

FDA Clears Human Hookworm Vaccine for Phase I Safety Trials

Sabin/GW Researchers Receive Word on Investigational New Drug Status for Vaccine

Clinical trials to test the safety of a first-of-its-kind human hookworm vaccine will begin in the Washington, DC area in the coming weeks after the U.S. Food and Drug Administration conferred investigational new drug status on the vaccine this past January. No current vaccine is available to prevent hookworm disease, which is one of the most common chronic infections of humans with an estimated 740 million cases in areas of rural poverty in the tropics and subtropics.

The Human Hookworm Vaccine Initiative (HHVI) is sponsored by the Albert B. Sabin Vaccine Institute, and is funded by the Bill & Melinda Gates Foundation. The research is conducted at The George Washington University Medical Center. Peter J. Hotez, MD, PhD, professor and chair of GW's Department of Microbiology and Tropical Medicine leads the scientific team and has been responsible for the development of the vaccine. "Approval to be-

gin safety trials is a major milestone for the human hookworm vaccine project," Hotez said. "It has taken an amazing amount of our team's effort to get us to the current stage of vaccine development. Of course, our ultimate goal is to take this research to developing countries where the vaccine will be tested

in individuals who suffer from hookworm infection."

Human hookworm infection is caused by parasitic worms that fasten onto the inner layers of the small intestine using their teeth-like projections and cause blood loss at the attachment site. Hookworm disease refers to the iron

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The village of Americaninhas, in a rural part of Minas Gerais state in Brazil, is the focus of a field study of hookworm disease burden, being conducted by the Human Hookworm Vaccine Initiative. The members of one village family posed for a photo during an HHVI Team site visit in March. SVI program manager of the HHVI, Kari Stoeber, furnished the photo and participated in the site visit.

Albert Z. Kapikian, MD, to be Awarded the Sabin Gold Medal

May 10 Ceremony in Baltimore for SVI's Highest Scientific Award

Albert Z. Kapikian, MD, physician, medical pioneer and viral diseases researcher, will receive the prestigious Albert B. Sabin Gold Medal at a ceremony on May 10, 2005. Kapikian is the 13th recipient of this recognition, awarded annually by the Sabin Vaccine Institute to honor achievements by vaccinologists and infectious disease experts. The ceremony will be held in conjunction with the National Foundation for Infectious Diseases Eighth An-

nual Conference on Vaccine Research at the Marriott Inner Harbor hotel in Baltimore, Maryland. The ceremony will begin at 7 pm.

Kapikian's career of more than 47 years, with groundbreaking medical research contributions, is distinguished by the development of the first licensed rotavirus vaccine. "Albert Kapikian's contribution to mankind through the

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**VIEW
POINT**

The following message from the Sabin Vaccine Institute is timed to mark **National Infant Immunization Week** (NIIW), April 24-30, in the United States and as members of the Americas mark **Vaccination Week in the Americas**, April 23-30. NIIW is an annual observance that highlights the importance of timely immunization for children and infants. This year more than 500 events are expected to take place across the nation to increase awareness of the importance of vaccination. NIIW was established 11 years ago by the U.S. Department of Health and Human Services and the Centers for Disease Control and Prevention. Vaccination Week in the Americas is coordinated by the Pan American Health Organization, focusing on the children normally left behind, those living in rural border regions, indigenous people and vulnerable groups, including women of childbearing age and the elderly. We offer thoughts on the importance of immunization in a spirit of solidarity with these efforts.

**The Childhood Immunization Schedule:
Why Are Immunizations So Important?**

As parents, we are constantly concerned about keeping our children safe and healthy. To protect them, we put them in child safety seats and install childproof door latches. One of the most important ways we protect our children is to follow the childhood immunization schedule and get them vaccinated against serious but preventable diseases.

Vaccines are one of medicine's greatest triumphs because they prevent serious disease and death. Many once common infectious diseases such as polio, mumps, whooping cough, and rubella (German measles), are now only distant memories for most Americans. Today in the United States, we have few reminders of the suffering, disabilities, and premature deaths caused by these vaccine-preventable diseases.

Many of today's parents have never even seen the diseases that vaccines prevent and don't fully understand the significance of following the childhood immunization schedule. Instead, a parent may ask, "Why does my baby need so many shots?"

Before age two, every child should be immunized against 12 potentially serious vaccine-preventable diseases: measles, mumps, rubella, diphtheria, tetanus, pertussis (whooping cough), polio, *Haemophilus influenzae* type b (Hib disease), hepatitis B, varicella (chickenpox), pneumococcal disease and influenza. At least one shot is needed for each of these diseases, and for a few diseases, several doses are needed for the best protection.

