THE CSTE WASHINGTON REPORT

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EDITOR'S NOTE: Centers for Disease Control and Prevention (CDC) Director Dr. Julie Gerberding released the first State of CDC report November 14 at the National Press Club in Washington, D.C. The report chronicles the agency's accomplishments during Fiscal Year 2003 and provides a snapshot of plans to meet future public health challenges.
"During this past year, the public health community faced a series of challenges, both domestically and internationally," Dr. Gerberding said in releasing the report. "Month by month, CDC consistently provided a strong return on the American people's investment, acting swiftly and decisively to control outbreaks like SARS, Monkeypox, and West Nile Virus while carrying out sound, science-based programs to reduce illness and death from conditions like heart disease and obesity." The report contains details about how CDC invested $7 billion in public health programs, both at home and abroad, that impact people's lives each day. Coverage of the report is included in this Washington Report.

The CSTE Washington Report is provided as an information resource for members of the Council of State and Territorial Epidemiologists on federal legislation and regulation affecting public health and epidemiology in the U.S. Legislation cited in the report can be

accessed via http://www.thomas.loc.gov Regulations cited can be accessed via http://www.gpo.gov

APPROPRIATIONS UPDATE – The House and Senate have filed the conference report accompanying the giant FY 2004 omnibus appropriations bill (Rep. 108-401) which includes the Labor-HHS-Education Appropriations bill. The conference report can be read at: http://thomas.loc.gov/cgi-bin/cpquery The House plans to take up and pass the omnibus conference report on December 8th. The Senate leadership hopes to take it up on December 9th under unanimous consent which would preclude any debate or amendments, but Sen. Byrd (D-WV) has indicated that he will not give his consent and many other Democrats are expressing extreme dissatisfaction with changes in the omnibus bill that the Senate had passed during independent consideration of several of the bills that were eventually wrapped into the omnibus. One of the contested provisions often mentioned is the prohibition on issuing new Labor Department overtime rules which was stripped out of the omnibus. However, both Senator Specter (R-PA), and Sen. Harken (D-IA), the respective Chairman and Ranking Democrat for the Subcommittee with jurisdiction have signed off on the omnibus conference report. The omnibus bill was largely conferenced by the Republican leaderships of both Houses of Congress and the White House. The likelihood is that the Senate will not take up the omnibus until late January. The current Continuing Resolution, in recognition of the conflict still surrounding aspects of the omnibus bill, funds the federal government through January 31st.

This report contains some details from the omnibus conference report for a number of CDC programs. These funding levels are unlikely to change as Congress works into next year to finish FY 2004 appropriations.

An important outcome of the omnibus conference deliberations was the application of a .59% across-the-board cut for all programs in the omnibus, which encompassed seven appropriations bills, to pay for a $1.3 billion increase for Veterans' health care, $1.2 million increase for special education programs, funding for elections reforms and upgrades, and other increases that put total discretionary spending above the agreed upon cap for FY 2004. The numbers below reflect the application of the across-the-board cut (noted in the chart below as a-t-b-).

CDC TOTAL

FY 2003	$ 5,728,400,000
FY 2004 PresRequest	$ 5,435,500,000
FY 2004 Conference	$ 5,873,800,000
FY 2004 After a-t-b	$5,840,400,000

CHRONIC DISEASE

FY 2003	$ 790,000,000
FY 2004 PresRequest	$ 834,000,000
FY 2004 Conference	$ 859,100,000
FY 2004 After a-t-b	$ 854,000,000

BRFSS (Non-AIDS)

FY 2003	**$**	**6,900,000**
FY 2004 PresRequest	**$**	**3,800,000**
FY 2004 Conference	**$**	**8,100,000**
FY 2004 After a-t-b	**$**	**8,052,210**

Prevention Initiative

FY 2003	$	15,400,000
FY 2004 PresRequest	$	125,000,000
FY 2004 Conference	$	44,000,000
FY 2004 After a-t-b	$	43,700,000

Heart Disease and Stroke

FY 2003	$	43,000,000
FY 2004 PresRequest	$	40,100,000
FY 2004 Conference	$	46,000,000
FY 2004 After a-t-b	$	45,700,000

