

2007 report of major accomplishments



Message from the Secretary

Dear Colleagues,

We are in the final year together and it is important that we look back at what we have accomplished in the past year, as a guide to what we can accomplish in the days ahead and leave for the next Administration.

In 2007 the Department was at the forefront of major national issues, leading the formulation of both national and international policy. Our work has taken me to all but two states of the union and to almost every continent on earth.

The range of our accomplishments is humbling in magnitude. We negotiated landmark product safety agreements with our country's primary trading partners. We made progress on all aspects of Value-Driven Health Care. We helped our Central American neighbors by treating the poor and training new health workers for a lasting positive impact. We continue to lead the world in medical research, to lead the country in preparing for future health emergencies, and to lead the federal government in providing vital human services to families in need.

Our accomplishments flow from the strategic architecture in our updated 500-Day Plan. That plan affirms six broad visions and, as you will read, we are making clear and significant progress toward each. We have built on past successes and laid foundations for greater achievements in the coming year.

Our shared goal is to improve and protect the quality of human life. I am reminded daily that every decision we make and every action we take directly touches people's lives.

Looking back on our accomplishments, I am humbled to lead such an expert and energetic organization. Your hard work and dedication is an inspiration to me, and I am deeply thankful for all that you do.

Michael O. Leavitt
Secretary
Department of Health and Human Services

Accomplishments

Vision 1: Transform the Health care System

Vision 2: Modernize Medicare and Medicaid

Vision 3: Advance Medical Research

Vision 4: Secure the Homeland

Vision 5: Protect Life, Family, and Human Dignity

Vision 6: Improve the Human Condition throughout the World



Vision 1: Transform the Health care System

We are entering the era of patient-centered health care—an era where we approach prevention and staying healthy with the same rigor as treatment after we become sick. HHS is advancing the adoption of a health care system based on value, where people have full access to cost and quality information. We have developed a framework that helps people visualize the major requirements of value-based health care. We call this framework the Four Cornerstones. The Four Cornerstones consist of quality measures, cost groupings, interoperable electronic medical records, and incentives. We are continuing efforts to do this on the national level while also providing groundbreaking support at the community level. We are connecting our health care system to give people ownership of their health records and the choices they make.

Value-Driven Health Care: Better Care, Lower Cost

In this past year, nearly a thousand major health care purchasers and other organizations have committed to implementation of the principles of value-driven health care.

www.hhs.gov/valuedriven

1st Cornerstone: Quality Measures

Consumers need access to information regarding the quality of care they receive to make confident decisions about their health care providers and treatment options,

Quality Measurement Enterprise:

This enterprise consists of a multitude of public and private organizations working collectively to define, align, and implement quality measures. It is gritty work that is

still in the maturing process. This year, our representatives have sought to increase the clarity of roles played by the various participating organizations and increase the pace of progress. We have emphasized our commitment to adopt endorsed measures when they are available. HHS is also inventorying all the quality measures the Department is currently using. We intend to harmonize these measures and then publish the result so everyone can see our current and planned measurement thinking. We hope this will have the effect of accelerating the quality standards process.

Compare Web sites:

CMS currently makes significant quality and cost information available on its Compare Web sites for hospitals, nursing homes, home health agencies, and other providers. We also have Web sites for Medicare Advantage and the Part D prescription drug program. CMS published the Skilled Focus Facility list for poor performing nursing homes, focusing attention on greater transparency and value. CMS plans to add patient satisfaction measures to the Hospital Compare Web site in the coming months. A Physician Compare Web site is in development.

www.hospitalcomare.hhs.gov

2nd Cornerstone: Cost Groupings

Consumers also need price information to make informed decisions about health care providers and treatment options. Efforts are underway to develop standardized approaches to measuring and reporting price information for consumers. Strategies are being developed to measure the overall cost of services for common episodes-of-care and the treatment of common chronic diseases.



Posting Hospital Pricing:

CMS is now posting price information along with quality information and patient-satisfaction survey information for specific procedures on their Hospital Compare Web site. This gives consumers the tools they need to make effective decisions about the quality and value of the health care available to them at local hospitals. The new price and volume information on the Hospital Compare Web site gives consumers the ability to make informed decisions—one more way beneficiaries can help improve their health.

www.hospitalcompare.hhs.gov

Physician Resource Use Reports:

In 2007, CMS completed a project exploring physician referral and utilization patterns of high-cost imaging services. The results from this and other work by CMS are being used to inform the design of more refined and effective physician resource use reports.

