- The Clinton Administration has reached 21 agreements with Japan since 1993, covering a range of market sectors: autos and auto parts, medical technology, flat glass, insurance, financial services, telecommunications, supercomputers, construction, cellular phones, chemicals, rice, paper, apples, wood, and intellectual property rights.

- According to the Council of Economic Advisers, U.S. exports in sectors covered by these market-opening agreements, have grown over 85% since 1993. That's three times as fast as other U.S. exports to Japan over the past three years. For example:

  - U.S. auto and auto parts exports to Japan increased over 35% since the agreement went into effect in August 1995, totaling $3.8 billion in 1995. The Big Three auto manufacturers and Japanese transplant producers sold over 140,000 U.S.-made vehicles in Japan in 1995, up 40% since 1994.

  - U.S. exports of telecommunications equipment to Japan have grown nearly 50% since November 1994 -- almost two times as fast as telecom equipment exports to the EU. U.S. telecom exports to Japan reached $1.7 billion in 1995.

  - U.S. exports of medical technology to Japan have grown over 35% since November 1994, reaching nearly $2 billion.

  - U.S. exports of chemicals to Japan have grown nearly 25% since the Uruguay Round was concluded, reaching $2.8 billion in 1995.

  - U.S. copper exports to Japan are up over 80% since the conclusion of the Uruguay Round, reaching $350 million in 1995.

  - Just a few years ago, rice exports to Japan were virtually banned. Since a crop failure in Japan, however, U.S. rice producers have sold $287 million of rice to Japan -- more than the previous 25 years combined. In 1995, U.S. exports of rice to Japan reached $31 million.

- U.S. manufacturing firms increased their share of the Japanese market over the past three years -- up 20% in 1995 over 1992.

- Overall agricultural exports surged to $56 billion in 1995, up almost 22% over 1994, with highs in poultry, pork, wheat, and cotton.

- Even with the difficult economic situation in Mexico, U.S. exports to Mexico in 1995 were $46 billion. That's 11% higher than 1993 -- the year before NAFTA was implemented. And 74 cents of every dollar that Mexicans spend on imported goods go to buy U.S. goods.

Created Over 1 Million High-Wage American Jobs Through an Unprecedented Export Boom: Implemented a National Export Strategy that has helped create American jobs by promoting U.S. goods and services abroad, including providing high-level government advocacy, financing and risk insurance for our American companies. Reduced tariff and non-tariff barriers to trade in the markets of our largest and fastest growing trading partners.

- The United States is the world's largest exporter. Exports have grown 31% since President Clinton took office. In 1995 alone, exports were up more than 14%.

- Exports accounted for one-third of overall U.S. economic growth since the beginning of the Clinton Administration.

- Over one million high-quality, high-wage jobs have been created as a direct result of increased exports. 11 million American jobs are supported by exports and since 1993, roughly one out of every ten American workers depends on exports for their jobs. Export-related jobs pay on average of 13-16% better than other jobs.

- One in five manufacturing jobs is supported by U.S. exports. Almost 300,000 manufacturing jobs have been created just in the past three years. Auto jobs have increased by 89,000 during the Clinton Administration, after declining during the previous four years.

- Put America First by Restoring U.S. Competitiveness: Put the United States' financial house in order through sound macroeconomic policies such as a smart and tough deficit reduction plan and reduced government. Promoted education and training programs to give the American people the tools they need to prosper in the new global economy. Strengthened our economy by opening up opportunities to sell American goods and services in foreign markets.

Put America First by Restoring U.S. Competitiveness: Put the United States' financial house in order through sound macroeconomic policies such as a smart and tough deficit reduction plan and reduced government. Promoted education and training programs to give the American people the tools they need to prosper in the new global economy. Strengthened our economy by opening up opportunities to sell American goods and services in foreign markets.

- The United States has been ranked Number One on competitiveness for two years in a row -- up from Number Five in 1992.

- The United States is the world's Number One producer of automobiles for the first time since the 1970's -- overtaking Japan.

- U.S. aircraft industry dominates the world market -- supplying 65% Asia's imports.

- The United States is once again the world's Number One producer of semiconductors, surpassing Japan.

THE CHALLENGES AHEAD:

President Clinton will continue to open markets around the world and will continue to promote American exports by:

- Aggressively pushing foreign trading partners to further open their markets to U.S. goods and services.
- Ensuring that our trading partners live up to their obligations by strictly enforcing our trade agreements, using sanctions and other punitive measures when necessary.
- Continuing to place special emphasis on the fast-growing emerging markets around the world.
- Continuing to help small and medium sized enterprises export.
- Continuing to give American workers and businesses the tools they need to compete and win in the new global economy.

Last Update: May 8, 1996

DRAFT

VETERANS AFFAIRS

"To honor our veterans...gratitude and ceremonies are not enough. We must protect the benefits you have earned, address fully the dangers imposed by modern warfare, and preserve what you fought for: the American Dream at home and our leadership around the world."

President Bill Clinton
March 6, 1995

President Clinton has fought to protect the benefits that veterans have earned in service to this nation and to address the new needs and challenges created by a changing world. The Clinton Administration has also worked to make the Department of Veterans Affairs more efficient and responsive, proposing and implementing changes at VA that will improve services and save money, many of which have long been advocated by veterans. The Administration has also aggressively responded to veterans of the Persian Gulf War suffering from unexplained illnesses, to the challenges created as the military downsized after the Cold War and to the needs of homeless veterans.

A RECORD OF ACCOMPLISHMENT:

- **Improved and Restructured VA Health Care System**: The Clinton Administration implemented significant management restructuring of VA medical system, creating integrated service networks and consolidating duplicative medical and administrative services, to ensure that scarce resources are focused on patient care. To further expand resources, the Administration proposed "gainsharing" to allow VA medical facilities to retain a portion of the money VA collects from third parties. These changes will allow VA to provide 1.6 million more patient visits in 1996 with fewer resources.

- **Protecting Veterans Benefits**: The Clinton Administration ensured full cost of living adjustment on benefits going to disabled veterans and military retirees; fought to fully fund benefit programs; expanded eligibility for disability compensation for Vietnam veterans exposed to Agent Orange; opposed Congressional proposals to eliminate compensation for certain mentally incompetent veterans; and proposed increased funding for national cemetery system to ensure that veterans and their families are buried with dignity.

- **Persian Gulf War Veterans' Illness**: President Clinton established the Presidential Advisory Committee on Gulf War Veterans' Illness aimed at finding the causes of these illnesses and improving the care available to Persian Gulf veterans. As part of Gulf War illness effort, the Administration expanded funding for research, medical care and communication at the Department of Defense, Veterans Affairs, and Health and Human Services.

- **Firm Commitment to Veterans in Federal Hiring**: Despite overall hiring declines across the federal government in the last three years, the percentage of jobs going to veterans has increased. The federal government continues to lead the nation in the percentage of veterans and disabled veterans in its workforce. The proportion of veterans in the federal workforce increased from 23.6% in 1992 to 33.3% in 1994.

- **Training and Assistance**: The Clinton Administration helped over 1.5 million veterans into jobs through the Department of Labor's veterans employment service. Nearly 500,000 separating service members and their spouses received job search training under the Department's Transition Assistance Program. The veterans' unemployment rate has been cut by almost a third during the first three years of the Clinton Administration (7.2% in January 1993 to 4.9% in January 1996).

- **Faster Benefits Delivery**: The Administration improved processing time and reduced pending caseload for compensation and pension claims at the Veterans Benefits Administration. The President's FY 97 budget included funding for 50 positions for the Board of Veterans' Appeals to improve timeliness in processing appeals. In FY 97, the Veterans Benefits Administration will process original compensation claims 33 days faster than in FY 96, and the pending caseload will be reduced from 378,600 at the end of FY 95 to 277,000 cases at the end of FY 97 -- a 27% reduction.

- **Targeted, Supportive Assistance to Homeless Veterans**: President Clinton fought for increased funding to assist communities in developing local, coordinated solutions to break the cycle of homelessness. The Administration more than doubled VA funding of homeless programs in three years, to the current level of $76 million. As part of a new Homeless Providers Grant Program, VA awarded more than $11.8 million to 59 public and private nonprofit groups to develop new programs to assist homeless veterans. The Administration's Interagency Council on the Homeless established a Homeless Veterans Task Force to improve services and programs for homeless veterans across agencies.

THE CHALLENGES AHEAD:

President Clinton will continue to fight to protect the benefits veterans have earned and to help veterans respond to new needs and challenges:

- Work for passage of reinventing government initiatives that will improve services to veterans, simplify complex eligibility rules, and save money through streamlining.

- Continue restructuring of VA's health care system.

- Continue to improve veterans' benefits delivery system to give veterans increased access and more efficient service.

- Continue to work with Presidential Advisory Committee to find causes and care for Persian Gulf Veterans with undiagnosed illnesses.

- Continue unprecedented outreach to veterans and veterans service organizations.

Last Update: May 8, 1996

SENIORS

"I think we're obligated to balance this budget to take the debt off our children and our grandchildren, but we're obligated to do it in a way that represents -- that reflects our responsibility to our parents and our grandparents..."

President Bill Clinton
September 20, 1995

Today, there are thirty-three million older Americans. By 2030, older Americans will number seventy million--twenty percent of our population. Older Americans are doing better today--healthier and wealthier--than ever before. As we move into the twentieth century, President Clinton is fighting to protect and improve those programs which have successfully provided older Americans a base of health, economic security and independence for decades, and to prepare for the challenges ahead.

A RECORD OF ACCOMPLISHMENT:

- **Fighting Drastic Cuts in Medicare and Medicaid**: President Clinton is fighting Republican proposals for Medicare and Medicaid that would shift a staggering financial burden to elderly and disabled Medicare beneficiaries, reduce Medicaid nursing home coverage for elderly and disabled Americans, and result in damaging structural changes in the Medicare program.

- **Strengthening and improving Medicare and Medicaid:** President Clinton enacted and continues to fight for proposals that strengthen the Medicare Trust Fund: the President's 1993 Economic Plan extended the life of the Trust Fund by 3 years, and his balanced budget guarantees the life of the Trust Fund for a decade. President Clinton is also strengthening the Medicare program by combating fraud and abuse, enhancing quality, and supporting an expansion of voluntary managed-care options to increase choices for beneficiaries -- not as a smokescreen for deep and arbitrary cuts. In addition, he has proposed providing more preventive services and a respite care benefit for families of victims of Alzheimer's disease under Medicare.

- **Long-Term Care:** The President opposes Republican proposals to reduce Medicaid long-term care coverage. He has consistently supported expanding state administered home and community-based care services, tax clarifications and consumer standards for private long-term care insurance, and penalty-free withdrawals from IRAs to pay for long-term care.

- **Social Security:** Recognizing that Social Security has successfully provided a foundation of economic security to older Americans for decades, President Clinton is committed to ensuring the long-term integrity of the Trust Fund through a bipartisan solution that keeps the program dependable for all recipients. The President firmly opposes proposals to use Social Security benefits to balance the budget or pay for tax cuts for the wealthy.

- **Promoting and Strengthening Retirement Savings**: President Clinton's pension initiatives are helping more Americans save for retirement and ensuring that pension benefits are safeguarded for retirement. The Retirement Savings and Security Act

proposed this year by the President would increase pension portability, enhance pension protection and expand coverage. The Retirement Protection Act signed by the President in 1994 strengthened pension plan standards and enhanced enforcement authority so that workers and retirees can count on receiving the pensions they have earned.

- **Strengthening Supportive Services and Opportunity**: This year, President Clinton proposed reauthorization of the Older Americans Act that will renew and strengthen critical Meals on Wheels, transportation, senior community employment and ombudsman services. The President is also fighting to support and protect the Corporation for National Service's Senior Service Programs -- Foster Grandparents, Senior Companions and the Retired Senior Volunteer Program. These programs give older Americans the opportunity for continued involvement in their communities and allow the nation to benefit from the rich resource that our elderly are.

- **Bringing Seniors to the Table**: President Clinton elevated the Commissioner of Aging to Assistant Secretary status and called for the fourth White House Conference on Aging, after the 1991 Conference failed to take place.

- **Making Our Communities Safer**: President Clinton broke six years of Congressional gridlock by signing the toughest and smartest Crime Bill ever with bipartisan support and endorsements from every major law enforcement organization. In addition, the President fought for and signed the Brady Bill which has prevented over 60,000 convicted felons, fugitives, stalkers and other criminals from buying handguns. These efforts are contributing to safer communities: in 1995, the number of murders fell 8% --one of the largest declines in more than three decades--and overall crime fall 6% in our nation's largest cities.

THE CHALLENGES AHEAD:

The President will continue to fight for policies that honor our commitments to older Americans and allow them to remain independent and active participants in our communities. The President will continue to work to:

- Preserve and strengthen Medicare through: assured financial solvency without substantial new costs on beneficiaries or damaging structural changes; expanded choices of high-quality health plans and delivery systems; and new preventive benefits and strong new protections against fraud and abuse.

- Improve access to home and community-based care and to protect nursing home coverage under Medicaid.

- Implement private long-term care insurance standards to protect consumers against substandard policies and unacceptable insurance practices.

- Maintain federal quality standards for nursing homes and protections against impoverishment for spouses of nursing home residents in the Medicaid program.

- Enhance economic security for older Americans through an improved pension

system and a strong long-term financial basis for Social Security.

June 1996

MEDICAID

"I vetoed the Republican budget plan that was sent to me by Congress . . . because [it included] the most massive cuts in Medicare and Medicaid in history, a tax increase on working people, and deep, deep cuts in education and the environment. . . . My seven year balanced budget plan reflects our values and protects our investments in the future. . . . At stake is far more than just numbers and abstract programs and proposals, and far more than the normal political debates in Washington. This debate is about people, the lives they lead, the hopes they have, the desires they have for a better life."

President Clinton
Radio Address
December 9, 1995

Overview. For 30 years, Medicaid has provided a guarantee to meaningful health benefits for millions of people with disabilities, pregnant women, poor children, and older Americans -- particularly those in need of nursing home care. President Clinton is committed to giving states flexibility to manage the program more efficiently, while retaining the Medicaid guarantee and refusing to go backwards on health care coverage for Americans.

Accomplishments.

- **Flexibility and Coverage Expansions.** Section 1115 of the Social Security Act gives the Secretary of Health and Human Services broad discretion to waive certain Medicaid requirements in order to set up experimental or demonstration projects. Through this authority, the Clinton Administration has worked with states to test new and innovative approaches to benefits and services, eligibility requirements and processes, payment and service delivery. These waivers are often aimed at saving money to allow states to extend Medicaid coverage to additional low-income and uninsured people. Since January 1, 1993, comprehensive health care reform demonstration waivers have been approved for 12 states and ten have already been implemented.
- **Improving Quality in Managed Care.** The Clinton Administration has also granted 1915(b) "freedom of choice" waivers that permit states to require beneficiaries to enroll in managed care plans. States often use these waivers to establish primary care case management programs and other forms of managed care. As the number of Medicaid beneficiaries enrolled in managed care has increased, the Clinton Administration has been working closely with states, insurers, health care professionals and consumers to assure the quality of care provided in managed care plans. For example, Medicaid HEDIS (Health Plan Employer Data Information Set), which was released in February 1996, will help monitor and improve quality in managed care plans and educate Medicaid beneficiaries about plan performance.

- **Simplifying and Streamlining Medicaid.** As part of its regulatory reform efforts, the Department of Health and Human Services has simplified the process of obtaining Medicaid home and community-based waivers and changed duplicative nursing home regulation while maintaining strong Federal quality standards.
- **Cracking Down on Fraud and Abuse.** Last year, the President announced a two-year partnership of Federal and state agencies to prevent and detect health care fraud in specific industries. Operation Restore Trust targets five states which together account for about 40 percent of the nation's Medicare and Medicaid beneficiaries.