Vaccines are given at this early age because the diseases they prevent are far more serious or common among babies or young children. Up to 60 percent of severe disease caused by Hib in children is among babies less than 12 months of age. Moreover, 90 percent of all deaths from whooping cough are among children under six months of age. The ages that doctors recommend vaccines in the immunization schedule are not arbitrary. They were chosen to give our children the earliest and best protection against disease.

Vaccinating a child according to the immunization schedule protects not only that child but also the entire community. Every day in the United States, there are 11,000 children born who need to be fully immunized before two years of age. The 12 diseases that infant immunizations prevent still exist and circulate in many parts of the world. For children who are not immune these diseases can still lead to pneumonia, blood infections, brain damage, liver, kidney or heart problems, skin deformation and blindness.

Talk to your child's health care provider about the childhood immunization schedule. Following it is one of the best ways parents can protect their children's health.

It Is Time for a Vaccines for Adults Entitlement Program

Message from Dean Mason, President and Chief Executive Officer, SVI



One of the most immediate and cost-effective government investment measures that could be taken to protect almost all Americans would be to establish a "Vaccines for Adults" (VFA) entitlement program.

In the early to mid-1990s, both the Bush and Clinton administrations and Congress responded to a public health problem. The measles epidemics of 1989-1991 provided the impetus. There were 55,622 reported cases of measles and 123 deaths. A full 90% of the deaths occurred in people not vaccinated against measles. Morbidity from diseases preventable by vaccination, lower immunization coverage among indigent and minority children, and "pockets-of-need" were contributing to a crisis in public health. The 64 deaths in 1990 were the largest number reported in almost 20 years.

Healthcare providers who negotiate their own prices were increasingly referring their young patients to public health clinics for all or some of their recommended vaccines. Not only were these children not receiving comprehensive health care, but the practice of referring children often meant they did not receive their vaccinations until required to do so for day care, Head Start, or school entry. Some insurance companies were scaling back on vaccines as a covered benefit while others were making it difficult for the "working poor" by raising the deductibles or limiting the amount of coverage for vaccines.

The response included the Infant Immunization Initiative, the development of Immunization Action Plans in all states and the legislative enactment of the Vaccines for Children (VFC) program. The public health community has benefited from more than a decade of the VFC program. Established through Title XIX in August, 1993, VFC was implemented nationwide in October, 1994. The VFC program guarantees the federal purchase of vaccines for children who are Medicaid eligible, without health insurance, American Indian, or Native Alaskan. It is one of the largest public and private healthcare partnerships, with over 80,000 private providers participating. It guarantees an open market for all vaccine manufacturers who negotiate through CDC's contracts.

Since the initiation of the VFC program the country has sustained high levels of immunization coverage among infants and children and record lows in vaccine preventable disease morbidity in the same age groups.

Unfortunately, the same cannot be said for adults. An estimated 114,000 excess hospitalizations and 36,000 deaths attributed to influenza occur annually with the highest morbidity and mortality occurring in adults 65 years-of-age and older. Influenza vaccine coverage in ages 18-49 years in 2002 was only 20%. It is estimated that 3500 people ages 65 years or younger die each year from pneumococcal disease that is vaccine preventable. In the 18-49 year age group, in those with defined risk factors, pneumococcal vaccine coverage is only 12%. Vaccine coverage rates among adults is woefully inadequate for other diseases. Additional vaccines to benefit adults, including possibly a vaccine against shingles that is now in clinical trials and awaiting FDA review, are on the horizon.

Vaccine protection against influenza, pneumonia, hepatitis A, hepatitis B, tetanus, diphtheria, pertussis and in some instances against meningococcal diseases should be offered to all adults. There is an occasional need to vaccinate susceptible adults against measles, mumps, rubella, and chickenpox. A government commitment to assure equal access to life saving vaccines for all adults at no cost, or at a reasonable cost if they can afford it, should be a guarantee. The cost savings of such a disease prevention program would more than justify the taxpayer expense.

A VFA program would guarantee the government's commitment to the purchase of vaccines at fair prices and as recommended by the authoritative bodies. It would expand and guarantee market share to industry, allow for vaccinations of all persons in need, encourage increases in vaccine production and supply and stimulate competition. Every adult should have the benefit of vaccines that can protect against certain diseases. Such a program would be a true example of government commitment to the protection and well being of its citizenry.