Physician/Hospital Collaborative Demonstration:

Medicare has solicited bids to implement a demonstration that will establish bundled payments for hospital-based episodes of acute care. Participating hospitals will be able to competitively bid for episodes, then savings will be shared with beneficiaries who choose hospitals providing services at below the per-episode rate. This improves quality and reduces cost by encouraging physicians and hospitals to work together. It also encourages more informed consumer decision-making.

3rd Cornerstone: Health Information Technology

The first cornerstone of Value-Driven Health Care is focused on interoperable systems for sharing health information. In 2004, President

Bush set a goal for most Americans to have access to secure, interoperable electronic health records (EHR) by 2014. We have made significant progress in advancing this goal to help clinicians deliver safer, more efficient care to consumers. The keystone of our work has been harmonizing standards for interoperability among electronic health records and e-prescribing.

www.hhs.gov/healthit/

Standards for Health IT—the American Health Information Community (AHIC):

The AHIC is a federal advisory committee with broad public-private representation that makes recommendations to the Secretary on interoperability standards to allow secure information exchange between different electronic systems. The Secretary has officially recognized 50 interoperability standards recommended by the AHIC. In 2007, HHS laid the foundation to transform an AHIC-like organization to the private sector to ensure the long-term sustainability of this work. Announced in early 2008, this successor organization, AHIC 2.0, will have broad public and private representation, but will not be dependent on federal funding, prioritization and follow-up action.

Certification:

The independent, non-profit Certification Commission for Healthcare Information Technology (CCHIT) completed its second year of EHR product certification to ensure functionality, interoperability, and security for EHR products. To date, the CCHIT has certified more than 75 percent of the EHRs in outpatient settings and more than a third of the vendors with Computerized Physician Order Entry products in inpatient settings.

www.cchit.org



Advancements in E-Prescribing:
HHS launched a pilot project involving providers, pharmacies, and plans to test the first set of e-prescribing standards through CMS last year. The pilot provided valuable information on how to improve the standards, and CMS proposed a rule to adopt new standards for aspects of e-prescribing under the Medicare Prescription Drug Benefit and Medicare Advantage plans. If this rule is adopted, all providers and pharmacies transmitting Medicare prescriptions electronically will be required to comply with the standards resulting in significant error reductions and cost savings.

The Department also supported bipartisan legislation to encourage e-prescribing through Medicare payment incentives. E-prescribing is critical to enable safe, high-quality medication use. AHRQ and the CMS collaborated on electronic prescribing pilot projects that supported the adoption of electronic prescribing standards.

Electronic Health Record Demonstration:
In 2007, HHS developed a groundbreaking demonstration program to expand adoption of electronic health records. Under this program, launched in early 2008, Medicare will provide financial incentives to as many as 1,200 physician practices if they can demonstrate that they deliver higher quality of care for their patients using certified, interoperable EHRs. The demonstration is designed to show that widespread adoption and use of interoperable EHRs will reduce medical errors and improve the quality-of-care for an estimated 3.6 million Americans.

Health IT and Telemedicine for Health Centers and Rural Communities:
HRSA awarded more than \$56 million

in 63 new grants to advance health IT and telemedicine in health centers and critical access hospitals in 35 states and the District of Columbia. These awards will support EHRs in more than 170 health centers representing over 900 sites and serving more than two million patients. This will help to establish 16 regional health-information exchange pilots that electronically link care providers with patients in rural communities.

www.hhs.gov/secretary/connecthealthcare

Electronic Health Records for the Indian Health Service (IHS):

IHS deployed EHRs at 116 IHS and tribally operated health care sites to improve health care quality and patient safety for American Indians and Alaska Natives.

www.ihs.gov/CIO/EHR/

4th Cornerstone: Incentives

All parties—providers, patients, insurance plans, and payers—should participate in arrangements that reward those who purchase, provide, and consume high-quality, competitively priced health care. Such arrangements may include implementation of pay-for-performance methods of reimbursement for providers or the offering of consumer-directed health-plan products such as account-based plans for enrollees in employer-sponsored health benefit plans.

