

AIA-L.B  
P.C.D.

**HOME AND COMMUNITY BASED SERVICES  
WORK GROUP  
PROGRESS REPORT**

**Submitted by:**

**U.S. Department of Health and Human Services**

**Bob Williams, Deputy Assistant Secretary for  
Disability, Aging, and Long-Term Care Policy  
Office of the Assistant Secretary for Planning and Evaluation**

**and**

**Sally K. Richardson, Director  
Center for Medicaid and State Operations  
Health Care Financing Administration  
March 1999**



TO: The Secretary  
Through: DS Ytaw  
COS MEP 9/21  
ES LR

FROM: Assistant Secretary for Planning and Evaluation  
Administrator, Health Care Financing Administration

SUBJECT: Progress Report from the Home and Community Based Services Work Group -  
ACTION

Action Requested By: 4/20/99

### ISSUE

Enclosed is the first Progress Report on the Home and Community Based Services Work Group, which you established after the President and Vice President met with disability advocates, Administration officials, and others in September, 1997. The purpose of the Work Group is to expand and promote community based long-term care services for people with disabilities. We request that you sign the Memorandum to the President and send the Progress Report and memo to him. If you approve the report, we suggest that it be widely disseminated.

### DISCUSSION

The attached report summarizes the activities of the Home and Community Based Services Work Group, from the time it was established in September 1997 to December 1998. Just over a year ago, you asked Sally Richardson, Director of the HCFA Center for Medicaid and State Operations, and Bob Williams, ASPE's Deputy Assistant Secretary for Disability, Aging, and Long-Term Care Policy, to head an interdepartmental work group to identify options for **reducing unnecessary reliance on nursing homes, expanding and promoting consumer directed home and community based services, and empowering consumers with disabilities to live the best lives possible, in the most integrated environments.** You challenged them to build off the experience of successful States that were already operating affordable and effective long-term care services systems, and "start a revolution" which would spread across the country.

The group has made substantial progress in meeting your goals. As indicated in the attached report, the Work Group also provides important visibility within the Administration for long-term care policy concerns. It has spawned a wide range of new activities and now serves as an organizing point for many home and community based services programs, policies, and research/demonstration activities that were already underway in HHS.

## Page 2 - The Secretary

The Work Group includes HHS staff, "federal partners" from other Departments, and "constituency partners," including advocacy and consumer organizations, state officials, service providers, and others involved in disability and long-term care issues.

This report reviews the work of the Home and Community Based Services Work Group and its goals to date. It also proposes elements of a long-term care reform strategy which includes the following elements:

- peer-to-peer technical assistance to help states reduce the "institutional bias" in their long-term care spending and expand access to home and community based services;
- a demonstration program to assist current nursing home residents who wish to live in the community to do so;
- a package of policy changes that HHS could consider to help shift the balance between institutional and community services;
- policy and research initiatives to equip people with disabilities who want to work with the necessary tools and supports to gain and sustain employment; and
- efforts to explore ways to increase the supply of qualified personal assistance services (PAS) workers while helping people with and without disabilities move off of the welfare rolls and into meaningful employment.

The Progress Report demonstrates extensive interest and activity in the community based long-term care arena. It provides a strong and positive response to questions about HHS activities to address the "institutional bias" and seek consumer based long-term care solutions.

### RECOMMENDATION

We recommend that you sign the memorandum to the President and send him the Progress Report and memo. We also recommend that you agree to distribute the report widely to people with disabilities, advocates for the elderly and people with disabilities, professional organizations, state officials, members of Congress and others interested in promoting home and community based long-term care services.

DECISION

Send the Progress Report and memo to the President.

Approved  Disapproved  Date APR 29 1999

  
Margaret A. Hamburg

  
Nancy-Ann Min DeParle

Attachments:

Progress Report of the Home and Community Based Services Work Group  
Memo to the President



THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C. 20201

MAR 22 1999

MEMORANDUM FOR THE PRESIDENT

Every American should be healthy and safe. Your Administration has vigorously pursued this fundamental goal. In doing so, the Administration has shown that there is a continuing and central role for government in meeting the basic needs of ordinary Americans. It has redefined this role by understanding the obstacles to meeting its commitments, and reinventing to find the appropriate ways to address persistent and difficult problems. After six years, the Administration has achieved lasting and important improvements in the health and safety of the American people.

Infant mortality is at an all time national low. The nation has achieved record high levels of childhood immunization against preventable diseases, reduced childhood vaccine-preventable diseases to the lowest levels ever recorded and has made great progress in eradicating others. Children, women, the elderly, and racial and ethnic minorities are receiving new and overdue focus in clinical care, outreach, prevention and research. The nation's food supply and blood supply are safer than ever before. Millions more working families and children are securing health insurance. New mechanisms are in place to strengthen the quality of the nation's health care, inform Americans about their health and facilitate involvement in their own care. Science and evidence-based research provide the underpinnings for new policy and practice. Investment in biomedical research and prevention is generating new knowledge at a rapid pace, paving the way to greater health and safety for generations to come.

The enclosed paper, **Legacy: Health and Safety 1993-2001**, reviews our progress in five general areas: access to quality health care; prevention, risk reduction and safety; expanding the frontiers of knowledge; collaboration among scientific research, delivery systems and practice, and consumer involvement; and strengthening stewardship and demanding accountability to protect and benefit consumers. Your commitment to improving the health and safety of all Americans has been critically important to these extraordinary advances.

Donna E. Shalala

Enclosure

3/24/99 #13

## Legacy: Health and Safety 1993-2001

Every American should be healthy and safe. The Clinton Administration has vigorously pursued this fundamental goal. In doing so, this Administration has shown that there is a continuing and central role for government in meeting the basic needs of ordinary Americans. It has redefined this role by understanding the obstacles to meeting its commitments, and reinventing to find the appropriate ways to address persistent and difficult problems. After six years, the Administration has achieved lasting and important improvements in the health and safety of the American people.

Infant mortality is at an all time national low. The nation has achieved record high levels of childhood immunization against preventable diseases, reduced childhood vaccine-preventable diseases to the lowest levels ever recorded and has made great progress in eradicating others. Children, women, the elderly, and racial and ethnic minorities are receiving new and overdue focus in clinical care, outreach, prevention and research. The nation's food supply and blood supply are safer than ever before. Millions more working families and children are securing health insurance. New mechanisms are in place to strengthen the quality of the nation's health care, inform Americans about their health and facilitate involvement in their own care. Science and evidence-based research provide the underpinnings for new policy and practice. Investment in biomedical research and prevention is generating new knowledge at a rapid pace, paving the way to greater health and safety for generations to come.

Progress has been marked and measurable. When the Administration took office in the early 1990's, Americans were faring poorly on many indicators of well-being. Thousands of children were dying in infancy. Tobacco use, the most preventable cause of death and disease, contributed to millions of deaths from cancer and heart disease as well as other diseases. Outbreaks of contaminated food emerged, spreading sickness and alarming the public. Millions of Americans lacked access to regular health care either because they had no health insurance or were under-insured. Families were regularly confronted with painful choices -- paying for child care so a parent can stay in the workforce, saving to send a child to college, or obtaining necessary medical care for themselves or their children in times of illness or injury.

To address these problems necessitated confronting existing economic and social realities and the political realities that developed. Progress was made more challenging because of the ongoing transformation and upheaval in the health care market. A recent report by the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry described the dimensions of the changes in the health care industry this way:

Four characteristics define the health insurance market today, with implications both for who gets coverage and also for the kinds of coverage and protections in place for those who have insurance coverage: (1) pluralism, with a focus on employer-based coverage for the non-elderly; (2) significant and growing numbers of uninsured Americans; (3) the continuing pressure of costs on employers and consumers; and (4) the shift to managed care and the growth of self-funded plans in the group insurance market. The implications of these characteristics are profound, generating potential tradeoffs among cost control, coverage and access.

The Administration initially chose to deal with a market that was changing rapidly, becoming increasingly complicated and functioning poorly for millions of Americans by proposing a plan for universal health insurance that gave every American a gateway to health care. This effort was based on an assumption that an unfettered market would continue to disadvantage significant groups of Americans across the country. With the blockage of the Health Security Act came critical lessons which informed the Administration's approach to improving health and health care. The public was not ready to accept massive intervention which it perceived would be accompanied by added layers of impenetrable bureaucracy. It was reluctant to entrust to government solutions to major systemic problems that touch the lives of ordinary citizens. Generating large-scale investments in the face of \$300 billion dollar budget deficits also proved increasingly problematic.

To achieve progress in this environment required a new, more strategic and evolving approach to government's role and responsibility. Extensive regulation had to be balanced against a need to foster, not stifle innovation. Traditional mandates had to be weighed against the potential paralysis of our efforts due to the opposition by some to any government intervention at all. The Administration's new approach called for strategies that were different from the past, buttressed by strong commitments.

The abiding commitment has been to the American people, to addressing their needs and to achieving better outcomes for them. Promoting scientific inquiry and evidence-based research to find the best remedies has driven the search for new and better ways to reach our goals. A quest for new and effective treatments has been matched by a strong focus on identifying the best methods for preventing or reducing the risk of harm or disease. Public health issues became legitimate arenas of public advocacy, education and program development by government leadership beyond the traditional public health community. As effective practices emerge from rigorous scientific analysis, there has been vigorous and concerted effort to spread them. Finally, there has been fidelity to the notion that interventions in markets should be targeted to protect vulnerable populations, ensure quality, and strengthen the capacity of the consumer to obtain needed care.

In light of these lessons and commitments, the Administration adopted an approach designed around defined, strategic steps. It focused on expanding access to the financing families need to secure health care. It placed priority on improving the benefits and services available to consumers. It demanded heightened accountability for results, which requires the ability to measure and report on progress to achieve desired outcomes. It promoted cooperation with every affected sector and everyone with a stake in the enterprise. These include states and other governmental entities, contractors, public and private health plans, providers, professionals, the public health sector broadly and consumers themselves.

In sum, the new means to achieving the goals are realistic and pragmatic, faithful to the goals of health and safety through coverage, quality and prevention, building progress at a pace appropriate to each aspect of this multifaceted and complicated problem. The Administration found ways to shape an active role for government, make the necessary investments, strengthen the market, and positively touch the lives of virtually every American.

This memorandum concentrates on five general areas which illustrate and incorporate these new approaches and reviews our progress in each: access to quality health care; prevention, risk reduction and safety; expanding the frontiers of knowledge; collaboration among scientific research, delivery systems and practice, and consumer involvement; and strengthening stewardship and demanding accountability to protect and benefit consumers.

## I. Access to Quality Health Care

### *Expanding Health Insurance Coverage*

One of the most critical components of the Administration's plan to strengthen the health of Americans involved expanding health insurance to the millions of Americans without it.

In 1993, more than 37 million Americans had no health insurance at all, and another 25 million had inadequate coverage with very high deductibles. Nearly 90 percent of the uninsured were employed. Other families risked losing health insurance if they changed jobs, were priced out of the health insurance market even though they were working, or were prevented from purchasing insurance as a result of specific medical conditions.

The Administration initially delineated a proposal for universal health insurance, the Health Security Act, opening an important national debate about need, health care and health delivery and articulating a goal of universal access to care through universal coverage. With rejection of this systemic approach, the Administration sought creative ways to address, step by step, specific areas of need: security, choice and eligibility. Another important area involved cost control, as the inflationary spiral in health care costs had contributed to making important routes to health care inaccessible.

Improving access to care for other groups stimulated different efforts to link public health financing with private health plans. For many recipients of Medicaid, the federal-state health insurance support for the nation's lowest income individuals, doctors and other critical health care services were not readily available. Using waivers and other administrative tools to demonstrate new approaches, nineteen states contracted with managed care plans, linking an estimated 1.4 million Medicaid recipients to a routine source of preventive and primary care in their community or to other critical benefits. For other low-income individuals making a transition into the workforce, and legal immigrants, the Administration's support for maintaining their eligibility for Medicaid has been critical.

The 1996 Health Insurance Portability and Accountability Act (HIPAA) strengthened protections for those who are insured through their employer to ensure they do not lose health coverage when they change jobs. The law also secured access to health insurance for individuals purchasing insurance individually rather than in a group health plan, limited the use of exclusions from health insurance as a result of pre-existing medical conditions, and prohibited discrimination against employees and dependents based on their medical conditions. In addition, HIPAA guaranteed access to health insurance for small employers, regardless of the health status of any of its group members and renewability of insurance to all employers regardless of size.

Next, the Administration sought to address the serious gap in insurance coverage for children. In 1993, more than ten million children had no health insurance, placing them in stark jeopardy during these formative years. Uninsured children are three times as likely to have unmet health needs as their insured counterparts, and much less likely to have seen a doctor in the previous year. Some of these children are eligible for but not enrolled in the federal-state health insurance program serving low-income families; for others, their parents' employer either provides no health benefits at all, provides benefits which do not extend to dependents, or provides health insurance which parents forego because it is unaffordable.

The 1997 State Child Health Insurance Program (CHIP), proposed by President Clinton, provides \$24 billion in federal resources, matching state funds, to provide health insurance coverage for children in families with too much income to be eligible for Medicaid, but not enough to obtain employer-sponsored health coverage. This is the largest investment in health care for low-income children since Medicaid was created in 1965, and paves the way for millions more children to be connected to a regular source of health care.

By the end of January 1999, 50 states and territories had plans approved that will extend health insurance to uninsured children in their states. States and territories estimate that by October 2000, under existing plans, they will be able to provide health insurance to 2.5 million more children. A recent report sponsored by the Commonwealth Fund estimates that, when combined with Medicaid outreach, the new CHIP program could reach 9 million of the 11.3 million children the report estimates are currently uninsured and eligible for coverage under one of the two programs.

Unlike the under 65-year old population, elderly and disabled Americans in this country have benefitted from a universal health insurance system -- Medicare -- for many years. The program serves 38 million people, the vast majority of whom rely solely on this source of health insurance coverage to pay for medical care. Some have been priced out of the complete Medicare package as a result of their low income, others have had limited access to critical therapeutics, including prescription drugs. With the cohort of older Americans increasing, diagnostic tools and treatments becoming more extensive, and health plans becoming more diverse, it is critical to modernize Medicare to ensure full participation and provide the elderly the range of choices that the health care market has to offer.

Given the size of the beneficiary population and the millions more who will be served by it each year, shifts in Medicare's structure or benefits have far-reaching effects on a huge number of people as well as on a substantial portion of the health care market.

During the past five years, the Administration has made significant advances in modernizing Medicare and improving access to it for the burgeoning elderly population. Medicare Plus Choice opens the Medicare program beyond traditional fee-for-service providers and health maintenance organizations to a wide array of health plans and benefits that serve many other Americans in the private market. Over time, as an expanded set of health plans and benefits become available to Medicare beneficiaries, the elderly will have a set of options that can be tailored more appropriately to a particular beneficiary's needs.

The Administration also targeted subgroups of the elderly who faced special barriers. It is now possible, for example, for approximately 6 million low-income elderly to get special help in paying their Medicare premiums so that they can get the benefits they are due like other senior citizens. Improving medical care for Medicare-eligible military retirees will be achieved, in selected communities, by enabling them to receive comprehensive health care services through military health care facilities.

Even as the Administration has made significant strides in expanding health insurance availability and widening choice of health care options, the private employer-based health insurance system continues to erode. With health care costs increasing again at a higher rate and purging profit margins, managed health plans migrate in and out of some communities, reflecting recurring volatility in local and regional health care markets and undermining the continuity of care for their patients. A continuing challenge involves addressing the increasing number of Americans who lack health insurance. Without the critical interventions during the past five years, however, millions more children and adults would risk losing insurance, not obtaining it in the first place or receiving inadequate care. (See Figure 1)

### *Creating Patient-Oriented Health Care Systems for Veterans and for the Military*

The largest health care system in the nation, Veterans Health Administration (VHA), serves veterans -- individuals who have previously served the nation through the military and have been honorably discharged or have retired from active duty. While more than 25 million Americans are veterans, VHA provides health care to about 3.7 million veterans-- those with service-connected disabilities or illnesses and that much larger proportion of veterans who are low income individuals with no private health insurance, including many who are homeless. This population is generally older and sicker than the broader public, with a significantly higher rate of substance abuse and mental illness.

Before 1995, VHA was rapidly becoming an outdated inefficient system based on acute care -- a collage of independent competing medical centers that provided hospital-focused, specialist-based, uncoordinated and episodic treatment for illness. This system was also experiencing many of the same market forces that were causing upheaval in the private health care market. In 1995, the Administration completely reorganized the VHA system to provide the most decent and reliable health care possible, to take advantage of exploding scientific and medical knowledge, and to address the spiraling costs of care. It is now a coordinated interdependent system in which patients are enrolled in primary care and have their care, from preventive to acute, managed by a single caregiver or team. Inter-facility and inter-provider variability in the provision of care is diminishing. More patients are being treated and are receiving a broader array of coordinated services in a greater number of locations.

VHA established 22 integrated health care networks (Veterans Integrated Service Networks, or VISNs) that emphasize ambulatory and primary care. Through this philosophical, management and operational reinvention, VHA closed, merged or consolidated hospitals and other treatment centers, developed new mechanisms for sharing assets between and among VA facilities, implemented patient care service lines, and redirected savings from these changes to vastly

expand ambulatory capacity. Numerous new community-based outpatient clinics were opened using new legislative authorities for leasing, contracting and sharing. Accompanying the restructuring of the system into networks, VHA instituted new systems of resource allocation, performance contracts, measurement and accountability, customer service standards and consumer feedback mechanisms.

The Veterans Health Care Eligibility Reform Act enabled all veterans to apply to receive health care at VA medical facilities nationwide. For the first time, as a result of this new program, enrolled veterans will be able to receive comprehensive benefits in the most appropriate cost-effective settings, within the resources available for the priorities of veterans being enrolled each year.

With a reinvented system and new legislative authority, veterans now have better access to care. Massive changes were accomplished in transforming from the old to the new system. Compared to FY 1994, annual inpatient admissions in FY 1998 decreased 32 percent while ambulatory visits increased by 35 percent. At the same time, 52 percent of hospital beds were closed, as were three acute care and one long-term care hospital. In 1994, less than 20 percent of VHA patients received primary care; by FY 1998, more than 90 percent were expected to be enrolled in primary care. Ambulatory surgeries increased from 35 percent of all surgeries performed in FY 1995 to 70 percent in FY 1998. Associated with this change has been increased surgical productivity and reduced mortality, with no change in the patient risk profile.

In addition to surgical mortality, one-year survival rates for the nine high volume conditions tracked by VHA also suggest the impact of these changes. From the baseline year of 1992 to 1997, the survival rates remained stable for five of the conditions and increased for four conditions: congestive heart failure from 75 percent to 84 percent, chronic obstructive pulmonary disease from 84 percent to 88 percent, pneumonia from 82 percent to 89 percent, and chronic renal failure from 72 to 81 percent.

The Defense Department provides health services to another 8 million eligible active duty service members, their dependents and military retirees. The same kinds of financial, social and technological pressures that affect private health systems were constraining the capacity, benefits and services of this large system. As part of health care reform, the DOD redesigned the military health care system into a managed care system called TRICARE, using inventive ways to enhance access, cost containment and performance. DOD purchased a substantial portion of health care through long term, regional, risk contracts with large health care providers but produces most care in military hospitals and clinics. The department created the Defense Health Program, bringing together into a more cohesive and collaborative entity resources for the three military services' medical operations and enabling them as a result to use resources and technology more efficiently, thereby serving patients more efficiently and effectively. DOD created a true tri-service defense health program using managed care on a regional basis.