Breast and Cervical Cancer

FY 2003	$	199,400,000
FY 2004 PresRequest	$	210,900,000
FY 2004 Conference	$	210,900,000
FY 2004 After a-t-b	$	209,700,000

Cancer Prevention and Control (excl breast and cervical)

FY 2003	$	89,400,000
FY 2004 PresRequest	$	76,600,000
FY 2004 Conference	$	104,700,000
FY 2004 After a-t-b	$	104,100,000

Cancer Registries

FY 2003	$	39,740,000
FY 2004 PresRequest	$	39,500,000
FY 2004 Conference	$	50,000,000
FY 2004 After a-t-b	$	49,705,000

Diabetes Prevention and Control

FY 2003	$	63,300,000
FY 2004 PresRequest	$	61,400,000
FY 2004 Conference	$	67,300,000
FY 2004 After a-t-b	$	66,900,000

Arthritis

FY 2003	$	14,600,000
FY 2004 PresRequest	$	13,800,000
FY 2004 Conference	$	14,900,000
FY 2004 After a-t-b	$	14,800,000

Health Promotion

FY 2003	$	21,600,000
FY 2004 PresRequest	$	16,100,000
FY 2004 Conference	$	24,100,000
FY 2004 After a-t-b	$	23,900,000

Nutrition, Physical Activity, Obesity

FY 2003	$	34,100,000
FY 2004 PresRequest	$	27,300,000
FY 2004 Conference	$	45,000,000
FY 2004 After a-t-b	$	44,700,000

Oral Health

FY 2003	$	11,700,000
FY 2004 PresRequest	$	10,800,000
FY 2004 Conference	$	12,500,000
FY 2004 After a-t-b	$	12,400,000

Safe Motherhood and Infant Health

FY 2003	$	54,000,000
FY 2004 PresRequest	$	50,500,000
FY 2004 Conference	$	54,300,000
FY 2004 After a-t-b	$	53,900,000

Tobacco

FY 2003	$	99,900,000
FY 2004 PresRequest	$	100,400,000
FY 2004 Conference	$	100,100,000
FY 2004 After a-t-b	$	99,500,000

Youth Media Campaign

FY 2003	$	51,000,000
FY 2004 PresRequest	$	5,000,000
FY 2004 Conference	$	36,000,000
FY 2004 After a-t-b	$	35,800,000

School Health

FY 2003	$	57,800,000
FY 2004 PresRequest	$	63,100,000
FY 2004 Conference	$	62,800,000
FY 2004 After a-t-b	$	62,500,000

ENVIRONMENTAL HEALTH LAB
Health Tracking Network

FY 2003	**$**	**27,800,000**

FY 2004 PresRequest $ 17,500,000
FY 2004 Conference $ 27,900,000
FY 2004 After a-t-b $ 27,700,000

Environmental Health Lab
FY 2003 $ 37,500,000
FY 2004 PresRequest $ 36,300,000
FY 2004 Conference $ 38,500,000
FY 2004 After a-t-b $ 38,300,000

Asthma
FY 2003 $ 36,900,000
FY 2004 PresRequest $ 34,400,000
FY 2004 Conference $ 37,400,000
FY 2004 After a-t-b $ 37,200,000

Childhood Lead Poisoning
FY 2003 $ 42,000,000
FY 2004 PresRequest $ 41,200,000
FY 2004 Conference $ 42,000,000
FY 2004 After a-t-b $ 41,700,000

INFECTIOUS DISEASE:

HIV/AIDS Domestic
FY 2003 $ 699,600,000
FY 2004 PresRequest $ 690,300,000
FY 2004 Conference $ 699,600,000
FY 2004 After a-t-b $ 695,500,000

Immunization total Including evaluation transfers
FY 2003 $ 650,600,000
FY 2004 PresRequest $ 620,500,000
FY 2004 Conference $ 647,400,000
FY 2004 After a-t-b $ 643,600,000