Value-based Purchasing:

Building on the Secretary's Four Cornerstones and pursuant to a Deficit Reduction Act of 2005 requirement, CMS is proposing a plan for hospital value-based purchasing (VBP). Through the use of VBP performance-based incentives and quality transparency, CMS will be transformed from a passive payer to an active purchaser of care for millions of Medicare beneficiaries.



Physician Quality Reporting Initiative:
On December 29, 2007, the President signed the Medicare, Medicaid, and SCHIP Extension Act of 2007, which authorized the continuation of the Physician Quality Reporting Initiative (PQRI) for 2008. The PQRI awards a 1.5% bonus payment (subject to cap) to physicians who voluntarily report applicable consensus-based quality measures. The 2008 version has an additional 45 measures bringing the total number of measures to 119.

Medicare Care Management Demonstration:

On July 1, 2007, CMS launched this demonstration, which provides financial incentives for small to medium-sized physician practices based on their performance on 26 clinical quality measures. Payments are enhanced if the quality data are submitted through a CCHIT-certified EHR.

Medicare Trigger Legislation:

Medicare spending in 2007 triggered a statutory obligation for the President to respond with legislation to establish Medicare solvency. Early in 2008, HHS submitted legislation on behalf of the President that supports the principles of value-driven health care and lays a foundation for the comprehensive Medicare reforms necessary to strengthen and improve the program for future generations.

<http://www.hhs.gov/asl/medicarefundingwarninglegislation.pdf>

Chartered Value Exchanges:

The Agency for Healthcare Research and Quality (AHRQ) has developed a framework for encouraging the implementation of national standards in communities across the country. This involves working through community-based multi-stakeholder collaboratives

nationwide, called Chartered Value Exchanges (CVEs). The first application period was held in the late fall 2007, resulting in an inaugural class of 14 CVEs, chartered on February 1, 2008. They will participate in a nationwide Learning Network sponsored by AHRQ. The Learning Network will provide peer-to-peer learning experiences through facilitated meetings, both face to face and on the Web. The network also features tools, access to experts, and an ongoing private Web-based knowledge management system. Additionally, CMS will begin sharing performance measurement results with CVEs later this year in support of local efforts to measure, report, and improve health care.

www.hhs.gov/valuedriven/communities/valueexchanges/exchanges

Personalized Health Care Defined

Secretary Leavitt launched the Personalized Health Care Initiative to define a vision of individualized approaches to patient care employing the emerging capabilities of genomic medicine and health IT. HHS also published *Personalized Health Care: Opportunities, Pathways, Resources*, inventorying HHS resources and identifying pathways toward achieving health care that could be more effective by being more patient-centric and individualized.

www.hhs.gov/myhealthcare

FDA Focuses on Personalized Health Care

FDA approved the first cleared molecular test that profiles genetic activity. The test determines the likelihood of breast cancer returning within five to 10 years after her first bout with cancer. FDA also further advanced its Critical Path Initiative to stimulate and facilitate the modernization of the scientific process transforming a discovery or “proof of concept” into a medical product.



Expansion of Care for People with HIV/AIDS

HHS awarded the first grants under the newly reauthorized Ryan White HIV/AIDS Program, which provides HIV/AIDS care and treatment for 530,000 low-income Americans. For the first time, no individual with HIV/AIDS is on a state-based waiting list to receive medications funded under HRSA's AIDS Drug Assistance Program (ADAP). In addition, CDC awarded \$35 million in funding to state and local health departments to increase HIV testing opportunities among populations disproportionately affected by HIV. This program seeks to test more than one million people.

www.aids.gov

Prevention

HHS initiated development of the first ever national Physical Activity Guidelines, which will provide science-based recommendations on the latest knowledge about activity and health, with depth and flexibility to target specific population subgroups, such as seniors, children, and persons with disabilities. The Surgeon General also launched a new Childhood Obesity Overweight and Obesity Prevention Initiative to raise national awareness of childhood obesity and to coordinate and expand existing federal childhood overweight and obesity prevention programs.

www.health.gov/paguidelines

www.healthierus.gov

Vision 2: Modernize Medicare and Medicaid

The heart of our Medicare and Medicaid modernization is to design a financially sustainable program providing high-quality health care to our seniors, the disabled, and those of low income—the most vulnerable

populations. We want to design a Medicaid program that is flexible so that benefits are tailored to needs, allowing millions more to obtain insurance.