Sabin Vaccine Institute Supports PAHO Project Targeting Rubella and CRS

One-Year Project to Contribute to Elimination of Rubella and Congenital Rubella Syndrome in the Americas

The Sabin Vaccine Institute partnered with the Pan American Health Organization (PAHO) to launch a one-year project contributing to elimination of rubella and congenital rubella syndrome (CRS) in the Americas. An agreement signed in March defines a project that will focus on four countries: Guatemala, Nicaragua, Bolivia, and Paraguay.

The project will emphasize adult vaccination and supplemental immunization activities. "Rubella, sometimes referred to as German measles, has rather benign symptoms in adults," said *Ciro de Quadros*, director of international programs, SVI. "For a developing fetus, whose mother is exposed in early pregnancy, the consequences can be devastating." Surveillance in the mid-1990s in-

dicated that as many as 20,000 infants were born with CRS in the Americas each year. Today, with strong immunization programs, rubella incidence, and consequently CRS, has declined significantly. It is estimated, however, that it will take more than 20 years for CRS to be controlled by routine childhood immunization. This project will accelerate the interruption of rubella transmission by a one-time adult mass campaign to achieve more rapid decrease of the number of rubella cases and infants born with CRS.

PAHO adopted a resolution in 2003 to eliminate rubella and CRS by 2010. The project is aimed at speeding up the progress towards this goal and will serve as a pilot program in rubella and

CRS elimination that might be adopted and applied in other regions of the world.



Ciro de Quadros, MD, MPH, director of international programs, SVI, and Mirta Roses Periago, director of PAHO, signed the agreement for the Rubella Elimination project.

Human Hookworm Vaccine Initiative Receives Vaccine IND

Several More Years of Research on the Horizon

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deficiency anemia that results from moderate and heavy infections. Because women and young children have the lowest iron stores, they are the most vulnerable to chronic hookworm blood loss. In children, chronic hookworm disease contributes to physical growth retardation and cognitive impairment. Hookworm is considered a major health threat to adolescent girls, women of reproductive age, and to outcomes in pregnancy and is a major contributor to misery and suffering in the poorest of the poor.

This first phase of clinical research will assess the initial safety of the new hookworm vaccine, as well as the immune system's response to vaccination. Several more years of subsequent research on the vaccine's effect will be required before it can be licensed for use. Looking towards the future, the Sabin Vaccine Institute signed a memorandum of understanding this past fall with federal and state vaccine production facilities in Brazil for clinical development of the vaccine. An HHVI team based in Bra-

zil is now assembling baseline data in a rural area impacted by hookworm disease. In just more than a year, that data and data from safety and tolerability trials in the United States will serve as required groundwork for a wider clinical trial, to ascertain the efficacy and safety of the new vaccine.

The HHVI received past funding from the National Institutes of Health, the March of Dimes, and the China Medical Board of New York. For more information, visit www.sabin.org.

BBC World Broadcast Features HHVI

Kill or Cure Segment Depicts Hookworm Disease, Vaccine Development



Filming of BBC's *Kill or Cure* series took place this past December at The George Washington University lab of the Human Hookworm Vaccine Initiative. Pictured with the film crew are, at right, HHVI's Peter Hotez and Maria Elena Bottazzi. The segment on hookworm was aired in February.

The plight of hookworm-infected poor and the potential for a vaccine headlined a segment of *Kill or Cure*, a science and health broadcast of BBC World. The documentary series, produced in 10-part installments, is currently examining diseases that blight millions of lives, and looks at the science behind the hunt for new treatments. The hookworm program aired in February.

The Human Hookworm Vaccine Initiative's Peter Hotez, MD, PhD, provided an in-depth understanding of hookworm and efforts underway to develop a hookworm vaccine. The story line was complemented by a profile of a Vietnamese girl whose life and the lives of those around her are profoundly affected by hookworm infection indigenous in their community.

The diseases covered in this season's series are river blindness, measles, multi-drug resistant TB, pneumococcal meningitis,

Chagas, worms, rotavirus, diphtheria, STDs and trachoma. The programs were filmed around the world in locations that included Tajikistan, Cameroon, Bolivia, Tanzania and South Korea. Producers of the series write, "Although many of these diseases have been neglected by modern medical science for decades, this is a documentary series about hope. While millions of lives are lost every year, there are people working on new life-saving treatments. The programs focus on the diseases, the victims and the handful of scientists searching for the answers. *Kill or Cure* examines the development of new drugs and new ways of preventing infection."