Statistical Backup.

- Over 650,000 people have received health care coverage under Medicaid because of implemented state demonstrations. When all 12 are implemented, 2.2 million previously uninsured individuals are expected to receive health coverage.
- Regulatory reform efforts across the Department of Health and Human Services will result in an almost 25 percent reduction in total pages of Department regulations.

Agenda.

- The President will not accept the Republican budget proposal to end the Medicaid guarantee to meaningful health benefits for millions of people with disabilities, pregnant women, poor children and older Americans -- particularly those in need of nursing home care.
- Instead, he has put forward a balanced budget proposal that maintains the guarantee while giving states unprecedented flexibility to manage the program. Key elements of the President's Medicaid proposal are:
  - Maintains guarantee of coverage.
  - Constrains Federal spending through a per capita cap that protects states in times of economic downturns, inflation, or other situations that cause enrollment to grow.
  - Gives states flexibility by repealing the Boren Amendment (so that states can determine payment rates without interference) and allowing states to implement managed care without waivers.
  - Maintains federal nursing home quality standards and enforcement.
  - Retains financial protections for families, including protections against impoverishment for spouses of nursing home residents.

Contact: Jennifer Klein or Chris Jennings
Last Update: March 10, 1996

MEDICARE

"...(W)e must have a common commitment to preserve the basic protections of Medicare and Medicaid.... In the past three years, we've saved $15 billion just by fighting health care fraud and abuse. We have all agreed to save much more. We have all agreed to stabilize the Medicare Trust Fund. But we must not abandon our fundamental obligations to the people who need Medicare and Medicaid. America cannot become stronger if they become weaker."

President Clinton
State of the Union Address
January 23, 1996

Overview. For over three decades, Medicare has provided basic health care benefits for millions of elderly and people with disabilities. A recent study has cited Medicare as one of the reasons why Americans who turn age 80 are more likely to live longer than any other 80-year-old in the world. President Clinton is committed to strengthening and modernizing Medicare by incorporating the positive aspects of innovations in the private sector health care delivery system, while preserving the nation's commitment to this important program. He has already presided over an unprecedented increase in the number of beneficiaries choosing managed care options. He has cracked down on fraud and abuse, and has asked Congress to give him the authority to do more. And finally, he has offered proposals to constrain growth in program expenditures and extend the life of the Medicare Trust Fund by at least ten years from now. The President has illustrated how these goals can be achieved while still providing new preventive care services and an even greater array of plan choices to the over 37 million beneficiaries the program now serves. But, unlike other proposals, his new plan options would compete on cost and quality -- not by "cherry-picking" the healthiest and wealthiest.

Accomplishments.

- **Cracking Down on Fraud and Abuse.** Building on the billions of dollars that the Clinton Administration has saved by tracking down purveyors of Medicare fraud and abuse in the last three years, the President announced a new two-year partnership of Federal and state agencies to further prevent and detect fraud in the parts of the program that are expanding the most rapidly. "Operation Restore Trust" targets five states that account for 40 percent of the nation's Medicare and Medicaid beneficiaries. This new initiative is already paying dividends and it is expected that the investment will yield a multi-fold return in recoveries, fines, penalties, and savings to the Medicare Trust Fund.

- **Expanding Plan Choices for Beneficiaries.** Through its ongoing efforts to collaborate with the managed care industry and provide objective information to beneficiaries about plan choices under Medicare, the Clinton Administration has presided over unprecedented growth in voluntary enrollment in Medicare managed care plans. The recently launched demonstration "Medicare Choices" is just one example of this commitment to provide more managed care options to beneficiaries, particularly for beneficiaries in previously underserved rural areas.

- **Improving Quality.** As plan choices are increased, the President has been vigilant to ensure that quality is preserved and enhanced. The establishment of the Medicare HEDIS (the Health Plan Employer Data Information Set), the Foundation for Accountability, and the Medicare Managed Care Quality Improvement Project are just a few examples of the Clinton Administration's commitment to quality. These initiatives will help ensure that managed care plans use standardized reporting criteria to help beneficiaries judge these plans' quality and medical outcome performance.

- **Simplifying and Streamlining Medicare.** Historically, the Medicare program has been over-regulated and micromanaged. In the last year alone, the President has directed the Department to (1) alter the focus of regulations to measures of outcomes of care rather than measures of process, (2) eliminate the so-called "physician attestation" form, which was required to certify the accuracy of all diagnosis and procedures before any claim could be submitted, and (3) reduce excessive reporting requirements and streamline inspections for excessively regulated clinical labs.

Statistical Backup.

- In the last three years, anti-fraud and abuse efforts have saved almost $15 billion in Medicare and Medicaid costs. Under Operation Restore Trust, there have already been 30 convictions, 12 indictments, 10 civil judgements and 36 program exclusions. These actions resulted in $2.2 million in program savings and $34.9 million in fines, recoveries, settlements and civil money penalties.

- As of February 1996, almost 4 million Medicare beneficiaries were enrolled in managed care plans. Since 1993, there has been a 67 percent increase in enrollment in these plans. In fact, in 1995, an average of 68,000 beneficiaries a month voluntarily enrolled in these plans.

- Regulatory reform efforts across the Department of Health and Human Services will result in an almost 25 percent reduction in total pages of Department regulations. Ending the "physician attestation" requirement alone will eliminate 11 million forms a year, saving almost 200,000 hours of physician time and decreasing hospital administrative costs by about $22,500 per hospital a year.

Agenda.

- The President has and will continue to reject Republican budget proposals that provide for excessive cuts in Medicare, unnecessarily increase out-of-pocket costs (directly through increased premiums and indirectly through the elimination of balanced billing protections), and that propose untested plans (such as Medicare Medical Savings Accounts) that would compete by attracting healthy and wealthy beneficiaries, rather than by providing high quality, cost-effective services.

- Instead, the President has submitted a balanced budget proposal that would reduce program growth and, in so doing, strengthen the Medicare Trust Fund. His plan provides more plan choices and more preventive care. Key elements include:

  -- Achieves $124 billion in savings over seven years through specific and scored initiatives without any new beneficiary cuts. This would extend the life of the Medicare Trust Fund by over a decade from now.

  -- Provides for more choices, including new Medicare Preferred Provider Organizations (PPOs) and new Provider Sponsored Organizations (PSOs).

  -- Provides for an unprecedented preventive care package that would include no copayments for mammograms, a new colorectal screening benefit, and a new diabetes maintenance program.

  -- Provides for a downpayment on long-term care through the establishment of a new respite benefit for families of Medicare beneficiaries who have Alzheimer's disease.

  -- Strengthens the hands of Federal fraud and abuse prosecutors with more penalties and other legal remedies, and increases financial incentives for Medicare to go after abusers of the system because they can reinvest these savings to help finance additional investigations.

Contact: Chris Jennings or Jennifer Klein
Last Update: March 11, 1996

HEALTH CARE REFORM

". . . [I]f our working families are going to succeed in the new economy, they must be able to buy health insurance policies that they do not lose when they change jobs or when someone in their family gets sick. . . . We have to do more to make health care available to every American. And Congress should start by passing the bipartisan bill sponsored by Senator Kennedy and Senator Kassebaum that would require insurance companies to stop dropping people when they switch jobs, and stop denying coverage for preexisting conditions."

President Clinton
State of the Union Address
January 23, 1996

Overview. Since taking office, the President has fought hard for health care reform. While we could not reach agreement on legislation in 1994, there is little disagreement that the problems remain.

- Nearly forty million Americans have no health insurance.
- 84 percent of the uninsured in 1993 were in working families, and more than 55 percent of the uninsured lived in families headed by full-time workers.
- As many as 4 million people have been affected by "job lock" -- the inability to change jobs for fear of losing insurance -- and every year 18 million people change insurance when someone in their family changes jobs.

Agenda. The President remains firmly committed to guaranteeing health security to all Americans. The President believes we should take a step-by-step approach.

That is why he included reforms in his balanced budget proposal that would:

- **Reform the insurance market** -- so that people don't lose health insurance when they lose their job or change jobs or a family member falls ill, and so that small businesses can afford to buy health insurance for their workers.
- **Help workers who lose their jobs keep health insurance** by making them eligible for premium subsidies to pay for private insurance coverage for up to six months. This proposal would provide coverage for 3.8 million Americans each year.
- **Level the playing field for the self-employed** by gradually increasing the self-employed tax deduction to 50 percent.

- **Crack down on fraud and abuse** by strengthening the fraud and abuse laws so that we can better prosecute health care fraud in all government programs and private plans, guaranteeing funding to investigate and prosecute fraud in Medicare and Medicaid, increasing penalties so that wrongdoers are punished severely, and better coordinating state and federal anti-fraud activities.

That is why the President has urged Congress to pass the Kassebaum-Kennedy health reform bill immediately. It is reasonable, bipartisan and has the support of business and labor. It will stop insurance companies from denying coverage because someone has a so-called "pre-existing condition." It will ensure that if you lose a job of change jobs you will not lose your health insurance. The General Accounting Office estimates that will help as many as 25 million American workers.

Contact: Jennifer Klein or Chris Jennings
Last Update: March 11, 1996

THE ENVIRONMENT UNDER PRESIDENT CLINTON: AN OVERVIEW

"We must ask more of ourselves, we must expect more of each other, and we must face our challenges together...Our fifth challenge: to leave our environment safe and clean for the next generation...People do have a right to know that their air and their water are safe."

President Clinton
State of the Union Address
January 23, 1996

Overview. During the last generation, we have made great progress in protecting the environment. We now have cleaner, safer air and water. Lead levels in children's blood have been cut 70 percent, and toxic emissions from factories have been cut in half. We must continue to move forward. A third of us still breathe air that endangers our heath, and in too many communities, the water is not safe to drink. President Clinton is committed to stopping attempts to roll back the progress made to provide safe food and water for our families while making the common-sense reforms that provide lasting economic opportunities.

Accomplishments.

- **Community Right to Know**. Issued a "Pollution Disclosure" Executive Order to require industry to disclose information about toxic releases to their neighbors, countering GOP attempts to allow polluters to keep people in the dark.
- **Safe Drinking Water.** Required drinking water systems to test for and eliminate dangerous contaminants, while the GOP Congress moved to block funds to help communities upgrade treatment and keep harmful pollutants out of drinking water.
- **Reinventing Environmental Regulation.** Cutting paperwork by 25% and allowing businesses to throw out the EPA rulebook and write their own if they can do it cleaner and cheaper. Issued an executive order to make health, safety and environmental programs more fair, efficient and effective.
- **Clean Air.** Issued new rule to reduce by 90% the toxic air pollutants released from chemical plants by 1997.
- **Clean Water.** Vowed to veto the lobbyist-written GOP bill to roll back the Clean Water Act that keeps billions of pounds of toxic pollutants and sewage out of our rivers, lakes and streams. Stopped the bill dead in its tracks.
- **Meat Safety.** Issued new standard to prevent E. *coli* contamination in meat, fighting off GOP attempts to block the rule and have fought off misguided "regulatory reform" legislation that would put food safety at risk.

Statistical Backup.

- Cut paperwork requirements by 25%.
- Eliminating 16,000 pages of unnecessary regulations.
- 50 million Americans breath cleaner air.

Agenda. President Clinton will continue to support policies that protect our health and natural resources while continuing to make common sense reforms to environmental programs by:

- Expanding community right-to-know laws and challenging communities to use the information to work with business to cut pollution;
- Challenging Congress to drop proposals to force taxpayers to pickup the tab for environmental cleanup. The President strongly believes the polluters must pay;
- Replacing one-size-fits-all regulations with result focused programs;
- Challenging American businesses to take more initiative in protecting the environment;
- Challenging Congress to re-examine and reverse those policies that would endanger our health and safety by weakening health and safety programs such as safe drinking water and clean air;
- Continuing to work with state and community leaders and businesses to find better ways to protect our natural resources and provide economic opportunities.

Contact: Dan Collins, 197 OEOB, 456-5691
Last Update: February 21, 1996

Due 3/11

ISSUE BRIEF FORMAT

TO: DPC STAFF
PLEASE GET TO JEN KLEIN IN WW AS WELL
RETURN TO JBA

TITLE

Recent quote

Overview:

Narrative description of the President's general view of the issue, the context or challenge of the issue, and his vision.

Accomplishments:

Listing of the Administration's accomplishments on the issue with full description of the purpose and expected results of the legislation/initiative/program.

Statistical Backup:

Listing of numerical facts and figures showing the impact and results of the accomplishments.

Agenda:

Narrative description of additional action the Administration plans to take on the issue.

Contact: Name, location, phone number
Last Update: xx/xx/xx

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

March 8, 1996

NOTE TO: JENNIFER KLINE
CHRIS JENNINGS

Here's the package on accomplishments. I'm sending the same one to both of you and letting you decide how to divide it up.

The core piece of the package contains a summary of major HHS accomplishments in 1995 (minus the section on welfare/child support). This is the best overview we have on the shelf of health related accomplishments. It isn't organized exactly the way either of you outlined, but it is easy to connect the dots (e.g., major pieces of AIDS and immunization sections would come under prevention).

I have supplemented the accomplishments summary with additional materials which either give a fuller description of something highlighted in the summary, relate to something you asked about specifically, or represent an additional accomplishment I thought might be of interest.

If you need to reach me over the weekend you can call me at home (202) 237-8422. I hope this helps.

Claudia
Claudia Cooley

Attachments

p. 3 deleted since it covers welfare

HHS FACT SHEET

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

January, 1996

Contact: HHS Press Office
(202)-690-6343

1995 -- A Year of Progress

In 1995, the impact of the Clinton Administration investments in HHS programs came into sharp focus. Guided by twin goals of a healthier and more independent citizenry, this department has made progress across the board -- with increased coverage and choice in the Medicare and Medicaid programs; higher rates of infant immunizations and lower levels of preventable disease; more and better treatment options for individuals living with AIDS; breakthroughs in breast cancer research; more children enrolled in Head Start programs; increased child support collections; and more people working rather than collecting welfare.

Meanwhile, we continued our drive to improve customer service, tighten management, cut red tape, and eliminate waste, fraud and abuse in all our programs. We have made further progress in reducing drug review times; finalized an innovative system to safeguard seafood safety; and eliminated an entire layer of management staff, folding the Office of the Assistant Secretary for Health into the Office of the Secretary.

Through the above innovations and in countless other ways, the Clinton Administration has been delivering on its mandate: to help people help themselves in pursuing more healthy and independent lives.

Donna E. Shalala
Secretary

A list of HHS accomplishments in five major areas follows:

HEALTH CARE

- State demonstrations flourish, increasing coverage and choice; efforts to eliminate waste, fraud and abuse are stepped-up.

More Choice, More Coverage: This Administration has enacted reforms in Medicare and Medicaid that protect the people we serve while enhancing the quality of care we deliver.

Medicaid: Since President Clinton took office, the Health Care Financing Administration has enabled 12 states to develop comprehensive health care reform demonstration projects through the Medicaid program. Seven of these waiver demonstrations were approved in 1995 alone. By comparison, there were no statewide health care reform projects approved between the years 1988 and 1992. Over 657,000 individuals otherwise not covered under Medicaid have been enrolled in the program under implemented state demonstrations approved by this Administration. With increased flexibility at the federal level, Medicaid beneficiaries are also moving into managed care at a record pace. In 1995, 11.6 million beneficiaries were in managed care, representing a one-year increase of 67 percent. More than 32 percent of all Medicaid beneficiaries have now enrolled in managed care.