Medicare Prescription Drug Coverage (Part D)

In its second year, the total number of Medicare beneficiaries enrolled in the Part D program has reached 24 million. Program satisfaction rate is at 87 percent. In addition, in large part due to strong, competitive bids by health care plans for 2007, average monthly premiums were approximately \$22 for beneficiaries, down from \$23 in 2006, for enrollees remaining in their current plans. Program costs are 30 percent less than predicted.

www.medicare.gov/pdphome.asp

Evaluating and Improving Medicare's Quality

The Centers for Medicare & Medicaid Services (CMS) continues to improve several aspects of traditional Medicare. As a result of strong efforts in oversight and fraud prevention, in 2007 the vast \$425 billion Medicare program experienced an estimated error rate of less than 4 percent. This decline in the error rate is the result of a continuing commitment to payment system accountability and integrity. CMS has also implemented new rules and efforts emphasizing value and quality for Medicare payments for inpatient, outpatient, and rehabilitation hospitals, home health and long-term care services. CMS continued its aggressive waste, fraud, and abuse initiatives and completed the second year of the recovery audit program. Specific programs include enhanced collaborations with the U.S. Department of Justice and the HHS Office of the Inspector General.

www.cms.hhs.gov/MedicareContractingReform

Transforming Medicaid

In 2007, Medicaid and SCHIP helped to finance the health care of 57 million low-income Americans. CMS has taken numerous



steps to increase accountability and flexibility in the Medicaid program, preserving scarce Medicaid dollars for the nation's poorest, most vulnerable citizens rather than reimbursing states for questionable schemes long-criticized by both the HHS Inspector General and the Government Accountability Office. In addition to more stringent oversight of the rules, CMS has increased program integrity efforts while providing flexibility to improve care for beneficiaries.

CMS has implemented an error-rate monitoring program similar to Medicare's, reformed the reimbursement for intergovernmental transfers between government health care facilities and the state, increased accountability in Targeted Case Management and school-based claims, and implemented state and beneficiary flexibility with the approval of transformation grants. In 2007, 12 states received approval of innovative reform plans incorporating many of the new flexibilities granted to Medicaid programs in the 2005 Deficit Reduction Act (DRA). Through the use of the transformation grants, states are working with CMS to create programs that are more aligned with today's Medicaid populations and health care environment. Since January 2007, through two rounds of competitive solicitations, \$150 million has been awarded to state Medicaid agencies in 36 states and Puerto Rico.
<http://www.cms.hhs.gov/MedicaidTransGrants/>

Preserving the Children's Health Care Program for the Poorest Children

We continued to support the President's proposal to reauthorize the SCHIP program to ensure appropriate coverage of children who are eligible. HHS helped maintain responsible and effective use of this program by preventing the enactment of proposals for greatly expanding a government-run health care program. The legislative proposals would have resulted in inefficient use of federal dollars and

diverted funds to children in middle income brackets who already have private health insurance.

www.hhs.gov/everyschipschipped/schip

Vision 3: Advance Medical Research

Our complimentary goals are to focus research on identified health care needs, and to speed the process by which viable research results benefit people in need. We are striving to have medications that are safer and more effective because they are chosen based on the personal characteristics of the patient. We are focusing on breakthroughs that protect Americans from a broad range of threats.

NIH Invests More in New Research

NIH awarded 10,100 competing research project grants, an 11 percent increase over grants in 2006. Of these, 7,320 were new research grants, an increase of close to 15 percent over 2006. Close to 1,600 of the new research grants were R01-equivalent grants to first-time NIH investigators. The funding rate of applicants with no prior support on an R01-equivalent grant was 21 percent. This represented a significant increase over the funding rate for such applicants in 2006, which was less than 17 percent.

NIH Projects Advance Research & Discovery in Personalized Health Care

The NIH-supported International HapMap Consortium completed the second-generation map of human genetic variation (Phase II HapMap) in October 2007. This higher resolution map offers greater power to detect genetic variants involved in common diseases, explore the structure of human genetic



variation, and learn how environmental factors have shaped the human genome. NIH continues its Genes, Environment and Health Initiative (GEI), to perform genetic analyses and development of innovative approaches to measuring environment—including diet, exercise, and psychosocial stress. In September 2007, the NIH funded the initial GEI projects: eight genome-wide association studies, two genotyping centers, a coordinating center, and more than 30 environmental technology projects.