The filming provided an opportunity to explain the immense problem of parasitic worm disease to a wide audience. "Worm infections are the most common infection of all human kind," Hotez said.



Sabin Fellow, Patricia Thomas, Named Knight Chair in Health and Medical Journalism

Author of Big Shot to Begin Project at University of Georgia



Patricia Thomas

The University of Georgia's Grady College of Journalism has named Patricia Thomas its first Knight Chair in Health and Medical Journalism. Thomas, a Sabin fellow for the past several years, will be responsible for an outreach project to improve the flow of public health news in the impoverished South.

Thomas, who has written about medicine, public health and life science re-

search for more than 30 years, will take up her new post in August. The University is located in the center of the bioscience corridor between Atlanta and Augusta. As holder of the Knight Chair, Thomas will partner with the Centers for Disease Control and Prevention, the Medical College of Georgia, the Morehouse School of Medicine, and Emory University to develop programs to improve media coverage and communication of health issues. She will develop and teach courses in health and medical journalism and create an outreach program aimed at improving the

flow of health news to the Southern Black Belt, a rural strip of hundreds of counties winding through 11 states.

Thomas was the first nonphysician to serve as editor of the Harvard Health Letter. She has been a Knight Science Journalism Fellow at the Massachusetts Institute of Technology, and in 1998 was awarded the Leonard Silk Journalism Fellowship for her book *Big Shot: Passion, Politics, and the Struggle for an AIDS Vaccine*. She was also among the first healthy volunteers to be injected with an experimental DNA vaccine for AIDS.

In Memory of Maurice Hilleman

Vaccinologist of the 20th Century

A long-time colleague of the Sabin Vaccine Institute, Maurice R. Hilleman, PhD, DSc, 85, died April 11 at a hospital in Philadelphia where he was being treated for cancer. Hilleman was a microbiologist who developed vaccines for mumps, measles, chickenpox, pneumonia, meningitis and other diseases. His discoveries have saved tens of millions of lives and reached into every home.

Though he was not as widely known among the general public as some other scientists of note, his achievements match or exceed many of the greats. Hilleman was the fourth scientist to receive the prestigious Sabin Gold Medal, which he was awarded in 1997. He maintained a close association with the Sabin Vaccine Institute since then, lending his expertise to Institute programs as a member of the SVI Scientific Advisory Council.

Raised on a farm in Montana, Hilleman credited much of his success to his boyhood work with chickens, whose eggs form the foundation of so many vaccines. He pioneered the development of eight of the 14 routine vaccines and much of modern preventive

medicine is based on his work. He is credited with having developed more human and animal vaccines than any other scientist, helping to extend human life expectancy and improving the economies of many countries. He retired from Merck in 1984 as senior vice president.

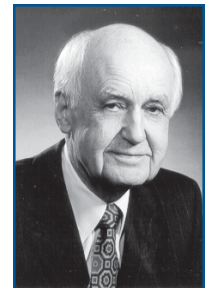
Hilleman pioneered the development of numerous vaccines, including measles, mumps, rubella, varicella, Marek's disease, hepatitis A, hepatitis B, and adenoviruses, and he participated in the evolution of vaccines against meningitis and pneumonia.

Another important aspect of his work was advancing the science of combination vaccines. For instance, the combined measles, mumps, and rubella vaccine prevents three diseases with only one vaccination. Children therefore receive fewer painful injections and parents and children face less anxiety. Pediatricians require less storage space for vaccines and less handling is required.

In March 2005, the University of Pennsylvania School of Medicine and the Children's Hospital of

Philadelphia, in collaboration with the Merck Company Foundation, announced the creation of the Maurice R. Hilleman Chair in Vaccinology.

The Hilleman Chair will be occupied by a physician/scientist contributing to vaccinology on the faculty of Penn and the post will serve to accelerate the pace of vaccine research there.



Six lucite-encased vials contain vaccines of which Maurice Hilleman led the development, a replica of an artifact included in the National Millennium Time Capsule.

Routine Meningococcal Vaccination Recommended by U.S. Advisory Committee

New Recommendation for Vaccination at the Pre-Teen Medical Visit

New Routine MCV4 Recommendation

The Advisory Committee on Immunization Practices (ACIP) to the Centers for Disease Control and Prevention (CDC) recommends routine vaccination of young adolescents with meningococcal conjugate vaccine (MCV4) at the pre-adolescent (11-12 year old) visit. The recommendation was announced February 10, 2005.