Finally, DOD took important steps to bring modern communication and biomedical technology to improve health care during deployment of military personnel and on the battlefield. Pioneering advances have occurred in telemedicine, mobile surgery, air medical evaluation techniques and

other critical technology which is enabling the military to push medical care further forward on the battlefield or provide it to deployed individuals wherever they are.

### *Consumer Protection and Quality*

Access to care is only as good as the quality of the care provided. In an increasingly complex and changing health care market, the Clinton Administration has focused significant attention on strengthening and assuring quality care, protecting all health care consumers, and using the purchasing power of the government to achieve important new benefits, new rights and new choices in health care for millions of Americans.

To ensure that the best professional knowledge is used in the health care system, and to identify the most promising ways to protect health care consumers, the President appointed an Advisory Commission on Consumer Protection and Quality, chaired by the Secretaries of Health and Human Services and Labor. The Commission made pioneering recommendations in a Consumer Bill of Rights and Responsibilities that addressed fundamental practices to enhance the capacity of consumers to secure quality care from health care providers: information disclosure, choice of providers and plans, access to emergency services, participation in treatment decisions, respect and nondiscrimination, confidentiality of health information, complaints and appeals and consumer responsibilities.

The Bill of Rights applies to all health care consumers regardless of the type of health plan in which they are enrolled. The Administration mounted a multi-faceted strategy, using administrative as well as legislative levers, to reach every consumer sector with these protections. First, given that the federal government itself is the largest purchaser of health care in the United States, the President directed the six federal agencies that are health care purchasers to pursue full compliance in their health programs, and to identify obstacles to meeting that goal.

Medicare, Medicaid, and the Indian Health Service, the largest programs affecting over 70 million people, have either already met or exceeded many of the Bill of Rights' recommendations. Where necessary, administrative steps are being used to upgrade standards in these programs. Medicare, for example, covers an estimated 38 million elderly and disabled individuals, about 6.5 million or 17 percent of whom are currently enrolled in managed care. The program is implementing rules which require new patient protections such as access to emergency services when and where the need arises, patient participation in treatment decisions and direct access to qualified specialists to address complex or serious medical conditions. Medicaid, which covers about 40 million individuals, about half of whom are in some managed care arrangement, is adding new protections including access to specialists and an expedited independent appeals process for patients.

The 285 participating health plans that reach nine million federal employees and their dependents, have been directed to institute a series of protections for patients this year. These include access to emergency room services, access to specialists, continuity of care, and disclosure of financial incentives and methods of compensation used to pay physicians. Over 8 million beneficiaries served by the Military Health System and another 3 million veterans will also receive the patient protections laid out in the bill of rights as a result of actions by the Department of Defense and the Veteran's Administration.

Second, the Administration has proposed legislation for a Patients' Bill of Rights, to ensure that consumers in private health plans are similarly protected. Without legislative action, the 125 million Americans covered by 2.5 million private sector health plans governed by the Employee Retirement Income Security Act (ERISA) will be denied most of the patient protections identified as critical to quality health care by the President's Advisory Commission.

Third, a variety of efforts have also been made to strengthen the capacity of health care plans and providers to develop and report quality data, and to share that information with the public. Use of this information by employers, employees and other purchasers is critical to ensuring a system that is driven by the quality of care and not simply by its cost.

The Quality Commission also made strong recommendations about the need to enhance the measurement and improvement of quality. It suggested that health care quality improvement draw on many of the same principles that have been applied in the Administration's reinvention of government. This evidence-based approach to quality improvement is narrowing the gaps between what we know how to do in medical care and what we actually do for the American public. The Administration's commitment to biomedical research has been matched by a renewed commitment to health services research about what works in the delivery of health care. This commitment was carried out by the Administration's support of evidence-based research, the development of the National Guideline Clearinghouse which will provide a central repository of best health delivery practices, a focus on prevention, and emphasis on research about health outcomes and effectiveness.

In addition to asking Federal agencies to lead the way to consumer protection in health care, the President organized the Quality Interagency Coordination Task Force (QuIC), a collaboration among all the federal health involved in health care, chaired by Secretaries of Health and Human Services and Labor. The purpose of the QuIC is to improve measurement, share best practices and knowledge about how to use information generated by measurement to improve health care quality, to inform patients about the options available to them, and to enhance the health care workforce's ability to provide quality services.

As technological invention has escalated the ability to store, analyze and distribute extraordinary volumes of data, confidentiality of personal health information has become a paramount concern. The Administration responded to this concern with recommendations to the Congress to preserve confidentiality of federal health records, guarantee rights for patients and define responsibilities for record keepers.

### *Strengthening Americans' Role in Health Care*

Respecting the health care needs of America's citizens and strengthening their influence have been principal elements of the Clinton Administration's approach to achieving a healthier nation. At virtually every opportunity, there have been efforts to reach Americans with accurate, accessible and understandable information about health and health care. Emerging knowledge about nutrition, fitness and disease prevention is disseminated widely and in highly visible mediums. Beyond these messages moreover, the information provided makes people's

expectations about choice real, by providing the practical information about how and where to obtain health and medical care, and how to choose among a range of health plans, providers and treatments. The Administration has taken a comprehensive approach, drawing on the reach and resources of every medium, advancing the use of high technology in the service of outreach, and calling upon the organizations and institutions, community networks and professionals of every sort who interact with the public on a daily basis.

The federally-sponsored Consumer Assessment of Health Plans (CAHPS), which can be used by managed care plans, employers and others to get consumers' views of the care they are receiving, illustrates the kind of information generation which can over time affect the basis on which health care purchasing is conducted. Among the first to get the benefit of this information will be Medicare enrollees in managed care plans and enrollees in the Federal Employees Health Benefits Program. Policy in these two programs frequently sets a standard that the private health care system follows.

A massive Medicare education program using print and electronic media, individual counseling, partnering with private organizations including employers, unions, advocacy groups and providers will aid the 38 million Medicare beneficiaries navigate an expanded set of health plan choices as they come to fruition. This tailored information program for beneficiaries and their families will strengthen understanding of the program, break down its complexity, and foster more effective use of the health and medical supports it offers. Such an information program will have lasting impact as senior citizens become more numerous, live longer, and have the ability to age actively and in good health.

In concert with states, there is also an extensive education and outreach initiative to reach families with children who may be eligible for existing or new child health insurance programs. Given the unique opportunity to link millions of currently uninsured children to a regular source of medical care, federal agencies are reaching out to every grantee, advocacy and professional network to send the message of the importance of health care for children. Virtually all states have developed plans and are seeking the resources to expand health insurance for low-income children. In addition, many states, including Connecticut, Vermont, Arkansas and Wisconsin have taken critical steps to remove the stigma of Medicaid so that more families and children who could take advantage of its benefits recognize its value and will enroll.

Using the information highway, scores of new government-generated web sites are enabling consumers to navigate easily the vast array of health and medical information produced by the federal government and its partners. New Internet resources like *Healthfinder.gov*, *Medicare.gov*, National Women's Health Information Clearinghouse and MEDLINE, which offers the most extensive collection of published medical information in the world, open new doors of knowledge and data for the public, improving their ability to become informed, make responsible choices, and contribute to improving their health and that of their family.

Product labeling offers another way to advance the ability of consumers to affect their own health and behavior. In general, consumers want to know more and more about the products they use, especially products central to their daily health and well-being such as food and drugs. In

addition to changing the ways in which information becomes available, the quantity of information available is being increased substantially. The Internet has accelerated dissemination of an increasing fund of information and the Administration has taken advantage of the new technologies as noted above. Careful and accurate labeling of consumer products offers another approach to enhancing information for public use. Just as with food labeling, over the counter drug labeling will be revised by the Food and Drug Administration to provide more useful information to the consumer. In the future, drugs for use by children will also be made safer by proper labeling, based on newly required studies of safety and appropriate dosage. This information can be used by physicians and health providers to make science-based judgments about appropriate treatments when prescribing drugs for children.

## II. Prevention/Risk Reduction/Safety

Many things have the potential to cause harm. Motivated by a commitment to a public health approach, the Administration saw an important role for government in increasing public attention to these factors, applying scientific tools to understand the nature, scope and characteristics of the factors, testing strategies to control and prevent them, and strengthening clinical practice to use the most effective methods to address them. The Administration sought to improve safety and reduce the risk of harm regardless of whether the harm resulted from disease, behavior and lifestyle, environmental hazards or under use of care. Consequently, issues from reducing susceptibility to communicable diseases to early detection of chronic illnesses, from securing the safety of the food supply to preventing hazards and violence at work and at home and to preparedness for global threats, took a central place in the roster of Administration priorities.

### *Child Immunizations*

In 1992, less than sixty percent of all children under age two received the recommended immunizations against vaccine preventable diseases. Low-income children's vaccination rates were considerably lower. Since 1993 the Administration's Childhood Immunization Initiative (CII) has been dedicated to reducing the risk to children of acquiring vaccine preventable infectious diseases. This national initiative focuses on five areas: (1) improving the quality and quantity of immunization services, (2) reducing vaccine costs for parents, (3) increasing community participation, education and partnerships, (4) improving systems for monitoring disease and vaccinations, and (5) improving vaccines and vaccine use.

Of particular note in this effort is the Vaccines for Children Program (VFC) which provides vaccines at not charge to many of the Nation's most vulnerable children. Not only has VFC program made vaccines more available and affordable to these children, but it also promotes continuity of health care and has also improved access to the latest vaccines. This year the rotavirus vaccine was recommended for use in young children. The vaccine works to prevent one of the most severe causes of diarrhea in children. In 1999 this vaccine will be available through VFC program. Prior to the VFC program, these children may not have received timely access to the newest recommended vaccines. Other efforts of the CII include many vigorous and creative public education campaigns conducted by public agencies, private agencies and many public-

private partnerships that have made possible wider acceptance and readier availability of immunizations to millions of children. Now a record high percentage of young children throughout the nation are immunized. For children under the age of two, the most vulnerable age group, the immunization rate for a recommended series has risen to 78 percent, a record high level.

This record has stimulated great strides in preventing specific pediatric illnesses. Measles is disappearing, moving from epidemic status to about 138 cases per year, most of which are imported from outside the U.S. Diseases such as acquired mental retardation, deafness, and often-fatal meningitis, caused by *Haemophilus influenzae* type b, have been substantially reduced. In all, childhood vaccines prevent 12 infectious diseases: polio, measles, diphtheria, mumps, pertussis (whooping cough), rubella (German measles), tetanus, *Haemophilus influenzae* type b, varicella (chicken pox), and hepatitis B. By 1997 over 90 percent of children under age two were immunized against measles, polio, and *Haemophilus influenzae* type b, and over 80 percent were immunized against diphtheria, pertussis, tetanus, and hepatitis B. (See Figure 2)

### *Mammograms and Other Preventive Screening*

As we have learned from research about the value of regular screening to identify the presence of disease at an early stage, the Clinton Administration consistently has sought ways to make these life-saving approaches available and affordable to the public. To make this possible, coverage is now provided through Medicare for vital preventive benefits that can help prevent future illness or injury.

Breast cancer is the most common non-skin cancer in women; and the second leading cause of cancer deaths for American women. Yet only 61 percent of women ages 51 and over had a mammography in the previous two years, according to a 1994 study by CDC. Based on evidence that screening measures could prevent approximately 15-30 percent of all deaths from breast cancer among women over the age of 40, in 1997 the NIH issued guidance that women age 40 and over should receive mammography screening once every one to two years. Now all Medicare beneficiaries over 40 have access to annual screening mammograms, and women ages 35-39 can obtain a one-time initial, or baseline, mammogram. The FDA also put in place standards that upgrade the quality performance of personnel and equipment at all U.S. facilities for mammography screening.

Changes in Medicare coverage also have made more accessible other critical cancer detection techniques, such as a screening pap smear, pelvic exam and clinical breast exam including mammography. Osteoporosis, for example, afflicts 10 million Americans annually, 80 percent of whom are women. Osteoporosis causes about 1.5 million fractures a year, costing \$10 billion in direct medical expenditures. With tests of bone mass density now covered for postmenopausal women, millions of women will have an opportunity to take steps to avoid this debilitating disease and avert many of its painful and costly consequences.

Preventive approaches are not limited to women. Screenings for prostate and colorectal cancers are now more widely covered benefits under Medicare. Approximately 16 million Americans

have diabetes and nearly 798,000 new cases are reported annually. Minorities - especially African-Americans, Native Americans and Hispanics/Latinos - comprise a disproportionate share of those who suffer from diabetes. Under Medicare, critical education and self-management training for diabetes, which will aid individuals in developing the skills and resources generally needed to control the disease, are now more widely available.

### *Curbing Tobacco Use*

Recently-appointed director of the World Health Organization, Dr. Gro Bruntland, calls tobacco use the most preventable disease worldwide. In the U.S., smoking is the largest single cause of morbidity and mortality. Every year more than 400,000 people die from tobacco-related cancer, respiratory illness, heart disease, and other health problems. At the same time, each year another million teenagers become regular smokers.

Research has demonstrated that children experiment with tobacco use at ages 10-13, become addicted at ages 14-16, and once addicted, by age 18 become tobacco industry customers for life. To break this cycle, the Administration set a goal of reducing the smoking rate among young people by 50 percent within seven years, thereby curbing unnecessary disease, disability and death in adulthood.

The insight that tobacco use is a pediatric disease persuaded the Administration to open a new comprehensive campaign in the war against smoking. First, the Administration used its regulatory powers to prohibit young people's access to tobacco and to curtail its visibility and appeal to youth by limiting the industry's marketing tools, such as advertising, billboards, giveaways and sponsorship of events and other products. Second, the proposed rule itself and the flood of public response to it exposed hundreds of thousands of pages of industry documents revealing the depth and duration of the industry's knowledge of tobacco's addictive qualities, and the manufacturing and marketing strategies used by the industry to expand and secure a customer base despite extraordinary compromises to public health.

Third, implementation and enforcement of the Synar rule became a priority. The Synar Amendment requires states to conduct random unannounced inspections of a sample of tobacco vendors to assess their compliance with laws prohibiting tobacco sales to underage children. States failing to meet their goal of reducing violation rates to 20 percent risk losing a percentage of their federal funds for substance abuse prevention and treatment. HHS placed a special Office on Smoking and Health at the CDC, including a clearinghouse to assist states with effective practices, established a public health research program to demonstrate and evaluate state-based programs, and created new strategies to address the effects of secondary smoke and other environmental issues. In 1999, CDC will be providing support to all 50 states, the District of Columbia, and the territories to conduct comprehensive tobacco control programs. Several states programs include counter-advertising, community coalitions, and policies on environmental tobacco.

Fourth, the Administration expanded the surveillance tools available to track tobacco use. In addition to the Youth Risk Behavior Survey and Monitoring the Future, which provide important national information about teens' health behaviors, by 2001 a household survey administered by SAMHSA will provide smoking-related data by state and by brand. This will advance markedly the ability to target specific geographic areas and specific company practices in order to reduce teen smoking.

Finally, significant initiatives have been taken to strengthen clinical practice to help people stop smoking. A 1993 CDC study found that 37 percent of smokers ages 18 and older were in the previous year given advice by a health professional to quit smoking. Research also demonstrated that such advice by a health profession was an effective intervention. In 1996, these findings, reviewed and enhanced by a consensus conference, generated governmental guidelines for health professionals on smoking cessation practices that recently have been widely disseminated.

There is little question that the social climate in the country has changed as a result of the Administration's willingness to confront the life-threatening nature of tobacco use. No longer are public health professionals the only ones calling to "take the billboards down." It is now widely accepted and politically safe for individuals to talk about the hazards of smoking and the impact of smoking on the environment and for communities to take measures to countervail the vast advertising and marketing by the tobacco industry. Several states and many localities have banned smoking in public places and work-sites. The November 1998 settlement between states and the tobacco industry bans billboard advertising everywhere as of April 1999.

More important, these efforts are affecting the smoking habits of millions of Americans. Massachusetts' aggressive set of activities against tobacco use has returned a 31 percent drop in cigarette consumption between 1992 and early 1997 and smoking among teenagers has remained level while it has risen in the rest of the country. In the U.S., adult smoking declined between 1992 and 1996. That the incidence of teen smoking nationwide continues to increase -- CDC reports that the number of teenagers taking up smoking as a daily habit has increased 73 percent between 1988 and 1996 -- reinforces the importance of holding steadfast to this campaign.

#### *Prevention and Response to Emerging Infections*

Just as new tools are needed to address a global economy, new tools are required to deal with global health. With trade more open and international travel more accessible and affordable, individuals from throughout the globe are coming into the U.S. At the same time, urbanization has brought more crowding in congregate spaces for both adults and children, and agricultural practices and food production are undergoing rapid change. Such transformations increase the risk of exposure to new pathogens that may never have been seen before in humans, increase the presence of infectious agents that previously were insignificant or less virulent, and increase the likelihood of diseases that were generally found in animals finding their way into humans.

The Administration faced these new dangers by establishing comprehensive plans for prevention and response systems to address new infectious diseases regardless of their origin, including building the capacity to identify, track, diagnose and treat them rapidly and effectively.

Strengthening the public health infrastructure as a whole (including federal laboratories and surveillance, as well as state and local capacity to identify, diagnose, and respond) will enhance the nation's capacity to deal with health emergencies of many types. The critical capacity necessary to address all of these issues of emerging infection involves detection of the infection, isolation of the infectious agent, identification and characterization of the microorganism, and linkage to a system of prevention and/or treatment.

Through the leadership of the Centers for Disease Control and Prevention, the U.S. launched in 1994 and updated in 1998 a strategic plan to prevent emerging infectious diseases. The strategic planning documents, developed with the Committee on International Science, Engineering, and Technology (CISET) and a score of federal agencies, provide the framework for specific action initiatives to address, for example, food safety, an influenza pandemic, and bioterrorism. The initial plan spurred Presidential action and congressional appropriations, a resolution and plan by the World Health Organization, a plan for Canada, a Department of Defense plan and an NIH infectious disease research plan. Other indicators of progress include new resources for state health departments, training young professionals to build new leadership, and renewed attention on infectious diseases which had been considered conquered rather than only controlled, and for which we had not imagined new kinds or sources of infectious agents.

In the international sphere, the United States recognized the importance of addressing global health through cooperation with international organizations and as a high priority issue in bilateral relationships. The World Health Organization (WHO) plays a critical role in coordinating establishment of international standards for vaccines, blood products, other biological products, drugs and medical devices and for the data and information that help medical and health professionals assess, diagnose, treat and prevent disease and disability worldwide. Working with other reform-minded countries, the U.S. led the effort to reinvigorate the WHO by searching for and recruiting new leadership, ultimately installing Gro Bruntland, of Norway, as the new WHO Director. In addition, global health is now an issue on the agendas of the European Union and the Organisation for Economic Cooperation and Development (OECD), and the U.S. is working closely with the Pan American Health Organization to increase the use of existing and newer vaccines, to strengthen the National Control Authorities and the National Control Laboratories involved in the regulation of vaccines and other biological products, and to increase the research and surveillance activities in the region. Finally, committees to address health through information, technical assistance and other exchanges were established as part of bilateral relationships such as the commissions between the U.S. and Russia and between the U.S. and South Africa. Several other bilateral working groups, including the US/European Union Task Force, the US/INDIA Joint Working Group, and the US/Japan Common Agenda, are pursuing activities to address emerging infectious diseases.

