

2008 report of major accomplishments



Message from the Secretary

Dear Colleagues,

As we reflect on our accomplishments from the last year, I am amazed and humbled. The dedication and hard work of every employee in every office in our vast Department has helped to make our country, and our world, a healthier, safer, and more compassionate place.

We have left things better than we found them, and we have laid the groundwork for future improvement. I've learned that public service is a generational relay. We took the baton from one generation; we'll hand the baton to another. The measure of our success is the remarkable distance we have moved the baton during our tenure.

Change is inevitable, but one thing won't change, and that is the deep sense of friendship and gratitude that all of us feel. I have been honored to have this opportunity to lead this great Department and to work alongside each of you. Whether you are staying or leaving, we are all now facing an exciting new time of change, and you know how I feel about change: You can fight it and fail, you can accept it and survive, or you can lead it and prosper.

Thank you for your dedication to the health and safety of the American people.

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 care system to give people ownership of their health records and the choices they make.

Patient Safety Regulation

AHRQ issued a final rule permitting the establishments of Patient Safety Organizations (PSOs). The final rule provides final requirements and procedures for PSOs, new entities, with which clinicians and health care providers can work to collect, aggregate and analyze data -- within a legally secure environment of privilege and confidentiality protections -- to identify and reduce patient care risks and hazards. PSOs are authorized by the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act).

The Patient Safety Act is intended to encourage voluntary, provider-driven initiatives to improve the safety of health care through the establishment of legal protections to ensure that providers who report patient safety information

do not incur new legal liability; to promote rapid learning about the underlying causes of risks and harms in the delivery of health care; and to share those findings widely, thus speeding the pace of improvement. <http://www.pso.ahrq.gov/>

Physical Activity Guidelines and Dietary Guidelines

HHS released the first ever comprehensive National Physical Activity Guidelines to educate the public about the minimal levels of activity necessary to maintain a healthy existence. The Guidelines provide science-based information to help all Americans aged 6 years and older improve their health through appropriate physical activity. HHS also published the bilingual "Road to a Healthy Life, Based on the Dietary Guidelines for Americans" for Hispanics and Latino families nationwide. www.health.gov/PAGuidelines

Value-Driven Health Care (VDHC) Initiative

HHS continues to encourage the implementation of national standards in communities across the country. HHS officials met with CEOs from Fortune 100 Companies, officials in pilot cities, and Governors. So far, 800 private sector companies, health care organizations, advocacy groups, as well as state, local and tribal governments pledged their support for the principles and goals of this important initiative. www.hhs.gov/valuedriven

1st Cornerstone of VDHC: Quality Measures

Quality Measurement Inventory Project
HHS conducted an inventory of all quality measures in the department that are currently used or those that will be used within the next three years. More than 1500 measures were identified and compiled through this process.

Standards in E-Prescribing

In April 2008, HHS finalized new



standards for several aspects of e-prescribing, including formulary and benefit transactions, medication history transactions, and fill status notifications. These standards built on foundational standards HHS published in late 2005.

All providers and pharmacies transmitting Medicare prescriptions electronically are required to comply with the standards, which will enable significant error reductions and cost savings. Furthermore, drug plans participating in the Medicare prescription drug benefit are required to support electronic prescribing using these standards.

HHS also took steps to implement a change in Medicare payments to physician practices that provides a financial incentive to e-prescribe. HHS held a two-day e-prescribing conference in October to raise awareness for these new payment incentives and encourage greater e-prescribing use. Through the new standards and payment incentives, HHS anticipates greater adoption of e-prescribing to enable safe, high-quality medication delivery and use.

American Health Information Community
Over the past three years American Health Information Community (AHIC), a Federal Advisory Committee established by the Secretary to provide key stakeholder input into a standards harmonization process, recommended more than 100 standards to the Secretary. The AHIC successfully designed the sun-setting of the federal organization and the establishment and transition of a successor organization to carry on this standards work indefinitely in the private sector. www.hhs.gov/healthit/community/background

Health care Information Technology Standards Panel (HITSP)

The Health care Information Technology Standards Panel (HITSP) continued its work to advance harmonization of interoperability standards. Fifty-two interoperability standards for medical history, laboratory result reporting, and biosurveillance were publicly recognized by the HHS Secretary in January 2008.

2nd Cornerstone of VDHC: Cost Groupings

Compare Web sites

CMS continues to post pricing and volume information, quality information, and patient experience of care survey information for specific hospital procedures on the Hospital Compare website. In March, patient experience of care information was added to the site. The information was gathered from Hospital Consumer Assessment Health Plans Survey (HCAHPS) of more than 2,500 hospitals. HCAHPS is the first national, standardized, publicly reported survey of patient perspectives on care during a hospital stay. Next year, CMS will update this information with the results from 3,900 hospitals that are currently collecting data. CMS also launched a five-star nursing home rating system of the quality and safety information on Nursing Home Compare. CMS is exploring ways to make quality information about physicians available.

Physician Resource Use Reports

CMS studied the way two commercially available tools group Medicare claims into episodes-of-care. This work resulted in a foundation for implementing the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) requirement to provide some portion of physicians confidential resource use reports.



Acute Care Episodes Demonstration
Medicare solicited bids to implement a demonstration that will test the use of a bundled payment for both hospital and physician services for a select set of hospital-based episodes-of-care involving certain cardiac and orthopedic procedures. Participating hospitals will be able to competitively bid for episode-based bundled payments and share savings with physicians who collaborate with the hospital to better coordinate care and generate efficiencies resulting in savings below the per-episode rate.

Value-based Purchasing
The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), enacted in July, 2008, extends the funding for Physician Quality Reporting Initiative (PQRI) through 2010. Work has begun on a Physician Value Based Purchasing Plan as required by MIPPA. Similar to the Hospital Value Based Purchasing Plan, the Physician Plan will include both performance-based incentives and quality transparency. HHS also instituted a Nursing Home Value Based Demonstration in 2008.

Health care Cost and Utilization Project
Research using the AHRQ's Nationwide Inpatient Sample (NIS) data from the Health care Cost and Utilization Project (HCUP) has helped the Centers for Disease Control and Prevention monitor pneumococcal disease and update national pneumonia and acute respiratory infection hospitalization rates in children. The HCUP-NIS was used to compare the rates of pediatric all-cause and pneumococcal pneumonia admissions before and after introduction of the pneumococcal conjugate vaccine. This vaccine is recommended for all children younger than 59 months. The

HCUP data was able to answer questions about pneumonia cases that could not be answered with laboratory-based surveillance. <http://www.ahrq.gov/data/hcup/>

3rd Cornerstone of VDHC: Health Information Technology

Federal Health IT Strategic Plan: 2008 – 2012

HHS released the first coordinated Federal Health IT Strategic Plan which includes the health IT activities of 18 federal departments and agencies. This comprehensive plan sets forth goals, objectives, and strategies that, for the first time, established an approach for coordinating all federal efforts in health IT.

Personal Health Records Pilots

HHS began implementation of a Medicare Choice Personal Health Records pilot in Utah and Arizona. This pilot will provide several Personal Health Records (PHRs) options to Medicare beneficiaries in the two States and will assess consumer use and satisfaction with PHRs as well as resulting health outcomes. HHS also began an evaluation of Medicare's Electronic Personal Health Records pilots for fee-for-service beneficiaries in South Carolina. The evaluation is still underway but aims to assess PHR adoption rates among consumers, satisfaction rates, and the impact of health care utilization and quality of care.