According to CDC, recommending MCV4 vaccination in pre-adolescents may strengthen the role of the pre-adolescent visit and have a positive effect on vaccine coverage. ACIP recommends that pre-adolescents see a healthcare provider at age 11-12 for a routine visit, at which time appropriate immunizations and other preventive services should be provided.

Expanding the MCV4 Recommendation

In order to extend the benefit of MCV4 vaccination for older adolescents, the ACIP recommends vaccination before high school entry (~15 years old). Within 3 years, the goal is routine vaccination with MCV4 of all adolescents beginning at 11 years of age. ACIP

recognizes that vaccine supply may be an issue in the first few years after licensure of MCV4. Adolescents in other age groups who wish to decrease their risk of meningococcal disease may elect to receive vaccine.

College freshmen who live in dormitories are at higher risk for meningococcal disease compared to other people of the same age. Because of the feasibility constraints in targeting freshmen in dormitories, colleges may elect to target their vaccination campaigns to all matriculating freshmen. The risk for meningococcal disease among non-freshmen college students is similar to that for the general 18-24-year-old population. However, the vaccines are safe and immunogenic and can be provided to non-freshmen college students who want to reduce their risk for meningococcal disease.

Meningococcal disease is caused by bacteria that infect the bloodstream and the linings of the brain and spinal cord, causing serious illness. Every year in the United States, 1,400 to 2,800 people get meningococcal disease. Ten to 14 per-

cent of people with meningococcal disease die, and 11-19 percent of survivors have permanent disabilities (such as mental retardation, hearing loss, and loss of limbs). The disease often begins with symptoms that can be mistaken for common illnesses, such as influenza. Meningococcal disease is particularly dangerous because it progresses rapidly and can kill within hours.

The new meningococcal vaccine was licensed by the U.S. Food and Drug Administration (FDA) on January 14, 2005 for use in people 11-55 years of age. It is manufactured by Sanofi Pasteur and is marketed as Menactra™.

The vaccine is highly effective, conferring protection against invasive disease caused by four meningococcal serogroups—A, C, Y, and W-135. However, it does not protect people against meningococcal disease caused by “type B” bacteria. This type of bacteria causes one-third of meningococcal cases. More than half of the cases among infants less than one year old are caused by “type B,” for which no vaccine is available.

Vaccination of the Elderly Remains a Key Goal of Influenza Prevention

“Impact of Influenza Vaccination on Seasonal Mortality in the U.S. Elderly Population” by Simonsen et al. (2005) Indicates the Need for Improved Vaccines and Influenza Treatments

A study published in the February 14 *Archives of Internal Medicine* reported that vaccination of the elderly population against influenza may be less effective in preventing death among the elderly than previously assumed. The study’s findings caused some confusion about whether people 65 years and older should receive an influenza vaccination.

The Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH) continue to support the Advisory Committee on Immunization Practices (ACIP) recommendation that people aged 65 and

older get vaccinated against influenza each year. They are at highest risk for complications, hospitalizations, and deaths from influenza. Vaccination remains the best protection from influenza available for the elderly and their loved ones.

In the current study by Simonsen et al., the authors in no way imply that the elderly should not receive influenza vaccine. Rather, the study concludes that the vaccine may prevent fewer deaths among the elderly than previous studies would have suggested. Therefore, the authors note that there is room for

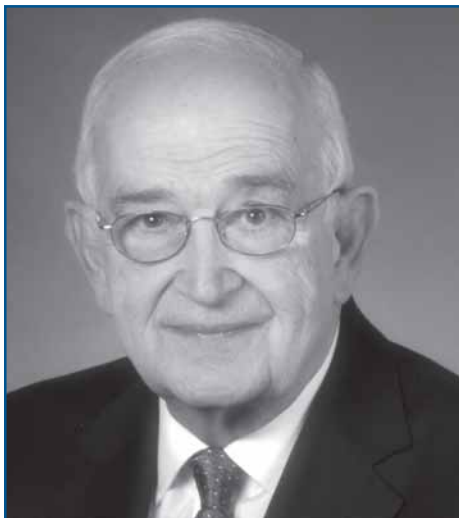
improvement in influenza prevention efforts, including research into developing more effective vaccines for the elderly and the increased use of medicines to treat influenza.

In addition, recently published studies raise the possibility that it may be beneficial to vaccinate larger numbers of healthy persons, including children, to prevent transmission of influenza viruses to high risk persons such as the elderly.

The ACIP and CDC continue to consider whether to expand the influenza vaccine recommendation to other groups pending ample vaccine supply.