Infectious Disease Control*
FY 2003 $ 359,200,000
FY 2004 PresRequest $ 331,600,000
FY 2004 Conference $ 372,500,000
FY 2004 After a-t-b $ 370,300,000
***Within the total, $162,263,000 was provided for Other Emerging Infections**

INJURY:

Injury Prevention and Control

FY 2003 $ 148,400,000
FY 2004 PresRequest $ 144,800,000
FY 2004 Conference $ 154,600,000
FY 2004 After a-t-b $ 153,700,000

NVDRS
FY 2003 $ 3,000,000
FY 2004 PresRequest $ 1,400,000
FY 2004 Conference $ 3,750,000
FY 2004 After a-t-b $ 3,727,875

NIOSH (Occupational Safety and Health total including evaluaton transfers)
FY 2003 $ 273,400,000
FY 2004 PresRequest $ 246,300,000
FY 2004 Conference $ 278,900,000
FY 2004 After a-t-b $ 277,500,000

OTHER

Preventive Health Block Grants
FY 2003 $ 134,100,000
FY 2004 PresRequest $ 135,000,000
FY 2004 Conference $ 134,100,000
FY 2004 After a-t-b $ 133,300,000

Public Health Improvement
FY 2003 $ 124,400,000
FY 2004 PresRequest $ 96,200,000
FY 2004 Conference $ 143,100,000
FY 2004 After a-t-b $ 142,200,000

Public Health Practice
FY 2003 $ 32,300,000
FY 2004 PresRequest $ 33,200,000
FY 2004 Conference $ 47,300,000
FY 2004 After a-t-b $ 47,200,000

Extramural Prevention Research
FY 2003 $ 16,100,000
FY 2004 PresRequest $ 0
FY 2004 Conference $ 16,000,000
FY 2004 After a-t-b $ 15,900,000

Eliminating Racial and Ethnic Disparities
FY 2003 $ 37,600,000
FY 2004 PresRequest $ 36,300,000

FY 2004 Conference $ 37,600,000
FY 2004 After a-t-b $ 37,300,000

National Electronic Disease Surveillance (NEDSS)
FY 2003 $ 28,600,000
FY 2004 PresRequest $ 26,700,000
FY 2004 Conference $ 28,600,000
FY 2004 After a-t-b $ 28,400,000

Bioterrorism Preparedness State and Local Emergency Response
FY 2003 $ 940,000,000
FY 2004 PresRequest $ 940,000,000
FY 2004 Conference $ 940,000,000
FY 2004 After a-t-b $ 934,454,000

BOLD=CSTE PRIORITY

LEGISLATIVE UPDATE – Sen. 1279, the Disaster Area Health and Environmental Monitoring Act passed the Senate on November 21st. Introduced by Sen. Voinovich (R-OH), the bill creates a program to monitor the short and long-term health effects of all those exposed to chemical, or other potentially hazardous substances in federal disaster areas. Specific authorized activities carried out through cooperative agreements include: (1) collecting and analyzing environmental exposure data; (2) developing and disseminating information and educational materials; (3) performing baseline and followup clinical health and mental health examinations and taking biological samples; (4) establishing and maintaining an exposure registry; (5) studying the short- and long-term human health impacts of any exposures through epidemiological and other health studies; and (6) providing assistance to individuals in determining eligibility for health coverage and identifying appropriate health services. Medical institutions, and local health departments approximate to the disaster area are eligible for cooperative agreement grants. The bill has been referred to the House Transportation and Energy and Commerce Committees. **H.R. 3539, the Hepatitis C Epidemic Control and Prevention Act** was introduced on November 19th by Rep. Heather Wilson (R-NM). A companion measure (S. 1143) was introduced in the Senate on May 23rd by Sen. Kay Bailey Hutchison (R-TX). The bills would require the HHS Secretary to develop and implement a plan for the prevention, control, and medical management of Hepatits C, including strategies for education and training, surveillance and early detection, and research. Under the early detection and surveillance provisions, the Sec. acting through the CDC would support/promote the development of state, local and tribal voluntary HCV testing programs, counseling to change behavior and reduce transmission risk, vaccination, and medical referral. The program would also provides States with Hepatits C coordinators. The Secretary is required to promote the establishment of State Hepatitis C databases to: identify risk factors for HCV infections; identify trends in the incidence of acute and chronic HCV; identify trends in the prevalence of HCV infection among groups disproportionately affected; assess and improve HCV infection prevention programs. A total of $90 million is authorized for FY 2004 and such sums for FY 2005-