Privacy Advances in Health IT

Public trust is crucial to achieving widespread participation in, and building public demand for, Health IT; and privacy is the key to creating that trust. HHS developed a privacy and security framework for electronic health information exchange (eHIE) and drafting guidance to address the application of



the HIPAA Privacy Rule to eHIE. The AHIC Confidentiality, Privacy, and Security Workgroup presented to the AHIC two recommendation letters which together included more than 10 recommendations related to electronic health information exchange and health IT.

Electronic Health Records

The Secretary Announced 12 Electronic Health Record Medicare demo sites to incentivize and facilitate the adoption of EHRs. CCHIT has also certified nearly 60 percent of inpatient EHR vendors representing over 75 percent of that market; and, has certified over 50 percent of ambulatory EHR product vendors representing over 75 percent of that market. In September 2008, the Nationwide Health Information Network (NHIN) successfully demonstrated the real-time electronic exchange of test data with 15 private-sector entities and DOD, VA, SSA. A nationwide survey and analysis of the survey published in the New England Journal of Medicine in July 2008 indicates that 17 percent of physician offices have an EHR that meets minimal functional capabilities. The Office of the National Coordinator and Office of Management and Budget, compiled an inventory of systems, contracts, and grants that exchange or provide money to support the exchange of health information which identified over 1,400 federal systems, contracts, and grants. <http://www.hhs.gov/healthit/framework.html>

4th Cornerstone of VDHC: Incentives Physician Group Practice Demonstration
With this three year demonstration, which was extended for a fourth year through March 2009, CMS is rewarding

physician groups for improving patient outcomes by proactively coordinating their patients' total health care needs, especially for beneficiaries with chronic illnesses. At the end of the second performance year, all 10 of the participating physician groups continued to improve the quality-of-care for their patients and earned performance payments totaling \$16.7 million.

Medicare Care Management Demonstration

In July 2007, CMS launched this demonstration to improve the quality-of-care for chronically ill Medicare beneficiaries while encouraging the implementation and adoption of health information technology by primary care physicians. Under this demonstration, physician groups will receive financial incentives based on performance on 26 clinical quality measures related to the care of beneficiaries with diabetes, congestive heart failure, coronary artery disease, and preventive care services. They will also be eligible to earn additional bonuses if the quality measure data is submitted electronically from a Certification Commission for Health Care Information Technology (CCHIT)-certified electronic health record.

Chartered Value Exchanges (CVEs)
An additional ten new Chartered Value Exchanges were certified in 2008. The 23 local private-public collaboratives of providers, health plans and consumers, and in some cases state data organizations, Quality Improvement Organizations, and health information exchanges, are committed to publicly reporting cost and quality information in their communities, and working in tandem to improve quality and value.



The CVEs participate in a nationwide Learning Network sponsored by AHRQ. In October 2008, CMS provided the CVEs with physician group practice quality performance measurement results to help support and expand local efforts. <http://www.ahrq.gov/qual/value/localnetworks.htm>

Efforts to Reduce Hospital Acquired Conditions

In accordance with the Deficit Reduction Act, CMS reduced Medicare payments for hospital-acquired conditions. CMS also proposed three National Coverage Decisions which would deny coverage for certain “never events.” Linking a payment incentive to hospitals’ prevention of HACs will combat HACs and lead to lower morbidity, mortality, and costs. CDC also piloted projects locally to prevent MRSA infections, leading to more than 60 percent reductions in MRSA infection rates in intervention units.

Revisions to Drug Label Proposed

In May 2008, the FDA proposed major revisions to prescription drug labeling to provide more complete information about the effects of medicines used during pregnancy and breast-feeding. The proposed changes to physician labeling would give health care professional better information for making prescribing decisions and for counseling women who are pregnant, breast-feeding, or of child-bearing age. http://www.fda.gov/CDER/regulatory/pregnancy_labeling/default.htm

Genetic Information Nondiscrimination Act Signed

On May 21, 2008, resident Bush signed the Genetic Information Nondiscrimination Act into law. The landmark act prohibits health insurers and employers from discriminating on the basis of genetic variation.

Delivery and Management of Primary Health care

HRSA is the lead Federal agency driving innovation in the delivery and management of primary health care to chronically ill, geographically isolated and economically distressed families. In 2008, the Health Center program exceeded all historic benchmarks for patient outreach in rural and inner-city communities long-burdened by shortages of medical services. Launched in 2002, the President’s Health Center Initiative aimed to significantly increase access to primary health care services. In just five years, the Initiative’s goal has been achieved: new or expanded Health Center sites in over 1,200 communities. The nation’s community health centers have treated more than 16 million patients in 2008 -- a third of them children -- without regard to their ability to pay; doubled their dental caseloads to 2.8 million; and tripled their mental health capacity to 613,000 clients.

Increasing access to substance abuse treatment and recovery services: Access to Recovery (ATR)

In 2008, the second cohort of ATR grants that were awarded to 24 grantees established an electronic voucher management system and continued to organize a diverse network of ATR providers. These grants completed their first year and exceeded the 30,000 target by serving 45,916 clients. <http://atr.samhsa.gov/>

Chronic Care Initiative

The Indian Health Service (IHS) is transforming health care provided to American Indians and Alaska Natives through its Chronic Care Initiative, which has established 40 pilot sites that are pioneering patient-centered, accessible health care focused on prevention. http://www.ih.gov/NonMedicalPrograms/DirInitiatives/index.cfm?module=fact_chronic



My Family Health Portrait

HHS, the Department of Veterans Affairs (VA) and the Department of Defense (DOD) collaborated to create and promote the Surgeon General's Family History Initiative. The campaign encourages American families to learn more about their family health history to help predict their risk and susceptibility to disease. The web-based tool "My Family Health Portrait" achieves a new level of interoperability between electronic health records and personalized health records. In October 2008, Secretary Leavitt visited Jordan and signed a Letter of Intent with the King Hussein Cancer and Biotechnology Center in Amman to develop and test an Arabic-language version of "My Family Health Portrait." Negotiations have begun on a Letter of Intent with the Federal Secretariat of Health in México for the adaptation and roll-out of the Spanish-language version of the "My Family Health Portrait." <http://www.hhs.gov/familyhistory>

National HIV Testing Mobilization Campaign

HHS launched the National HIV Testing Mobilization Campaign, a nationwide effort to encourage all sexually active Americans to get tested for HIV, which reached 3.5 million people. <http://www.aids.gov/takecontrol> www.hivtest.org

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 Program (Part D)

In its third year, the total number of Medicare beneficiaries enrolled in the Part D program has reached 25 million, including over 9 million beneficiaries who are receiving drug coverage for little or no cost through the Low-Income Subsidy benefit. Program satisfaction also increased with more than 85 percent of enrollees reporting satisfaction with their coverage. In 2008, the average premium for coverage under the standard benefit was \$25, which is 40 percent lower than originally estimated. In addition, beneficiaries in every state had access to at least one prescription drug plan with premiums of less than \$20 per month, and a choice of at least five plans with premiums of less than \$25 per month. Over 90 percent of beneficiaries enrolled in a stand-alone prescription drug plan (PDP) had access to a Medicare drug plan that costs the same or less than their coverage from 2007. More than 37,500 American Indians and Alaska Natives, who are Medicare-eligible beneficiaries and use Indian Health Service-funded services, are enrolled for MMA drug benefits.