Medicare: Because of the Medicare program, elderly Americans live longer and fuller lives without the threat of medical costs throwing them into bankruptcy. The Administration has bolstered this vital protection with an unprecedented menu of medical choices. As a result of reforms in the past three years, most Medicare beneficiaries now have the option to enroll in a managed-care plan. And seniors are embracing the new options. Since the beginning of 1993, there has been a greater than 66 percent increase in Medicare beneficiaries choosing managed care. As of December 1995, more than 3.8 million people, or 10 percent of Medicare beneficiaries, have voluntarily enrolled in managed care. As we work together to balance the federal budget, we will continue to protect and improve the Medicare program.

Study of Managed Care: As the public health programs explore managed care options, the Department continues to ensure that such care provides essential protections for beneficiaries. Dr. Philip R. Lee, Assistant Secretary for Health, and Dr. Bruce Vladeck, Administrator, Health Care Financing Administration, are co-chairing an "HHS Managed Care Forum" to focus the Department's extensive efforts at measuring and analyzing the effects of this important development in health care delivery.

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Efforts to Combat Fraud and Abuse: In 1995, the Administration launched "Operation Restore Trust," a new effort to combat health care fraud, waste and abuse in the five states with the highest Medicare and Medicaid expenditures. In partnership with the Department of Justice and state governments, HHS is coordinating an interdisciplinary strategy to stem fraud in California, Florida, New York, Texas and Florida. These interdisciplinary teams are focusing on three of the fastest growing areas of health expenditures -- home health care, nursing home care and durable medical equipment.

These investments in program integrity are paying dividends. In the last three years, anti-fraud and abuse efforts have saved almost $15 billion in Medicare and Medicaid costs. An agreement with the Los Alamos National Laboratories to use our nation's most powerful computer systems will keep our anti-fraud efforts on the cutting edge of technology.

Nursing Home Reform: Roughly 68 percent of nursing home residents rely on Medicaid and they are among the most vulnerable of Medicaid beneficiaries. On July 1, 1995, HHS implemented the last major phase of a longstanding bipartisan agreement to assure quality care in America's nursing homes. A flexible system is now in place to enforce uniform quality standards while giving state and federal officials a choice of remedies, depending on the seriousness of the situation. The enforcement system shows the standards are working: only 7 to 10 percent of homes surveyed are expected to be ultimately sanctioned for violations.

Proposal to Reduce Teen Smoking: In 1995, the Clinton Administration proposed a coordinated plan to reduce smoking among children and adolescents by 50 percent. It builds on previous actions taken by Congress and follows recommendations by the American Medical Association and the Institute of Medicine. In part, the proposals reduce easy access by children through requirements for age verification and face-to-face sale and reduce appeal to children through bans on outdoor advertising within 1,000 feet of schools and playgrounds.

IMMUNIZATIONS

- In 1995, vaccine-preventable diseases in the United States fell to an all-time low while immunization rates reached an all-time high.

Childhood Immunization Initiative: In 1995, the United States reported the highest levels of immunizations among pre-school children in history. Approximately 75 percent of two-year old children were fully immunized -- up from 50 percent or lower in most communities during the 1989-91 measles outbreak. Public service announcements and national conferences bolstered the effort.

Measles: As of December 31, 1995, the U.S. recorded just 288 cases of measles in 1995, compared with 963 cases in all of 1994. Measles can cause pneumonia, brain inflammation, diarrhea and even death. States have also reported that cases of other vaccine-preventable diseases were at or near all-time low levels in 1995.

Flu Shots for the Elderly: A flu shot is prevention that works, and since 1993, the Clinton Administration has covered flu shots under the Medicare program. In 1994, more than 10.9 million people received a flu shot through Medicare, up from 9.8 million in 1993. According to methodology from a HCFA study, the additional 1.1 million beneficiaries receiving the shot translates into roughly 5,000 avoided hospital admissions and $25 million in savings to beneficiaries and the Medicare program.

Chicken-pox vaccine: The Food and Drug Administration approved the first vaccine to prevent chicken pox in 1995.

Polio: The World Health Organization reports that it is on track to reach its goal of worldwide eradication of polio by the year 2000. Worldwide, reported polio cases fell to 7,524 in 1994 from 10,505 in 1993. Polio has been eliminated in North America and the Western Hemisphere has been declared officially free of this devastating illness. Upon worldwide eradication, the U.S. will be able to save $200 million spent annually for polio vaccine and its administration.

AIDS

- Patients live longer as treatment options increase; new prevention campaign launched; President hosts White House conference.

New treatments: When the Clinton Administration took office, we had only one anti-viral drug for the treatment of HIV/AIDS. We now have six such drugs licensed by the Food and Drug Administration -- including the first of a promising new class of drugs called protease inhibitors. Saquinovir, the first protease inhibitor approved by the FDA, was given the green light in a record 97 days after the manufacturer submitted the application. This is the most potent drug yet to stall the spread of HIV, the virus that causes AIDS. We have also moved rapidly to stem transmission of the HIV virus to babies by promoting voluntary testing and treatment with zidovudine (AZT) among pregnant women who are infected.

see 3/1/96 for update on new inhibitor approval

Prevention: In December, HHS launched a new public service announcement campaign, titled "Respect Yourself, Protect Yourself." Featuring young adults speaking candidly to young adults, the campaign has already more than paid for itself in free television time.

Funding: This Administration has made AIDS programs a top investment priority. In his three budgets submitted to Congress, President Clinton has increased total government funding for AIDS research, prevention and treatment by 37 percent.

Leadership: In December, President Clinton hosted the first White House Conference on HIV/AIDS. He also named a Presidential Advisory Council on HIV and AIDS to provide him and his Administration with expert outside advice on developing effective responses to the HIV/AIDS epidemic. This council will provide recommendations to the Office of National AIDS Policy, which brings a central focus to the federal government's efforts on the issue.

BREAST CANCER

- Research funds rise; new breast cancer genes found; death rates fall; public service announcement campaign launched.

Federal Breast Cancer Research Funding Increased: Funding for breast cancer research and programs at NIH totaled $377 million in 1995, up from just $88 million in 1990.

New Breast Cancer Genes Isolated: Building on the breakthrough discovery in late 1994 of a breast-cancer susceptibility gene (BRCA 1), researchers in 1995 identified two additional genes that are associated with increased risk of the disease. Genetic links were found to be especially prevalent among Jewish women of eastern European descent. And in early 1996, two studies indicate that the younger women are when they get breast cancer, the more likely that the cancer is related to problems with an identified gene. These findings hold promise for the development of new research and treatment strategies.

Death Rates Fall: The National Cancer Institute reported in 1995 that death rates from breast cancer decreased an average of 5 percent from 1989 to 1992. The decreases were most pronounced among younger women and caucasians. These data suggest the value of early detection and treatment, and the need for further outreach to older women and minorities.

Record Inspections of Mammography Facilities: To ensure the safety and effectiveness of the mammograms women receive, the Food and Drug Administration continues its inspection and certification of all new and existing mammography facilities. Since October, 1994, FDA has certified 10,200 such facilities in the United States -- nearly every facility nationwide.

Early Detection Program for Breast and Cervical Cancer: In partnership with 35 states and 9 tribal organizations, the Centers for Disease Control and Prevention offer free or low-cost mammography screening to women in need. Over 700,000 women have been screened through the program, which will ultimately be available in all states and U.S. territories.

Outreach -- "Mammogram: It's a picture that can save your life": On Mother's Day, 1995, First Lady Hillary Rodham Clinton, the Health Care Financing Administration and the Office on Women's Health began a campaign to educate women over 65 that mammograms save lives. The campaign continues this year with public service announcements by Mrs. Clinton and the President, whose mother died of breast cancer.

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HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOR IMMEDIATE RELEASE
Thursday, Nov. 9, 1995

Contact: FDA Press Office
(301) 443-3285

REINVENTING REGULATION OF DRUGS MADE FROM BIOTECHNOLOGY

The Food and Drug Administration today is proposing several measures that will reduce costs for manufacturers of biotechnology derived pharmaceuticals, increase the agency's efficiency and continue to protect the public health. The six proposals -- which constitute FDA's most significant overhaul of biotech regulations to date -- complement and build on the drug and medical device reforms announced last spring as part of the Clinton Administration's National Performance Review.

"Biotechnology holds great promise for American patients. These reforms will help industry deliver on those promises while maintaining the Food and Drug Administration's critical role in protecting the American people," said Vice President Gore.

The Vice President also announced the release of a report by the National Science and Technology Council, "Biotechnology for the 21st Century: New Horizons," which describes the federal investment in biotechnology and identifies research priorities and opportunities for the future.

Two of the most far-reaching FDA modifications apply to well-characterized, therapeutic biotechnology-derived drugs, a product category that includes most biotech drugs.

The United States biotech drug industry has estimated that the proposed changes will cut drug development time by months, reduce

the required paperwork by thousands of pages, and save the companies millions of dollars. None of the proposed changes will diminish the safety and effectiveness of the industry's products.

The proposals include the following changes:

* Elimination of establishment license application (ELA) for well-characterized therapeutic biotech drugs.

Impact: Firms developing and manufacturing these products will be spared the cost of preparing ELAs, some of which may be lengthy and elaborate. FDA will save review time.

* Elimination of FDA's lot-by-lot release for well-characterized therapeutic biologic drugs that are licensed for marketing.

Impact: Significant savings of time and resources for the industry. The agency will monitor companies' compliance with the requirement that they release only lots that have been tested and found to be acceptable.

* Consolidation of 21 different approval application forms into a single, user-friendly format.

Impact: Manufacturers should save time and be able to prepare higher quality submissions. The agency should be able to expedite the application review and use the standard format as a basis for electronic submissions.

* Elimination of the need for approval of promotional labeling before launching a new product.

Impact: Industry will no longer need to wait for FDA's approval of promotional labeling before disseminating it, and FDA will save resources for other activities.

* FDA commitment to review and respond within 30 days to information submitted in response to a clinical hold on a study of an investigational drug or biologic.

Impact: The measure will prevent unnecessary delays of the clinical trials because the agency's failure to respond within the time limit will automatically terminate the hold, and the investigation will be able to proceed.

* Revision of the manufacturers' requirements to appoint a "responsible head" for compliance and official contacts with FDA.

Impact: Firms will be able to divide management responsibility among appropriate regulatory, medical or manufacturing staff. These individuals will be able to communicate directly with the agency on official matters related to their company's biological products.

The U.S. biotech industry comprises about 1,300 mostly small-to-medium-size companies, which explore new approaches to the diagnosis, prevention, treatment and cure of life-threatening and seriously debilitating diseases.

The industry has developed all of the two dozen biotech drugs on the U.S. market today, and exports about $1 billion worth of these products each year. More than 450 biotech drugs are being tested by U.S. biotech companies in humans for diseases for which there are no satisfactory therapies, such as cancer, AIDS, and arthritis.

Recognized as the world's leader in its field, the U.S. biotech industry employs more than 100,000 skilled workers, and last year invested $8 billion in research and development.

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NOTE: We expect to issue this soon, but exact date not certain as yet.

DRAFT #38

P96-
FOR IMMEDIATE RELEASE
Date

Food and Drug Administration
Sharon Snider (301) 443-3285
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FDA TO TEST THIRD PARTY REVIEW OF MEDICAL DEVICE APPLICATIONS

The Food and Drug Administration today announced a pilot program to use third parties to review marketing applications for certain medical devices.

The program will test whether using third parties to help review some of FDA's 17,000 medical device applications each year will hasten the review process and get products to patients sooner.

The pilot program is one of the drug and medical device reforms resulting from the Clinton Administration's National Performance Review.

"FDA's highest priority is to get safe and effective medical devices to patients who need them, as quickly as possible," said FDA Commissioner David A. Kessler, M.D. "The pilot program will demonstrate whether the process can be speeded up, without compromising the public health."

Third party review will be used for low and moderate risk devices for which FDA does not require clinical data on safety and effectiveness -- products such as electronic thermometers, surgical gloves and menstrual pads. FDA receives about 1,500 applications a year for these types of products. Manufacturers are required to show in premarket notification (510k) applications that products

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DRAFT #38

are comparable in safety and effectiveness to a product already legally marketed.

High risk devices, such as artificial heart valves, artificial hips, and implanted pacemakers, will not be included in the third party review program. FDA will continue a full review of applications for these devices.

Participation in the pilot program is voluntary. Firms can choose to have their applications reviewed by a third party or continue to have them reviewed entirely by FDA.

If third party review is chosen, the manufacturer selects an FDA-recognized third party reviewer and submits its marketing application to that party for review. When the review is completed, the third party reviewer submits the application, the results of its review, and its recommendation to FDA. The application will bypass the first phase of FDA's normal review process and instead go directly to an FDA supervisor for a final assessment. An agency decision will be made within 30 days -- much quicker than the 90 days normally required for review.

Third party reviewers must be impartial, independent and recognized by FDA as fully qualified to assess the comparability of the new product to a legally marketed one. Third party reviewers will be trained by FDA on how to properly review 510(k) applications and must meet strict conflict-of-interest criteria.

FDA will monitor the pilot program closely and will make any necessary changes to protect the public health.

The pilot program will begin (date) and run for two years.

FDA will accept applications for recognition as third party

DRAFT #38

reviewers through (date). An information session for prospective third party reviewers will be held (date) to clarify the criteria by which third parties will be evaluated.

Details of the pilot program are published in today's Federal Register.

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Drug Approvals - Reduction in processing times,

THE FOOD AND DRUG ADMINISTRATION IN 1996

MEETING AND EXCEEDING THE PRESCRIPTION DRUG USER FEE PERFORMANCE GOALS

According to the General Accounting Office (GAO), the average approval time for new drug applications (NDA) submitted to the Agency in 1987 was 33 months. For NDAs submitted in 1992 the time had been reduced to 19 months. These improved approval times have been made possible by shortening the time for completion of most first reviews to only 12 months. How did we do it? Congress, the Agency, and the pharmaceutical industry recognized that additional resources were one key to improving FDA's review of drugs and biologicals, and Congress enacted the Prescription Drugs User Fee Act of 1992 (PDUFA). The Agency, in turn, committed to very aggressive performance standards, with higher hurdles in each succeeding year until full implementation in fiscal year 1997. These performance standards were negotiated with and agreed to by the pharmaceutical and biotech industries.

We already have achieved one of the major 1997 performance goals. We achieved it in fiscal year 1994 -- a full three years ahead of schedule. For the drugs submitted to FDA in fiscal year 1994, we reviewed and acted upon 96 percent of them on time. In most cases, that meant first action within 12 months.[1]

This improved performance has been validated by GAO. At the request of this Committee, GAO looked at how FDA was performing even before PDUFA was enacted. GAO found that review and approval times for new drugs have been reduced dramatically. In addition GAO found that by 1994, FDA review and approval times were faster than those in the United Kingdom -- a country many critics like to cite as a way of doing things better and faster.

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[1] If a major amendment is submitted by the manufacturer late in the process, an additional three months is granted.

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HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

P96-4
FOR IMMEDIATE RELEASE
March 1, 1996

Food and Drug Administration
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FDA APPROVES SECOND PROTEASE INHIBITOR TO TREAT HIV

The Food and Drug Administration today approved the second in a new class of AIDS drugs called protease inhibitors. Ritonavir, the new drug, received full approval for use alone or in combination with nucleoside analogue medications, such as AZT, in people with advanced HIV disease. Ritonavir also received accelerated approval for less advanced HIV disease. FDA approved the drug about two months after receiving its application for its marketing.

"Even as we celebrate this milestone, we must recommit ourselves to President Clinton's goal of finding a cure," said HHS Secretary Donna E. Shalala. "We must also face the new challenge of providing life-prolonging medications to all who need them."