Focus on Multi-drug Resistant Diseases

NIH's National Institute of Allergy and Infectious Diseases (NIAID) set its research agenda for MDR/XDR TB, building on a foundation of more than 300 NIAID-supported TB research projects worldwide. CDC published a landmark study that estimates 94,360 life-threatening MRSA infections in 2005 and a growth in community-associated MRSA infections. FDA cleared the first rapid blood test for MRSA (methicillin-resistant *Staphylococcus aureus*), which can cause potentially deadly infections.

Expansion of Access to Clinical Trials for Cancer

NIH's National Cancer Institute (NCI) launched a three-year pilot Community Cancer Centers Program to extend the reach of NCI research into more U.S. states, cities, and towns, including rural areas and inner cities. The pilot project will focus on bringing more Americans into a system of high-quality cancer care, increasing participation in clinical trials, and reducing cancer health care disparities. NCI has selected 16 community hospitals in 14 states to participate in the pilot program.

CDC Researchers found possible animal source of Marburg virus

In August, scientists at CDC and their collaborators successfully identified Marburg

virus infection in a common species of African fruit bat (*Rousettus aegyptiacus*). This effort supports the goal to protect Americans at home and abroad from health threats through a transnational prevention, detection and response network. Marburg virus causes severe, often fatal, hemorrhagic fever in humans and other primates.

HHS Announced Autism Coordination Efforts

HHS Secretary Michael Leavitt convened the new Interagency Autism Coordinating Committee, authorized by the Combating Autism Act of 2006. NIH continues to make progress in uncovering possible causes of autism. One NIH-sponsored study shows a variation in the gene CNTNAP2 may raise the risk of developing autism. A second study shows tiny gene mutations, each individually rare, pose more risk for autism than had been previously thought. CDC published a significant study finding an average of 6.6 and 6.7 per 1,000 eight-year-olds in assessed communities have an autism spectrum disorder.

www.hhs.gov/autism/

Alternatives to Human Pluripotent Stem Cells

NIH announced a plan to implement President Bush's Executive Order to explore methods to expand the number of approved pluripotent stem cell lines "without creating a human embryo for research purposes or destroying, discarding, or subjecting to harm a human embryo or fetus." NIH announced new funding opportunities to aggressively pursue new or accelerated research on alternative sources of pluripotent stem cell lines. In a separate development, an NIH-funded research team led by Dr. James Thomson and a separate team led by Dr. Shinya Yamanaka were able to demonstrate successful reprogramming of somatic cells into induced pluripotent stem cells, a major scientific advance.



Vision 4: Secure the Homeland

Our goal is to seamlessly and rapidly provide resources and public health personnel when needed anywhere in the United States. Our outreach activities focus on bolstering state and local ability to help themselves and others in the event of a biological attack, pandemic influenza, or other major health emergency.

Pandemic Influenza Preparedness

Two years ago, the President called upon the nation to prepare for an influenza pandemic. The response has been unprecedented and the progress considerable.

www.pandemicflu.gov

Influenza Antiviral Drugs:

Reached the national pandemic preparedness influenza antiviral drug treatment goal of 50 million treatment courses by purchasing 12.6 million treatment courses of Tamiflu® and Relenza®, from Roche and GlaxoSmithKline, respectively, for the Strategic National Stockpile. To date, 37.8 million treatment courses have been received by the Stockpile, and the remaining 12.2 million treatment courses are due by the end of January 2008.

H5N1 Vaccine:

Licensed the first vaccine against an H5N1 human influenza virus in April 2007. *Time Magazine* rated this work as the number one global health care advancement in 2007. Awarded contracts totaling \$133 million for retrofitting existing domestic manufacturing facilities for the production of pandemic influenza vaccines in Jan. 2007.

Cell-based Vaccine:

Supported the design and construction of the first cell-based influenza vaccine

manufacturing facility in the U.S. started by Novartis in July 2007.

PREP Act:

Issued the first PREP Act declaration in January 2007 and an amendment in November 2007. This provided liability immunity to manufacturers, distributors, program planners, and qualified persons who prescribe, administer, and dispense H5, H7, and H9 influenza vaccines.