Medicare Sustainability

In April of 2007, the Medicare Board of Trustees released a report that triggered the first-ever Medicare funding warning. In their report, the trustees warned that program costs were expected to reach 45 percent of the nation's



gross revenue by 2013. As a result, HHS — under the leadership of Secretary Leavitt — has made every effort to highlight the Trustees' message regarding the sustainability of the Medicare program. In February of 2008, HHS submitted proposed legislation to the Hill to respond to the Medicare funding warning. The draft legislation was intended to strengthen Medicare by expanding the use of health information technology and electronic medical records; increasing transparency in price and quality information; and providing greater incentives for providers to deliver, and Medicare beneficiaries to choose, high-quality, low-cost health care.

Evaluating and Improving Medicare's Quality

In August 2008, CMS awarded contracts for the 53 contractors participating in Medicare's Quality Improvement Organization (QIO) Program. The QIO contracts are in place through July 31, 2011, and focus on improving the quality and safety of health care services to Medicare beneficiaries. The contracts build on the Administration's health care quality improvement initiatives and a growing evidence base about how to improve the quality and efficiency of health care delivery. Specific priorities include prevention (immunization and screening), patient safety, and patient pathways.

Medicare Program Integrity

CMS significantly increased its oversight and fraud, waste and abuse prevention activities this past year. In high fraud areas, CMS launched three demonstration projects on the effectiveness of intensified provider enrollment and enhanced program integrity efforts focused on durable medical equipment (DME), home health agency (HHA) and infusion therapy services. The results included the revocation of billing numbers for 1,139 DME suppliers and 37 HHAs, and over \$250 million related to infusion therapy. CMS also implemented a wide-ranging plan to eradicate fraud and improper payments related to DME billings in FL, CA, NY, TX, MI, IL, and NC.

CMS recouped \$610.9 million during FY 2008 through the recovery audit contractor (RAC) demonstration required by the Medicare Prescription Drug, Improvement and Modernization Act. Over the course of this three year demonstration, CMS recouped a total of almost \$1 billion dollars in improper payments. The early success of the demonstration brought about statutory expansion of the demonstration in the Tax Relief and Health Care Act of 2006 requiring CMS to utilize RACs nationwide by January 1, 2010.

Competitive Bidding Program for Durable Medical Equipment

CMS implemented the first round of the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program on July 1, 2008 with 330 contract suppliers, paying an average of 26 percent less than current rates for competitively bid items and services. The new program changed the way Medicare pays for DMEPOS services under Part B of the Medicare program saving significant dollars for both beneficiaries and taxpayers. It included important reforms for this area of Medicare such as quality standards, accreditation, and financial standards, to improve quality and customer service, and ensure only legitimate viable suppliers participate in Medicare. While the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) retroactively delayed the program on July 15, 2008, its initial success provides significant momentum for its re-implementation in 2009. www.hhs.gov/medicarefraud

Medicare Advantage Plans

In 2008, Medicare Advantage (MA) plans are available to people with Medicare in every region of the country and enrollment is at an all-time high. This wide availability and variety of plan types makes MA plans an important alternative delivery system option for more than 9.8 million Medicare beneficiaries, an enrollment increase of over 18 percent since



2007. These plans provide extra value for their Medicare enrollees, primarily through reducing cost sharing for Medicare benefits and providing additional benefits such as routine vision and hearing exams. MA beneficiaries also report high satisfaction with eighty-six percent of respondents rating their plan 7 or higher (on scale of 10). To ensure that Medicare beneficiaries are not subject to deceptive or high-pressure marketing practices from MA plans or their agents, CMS released final regulations that prohibit a host of activities including unsolicited sales contacts.

Transforming Medicaid: First Annual Medicaid Spending Report

In October 2008, the Department issued the first actuarial report on Medicaid spending. The Report was compiled by actuaries from CMS and contains analysis of past program trends and projections of Medicaid expenditures and enrollment for the next 10 years. The report projects that Medicaid benefits spending will increase 7.3 percent from 2007 to 2008, reaching \$339 billion and will grow at an annual average rate of 7.9 percent over the next 10 years, reaching \$674 billion by 2017. That compares to a projected rate of growth of 4.8 percent in the general economy.

Expanding State Flexibility Under the Medicaid Program

In December of 2008, CMS published two final Medicaid rules that expand the flexibility States have in managing their Medicaid programs. These two regulations were required in the 2005 Deficit Reduction Act and will allow States the ability to design benefit packages that best meet the needs of their beneficiaries and the flexibility to impose premium and cost sharing requirements on certain Medicaid recipients. In addition to these regulatory changes, CMS continued to allow states the flexibility to operate their Medicaid programs through the waiver and demonstration application process.

In 2008, CMS approved Section 1115 reform demonstration waivers for [enter number] state Medicaid program.

State Children's Health Insurance Program (SCHIP)

The Department and the Administration extended funding for the State Children's Health Insurance Program (SCHIP) in a fiscally responsible manner that put covering low-income children first.

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.

New Data and Tools for Drug Evaluation, Quality, and Safety

In May 2008, FDA launched the Sentinel Initiative to create and implement the Sentinel System — a national, integrated, electronic system for monitoring medical product safety that ensures personal information is protected and kept anonymous, consistent with the Federal Privacy Act and HIPAA regulations. And in May 2008, HHS published a final rule permitting Medicare Part D prescription drug event data to be used by government agencies, states, beneficiaries and external researchers for a variety of important purposes including



protecting and improving public health, research, program management, personal health records, and oversight. This collaborative project with CMS enables FDA to proactively identify specific adverse effects among particular types of patient populations. And FDA will be able to get this information to health-care providers much faster, so they can contact their patients. To further develop the initiative, FDA is leading a public-private partnership research pilot called the Observational Medical Outcomes Partnership- a \$22 million initiative at the National Institutes of Health Foundation that will perform research on methodologies to link health care databases for analysis. CMS will use the drug claims for a variety of purposes including monitoring the new prescription drug benefit and assessing its impact on the health and spending of Medicare beneficiaries and the data will also be made available researchers. <http://www.fda.gov/oc/initiatives/advance/sentinel/>

Reducing Mother-to-Infant HIV Transmission

HIV transmission via breastfeeding accounts for about 150,000 infant infections annually, mostly in low-income settings. Three clinical trials funded by the NIAID showed that an extended course of the antiretroviral drug nevirapine (NVP) cut the rate of HIV transmission via breastfeeding by almost half at 6 weeks, compared with a single dose of NVP at birth, which is the current standard of care in many low-income settings. At 6 months, the risk of post-natal HIV infection or death for babies who received NVP for six weeks was nearly one-third less than the risk for infants given a single dose. http://www3.niaid.nih.gov/news/newsreleases/2008/SWEN_PEPI.htm

Understanding Drug Resistance

Community-associated methicillin-resistant Staphylococcus aureus (CA-MRSA) infections is an emerging public health concern that can be life-threatening. Using genome sequencing techniques, scientists at the NIAID found that

CA-MRSA is caused primarily by a single strain of the bacterium. NIAID scientists also uncovered new information about how MRSA bacteria elude the human immune system, allowing rapid transmission throughout the U.S. during the past five years. These findings add new insights into the cause of these infections and are a first step in developing new diagnostic tests and treatments. http://www3.niaid.nih.gov/NIAID/Templates/Specialized/PreseedableLeftRightNav.aspx?NRMODE=Published&NRNODEGUID=percent7b0147DD45-3872-4857-9DB9-8E65ECEFCAB5_percent7d&NRORIGINALURL=percent2fnews_percent2fnewsreleases_percent2f2008_percent2fMRSAevolution_percent2ehtm&NRCA_CHEHINT=Guest#