2008. **Sen. Leahy (D-VT) introduced S. 1939, the Mercury Health Advisory Act** on November 23rd. Provisions ensure that the public is provided adequate notice and education on the effects of exposure to mercury through the development of health advisories and by requiring that such appropriate advisories be posted, or made readily available, at all businesses that sell fresh, frozen, and canned fish and seafood where the potential for mercury exposure exists; to the Committee on Health, Education, Labor, and Pensions. There is authorized to be appropriated to support the efforts of States to sample noncommercial fish and inland waterways for mercury and to produce State-specific health advisories related to mercury, $2,000,000 for each fiscal year.

NEW STUDY SHOWS OVERALL INCREASE IN HIV DIAGNOSES -- The most comprehensive analysis of US HIV cases completed to date reveals that new HIV diagnoses in 29 states increased in 2002, the Centers for Disease Control and Prevention announced November 26. Overall, new diagnoses in these states rose by 5.1 per cent over the four-year period 1999 to 2002. The increases underscore the urgent need for public awareness and action as countries around the globe observe World AIDS Day.

The new analysis of 102,590 people diagnosed with HIV in the 29 states between 1999 and 2002 shows that African-Americans continued to account for more than half (55%) the new diagnoses. Additionally, significant increases in new HIV diagnoses were observed among Latinos (26% increase) and non-Hispanic whites (8% increase). HIV diagnoses increased 17 per cent among gay and bisexual men, and 7 per cent among men overall. The study found no significant changes in the number of new HIV diagnoses among Asian/Pacific Islanders or Native Americans. The analysis was published in the November 28 issue of *Morbidity and Mortality Weekly Report (MMWR)*.

"Fighting HIV in America is as urgent on World AIDS Day in 2003 as it was more than two decades ago when the epidemic began," said Dr. Julie Gerberding, CDC director. "These new findings strongly support three key realities of today's epidemic: the HIV epidemic in this country is not over; more often than not the face of HIV in this country is black or Latino; and gay and bisexual men in several communities are facing a possible resurgence of HIV infection."

"Stigma and discrimination – themes for this year's World AIDS Day – help perpetuate the HIV epidemic around the world and here in our own country, said Dr. Harold Jaffe, director of CDC's HIV prevention programs. "These obstacles deter people from getting tested and prevent HIV-infected people from receiving treatment. They also increase the already heavy burden of HIV in communities of color."

The 29 states included in the analysis have conducted confidential, name-based HIV case reporting since 1999. The study is based on reported new HIV diagnoses, which is the point at which an individual learns of his/her HIV infection, not necessarily the point at which a person became infected. Increases in HIV diagnoses do not always reflect increases in new infections because numbers showing new diagnoses include individuals who were recently infected as well as those who were infected long ago but only recently tested and diagnosed.

Study authors believe, however, the data suggest that the rise in new HIV diagnoses likely represents actual new infections and not a greater amount of testing. Increases in HIV testing can lead to increased numbers of people being diagnosed with HIV. The study authors note, however, that more people who had progressed to AIDS before their HIV diagnoses might have been detected if increased testing were a major factor, and this was not the case in this study.

"Even with this still-incomplete picture of HIV infection in America, it's clear that we still face enormous challenges in continuing to confront the AIDS epidemic," Dr. Jaffe said. "Foremost among these challenges is working to encourage HIV-positive persons in our country, who are unaware of their infections, to seek testing, treatment and prevention counseling. CDC announced a new initiative in April of this year aimed at increasing opportunities for testing, counseling and treatment for these individuals." Through its new "Advancing HIV Prevention" initiative, CDC is working with communities, government groups and health care providers across the nation to help at-risk individuals learn of their HIV status, better understand ways of preventing HIV infection, and, if infected, receive treatment and care. At-risk populations include people infected with HIV, those not infected, and those who are unsure of their status. A new rapid HIV test which can provide preliminary results in as little as 20 minutes is central to this effort.