Vaccine Developer Albert Z. Kapikian, MD, to be Awarded the Sabin Gold Medal

NIH Officer John La Montagne, PhD, to be Recognized with Posthumous Award



Albert Kapikian

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field of vaccines is truly extraordinary,” said H.R. Shepherd, chairman of the Institute. “It takes a great vision and dedication to achieve such progress for humanity.”

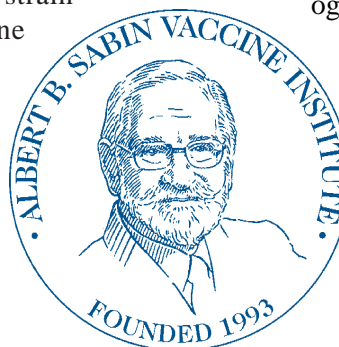
In the 1950s Kapikian began studying the epidemiology and causes of various viral diseases. He is renowned for pioneering studies using electron microscopy to discover and characterize viruses causing major diseases in humans. In 1972, Kapikian identified the Norwalk virus, the first virus associated with acute epidemic gastroenteritis, gaining recognition as “the father of human gastroenteritis virus research.” In 1973, he and two colleagues identified the virus that causes hepatitis A. He also became the first person in the United States to detect and visualize human rotavirus, which was discovered by others in Australia. He dedicated his efforts to studying this leading cause of severe diarrhea in infants and children, which accounts for more than 500,000 deaths annually, predominantly in the developing world.

Working with the National Institute of Allergy and Infectious Diseases (NIAID), Kapikian led a nearly 25-year effort to develop an oral rotavirus vaccine. The team’s neo-Jennerian rotavirus

vaccine strategy involved mating outer proteins from different human rotavirus strains with a monkey rotavirus that is attenuated (weakened) for humans and combining the resulting hybrid viruses into one vaccine. From a single-strain vaccine in 1984, the vaccine was gradually made protective against the four most important clinical strains of rotavirus. In 1998, this vaccine became the first rotavirus vaccine licensed in the United States.

Kapikian graduated from Cornell University Medical

College in 1956 and in 1957 joined the National Institutes of Health (NIH) as a commissioned officer of the U.S. Public Health Service. In 1967 he was appointed head of the Epidemiology Section of the Laboratory of Infectious Diseases, a position he holds today as a member of the Civil Service. He has received numerous honors and is the author of many scholarly papers.



John La Montagne to be Posthumously Honored

John R. La Montagne, PhD, who served as NIAID deputy director from 1998 until his sudden death this past November, will be posthumously recognized at the Sabin Gold Medal ceremony. He was a presenter of the Sabin Gold Medal at last year’s ceremony. During his 30-year career at NIH, La Montagne was a noted scientist and an influential leader in the field of infectious diseases. His contributions to domestic and global efforts to fight emerging and re-emerging infectious diseases included biodefense.

John R. La Montagne received his PhD from Tulane University in 1971. In 1976, he came to NIH as the Influenza Program officer at NIAID. He became the program officer for the Viral Vaccines Program in 1983, and the Influenza and Viral Respiratory Diseases program officer in 1984. Beginning in 1986, La Montagne assumed the role of director of the AIDS Program. In 1987 he was appointed director of the Microbiology and Infectious Diseases Program, which became a division in 1988. He was appointed deputy director of the NIAID in February 1998.



John La Montagne

He received numerous awards for his scientific accomplishments, including the Public Health Service Special Recognition Award for leadership in childhood vaccine research programs, the Surgeon General’s Certificate of Appreciation, and the Secretary’s Award for Distinguished Service for design and implementation of critically important biodefense strategies. His longtime colleague, Regina Rabinovich, MD, MPH, director, Infectious Diseases, Bill & Melinda Gates Foundation, will present the special award to his widow, Mary Elaine Elliot La Montagne.

Cancer Vaccine Consortium Breaks New Ground in ELISPOT Testing

ELISPOT Proficiency Panel Project is Launched

Validation is essential for all immunological assays that are used to monitor patient's immune response to vaccines, and validation efforts need to include external proficiency testing. The Cancer Vaccine Consortium (CVC) has organized a groundbreaking project to help establish validation standards for an ELISPOT assay for interferon-gamma. This project, an ELISPOT proficiency panel, will, for the very first time, bring many members of biotech companies and academia together to compare and test ELISPOT performance and various protocol approaches. This effort will join 34 laboratories working on a wide variety of cancers, and with a broad range of vaccine types.