More Accurate Method to Detect Breast Cancer Risk in African-American Women

Researchers at NIH developed the CARE model, a new tool for calculating invasive breast cancer risk in African-American women. The model more accurately estimates the number of breast cancers that would develop in African-American women 50-79 years of age than the earlier BCRAT model which was based primarily on data from white women. Experts are now recommending use of the CARE model for counseling African-American women regarding their risk of breast cancer. <http://www.cancer.gov/newscenter/pressreleases/CARErelease>

FDA Approves Expanded Uses for Gardasil to Include Preventing Certain Vulvar and Vaginal Cancers

FDA approved the vaccine Gardasil for girls and women ages 9 to 26 for the prevention of vaginal and vulvar cancer caused by two types of Human Papillomavirus (HPV). HPV is the most common sexually transmitted infection in the United States with 6.2 million Americans becoming infected with HPV each year. Some HPV types can cause abnormal cell growth in areas of the cervix, vagina, vulva, and other



areas that years later may turn into cancer. <http://www.fda.gov/bbs/topics/NEWS/2008/NEW01885.html>

Personalized Medicine: Warfarin Dosing

FDA initiated several projects designed to further personalized medicine, including an evaluation of pharmacogenomics to improve the safety and efficacy of individual warfarin dosing, developing PET ligands to guide antitumor therapy, and understanding gender and ethnic differences in pharmacotherapy. In early 2008, FDA initiated and developed labeling recommendations for genetic testing to guide appropriate dosing for warfarin, a drug prescribed to help prevent blood clots. One of the side effects of Warfarin is increased risk for bleeding for people with genetic variations. The recently approved change in the warfarin label provides information on how people with certain genetic differences may respond to the drug and better manage patient care. To help consumers, AHRQ developed various patient and consumer guides including “Your Guide to Coumadin/Warfarin Therapy,” an easy-to-read brochure that explains warfarin treatment. <http://www.ahrq.gov/consumer/coumadin.htm> <http://www.fda.gov/cder/drug/infopage/warfarin/default.htm>

Critical Path

Significant Critical Path achievements include conducting public workshops (1) with NIH and the Juvenile Diabetes Research Foundation that focused on the state of the art in the research and development of an artificial pancreas; (2) on Clinical Trials for Local Treatment of Breast Cancer by Thermal Ablation; and (3) on a Coronary Drug-Eluting Stent (DES) Guidance Document; and (4) conducting the public meeting: FDA Critical Path Initiative (CPI) on the Move: Complexities and Challenges. <http://www.fda.gov/oc/initiatives/criticalpath/>

FDA Issues Cloning Risk Assessment

FDA issued a risk assessment, a risk management plan, and guidance for industry on animal cloning outlining the agency’s regulatory approach. Through a robust and transparent six-year process, FDA’s leadership resulted in the US being the first government to issue science-based decisions regarding the safety of food from clones. FDA’s ongoing interactions with the trade components of the US Government help to ensure that factual information is communicated about animal health and food safety. <http://www.fda.gov/cvm/cloning.htm#Updates>

Advanced Development

All targets were exceeded for contract award of advanced development of medical countermeasures. Seven contracts were awarded to advance the development of therapies for Hematopoietic Syndrome, bone marrow stromal cell loss, and vascular injury resulting from acute exposure to ionizing radiation. Additional contracts were granted to develop anthrax vaccine enhancement and therapeutics, smallpox antivirals, MCMs for skin and lung injuries from radiological and nuclear agents, and MCMs for a volatile nerve agent. In addition, the Domestic Cell Culture Vaccine Facility Request for Proposal (RFP) was posted and will result in contract awards, up to \$600M, to increase capacity and reach established goals for vaccine production in the event of an influenza pandemic.

Pandemic Research

A Cell Culture Grown Pandemic Vaccine entered Phase 1 Vaccine trials in July, the first in the U.S. that resulted from significant scientific advancements due to 1.5 years of large awards, totaling \$1.2B, to 6 companies to advance this vaccine type. Also, the first pre-Emergency Use Authorization for potential use of an H5N1 vaccine, plus adjuvant, for pre-pandemic vaccination of the critical workforce.



In addition, Clinical trials, initiated in FY2008, advanced development of new antivirals have resulted in encouraging scientific results.

<http://www.hhs.gov/disasters/press/newsroom/countermeasures/index.html>

Heparin Adverse Reactions

In FY2008, NIH and FDA led a successful resolution of international crisis involving contaminated heparin, a blood-thinning drug that contained active pharmaceutical ingredient (API) from China, which caused serious injuries and deaths. FDA identified the contaminant within a week of obtaining samples and developed robust analytical tests for contaminant followed by posted on Web site. To ensure the safety of heparin products in the United States market, the FDA has asked companies that manufacture heparin-containing products to test the heparin active pharmaceutical ingredient (API). These results facilitated ensuring the safety of the heparin supply, highlighting future approaches to promote drug safety. FDA also identified medical and in vitro diagnostic devices sold in the US that were manufactured with contaminated heparin, resulting in multiple medical device recalls <http://www.fda.gov/cder/drug/infopage/heparin/> <http://www.nigms.nih.gov/News/Results/FDANIGMS04232008.htm> www.fda.gov/cdrh/safety/heparin-device-list.html

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.

Emergency Response

During 2008 Administration for Children and Families (ACF) helped thousands of Americans recover from widespread flooding in Iowa, Kansas, Missouri, Illinois, Michigan and Wisconsin; severe hurricane damage in Texas, Louisiana, Mississippi, and Florida; and wildfires in California. ACF provided support to FEMA, to state governments, to cities devastated by flooding and hurricane damage, and most importantly to disaster victims in evacuation shelters.

Pandemic Influenza: Real-Time Flu Detection Test

On September 30, 2008, the U.S. Food and Drug Administration cleared CDC's human influenza virus real-time (RT) polymerase chain reaction (PCR) detection and characterization panel (RT-PCR flu panel), an important new test that can rapidly detect and identify human influenza viruses, including those that may pose a pandemic risk. Using a molecular biology technique, the RT-PCR can test multiple samples at once, and renders results within just four hours (a dramatic improvement over the previous 24-hour timeframe).

Production of new H5 Reference Strain

As new variants of H5N1 viruses continue to emerge, FDA recognizes the importance of generating new reference strains from these variants, which can then be used in vaccine manufacturing. During FY 2008, FDA produced



one new H5 reference strain for the H5N1 strain A/duck/Laos/3295/06. This strain is an attenuated reassortant of A/duck/Laos/3295/06 with modified internal genes. The continued testing and characterization of such reassortant viruses will aid in the development of vaccines and treatments which could be useful in the event of a pandemic outbreak.

Pre-Pandemic Influenza H5N1 Vaccine developed, Guidance Published

CDC developed six H5N1 pandemic influenza vaccine candidates, derived from viruses from Indonesia and China, for use in manufacturing pre-pandemic vaccines, including H5N1 vaccine candidate Clade 2.1 and H5N1 vaccine candidate Clade 2.2. CDC also developed in-house, five-target polymerase chain reaction (PCR) for influenza (A, B, H1, H3, H5). FDA approval is pending. This is a new area of diagnostics for CDC, and it will greatly enhance capability to detect disease as well as provide a path for future development.