CDC estimates that between 850,000 and 950,000 Americans are now living with HIV. This is the greatest number since the epidemic began more than two decades ago. It is estimated that one fourth of the people living with HIV, approximately 180,000 to 280,000 people, remain unaware of their infections. An estimated 40,000 new HIV infections continue to occur in the US each year.

U.S. SYPHILIS RATES CLIMBS FOR SECOND CONSECUTIVE YEAR -- The syphilis rate in the United States rose in 2002 for the second consecutive year, following a decade-long decline that led to an all-time low in 2000, according to new data released November 20 by the Centers for Disease Control and Prevention (CDC).

The increase was due in large part to increases in reported syphilis cases among men, particularly gay and bisexual men. At the same time, continued declines in syphilis among African Americans and women point to the success of STD prevention efforts in some areas and populations, although African Americans remain the population most affected by syphilis.

The data, published in the November 21 issue of CDC's *Morbidity and Mortality Weekly Report* (MMWR), include cases of primary and secondary syphilis (referred to as "syphilis cases" in this release). These new syphilis cases represent the early, contagious stage of syphilis infection.

Between 2001 and 2002, the overall rate of syphilis increased 9.1 percent, from 2.2 cases to 2.4 cases per 100,000 population – the highest rate since 1999. The total number of

reported cases increased 12.4 percent, from 6,103 to 6,862 cases. However, since some syphilis cases go undiagnosed, the actual number of infections is likely higher.
The increases in reported syphilis cases in 2002 might be due in part to expanded syphilis testing in some areas. However, on a national level, there has been no significant increase in latent syphilis, the later stage of the disease, which would likely occur if increased screening was a major factor nationally.

Syphilis cases among men increased 27.4 percent between 2001 and 2002 (from 4,134 to 5,267 cases). CDC does not collect syphilis data by sexual orientation; however, study authors estimate that more than 40 percent of all syphilis cases reported in 2002 occurred among gay and bisexual men, accounting for much of the reported overall increase in the disease.

By race, the increase in syphilis cases among men included an 85.2 percent increase among non-Hispanic white men and a 35.6 percent increase among Latino men. Syphilis cases among African-American men declined slightly (2.6 percent), but African-American men continue to have the highest rate among men – 13.5 cases per 100,000 population, compared to 4.5 among Latino and 2.2 among non-Hispanic white men.
In contrast, there was a 19.0 percent decline in syphilis among women overall (from 1,967 to 1,594 cases). Cases declined 21.7 percent among African American women (from 1,527 to 1,195 cases).

The continued declines in syphilis among African Americans (10.3 percent in 2002) and among women of all ethnic groups are likely the result of ongoing syphilis education and testing efforts in these populations, especially in the South. Overall, the rate in that region has declined in recent years, and fell by 8.8 percent between 2001 and 2002. However, the syphilis rate among African Americans in 2002 was still 8.2 times higher than among non-Hispanic whites, signaling the continuing need for STD prevention in this population.

“The campaign against syphilis in the United States is now being waged on two fronts,” said Dr. Ronald O. Valdiserri, deputy director of CDC’s HIV, STD and TV prevention center. “We’re working on one front to sustain the progress made among populations formerly hardest hit by syphilis, including African Americans and women. On the second front, we are combating new challenges among gay and bisexual men.”
Recent research has highlighted increases in unprotected sex among some groups of men who have sex with men (MSM), as well as high rates of HIV co-infection among men diagnosed with syphilis (averaging about 50 percent). These findings, plus HIV surveillance data from a recent CDC 25-state study showing a 17.7 percent increase in HIV diagnoses among men who have sex with men between 1999 and 2002, have raised concerns about a resurgence of HIV in this population.