There are currently no such testing programs set up for repeated use through any agency or institution. Typically, they are run in small collaborative efforts of groups working in a similar scientific environment. For example, the CVC proficiency panel is based on recently completed work by the ELISPOT Collaborative Study Group, a network of 11 labs involved in HIV vaccine trials.

This validation project offers an effective tool for testing the proficiency in performing an ELISPOT assay. It also provides documentation for regulatory and sponsoring agencies about the participants' approach to this technique.

This project further allows comparison of individual ELISPOT protocol details with those of the entire panel, without compromising anyone's confidentiality. To protect the intellectual property of each participant, the panel will be performed and results will be shared in coded format.

This panel is planned to be the first in a series of validation and standardization projects to address the various complex setup modalities for ELISPOT testing in the cancer research community. Various other follow-up panels are being discussed, for instance testing of weak antigens, in vitro stimulation strategies before ELISPOT testing, various antigen presentation strategies, and more.

This project fits the CVC's mission, which is to help its members pursue common goals and overcome common hurdles in the development of cancer vaccines. Overall Consortium goals include accelerating the development of cancer vaccines through interaction with the FDA and other regulatory agencies; establishing communication networks among public and private organizations pursuing cancer vaccines; and educating the public, media and other constituencies about cancer vaccines.

The Consortium has a number of goals for this proficiency panel. They include:

1. Establishing leadership in shaping assay standards
2. Initiating the process of working with the FDA on common assay standards
3. Reducing time and cost of assay development
4. Preserving current standards of practice while providing a basis for improving individual protocols
5. Building connections to other research groups
6. Providing support for broader assay development efforts

This initiative was first presented at the CVC's San Francisco meeting in November 2004. In response to the high level of interest shown by Consortium members, the CVC went forward with the plan. Dennis Panicali, PhD, co-chair of the Consortium's Assay Working Group, is overseeing the project. Sylvia Janetzki MD, PhD (ZellNet Consulting), an ELISPOT specialist, is managing the project. The Consortium has also engaged the services of BBI Biotech Research Laboratories and statistician Kathy Panageas, PhD, of Memorial Sloan-Kettering Cancer Center.

For more information about the ELISPOT proficiency panel, please email Susan Geiger, Executive Director of the CVC, susan.geiger@sabin.org or call 414-918-3199.

Save the Date

Celebrating Leadership in Global Health

2005 Albert B. Sabin Vaccine Institute Awards

Wednesday, June 29, 2005—The University Club, New York City

6:30 PM Reception—7:30 PM Dinner and Awards Presentation

Ticket information, (212) 997-0100 or (203) 972-7907

Ciro de Quadros Honored by UC Berkeley with Public Health Hero Award

International Award Recognizes Efforts to Rid the World of Infectious Diseases

The School of Public Health at the University of California (UC), Berkeley, celebrated the 9th annual Public Health Heroes Awards Ceremony on March 18. SVI's **Ciro de Quadros, MD, MPH**, was presented with the International Public Health Hero award for his work to rid the world of infectious diseases at the event at San Francisco's Exploratorium.

The Public Health Heroes honor was established by the UC Berkeley School of Public Health to broaden awareness and understanding of the public health field by recognizing individuals and organizations for their significant contributions and exceptional commitment to promoting and protecting the health of the human population.

"I am deeply honored by this special award," de Quadros said. "I am pleased that it draws attention to important public health efforts being carried out around the world." De Quadros has dedicated his career to freeing the world of infectious diseases, especially those that disproportionately affect the health and social development of the world's poorer countries.

A pioneer in developing effective strategies for surveillance and containment, de Quadros served as the World Health Organization's chief epidemiologist for smallpox eradication in Ethiopia in the 1970s. Following the global eradication of smallpox, he became director of the Division of Vaccines and Immunization for the Pan American Health Organization, for whom he successfully directed efforts to eradicate poliomyelitis and measles from the Western Hemisphere.

Since 2003, de Quadros has led SVI's international programs. Upon presenting the award, **David Brandling-Bennett, MD**, senior program officer, Infectious Diseases Division, Global Health Program, Bill & Melinda Gates Foundation, described de Quadros as

one whose name is "synonymous with successful immunization." He added, "Ciro showed the countries how to get political commitment, secure international and external resources, and build effective programs."

Four additional honorees were **Sarah Weddington, JD** (National Hero); former California state senator **John Vasconcellos, JD** (Regional Hero); and the Pacific Business Group on Health (Organizational Hero).