Advanced Development:

Awarded new contracts totaling \$240 million for advanced development of three antigen-sparing influenza vaccines and an antiviral drug toward U.S.-licensure, reaching a total of 10 contracts at \$1.55 billion for advanced development of pandemic influenza medical countermeasures.

Antigen-Adjuvant Study:

Used the anti-trust exemption provided by Pandemic and All-Hazards Preparedness Act for the first time in June 2007 in the planning and execution of a joint BARDA H5N1 vaccine antigen-adjuvant study with NIH, CDC, and industry vaccine partners.

Cooperative Agreement in Panama:

Funded and managed a Cooperative Agreement with the Gorgas Memorial Institute in Panama to build institutional capacity in pandemic influenza field surveillance.

Emergency Response

The September 11th 2001 attacks and Hurricanes Katrina, Rita, and Wilma were devastating events. HHS has taken several important steps to ensure our nation can respond to the health and human service needs of Americans in the wake of a natural disaster or terrorist attack.



Anthrax Vaccine:

Contracted for 18.5 million doses of Anthrax Vaccine Adsorbed (\$450 million) to be stockpiled primarily for protection of first responders to a naturally occurring, accidental, or terrorist-induced anthrax incident. Contract includes extension of the shelf life to four years and eventually five years.

Smallpox Vaccine:

Approved ACAM 2000, a second-generation smallpox vaccine, for inoculation of people at high risk of exposure to smallpox. This vaccine is stored in the Strategic National Stockpile and could be used to protect populations in the wake of a bioterrorism attack. This vaccine is produced using modern cell culture technology, thereby allowing for rapid and large-scale production with consistent product quality.

Strategic National Stockpile:

Enlarged the antibiotic holdings of the Strategic National Stockpile to 60 million 60-day treatment courses. These antibiotics would be the first line of defense against a bioterrorism attack involving the organisms that cause anthrax, plague, and tularemia.

Operational Drills:

Conducted successful real-time, operational drills in Philadelphia and Boston of the Cities Readiness Initiative postal module. These drills, which targeted approximately 53,000 and 23,000 residences, respectively, and built on results of the first drill of this type (in Seattle in November 2006).

Emergency Deliveries:

Provided proof-of-concept for use of the United States Postal Service carriers and local law enforcement escorts to effect direct emergency delivery of antibiotics to every residence in a large geographic area within one day of a bioterrorism attack.

Food Safety

Americans rightly expect that the food they find on store shelves is safe to eat, and HHS has led national efforts to improve food safety, through the work of the Food and Drug Administration and the Department's support for the President's Working Group on Import Safety, which Secretary Leavitt chaired.

www.importsafety.gov

Import Safety Web site:

Created a Web resource for all federal import safety activity. The cross-departmental Web site includes recall information and the latest reports from the Import Safety Work Group.

New Plans to Improve the Safety of Food and Imports:

In November, Secretary Leavitt delivered to the President the Action Plan for Import Safety containing 14 broad recommendations and 50 action steps that provide a road map for better protecting American consumers and enhancing the safety of the increasing volume of imports entering the United States. That same month, the FDA unveiled its new Food Protection Plan. The plan is a strategic and comprehensive approach to improve food safety and defense in the United States. Its core elements—prevention, intervention, and response—incorporate four cross-cutting principles for comprehensive food protection along the entire production chain.

FDA Responds Rapidly to Pet Food Recall:

FDA conducted the largest emergency response in FDA history when faced with melamine contamination of pet food. FDA coordinated a widespread investigation and massive recall of over 5,300 pet food products by several major companies that resulted following the reports of illnesses and death of both cats and dogs. FDA



laboratories analyzed more than 1,500 samples of finished products and raw materials of which 583 samples were found positive for melamine and analogs. The Prior Notice Center conducted approximately 73,000 import security reviews to identify and intercept potentially contaminated food and animal food/feed products before they entered the U.S. FDA investigations into the melamine contamination of pet food resulted in criminal indictments of several corporations and individuals.

Memorandum of Agreement between HHS and China:

Secretary Leavitt joined his counterparts from the People's Republic of China in signing two binding Memoranda of Agreement on the safety of food, feed, drugs and medical devices. These agreements will enhance the safety of hundreds of household items imported from China that the American people consume on a daily basis.