### *Food Safety*

Foodborne illnesses kill approximately 9,000 people annually and make up to 81 million others sick. New, more virulent, more drug-resistant pathogens, life style changes such as eating more meals outside the home, the importation of more foods from around the world, the increased consumption of seafood, and other shifts in food production are creating new challenges for the

nation's food safety system. The inspection system, first established in the 1920s and operated by several different agencies, had become completely outmoded.

To overcome this fragmented, divisive and archaic system of monitoring and protecting the food supply, the Administration advanced a comprehensive new initiative to make sure that the food Americans consume is one of the safest in the world. This concentrated attention to the food safety system has resulted in substantial improvements, from modernizing inspections to creating a high technology early warning system to detect and control outbreaks of foodborne illness.

Not all the improvements in food safety rely on high technology solutions. The Administration also has given renewed visibility to high impact low technology practices, such as hand washing and everyday actions that individuals can take to handle and prepare food safely. Fight Bac!, a consumer education campaign, focuses on four basic principles: CLEAN, SEPARATE, CHILL, and COOK. Mounted by the Partnership for Food Safety Education, a coalition of government, industry and consumer organizations, the campaign is vigorously communicating messages to the broad public to convince them to change unsafe food handling behaviors and to adopt sound, science-based public health practices that ensure food safety.

Both the U.S. Department of Agriculture (USDA) and FDA now use a new highly science-based approach to inspections and enforcement, called Hazard Analysis and Critical Control Points (HACCP), which places considerably more responsibility than in the previous system on the commercial food producers or processors. This new basis for inspection and detection has been put into place for seafood, meat and poultry and will be applied as well to juices.

The new system also includes enhanced surveillance capacity through FoodNet, a network of laboratories to do active surveillance regarding foodborne illness, and PulseNet, a network of laboratories specializing in genomics and genetic fingerprinting, which will facilitate rapid recognition of outbreaks so they can be investigated and controlled before they spread. PulseNet is expanding its reach and capacity by connecting many state public health laboratories with CDC, and by bringing USDA and FDA laboratories on line. A Food Safety Council, established by the President in 1998, will institutionalize coordination among the nine agencies involved in food safety across the government to ensure that a seamless food safety system is achieved.

One early indicator of progress is the reduction in time between detection, diagnosis and response with regard to certain emerging infections. In 1993, it took weeks to determine the common food source of the outbreak of foodborne illness caused by a deadly strain of bacteria, *E. coli* 0157:H7. Today, it can take PulseNet and its new computer links as little as 48 hours to match strains of bacteria and recognize foodborne illnesses occurring at the same time but in different communities. In the near future, PulseNet will be able to perform these functions not only on *E. coli* 0157:H7 isolates, but also on other bacteria that cause illness through food. This technology and coordination can detect major outbreaks and provide the basis for determining public health actions, including product recalls, ultimately reducing illness and saving lives.

## *Bioterrorism*

The U.S. has increasingly become vulnerable to terrorist attacks with weapons of mass destruction. Biological weapons present some unique challenges, including a silent release in a public space and a prolonged process of identification more likely to occur in context of a health professional, which call for a special response capability.

To address the health consequences of any incident involving use of nuclear, biological or chemical materials, the Administration is developing a strategic plan with four components: enhancing the public health infrastructure with emphasis on the surveillance system; strengthening the medical response capability; creating and maintaining a stockpile of pharmaceuticals and other materials; and enhancing research, design, development and approval of diagnostics, antibiotics/antivirals and vaccines. Implementing this plan will require creating partnerships to enhance the local health and medical system capability to respond effectively, while at the same time improving the federal capability to augment rapidly state and local response resources, including local emergency medical systems.

### *Promoting Reproductive Health; Preventing Infertility*

"Reproductive health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity, in all matters relating to the reproductive system and its processes. Reproductive health therefore implies that people are able to have a satisfying and safe sex life and that they have the capability to reproduce and the freedom to decide if, when, and how often to do so."

These words represent the resolve of the 1994 International Conference on Population and Development that publicly transformed the world understanding of health and reproduction. No longer are these issues to be viewed only from the perspective of controlling population. Instead, with significant engagement by the U.S., the delegates from around the world crafted a "programme of action" designed to promote reproductive health and to recognize reproduction as a health and human rights issue. As the National Research Council subsequently stated, implicit in this vision of reproductive health are three principles: 1) every sex act should be free of coercion and infection; 2) every pregnancy should be intended; and 3) every birth should be healthy.

These have been defining tenets since the Clinton Administration took office. In one of his earliest actions, the President overturned a previous directive prohibiting women in the military from receiving abortions. There have been consistent efforts to promote choice, enhance reproductive health and take a comprehensive view of women's health.

Stemming sexually transmitted diseases, especially chlamydia and syphilis, is one of the arenas in which progress is most promising as a result of this important shift in framework. Chlamydia, the most common infectious disease reported to the CDC, is the most common preventable cause of potentially fatal tubal pregnancies and involuntary infertility. This sexually transmitted disease can facilitate the spread of HIV, and infant eye infections and newborn pneumonia can result from maternal transmission of chlamydia.

In the past six years, the nation has tackled chlamydia using a reproductive health paradigm, a different strategy than is used to address other STDs. To address jointly the prevention of pregnancy and prevention of STD infection required collaboration across STD prevention and family planning programs at the federal, state and local levels. Federal funding for chlamydia prevention are now shared between these two branches of public health departments, creating more connection across the two programs. Data from the states in which this approach has been mounted indicate dramatic declines in chlamydia positivity in both older women and teenagers attending family planning clinics that were participating in the screening program. A similar effort use chlamydia screening in a managed care setting showed a reduction by 60% of pelvic inflammatory disease (PID) which is the central link to negative health outcomes.

Building on this recognized success, federal resources now cover about 40-50 percent of women in publicly funded family planning clinics in 20 states. However, in the other 20 states, only about 15 percent of women at risk are reached with the screening protocol. The Administration is proposing to expand successful screening and treatment programs for chlamydia.

Another STD, syphilis, is targeted for total elimination in the U.S. Prevention of syphilis is critical to reducing transmission of HIV. Currently, the U.S. is at record low rates of syphilis; 75 percent of counties have eliminated the disease. In the past several years, progress has also been made in bringing down the disparate impact of the disease by race from 60 percent higher among African Americans than whites to 40 percent higher. Nevertheless, just 31 counties produce half of all the new syphilis cases, and the racially disproportionate impact persists. A focused effort to eliminate the disease will involve using the biomedical tools already available and building the public health infrastructure which is necessary to address other persistent and new infectious diseases -- other STDs, AIDS, tuberculosis, bioterrorist threats -- in areas that currently suffer from severe lack of capacity.

### *Traffic Safety*

In the decade preceding the advent of the Administration, considerable progress had been made in improving traffic safety. However, a robust economy stimulates greater mobility and increased use of vehicles. As a result, stagnation in traffic safety markers such as fatality rates, fatalities related to alcohol use, and the use of seat belts essentially meant falling behind with more deaths and injuries -- virtually all preventable.

New leadership at the National Highway Traffic Safety Administration (NHTSA) reengineered its approach to traffic safety to place it once again on the public agenda not only of government, but of industry, public health professionals and a wide variety of community stakeholders. Further, it found a range of non-regulatory remedies to promote positive safety practices on the road. As with other public health problems, many of these new solutions relied on reaching out to a broader constituency, and developing partnerships at the state and community level, to share responsibility and ownership of the problem of motor vehicle injuries.

To make the new collaborations effective, NHTSA created constituency-specific networks to focus on discrete problems. The Network of Employers for Traffic Safety (NETS), for example, enables industry to focus on traffic crashes as an internal cost issue. Techniques for Effective Alcohol Management (TEAM) draws together representatives of athletic stadiums and arenas, initially to address alcohol-related motor vehicle injury, and more recently to highlight seat belt use. Engineers from the automobile industry are now linked to a wide spectrum of scientists, health professionals, law enforcement personnel, and crash investigators at seven trauma centers around the country through CIREN (Crash Injury Research and Engineering Network) to improve the knowledge base about injury resulting from vehicle crashes and about the factors contributing to crashes. Through this new information, medical professionals can make better decisions about risk, diagnosis and interventions.

Scientific knowledge became a catalyst for change in other arenas as well. Research findings stimulated renewed interest by law enforcement agencies whose participation was essential. The fact that the majority of felony arrests result from routine traffic stops energized police and other law enforcement personnel to give greater visibility to enforcing use of child safety seats, seat belt usage and other safety measures.

Strengthening the data system which undergirds traffic safety efforts has also proven particularly effective in engaging states in taking actions to address their local problems. NHTSA linked state data to enable states to analyze and assess their own information instead of relying solely on the federal agency to identify the problems. In addition, through CODES (Crash Outcome Data Evaluation System) traffic records are connected with data about hospital discharges emergency medical services.

Finally, NHTSA created the Safe Communities program to elevate traffic safety as a public health issue, catalyze community-based coalitions, and make available the tools communities need to address the problem in a sustained and results oriented way. Other federal agencies such as CDC, intergovernmental organizations such as the National Association of Governor's Highway Safety Representatives, and other public and private organizations became partners with NHTSA to assist localities to identify and take control of the safety issues in their communities. More than 550 communities have opted to be "Safe Communities," and with support from other federal agencies, these coalitions are mobilizing to address other safety issues as well.

The renewed interest in traffic safety at all levels of government and the community is beginning to reap benefits in greater use of safety measures and reduced injuries. In 1997, seat belt use inched up to 69 percent, alcohol-related traffic deaths dropped by two percent, declining to a record low of 38 percent, and the fatality rate from crashes fell slightly to 1.6 percent, also an all time low. With Americans traveling more every year, continued effort along this path will be necessary to meet NHTSA's goals of a 20 percent reduction in traffic fatalities and injuries by the Year 2008.

## *Improving the Safety and Health of America's Workers*

Many serious workplace hazards threaten the health of workers who labor in their midst. Whether through injury or disease, these hazards jeopardize the productivity of the workforce, the well-being of the workers and their families, and the fiscal vitality of the industries involved. Despite progress in reducing workplace deaths between 1980 and 1994, an average of 137 individuals die each day from work-related disease and an additional 16 die from injuries on the job. Millions more are injured or permanently or temporarily disabled. The estimated annual economic burden of disease and injury for occupational disease and injury in 1992 was \$171 billion. Yet reducing the risks presented by many of these hazards has proven an arduous task as a result of the polarization of interested sectors, debates over regulation, and tensions about what, if any, degree of risk is acceptable.

The Administration realized that the debates were protracted, resolved little and often resulted in stalemate. Millions of workers remained unprotected. Both public and private sector efforts have faced increasing fiscal constraints brought about by the downsizing trends of the 1990's. It was clear to the Administration that it was necessary to go beyond tradition and the usual approaches to test a different strategy. To address this issue, the National Institute for Occupational Safety and Health and its more than 500 partners created the National Occupational Research Agenda (NORA) in 1996 to target and coordinate occupational safety and health research and to leverage resources for research to protect working Americans.

The Agenda identifies 21 priority research areas for the entire occupational safety and health community. In 1998, the largest single infusion of federal funding for extramural occupational health and safety research was achieved. Science and new technology became tools for consensus building around pragmatic solutions rather than the source of debate about relative levels of risk reduction.

Partnership is vital to the Agenda's success. An illustrative example involves a pioneering partnership with the asphalt industry and the associated labor organizations which led to a timely voluntary solution to the problem of workers' exposure to asphalt fumes during paving operations. The partnership turned the traditional approach on its head, seeking to prevent rather than react to the carcinogenic effects of asphalt fumes on workers. Traditional rulemaking in this case would have provoked years of litigation and would have lost time to protect the affected workers. The partnership, by contrast, was able to sidestep a protracted debate and deliver practical controls in the workplace. Through the use of innovative engineering controls, the partners were able to achieve 100 percent of an industry voluntarily agreeing to implement control technology equipment -- which reduces worker fume exposure by about 80 percent -- on all new highway pavers.

Over the past five years, successful occupational health and safety research partnerships with private industry and labor, including General Motors, Walmart, United Auto Workers, Browning Ferris Industries, Laborers' Health and Safety Fund of North America, Ford Motor company, and others have laid the groundwork for a new era of protecting America's workforce.

## *Strengthening Safety of Consumer Products*

Partnerships have also become the hallmark of efforts to improve the safety of consumer products. The U.S. Consumer Product Safety Commission has, whenever possible, used voluntary and pragmatic approaches to achieving safety for the public in preference to more adversarial regulatory measures.

Recalls of hazardous products are now accomplished, for example, with an innovative process of collaboration with industry. This Fast Track Product Recall Program, which received the 1998 Innovations in American Government Award from the Ford Foundation and Harvard's Kennedy School of Government, achieves recalls three times more quickly than in 1995. In this program, if an industry voluntarily identifies and reports a product problem to the CPSC, and agrees to do recalls within 20 working days, the CPSC agrees not to make a letter of findings that would otherwise be placed in public files about the industry. This new process has minimized adversarial proceedings, increased the rate at which products are returned to the manufacturer, effectively getting unsafe products off the shelf faster and away from consumers. From products such as Hasbro's "Soft Walkin' Wheels" toy to Sunbeam's Gas Grill, fast-track recalls occur in an average of seven to ten days, effectively deterring most hazardous products from ever getting to consumers in the first place.

Regulating product safety has traditionally been time consuming and often contentious. CPSC sought alternatives to regulation as ways to achieve safety while retaining the power to regulate. For example, to overcome the problem of children strangling when the strings at the neck of their outerwear garments caught on playground or other equipment, CPSC asked industry voluntarily to remove the strings and replace them with snaps, buttons or Velcro closures. Industry agreed to do so voluntarily and later adopted a voluntary standard on this issue. Industry solved a different problem, eliminating the loops on venetian blinds cords in which some children were strangling, in a similar cooperative fashion. First, the industry agreed to give away replacement safety tassels free. Subsequently, a new voluntary standard was adopted and industry developed a number of new safer products to eliminate the strangulation hazard. When CPSC told manufacturers of baby walkers that it was considering a mandatory standard to address the thousands of injuries to children resulting from falls down stairs, the industry came up with a variety of new designs. Both the affirmative efforts to collaborate with industry and the continuing authority and willingness to regulate where necessary have produced significant improvements in the safety of consumer products.

Efforts to promote safe products and to reward good practice have also heightened awareness and attention by the public of ways to protect people from harm. In cooperation with Gerber Foods, CPSC developed the "Baby Safety Showers" program, which the First Lady helped launch. This idea has been picked up by hospitals, organizations that work with new mothers, parenting education programs and many others to help educate new parents about safety in infancy. The CPSC Chairman also initiated a Commendation for Substantial Contributions to Product Safety, given periodically to industry, which offers another way to give public attention to positive actions for safety.

## *Prevention of Family and Interpersonal Violence*

Intentional injury between intimates reached very high levels in the early 1990s. In 1993, there were more than one million violent victimizations of women by an intimate. A 1994 study of child abuse and neglect, using a methodology that includes children both reported to child protection agencies as well as children believed to be maltreated but not reported, found that 2.8 million children were abused or neglected. The Administration made a major commitment to the prevention of family and intimate violence.

In the context of a comprehensive effort to address crime, the Administration collaborated with the Congress to gain adoption of the Violence Against Women Act. While efforts to prevent and end sexual violence began as grass-roots, community-based movements more than two decades ago, these landmark provisions of the Crime Act of 1994 provided new legal tools and bolstered funding to address violence against women. The Violence Against Women Act made certain acts federal crimes. It doubled funding for shelters and other critical community-based help for battered women and their children. It also substantially increased funding for rape prevention and education, especially for school-age children. It provided new support to local law enforcement and police for training and special focus on domestic abuse. It enhanced research opportunities, stimulating collaborative investigations across domains and disciplines. It strengthened surveillance and applied to crimes against women public health methods of tracking, testing and evaluating interventions, and spreading effective practices and public health messages. These approaches are making it possible to link more closely surveillance processes and service delivery systems to strengthen the science base for systems that prevent and respond to family violence.

Signs of progress are emerging. The Crime Victimization Survey, administered by the Department of Justice, reports that since 1993, the rate at which women experience violent victimizations at the hands of an intimate has declined. For every 1000 women in the population, the rate dropped from 9.8 violent victimizations in 1993 to 7.5 in 1996. Vigorous implementation of the Violence Against Women Act, knitting together legal protections, social supports and public health approaches at the community level have contributed to a climate in which violence between intimate partners is not condoned.

Escalating reports of abuse and neglect of children propelled the Administration to seek ways to reassert the importance of safety in both policy and practice. Through the Adoption and Safe Families Act of 1997, states are given streamlined legal requirements and new financial incentives to facilitate and expedite adoptive or permanent families for maltreated children who have been languishing in foster care. The new law also increases support for preventive and early intervention activities to help vulnerable families stay together safely.

Together, these new laws and the additional resources flowing into communities are establishing for the next century essential frameworks for enhancing family safety.

### III: Expanding the Frontiers of Knowledge

Commitment to the continuous development of knowledge has been a canon of the Clinton Administration. Scientific discovery is exploding at an unprecedented pace. Technology, genetics, and information capacity have all contributed to this flourishing and complex enterprise. Finding ways to continue and accelerate these developments and harness them for the public good has required many careful and strategic steps, as well as a deep respect for and understanding of the nonlinear nature of the processes of scientific research and advancement. Rigorous research usually takes not only talent and creativity but time, rarely proceeds without complications or detours, and requires commitment for the long course.

A first and fundamental step taken by the Administration involved recognizing the need to strengthen the intellectual, managerial and financial underpinnings of the government's vast scientific activities. The Administration attracted one of the world's most distinguished scientists to lead the National Institutes of Health, the world's largest biomedical research institution. He, in turn, attracted a number of distinguished biomedical researchers to lead the various Institutes and Centers. In addition, the Administration called annually for significant support for science research, and crafted a 21st Century Research Fund to stabilize high level investment in biomedical, behavioral, and prevention research for the next generation.

Over the past five years, building on the multi-year research activities of a large number of investigators and collaborators, many important discoveries have emerged and several have been swiftly transferred into clinical practice. Significant and durable changes have generated much more active processes for translating basic science into clinical practice and then into broad use. New communication tools are making it possible to give greater visibility to and graphically portray basic science stories. These stories attract public attention, convey vividly the excitement of new scientific discoveries, show the progress that is occurring and give a vision of what is possible. Through stories, the public can become more knowledgeable about personal health, allowing individuals, where possible, to be healthier.

One result is a much more holistic approach to disease, to health and to basic human behavior and functioning. It is possible now, for example, to understand and promote the notion that when diet is changed in certain ways, it is affecting risk factors not just for one disease -- heart disease or cancer or osteoporosis -- but potentially for many of them at the same time. Further, research on any disease frequently confers unanticipated insights into other diseases.

#### *Vaccine Development and Use*

The development of safe and effective vaccine has been one of the outstanding accomplishments of biomedical research in the 20th century. The beneficial impact of vaccines has been especially great in improving the health of children. Childhood vaccines, used in national immunization programs, have eradicated one infection (smallpox), eliminated another from the Americas (polio), and dramatically reduced the incidence of many other infectious diseases of children. In the last five years there has been significant progress in vaccine development, led in major part by the National Institutes of Health (NIH). (See above) The FDA and its biologic laboratories in

cooperation with the NIH and the CDC have provided critical contributions fostering the acceleration of new cutting edge technologies by establishing standards and methodologies ensuring the safety of these new product areas.