Guidance on Allocating and Targeting Pandemic Influenza Vaccine

CDC published [Guidance on Allocating and Targeting Pandemic Influenza Vaccine](#) to provide strong advice that supports planning an effective and consistent pandemic response by States and communities. Through the annual seasonal influenza vaccination campaign, vaccine coverage among adults over 50 years of age has risen to more than 50 percent and health care worker influenza immunization coverage has increased to 50 percent.

Tamiflu Stockpile

The U.S. Food and Drug Administration (FDA) extended the expiry of Tamiflu (oseltamivir) capsules from 5 years to 7 years, meaning that Tamiflu retro-viral drugs stockpiled for 7 years remain an effective weapon against the next flu pandemic. Tamiflu is indicated for the treatment of uncomplicated acute illness due to influenza infection in patients 1 year and older who have

been symptomatic for no more than 2 days and for the prophylaxis of influenza in patients 1 year and older. <http://www.fda.gov/CDER/Drug/infopage/tamiflu/default.htm>

Strategic National Stockpile Continues to Build Readiness

By August 2008, CDC pre-positioned over 250,000 antiviral regimens overseas to support international containment in coordination with the Department of Defense and the Department of State and built the Strategic National Stockpile (SNS) inventory to about 50 million antiviral regimens, 105.8 million N95 respirators, and 51.7 million surgical masks. The SNS also completed the forward-placement of more than 1,900 CHEMPACK containers containing nerve agent antidotes to more than 1,000 sites. As a result, over 92 percent of the U.S. population is now within a one-hour window of access to these life-sustaining antidotes. The SNS also completed its first annual Formulary and inventoried category Threat A agents. In response to Hurricanes and Gustav and Ike, the SNS delivered 24 Federal Medical Station sets to 5 states and 11 cities. The sets were delivered and installed in a timely manner and became host to several hundred persons displaced from home care, nursing homes, and hospitals by hurricane events, rapidly recovering assets without loss and reconstituted packages for deployments.

Emergency Response

IHS teamed with other agencies and provided financial assistance, rapidly deployed civilians and 20 USPHS Commissioned Corps officers, purchased and distributed 2,000 N-95 particulate respirators, and arranged for two air quality monitors for Tribes impacted by wildfires in southern California. <http://www.ihs.gov/AdminMngrResources/EPEMS/>

Response to Rosebud Suicide Tragedy

The Indian Health Service (IHS) assisted in the Secretary's response to the suicide



prevention activity on the Rosebud Sioux Tribal Reservation. The IHS led a coordinated response to help avoid such tragedies. Eight USPHS Commissioned Corps officers serving in the IHS, representing 52 deployments, worked within the Rosebud Sioux community on suicide prevention activities. <http://www.ihs.gov/AdminMngrResources/EPEMS/>

NIH Countermeasures Against Chemical Threats (CounterACT) Research Network

NIH leads development of medical countermeasures to prevent, diagnose, and treat the conditions caused by chemical agents of terrorism, some of which also pose threats from accidental release. The CounterACT Research Network, which works extensively with the Department of Defense, now includes Research Centers of Excellence, individual research projects, Small Business Innovation Research projects, contracts, and other programs that conduct basic, translational, and clinical research to develop better therapeutic and diagnostic medical countermeasures against chemical threat agents, and to move them quickly through the regulatory process. http://www.ninds.nih.gov/funding/research/counterterrorism/counterACT_home.htm

Shelter Intake Assessment Tool

Over the past two years, the Office of Disability (OD) worked with ASPR and the American Red Cross (ARC) to develop and revise a Shelter Intake Assessment Tool designed to appropriately assign individuals to the type of shelter that best meets their needs. Red Cross shelters utilized this tool in FY08 during the California wildfires, the Midwest flooding and in Louisiana in the aftermath of Hurricane Gustav.

Commissioned Corps Transformation

The Corps trains and equips its entire force to respond quickly and effectively to natural and/or manmade disasters or other urgent public health needs. In FY 2008, over 1,900 officers were deployed in response to 29 separate incidents where public health was at risk. In 2008, the Corps force strength grew to more than 6,200

in FY 2008, the largest number of officers in 10 years. A key component to this public health and response asset's competence and capability is officer training. During FY 2008, the Corps conducted 11 Officer Basic Courses and provided training to over 500 newly accessed officers. www.usphs.gov

Draft Pilot Proposal for Public-Health Materials across US-Mexican Border

Secretary Leavitt and Mexican Secretary of Health José Ángel Córdova, M.D. proposed a pilot project to determine the barriers to the transport of public-health materials, and to revise current operating procedures to allow for a more regular flow of samples and medications for public-health purposes across the U.S.-Mexican border. After consultations with the U.S. Departments of Homeland Security, State, and Commerce, HHS proposed a draft pilot proposal, scheduled for implementation in November 2008.

Serving Those Serving our Nation: Veterans Suicide Prevention Hotline

The Suicide Hotline (1-800-273-TALK (8255)) has provided immediate, often life-saving, help to tens of thousands of veterans and their loved ones since its inception in the summer of 2007. Over 22,000 calls have come directly from veterans, with the remainder coming from family members or friends seeking help for veterans. The Hotline is a collaborative effort by the U.S. Department of Veterans Affairs and SAMHSA to meet the special needs of veterans in crisis. <http://www.samhsa.gov/vets/index.aspx>

Guidance to Industry on Considerations for Plasmid DNA Vaccines for Infectious Disease Indications

Various investigational DNA vaccines for infectious disease, including malaria, hepatitis B, and HIV, are under development. Considerable preclinical and clinical experience on plasmid DNA vaccines has been accumulated since the issuance of the 1996 Points to Consider Document on Plasmid DNA Vaccines for Preventive Infectious Disease



Indications. To facilitate improvements in the development of these vaccines, FDA revised this guidance. <http://www.fda.gov/Cber/gdlns/plasdnvac.htm>

Home Preparation Instructions for Exposure to Anthrax

In the event of declared public health emergency exposure to Anthrax, FDA posted on July 2, 2008 revised home preparation instructions to prepare Doxycycline for children and adults who cannot swallow pills. http://www.fda.gov/cder/drug/infopage/penG_doxy/home_prep.htm

FDA Approves Levaquin For Use in Pediatric Patients

On May 14, 2008, the U.S. Food and Drug Administration (FDA) approved Ortho-McNeil's antibiotic Levaquin to treat pediatric patients exposed to inhalational anthrax (post-exposure) to reduce the incidence or progression of disease following exposure to aerosolized B. anthracis in pediatric patients. The drug previously was approved to treat adults after exposure to inhaled anthrax. <http://www.fdanews.com/newsletter/article?articleId=106720&issueld=11584>

Food and Agriculture Vulnerability Assessments

The U.S. food and agriculture industries generate more than \$1 trillion in economic activity and employ more than 10 million people. The FDA developed tools that help the food industry conduct security assessments of its operations and identify concerns. The CARVER + Shock software tool and the Food Defense Self Assessment Tools have been used by thousands of firms to help better secure the global food supply. www.cfsan.fda.gov/fooddefense

FDA Develops Method for Detecting Melamine and Cyranic Acid in Infant Formula

In order to quickly respond to the discovery of melamine adulterated infant formula in China,