FDA Focuses Initiatives on High-Risk Produce:

In 2007, FDA issued final guidance on the safe production of fresh-cut produce and low-acid juices. FDA continued its efforts on the Leafy Greens Initiative and launched the Tomato Safety Initiative in conjunction with state health and agriculture departments in Virginia and Florida, and in cooperation with several universities and members of the produce industry.

Trilateral Declaration for Mutual Assistance During a Public Health Emergency

The Health Ministers of Mexico and Canada joined Secretary Leavitt in Washington, D.C., to sign a Trilateral Declaration for Mutual Assistance during a Public-Health Emergency. The Declaration establishes a plan for the three

countries to provide mutual assistance in the event one (or more) of them faces a public-health emergency. It is a major step toward implementing the North American Plan for Avian and Pandemic Influenza, completed in August 2007.

Responding to Virginia Tech

The President directed top officials at the Departments of Education, Justice, and Health and Human Services to participate in a federal review of the broad questions raised by the shooting tragedy at Virginia Tech. Secretary Leavitt led the effort to report back to the President with recommendations about helping to avoid such tragedies. The *Report to the President on Issues Raised by the Virginia Tech Tragedy* addresses the issue from the perspectives of law enforcement, schools, health providers, and families.

www.hhs.gov/vtreport.html

Vision 5: Protect Life, Family, and Human Dignity

HHS programs emphasize dignity and respect for the care of senior citizens and those with disabilities. Our work supports a culture of life and family that encourages prevention and self-reliance.

Increasing Access to Safe and Effective Medical Products

In September 2007, President George W. Bush signed into law the Food and Drug Administration Amendments Act of 2007, giving FDA additional resources, responsibilities, and authority to ensure our pharmaceuticals and medical devices are safe and effective. The Act grants FDA new authorities to focus on the entire life-cycle of medical products, including post-approval.



FDA has taken other important steps to ensure safe drugs, including creating a new web-based newsletter entitled “Drug Safety Newsletter” and establishing a new Risk Communication Advisory Committee to provide expert advice on communicating with the public.

Action Against Unapproved and Counterfeit Drugs

FDA initiated 31 counterfeit drug investigations in 2007, resulting in 75 arrests and 53 convictions with fines and restitutions in excess of \$25,225,126. FDA also warned consumers of 24 Web sites possibly involved in the distribution of counterfeit drugs. FDA took action against approximately 100 firms for marketing some 200 unapproved products. FDA and FTC also worked with partners in Mexico and Canada to stop deceptive Internet promotions of fraudulent products to treat or cure diabetes.

Record Number of Generic Drug Approvals

FDA approved a record 682 new generic drugs—a 33-percent increase over the previous year. These approvals were completed despite a continuing increase in workload, with FDA receiving almost 900 new original applications in FY 2007. FDA also launched the Generic Initiative for Value and Efficiency (GIVE), to help FDA modernize and streamline the generic drug approval process.

Response to Hurricanes Katrina, Rita, and Wilma

HHS provided \$370 million in grant funds in 2007 to improve health care in areas affected by Hurricane Katrina. To date, HHS has provided the region with more than \$2.5 billion in funding for social services, health care and efforts to rebuild the health care system in the Gulf Coast region.

Access to Recovery (ATR)

SAMHSA expanded Access to Recovery, a key substance abuse treatment and recovery program that enables broader participation

of faith-based and community organizations in service delivery with a voucher payment mechanism, expanding system capacity and consumer choice. SAMHSA awarded ATR grants totaling \$96 million to 18 States, 5 tribal organizations, and the District of Columbia. <http://atr.samhsa.gov/>

Temporary Assistance for Needy Families (TANF) Welfare Reform Implementation

The TANF program focused increased efforts on building stronger families through work, job advancement and research on programs promoting healthy marriages and responsible fatherhood. The renewed emphasis by the States on productive work requirements continues to yield positive results, including the decline in families receiving cash assistance. By June 2007, the number of families receiving cash assistance from TANF had fallen to 1.67 million, the lowest level of welfare participation recorded since 1968.

www.acf.hhs.gov

Nursing Home Diversion Program

The Administration on Aging selected 20 states to receive Nursing Home Diversion Modernization Grants, and 12 states received funding totaling \$8.8 million. This grant program encourages states to transform their existing OAA and state revenue funds into flexible service dollars to provide individuals and their family caregivers with options to get the services and support they need.

http://www.aoa.gov/press/pr/2007/September/9_24_07.asp

The Mentoring Children of Prisoners (MCP)

The MCP program matched 28,256 children of prisoners with mentors in fiscal year 2007, more than any previous year. The program remains on track to reach its target of 100,000 matches in 2008. Moreover, annual interviews show that 90% of the children surveyed report satisfaction and happiness with their mentoring relationships. This is a five-point increase over fiscal year 2007.