Several vaccines for use in children are in advanced stages of development. One of these, the vaccine to prevent rotavirus diarrhea has been licensed by FDA for use in the United States in 1998 and has been recommended for routine use in children by the Immunization Practices Advisory Committee. This vaccine prevents the most common cause of dehydrating diarrhea in infants and is widely expected to markedly reduce this problem. An experimental live vaccine, the cold-adapted (ca) influenza virus vaccine is also under development. Based on reports of investigational clinical trials, it is expected to improve significantly the health of children by preventing about 90 percent of the cases of acute influenza infection that occur in children and also reduce the rates of middle ear infection by nearly one third. Vaccines to prevent the serious complications of the food borne infection caused by Escherichia coli O157:H7 and related enterotoxigenic strains are also on the horizon.

### *Pediatric AIDS*

HIV has been one of the leading causes of death in the U.S. between the ages of 1 and 24 years since 1991. Transmission of the virus from HIV-infected pregnant women to their offspring is the major source of new pediatric infections in the U.S. and worldwide. In 1994, an NIH-sponsored study group reported a clinical trial which demonstrated that zidovudine (ZDV or AZT) administered to the mother during pregnancy, labor and delivery and to the infant in the first weeks of life can reduce mother to child transmission of this fatal infection from 25 to 8 percent. A Public Health Service Task Force led by an NIH researcher published recommendations which form the major basis for the use of this drug to prevent perinatally-transmitted pediatric HIV and AIDS. Recent reports from a number of areas around the country indicated that maternal-fetal transmission of HIV has fallen to 5-7 percent as a result of this treatment regimen. Drug development for therapies for HIV is an area which facilitated and broadened the ability of children to access both clinical trials and new therapies.

The recently presented findings of another NIH researcher, based on a comprehensive international study, suggests that elective cesarean delivery can reduce further the transmission rate in ZDV-treated pregnant infected women to only two percent. Furthermore, as a result of NIH-sponsored research and public health service clinical guidance, this nation is also on the way to eradicating mother-to-child transmitted pediatric AIDS, beating the two percent rate of perinatal HIV transmission set as a goal a few years ago by the private Pediatric AIDS Foundation.

### *Chronic Disease*

New knowledge has changed some chronic diseases to acute diseases and these can be treated more effectively. For example, with the discovery that about half to three-quarters of peptic ulcers are a result of an infectious agent, the disease can now be managed through the use of antibiotics. The length and frequency of crises from sickle cell disease, which affects African-Americans disproportionately, have been diminished through the use of hydroxyurea added to penicillin to prevent infection. This treatment has been approved for use by adults but not yet for children.

The first indications have emerged of a decline in the incidence and death rates from cancer. While not yet confirmed, likely contributors to this decline include: a decrease in smoking among adult men and improved screening procedures including mammography and pap smears, which lead to earlier detection and management of the disease, increasing the survival rate. Another likely contributor involves greater sophistication in defining risk, enabling better advice to be proffered on prevention.

Deaths from coronary heart disease continue to decline, reflecting new treatments such as beta blockers. New diagnostic techniques also enable earlier detection, finding heart disease that may have gone unnoticed in the past. On the horizon is making sure that the successful treatments are made widely affordable and available.

#### IV. Collaboration Among Science Research, Delivery Systems, Prevention, and Consumer Involvement

One of the hallmarks of Clinton era strategies for change has been to maximize collaborations between government and anyone with a real interest in the issue. Complexity has been a major factor inherent in trying to conquer health and safety problems that contain scientific and technological, fiscal, political and social dimensions. The Administration made certain assumptions in the face of these complexities. Foremost among them was that no one sector could devise solutions or take action alone. So the Administration crafted collaborations to bridge scientific research, dissemination of findings, application of findings to new treatments and making the treatments available safely and as quickly as possible. These partnerships drew on both public and private health care delivery systems to put new findings into practice, and involved consumers as teachers as well as beneficiaries. Wherever possible, cooperation included providing information, and developing, testing and marketing prevention strategies.

##### *HIV/AIDS: A Case Study*

Nowhere has this collaborative approach been more historic and had greater impact than in the fight to stem HIV/AIDS in the United States. In the 1990s, AIDS diagnoses and deaths dropped markedly in this country. At least 15,000 fewer people died of AIDS in 1997 than in the previous year alone, a 42 percent decline. (See Figure 3) Among the leading causes of death, HIV infection fell from 8th to 14th place between 1996 and 1997. The result is increasing numbers of people who are HIV-infected and still alive and whose quality of life has improved. The number of new cases of HIV infection reported annually in the United States has leveled off to approximately 35,000 to 40,000 per year, far less than in the early years of the epidemic. However, rates of infection in some racial/ethnic minority communities have increased over the years and remain alarmingly high.

This legacy builds on the work, creativity and perseverance of many who came before and has achieved its significant changes through the multiple and layered efforts of many throughout the government, the private sector and by the public. Actions by the President from the outset of the

Administration, dedication of the federal scientific enterprise, public health agencies and many others, and unprecedented investment of resources for treatment and prevention, however, have contributed to deepening and accelerating progress in controlling this disease.

Since the disease was identified in 1981, the past five years stand out for the number, nature and pace of changes that have been made. During the 1980's, HIV was addressed using a rehabilitative, chronic care model, focusing heavily on hospice care and with virtually no resources devoted to treatment. The period of time from diagnosis to death was 12-18 months. From the mid-eighties until 1990, scientists began to be able to describe opportunistic infections. With the ability both to identify and to anticipate infections, practitioners began to apply a therapeutic model, resulting in significant drops in morbidity and to some extent mortality. Still, however, only minimal funds were available for treatment and the period of time from diagnosis to death, while widening, was about 18 to 26 months. The early 1990's brought significant scientific breakthroughs in the development of nucleosides (AZT, DDI, DDC, 3TC, D4T), extending the time from diagnosis to death to about 36 months. In 1991, the Ryan White Act provided for medical treatment and support services that identify and retain people in care.

Adequate funding for these treatment and support services, though, were only realized when the Clinton Administration fought for them. Provided in combination with the nucleosides, these new services extended significantly the amount of time someone could live with HIV/AIDS, lengthening the time from diagnosis to death to four to five years. These shifts were accompanied by consistent presidential attention marked by establishing an AIDS office in the White House, creating a Presidential AIDS Advisory Council and holding a Presidential Summit on AIDS. Funding for AIDS research, treatment and prevention was a priority in every budget submitted by the Administration, resulting in a 266 percent increase in Ryan White CARE Act funds, and a 787 percent increase in assistance for the purchase of AIDS drugs. In addition, the President used his executive powers to heighten focus on ensuring that teenagers get the message that they are not immune to HIV and that employers, including the federal government, have an obligation to provide accurate, sensitive training for employees about HIV/AIDS in the workplace.

The most promising developments emerged in 1995. The use of protease inhibitors in combination with nucleosides was rigorously tested and returned promising findings with unusual speed. These findings provided incentive to place HIV-infected individuals in phase 3 clinical trials enabling them to receive the new treatment regimens. The early 1990's brought significant scientific breakthroughs, including the development of nucleoside analogues, that dramatically improved the duration and quality of life for people infected with HIV. They have also decreased the number of new cases and shifted the mix of who is affected by the disease.

HIV/AIDS has become a disease of major proportions in poor, minority communities. Stemming the disease in these communities by strengthening access to care and treatment, ensuring that the drug combination is available and affordable, and investing in outreach, education and prevention poses critical challenges for the future. In collaboration with minority elected officials, the Administration has enhanced its activities and garnered new funding to address the AIDS crisis in these communities.

Development of a vaccine that can lead to eradication of the disease remains an essential goal. The President, in May 1997, laid a challenge to develop such a vaccine within ten years, and established a comprehensive AIDS vaccine research initiative. After only one year, the Food and Drug Administration authorized the first large-scale trial of an AIDS vaccine in this country.

The Administration is also taking the lessons from the recent U.S. progress in reducing the devastating impact of HIV/AIDS to the developing world which is suffering even more far reaching and catastrophic effects. It is worth illustrating more specifically the nature of these contributions, since they reflect robust and continuing attention, consistent and high level investment, and engagement of every sector of government from the scientific enterprise to the public health infrastructure. They also reflect critical partnerships with social, faith, education, business and community networks, and those who have been directly affected by HIV/AIDS.

This collaboration has yielded significant results in development of knowledge and application of new interventions, ways to position surveillance systems to monitor target populations in the face of emerging infections, and rapid translation of research into medical therapeutics and clinical information for systems of care. Also emerging from the collaboration has been scientific definition of the mechanisms in the replication and distribution of the virus, a description which then enabled drug companies to focus on developing drugs that could block or inhibit the functioning of these mechanisms and not harm the cells of the body.

Development of new effective drugs led to the creation of standards of care for the combined use of protease inhibitors and nucleosides for adults and adolescents, infants, and pregnant women. These guidelines were disseminated and applied in care systems in a timely fashion, protecting thousands of individuals who otherwise would not have received treatments appropriately. Aligning the regulatory approval process for new drugs with emerging scientific findings and dialogue with the affected community fostered understanding that the better established, the earlier in the process and the more open the dialogue, the better quality the product is likely to be. A similar finding arose from involving the affected community in devising services for a continuum of care.

#### *Breast Cancer: A Case Study*

As noted earlier, breast cancer is the most common cancer in American women. As reported in the July 1998 issue of the journal *Cancer*, scientists have found that the recent decline in mortality among all decades of ages of white women between 30 and 79 and black women between 30 and 69 is due to a trend toward progressively earlier diagnosis of breast cancer.

Through investment in treatment and prevention, research, outreach and education, the past five years have generated a significant expansion in the awareness and understanding of breast cancer, identification of alterations in two important genes that are associated with inherited breast cancers, enhanced and higher quality tools for and use of early detection, approval and testing of new drugs and treatment regimens, and greater access to clinical trials. The fight against breast cancer is another arena in which the Administration's model of partnership and collaboration across disciplines, professionals and citizens, and the public and private sector is reaping significant dividends.

Two key collaborations set the framework for these efforts. The first drew together a pioneering effort with public and private sector partners. In late 1993, the Secretary of Health and Human Services launched a process which established the National Action Plan on Breast Cancer. A working group representing government agencies, elected officials, the scientific community, private industry and breast cancer survivors developed and oversees implementation of the plan which focuses on six priorities: 1) information for consumers, practitioners and scientists; 2) expansion of biomedical, epidemiological and behavioral research; 3) establishment of a national biological resources bank for obtaining and storing tissue for research; 4) involvement of consumers in all levels of research, education and services programs; 5) improving access and participation in clinical trials; and 6) assessing the legal, ethical and policy issues connected with hereditary susceptibility to breast cancer.

In 1994, a second collaboration formed, this one to draw together federal government agencies with responsibilities that in some way affect, or could affect, the campaign for earlier and more effective diagnosis, treatment and elimination of this disease. This Federal Coordinating Committee on Breast Cancer was designed to strengthen cooperation across the federal government in order to ensure a coherent, strategic and organized effort to address this disease.

Resources to address breast cancer have grown markedly during the past six years. A significant breast cancer research program, at the Department of Defense, has grown to \$650 million in FY 1999. The National Institutes of Health resources dedicated to research on breast cancer will reach \$430 million, an 11 percent increase from the previous year alone. Additional funds at HHS are dedicated to early detection, diagnosis, and prevention, including funds to improve access for all women to mammography screening and follow up services. Resources are also derived from Medicare for coverage of mammography screening for all recipients over age 40, as well as from Medicaid and the Indian Health Service.

As evidence grew about the benefits of early detection, these public-private efforts took several steps to improve the knowledge base, make the tools affordable, and encourage women to become aware of and to take advantage of the various methods available. As mentioned above, the President attained expanded Medicare coverage to help pay for screening mammograms for all Medicare beneficiaries age 40 and over. Several targeted campaigns, some featuring the President and the First Lady, have been launched urging older women, African American women and Hispanic American women to obtain regular mammograms and highlighting the new Medicare benefits. Through a CDC program, more than half a million free and low-cost mammography screenings have been provided to uninsured, low-income, elderly, minority and Native American women and the program now reaches every state. Efforts have also been made to ensure that substance abuse and mental health programs providing primary health care services to women also include education on early detection methods and counseling on risks for breast cancer. The most recent data available, based on median of state estimates from the Behavioral Risk Factor Surveillance System, show that the percent of women 50+ receiving a mammogram and clinical breast exam in the past two years continues to grow, increasing 14% between 1991 and 1997. (See Figure 4)

Access to mammography screening must be accompanied by quality technology and accountability if women are to be reassured that detection efforts will produce accurate results. In keeping with

its general attention to health care quality, the Administration took two important steps to ensure the quality of mammography screening. First, in implementing the Mammography Quality Standards Act of 1992, the FDA issued high standards for the estimated 10,000 accredited mammography facilities throughout the nation as well as for the equipment used and the personnel who administer and interpret the screenings. Second, clinical practice guidelines for mammography were developed and disseminated to mammography providers, health care professionals and consumers. Finally, a variety of efforts are underway to improve mammography technology and quality, including use of new technologies to interpret the screenings. Several agencies, including the Departments of Defense, CIA, NASA and HHS, have also been collaborating with private sector partners to examine ways to apply new imaging technologies to the early detection of breast cancer.

On the treatment front, several promising drugs have been developed to stem advanced stage breast cancer as well as to retard the cancers detected earlier. In 1998, the FDA approved Herceptin, the first genetically-engineered antibody therapy for individuals with advanced stage breast cancer. In 1998, the FDA also approved the use of tamoxifen for reducing breast cancer risk in women at high risk for the disease. A multi-site clinical trial of the drug Taxol is producing promising early findings with regard to the drug's effectiveness, when used in combination with standard chemotherapies, in initial post-surgical treatment of some women with localized, node positive breast cancer. STAR (The Study of Tamoxifen and Raloxifene), a large-scale clinical trial involving 200 institutions across the U.S. and 22,000 high risk post menopausal women, will compare the effectiveness of the drug Raloxifene to the drug Tamoxifen in reducing invasive breast cancer incidence among women who have not been afflicted. Another clinical trial, the Women's Health Initiative, involves 49,000 women in a test of the impact of a low-fat, high fiber diet on breast cancer prevention.

Advances in genetics are also revealing important information about inherited breast cancers. Research sponsored by the National Human Genome Research Institute and the National Institute of Environmental Health Sciences has found that alterations in two important genes, BRCA1 and BRCA2, are associated with many inherited breast cancers. NCI has established the Cancer Genetics Network, a national network of centers focused on issues related to inherited predispositions to cancer, including breast cancer, and also a Cooperative Family Registry for Breast Cancer Studies to gather family histories and a range of other family information and specimens in the hope of preventing or delaying inherited breast cancers in individuals with genetic susceptibility. The Administration recognizes the value of enabling the public to understand and become knowledgeable about breast cancer, and that there is an important role for government in both developing the information and making sure it is accessible and widely available.

Given the increased knowledge and breakthroughs in detection and treatment, there are now a record 2 million American women who are breast cancer survivors. Through the National Breast Cancer Action Plan and many other initiatives, cancer survivors are now participating in a wide range of governmental entities that review and make critical decisions about research, education and outreach activities. In addition, the Administration created an Office of Cancer Survivorship, opened at NCI in 1996, to study the economic, psychological and physical status of women who

have survived their cancers. Through these mechanisms, cancer survivors are collaborating with government in finding ways to improve the survival prospects of millions of other women as well as their own.

The partnerships spawned in the past six years across science, government, clinicians, the pharmaceutical industry, and women either afflicted with or survivors of breast cancer have made significant advances in the early diagnosis, the nature of the treatments available, and the likelihood of survival of the breast cancers which affect millions of American women. Government has played an important role in providing empowerment and hope in efforts to conquer a deadly disease.

#### V. Strengthening Stewardship and Demanding Accountability

Executing our fiduciary responsibilities for benefits and services on which millions of Americans rely has generated a new frontier of accountability. The Administration has taken a broad-based, multifaceted approach to detecting, identifying, and rooting out fraud, waste and abuse. Using new technologies and incentives for identifying illegal acts, government has become more efficient and prudent in managing its funds in the service of the public. Creative partnerships with providers, consumers and enforcement agencies, performance measurement, and increased resources are all elements of the efforts to protect the integrity and quality of the nation's publicly funded health enterprise.

##### *Drug Approval Process*

To bring to the public quickly and safely the benefits of advances in science and medicine, the Food and Drug Administration streamlined operations and redesigned its drug approval process. It added several hundred new reviewers, increased its spending on information technology and implemented new review process management initiatives. These changes have helped the agency to reduce the time it takes to get a drug reviewed by nearly half. Similarly, the number of drugs reviewed in a year has increased by approximately half and those applications with the requisite data to support approval get through the system. Similar strides are being made in review of medical devices. The FDA Modernization Act of 1997 will extend this progress by improving regulation of food, medical products and cosmetics. A "new use" initiative issued by the FDA in 1997 will also accelerate the development of new and supplemental uses of medications. By bringing new medical treatments to the public as quickly as possible while holding firm to high scientific standards of review, the health of Americans is demonstrably affected by this improvement in management and accountability.

##### *Fighting Medicare and Medicaid Fraud, Waste and Abuse*

The Administration instituted a fundamentally new strategy to root out waste, fraud and abuse in the nation's most expansive and far-reaching health programs -- Medicare and Medicaid -- involving the Inspector General, Health Care Financing Administration and the Administration on Aging in HHS, plus the FBI and the Department of Justice.

Operation Restore Trust, initiated as a five-state pilot in 1995 and expanded nationwide in 1997, reoriented the health fraud-busting apparatus of the government with a new comprehensive approach.

Three areas of the Medicare program were targeted for additional vigilance and specific fraud control measures: home health care, durable medical equipment and nursing home services. In all of these areas, audits were increased, control processes were tightened, law enforcement was strengthened and program structures were reformed. For home health, the segment of Medicare that is growing fastest, a temporary moratorium on bringing in new providers provided time to strengthen the enrollment process. New legislation provides that home health care will be paid on a prospective basis for each episode of care and eligibility standards were augmented to ensure that home health companies are qualified and experienced in service delivery. Similarly, nursing homes now are subject to prospective payment or consolidated billing systems. These will not only ensure that services are obtained at reasonable costs, but also promote a more coordinated and thorough program of care of each nursing home resident. New requirements have been set for suppliers of durable medical equipment and for home health care providers to ensure that they are legitimate and capable contractors. Eligibility for long term hospice care patients will be reviewed more frequently, ensuring appropriateness and adequacy of care provided.

The lessons learned from Operation Restore Trust are now being institutionalized. Stepping up government fraud control activities in health care programs required stable and enhanced resources. The Health Insurance Portability and Accountability Act (HIPAA) provided a new dedicated Health Care Fraud and Abuse Control account, funded each year through Medicare Part A Trust Fund. These funds are enabling HHS and the Department of Justice to expand investigations, audits, evaluations and inspections related to the delivery and payment of health care; increase training of older persons who can help inform peers about how to remain alert to health care fraud; strengthen enforcement of civil, criminal and administrative statutes addressing health care fraud and abuse; devise and disseminate information for the health care industry about fraud and abuse; and create a national data bank to receive and report final adverse actions against health care providers. These new resources also have supported expansion of the HHS Office of Inspector General's field operations from 26 to 31 states.