FDA needed a method for detecting both melamine and cyranic acid in infant formula in a single analysis. By leveraging the research initiated in FY2007 and by adapting an existing feed method, FDA achieved this method in September of 2008, in time to have a critical and timely impact on public health. <http://www.cfsan.fda.gov/~frf/lib4421.html>

Melamine in Pet Food

FDA performed a criminal investigation into the manufacture and distribution of pet foods contaminated with melamine and suspected in numerous deaths and injuries to pets. OCI investigations led to a 26-count federal indictment against two Chinese businesses and their top executives, and a U.S. firm and its two owners. All were charged with the illegal importation of 800 metric tons of melamine-contaminated wheat gluten later used in the manufacture of pet foods. <http://www.fda.gov/bbs/topics/NEWS/2008/NEW01792.html>

FDA's Beyond Our Borders Initiative

FDA's Beyond Our Borders Initiative is a systems-based approach to the systemic problem of FDA's regulation of food, cosmetics, and medical products. The Beyond Our Borders Initiative includes increased collaboration with foreign regulators, use of third parties to provide information about regulated industry compliance with FDA standards, and providing additional direction to regulated industry for their global activities. Throughout FY 2008, HHS worked to secure agreements to establish an HHS/FDA presence for the first time in locations around the world. The HHS/FDA offices in three Chinese cities (Beijing, Shanghai and Guangzhou) were opened in November 2008. HHS/FDA offices in India, Central America, and Europe will also open before the end of the calendar year.

FDA signed two MOAs with China and held bilateral talks with the Chinese regulatory



agencies to work toward creation of a certification program to help ensure items exported to the United States meet HHS and FDA safety standards. Additionally, these MOAs provide a streamlined process for facilitating FDA inspections conducted in China. This aspect of the agreements has already proven effective in giving FDA prompt access to conduct inspections, and paves the way for permanent overseas offices in China. <http://www.fda.gov/oia/agreements/Safety-of-food-and-feed.pdf> <http://www.fda.gov/oia/agreements/Drugs-and-Medical-Devices.pdf>

Secretary Leavitt also signed Memoranda of Understanding on import safety (food/feed and drugs/medical devices) with the Socialist Republic of Viet Nam, the Republics of Central America, and the United Mexican States. The Department also had diplomatic and political interaction with the Governments of Honduras and México over outbreaks of food-borne diseases tracked back to fresh produce imported from those nations.

ORA Rapid Response Team

In FY 2008, ORA awarded the first-ever Rapid Response Team (RRT) cooperative agreements to the States which will develop and exercise a food-borne illness response capability to more rapidly react to potential threats to the food supply. Each recipient was awarded up to \$500,000 to exercise its response team, conduct a program assessment, purchase equipment, fund personnel, train, and share information. The funded states were North Carolina, Massachusetts, California, Michigan, Florida and Minnesota. <http://www.fda.gov/bbs/topics/NEWS/2008/NEW01894.html>

Response to Public Health Emergencies and Disasters

HHS had an integrated response to 42 ESF-8, ESF-6 and ESF-14 public health emergencies and disasters including Hurricanes Gustav and Ike, deploying nearly 2,000 HHS, DOD and

other National Response Framework partners to Louisiana, Texas, Florida, Mississippi and Georgia to support medical and public health assets. Efforts included 14 Federal Medical Shelters comprised of 250 beds each staffed by Federal and State personnel to provide basic care, 22 Disaster Medical Assistance Teams from the National Disaster Medical System (NDMS) to coordinate patient evacuations, 1 Disaster Mortuary Assistance Team and 1 Disaster Portable Morgue Unit to provide mortuary services for disinterred remains, 7 Rapid Deployment Force teams from the USPHS to provide medical, mental health and public health staff augmentation, 3 Incident Response Coordination Teams to provide on-the-ground operational, logistical and administrative management, and over 300 medical personnel from the Veterans Health Administration that coordinated patient movements and staffed Federal Medical Shelters in Ruston, Louisiana and Kelly Air Force Base, Texas. HHS also awarded \$400 million to States, Territories, and jurisdictions for hospital preparedness to cover areas such as medical surge, communications, fatalities management, medical evacuation, and bed tracking. <http://www.hhs.gov/disasters/emergency/naturaldisasters/hurricanes/index.html> <http://www.hhs.gov/aspr/opeo/ndms/index.html>

Hospital Emergency Preparedness

HHS exceeded the target for developing State and local capacity for Mass Casualty Care and Countermeasure distribution by 20 percent, requiring as a condition of the FY 2008 award, 100 percent of the 62 Hospital Preparedness Program and Public Health Emergency Preparedness grantees to conduct within the project year at least 1 mass casualty preparedness exercise and 3 exercises to test proficiency of local points of distribution (PODs). HHS also implemented the Hospital Available Beds for Emergencies and Disasters System (HAvBED) that allows states to report bed availability within 4 hours and established



a cross-disciplinary information fusion cell for near real-time situational awareness.

First Response Emergency Medical Care Programs

The First Responder Safety Policy, in collaboration with interagency partners, was developed to provide a framework to address personnel protective equipment, respiratory protection, post-exposure prophylaxis and pre and post event vaccination issues for First Responders. HHS also established the Emergency Care Coordination Center (ECCC) which developed an integrated Federal Emergency Care Enterprise that addresses the emergency medical care continuum (pre-hospital through discharge), and the Council on Medical Care (CEMC) to foster collaboration between USG programs and initiatives and; serve as a platform for public and private stakeholders to identify and promote evidence-based practices.

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.

Protecting the Conscience of Health Professionals

In December of 2008, HHS issued a final regulation protecting the right of federally funded health care providers to decline to participate in services to which they object, such as abortion. Over the past three decades, Congress enacted several statutes to safeguard the freedom of health care providers to practice

according to their conscience. The new regulation will increase awareness of, and compliance with, these laws.

Childhood Obesity Prevention

The Secretary's Childhood Overweight and Obesity Prevention Initiative, Healthy Youth for a Healthy Future, has made great strides and achieved significant milestones in bringing communities together to resolve this public health epidemic. The Surgeon General participated in 39 events, traveled to 34 states, convened 5 HHS Council on Childhood Obesity Prevention meetings, and helped facilitate 10 partnerships to leverage existing HHS programs. <http://www.surgeongeneral.gov/obesityprevention/index.html>

Mentoring Children of Prisoners (MCP)

In July 2008 the MCP program reached its goal of 100,000 matches of children to mentors. This year marked the successful launch of the MCP voucher program, "Caregiver's Choice," designed to reach out to children in underserved areas, with a particular focus on rural and Tribal populations. <http://www.acf.hhs.gov/programs/fysb/index.htm>

Support for Strong Families and Healthy Marriages

ACF provided more than \$150 million in funds for the Healthy Marriage and Responsible Fatherhood Initiatives. ACF dedicated \$118 million in funding to assist 215 organizations: 119 to promote healthy-marriage programs and 96 to encourage responsible fatherhood programs. In addition, ACF made available approximately \$1.5 million of funding for demonstration projects designed to test the effectiveness of tribal governments or tribal consortia in coordinating the provision of Tribal TANF services and child welfare services to tribal families at risk of child abuse or neglect. www.acf.hhs.gov/healthymarriage



Picturing America and Early Childhood Education

Picturing America is an Office of Head Start partnership with the National Endowment for Humanities. Every Head Start Center (20,000 nationwide) will receive a series of quality posters of 40 images representing American history. The Office of Head Start developed program and education guides to prepare teachers with ideas for using these posters to support language, literacy, mathematics, science, creative and socio-emotional development. http://picturingamerica.neh.gov/flash_acknow.php