Healthy Marriage Initiative

In support of the Department's Healthy Marriage Initiative, ACF debuted the publication, *Building Assets * Building Stronger Families*, to highlight the need for couples to communicate openly and effectively with each other about personal finances. HHS also created the first-ever National Center for Marriage Research at Bowling Green State University to improve our understanding of how marriage and family structure affect the health and well-being of individuals, families, children and communities.

<http://aspe.hhs.gov/hsp/news/NCMR07.htm/>

Federal Response to Homelessness

In March 2007, Secretary Leavitt assumed the Chairmanship of the U.S. Interagency Council on Homelessness for a one-year term. Secretary Leavitt released a Strategic Action Plan on Homelessness which outlines a set of goals and strategies to guide the Department's activities in addressing how individuals, youth, and families experiencing homelessness can be better served through the coordinated administration of departmental resources.

<http://www.hhs.gov/homeless>

Vision 6: Improve the Human Condition throughout the World

HHS is intensely involved in international efforts to monitor, plan, and prepare for the potential of a flu pandemic. We are working at reducing HIV/AIDS around the world and expanding our efforts to have an international network of early-warning infectious disease surveillance. The Department is supporting emerging

democracies with health diplomacy, care, and compassion.

U.S.-China Strategic Economic Dialogue and HIV/AIDS

Health officials in the U.S. and China renewed a Memorandum of Understanding to cooperate in the field of HIV/AIDS, as part of President Bush's Emergency Plan for AIDS Relief. Joint bi-national efforts will strengthen Chinese disease-surveillance, laboratory capacity, support confidential, voluntary counseling and testing, and develop care and treatment activities for Chinese communities.

Strengthening Central American Public Health Systems

In Washington, D.C., Secretary Leavitt and the Ministers of Health of the Republics of Panama, Honduras, Costa Rica, Guatemala, Nicaragua, and El Salvador signed a Memorandum of Understanding to strengthen public-health surveillance, laboratory systems, and response capacity in the Central American region, and to support the Regional Health care Training Center in Panama City, Panama.

Peleliu Pacific Partnership Humanitarian Mission

Commissioned Corps officers from the HHS U.S. Public Health Service joined the U.S. Navy's *Peleliu Pacific Partnership* humanitarian mission. The *Peleliu* served as an enabling platform from which U.S. Government personnel and non-governmental partners carried out humanitarian efforts in several South-East Asian nations. Mission personnel treated 4,200 patients, performed 63 surgeries, and provided 2,098 pairs of eyeglasses.

Health Agenda for the Americas

HHS was the USG lead in an 18-month negotiation to establish a Health Agenda of the Americas, 2008-2017, to guide the actions of stakeholders who seek to improve health in the



Americas. The Governments of the hemisphere approved the Agenda emphasizing universality, access, and equity, and Pan American solidarity as important to promoting better health.

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USNS Comfort

On June 15, the USNS Comfort set sail on its 120-day humanitarian mission to 12 Latin American and Caribbean ports. A cadre of 70 Commissioned Corps Officers from the U.S. Public Health Service (PHS) joined Navy personnel in providing medical and dental care to 85,000 patients and performing 1,500 surgeries.

Regional Health care Training Center (RHCTC) in Panama

With the Minister of Health of Panama, Secretary Leavitt formally opened the Regional Health care Training Center (RHCTC) in Panama City, Panama. The Center held its first four training courses in 2007, teaching 200 students the clinical, epidemiological, and laboratory aspects of highly pathogenic avian influenza, and related preparedness and response to a potential influenza pandemic.

Response to Ebola Outbreaks in Congo and Uganda

The HHS Office of Global Health Affairs and the HHS CDC worked together to deploy teams of epidemiologists and laboratory scientists to assist the World Health Organization and the Governments of the Democratic Republic of the Congo and the Republic of Uganda in investigating and containing outbreaks of Ebola Hemorrhagic Fever in those countries, where they established field laboratories to speed diagnosis of the disease.