"The review of ritonavir is the fastest approval of any AIDS drug so far -- 72 days," said Commissioner of Food and Drugs David A. Kessler, MD. "This drug provides real hope for patients with AIDS. Patients will live longer."

FDA based its approval for ritonavir on data showing that the drug not only improves laboratory markers, such as CD4 counts and viral load, but that it can reduce disease progression and mortality in people with advanced HIV disease.

Both protease inhibitors and nucleoside analogues chemically inhibit HIV development, although at different points in the

- More -

replication process. FDA approved the first nucleoside analogue, AZT, in 1987 and the first protease inhibitor, saquinavir, in December 1995.

In clinical studies, ritonavir was studied alone and in combination with nucleoside analogues in HIV-infected people in various stages of disease. Each of these trials monitored changes in participants' CD4 cell counts, an indication of immune system strength and viral load, a measure of the amount of virus that can be detected in the bloodstream.

The largest of the studies also examined mortality rates in advanced HIV patients. The cumulative mortality rate among ritonavir participants was approximately 40 percent of that seen in the placebo-controlled participants, and ritonavir participants also experienced a 50 percent greater reduction in disease progression during the six months of the study.

Another study compared patient groups on ritonavir alone, ritonavir in combination with AZT, and AZT alone. Those in the groups taking ritonavir experienced a marked increase in their CD4 cell counts and a significant decrease in their viral load.

A third noncomparative study assigned 32 HIV-infected individuals to receive a triple combination of ritonavir plus AZT and ddc. Again, the results showed marked increases in CD4 counts and significant decreases in viral load.

For patients with less advanced HIV disease, none of these studies included clinical endpoints. Accelerated approval for ritonavir in this patient population requires that longer-term data be collected.

Accelerated approval is a regulatory mechanism under which FDA bases early marketing approval for a product on laboratory markers such as CD4 cell counts until information about clinical endpoints such as disease progression or mortality is available.

Adverse events associated with ritonavir treatment included diarrhea, nausea, vomiting, weakness, tingling, liver inflammation, elevation of lipid levels and taste disturbance. FDA has worked with the drug manufacturer to assure that potentially severe drug interactions with ritonavir are clearly highlighted in the package label and that patient education materials are made available to patients.

Abbott Laboratories is marketing ritonavir under the trade name Norvir.

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Reduction in CFR Pages – Health
(note: nothing to brag about.

The June reports projected that:

- FDA would eliminate 941 CFR pages; as of 2/29/96, the actual figure eliminated was 163
- FDA would reinvent 1170 pages; as of 2/29/96, the actual total eliminated was 242

The June reports projected that:

- HCFA would eliminate 397 CFR pages; as of 2/29/96, the actual figure eliminated was 37
- HCFA would reinvent 525 CFR pages; as of 2/29/96, the actual figure reinvented was 178

Operation Restore Trust
(Initiative on Health Care Fraud)

Last year, the President announced a two-year partnership of Federal and State agencies working together to prevent and detect health care fraud in specific industries. Operation Restore Trust targets five States which together account for 40 percent of the nation's Medicare and Medicaid beneficiaries. The project uses the shared resources of the U.S. Department of Health and Human Services as well as State and local resources to address fraud, waste and abuse in three rapidly growing sectors of the health care industry: home health agencies, nursing facilities and durable medical equipment suppliers.

The project is now one year old. Already we have accomplished much. New and innovative projects are underway to identify fraud, waste and abuse, from the use of new computer technology and data gathering techniques, to personal contact with beneficiaries during the course of provider audits, to the use of state surveyors and long term care ombudsmen in the fight against fraud. We have over 250 active investigations of fraud underway. Since the beginning of ORT, in the areas targeted, we have obtained 30 convictions, 12 indictments, 10 civil judgements and 36 exclusions. These actions resulted in $2.2 million in program savings and $34.9 million in fines, recoveries, settlements and civil money penalties. In addition, we have undertaken scores of audits of providers to determine if payments were properly made, and have identified millions of dollars in potential overpayments.

We expect that at the conclusion of this project we will find that our investment in the detection and pursuit of fraud, waste and abuse is returned many times over in recoveries, fines, penalties, and savings to the Medicare trust fund.

HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOR IMMEDIATE RELEASE
Wednesday, Sept. 6, 1995

Contact: HHS Press Office
(202) 690-6343

HHS WILL ABOLISH MORE THAN 1,000 PAGES OF UNNECESSARY REGULATION

HHS Secretary Donna E. Shalala will propose the elimination of more than 1,000 pages of rules under the jurisdiction of the Department, furthering efforts to reduce the regulatory burden on HHS' partners and beneficiaries. The Secretary will also propose the elimination of an additional 700 pages that would take effect with congressional approval. Taken together, these proposals represent close to a 25 percent reduction in the total pages of the Department's published regulations.

As a down payment on these commitments, the Department has already eliminated more than 300 pages of regulations under the authority of the Administration for Children and Families. HHS will also revise an additional 2,200 pages of regulation. All told, more than half of HHS' 6900 pages in the *Code of Federal Regulations* will be targeted for elimination or revision.

"We're putting outdated regulations out-of-print," Secretary Shalala said. "This is another step in our continuing drive to eliminate unnecessary regulations while maintaining the critical public health standards that Americans expect."

These proposals represent another step in the Department's efforts to institute real and lasting regulatory reform. Taken together, these ongoing efforts are intended to reduce regulatory

burden and promote consensus building with HHS' partners. [Fact sheets on further reinvention efforts are available.]

FDA will propose to eliminate 941 pages of regulation that it has determined are obsolete or no longer achieve public health goals (735 pages require congressional approval). In addition, FDA plans to revise or modify an additional 1,170 pages of regulation to ease the burden on regulated industries and consumers without sacrificing public health protection. HCFA will propose to eliminate 397 pages and revise an additional 525 pages.

In addition to the results of the page-by-page review released today, Shalala spotlighted additional examples of cooperation and coordination with the Department's beneficiaries and partners. In creating a government that works better and costs less, HHS has:

-- Eliminated reporting requirements when unnecessary.

Example: HCFA will no longer require the "attestation statements" that physicians had to sign before hospitals could submit claims for payment by Medicare. These statements will be officially abolished on October 1, 1995. Ending this requirement will eliminate 11 million forms a year, saving almost 200,000 hours of physician time and decreasing hospital administrative costs by approximately $22,500 per hospital annually.

-- Promoted smart regulation that can lead to cost savings.

Example: Before a regulation issued in July by the National Institute for Occupational Safety and Health (NIOSH), the only respirator that met criteria for the prevention of tuberculosis cost the purchaser approximately $8.00. Working closely with the industry, NIOSH developed a revised regulation that provides better protection for workers and increased savings for industry. The first respirators certified under this revised regulation range in price from about $1 to $3, according to the manufacturers' data.

-- Proposed grassroots partnerships that give states enhanced flexibility to direct federal money.

Example: As part of HHS' budget request in May, we proposed a new basis for relationships with the states: performance partnerships. The Administration has proposed consolidating more than 100 separate health programs into 6 new partnership grants and 11 consolidated grants. These will offer states greater flexibility in setting priorities and managing their programs.

"Taken together, these regulatory reforms improve services to our customers, strengthen our partnerships with states and local governments and make better use of the public's dollars," Shalala said.

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HHS FACT SHEET

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOR IMMEDIATE RELEASE
Wednesday, Sept.6, 1995

Contact: HHS Press Office
(202) 690-6343
FDA Press Office
(301) 443-1130

REINVENTING DRUG AND MEDICAL DEVICE REGULATION

Introduction

The high standards of the Food and Drug Administration (FDA) have given Americans access to drugs and medical devices that are safe and effective. The Clinton Administration is building on these high standards with efforts to speed up drug and device approval through regulatory reforms. Some of these reforms will directly expedite the review process. Others will reduce unnecessary regulatory burdens on industry. All will maintain and protect Americans' confidence in the safety and effectiveness of the drugs they take and the medical devices they use.

FDA has already reformed drug and medical device regulation by:

-- Pre-Approval: Making guidance available to manufacturers of drugs and biologics (products made from biological materials) that markedly reduces the number of changes in manufacturing that must be pre-approved by FDA if the risk is negligible.

Impact: Industry can modernize facilities and processes more easily; FDA can shift resources to more critical review needs.

-- Pilot Facilities: Clarifying that manufacturers of biological drugs may use pilot and small-scale facilities to demonstrate the safety and effectiveness of their products.

Impact: Manufacturers will have lower start-up costs and can more quickly begin production of new drugs.

-- No Reference List: Eliminating the "reference list" and clarifying that premarket review of medical devices can be affected only if good manufacturing practice (GMP) violations are related to a specific device.

Impact: Industry concerns that GMP for one product can slow down approval for other devices unrelated to those problems will be alleviated.

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-- Effectiveness Standard: Clarifying the effectiveness standard for new drugs.

Impact: Industry will have a better understanding of how to develop new products, reducing the time it takes to bring a drug to FDA for review.

FDA plans to further reform drug and device regulation by:

-- Permitting greater flexibility in how distributors' names appear on biological product containers, package labels and labeling.

Impact: Small start-up companies, many of them biotechnology firms, may more readily enter into manufacturing arrangements with larger companies and bring products to market quicker.

-- Eliminating special requirements for manufacturing insulin and antibiotic drugs.

Impact: Industry will no longer be burdened with outdated requirements and FDA can regulate these products the same way it does other drugs.

-- Excluding drug and biologics manufacturers from requirements for most environmental assessments.

Impact: Industry will be spared the expense of preparing assessments that FDA has found unnecessary.

-- Developing a pilot program for the review of low to moderate risk medical devices by outside organizations.

Impact: This program will help determine if such a system can speed the review of these devices, maintain the independence of the review process and save money.

-- Speeding the marketing of medical devices by charging industry user fees to give FDA more resources for product reviews and committing FDA to strict performance goals.

Impact: A similar program for prescription drugs has substantially reduced review times.

-- Expanding the opportunities for the export of unapproved drugs and medical devices to industrialized countries.

Impact: Industry will have wider markets for its products and will be encouraged to maintain operations in this country.

In the coming months, the agency will propose further reforms in the drug and device area in addition to reforms in the areas of human food products, animal drugs and medicated animal feeds.

This is still current as of 3/8.

HHS FACT SHEET

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

January 1996

Contact: HCFA Press Office
(202) 690-6145

STATE MEDICAID DEMONSTRATIONS

Section 1115 of the Social Security Act provides the Secretary of Health and Human Services broad discretion to waive certain laws pertaining to Medicaid, in order to conduct experimental, pilot or demonstration projects. This allows states, and the federal government, to pursue Medicaid projects which test new and innovative ideas relating to benefits and services, eligibility requirements and processes, program payment, and service delivery.

These demonstrations are frequently aimed at serving more low-income and uninsured people while saving money through new program efficiencies.

HHS is fully committed to assisting states in using this waiver authority to test well designed and creative approaches to health care. Significant strides have been made to make the waiver review process more efficient and straightforward, and HHS continues to seek improvement.

- ***Since January 1993, HHS has approved 12 comprehensive health care reform demonstration projects, and the framework of one additional demonstration.***

- ***In addition, 14 states have received Medicaid waivers since January 1993, as part of larger welfare reform projects. These complementary Medicaid waivers enable states to continue providing essential health care services while encouraging independence from welfare.***

- ***Finally, 24 sub-state Medicaid demonstration projects have been approved affecting smaller components of state Medicaid programs.***

In the years 1988-1992, no statewide health care reform projects were approved, four states received welfare-related Medicaid waivers, and 16 sub-state demonstrations were granted. Demonstrations are monitored by HHS' Health Care Financing Administration.

HHS FACT SHEET

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

February 1996

Contact: HCFA Press Office
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MANAGED CARE IN MEDICARE AND MEDICAID

Overview: Since 1993, the number of Medicare and Medicaid beneficiaries enrolled in managed care plans has experienced unprecedented growth. As a result, the Health Care Financing Administration (HCFA), which administers these two programs, is the largest purchaser of managed care in the country, accounting for 15.5 million Americans. The Clinton Administration has worked in close partnership with the states to provide maximum flexibility through the waiver of Federal rules to expand the availability of managed care plans to Medicaid beneficiaries. The Administration has also worked to expand choices for Medicare beneficiaries and to ensure that all beneficiaries enrolled in managed care receive quality care.

As part of his seven-year balanced budget proposal, President Clinton would further expand the availability of managed care to Medicare and Medicaid beneficiaries by increasing the number of Medicare options available and providing states with additional flexibility to enroll Medicaid beneficiaries in such plans without requesting a waiver of federal Medicaid rules.

Medicare

As of Feb. 1, 1996, almost 4 million Medicare beneficiaries were enrolled in managed care plans, accounting for more than 10 percent of the total Medicare population. That represents a 67 percent increase in managed care enrollment since 1993. In 1995, an average of 68,000 Medicare beneficiaries voluntarily enrolled in risk-bearing HMOs each month. Medicare beneficiaries can enroll or disenroll in a managed care plan at any time and for any reason with only 30 days notice.

Managed care plans can serve Medicare beneficiaries through three types of contracts: risk, cost, and health care prepayment plans (HCPPs). All plans receive a monthly payment from the Medicare program.

- **Risk plans** are paid a per capita premium set at approximately 95 percent of the projected average expenses for fee-for-service beneficiaries in a given county. Risk plans assume full financial risk for all care provided to Medicare beneficiaries. Risk plans must provide all Medicare-covered services, and most plans offer additional services, such as prescription drugs and eyeglasses.

With the exception of emergency and out-of-area urgent care, members of risk plans must receive all of their care through the plan. However, as of January 1, 1996, risk plans can provide an out-of-network option that, subject to certain conditions, allows beneficiaries to go to providers who are not part of the plan. Since Jan. 1, 1993, enrollment in risk plans has grown 105 percent. Currently, 81.6 percent of Medicare beneficiaries in managed care are in risk plans. As of Feb. 1, 1996, risk plans made up 194 of the 278 managed care plans participating in Medicare.

- **Cost plans** are paid a pre-determined monthly amount per beneficiary based on a total estimated budget. Adjustments to that payment are made at the end of the year for any variations from the budget. Cost plans must provide all Medicare-covered services but do not provide the additional services that some risk plans offer. Beneficiaries can also obtain Medicare-covered services outside the plan without limitation. When a beneficiary goes outside the plan, Medicare pays its traditional share of those costs and the beneficiary pays Medicare's coinsurance and deductibles.

- **Health Care Prepayment Plans (HCPPs)** are paid in a similar manner as cost plans but only cover part of the Medicare benefit package. HCPPs do not cover Medicare Part A services (inpatient hospital care, skilled nursing, hospice, and some home health care) but some do arrange for services and may file Part A claims for their members.

Nationally, 74 percent of beneficiaries have a choice of at least one managed care plan while 56 percent of beneficiaries have a choice of two or more plans. Medicare managed care enrollment varies greatly depending on geographic location. The majority of beneficiaries enrolled in such plans live in California, Florida, Oregon, New York, Arizona, and Hawaii.

HCFA recently launched "Medicare Choices," a demonstration project designed to allow beneficiaries to join a greater variety of managed care plans, including provider sponsored organizations (PSOs) and preferred provider organizations (PPOs). This project will also experiment with alternative payment methods such as partial capitation, risk adjustment, and competitive bidding. Another goal of this project is to increase access to Medicare managed care organizations in rural communities.

Medicaid

The growth in Medicaid managed care enrollment has been even greater than that experienced in Medicare. Since Jan. 1, 1993, enrollment in Medicaid managed care plans has increased 140 percent, including a 51 percent increase in 1995 alone. As of June 30, 1995, 11.6 million Medicaid beneficiaries were enrolled in managed care plans, representing 32 percent of total beneficiaries.