Law enforcement is being improved with better coordination of resources and activities of organizations both within the Federal government and the States. New enforcement tools, including stronger penalties and disclosure requirements, were authorized and better methods for identifying, referring, investigating and prosecuting those who would defraud the Federal government of public resources and take from the consumers of health care resources to which they were entitled.

New approaches were also developed to prevent fraud and waste from even getting started or to cut it off at its source. For example, with the cooperation of the health care industry, the Inspector General has developed compliance guidelines for health care providers to give them better tools to reduce their own risk of fraud. Incentives have stimulated the involvement of beneficiaries themselves in the identification and reporting of fraud. A fraud hotline was greatly expanded, made more user friendly and widely publicized to beneficiaries. The Administration has recruited

thousands of volunteer and paid long term care ombudsmen and other service providers in the field of aging and provided training in how to identify and report fraudulent practices in nursing homes and other long term care settings.

Under the Health Care Fraud and Abuse Control Program created under HIPAA, HHS has reported more than \$1.2 billion in fines and restitution returned to the Medicare Trust fund during fiscal years 1997 and 1998. During these years, HHS also excluded more than 5,700 individuals and entities from doing business with Medicare, Medicaid, and other federal and state health care programs for engaging in fraud or other professional misconduct -- up from 2,846 in the previous two years. In addition HHS increased convictions by nearly 20 percent in 1997 and another 16 percent in 1998. Since 1993, actions affecting HHS health care programs have saved taxpayers more than \$38 billion, and have increased convictions and other successful legal actions by more than 240 percent.

## VI. Continuing Challenges

Americans are healthier and their prospects for living longer are greater today than they were just six years ago. The Clinton Administration set out to contribute to a healthier and safer nation, and has succeeded in that goal. Millions more children will be able to enjoy their early years protected from contagious and debilitating childhood diseases or premature death. Millions more families will be connected to a regular source of affordable quality medical care. Children and adults alike will reap the benefits of new medical treatments for chronic illness. The food Americans eat will be the safest in the world.

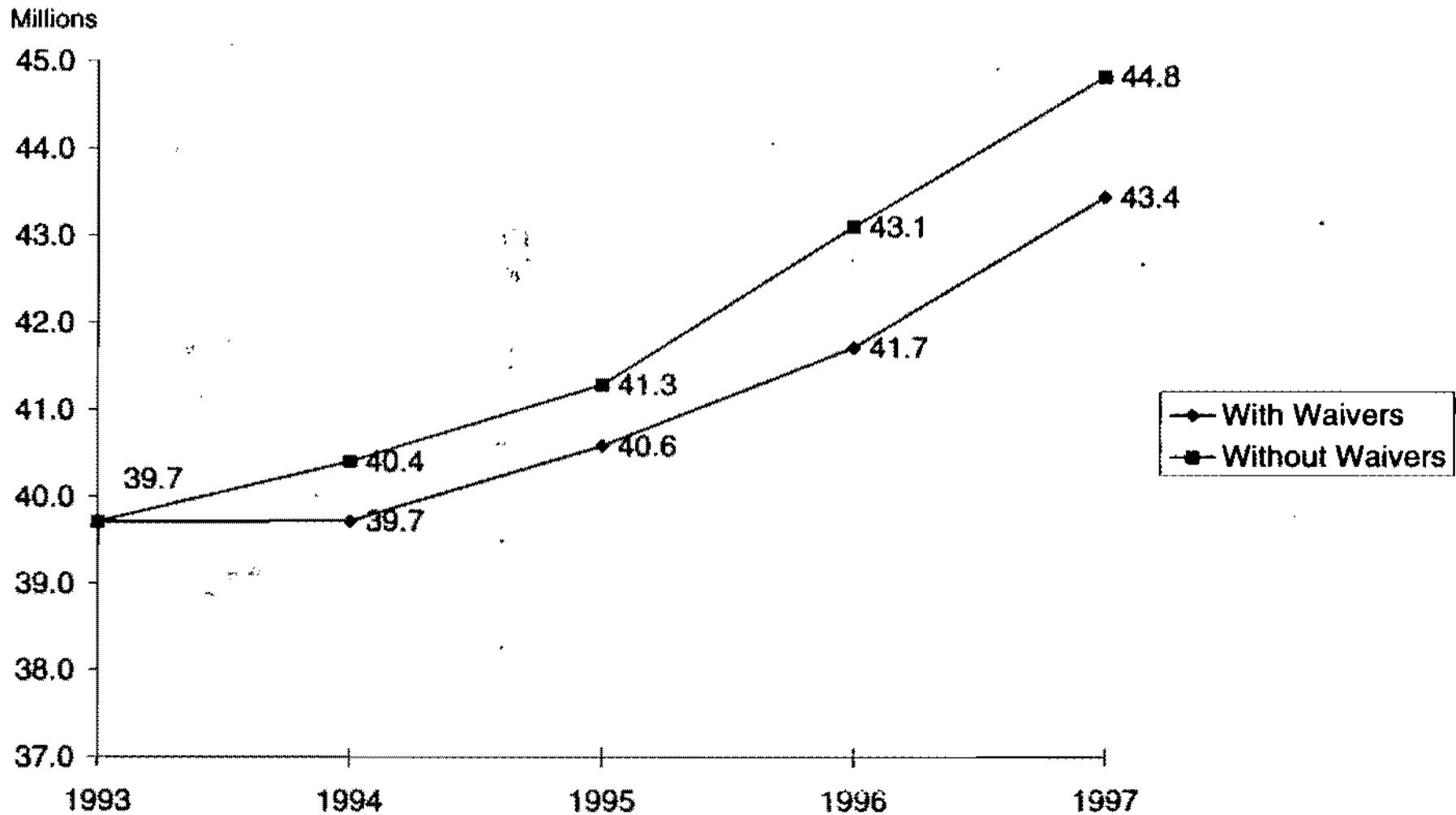
While there have been measurable gains, gaps in bringing good health and safe surroundings to every American remain. Serious challenges - economic, philosophical and ethical - remain about how to get sophisticated care to millions of Americans who may not be wealthy or well informed. We have yet to fully comprehend and surmount all the reasons that far too many people compromise their health by ignoring proven evidence about the importance of nutrition and physical exercise. We do not yet have proven ways to stop young people's abuse of substances -- drugs, alcohol, tobacco -- that can be life-threatening either immediately or later in their adulthood. We have yet to test, and hope never to have to use, comprehensive plans to address global health risks such as pandemic flu or bioterrorist attacks.

In all these instances, however, the Administration has recognized the dangers and the opportunities, expanded and retooled the capacity to understand, identify, track and respond to public health emergencies, tested new strategies and incentives for reaching special groups to prevent unnecessary illness, injury, disability or death and to promote healthful lifestyles and behavior. We have invested in biomedical, behavioral, health services, and prevention research which is producing an extraordinary array of discoveries and will provide the engine for future progress in achieving a healthier and safer nation.

Finally, while the legacy of specific improvements in health and safety positions the nation for making additional improvements into the next century, what may be an even more enduring legacy is the active, pragmatic, nonideological approach to governing that the Clinton Administration

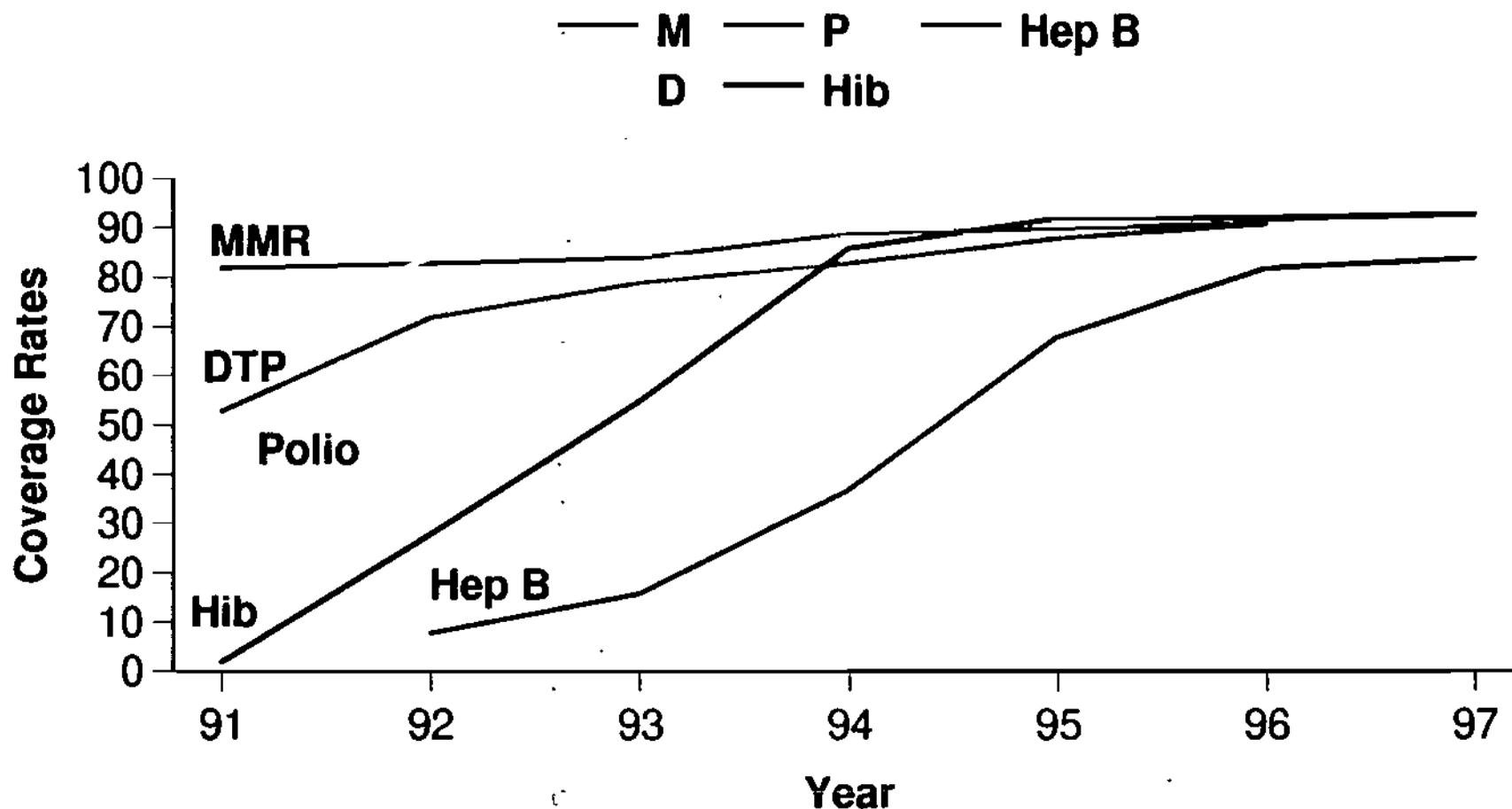
pioneered and used successfully. This legacy underscores the critical role for the federal government to meet people's evolving needs, and the imperative to hold firm in the belief that government matters.

### The Effect of 1115 Waivers on the Number of Uninsured



Source: ASPE Calculations of HCFA and Census Bureau Data

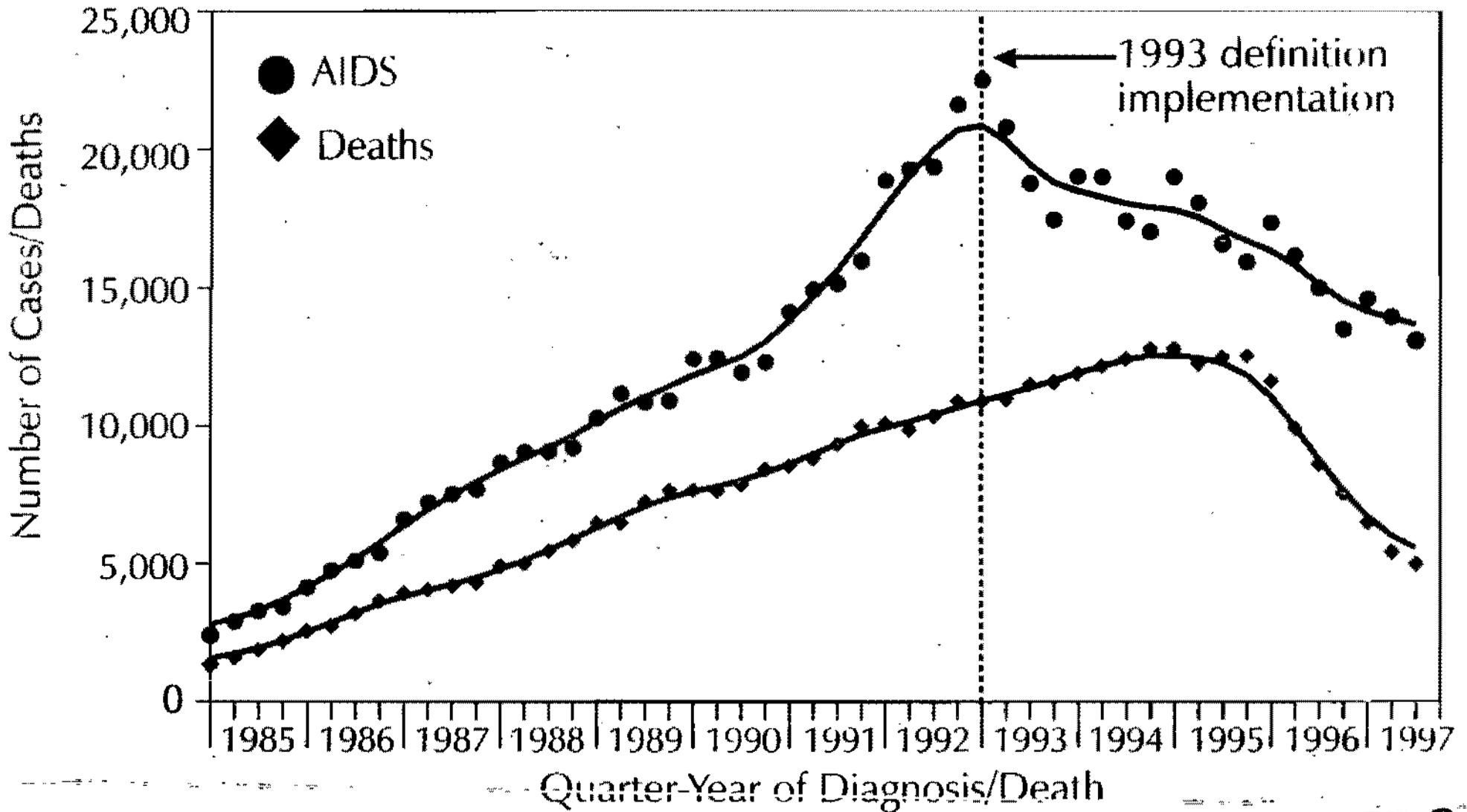
# Vaccine Specific Coverage Rates Among U.S. 2 Year Olds, 1991 - 1997



Source: USIS (1967-1985) and NHIS (1991-1993)  
National Immunization Survey, 1994-1997



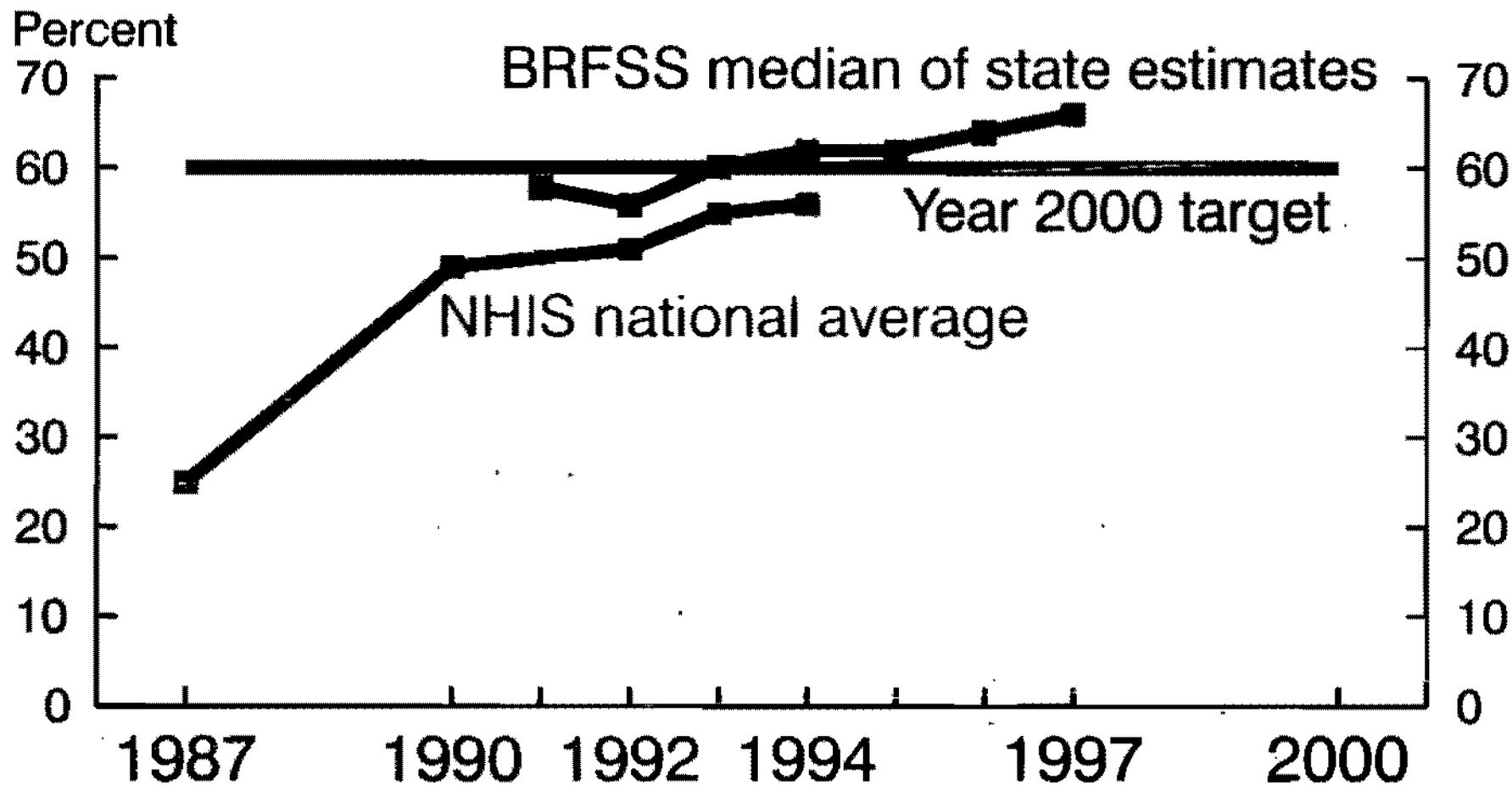
# Estimated Incidence of AIDS and Deaths of Persons with AIDS\*, 1985 - September 1997, United States



\*Adjusted for reporting delays

# Mammogram and Clinical Breast Exam in the Past Two Years

## Percent of All Women, 50 Years and Over



SOURCE: 1987, 1990, 1992-94 national data from CDC, NCHS, National Health Interview Survey; 1991-97 median state estimates from CDC, NCCDPHP, Behavioral Risk Factor Surveillance System.



MAR 22 1993

## MEMORANDUM FOR THE PRESIDENT

### Introduction

The purpose of this memorandum is to provide a summary of:

- what we know now about the effects of welfare reform;
- what we know about the implementation of welfare reform, including State policy and spending choices; and
- what implications this information has for the next steps and the unfinished agenda of welfare reform.