National Center on Physical Development and Outdoor Play

The National Center on Physical Development and Outdoor Play was funded by the Office of Head Start in response to the increasing prevalence of pediatric obesity and overweight. This project will receive \$3 million per year for four years to function as a resource center that will assist grantees in improving the accessibility, safety and appropriateness of outdoor play space. http://www.aahperd.org/aahperd/template.cfm?template=pr08_1010.html

Increased U.S. Refugee Resettlement

In FY 2008, 60,192 refugees were resettled in the U.S., which is the highest refugee arrival since 2001. In anticipation of these refugees, HHS funded various states and non-profit organizations over \$4 million for the Supplemental Services Program to assist newly arriving refugees, such as Iraqis and Burmese. Some of the allowable services under the Supplemental Services Program includes employment services, translation and interpretation, citizenship and naturalization preparation services, and on the job training. In FY 2008, the U.S. Office of Refugee Resettlement experienced an increase of 50 percent in unaccompanied refugee minors (URM) placement. Working with states and

non-profit organizations, HHS increased capacity to support and provided foster care services and other benefits to 300 URM. http://www.acf.hhs.gov/programs/orr/programs/unaccompanied_refugee_minors.htm

Home Visitation Program

The Administration for Children and Families selected 17 sites to receive cooperative agreements totaling approximately \$8.0 million to support evidence-based home visitation programs. These grants provide funds and encourage States to leverage additional resources to invest in these programs which have been shown through rigorous research to improve outcomes for children to prevent child abuse and neglect. http://www.acf.hhs.gov/programs/cb/programs_fund/discretionary/2008.htm

Reauthorization of the Reconnecting Homeless Youth Act

The Runaway and Homeless Youth (RHY) program was reauthorized by the Reconnecting Homeless Youth Act of 2008. The RHY program assists homeless youth, providing basic necessities, reuniting youth with their families when possible, and aiding the transition to adulthood for older homeless youth who cannot return home. More than 500,000 youth across the nation are served each year. The National Runaway Switchboard has handled more than 3.5 million calls since it began operating in 1974. <http://www.acf.hhs.gov/programs/fysb/content/youthdivision/index.htm>

\$43 Million in Grant Programs To Help Older Americans, Veterans And People With Alzheimer's

In September 2008, 28 states received \$43 million in funding to help older Americans, veterans and people with Alzheimer's receive home and community-based care. Just over \$26 million in funding involves a new collaboration between HHS and the U.S. Department of



Veterans Affairs to provide essential consumer-directed services to older Americans and veterans of all ages through the AoA Nursing Home Diversion grants program. The remaining \$17 million will serve individuals with Alzheimer's disease and their caregivers through AoA's Alzheimer's disease demonstration program. http://www.aoa.gov/press/For_the_press/pr/archive/2008/September/9_29_08.aspx

Own Your Future Awareness Campaign

AoA, in partnership with ASPE, CMS, and the National Governors Association, sponsored the Own Your Future Long-Term Care Awareness Campaign that seeks to increase consumer awareness about planning for long-term care through Federal-State partnerships. To date in FY 2008, nearly 3,360,000 individuals have been reached through the campaign, which represents an increase of approximately 33 percent upon the 10 million individuals reached in FY 2007. We anticipate reaching at least an additional 1,400,000 before the end of the year. http://www.longtermcare.gov/LTC/Main_Site/Planning_LTC/Campaign/Kit/index.aspx =

Racial and Ethnic approaches to Community Health

CDC's Racial and Ethnic Approaches to Community Health (REACH) "percent" program reports a dramatic impact on health behaviors. Among Hispanics, 69.8 percent had cholesterol checked (versus 54.6 percent the prior year), which surpassed Hispanics nationally and significantly closed the national disparity gap. Taking medication for high blood pressure increased dramatically among Asian American men, closing the disparity gap at 19.4 percent versus the U.S. population at 24.4 percent. Among all participating groups, dramatic improvements were observed in risk factors for diabetes-related complications: Blood sugar measures below 7 improved by 8.7 percent systolic blood pressure below 130 mm Hg

improved by 17.5 percent, and diastolic blood pressure for this population also improved.

Civil Rights Agreements with National Health Care Corporations

OCR has entered into Agreements with seven major health care corporations serving Medicare beneficiaries to promote and ensure compliance with Federal laws prohibiting discrimination on the basis of race, color, national origin, disability or age. These corporations operate over 1200 health care facilities nationwide, ranging from home health, to hospice care, hospital, rehabilitation and nursing facilities, and serve over 5.5 million people a year. For more information about OCR's Medicare provider certifications, go to <http://www.hhs.gov/ocr/crclearance.html>

Promoting Preconception Care and Healthy Pregnancies

Nearly 30 outreach events for African-American women of childbearing age and their partners were conducted by the new A Healthy Baby Begins with You campaign. The Office of Minority Health organized the campaign with national spokesperson Tonya Lewis Lee and partners in Healthy Start programs, state and local health departments and national organizations including the Association of Maternal and Child Health Programs, CityMatCH and the March of Dimes. It offers community-wide education about risk factors and bringing women and their partners to care. It also began four pilot tests of a peer education program on preconception health care in concert with five historically black colleges and universities and another institution of higher education.

Sustaining declines in illicit drug use among our nation's citizens

National Survey on Drug Use and Health (NSDUH)
SAMHSA's 2007 NSDUH, released in September



2008 indicates the success of efforts to reduce substance abuse in this country. Reductions in youth drug use occurred for nearly every type of illicit drug, including prescription-type drugs. Specifically, among 12-17-year olds: a significant decline in overall illicit drug use from 11.6 percent in 2002 to 9.5 percent in 2007; current marijuana use, 8.2 to 6.7 percent; current alcohol use, 17.6 percent to 15.9 percent; and current tobacco use, 13 percent to 9.8 percent.

<http://www.oas.samhsa.gov/NSDUHlatest.htm>

Decreasing underage alcohol use among America's youth

Surgeon General's Call to Action and the Interagency Coordinating Committee on the Prevention of Underage Drinking (ICCPUD) SAMHSA, in collaboration with the ICCPUD, the National Prevention Network, and the Leadership to Keep Children Alcohol Free, sponsored over 1,800 Town Hall Meetings (THMs) nationwide in 2008. The THMs provided a community forum to engage youth and adults in a discussion of underage drinking's impact on individuals, families, and the community. Many communities built upon this momentum by forming parent networks and other action groups, and making plans to address the problem. <http://www.stopalcoholabuse.gov>

Disaster Case Management Program

ACF created a Disaster Case Management pilot (DCM) to connect individuals to human services. DCM, based on the principals of self-sufficiency, federalism, flexibility and speed, and support for states, integrates with existing state, local, and voluntary programs. Following Hurricane Gustav, FEMA funded ACF to provide DCM to serve the needs of vulnerable populations. Currently, ACF DCM has served more than 3,000 people, of which approximately 15 percent are elderly and 25 percent have a disability. <http://www.dhhs.gov/news/press/2008pres/09/20080903b.html>

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.

Global Immunization

The Polio and Measles Initiatives

This initiative demonstrate the impact of immunizations on averting disease, disability, and death. Globally, more than 5 million cases of childhood paralysis have been prevented, 1.25 million deaths prevented through vitamin A supplementation during immunization activities. While both polio and measles have been successfully eliminated from the Western Hemisphere, American children remain at risk for both diseases as long as they persist anywhere in the world. For the first time, CDC's Measles Initiative supported vaccination campaigns in all regions of the world, resulting in significant reduction of deaths due to measles.