Currently, 49 states offer some form of managed care. Since 1993, states have utilized federal Medicaid waivers to increase enrollment in managed care and to develop other innovative changes to their Medicaid programs. Several states have used the resulting savings from managed care enrollment to expand the number of individuals covered by Medicaid and/or the number of services covered under their programs.

The federal government grants two kinds of Medicaid waivers: Section 1915(b) "freedom of choice" waivers and Section 1115 demonstrations. Freedom of Choice waivers permit states to require beneficiaries to enroll in managed care plans. To receive such a waiver, states must prove that these plans have the capacity to serve Medicaid beneficiaries who will be enrolled in the plan. States often use Freedom of Choice waivers to establish primary care case management programs and other forms of managed care. In 1995 alone, HCFA approved 58 Freedom of Choice waivers.

Section 1115 demonstrations allow states to test new approaches to benefits, services, eligibility, program payments, and service delivery, often on a statewide basis. These approaches are frequently aimed at saving money to allow states to extend Medicaid coverage to additional low-income and uninsured people. Since January 1, 1993, comprehensive health care reform demonstration waivers have been approved for 12 states and eight have already been implemented. When all 12 are implemented, 2.2 million previously uninsured individuals are expected to receive health coverage.

Quality

As the number of beneficiaries enrolled in managed care plans has increased, the Clinton Administration has been working closely with states, insurers, health care professionals, and consumers to assure the quality of care provided in that setting. Several initiatives are already underway. For example:

Medicaid Health Plan Employer Data Information Set (HEDIS) was developed in partnership with the National Committee for Quality Assurance (NCQA) to provide states, managed care plans, health care professionals, and consumers with the information and tools they need to assure high quality in managed care plans serving Medicaid beneficiaries. Medicaid HEDIS is an adaptation of the commercial sector's HMO performance measurement system used by more than 300 private plans.

Medicaid HEDIS will provide states with information on the performance of their Medicaid managed care contractors, assist managed care plans in quality improvement efforts, support efforts to inform Medicaid beneficiaries about managed care plan performance, and promote standardization of managed care plan reporting across the public and private sectors. Medicaid HEDIS was released to the states in February 1996.

Medicare HEDIS is a parallel effort in partnership with the Kaiser Family Foundation to establish a proven performance measurement system that will minimize reporting burdens on managed care plans serving Medicare beneficiaries. The new measures will help plans to improve the quality of their care and support efforts to improve the health status of beneficiaries. Medicare HEDIS is expected to be implemented in the beginning of 1997.

Foundation for Accountability (FAcct) is a collaboration of private and public health care purchasers (including HCFA) and consumer groups working to develop outcomes measures that will allow comparison of the quality of care delivered in managed care settings to that provided in fee-for-service settings. Information will be released later this year.

Quality Assurance Reform Initiative (QARI) is a collaborative effort of HCFA, states, the managed care industry, consumer advocates and others to design practical and credible approaches to monitoring and improving the quality of Medicaid managed care services. In July 1993, QARI issued *A Health Care Quality Improvement System for Managed Care*, providing states with a broad range of Federally-recommended guidelines for building and operating quality assurance and improvement systems. These guidelines were tested in three states in 1993-95 by the Kaiser Family Foundation and the results were issued in 1995 through the National Academy for State Health Policy's *Quality Improvement Primer for Medicaid Managed Care*. In 1995, QARI published *Health Care Quality Improvement Studies in Managed Care*, in partnership with the National Center for Quality Assurance (NCQA).

Medicare Managed Care Quality Improvement Project is being conducted in partnership with the Delmarva Foundation for Medical Care to develop performance measures as part of the strategy to overhaul external peer review of HMO contractors and promote quality improvement in Medicare managed care. Preliminary results are expected in Spring 1996.

HHS Interagency Managed Care Forum is chaired by HCFA Administrator Bruce C. Vladeck and Assistant Secretary for Health Philip R. Lee, M.D., and is made up of representatives from operating and staff divisions of the Department of Health and Human Service. The forum meets regularly to share information concerning ongoing managed care activities and to coordinate managed care policy on cross-cutting issues before the Department. Managed care quality is a top priority for this group.

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HHS FACT SHEET

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOR IMMEDIATE RELEASE
Wednesday, Sept. 6, 1995

Contact: HHS Press Office
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REINVENTING HEALTH CARE REGULATION

Introduction

The Health Care Financing Administration (HCFA) serves nearly 37 million Medicare beneficiaries and, in partnership with state governments, another 36 million Medicaid beneficiaries. HCFA ensures program beneficiaries are aware of the services for which they are eligible and that those services are accessible, meet quality standards and are delivered in an efficient manner. HCFA also ensures that health care providers meet approved standards and program funds are used effectively.

Regulatory Reform Initiatives

The following are the major HCFA initiatives and proposals in the regulatory reform process. Some result directly from collaborative efforts and public consultation with industry groups, beneficiary organizations, state associations and state agencies. All proposals cut red tape and demonstrate HCFA's customer-focus and responsiveness to the changing needs of its customers and partners.

1. **Physician Attestation:** HCFA is eliminating the physician form required to certify the accuracy of all diagnosis and procedures before submission for payment by Medicare. These statements will be officially abolished on October 1, 1995. Ending this requirement eliminates 11 million forms a year, saving almost 200,000 hours of physician time and decreasing hospital administrative costs by approximately $22,500 per hospital annually.

2. **Physician Acknowledgment:** HCFA has replaced the requirement for physicians to provide hospitals annually with a signed acknowledgment concerning penalties for misrepresenting certain information with a one-time signing requirement at the time a physician is initially granted hospital admitting privileges. One major medical association said this change will alleviate the "hassle factor" for physicians and marks an important step toward restoring mutual trust between the federal government and the medical industry.

3. **Medicaid Home and Community-Based Services Waivers:** HCFA has simplified the process of obtaining Medicaid home and community-based waivers. States now may offer a wide variety of home and community-based services as cost-effective alternatives to more expensive institutional care. Without this regulatory change, joint state and federal efforts to expand cost-effective options would have been frustrated.

4. **Modify Annual Resident Review Requirements:** Currently, states must perform annual assessments of Medicaid nursing home residents with mental illness or mental retardation. This duplicates the requirement for Medicare- and Medicaid-certified nursing homes to assess their residents promptly after admission, after a significant change in condition, and no less often than annually. Under a legislative proposal, the duplicative requirement for annual state reviews would be eliminated, reducing costly duplication and improving health care outcomes for residents. The assessments conducted by the nursing homes ensure that residents' continuing needs are properly evaluated and met.

5. **Clinical Laboratory Improvement Amendments:** Improve the CLIA system and reduce regulatory burden by rewarding good laboratory performance. This will help create incentives for manufacturers to develop more reliable testing equipment; allow private organizations under certain criteria to accredit laboratories; and use proficiency testing as an outcome measure to monitor laboratory performance. A flexible, targeted survey system to reduce information requirements and streamlined inspection process has been initiated.

6. **Outcome Performance Measures:** Change focus of regulations to measures of outcomes of care rather than measures of process requirements. Changes will eliminate unnecessary process requirements and instead develop outcome-based performance standards; collect and analyze patient care data needed for continuous quality improvement; increase consistency of requirements across providers; and ask the customer to provide input on what the outcome measures should be.

Changes involve:

- Home Health Agency Conditions of Participation
- Medicare Hospital Conditions of Participation
- ESRD Facility Conditions of Coverage

##

NIH Science Advances

Prepared for the FY97 OMB Request

September 1995

The Benefits of Biomedical Research

The NIH record of performance and the number of truly outstanding scientific opportunities provides assurance that current and future investment in NIH biomedical and behavioral science will result in sustain progress in our fight against human disease and disability. In FY 1995, NIH-supported researchers realized a number of significant scientific advances. This work can be divided along three fronts: laboratory research, clinical research, and applied research. A few examples follow.

Laboratory Research Advances

- Scientists have for the first time identified genes involved in hereditary predisposition to **breast cancer.** This is a critical step in beginning to understand the biochemical events that can lead to cancer. Ultimately, this may lead to improved diagnostic tools, drug therapies, and preventive measures. The discovery and isolation of breast cancer susceptibility genes bring us significantly closer to understanding the origins of this devastating disease. This will also allow scientists to begin to study the effects of environmental agents that may contribute to many cases of breast cancer. As important, tests may be developed to identify women who are at increased risk for the disease.

- Researchers have also identified key pieces in the puzzle of **melanoma,** the most serious form of skin cancer. Investigators found that about 10 percent of all melanoma cases arise from inherited mutations in a gene that normally suppresses tumor growth. This finding is an important milestone in identifying persons who are especially prone to this fast-spreading and often deadly cancer, and in developing vital treatment and preventive measures.

- Investigators have made a key discovery about the role of a protein associated with von Hippel-Lindau (VHL) disease. This inherited cancer syndrome is characterized by the development of multiple tumors, including **kidney cancer**, kidney cysts and non-malignant tumors in the adrenal glands. Although VHL disease is rare, a non-inherited form of kidney cancer is much more common. Mutations in a tumor suppressor gene associated with VHL have been identified in families with the disease as well as in about 90 percent of patients with non-inherited kidney cancer. These findings could lead to methods for identifying family members at risk for developing tumors associated with VHL, and to new ways to prevent and treat cancer.

- A mouse model for **obesity** was instrumental in the recent identification and isolation of a hormone (leptin) that significantly reduced body weight in obese mice. This intriguing finding hold promise for new insights into human obesity.

- Researchers found that mice with mutations in specific genes involved in the immune response develop a disease that resembles human **inflammatory bowel disease.** This

debilitating disorder that affects 500,000 Americans and is characterized by extreme intestinal inflammatory reactions that cause chronic tissue injury and destruction.

- Scientists succeeded in producing mice that contain a defective human gene known to be involved in a hereditary form of Lou Gehrig's disease (ALS, or amyotrophic lateral sclerosis). The mice develop symptoms similar to those experienced by humans afflicted with ALS, including limb weakness, impaired gait, limb tremor, paralysis and ultimately, die.

- Lupus erythematosus is a chronic and potentially fatal disease that occurs primarily in women of child bearing age. It affects many systems of the body, including the joints and the kidneys. Investigators discovered that a strain of mice which develop a lupus-like illness have a defective gene for controlling the process of programmed cell death. When they replaced the defective gene with a normal one, the mice no longer developed signs of lupus.

- Using an animal model of osteoarthritis, researchers determined that prophylactic oral administration of the commonly used antibiotic doxycycline reduced the severity of cartilage damage typical of this disease.

- Investigators have created a mouse model for studying a type of lymphoma that arises in persons with AIDS. The model was used to gauge the potential effectiveness of immunotherapy with interleukin-2, a natural substance produced by specialized immune system cells. This approach is now being tested as an innovative strategy in human AIDS-related lymphomas.

- Researchers are exploring the dynamics of HIV-1 production and destruction in infected individuals. They are using as a tool a class of drugs that inhibit crucial enzymes involved in HIV-1 replication. These critical studies will be vital for developing innovative strategies for long-term control of HIV-1 replication.

- Recent findings about Kaposi's sarcoma (KS), a normally rare cancer that affects a significant number of HIV-infected persons, may lead to novel approaches for treatment and prevention. Scientists analyzing AIDS-KS tumor tissue detected unusual stretches of DNA in more than 90 percent of the tumors. The DNA was very similar to that of two known herpesviruses which are associated with lymphomas in primates and humans. This finding and subsequent epidemiologic studies provide strong support for the idea that infection with a new herpesvirus plays a role in the development of KS. The same stretches of DNA were also detected in AIDS-related lymphomas of the body cavity. These findings raise the possibility that AIDS-related malignancies may be prevented or treated with antiviral drugs.

Clinical Research Advances

- Scientists are gaining key insights into the control of HIV-1 by studying a unique subset of HIV+ individuals who have survived for more than 10 years with no evidence of disease. Understanding the mechanisms by which these infected individuals continue to survive with intact immune systems may lead to novel approaches to the treatment of HIV+ men and women who experience the normal rapid progression of disease.

- A number of recent advances have enhanced our understanding of factors which predispose individuals to develop cardiovascular, pulmonary and blood diseases across the life span. For example, results from a recent study will help postmenopausal women and their physicians assess the risks and benefits of hormonal regimens to improve heart disease risk factors. Researchers found that with the four hormonal regimens tested—including estrogen and combinations of estrogen and progesterone—post-menopausal women safely and significantly increased their levels of HDL cholesterol, which protects against coronary heart disease. In addition, the hormonal regimens decreased LDL ("bad") cholesterol and fibrinogen (a blood clotting factor predictive of stroke and heart attack).

- For the first time a medication which effectively reduces craving for alcohol has been identified. Clinical trials of naltrexone—a chemical that neutralizes or impedes the effects of opiates—showed it to be very effective in reducing both alcohol craving and consumption. If it is approved by the FDA, naltrexone will be the first medication for the treatment of alcoholism since antabuse.

- Sickle cell disease (SCD) is a painful, debilitating, inherited disorder that primarily affects blacks, including an estimated 72,000 Americans. Researchers have shown that treatment with a chemical known as hydroxyurea effectively relieves the severe pain of sickle cell crises, reduces the number of recurring episodes and their associated complications, and significantly lessens the need for transfusions and hospitalizations. This important discovery was based on extensive laboratory research on the expression and regulation of the genes for hemoglobin, the oxygen-carrying molecule in red blood cells. Scientists learned that at birth, the body "switches" from producing fetal hemoglobin to an adult form. They also determined that adult hemoglobin, but not the fetal form, is defective in SCD. Researchers studied the biochemical differences between fetal and adult hemoglobin and focused on ways to switch back on the production of fetal hemoglobin. They discovered an agent that increased fetal hemoglobin levels, but was toxic in humans. After learning how that chemical worked in cells, they found that hydroxyurea acted in the same way and was not overly toxic in humans.

- Retinitis pigmentosa (RP) is a group of inherited diseases that affects the sight of 100,000 Americans and 1.5 million people worldwide. In RP, cells in the retina progressively degenerate, resulting in night blindness, loss of peripheral vision, tunnel

HHS FACT SHEET

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Feb. 9, 1996

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REVITALIZING THE NIH CLINICAL CENTER

Overview: In an effort to reduce the costs and improve the efficiency of government programs, the Vice President's Reinventing Government II initiative designated the NIH Clinical Center as an organization to be critically reviewed and reengineered to improve its effectiveness and efficiency. An NIH Clinical Center "Options Team" was created by HHS Secretary Donna E. Shalala to perform that review, under the leadership of Helen L. Smits, M.D., Deputy Administrator of the Health Care Financing Administration. A report has been presented to the Secretary, summarizing findings, conclusions and recommendations.

Background

The Warren Grant Magnuson Clinical Center is the core clinical research facility at the National Institutes of Health (NIH) and is the largest center of its kind in the world. A recent study of NIH described the Clinical Center as "a unique and invaluable resource for the direct clinical application of new knowledge derived from basic research." The Clinical Center provides protocol-specific patient care in support of the intramural research programs sponsored by most NIH Institutes. The Clinical Center also serves as a resource for training clinical investigators.

Clinical Center patients are drawn from a nationwide patient referral base to participate as research volunteers in NIH-sponsored protocols. In Fiscal Year 1994, 72,200 inpatient-days and 73,400 outpatient visits occurred at the Clinical Center. This represents approximately 50 percent of the research days and 27 percent of the research outpatient visits supported by NIH throughout the United States. The Clinical Center supports a portfolio of approximately 1,000 active protocols. The research mix at the Clinical Center emphasizes Phase I and Phase II clinical trials and the study of the pathogenesis and natural history of disease. On occasion, investigators from outside NIH also use the Clinical Center.