“Prevention challenges for gay and bisexual men may include a low level of concern about other STDs, as well as the belief that treatment advances mean HIV is no longer a deadly illness, resulting in relaxed attitudes toward safer sex practices,” said Dr. John Douglas, director of CDC’s STD prevention programs.

Other New STD Data
CDC also released new data from the "2002 Sexually Transmitted Disease (STD) Surveillance report." The STD surveillance report also includes the latest statistics on gonorrhea and chlamydia trends in the United States. Overall, the national gonorrhea rate decreased by 2.7 percent to 125 cases per 100,000 population in 2002 – lower than in any of the previous four years. Chlamydia remained the most commonly reported STD, with 834,555 chlamydial infections reported in 2002. The full surveillance report will be available at the following website on the afternoon of November 20:
http://www.cdc.gov/mmwr/mmwr_ss.html

CDC RELEASES FIRST STATE OF CDC REPORT -- Centers for Disease Control and Prevention (CDC) Director Dr. Julie Gerberding released the first State of CDC report November 14 at the National Press Club in Washington, D.C. The report chronicles the agency's accomplishments during Fiscal Year 2003 and provides a snapshot of plans to meet future public health challenges.

"During this past year, the public health community faced a series of challenges, both domestically and internationally," Dr. Gerberding said in releasing the report. "Month by month, CDC consistently provided a strong return on the American people's investment, acting swiftly and decisively to control outbreaks like SARS, Monkeypox, and West Nile Virus while carrying out sound, science-based programs to reduce illness and death from conditions like heart disease and obesity."

The report contains details about how CDC invested $7 billion in public health programs, both at home and abroad, that impact people's lives each day. Highlights of the fiscal year 2003 report include:

October 2002 – CDC staff investigates outbreaks of Norwalk virus, which sicken thousands on cruise ships.
November 2002 – CDC teams with other federal agencies and businesses to ease burden of diabetes in the workplace.
December 2002 – President George Bush announces nation's smallpox preparedness plan.
CDC reports new state data showing diabetes and obesity still on the rise.
January 2003 - CDC begins shipping smallpox vaccination to states. President Bush announces multi-billion dollar Emergency Plan for AIDS Relief in State of the Union address. CDC releases first ever population-based estimates of autism in the United States.
February 2003 – CDC releases data showing stroke is a leading cause of death in the United States. Also releases report showing deaths related to pregnancy remain substantially higher among blacks than whites.
March 2003 – CDC issues health alert notice about atypical pneumonia (later called SARS) circulating in parts of Asia and Canada. Lab analysis suggests new coronavirus may cause SARS.

April 2003 – CDC labs sequences entire genome of SARS coronavirus. CDC dedicates new Emergency Operations Center that allows for a more efficient response to infectious disease outbreaks and other public health emergencies. CDC also launches a new initiative to increase HIV testing and enhance prevention for people with HIV infection.
May 2003 – CDC's virtual reality lab advances job injury prevention. CDC awards more than $27 million to state diabetes control programs.
June 2003 – CDC releases new edition of *The Yellow Book* – gold standard for international travel information. CDC scientists confirm the first outbreak of monkeypox in the Western Hemisphere.
July 2003 – CDC and partners launch autism awareness initiative. CDC confirms first human case of West Nile Virus in 2003.
August 2003 – CDC and partners report that investigational screening tests are effective in identifying West Nile Virus in blood donations. CDC reports overall high vaccination rates in school-age children.
September 2003 – CDC and partners unveil a new campaign to promote proper antibiotic use. CDC and New York City Health Department announce World Trade Center Health Registry. HHS awards $13.7 million for community programs to address diabetes, asthma, and obesity.

Also highlighted in the report are details about what CDC is doing through its "Futures Initiative" to meet anticipated and unexpected public health challenges in the future. "This initiative is one of my top priorities," said Dr. Gerberding. "We soon will be implementing new ways of doing business, new processes and new directions for the agency to ensure that CDC continues to achieve the best possible science and best possible service to our customers."