Polio Eradication

The number of polio endemic countries has been reduced from 125 in 1988 to 4 (to date): Afghanistan, India, Nigeria, and Pakistan. Although in 2008 an additional 10 countries have been affected by polio cases or outbreaks following an importation of polio, these affected countries remain free of indigenous circulating virus.

Emergency Plan for AIDS Relief (PEPFAR)

FDA tentatively approves antiretrovirals for HIV/AIDS in association PEPFAR through an expedited review process. This initiative helps



ensure that those being served by the Presidents' Plan would receive safe, effective and quality manufactured antiretroviral drugs. In FY2008, the total number of antiretrovirals approved or tentatively approved under PEPFAR is 71, including 2 pediatric fixed doses combination thereby increasing antiretroviral drug access for children with HIV Infection. This increases by 20 the arsenal of low cost, high-quality HIV/AIDS therapies for purchase under PEPFAR compared to last year.

CDC exceeded the target for increasing the numbers of HIV-infected persons who receive antiretroviral treatment through PEPFAR, and as a result, over 1.3 million persons have been treated. In more than 1 million pregnancies, CDC provided antiviral prophylaxis to the mother and spared an estimated 194,000 infant HIV-infections. CDC also supported HIV/AIDS care for more than 6.6 million people with HIV/AIDS, including care for more than 2.7 million orphans and vulnerable children, and supported over 33 million counseling and testing sessions to date.

HRSA supports a global prevention and treatment campaign against HIV, tuberculosis and malaria that touches 1.7 million people in 12 sub-Saharan nations, Guyana, Haiti and Vietnam. HRSA's Global AIDS program is the third largest U.S. effort to combat HIV/AIDS in developing nations, with primary responsibility for training 140,000 new health care workers over the next five years. HRSA-developed patient tracking software (CAREware) has been "exported" around the globe to such nations as Uganda, Nigeria, Vietnam, Russia, Thailand and Spain, and has been translated into at least four languages. <http://www.fda.gov/oia/pepfar.Htm>

Improving the Health Status of Native Communities

The Indian Health Service administered activities under a Memorandum of

Understanding (MOU) between the United States and Health Canada targeted at improving the health status of Native communities in both countries. <http://www.ihs.gov/publicaffairs/PressReleases/index.cfm>

United States Public Health Service (USPHS)

Fifty USPHS Commissioned Corps officers serving in the Indian Health Service (IHS) worked with other nations and international agencies on global health problems and their solutions. One IHS officer completed a 1-year deployment as Health Attaché in Iraq. <http://www.ihs.gov/NonMedicalPrograms/COliaisonStaff/>

Cerebral Malaria May Be a Major Cause of Cognitive Impairment in Children in sub-Saharan Africa

The FIC supported the first prospective study to assess cognitive consequences for children who survive cerebral malaria (CM), a condition that affects 575,000 children in sub-Saharan Africa every year. To obtain an estimate of the frequency of these deficits in children who survive CM, U.S. and Ugandan scientists examined cognitive function in the areas of working memory, attention, and learning in Ugandan children age 5-12. The study demonstrates that CM may be a major cause of cognitive impairment in children in sub-Saharan Africa and the importance of better understanding the pathogenesis and treatment of CM. <http://www.pediatrics.org/cgi/content/full/119/2/e360>

Seasonality of Influenza in Brazil: Implications for the Brazilian National Influenza Vaccination Program

The selection of influenza (flu) strains to be included in vaccines is based on international surveillance and scientists' evaluation about which strains will circulate in the two hemispheres in a given year. Little is known about the circulation of flu viruses in tropical regions which span the equator. Researchers



studied the seasonal spread of flu viruses and mortality patterns across Brazil over two decades. This research is now influencing vaccination strategies in Brazil and will provide a significant model for other tropical countries.

Health Diplomacy

Secretary Leavitt visited Pakistan where he met with leaders and toured a Basic Health Unit in the community of Bagh (near the epicenter of the 2005 Kashmir Earthquake), and spoke at Aga Khan University in Karachi. Secretary Leavitt and a high-level delegation also visited the African nations of Ethiopia, Côte D'Ivoire and Mali, to review the U.S. Government's efforts on HIV/AIDS, malaria and highly pathogenic avian influenza. The delegation met with senior representatives of the Governments; visited hospitals, clinics and research facilities; and traveled to rural communities to see how medical care in remote locations. The delegation also met religious leaders, and toured health facilities operated by faith-based organizations. www.globalhealth.gov

Afghanistan Health Initiative

During FY 2008, HHS engaged experts from the CDC, IHS, CMS and OPHS for effective implementation of the public health and clinical programmatic aspects of the Afghanistan Health Initiative, and improved collaboration with our awardees, including non-governmental organizations in the United States and Afghanistan and the Afghan Ministry of Public Health. HHS also successfully executed Memoranda of Understanding to assign U.S. Public Health Service (USPHS) Commissioned Corps Officers to DoD health teams in Afghanistan.

FDA Re-designated as PAHO/WHO Collaborating Center for Biological Standardization

The World Health Organization (WHO)

Director-General re-designated FDA's Pan American Health Organization (PAHO)/ WHO Collaborating Center for Biological Standardization for another four-year term (2008 – 2012). As one of four collaborating centers, FDA works with its partners (governments, industry, and others) in an international collaborative network carrying out WHO activities. This effort improves standards and norms for producing high quality biological products and helps protect the public from harm and disease. http://www.who.int/bloodproducts/collaborating_centres/en/ <http://www.who.int/biologicals/en/>

Collaboration with the European Centre for Disease Prevention and Control, World Health Organization (WHO) Blood Regulators Network, and WHO Developing Countries Vaccine Regulators Network

FDA provided global leadership in public health, product quality, safety and standards through its collaboration with the European Centre for Disease Prevention and Control, World Health Organization (WHO) Blood Regulators Network, and WHO Developing Countries Vaccine Regulators Network. These global collaborations support the development and regulation of products needed to effectively combat deadly diseases such as HIV, TB, malaria and pandemic influenza. <http://www.who.int/bloodproducts/brn/en/> http://www.who.int/immunization_standards/vaccine_regulation/dcvrn/en/index.html

Global Public Health Emergency Preparedness and Response

HHS has taken the lead on international activities to enhance global public health emergency preparedness and response. It has served and been recognized in establishing an enterprise strategy that links medical countermeasure development (MCM) and acquisition to an integrated national delivery platform. ASPR will host the first Global



Health Security Initiative (GHSI) Public Health Emergency Medical Countermeasures (MCMs) Workshop. The GHSI will establish a collaboration path to building a global infrastructure for MCMs.

Also, the International Health Regulations Program (IHRP) expanded its engagement of international partners in the reporting of potential public health emergencies of international concern (PHEIC) to include Canada, Mexico and the Western Pacific Regional Office (WPRO) of the WHO. The IHRP provided technical assistance in IHR implementation to 43 countries in all six WHO regions. In addition, ASPR provided oversight to two multilateral initiatives (SPP and GHSI) and five international cooperative agreements were provided to 15 developing countries to develop pandemic field surveillance, vaccine infrastructure development, laboratory diagnostics, and international alert and connectivity capabilities.