- More -

Issues

The Clinical Center is at a critical point in its history. The translation of bench research to clinical practice in areas such as genetic and immunologic therapy will accelerate in the next decade, placing new demands on the Clinical Center. At the same time, changes in the delivery of health care have already decreased the traditional flow of referrals from physicians to the Center, and patient loads for inpatient and outpatient care have declined in recent years. Patients are less willing to accept long hospital stays and to return to the Center for follow-up procedures. The Clinical Center needs new relationships with outside physicians, insurers and patients to facilitate recruitment. New approaches, such as the use of telemedicine to broaden access of patients to protocols, are critical to maintaining the viability of the Center.

At present, the Clinical Center lacks a clear structure of governance to implement necessary changes. Responsibility for the Center is in the hands of a series of NIH committees and this structure restricts formal access to the experience of external experts in hospital and research management.

The Center's budget is also unstable and unwieldy. Funding must be first appropriated to individual Institutes and then transferred from an Institute to the Clinical Center. As currently configured, the procurement and personnel systems provide no incentives for increased efficiency and do not encourage increased use of the Center to lower unit costs.

Finally, the physical structure of the Clinical Center needs improvement. Built in the 1950s, the physical plant is not well suited to sustain modern practice in either patient care or research because of deteriorating infrastructure, including air heating systems and other utilities.

The Options Team

The internal NIH Options Team evaluated Clinical Center functions in the broadest sense possible, exploring everything from the Center's structure and strategic direction to the details of day-to-day management, information systems, and benchmarking.

Subcommittees of the Options Team visited a variety of government, academic and private-sector organizations. In interviews with staff, they learned how other institutions have dealt with the problems the Clinical Center now faces.

Outside advisors met with the Options Team in a two-day retreat held in Annapolis, Maryland, during October 1995. These same advisors had served as hosts to various team members during visits to their institutions. The recommendations in the report reflect information gathered from visits to many institutions and input from these outside advisors or consultants.

Major Recommendations

The recommendations that follow propose that the Clinical Center undergo significant change to improve efficiency and to ensure that the Center flourishes into the next decade. To remain the national core of clinical research in this information age, the Clinical Center must change the way it is governed, funded, and managed.

The Options Team and the external consultants agree that the following recommendations are the most important for the Clinical Center to address now:

- A Board of Governors should be created to oversee the Clinical Center. The Board's responsibilities should include annual budgeting and strategic planning as well as oversight of operations. The majority of this Board and the chair should be individuals from outside government; the remainder of the Board should be representatives of NIH Institutes. Appointments should be made by the Director of NIH upon the recommendation of Institute directors and the Director of the Clinical Center.

- The Clinical Center should have a clearly defined budget of its own, and this budget should be as stable as the NIH budget as a whole.

- The Clinical Center should have a means of retaining reserves from year to year. The Center should also be permitted to accept monies from insurance companies for some services and to solicit donations. The new budgeting process should include methods to (1) ensure that all Institutes have continued access to a baseline level of activity at the Center; (2) permit Institutes that improve the efficiency of their protocols to increase their overall activity; and (3) permit outside investigators to use the Clinical Center.

- As one of its first official actions, the new governing Board of the Clinical Center should direct development of a strategic plan for operations with clear and measurable objectives. The plan should serve as the keystone by which managers can allocate and distribute resources. Clinical Center management should immediately begin to develop the background information upon which such a plan can be based.

- The Options Team and external consultants recommend that the Clinical Center be designated a "Reinvention Laboratory," a Federal demonstration site with reduced regulation, enhanced local autonomy, and improved federal personnel and procurement practices. The Options Team did evaluate several other structural approaches that were not ultimately right for the Center. These include continuing to operate the Center as a standard Federal organization; converting it to one of many federally-sponsored organizational arrangements; and managing the Center by contract.

The Options Team also recommends that the Center do the following:

- Actively seek funding for a new clinical research center facility that will be more efficient to run and maintain and that will permit more efficient use of staff.

- Explore increased contracting out of individual Clinical Center functions.

- Invest in integrated information systems that provide real-time information for managers about costs and human resources.

- Adopt an ongoing program of benchmarking, integrated with the strategic plan adopted by the new Board of Governors.

- Establish new methods for recruiting patients to protocols.

The body of the report contains additional recommendations, background information, justification, and methods for implementation.

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This document was a cooperative effort between HHS and the White House Office of AIDS Policy — done in the fall of 1995.

The Clinton Administration and HIV/AIDS

In 1992, when he ran for President of the United States, Bill Clinton said he would "provide the leadership this country needs for a loud, clear, and consistent war on AIDS." In his first three years in office, the President has translated that pledge into action, turning around more than a decade of governmental policies that were regarded as at best apathetic and at worst hostile to those living with HIV/AIDS. Following are the highlights of the Administration's HIV/AIDS-related actions taken since January 20, 1993.

AIDS Advisory Council. The President has created a 30-member Presidential Advisory Council on HIV and AIDS to provide him and his Administration with expert outside advice on the ways in which the Federal government should respond to the HIV/AIDS epidemic. Specifically, the Council is charged with making recommendations in the areas of AIDS-related research, prevention, and care.

AIDS Funding. The President has placed AIDS programs among his investment priorities. In the three budgets he has submitted to the Congress, the President has increased total government funding for AIDS research, prevention, and care by 40%, including a 108% increase for the Ryan White CARE Act programs.

Anti-Discrimination. The Justice Department and the Equal Employment Opportunity Commission have vigorously enforced provisions of the Americans with Disabilities Act that prohibit discrimination against people with HIV/AIDS. The EEOC has received more than 900 charges alleging employment discrimination against people with HIV and AIDS and has resolved 789 charges, obtaining monetary benefits of over $6.1 million. The Health Care Financing Administration (HCFA) has taken action on nearly 20 complaints of denial of care by health care facilities or providers to persons with HIV/AIDS and new efforts are being made to address discrimination in nursing homes.

Blood Safety. The Food and Drug Administration (FDA) held ground-breaking public meetings on the use of new technologies to reduce the risk of HIV transmission by blood product transfusion. The Administration has received the Institute of Medicine report examining the issues surrounding transmission of HIV throughout the blood supply before 1987. The Department of Health and Human Services has named the Assistant Secretary for Health to be the Department's blood safety director, with overall responsibility for ensuring the IOM's recommendations are carried out and the coordination and oversight of the Public Health Service's blood safety programs.

Consumer Protection. The FDA is working with community organizations to prevent fraudulent activities aimed at people living with HIV disease. To date, 10 FDA-funded coalitions throughout the country – including representatives from the community, health professionals, and law enforcement agencies – have been established to educate and protect people with HIV and AIDS from fraudulent products.

Data Gathering. The Department of Health and Human Services (HHS) is supporting three major efforts directed at gathering and analyzing services provided to persons with HIV disease. The "AIDS Cost and Services Utilization Survey," the "HIV Cost and Services Utilization Survey," and the "Hospital Cost and Utilization Project," will provide an important data base on the cost of AIDS care and the use of health care services by people living with HIV.

Dental Care. The AIDS dental reimbursement program was expanded to address the lack of dental care available to low-income and under-insured individuals living with HIV/AIDS. The program, which reimburses accredited dental schools and post-doctoral dental training programs for uncompensated costs incurred in providing oral health care to HIV-positive individuals, includes 124 institutions in 35 states.

Disability Eligibility. The Social Security Administration published revised regulations expanding the list of health manifestations that will be considered in determining eligibility due to HIV/AIDS for Social Security and Supplemental Security Income disability benefits. The agency also revised its rules to allow physicians and other health professionals to provide information to Social Security field offices, which then can make immediate disability findings.

Drug Approval. The FDA has approved or provided new labelling indications for fifteen new products to treat HIV or HIV-related conditions while dramatically reducing the time it takes for drug review and approval.

Drug Development. HHS created the National Task Force on AIDS Drug Development, an historic partnership between government, industry, academia, medicine, and AIDS-affected community organizations to identify and eliminate barriers to the rapid development of drugs for HIV and HIV-related conditions. The Task Force has issued 45 specific recommendations, many of which are currently being implemented.

Early Intervention. The Agency for Health Care Policy and Research issued clinical practice guidelines for health care professionals to assist in the evaluation and management of early HIV infection. The guidelines stress the importance of prevention of HIV-related opportunistic infections and the link between prevention and early diagnosis and care. A quick reference guide for physicians and consumer guides for adults, adolescents, and the parents of children with HIV infection was also made available. The U.S. Public Health Service provided support for a new campaign by the National Minority AIDS Council to promote the use of prophylactic treatment to prevent the occurrence of pneumocystis carinii pneumonia in people with HIV.

Health Benefits. Federal medical assistance programs serve nearly 50% of people living with AIDS and more than 90% of children with AIDS. Medicaid is the largest single payer of direct medical services, paying an estimated 25% of the aggregate cost of AIDS-related care. Under Title II of the Ryan White CARE Act, 18 states operate health insurance continuation programs that allow low-income people with HIV to continue their private health insurance.

Home Care. A total of 15 Medicaid State waivers are in place, allowing States to provide targeted home and community-based services to people with HIV/AIDS. In 1995, those programs will serve an estimated 21,170 individuals. HHS also is developing prototype waivers to help other States gain quick approval of future waiver applications.

Housing. In the last two years, the Department of Housing and Urban Development's (HUD) Housing Opportunities for People with AIDS (HOPWA) program has provided $300 million to communities with a high incidence of HIV infection to provide housing assistance to people living with HIV/AIDS. HUD also has established the National Office of HIV/AIDS Housing to assist low-income people with HIV/AIDS to pay for housing. President Clinton cited the proposal to cut $30 million from HOPWA as one of the reasons for his veto of the fiscal year 1995 rescissions bill.

International Cooperation. The U.S. is actively cultivating international cooperation in HIV/AIDS prevention and care through participation in the United Nations' new Joint Programme on HIV/AIDS. Representatives of the U.S. participated in the Tenth International HIV/AIDS Conference in Yokohama, Japan, and the World AIDS Summit in Paris and is participating in regional conferences for Latin America and the Caribbean, Asia, and Africa. The U.S. Agency for International Development sponsored the Third HIV/AIDS Prevention Conference in Washington DC, which allowed for an exchange of information among diverse prevention and care groups from around the world and resulted in an agenda of effective prevention measures to be pursued worldwide. Through USAID, the U.S. is the largest bilateral donor in international assistance for prevention HIV/AIDS transmission, providing more than $120 million annually.

Mental Health. HHS awarded the first Federal grants to develop mental health services for persons living with HIV/AIDS and their families and partners. Approximately 260,000 mental health counseling sessions for people with HIV were reported during the last six months of 1994. Approximately 100,000 individuals with HIV also received mental health services under the Ryan White CARE Act.

Minority Communities. The Public Health Service convened the National Congress on the State of HIV in Racial and Ethnic Communities, bringing together individuals and organizations to develop plans to alter the course of HIV in those communities. The National Institutes of Health (NIH) added four new sites to its AIDS Clinical Trials Group at institutions that serve predominantly minority populations.

Perinatal Transmission. An NIH-sponsored clinical trial (ACTG 076) provided strong evidence that use of AZT by HIV-positive pregnant women dramatically reduced the rate of HIV transmission from mother to infant. The FDA expeditiously approved changes in labelling indications for AZT to include treatment of HIV-infected pregnant women. The U.S. Public Health Service issued guidelines in August 1994 on using AZT during pregnancy to reduce the risk of perinatal HIV transmission. In July 1995, CDC published PHS recommendations for routine HIV counseling and voluntary HIV testing for all pregnant women in the U.S.

Widespread implementation of these recommendations will enable women to seek and receive the care they need for themselves and to reduce the risk of transmitting HIV to their infants by as much as two-thirds.

Policy Coordination. To provide a central focus for governmental efforts against HIV/AIDS, the President created the Office of National AIDS Policy within the White House, to advise him on AIDS policy issues and coordinate interdepartmental activities. An Interdepartmental Task Force on HIV/AIDS, chaired by National AIDS Policy Director Patricia Fleming, was created to assist in that effort.

Prevention. CDC has initiated a comprehensive community planning process for HIV prevention programs, placing control of such programs in the hands of local community organizations rather than having them dictated by the Federal government. CDC also initiated an unprecedented review of government-funded HIV/AIDS prevention activities conducted by panels of individuals from outside of the government. In January 1994, the Centers for Disease Control and Prevention (CDC) launched the Prevention Marketing Initiative aimed at young adults (ages 18-25) to change behaviors that contribute to the transmission of HIV. The initiative features production of frank, forward-thinking public service announcements promoting both abstinence and the consistent and correct use of latex condoms.

Research Organization. The President signed the National Institutes of Health Revitalization Act of 1993, placing full responsibility for planning, budgeting, and evaluation of the AIDS research program at NIH in the Office of AIDS Research. Dr. William Paul, an internationally acclaimed immunologist, was appointed to head that office and has developed the first comprehensive plan and budget for AIDS research.

Ryan White CARE Act. In the three budgets he has sent to Congress, the President has increased funding for the Ryan White CARE Act by 108%, fulfilling the President's promise to fully fund that program. During the last two years, the number of metropolitan areas eligible for assistance under Title I of the Ryan White CARE Act has increased from 25 to 49. Preliminary data indicate that approximately 360,000 clients were served under Title I of the Act. Eighty percent of U.S. metropolitan areas report providing new or expanded Ryan White services to people living with HIV, including HIV/AIDS drug assistance; services for women, children, and other special needs populations; and expanded rural services. All 54 states and territories are currently funded under Ryan White Title II, serving an estimated 296,000 clients with those funds. Title III(b), which pays for counseling, testing, and early intervention services, including treatment, served more than 175,000 clients, including a large number of women and minorities. Currently, 144 community-based organizations, located in 33 states, the District of Columbia, and Puerto Rico, are supported with Title III(b) funds. Title IV develops comprehensive coordinated care systems linked to clinical research in more than 80 communities, meeting the unique needs of children, youth, women, and families. Reauthorization of the Ryan White CARE Act is a top priority for the Administration in 1995.

Treatment. The NIH Preclinical AIDS Drug Screening Program has screened 72,000 potential agents for treatment of HIV disease and approved six compounds for Phase I clinical trials. NIH clinical trials involve more than 45,000 HIV-infected individuals. Several promising HIV protease inhibitors and potent combination drug regimens are slated to begin Phase III efficacy trials in the near future. Thousands of other HIV-positive individuals are receiving promising investigational therapies through clinical trials and various expanded access programs.

Vaccines. The NIH has significantly expanded its basic research efforts to design new approaches to developing AIDS vaccines. It is now evaluating 14 vaccine candidates to identify those that might be appropriate for efficacy trials. The Department of Defense is also developing and testing several candidate HIV vaccines to protect U.S. military personnel.

Veterans. The Department of Veterans Affairs (VA) provides care to nearly 17,000 veterans with HIV-related diseases. The VA operates four specialized AIDS Clinical Units in New York City, Miami, West Los Angeles, and San Francisco medical centers. AIDS research is conducted at 85 medical centers, comprising over 800 individual research projects. Specialized AIDS Research Centers dedicated to conducting HIV research are located in New York City; Durham, NC; San Diego CA; and Atlanta. VA AIDS research is funded by about $6 million in VA research funds and over $24 million in extramural grants. VA also maintains a national AIDS data base to track the epidemic within the veterans' population.

Water Safety. The Centers for Disease Control and Prevention and the Environmental Protection Agency issued guidance for vulnerable populations recommending steps to purify drinking water to protect against Cryptosporidium, which can be fatal to those with compromised immune systems. These agencies have also conducted research and outreach about threats of water-borne diseases to such individuals through funding and hosting several workshops and training programs.