NIAID EBOLA VACCINE ENTERS HUMAN TRIAL -- The first human trial of a vaccine designed to prevent Ebola infection opened November 18. Scientists from the Vaccine Research Center (VRC) at the National Institute of Allergy and Infectious Diseases (NIAID), one of the National Institutes of Health (NIH), designed the vaccine, which was administered to a volunteer at the NIH Clinical Center in Bethesda. The vaccine does not contain any infectious material from the Ebola virus.

Just three years ago, VRC Director Gary Nabel, M.D., Ph.D., together with a team of scientists from the VRC and the Centers for Disease Control and Prevention, described an experimental Ebola vaccine that fully protected monkeys from lethal infection by the virus. One component of that vaccine will now be assessed for safety in human volunteers. The trial vaccine, a type called a DNA vaccine, is similar to other investigational vaccines that hold promise for controlling such diseases as AIDS, influenza, malaria and hepatitis.

"This trial is further evidence of the ability of the VRC to rapidly translate basic research into tangible products," notes NIAID Director Anthony S. Fauci, M.D. "Our accelerated effort to understand and combat Ebola infection is part of the NIAID commitment to its biodefense mission. An effective Ebola vaccine not only would provide a life-saving

advance in countries where the disease occurs naturally, it also would provide a medical tool to discourage the use of Ebola virus as an agent of bioterrorism."

Outbreaks of Ebola in Africa kill up to 90 percent of those infected. No effective treatment exists for this highly infectious disease, which causes extensive internal bleeding and rapid death. According to experts, vaccination is the best strategy for preventing or containing this deadly infection.

A gap of two decades separated the first Ebola epidemic of 1976 and the next, which arose in 1995. In recent years, for reasons unknown, outbreaks of Ebola are occurring with increasing frequency.

On November 17, 2003, the World Health Organization reported 11 cases of Ebola hemorrhagic fever in the Republic of the Congo. Dr. Nabel notes, "The current Ebola outbreak in the Congo provides a stark reminder of the need to rapidly develop vaccines against such perilous infections. A few years ago, we did not imagine that our vaccine would enter human trials so quickly, but the re-emergence of such viruses makes it all the more important to respond quickly. Individuals who volunteer for these vaccine trials can help us understand if our new vaccines ultimately will be effective."

Twenty-seven volunteers between the ages of 18 and 44 will participate in the study. Six people will receive a placebo injection and 21 will receive the investigational vaccine, manufactured by Vical Inc., a San Diego biotechnology company working in collaboration with the VRC. Vical has also secured a nonexclusive license from NIH to proprietary gene sequences used in the DNA Ebola vaccine. In the new trial, volunteers will receive three injections over two months and will be followed for one year. Volunteers will not be exposed to Ebola virus. Individuals interested in enrolling in the trial may visit http://www.clinicaltrials.gov or call the VRC toll-free at 1-866-833-LIFE (5433).

The candidate vaccine is synthesized using modified, inactivated genes from Ebola virus. This gives the immune system information about viral structures so that it can mount a rapid defense should the real virus ever be encountered. There is no infectious material in the vaccine, and the virus was not present during any stage of the manufacturing process, notes Barney Graham, M.D., Ph.D., director of the clinical trials unit of the VRC. "It is impossible for the vaccine to cause infection," he adds, "because it employs new technology known to safely stimulate broad immune responses."

Besides assessing the vaccine's safety, researchers will also examine the volunteers' blood to look for signs of immune system reaction to the vaccine. Ultimately, the scientists envision this vaccine as the first in a two-stage vaccination strategy called prime-boost: after "priming" with the DNA vaccine, the immune system response is "boosted," or augmented, by a second inoculation with modified, non-disease-causing cold viruses that make selected Ebola proteins. The booster essentially sets the immune system on alert against future infection by Ebola virus.

In August, Dr. Nabel and his colleagues reported using the booster shot to quickly and completely protect monkeys against Ebola. A fast-acting vaccine would be of great use during an outbreak of Ebola. The full prime-boost strategy, which uses the DNA vaccine being tested in this study, elicits a stronger immune response and is important to pursue for individuals at high risk, such as health care workers. Dr. Nabel says that expanded human trials of Ebola vaccines using the prime-boost strategy could begin by 2005.