Welfare reform has been successful in moving many, many families from welfare to work. Yet, the available evidence suggests that there are "winners" and "losers" among welfare families - some families are benefiting substantially from the new incentives, requirements, and opportunities and others are being left behind. And while a variety of studies show positive impacts on earnings, many parents leave welfare for work yet still do not earn enough to raise their families out of poverty. Our challenge now is to make work pay so that no working family is forced to live in poverty.

In order to achieve this full promise of welfare reform, we need to focus attention on supporting working families through a range of strategies, including health insurance, child care, Food Stamps, and other supports, so that families who leave welfare for work that may be low-wage and less than full-time are able to support themselves and their children. We also need to strongly encourage States to focus policy attention and resources on those families who remain on welfare and need more intensive services, including substance abuse and mental health services, domestic violence services, and supported work. Finally, we need to continue our efforts to ensure that legal immigrant families are treated fairly.

### The Research Evidence

Despite the broad array of ongoing research about welfare reform, it is still early and our knowledge in many areas is still limited. We know a lot about effects on employment and earnings, but we know little about effects in other domains, such as child well-being or family structure, and we know very little about low-income families who do not enter the welfare rolls. Also, welfare reform has been implemented in the context of a strong national economy, so we know little about the effect of welfare reform in other economic circumstances.

Prepared by AEF/Quigley

3/22/93/0028

## Employment and Earnings

There is solid and consistent evidence from a variety of sources that welfare reform has increased the average employment and earnings of welfare recipients. This finding, that welfare reform and the strong economy have indeed had a positive impact on work, is the most solid of the research findings we have, because it comes from so many different sources.

- Experimental studies of State waiver demonstrations and other work programs that are very similar to TANF programs show consistently positive impacts on employment and earnings<sup>1</sup>. Recent results from specific State programs at the upper range show employment increases in the range of about 7 to 29 percent, and earnings increases of about 16 to 27 percent. For example, in the evaluation of the Minnesota Family Investment Program (MFIP), earnings for single-parent long-term recipients in urban counties increased by \$1,041 (26.9 percent), and the percent ever employed increased by 17.0 percentage points (28.8 percent) over 18 months.<sup>2</sup>
- TANF administrative data from 39 States shows a 30 percent increase in employment among TANF recipients in the fourth quarter of FY 1997, compared to the first three quarters. Over the same period, the average earnings of those employed increased by 17 percent, from \$506 to \$592 per month.
- Analyses of data from the Census Bureau's annual Current Population Survey (CPS) indicate a clear pattern of increased employment. The March employment rate of previous-year AFDC adult recipients increased from 19 to 25 percent between 1992 and 1996, and jumped to almost 32 percent in 1997. Also, the March employment rate of single mothers whose previous-year income was under 200 percent of poverty rose from 44 percent in 1992 to 54 percent in 1997, with average annual increases in 1996 and 1997 twice as large as in the previous 3 years.<sup>3</sup>

## Other Impacts of Welfare Reform

The evidence about impacts on family income, on food security and hunger, on health insurance status, on child outcomes, and on other family experiences, are much less clear at this point. The best reading of the available evidence suggests that because the baseline levels of employment and earnings for welfare recipients are so low, even with substantial increases most families exiting welfare continue to be poor, and that while some families are benefiting dramatically

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<sup>1</sup> Fein, David et al, *Indiana Welfare Reform Evaluation: Program Implementation and Economic Impacts After Two Years*, Abt Associates, Inc., November 1998

<sup>2</sup> Bloom, Dan et al, *The Family Transition Program: Implementation and Interim Impacts of Florida's Initial Time-Limited Welfare Program*, MDRC, April 1998.

Miller, Cynthia et al, *Making Welfare Work and Work Pay: Implementation and 18-Month Impacts of the Minnesota Family Investment Program*, MDRC, October 1997.

<sup>2</sup> Miller, Cynthia et al, *Making Welfare Work and Work Pay: Implementation and 18-Month Impacts of the Minnesota Family Investment Program*, MDRC, October 1997.

<sup>3</sup> U.S. Department of Health and Human Services, Administration for Children and Families, *Temporary Assistance for Needy Families (TANF) Program: First Annual Report to Congress*, August 1998.

from the new incentives, requirements and opportunities, others are being left behind. However, current evidence does not support the hypotheses that large numbers of people are becoming homeless or that more children are being moved into foster care (see below).

- Results from waiver demonstrations and studies of recipients who left welfare ("leaver" studies) for the most part indicate that average family income has been unchanged with some families increasing their income but others experiencing declines. For example, 2-year impacts on clients assessed as "job-ready" from Indiana's waiver demonstration showed earnings up 17.0 percent (\$1,374) and quarters of employment up 12.8 percent, but total combined income from earnings and benefits was unchanged.<sup>4</sup>
- When earnings are combined with the EITC and other benefits, most families who go to work would have a higher income than if they had remained on welfare. In the average state, a woman with two children could be better off working 20 hours a week than she would be on welfare. However, not all eligible families are accessing tax credits and benefits, such as Food Stamps, child care, and transportation subsidies. In some cases State policy choices may have the effect of restricting families' access to Food Stamps and Medicaid.
- There is some early evidence that the most disadvantaged families may be losing income. CPS data indicate that real average family income for the bottom quintile of female-headed families with children declined between 1995 and 1997, after increasing from 1993 to 1995.<sup>5</sup>
- Some individuals leaving welfare may earn too much to qualify for Food Stamps, or they may be unaware of their eligibility. For example, a South Carolina leaver study found that 17 percent reported having had no way to buy food some of the time since leaving TANF. (This was true of nine percent while on TANF.) Having a job did not reduce the probability of not having a way to buy food.<sup>6</sup>
- Another area of concern is the impact of welfare reform on child well-being in such areas as adequate shelter, health and development, family stability and other outcomes. In particular, we need to measure effects on child health and development, foster care and child abuse. There are no early indications that rates of the latter two have increased with welfare reform.

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<sup>4</sup> Fein, David et al, *Indiana Welfare Reform Evaluation: Program Implementation and Economic Impacts After Two Years*, Abt Associates, Inc., November 1998

South Carolina, Department of Social Services, *Survey of Former Family Independence Program Clients; Cases Closed During April Through June, 1997*, July 1998.

Cancian, Maria et al. *Post-Exit Earnings and Benefit Receipt Among Those Who Left AFDC in Wisconsin*, Institute for Research on Poverty, University of Wisconsin-Madison, October 1998.

Bloom, Dan et al, *The Family Transition Program: Implementation and Interim Impacts of Florida's Initial Time-Limited Welfare Program*, MDRC, April 1998.

Fein, David, and Karweit, Jennifer, *The ABC Evaluation: The Early Economic Impacts of Delaware's A Better Chance Welfare Reform Program*, Abt Associates, Inc., December 1997.

<sup>5</sup> Bavier, Richard, "An Early Look at the Effects of Welfare Reform," unpublished manuscript.

<sup>6</sup> South Carolina, Department of Social Services, *Survey of Former Family Independence Program Clients; Cases Closed During April Through June, 1997*, July 1998.

A 1997 Maryland study found that, of the 1,810 children in their sample of families leaving welfare, only 3 children, in one family, had been placed in foster care in the 3-6 months of follow-up. The recently published Wisconsin report found that 5 percent of respondents - 19 families - reported that since leaving welfare they have had a child live with someone else because they couldn't care for them, but almost as many respondents - 16 families - reported that this had happened to them before they left welfare.<sup>7</sup> We are investing in additional research on child outcomes under welfare reform, and reports will be available over the coming months.

- We are currently supporting research in a number of other areas where we do not yet have results to report. For example, we do not yet know what the full impact of time limits will be, as only a small fraction of recipients have reached them. Over the next four years, an increasing share of the caseload will come up against them. We are also currently undertaking studies to increase our limited knowledge of how families are faring in which there are persons with disabilities, substance abusers, or victims of domestic violence. Finally, early research is not yet available on the effects of welfare reform on child health and development.

#### Participation in Medicaid and Food Stamps

Enrollment in both Medicaid and Food Stamps has fallen recently, for a variety of reasons.

- Because of your efforts, Medicaid coverage has been preserved to a substantial extent under welfare reform. Nonetheless, Medicaid enrollment dropped by about 1 million from 1996 to 1997. There are many potential reasons for the decline, and we do not have any definitive answers about why it has occurred. Improvements in earnings and employment resulting from the strong national economy have probably played an important role in this decline, making it possible for some low-income Medicaid families to find jobs that offer health insurance. It is also important to note that, while Medicaid enrollment has declined, the number of people under the poverty level who are uninsured has not increased from 1996 to 1997. Changes in attitudes toward public assistance may also be playing a role in falling TANF, Food Stamp, and Medicaid caseloads.

However, as States change how they deliver cash assistance, we need to be concerned that a variety of other factors might be affecting Medicaid participation. These include: termination of the long-standing programmatic linkage between eligibility for cash assistance and Medicaid; potential barriers to enrollment for working families (e.g., limited application sites and hours of operation); and confusion about the eligibility of legal immigrants and their citizen children. Finally, as States continue to experiment with strategies that encourage families to seek employment prior to applying for TANF, some eligible adults and children may be diverted from Medicaid, and may not even know they are eligible.

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<sup>7</sup> Born, C. et al. *Life After Welfare*. Family Investment Administration, MDHR and University of Maryland School of Social Work. September 1997. (This analysis was not repeated in the later reports in this series.)  
*Survey of Those Leaving AFDC or W-2 January to March 1998*, Preliminary Report, Wisconsin Department of Workforce Development, January 1999.

- Food Stamp participation fell from an average of 27.4 million persons in 1994 to 21.5 million persons in 1997 – a drop of 5.9 million. During this same period, the number of persons living in poverty fell by only 1.5 million, from 38.1 million to 36.6 million. Since 1997, Food Stamp participation has dropped even further to 18.6 million persons in December 1998. Part of this drop is due to the new restrictions on Food Stamp participation by certain legal immigrants and able-bodied unemployed adults without dependent children. Also, many eligible individuals may erroneously believe that once they leave or are diverted from TANF they are also ineligible for Food Stamps. In addition, many of the factors cited for the decline in Medicaid participation also apply to Food Stamps. While immigrants and able-bodied unemployed adults without dependent children account for a significant portion of the decline in Food Stamp participation, 60 percent of the decline can be attributed to fewer AFDC/TANF participants.

### Legal Immigrants

Legal immigrant families were among those most at risk after welfare reform. Their disproportionate declines in participation are consistent with anecdotal reports we have received about the chilling effect of public charge policies and confusion over changing eligibility requirements on the use of benefits by legal immigrant families. The findings lend support to our interagency efforts to develop clear guidance on public charge policies, and they provide support for the Administration's recent accomplishments and current budget proposals to restore certain benefits to vulnerable legal immigrants. We also have research efforts underway in New York City and Los Angeles that are studying the situation of legal immigrants.<sup>8</sup>

### State Policy Choices

States have a wide array of choices when it comes to designing their programs. However, the primary focus of State policy choices continues to be encouraging, requiring, and supporting work. A major study of the implementation of welfare reform noted that the pervasive changes in social programs since enactment of the Personal Responsibility and Work Opportunity Reconciliation Act "have occurred in large part because strong signals have been sent by governors and State legislators that a work-based approach to welfare reform is no longer just one Federal priority among many but is now a central objective within each State."<sup>9</sup> Almost all of the States have moved to "Work First" models, requiring recipients to move quickly into available jobs.

Beyond the focus on work, three other themes stand out about State policy choices:

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<sup>8</sup> Zimmerman, Wendy and Michael Fix, *Declining Immigrant Applications for MediCal and Welfare Benefits in Los Angeles County*, The Urban Institute, Washington, D.C., July 1998.

Fix, Michael and Jeffrey S. Passel, *Trends in Noncitizen's and Citizen's Use of Public Benefits Following Welfare Reform, 1994 to 1997*. The Urban Institute, March 1999.

<sup>9</sup> Nathan, Richard P. and Gais, Thomas L., *Implementation of the Personal Responsibility Act of 1996*; Federalism Research Group, The Nelson Rockefeller Institute of Government, State University of New York.

- As envisioned in the statute, there is considerable variety in the choices States have made about policies such as time limits, sanctions, diversion, and policies for families who face specific barriers to work. There is no single, typical program.
- State choices about TANF policy and implementation can affect families' ability to receive other benefits for which they are eligible (such as Medicaid and Food Stamps), sometimes in unintended ways. The "delinking" of eligibility for Medicaid and TANF, for example, offers States both challenges and new opportunities. When families learn they can receive Medicaid coverage without having to receive welfare, they may be less likely to turn to welfare in the first place. Therefore, we must be clear that States are accountable for ensuring access to these benefits for eligible families.
- Many States have not yet reinvested the TANF resources freed up by declining caseloads to help families with more intensive needs (for example, families with a disabled parent or child, families with a member who needs substance abuse or mental health treatment, families suffering from domestic violence) move to self-sufficiency before the time limits take effect. We must keep challenging States to make these investments, while at the same time protecting the TANF resources in the Congress.

### Making Work Pay and Requiring Work

States have enacted policies to make work pay, generally by increasing the amount of earnings disregarded in calculating welfare benefits. Forty-seven States made changes to simplify and expand the treatment of earnings compared to the AFDC treatment. In conjunction, all States have raised their limits on assets and/or vehicles so that families do not have to get rid of a vehicle that may be their only transportation to work and so that they can accumulate savings.

Parents or caretakers receiving assistance are required to engage in work (as defined by the State) within 24 months, or shorter at State option. Most States have opted for a shorter period, with 23 States requiring immediate participation in work; 8 States requiring work within 45 days to 6 months; 17 States requiring work within 24 months; and 3 States with other time frames for work. In addition, some States use a narrow definition of "work," whereas others allow for a broader range of activities, including training or volunteering. There is no Federal penalty associated with failing to meet this requirement, so States have considerable flexibility in how they structure and enforce it. Many States have chosen to treat this requirement as a broad goal for the system, and we are not aware of any State except Pennsylvania that is treating it as a strict time limit that could lead to termination of individual families from assistance.

Another major feature of State policy regarding work is the increased use of sanctions if a family fails to participate in required activities. While we do not have good national data at this point, the State waiver studies suggest that there is much more aggressive State use of sanctions under welfare reform. For example, waiver demonstrations indicate that a demonstration county in Florida increased its sanction rate from seven to thirty percent and Delaware's sanction rate increased from nearly zero to fifty percent.<sup>10</sup> Under PRWORA, if the individual in a family

<sup>10</sup> Bloom, Dan et al, *The Family Transition Program: Implementation and Early Impacts of Florida's Initial Time-Limited Welfare Program*, MDRC, May 1997.

Fein, David, and Karweit, Jennifer, *The ABC Evaluation: The Early Economic Impacts of Delaware's A Better Chance Welfare Reform Program*, Abt Associates, Inc., December 1997.

receiving assistance refuses to engage in required work, the State has the option to either reduce or terminate the amount of assistance payable to the family, subject to good cause. Thirty-eight States have elected to terminate the amount of assistance payable to a family for not cooperating with work requirements (typically after several infractions), and thirteen States have chosen to reduce the amount of cash payable to a family.

### Time Limiting Assistance

State policies related to time limiting assistance to a family vary greatly. States have chosen the following time limit policies:

- 27 States use the federal time limit (Alabama, Alaska, Colorado, District of Columbia, Hawaii, Iowa, Kansas, Kentucky, Maine, Maryland, Minnesota, Mississippi, Missouri, Montana, New Hampshire, New Jersey, New Mexico, New York, North Dakota, Oklahoma, Pennsylvania, South Dakota, Vermont, Washington, West Virginia, Wisconsin, and Wyoming);
- 6 States (Louisiana, Nevada, North Carolina, South Carolina, Tennessee, and Virginia) have chosen "intermittent" time limits with a lifetime limit of 60 months (for example, Louisiana limits TANF receipt to 24 months in any 60 month period, with a lifetime limit of 60 months);
- 8 States have chosen a lifetime time limit shorter than the federal limit (Arkansas, Connecticut, Delaware, Florida, Georgia, Idaho, Ohio, and Utah);
- 5 States have chosen options involving supplements for families reaching the federal time limit (Illinois, Massachusetts, Michigan, Nebraska, and Oregon); and
- 5 States have chosen time limits for adults only (Arizona, California, Indiana, Rhode Island, and Texas).

### Diversion

Many States are experimenting with a variety of strategies to divert families from receiving cash assistance. These strategies are quite diverse and include lump-sum cash payments, where families receive a payment sufficient to resolve an immediate emergency (such as a car breakdown) and keep the family working and off of cash assistance; applicant job search, where the applicant is required to look for a job for some period of time (with or without structured assistance from the welfare office) before receiving benefits; and other alternative support services (such as linkages to child care or community resources). These strategies are quite new and there is little research yet on their effects.

However, a recent study, funded by the Department, has examined the emergence of diversion programs as a welfare reform strategy and the potential for diversion to affect access to Medicaid. The study reported on the use of diversion in all 50 States and the District of Columbia; and also included an examination of the experiences of five local communities in establishing and operating diversion programs. In addition to noting the importance of processing Medicaid applications even in cases in which TANF assistance is deferred, it highlights promising approaches that other States may follow to ensure access to Medicaid and

other supports, such as child care, for those who obtain employment through diversion or are otherwise diverted from the TANF rolls.<sup>11</sup>

One of the local programs examined in the study is Montana's, which provides a child care and Medicaid only option for families with work or child support income. The study found that this has greatly increased demand for child care in Montana.

### Families Facing Specific Barriers to Employment

Although there have been dramatic gains in work for many TANF families, too many families with multiple barriers to success could be left behind. While many parents on welfare have succeeded in moving to work despite extraordinary obstacles, others will need additional treatment and support services to work and succeed at work, and the States vary a great deal in the extent to which they have planned and invested in programs to provide these supports. There are no completely reliable estimates of specific family needs among welfare families, but recent studies suggest that as many as 27 percent of adults in the caseload nationally have a substance abuse problem; up to 28 percent have mental health issues; up to 40 percent have learning disabilities or low basic skills; and up to 32 percent are current victims of domestic violence.

The Department (including both the Administration for Children and Families and the Substance Abuse and Mental Health Administration) has co-sponsored with the Department of Labor a series of conferences on Promising Practices under welfare reform, which has featured practitioners and researchers providing information on the approaches to treatment and support that enable parents facing these obstacles to prepare for work and succeed at work. However, while there are a number of States that have developed innovative and impressive approaches and a few States that have already made substantial investments,<sup>14</sup> we are concerned that too few States are operating at a scale that will meet the need. One important accomplishment to note is that as a result of your strong focus on domestic violence, many States have made policy decisions and investments that focus for the first time on protecting and supporting women on welfare who have experienced domestic violence.<sup>15</sup> The challenge now is to convince States of the importance of investing unspent TANF funds in these hard-to-serve adults remaining on the rolls.

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<sup>11</sup> Maloy, K., et al, *A Description and Assessment of State Approaches to Diversion Programs and Activities Under Welfare Reform*. The George Washington University Medical Center, Center for Health Policy Research, August 1998.

Pavetti, LaDonna A., et al, *Diversion as a Work-Oriented Welfare Reform Strategy and Its Effect on Access to Medicaid, An Examination of the Experiences of Five Local Communities*. The George Washington University Medical Center, Center for Health Policy Research, publication pending.