Women and AIDS. The NIH created a Women's Interagency HIV Study to identify the nature and rate of HIV disease progression in women. NIH requires that women and members of minority groups be included in all NIH supported biomedical and behavioral research involving human subjects. NIH has initiated a major research effort to develop female-controlled barrier methods, including vaginal compounds, to prevent HIV transmission.

# # #

THE CLINTON ADMINISTRATION RECORD ON REDUCING TEEN PREGNANCY

A Summary Report

President Clinton has called teen pregnancy one of the nation's most serious social problems, and reducing its incidence has been a key goal of this administration's policy for young people. All over the country Americans are beginning to address this and other issues by reasserting responsibility for themselves, their families and their communities, and they are starting to make a difference -- the teen pregnancy rate has come down two years in a row.

Although there has been progress, teenage pregnancy remains a profound problem, and we need to do more. Real solutions lie at the grassroots level, with families, communities and young people themselves. The federal government can help focus resources in support of work at the local level, and most important, it can help ensure that our policies support our national values. The Clinton Administration's policy on teen pregnancy, and on youth generally, have been built on two fundamental values:

> *Responsible Behavior*: Personal responsibility has been a central part of the President's message to young people, as he has urged them not to become parents before they are adults, have finished school, and are ready to support their children. He has supported policies that embody this principle, including abstinence-based curricula, welfare reforms that discourage early parenting and require young mothers to live at home and stay in school, and tough new child support enforcement provisions that drive home the responsibility of parenthood to young men.
>
> *Opportunities for Youth*: Teen pregnancy cannot be addressed in isolation from the wide range of other problems confronting youth, their families, their communities and their schools. Much of the Administration's social and economic agenda, ranging from education to crime prevention to empowerment zones, is designed to provide increased opportunities for young people and to give them something to say 'yes' to. If our youth do not have access to education, health services, jobs, or safe places to go after school and on weekends, they will not have a chance to make the right choices.

This summary report provides some facts about teen pregnancy in the United States and highlights some of the key components of Administration's teen pregnancy and youth agenda, including: (1) Research and Evaluation to learn more about the causes of teen pregnancy, (2) Community demonstrations to help communities try different approaches to learn what works, (3) Policies that promote responsible behavior among young people, and (4) Policies that provide young people with greater opportunities.

Recognizing that government cannot solve this problem alone, the President has called for a national private sector campaign to prevent teen pregnancy, and the administration has been working to catalyze such an effort. This report is not intended to address the status of private sector initiatives, nor does it provide a comprehensive description of all federal efforts directed at teens.

January 27, 1996

The Facts About Teen Pregnancy

A NATIONAL EPIDEMIC

- Every year, about 1 million American teenagers become pregnant -- that's approximately 11% of women ages 15-19.

- From the 1950s through the early 1980s, the rate of births to teens decreased steadily. However, in 1986, that trend reversed, and over the period 1986-91, the rate grew by 24%. Recent news has been somewhat positive: From 1991 to 1993, the national rate declined by 4%.

- As the teenage population grows, teen births are expected to increase. Even if the teen birth rate remains constant, the number of births is expected to jump 30% by the year 2010.

TREND TOWARDS OUT-OF-WEDLOCK CHILDBEARING

- In 1960, only 15% of teenage mothers were unmarried. As of 1993, 71% were unmarried.

INTERNATIONAL COMPARISONS

- The rate of births to teens in the United States is now twice as high as in the United Kingdom and six times as high as in France, Italy, and Denmark.

ROLE OF ADULT MALES

- A recent survey indicates that at least half the babies born to teenage women ages 15-17 are fathered by adult men ages 20 or older.

COSTS TO THE CHILDREN

- Children born to teens are more likely to die in their first year of life, to have lower cognitive achievement, to repeat a grade in school, to be victims of abuse and neglect, and to become teen parents themselves.

- 80% of children born to unwed teenage mothers who have not completed high school live in poverty. In contrast, of those children born to 20 year-old married parents who are high school graduates, only 8% live in poverty.

COSTS TO SOCIETY

- In 1990, slightly more than half of all mothers receiving Aid to Families and Dependent Children (AFDC) first had children as teenagers. And 43% of the long-term welfare recipients are women who gave birth at or before age 17.

- More than three-fourths of all unmarried teen mothers receive welfare (AFDC) at some point during the 5 years following the birth of their child.

Research and Evaluation: Learning What Works to Prevent Teen Pregnancy

The Clinton Administration supports comprehensive approaches to research and evaluation with an emphasis on prevention of both first and repeat pregnancies. Working to understand teen populations and the many forces that influence behavior both in and outside of the home, monitoring and targeting new data, and evaluating old and new programs to learn more about what approaches may be most effective in lowering teen pregnancy rates in the United States are priority elements of our approach to research and evaluation. Following are some examples:

- Comprehensive Study: In June of 1995, the Department of Health and Human Services issued, **"Beginning Too Soon: Adolescent Sexual Behavior, Pregnancy, and Parenthood,"** a two volume report containing a comprehensive and exhaustive review of the most recent research literature on teenage sexual behavior, pregnancy and parenthood and on effectiveness of teenage pregnancy prevention programs. This report was produced by Child Trends, Inc. with funding from the Department of Health and Human Services, and is now available on the Internet at http://aspe.os.dhhs.gov/hsp/cyphome.htm.

- State Data: In September 1995, HHS reported **state-level teenage pregnancy data** for 1991 and 1992. This marks the first time that HHS is able to report state-level teen pregnancy data. Updating trends on a state-by-state basis regularly provides more information for making effective policy decisions and enables us to see where we need to target our resources.

- Family Planning and Adolescent Family Life : HHS funds, as part of Family Planning and Adolescent Family Life programs, research projects and studies that focus on **adolescent sexual behavior.** Goals of these studies range from developing strategies to improve services to sexually active adolescents who are at-risk for contraceptive non-compliance and young women who visit family planning clinics, to learning more about: precursors and results of pregnancy and birth among adolescent males, the factors that influence teen attitudes toward sexual behavior, and the consequences for teen mothers who decide to parent as compared to those who place their children for adoption.

- New Mothers' Study: HHS funds The New Mothers' Study and has expanded its original scope to provide support for a 5-year follow-up to look at longer term outcomes, including employment and welfare dependency. *The Study focuses on research and analysis of a study in Memphis, Tennessee, where a sample of first-time, low-income, pregnant women received weekly visits from a nurse. Approximately 65% of the research sample were 18 or younger at enrollment. Early findings indicate that there were significantly fewer repeat pregnancies within two years following the birth of the child for those women who received home visits. It was originally started in 1988, and is also supported by other government agencies and private foundations.*

- Teenage Parent Demonstration: In order to gain further insight into the occurrence of repeat pregnancies, in 1993, HHS funded a 5-year follow-up evaluation of the Teenage Parent

Demonstration, initially conducted from 1986 to 1991. This program targeted the high-risk population of teenage mothers on welfare, providing case management and support services such as education, training and child care. The follow-up evaluation continues to monitor these mothers and focuses on the occurrence of repeat pregnancies.

Reaching Into Our Communities And Promoting Partnerships to Prevent Teen Pregnancy

"I'm trying to do things that I believe will help our country meet the challenges we face today so that young people will have a better future. And it's obvious to me that.... unless young people have good, healthy, constructive lives at the grass-roots level, the things that I do will not succeed in getting you the future you deserve." **President Clinton; August 9, 1995**

The Clinton Administration encourages local governments and communities to pilot new and innovative demonstration efforts to prevent teenage pregnancy, and works with them to help make these programs a reality. The Administration has sponsored a range of approaches from abstinence-based education to service-oriented community collaborations. If a program proves effective, one goal of collaboration is to foster sustainability so that it can eventually operate without government assistance. Following are some examples of programs funded under the Clinton Administration:

- Adolescent Family Life Program: In September of 1995, HHS's Adolescent Family Life Program awarded 15 grants totaling $4.2 million dollars for comprehensive demonstration programs aimed at preventing early teenage sexual activity and reducing teenage pregnancies. These programs feature innovative ways to **emphasize abstinence as the best way to prevent adolescent pregnancy** and to encourage the involvement of parents in these discussions with their children.

- Community Coalition Partnership Programs for Prevention of Teen Pregnancy: In September of 1995, Centers for Disease Control and Prevention launched the new Community Coalition Partnership Programs for Prevention of Teen Pregnancy by awarding 13 grants totalling $6.5 million over two years. These grants enable communities to develop plans for implementing and evaluating **community-wide interventions** that are innovative, comprehensive and sustainable. In addition, these demonstrations include an evaluation component.

- Healthy Schools/Healthy Communities: In 1994, the Administration started the new Healthy Schools/Healthy Communities program -- funding 27 **new school-based health centers** in 20 states and the District of Columbia. These centers provide for

the health services and education needs of children and teenagers at high risk for poor health, teenage pregnancy, and other problems. A comprehensive evaluation of this program is currently being conducted.

- The Corporation for National Service: Created under the Clinton Administration in 1993, the Corporation for National Service supports over 50 teen pregnancy programs in 20 states across the country -- working both to prevent teen pregnancy and to assist teen parents. National service participants provide case management, mentor pregnant teens, sponsor health fairs, teach parenting skills to teen parents, make presentations on teen pregnancy prevention to school-age youth, help youth access health care, provide referrals to health care providers, and develop social supports for teen parents. *National service programs are operated with members of AmeriCorps, Learn and Serve America, and the National Senior Service Corps, who work collaboratively with school districts, universities, churches, health departments, national non-profits, and community-based organizations.*

- Healthy Start Program: HHS continues to support the Healthy Start Program, which has demonstration projects underway in 22 communities nationwide to reduce infant mortality in the highest-risk areas and to improve the health and well-being of women, infants and their families. Among a broad array of services provided, thousands of teenagers participate in prevention programs exclusively designed for them that encourage healthy lifestyles, youth empowerment, sexual responsibility, conflict resolution, goal setting, and the enhancement of self-esteem. A comprehensive evaluation is ongoing and results are expected in 1997.

- The Home Visiting Services Demonstration: In September 1994, HHS launched this new grant program that is currently operating in three sites. Under the demonstration, paraprofessional home visitors provide first-time teenage parents on welfare with instruction and supportive guidance related to family planning, parenting skills, health care for themselves and their children, and child support. The visitors also facilitate the teenagers' participation in the required education and employment-related activities.

Promoting Personal Responsibility Among Young People

President Clinton has made personal responsibility a central part of his message to young people, urging young people not to get pregnant or father a child. Estimates indicate that over half the mothers who receive Aid to Families with Dependent Children were teenagers when they had their first child. To prevent welfare dependency in the first place, teenagers must get the message that staying in school, postponing sexual activity, and preparing to work are the right things to do.

By supporting welfare reform that promotes work, demands responsibility, and toughens child support enforcement activities, President Clinton has sent a message that, "Nobody should get pregnant or father a child who isn't prepared to raise the child, love the child, and take responsibility for the child's future."

Welfare Reform: The President supports welfare reform that sends a clear message to minor parents seeking assistance: to get help, you have to live with a responsible adult, you have to stay in school, and you have to prepare for work. Congress has endorsed the President's proposal requiring unmarried teen mothers to live at home and stay in school in order to qualify for assistance. Congress also supports the Administration's efforts to establish "Second Chance" homes, or adult-supervised group homes, as alternative living situations to help teen parents break the cycle of welfare dependency.

Strengthening Child Support Enforcement: In 1995, the Administration collected a record $11 billion in child support from non-custodial parents, an increase of 40% since 1992. From 1992 to 1995, paternity establishments have also risen by over 40%, to an estimated 735,000. This increase includes, for the first time, paternities established as part of the Clinton Administration's in-hospital paternity establishment program.

President Clinton proposed a comprehensive child support enforcement plan as part of his welfare reform legislation. The plan would streamline paternity establishment; require new hire reporting; make child support laws uniform across state lines; computerize state-wide collections to speed up payments; and require states to revoke drivers' and professional licenses to parents who refuse to pay child support. Both House and Senate have adopted these provisions--changes that should increase child support collections by $24 billion over the next 10 years. In addition, in 1995 President Clinton signed an Executive Order to crack down on Federal employees who owe child support.

State Welfare Reform Demonstrations: The Administration has approved state welfare reform demonstrations to a record 35 states that include various provisions affecting minor parents. Nineteen states have authority to implement provisions linking AFDC benefits to the school attendance of minor parents. Seven states have received waiver authority to require minor parents to live with their parents or guardians or in an adult-supervised setting. A comprehensive evaluation will be conducted for each of these demonstrations.

Teen Pregnancy Prevention As Part Of A Comprehensive Approach to Youth Policy

The Clinton Administration has worked to address the high rate of teen pregnancy by confronting the complex economic and social factors often behind these high rates. We have stressed the importance of investing in young people and in the communities where they live in order to offer them positive alternatives to early parenting and sexual behavior. Critical to this effort are Administration initiatives to invest in early childhood and adolescent development, to provide equal educational opportunities for our children and youth, to invest in distressed urban and rural communities, and to create more jobs.

Researchers have documented correlations between poor academic skills and early childbearing; high dropout rates, illiteracy, a history of physical and/or sexual abuse, and poor employment prospects are all risk factors for early childbearing. Research has also shown that the risk factors for teen pregnancy, violent behavior, delinquency, and drug use are similar and that comprehensive programs focused on changing behaviors related to alcohol, drugs and teen pregnancy – such as focusing on raising self-esteem -- have an impact.

Following are examples of programs and initiatives in this area that the Administration supports:

LEARNING MORE ABOUT YOUTH AT-RISK

- National Adolescent Health Survey: Teens have been a significantly understudied sector of the population. In 1994, the National Institutes of Health began funding a new 5-year study known as Add Health, the first comprehensive study of the determinants of adolescent health. Using a national sample of 7th through 12th graders, Add Health examines the personal, familial, peer-related and community related influences on health behavior, taking a more comprehensive look at the health of our nation's teenagers in order to provide a better understanding of the complex forces that promote good health for our young people and those factors that put youth at risk.

- Preventing Youth Violence in Public Housing: This year, HUD and CDC have awarded a $550,000 grant to collect and develop information on youth violence prevention research. The intent is to disseminate existing information on successful programs to Indian and Public Housing authorities so that they can make more informed choices about prevention programs, which offer alternative services and activities for youth that can play a major role in preventing teen pregnancy as well.

- Comprehensive Strategy and Guide for Implementation: In December of 1993, the Department of Justice published a *Comprehensive Strategy for Serious, Violent, and Chronic Juvenile Offenders*, following up with a *Guide* to implementing the *Comprehensive Strategy* in June of 1995. Studies on the causes and correlates of delinquency, which used large random samples of inner-city, high-risk youth in three sites, provided the research underpinnings for these publications. All three studies showed that **chronic violent delinquent offenders have higher rates of dropping out of school, gun ownership for protection, gun use, gang membership, teenage sexual activity, teenage parenthood, and early independence from their family.**

  Comprehensive Strategy and its *Guide* for implementation provide an alternative to increasing reliance on the criminal justice system by calling for the establishment of a **coordinated system of prevention** and graduated sanctions programs that provide a continuum of care for each child.

- Review for Practitioners: *Family Life, Delinquency, and Crime: A Policymaker's Guide--Research Summary*, was completed in May of 1994 by the Department of Justice. Its findings indicate that **family is one of the most powerful socializing forces for young people**, and can therefore seriously impact children's behavior.

- Parenting Initiative: The Department of Justice completed research work in 1993 under a grant to the University of Utah and the Pacific Institute for Research and Evaluation. This four-year major parenting initiative resulted in a document entitled *Effective Parenting Strategies for Families of High-Risk Youth (December 1993)*, which identified a representative group of 25 programs as potentially the most promising. The research findings underscore the **importance of a family-focused approach to prevention and intervention of youthful problem behavior.**

EXPANDING OPPORTUNITIES FOR YOUTH AT-RISK

- SafeFutures: In September 1995, the Department of Justice created the SafeFutures Program, a five-year program which will provide approximately $8 million per year to six jurisdictions for a comprehensive and coordinated **delinquency prevention and intervention program for at-risk and delinquent youth.** Several programmatic components allow the four cities, one rural jurisdiction and one tribal government, to address teen pregnancy and receive support for specific counseling and education services. These include support for family strengthening activities, mentoring, specific services to at-risk and delinquent females, and general delinquency prevention activities.

- High Risk Youth Demonstration: HHS supports the High Risk Youth Demonstration program, which funds **innovative and effective model programs for preventing alcohol and drug use among high-risk youth.** One component of the program targets the specific needs of females from 12 to 20 whose use of substances often occurs with special factors (e.g. sexual abuse and domestic violence) that underlie or contribute to women's addictive problems. Every component of the program is evaluated.

- School Health Programs: The CDC has established a national framework to support school health programs that are locally determined and consistent with community values. Programs in all 50 states and 18 major cities are designed to help young people avoid those risk behaviors that result in HIV infection, other sexually transmitted diseases, and unintended pregnancies. CDC's Youth Risk Surveillance System provides information about the prevalence of behaviors practiced by youth that put their health at risk, and states, cities, and CDC use this information to more effectively target and evaluate school health programs.

- Youth Development Initiative: Started in 1994 under the Departments of Veterans Affairs and Housing and Urban Development, the purpose of this initiative is to address the problem of violence in low-income communities by providing young people aged 13 to 25, with access to education and employment opportunities and supportive services. Offering these positive alternatives and services to youth to reduce violence are shown to be effective for affecting other teen behavior as well, such as sexual behavior that could lead to teen pregnancy.

- Youth Fair Chance: In July 1994, the Department of Labor implemented the Youth Fair Chance program, funding seventeen sites. Youth Fair Chance is a community-based program that targets money directly into **high poverty areas where youth problems are greatest.** Working in cooperation with local service providers, these sites use in- and out-of-school components to provide a variety of services that focus on youth problems, like teen pregnancy, unemployment, drug and gang involvement, and dropping out of school. Some of the sites utilize AmeriCorps volunteers.

- The Community Schools Youth Services and Supervision Grant: Through this new program established in 1994 under the Crime Bill, HHS provides matching grants to communities with significant poverty and juvenile delinquency for **after-school, weekend and summer recreation and education programs.** The program includes an evaluation component.

- Family Planning: In the face of strong opposition, the President has proposed budget increases for the federal Family Planning Program each year and successfully maintained the program. Among other reproductive health and education services, this program makes family planning information and contraception available to millions of women who might not otherwise get reproductive health care.

- 4-H Youth Development Program and Children, Youth and Families at Risk Initiative: The Department of Agriculture, through the Cooperative Extension System, funds these important initiatives serving young people. These programs work with communities to implement effective research-based programs which address a broad range of issues and needs, including teen pregnancy, child abuse, infant mortality, community crime and violence, and child care.

- Safe and Drug-Free School Act: Passed in 1994, this act responds to the continuing crisis of violence and drugs in our schools by **supporting comprehensive school-and community-based drug abuse and violence prevention programs.** Local school districts in high need areas are coordinating violence and drug prevention programs with comprehensive school health education programs.

- Comprehensive Services for Teenage Parents on Welfare: In 1994, HHS funded these grants, which supported development of programs providing **comprehensive services to meet the personal, physical and social needs of teenage parents,** as well as aiding the cognitive, physical and emotional development of their children. They were implemented in conjunction with mandatory participation requirements for education and employment-related activities.

LIFELONG LEARNING: INVESTING IN OUR YOUNG PEOPLE

> *"We can do all these things -- put our economic house in order, expand world trade, target the jobs of the future, guarantee equal opportunity -- but if we're honest, we'll admit that this strategy still cannot work unless we also give our people the education, training, and skills they need to seize the opportunities of tomorrow."* **President Clinton; January 25, 1994**

Under the Clinton Administration, the Department of Education has launched a number of initiatives that address teen pregnancy prevention through improved schooling for disadvantaged students, coordination of health and social services, and school-to-work opportunities to increase economic self-sufficiency. Drop-out prevention and drug-free schools and communities programs address risk factors that are the same or related to those leading to teen pregnancy.

Specific initiatives started or expanded include: **The Goals 2000: Educate America Act, Improving America's Schools Act, Title I Program; 1994 School-To-Work Opportunities Act;** and **Head Start.**

EMPOWERING COMMUNITIES TO SOLVE PROBLEMS

The Clinton Administration has worked hard to encourage investment in distressed communities, to create jobs and to help these communities rebuild themselves by designing initiatives like the **Empowerment Zones and Enterprise Communities** and **The Community Development Banking and Financial Institutions Act.**

HEALTH RESOURCES AND SERVICES ADMINISTRATION
Bureau of Health Professions

Items highlighted relate to timeframe of this Administration

• Program Data •

BENEFITS AND ACCOMPLISHMENTS

Title VII and Title VIII programs have been the key to the growth and development of primary care medicine and public health training, area health education centers, health professions workforce, minority/disadvantaged representation, and nursing education and practice. Despite funding appropriations which are only 15% in constant dollars of the level twenty years ago, Title VII and Title VIII programs have made substantive in-roads in meeting their statutory objectives. Program data analyses, as summarized below, clearly document the benefits and accomplishments of these programs towards meeting these goals.

TITLE VII

Training in Family Medicine, General Internal Medicine, General Pediatrics, Preventive Medicine, Physician Assistants, and General Dentistry

- The ratio of primary care physicians to the population has increased by over 32% since the inception of Title VII programs. For the five years prior to Title VII programs, there had been more than a 10% decrease in the ratio of primary care physicians to the population.
- Targeted funding has been a primary influence for a nearly 25% increase in the number of Departments of Family Medicine since 1980.
- Targeted funding has resulted in an increase of 40% in the number of required family medicine clerkships in just the past four years.
- Title VII funding provided the means for expanding the number of family medicine residency training programs by nearly 10% in just the past four years. The current rate of expansion is the highest in the past twenty years. Since 1978, Title VII funded family medicine residency programs have resulted in the training of nearly 9,000 residents.

- Title VII funded 43% of the current General Internal Medicine (GIM) residency programs.
  - Nearly 14,000 general internal medicine residents have been trained through Title VII funded institutions since the inception of the program.
  - Over 88% of the graduates of currently funded programs practice in primary care, a rate nearly twice that of programs not receiving Title VII funds.
  - Over 37% of the graduates of the currently funded programs have established practices in medically underserved communities in the past two years.
- Title VII funding has been the primary influence for a 25% increase in divisions of general pediatrics over the past 10 years.
- Title VII funded 28% of current General Pediatrics (GP) residency programs. Over 33% of the graduates of these programs have established practices in medically underserved communities in the past two years.
- Title VII funding has been instrumental in establishing Departments of Family Medicine in 100% of the current colleges of osteopathic medicine.
- Title VII funds have been key to the training of nearly 2,300 osteopathic interns and over 1,200 general practice/family practice osteopathic residents over the past 15 years.
- Title VII provided training support which developed or fostered 90% of the current physician assistant programs. On average, Title VII has provided nearly one quarter of the infrastructure support for physician assistant programs over the past four years.
- Title VII funded nearly 80% of the 27,000 physician assistants (PAs) graduates. Over 50% of the graduates from Title VII supported programs entered practice in primary care last year.

- Nearly 20% of the graduates from Title VII funded physician assistant programs started practice in rural communities last year. Title VII funding has served to increase PA practice in rural areas by nearly 40% in the just past four years.

- Since grants were first awarded in 1983, Title VII funding has played an essential role in the development of nearly 100% of the General Preventive Medicine and Public Health Residency Programs. As a result, nearly 350 resident physicians have received graduate medical education in the specialty of preventive medicine.

- The Advanced General Dentistry grant program resulted in the creation of 53 new postgraduate general dentistry programs, or 67% of the total growth in those programs.

  - Nearly 80% of the graduates of these programs provided primary care dentistry in the past year.

  - Nearly 30% of these graduates provided care in medically underserved communities over the past 4 years.

  - Title VII funding incentives have resulted in an increase of almost 100% in the enrollment of disadvantaged dental students in the past eight years.

Area Health Education Centers

- Area Health Education Center programs have coordinated and supported the training of nearly 1.5 million health professions students and primary care residents in underserved areas.

- Area Health Education Centers provided community-based clinical training to nearly 10,000 medical school students, or 13% of the nation's total medical school enrollment, in the past fiscal year.

- In just the past year, 32 Area Health Education Center programs assisted in providing community-based training experiences at 1400 rural and urban areas nationwide for: 2,900 primary care residents; 600 physician assistant students; 1,100 nurse practitioner students; and 8,800 other health professions students.

- Over 10% of all National Health Service Corps personnel utilized Area Health Education Center supported training last year.

- Fifty-four percent (54%) of graduates from the recently enacted Interdisciplinary Rural Training Grant program are employed in rural or frontier areas since the program began three years ago.

- Title VII funding has established geriatric education centers in 86% of the 29 states whose aged populations exceed the national average. Geriatric education centers have provided training to over 226,000 participants in the last 10 years.

- Title VII support has developed public health training projects in 40% of the states in just the past 4 years to address substance abuse, violence, HIV/AIDS, infant mortality, geriatric health care and other serious public health issues in underserved communities.

- Title VII supports graduate training in public health for over 8,000 students annually. This support targets improvement in the quality and representativeness of the public health workforce and channels graduates to positions serving underserved and high-risk populations.

Health Professions Workforce Development

- Distance-Based Learning (DBL) projects have been highly successful in providing training to allied health professionals in remote areas. For instance, 84% of the University of Nebraska Medical Center's DBL graduates are employed in underserved communities.

- Title VII funding has been instrumental in prompting an increase of more than 350% in accredited health administration programs over the past 25 years.

  - Title VII funded 80%, or over 5,500, of all graduating health administration students.

  - During this same time period, minority/disadvanteged representation in health administration increased nine-fold.

- Title VII funding was instrumental in the startup of 70% of the current podiatric primary care residency training programs.

National Health Service Corps Scholarship and Loan Repayment and Related Programs

The National Health Service Corps (NHSC) placed nearly 2,000 health professionals in underserved rural and urban areas in just the past year. On average, nearly 60% of all NHSC placements have been retained in underserved areas over the past four years.

- National Health Service Corps members provided care to over 3 million patients, and made nearly 7 million patient visits to residents of underserved urban and rural areas in just the past year.

Minority/Disadvantaged Health Professions Institutional Assistance

- Underrepresented minority enrollment in health professions schools has increased more than 200% since the implementation of Title VII funding for minority/disadvantaged programs.

- Medical schools participating in the Health Careers Opportunity Program have accepted underrepresented applicants at a rate over 20% higher than the national average over the past five years.

- The first year of implementation of the Health Careers Opportunity Post-Baccalaureate Program directly resulted in a 15% increase in the number of underrepresented minority medical school matriculants. As a result of this program, 90 additional underrepresented minorities enter medical school each year, a number equal to the first year enrollment of most medical schools.

Financial Assistance to Minority/Disadvantaged Students

- Eighty-three percent (83%) of allopathic medical, osteopathic medical, and dental schools provide Title VII financial assistance to disadvantaged students. Over 53% of disadvantaged health professions students from those institutions rely upon disadvantaged student financial assistance as their primary means of financial support to gain access to health professions schools.

Other Student Assistance

- Over 96% of all allopathic medical, osteopathic medical, and dental schools provide primary care and health professions student loans to students in need. In just the past year, over $60 million in loans were provided to nearly 11,000 students.

- Over 70% of allopathic medical, osteopathic medical, and dental schools include Health Education Assistance Loans (HEAL) as a key part of their financial assistance to students. In just the past year, nearly 12,000 students relied on HEAL loans as their primary means of financial support for attending school.

TITLE VIII

Nursing Workforce Development

- Title VIII funded more than 60% of all current nurse practitioner programs in the United States.
    - Approximately 50% of the graduates of these programs are employed in inner city and rural areas.
    - Over 75% of working nurse practitioners are in ambulatory care and outpatient settings providing primary care.
    - Nearly 50% of certified nurse practitioners provide primary care services to predominantly minority/disadvantaged patients.
    - Nearly 45% of nurse practitioners care for patient populations in areas with a high proportion of Medicaid beneficiaries (levels of 25% or more).
- Title VIII has provided substantial support to over 83% of the existing nurse-midwifery programs over the past 20 years.
    - Over 30% of the graduates of these programs started practice in underserved areas.
    - Nearly 100% of the 3,000 currently practicing nurse-midwives provide primary care services.

- Over 80% of current practicing nurse midwives devote a significant portion of their service to low-income or uninsured women.

- Title VIII has provided funding for the development and/or expansion of nearly 20% of all nurse anesthetist educational programs, and supported over 75% of nurse anesthetist graduates in the past year.

  - Nurse anesthetists provide 65% of the 26 million anesthetics administered each year.

  - Nurse anesthetists are the sole providers of anesthesia in 85% of rural area hospitals.

  - Last year, 34% of nurse anesthetists practiced in communities with populations of less than 50,000.

- The Professional Nurse Traineeship Program supported nearly 95% of the 5,845 full-time graduate nursing students. Over 35% of Title VIII supported nurse graduates over the past 3 years serve in medically underserved communities.

- Programs receiving support from Title VIII funding for minority and disadvantaged students have enrollments in which 75% of students are from minority groups, compared to the 18% national average. Over the past five years, the number of new nursing graduates from disadvantaged backgrounds rose over 24% nationally.

- Title VIII established and/or expanded over 50% of the currently operating nurse managed clinics providing care to high risk and vulnerable populations. These federally-funded clinics provided an estimated 32,000 primary care visits in elementary schools, senior citizens centers, colleges, housing complexes, homeless shelters, and other areas of need last year.

DRAFT

CLIA REGULATORY REFORM INITIATIVES

Proposal: Waive routine 2-year survey of users of certain test systems that demonstrate their accuracy and precision. This will create incentives for manufacturers to develop more reliable testing equipment by stimulating demand for accurate and precise testing systems.

Implementation: A proposed rule was published on November 14, 1995, and the public comments are being considered.

Proposal: Clarify and expand the waiver criteria and streamline the waiver process so that CLIA regulations can be waived for more tests.

Implementation: A proposed rule was published on November 13, 1995, and the public comments are being considered. In the interim, a streamlined review has already been introduced resulting in waiver of five additional test systems.

Proposal: Reward good performers with fewer inspections as a positive incentive to improve performance.

Implementation: The Health Care Financing Administration has began recertifying certain laboratories with past exceptional performance by allowing them to complete a self-survey questionnaire. Laboratories can go for 4 years without an on-site survey if they are excellent performers as compared to the usual bi-annual inspection schedule.

Proposal: Recognize private accrediting organizations and State laboratory quality programs as alternative avenues for compliance with CLIA requirements.

Implementation: Six major private organizations that accredit laboratories and two state licensure programs have been approved as alternatives to the regular CLIA program.

Proposal: Use proficiency testing "failures" for education and as an outcome indicator in laboratory quality.

Implementation: The Health Care Financing Administration is now directing laboratories which demonstrate potential testing problems by poor proficiency testing performance to obtain technical training and education to correct problems in lieu of imposing sanctions. Sanctions (such as loss of approval to perform a test) are imposed only in rare situations where a laboratory fails the same tests repeatedly or refuses to take corrective action or otherwise poses immediate jeopardy to patient health and safety.