<sup>12</sup> *Ancillary Services to Support Welfare-to-Work*, prepared by Mathematica Policy Research, Inc., under contract to DHHS/ASPE, June 1998.

<sup>13</sup> *In Harm's Way? Domestic Violence, AFDC Receipt and Welfare Reform in Massachusetts*, University of Massachusetts, 1997.

<sup>14</sup> For example, North Carolina is reported to be doing innovative programming with substance abuse clients, and Washington is reported to have focused attention on the learning disabled.

<sup>15</sup> *Ancillary Services to Support Welfare-to-Work*, prepared by Mathematica Policy Research, Inc., under contract to DHHS/ASPE, June 1998.

### Unobligated TANF Funds

While 17 States (including California, Illinois, and Texas) have committed all of their FY97 and FY98 Federal TANF funds, the remainder of the States have about \$3 billion (10 percent of the total) unobligated as of the fourth quarter of FY 98, the subject of much attention in Congress and the press (see attached chart). The reasons include: State choices to hold resources for the future in rainy day funds; a time lag in reallocating funds left uncommitted as a result of unexpected caseload declines; and a time lag in implementing welfare reform on a statewide basis.

Innovative investment of these funds is essential to the success of welfare reform. States need both to help working families to sustain and improve their employment and to help hard-to-serve family members overcome their various obstacles within the time limits, so that all families are given the chance to succeed.

### The Unfinished Agenda

Making work pay — to lift families out of poverty — has always been one of this Administration's major goals. Your initiatives to expand the EITC and child care, to raise the minimum wage, and to encourage States to expand their earnings disregards through waivers, have been important steps toward the goal of every working parent being able to provide for their children's basic needs. Yet millions of young, low-income parents are not benefiting from programs like Medicaid, Food Stamps, and child care that could support their entry into the workforce and lift them out of poverty once they do work.

Working parents, including both those who have left welfare and those never on assistance, should not have to worry about being unable to feed, house, clothe, or secure medical care for their children. Yet there are millions of children now living in working families with incomes below the poverty level. To make work pay and ensure the long-term success of welfare reform, forceful action is needed in at least three areas: supporting low-income working families who no longer receive, or never received, cash assistance; helping the less employable TANF recipients secure stable jobs; and continuing our efforts to ensure that legal immigrant families are treated fairly.

Many of the proposals below are in your FY 2000 budget. We will see them enacted only if the Administration as a whole makes these items high priorities in any budget, tax or appropriations negotiations.

### Helping low-income working parents keep their jobs and find better ones

1. **Hold the States' feet to the fire.**

Millions of eligible individuals are not participating in programs that would lift them out of poverty. We must use every means available to get States to reach out to these people and provide them with the benefits and services they need.

2. **Enact your Child Care Initiative, which would make child care more affordable for hundreds of thousands of low-income working families and, through the Early Learning Fund, increase the quality of child care and promote school readiness for children across income levels. (in FY 2000 budget)**

We are currently providing child care assistance through Child Care and Development Block Grants for only 1.25 million of the 10 million children eligible.

In addition, an extensive body of research shows that the poor quality of care many young children receive threatens their cognitive and social development. As you and the First Lady highlighted in the 1997 White House conference on early learning and the brain, the first three years are absolutely critical to an individual's intellectual development. Children who fall behind during this crucial period may never catch up, with devastating educational and economic consequences. This is why the Early Learning Fund should be a centerpiece of the Administration's education agenda.

3. **Maximize access to Medicaid by publicizing the range of options available to States under current law to widen outreach and broaden coverage, and by continuing to act on reports that States may be inappropriately diverting eligible persons from Medicaid.**

Shortly, we will issue a guidebook describing the requirements governing Medicaid eligibility, application and enrollment. Under Medicaid, States have great flexibility in how they operate their programs. The guide will also highlight the options States have for facilitating enrollment -- such as expanding coverage of working families under section 1931 and providing presumptive eligibility and 12 month continuous eligibility. As part of our ongoing technical assistance activities, the Department will sponsor a "best practices" conference to help disseminate information on how to improve enrollment. We are also, as you know, working with the NGA on a range of outreach activities for both Medicaid and CHIP.

4. **Eliminate unnecessary reporting requirements for transitional Medicaid, in order to provide this transitional health coverage to more working families. (in FY 2000 budget)**

This will lessen one of the main reasons cited by States and families for low utilization of transitional Medicaid.

5. **Expand allowable uses of the \$500 million Medicaid fund created to cover the cost of extra eligibility determination work resulting from the breaking of the link between welfare and Medicaid. (in FY 2000 budget)**

Giving States greater flexibility in the use of these funds for outreach would allow them to enroll in Medicaid and CHIP more children in families that are diverted from or never connected to TANF.

6. **Resist efforts to rescind the funds available for CHIP.**
7. **Enact your proposal to increase the minimum wage from \$5.15 to \$6.15.**

Various studies have found that the average wage for those leaving TANF for work ranges from approximately \$5.50 to \$7.50 per hour. A minimum wage increase would put significantly more money in the pockets of those parents currently working for less than \$6.15 per hour and would likely also bump up the wages of many now earning just over \$6.15.

8. **Make Food Stamps more accessible to working families by:**

- **Eliminating the vehicle fair market value test (while retaining the more appropriate equity test; the equity is the amount the household would receive, and could use for food, if the car were sold);**
- **Giving States the option to implement quarterly reporting (in addition to the current options of monthly reporting or reporting any change within 10 days); and**
- **Increasing the error rate tolerance from the current \$5, an action that would reduce potential State liabilities for serving working families with changing circumstances.**

The latter two proposals do not require legislation.

If savings are identified from the larger-than-expected decline in the Food Stamp caseload, it would be appropriate and desirable to reinvest those dollars in the Food Stamp program to expand access for working families. I know this is a priority for Secretary Glickman, and I completely share his goals in this area.

The availability of Food Stamps as a support for such families can also be enhanced by encouraging State outreach, especially for families diverted from or leaving TANF, and by clarifying State obligations under current law and regulations (which USDA did in a January 29 letter to State commissioners).

9. **Publish the final TANF regulations, which will encourage States to help working families with transportation, child care or post-employment education or training (to upgrade skills), and to otherwise use TANF dollars creatively to accomplish the goals of welfare reform.**

In addition, the Department will continue to explore through demonstration projects innovative strategies to stabilize the employment and boost the earnings of TANF recipients who find jobs.

This year, the Department will award the first High Performance Bonuses on job retention and earnings gains, as well as initial job placement. We will continue to encourage States to focus on these goals, which will in turn provide us with a wealth of information regarding State performance in welfare reform.

10. **Secure the additional \$144 million requested for HUD's Welfare-to-Work housing vouchers and the additional \$75 million sought for the Department of Transportation's Job Access program in the FY 2000 budget.**

Investing in all families, including the hardest to serve

11. **Reauthorize DOL's Welfare-to-Work program, which is targeted to high-poverty areas and to hard-to-employ recipients. (in the FY 2000 budget)**
12. **Encourage States to make the additional TANF investments (e.g., in substance abuse and mental health services, services for victims of domestic violence, intensive work services) needed to move some of the more disadvantaged recipients into long-term employment. Also encourage States to invest in services for non-custodial parents, to help them increase their earnings and child support payments.**

Treating immigrants fairly

13. **Give States the option of providing Medicaid and CHIP to legal immigrant children who entered the country after enactment of welfare reform. (in the FY 2000 budget)**
14. **Give States the option of providing Medicaid to pregnant legal immigrants who entered the country after enactment of welfare reform, to ensure that their children, who will be U.S. citizens, get the best start in life. (in the FY 2000 budget)**
15. **Release DOJ/INS/State guidance on public charge.**

Clarifying the public charge policy will ensure that immigrant families know which benefits they can access without fear of deportation or other adverse impact on their immigration status, thus addressing the potential effect of public charge on this community's receipt of needed benefits.

16. **Restore SSI and Medicaid for legal immigrants who entered after enactment of welfare reform, have been in the country for five years, and became disabled after entry. (in the FY 2000 budget)**
17. **Restore Food Stamps for aged legal immigrants who were in country prior to passage of welfare reform and turned 65 after that date. (in the FY 2000 budget)**

Maintaining TANF funding

18. **Resist efforts to reduce the TANF block grant and enact the Administration's budget proposal to uncap the contingency fund; this combination will enhance States' ability to meet needs not currently anticipated.**

As welfare reform has been implemented in a time of a strong national economy, we know little about how effective the TANF program would be in other economic circumstances. In addition,

it is likely that falling caseloads have left on the welfare rolls a higher proportion of families who need intensive services.

### Conclusion

Perhaps the most important step you can take as President is to help working families by fundamentally changing the perception of programs such as Food Stamps, health care (Medicaid/CHIP), and child care so that they are seen as supports for working families. Low and moderate-income working families should think of Food Stamps, Medicaid, CHIP or child care subsidies as no different from student loans, Hope scholarships, or Pell Grants - which no one considers welfare. States are the critical actors in this transformation and we need to hold them accountable for both moving more forcefully in restructuring their income support systems to make them worker-friendly, and investing TANF resources to ensure that all families move to work and succeed at it. The States need to focus on lifting working families out of poverty, not just getting them into jobs.

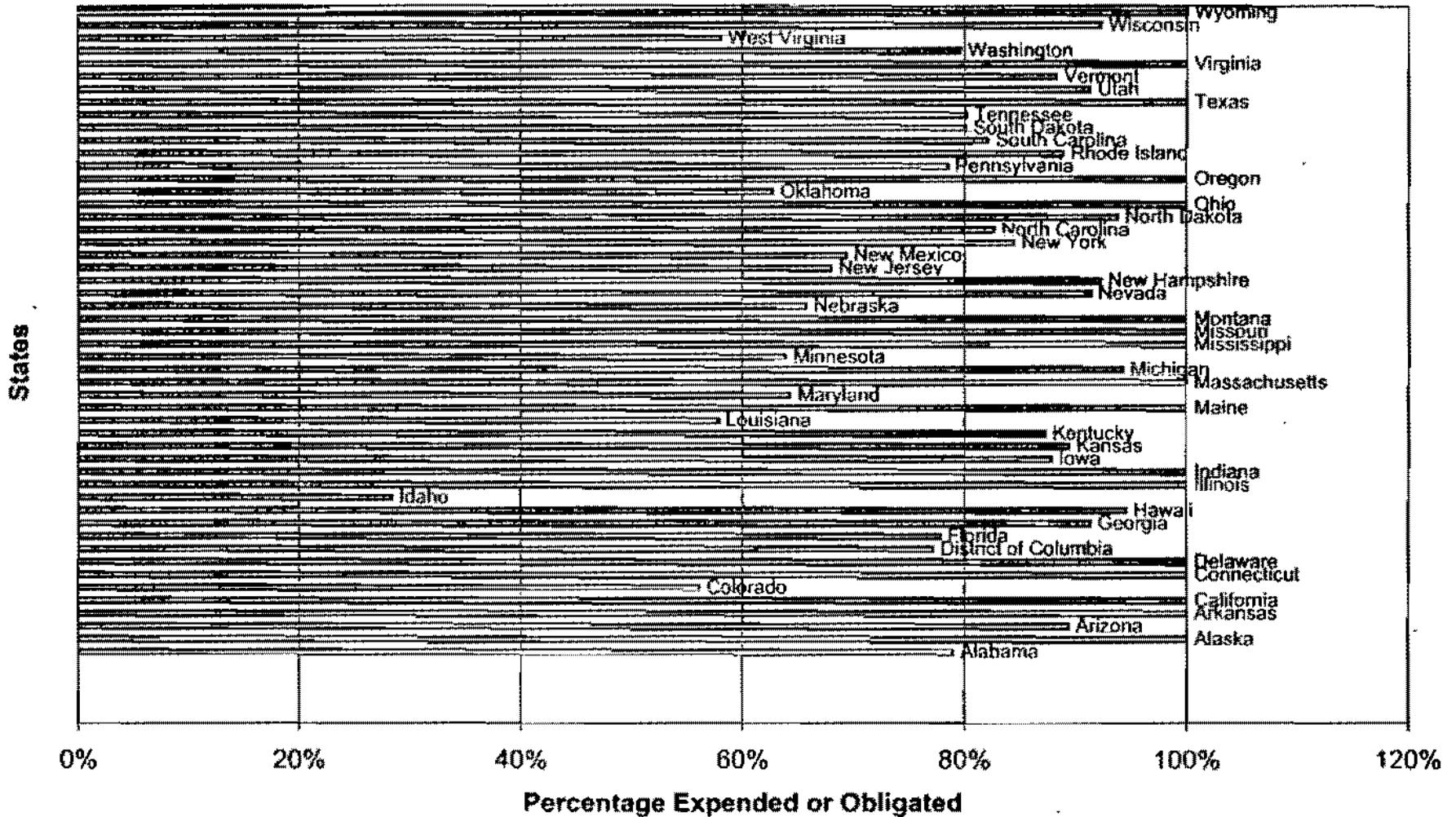
The initial success of welfare reform is clear. Now we must, through the actions described above, take the next steps toward making work pay and ensuring that no working parent is unable to meet their children's and their own basic needs. Our goal must be to lift every working family out of poverty.



Donna E. Shalala

Attachment

## 90% OF FY 97 & 98 FEDERAL TANF FUNDS HAVE BEEN EXPENDED OR OBLIGATED BY STATES





THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C. 20201

MAR 3 1999

MEMORANDUM FOR THE PRESIDENT

The attached is an Urban Institute analysis of Census' Current Population Survey (CPS) data regarding the participation rates of eligible citizens and non-citizens under welfare, Medicaid, and Food Stamp programs. The analysis finds evidence of "chilling effects" in that fewer immigrant families, compared to citizen families, have been accessing a wide array of public benefits, including important health and nutrition benefits. This greater rate of decline was evident prior to the implementation of eligibility changes as part of welfare reform. For example, welfare use by noncitizens declined by 35 percent from 1994 to 1997, while use by citizens declined 15 percent. While Medicaid use by citizen households under 200 percent of poverty did not change significantly, non-citizen family participation dropped 19 percent.

These findings replicate at a national level the findings that were released last summer by the Urban Institute for Los Angeles based on county administrative data. Both analyses were funded primarily under a cooperative agreement grant supported by the Department of Health and Human Services (HHS), the Department of Agriculture and the Immigration and Naturalization Service. We shared an embargoed version of the analysis with interested Members of Congress and their staffs the week of February 22nd, and HHS staff briefed Hispanic Caucus staff on February 26th. The Urban Institute had originally targeted release for March 1, 1999, but now plans to issue a press release regarding the analysis on March 9, 1999.

These findings are important for several reasons.

- **They provide evidence of a chilling effect on immigrant families' access to benefits, consistent with many reports we have received. These effects, which include benefits use by citizen children, may be the result of public charge policies, as well as confusion over changing eligibility requirements. We have been engaged for some time in extensive inter-agency discussions about how immigration officials should treat benefit use within the context of public charge provisions in immigration law and eligibility provisions in benefit laws. We have made significant progress and are hopeful that we can resolve expeditiously the few remaining issues.**
- **The findings also provide support for the Administration's current budget proposals to restore health, nutrition, and cash benefits to particularly vulnerable legal immigrants (e.g., children, pregnant women, and disabled immigrants entering the country after 8/22/96). The pre-implementation declines in immigrant use of benefits may in part be due to the well-publicized debate and passage of welfare**

3/01/1999 GAO

reform and immigration reform. The trends bear careful monitoring as current law immigrant eligibility restrictions, which will likely further reduce access to vital benefits, are implemented. The Administration's current and past (e.g., BBA) benefit restoration proposals, in conjunction with clear guidance on public charge policies, will allow us to begin sending clearer messages to immigrant families regarding their eligibility for benefits.

The analysis provides an important and timely contribution to the literature regarding both welfare reform and the fiscal impacts of immigration and immigrants. The analysis confirms that, contrary to assertions made during the welfare and immigration reform debates, low-income immigrant families in 1994 were no more likely than low-income citizen families to receive welfare (AFDC/TANF, SSI, GA), and by 1997 were *less* likely than citizen families to receive welfare. In 1994 immigrant families were more likely to receive Medicaid and Food Stamps, but immigrant enrollment dropped significantly so that by 1997 they were only as likely as citizen families to be enrolled. This information will be important as we develop policies and outreach strategies for our TANF, Medicaid and CHIP programs.



Donna E. Shalala

Attachment

cc: Vice President  
First Lady of the United States  
Bruce Reed  
Gene Sperling

**TRENDS IN NONCITIZENS' AND CITIZENS' USE OF PUBLIC BENEFITS  
FOLLOWING WELFARE REFORM, 1994-1997**

**Michael Fix  
Jeffrey S. Passel**

**The Urban Institute  
Washington, DC**

**February 1999**

(202) 261 5517; mfix@ui.urban.org  
(202) 261 5678; jpassel@ui.urban.org

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The views expressed are those of the authors and do not necessarily reflect those of the funders or the Urban Institute and its trustees.



MAR 2 1999

MEMORANDUM FOR THE PRESIDENT

I am writing because of my deep concern about the direction of the recent Medicare Commission discussions as Senator Breaux and Representative Thomas continue to court support for their proposal. While I believe the Administration has and should continue to vigorously articulate specific recommendations for strengthening and modernizing Medicare, we should be extremely cautious about accepting the vague "premium support" model developed by the Commission without fully exploring the significant policy issues it raises. In my view, it would also be a tactical mistake to cede political leverage by validating a premium support approach in advance of the upcoming congressional debate.

Despite the very hard work of your appointees, your staff, and the other Democrats involved with the Commission, I think that we must conclude that the Commission has failed in its primary task, which was to engage the policy community and the public in an open process that could develop reasonably broad, bipartisan agreement on how to address the long-term financing issues facing Medicare. Instead, the work of the Commission has focused largely on recasting and dressing up the Republican's 1995 Medicare reform goal of privatizing Medicare under the guise of "premium support." While the Democrats (helped considerably by your budget proposal) have remained willing to engage on the primary mission of the Commission - long-term financial solvency - little progress has been made in this area. Indeed, at the last Commission meeting, Republicans sought to recast the solvency debate in terms of the "rate of program growth" rather than trust fund solvency - a fairly transparent attempt to dismiss your strong argument for dedicating a portion of the surplus to extend the life of the Medicare Part A trust fund.

As the Commission winds up its work, we are left with a vague proposal that enjoys no public credibility, that fails to address the long-term financing problem of Medicare, that fails to address the critical need for an outpatient prescription drug benefit, and that fails to achieve any true bipartisan consensus on the appropriate future direction for Medicare. These problems are fundamental. Even if some last minute maneuvering brings about some coverage for prescription drugs or some use of the surplus, it seems doubtful that, after a thorough review, the "deal" would long survive the Commission's end.

In addition, we have extraordinarily few details on many of the major elements of the proposal, leaving the door open for the Republican leadership and Commission members to later selectively invoke the Commission's endorsement for items they decide to include in their legislative proposals. Another serious problem is that we only last week received an objective analysis (from the HCFA actuary) of the financial impacts of the proposal, and we have yet to receive any information on the distributional consequences (the winners and losers). I do not see how we or the congressional Democrats can move forward on a bipartisan basis when there is no

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firm meeting of the minds about what this proposal is intended to do, who it affects, how it would be structured, and who would pay for it.

Although the proposal put forth by Senator Breaux and Representative Thomas lacks specificity in many areas, the information that has been provided raises significant policy concerns. These include:

- **A substantial portion of the savings from the proposal result from raising beneficiary costs.** The estimates from the HCFA actuary indicate that roughly 45 percent of the savings from the Breaux/Thomas proposal come from increasing costs to beneficiaries, including specific proposals that would increase cost sharing (particularly for home health care), delay program eligibility to age 67, and create a new income-related premium (although these savings may be spent on new low-income protections). The income-related premium would begin at \$24,000 for single beneficiaries and \$30,000 for couples, a threshold so low that it essentially changes the social insurance nature of the program. In contrast, the income related premium proposed in the Health Security Act began at \$90,000 for single beneficiaries and \$110,000 for couples. The change in the eligibility age will increase the number of uninsured Americans, whether or not a buy-in proposal is included in the package. I do not believe that these proposals, as currently specified, are good for Medicare or will be acceptable to most congressional Democrats.
- **The proposal places the traditional fee-for-service Medicare program and the beneficiaries that it serves at risk.** While the Breaux/Thomas proposal contains some improvements for fee-for-service Medicare, including the new authorities that you have regularly requested to make HCFA a more prudent purchaser, the premium support program that is being considered would increase costs for those beneficiaries who elect to stay in fee-for-service or who have no choice of plans (e.g., millions of beneficiaries in rural areas). According to the HCFA actuary, fee-for-service premiums will increase by roughly 18 to 30 percent under premium support, with somewhat lower increases, 10 to 20 percent, if BBA extenders are enacted at the same time. Such increases may force lower income beneficiaries into private plans; beneficiaries in rural areas with no private plan choices will be forced to pay much higher premiums.
- **The proposal does not guarantee that all beneficiaries will receive the Medicare defined benefits.** Although the Democrats on the Commission have repeatedly stated that the benefit package for private plans should be defined so that it includes all existing Medicare benefits, the proposal appears to allow a proposed Medicare Board to approve benefit variations. Without a defined benefit package, aggressive risk selection activities by private plans could lead to greater adverse selection against the fee-for-service program. Without perfect risk adjustment, which we do not have, fee-for-service costs and premiums will increase.

- **Premium support, which is the most contentious element of the proposal, neither addresses Medicare's long-term financing problem nor produces sufficient savings to justify its adoption at this time.** According to the estimates of the HCFA actuaries, the inclusion of premium support will reduce Medicare spending in 2030 by just 2.5 to 3.1 percent. Over the 30-year period, premium support would provide only a little more savings than would be gained from the combination of the proposed fee-for-service modernizations and extending the BBA savings policies for about 5 years. While any method of improving the efficiency of Medicare should be seriously explored – and premium support has some positive attributes – it is clear that premium support has little impact on the long-term financial problems faced by the program.

As stated above, while we know something about the savings that may come about from premium support, we still do not have distributional analyses of who wins and who loses under different premium support approaches. Given the political controversy that premium support engenders, combined with its adverse impacts on beneficiaries without other choices, it would be premature for us to give any indication that premium support might be appropriate for Medicare.

We also need to be mindful that the premium support concept remains a moving target, despite the attempts of Senator Breaux and Representative Thomas to provide some direction. For example, at the last Commission meeting, three of the advocates of premium support suggested that their support was based primarily on the ability of private plans under premium support to provide substantial additional benefits to beneficiaries. However, the premium support specifications released by Senator Breaux either eliminate or substantially restrict (two options) the ability of private plans to offer additional benefits. Some members of the Commission and most of the public are not yet aware of this fact, and many potential supporters may have second thoughts when they understand the new direction. Again, I think that there is need for extreme caution in our public pronouncements until the details are written down and well understood by all of the relevant parties.

- **The proposal does not include a critically needed outpatient pharmaceutical benefit for all beneficiaries.** As you well know, prescription drug therapies are increasingly important to improving the health and well-being of our citizens, particularly those with chronic health conditions. Medicare simply cannot operate efficiently unless providers and health plans can use all of the tools available to improve the health of the elderly and the disabled.

Unfortunately, Senator Breaux and Representative Thomas have not agreed to support inclusion of a prescription drug benefit that would be available to all Medicare beneficiaries, instead suggesting a combination of different approaches for different segments of the Medicare population. Their stated reason for opposing a Medicare outpatient pharmaceutical benefit is a concern about substituting for existing prescription

drug coverage, but much of this concern is misdirected. A substantial portion of existing spending is either in public programs (i.e., Medicaid) or government subsidized (i.e., employer-provided retiree benefits, Medicare+Choice plans). Further, all of the trends indicate that employers will be providing fewer retiree health care benefits in the future.

Another concern raised by some Commission members is that a Medicare pharmaceutical benefit would give HCFA too much power over the prices that the elderly pay for prescription drugs. I view this argument as saying that we should be putting the profit needs of the pharmaceutical industry above the needs of beneficiaries to have access adequate health care. We must assure that beneficiaries are provided an affordable prescription drug benefit and that HCFA and private plans have sufficient authority to procure needed drugs at the best possible prices for beneficiaries and taxpayers.

**The new Medicare Board that would be created under the proposal would bifurcate federal responsibility for Medicare and significantly reduce executive branch influence over Medicare policy and spending.** The Breaux/Thomas proposal to create a new Medicare Board would result in a split of administrative responsibility for Medicare, with the new Board overseeing private plans, and HCFA continuing to have responsibility for fee-for-service Medicare. This split of responsibility would eliminate the single point of accountability for Medicare that we have today, and would make it much more difficult for the President and the Executive Branch to coordinate overall Medicare policy in a way that focuses on the needs of all beneficiaries. It also could diffuse our successful anti-fraud efforts, particularly the aggressive initiatives undertaken by the HHS Inspector General, by separating accountability over program finances. Such a change is not prudent given the important role that Medicare plays in the lives of millions of Americans as well as its significant impact on the federal budget.

**Current beneficiaries may experience significant disruptions.** We also need to be cautious about the extent to which we cause large disruptions for current beneficiaries. Last year, when a large number of managed care plans left the program, there was a considerable backlash from beneficiaries who experienced changes in plans, benefits and providers. Significantly greater changes for beneficiaries are likely under the Breaux/Thomas proposal. For example, the proposal would significantly limit the extent to which private plans could offer additional benefits to beneficiaries, which would mean that most current beneficiaries in Medicare+Choice plans would lose many of the benefits that they have today. In addition, market shake-ups and plan withdrawals could well be more frequent and more extreme under premium support, particularly in the early years before the system stabilizes. These issues have received no attention by the Commission.

In raising these serious concerns, I am also reminded that the Administration has a vision for addressing Medicare's financial problems and for strengthening and modernizing the benefits and program operations. As your budget proposal demonstrates, the Administration, working with congressional Democrats and interested Republicans, can begin to address Medicare's

problems without undermining the financial security of present and future beneficiaries. A thoughtful approach that includes dedication of a portion of the surplus to Medicare, the authority for HCFA to use more competitive purchasing practices, a responsible income-related premium aimed at truly higher income beneficiaries, an affordable prescription drug benefit, more rational cost sharing, and an extension of BBA savings proposals would be a package that could receive substantial support. These policies have been discussed before and are fairly well understood by the public and the Congress, and, unlike premium support, would not be considered radical change to the program.

We have an opportunity this year to make real improvements in Medicare that both secure the financing of the program for years and enhance the health care protection that we offer the elderly and disabled. But as we continue to put forth our vision for change, I believe that we need to be careful not to provide political cover to an untested, radical restructuring proposal that may be taken up in Congress this year. In my opinion, providing Administration validation of premium support would diminish our ability to control the details through the legislative process, potentially handing us a take-or-leave-it proposal for Medicare restructuring imbedded in a broader legislative vehicle at the end of this session. As we move forward, we need to protect the program from those whose ultimate goal is simply to privatize rather than improve Medicare.

The Commission process has been a trying one for all of us, and everyone who supports this program appreciates the effort that you personally and your appointees and staff have made to try and make the process a success. I hope that we can shift those energies now toward developing a proposal that is consistent with the values that underlie this program and which can garner broad public support and bipartisan support in Congress.



Donna E. Shalala



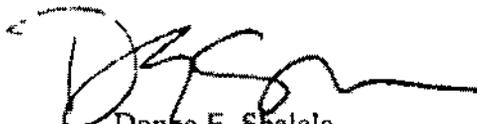
THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C. 20201

JAN 6 1999

MEMORANDUM FOR THE PRESIDENT

Please accept the enclosed implementation plan in response to your Executive Memorandum directing the Department to take steps to make tobacco industry documents more readily accessible to the public health community, the scientific community, the States, and the public at large. The plan we have developed will ensure greater access to these important documents and significantly increase our understanding of the health consequences of tobacco use and the extent to which this information has been systematically concealed from the public.

With your concurrence, we are prepared to immediately execute the plan and launch a broad, collaborative initiative of research and education that will help us to better understand the tobacco epidemic and identify the most effective regulatory and programmatic strategies to reduce the harm caused by tobacco products. Your challenge to the Department and commitment to the nation's public health have been critically important to the success of this historic undertaking and to our common goal of a tobacco-free adolescence for every child.



Donna E. Shalala

Enclosure

7/21/1998 0001

## **Response to Executive Memorandum Public Availability of Tobacco Documents**

On July 17, 1998, the President issued an Executive Memorandum highlighting the importance of tobacco industry documents that have been released as a result of recent tobacco litigation and congressional subpoenas. This initiative is designed to lift the tobacco industry's veil of secrecy so that all Americans can know the origins of our epidemic of teen smoking and the history of our national addiction to tobacco, and allow us to use the industry's darkest secrets to save a new generation of children from the deadly habit of tobacco use. Citing the potential value of these documents to the American people and the nation's public health community, the Memorandum directed the Secretary of Health and Human Services to do the following:

1. Propose a method for coordinating review of the documents and making available an easily searchable index and/or digest of the reviewed documents.
2. Propose a plan to disseminate widely the index and/or digest as well as the documents themselves, including expanded use of the Internet.
3. Provide a strategy for coordinating a broad public and private review and analysis of the documents to gain critical public health information. Issues to be considered as part of this analysis include: nicotine addiction and pharmacology; biomedical research, including ingredient safety; product design; and youth marketing strategies.

This paper proposes a plan to fulfill the objectives outlined in the Executive Memorandum.

### **I. Preface**

#### **Importance of Tobacco Industry Documents**

Landmark tobacco litigation brought by the State Attorneys General and others, Congressional inquiries, and the Food and Drug Administration's historic investigation have resulted in the release of millions of previously inaccessible internal tobacco industry documents. Among other things, the documents contain information about what manufacturers know and have known about the health consequences of tobacco use, how they have concealed this knowledge from the public, how cigarettes are designed, how the industry abandoned research into safer products for fear of litigation, how the industry has targeted its marketing to particular demographic groups including youth, what factors are most important in determining tobacco use, and how the industry has worked to undermine public health efforts that effectively reduce tobacco use.

The information that is now available, but not yet analyzed in detail or effectively disseminated, will be invaluable in helping scientists, educators, public health specialists, and regulators understand the development of the tobacco epidemic, and will allow them to better educate the public and to develop effective regulatory and public health strategies to reduce the harm caused by tobacco products. This information will help us design better public health strategies to break the addictive hold that tobacco currently has on 4.5 million children and 47 million adults in this nation.

### **Available Documents**

The single most comprehensive holding of documents is in Minneapolis, Minnesota, at the State of Minnesota's Document Depository, established as part of the settlement reached in May 1998 to resolve the lawsuit brought by the Minnesota Attorney General and Blue Cross and Blue Shield of Minnesota against the tobacco companies. The depository contains an estimated 26 million pages of documents acquired through discovery in the Minnesota litigation and will, as a condition of the Minnesota settlement, incorporate documents released in any other smoking and health litigation in this country. Another 7 million pages of documents acquired through the litigation are stored in Guildford, England. However, the vast majority of these 33 million pages are only available on site at the two depositories.

Additionally, the depository is also home to the Minnesota Select Set, which contains the 1-2 percent of the 33 million pages selected by the Minnesota trial attorneys as possible trial exhibits. Also available only on site is an electronic search engine and index (the "4-B Index") which allow documents to be searched by date, author, and title [etc.], but not by subject matter.

A fraction of the documents in the depository, as well as other documents, are available through five primary Internet sites: the House of Representatives Commerce Committee Site (<http://www.house.gov/commerce/TobaccoDocs/document.html>; 39,000 documents released in the Minnesota trial for which the industry had claimed privilege; these documents were subpoenaed by Commerce Committee Chairman Bliley and are not available at the depository); the Smokescreen site where many of the Commerce Committee documents are available in a searchable format (<http://www.smokescreen.org/documents>); University of California Library site (<http://www.library.ucsf.edu/tobacco>; Brown & Williamson documents released in 1994 and the Mangini collection released in 1998); the Tobacco Resolution (tobacco industry) site (<http://www.tobaccoresolution.com>); and the Blue Cross/Blue Shield of Minnesota site (<http://www.mnbluecrosstobacco.com/toblit/trialnews/index.html>; the 3,000 documents used as Minnesota trial exhibits).

The challenges to researchers and others interested in obtaining information from the documents include the following:

- a fraction of the documents are in electronic format, and the vast majority of documents are available only in hard copy at the Minnesota depository;
- the 4-B index is only available on site at the Minnesota depository;
- documents are not organized by broad subject categories;
- lack of subject indexing prevents searching of documents by subject or key word;
- full-text searches for most documents are not possible; and
- documents are sorted separately by company or institution, requiring searching of several databases for a single area of interest.

### **Users of Documents**

In determining priorities to improve accessibility to the documents, it is critical to understand the wide range of potential users of the documents and the needs of those users.

Three primary groups of users will be the research community, the public health community, and regulators. Researchers will play the critical role of analyzing the documents for their public health value, including decades-worth of industry-sponsored studies on the nature of nicotine addiction, tobacco-related illnesses, and marketing strategies targeting children. Members of the public health community will use the documents to determine strategic priorities for shaping public policy, devise interventions to help people quit and prevent young people from starting to smoke, and educate policy makers and the public. Regulators will use the documents to obtain detailed information that will help guide and inform their work.

Other users include the journalistic and legal communities. Journalists and lawyers will want direct access to documents, but they will also rely on researchers and members of the public health community to learn about information of potential value in the documents.

While the general public will not be the primary users of these materials, the American people -- especially educators, parents and youth -- should be the ultimate beneficiary of information contained in the documents. The public deserves to learn both what the industry knew about the dangers of smoking while marketing their products, and steps that can be taken to improve their health. Researchers, advocates and journalists can help the public better understand how the tobacco industry sought for years to hide the truth about the dangers of smoking and about their own systematic efforts to target children. Finally, these documents can be an immensely important education tool and should be provided to teachers, parents, and students. Because research shows that an effective way to reduce youth smoking is to expose industry efforts to lure children by glamorizing

smoking, special attention should be devoted to packaging and distributing educational materials based on documents that reveal this practice.

### **The Changing Landscape of Document Accessibility**

In taking steps to increase the accessibility of tobacco industry documents, the federal government should devise a system that can be adapted and upgraded to keep pace with other public and private efforts. As litigation continues, more documents and information will become available to the public. For instance, the recent settlement between the states and the tobacco industry promises to improve access to documents. Moreover, the Department of Justice has filed a brief on behalf of the Department of Health and Human Services in support of the State of Minnesota's efforts to unseal the tobacco industry's own multi-million dollar computerized index (the "4-A Index"). The court has recently ruled in favor of the government. The 4-A index would permit far more precise searches and focused identification of documents than the 4-B index currently available at the Minnesota Depository.

The private sector has expressed a keen interest in processing the documents. Firms are already marketing full-text searchable CD-ROMs of subsets of the documents, but these sets are often expensive. It is likely that the activities of the marketplace will expand, making more documents more easily accessible.

## **II. Next Steps**

Important steps can and should be taken now, however, to make the incredibly valuable public health information in these documents available and easy to use. Working with the Department of Justice, the Department of Health and Human Services will:

- o Within 60 days, create a comprehensive HHS Internet site with a searchable version of the 4-B index that will enable the public to locate and order through fax or mail from the Minnesota Depository at cost electronic images or paper copies of its tobacco industry documents. For the first time, the tobacco industry documents in the Minnesota Depository will be readily accessible. In addition, this gateway site will have links to other Internet sites with tobacco industry documents and will provide information on how best to use those other sites. To expedite and facilitate coordination in the research effort, HHS will establish communications systems through the Internet site and other electronic means to enable researchers to coordinate their activities and share the results of their findings. As additional research tools or indices become available, they, too, will be added to the HHS Internet site.

- o Within 120 days, make available to the public on CD-ROM, imaged copies of all the tobacco industry documents contained in the Minnesota Select Set. These documents, totaling about 500,000 pages, were chosen by the Minnesota Attorney General's office and its co-counsel

as the most important documents for that state's litigation. Currently, most of the documents are not available electronically, but instead are available only in hard copy on-site at the depository.

o Within 120 days, announce the intention of the National Cancer Institute (NCI) to support additional research on tobacco industry documents. NCI has already taken an initial step in this direction by funding research based on recently disclosed tobacco industry documents. This additional funding will enable NCI to expand its research in this area and others of critical importance to public health, including nicotine addiction and pharmacology; biomedical research, including ingredient safety; product design; youth marketing strategies; and environmental tobacco smoke. A special ad hoc review group will be formed to review research proposals in this unique field. Under this program announcement, tobacco industry documents used in the research along with an index prepared by the researchers will be made available in an appropriate electronic format on the HHS Internet site. In addition, NCI will convene semi-annual research meetings to give tobacco document researchers the opportunity to report on their progress, to discuss common problems and solutions, and to develop collaborative research. A centralized inventory of published analyses in the scientific literature will be maintained on the HHS Internet site to monitor progress toward the Department's goals.

o Within 180 days, the Minnesota Select Set will be made available in a text-searchable format on the HHS Internet site. At the same time, HHS will post on the HHS Internet site a single search interface able to search other tobacco industry document sites, within technological limitations. This would allow a user to enter a single set of search parameters into the HHS search interface (which would sequentially search all other sites that it is technically able to search), browse the results of the search on the HHS site, and link to the documents on other sites resulting from the search.

o Within a year, an assessment will be made on what additional steps can be taken to ensure the widest available dissemination and most efficient public health analysis of the information contained in the tobacco industry's secret documents.

### **III. Conclusion**

The documents discussed in this paper offer the most valuable information on tobacco and health issues to become available in the past several years. As research into effective tobacco use reduction suggests a shift from clinical to public health and public policy approaches, the industry's internal documents provide information relevant to these approaches not obtainable through other means.

The steps outlined in this plan will greatly enhance the ability of researchers and the public health community to understand the tobacco epidemic and to identify effective strategies to combat the epidemic. Improved access to documents and the activities of researchers and public health interests will ultimately result in a nation better informed

researchers and public health interests will ultimately result in a nation better informed about the risks of tobacco use, about the nature of tobacco marketing, and about steps that individuals and government can take to reduce tobacco use in their families and communities.



January 6, 1999

**MEMORANDUM FOR THURGOOD MARSHALL, JR.**

Attached is a Memorandum for the President detailing a departmental implementation plan to make tobacco industry documents more readily accessible to the public health community, the scientific community, the state and the public at large. This implementation plan was prepared in response to an Executive Memorandum from the President.

Should you need further assistance, please contact me at (202) 690-7431.

  
Mary Beth Donahue

Attachment