Dr. Ciró de Quadros, right, is presented the International Public Health Hero award by **David Brandling-Bennett, MD**, senior program officer, Infectious Diseases Division, Global Health Program, Bill & Melinda Gates Foundation. Photo: *Peg Skorpinski*

Vaccines Wins Acclaim Among Publishers

Book Edited by de Quadros Merits Excellence Award

Vaccines: Preventing Disease and Protecting Health, a publication of the Pan American Health Organization, edited by **Ciro de Quadros**, SVI director of international programs, won an award from the Association of American Publishers in the medical science category. The award, presented February 8 at the annual conference of the group's Professional and Scholarly Publishing Division, is given "to acknowledge excellence in book, journal and electronic publishing in all the disciplines represented by professional, scholarly and reference publishing."

The publication recounts the various ways vaccines have played a role in improving the health of the world's populations, ranging from early efforts against yellow fever at the turn of the century to the eradication of smallpox and polio from the Americas to the challenges of vaccines for emerging and re-emerging diseases, such as HIV/AIDS and malaria.

The publication may be ordered from the PAHO publications website, publications.paho.org.

Smithsonian's Museum of American History Marks 50th Anniversary of the Polio Vaccine

New Exhibition Explores Extraordinary History of a "Medical Miracle"

Last Spring, *The Sabin Vaccine Report* reported on the celebrations commemorating the polio vaccine trials that commenced in 1954. The results of the trials were announced with jubilation in April 1955. So, new commemorations have begun this month for the 50th anniversary of the announcement of a safe and effective vaccine, including a special museum exhibit.

The exhibit at the Smithsonian's National Museum of American History in Washington, DC, evokes the dread fear of polio that preceded a vaccine and delineates the years of its use to the point where many young people have no recollection of the disease. "Whatever Happened to Polio?" tells the story of polio disease in the United States, the vaccine development, current world efforts to eradicate polio and the stories of survivors and the influence they have had on American society.

"The introduction of a successful polio vaccine in 1955 was one of the most significant events of the 20th century," said Brent D. Glass, director of the museum. "The disease has had far-reaching effects both in the lives of commu-

nities and individuals and in unexpected places in American society."

Those over 55 years of age probably remember summers when whole communities shut down as families kept children home out of fear of exposure to polio. Today, transmission of polio worldwide has nearly ended.

Poliomyelitis is a viral disease that primarily affects the motor neurons that control muscles, especially those of the limbs, breathing and swallowing, and can cause paralysis and sometimes death.

The inactivated (killed) polio vaccine (IPV) was developed in 1955 by Jonas Salk, MD. A live attenuated (weakened) oral polio vaccine was developed by Dr. Albert Sabin in 1961. As a result of the Salk and Sabin vaccines, the last case of wild polio occurred in the United States in 1979. A massive international public-private sector collaboration began in the 1980s with the goal of eliminating transmission of poliovirus everywhere in the world.

During their exhibit preparation, the Smithsonian curators conducted extensive research, including an interview about polio elimination achievements in

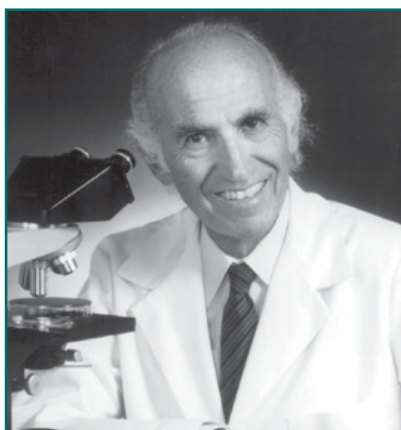
the Americas with Ciro de Quadros, MD, MPH, director of international programs at the Sabin Vaccine Institute.

The exhibit is a one-year display that will explore some of the changes in American medicine in the 20th century and the impact a disease can have on society as a whole.

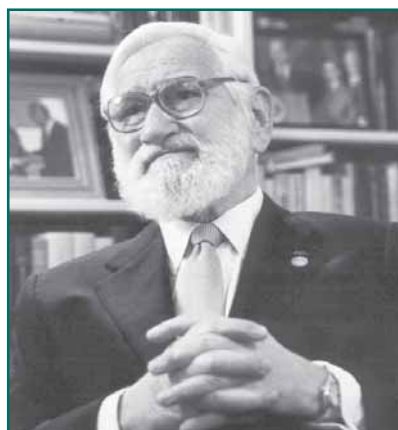
According to the Smithsonian, the show draws upon the themes of community activism, human resilience, the development and use of medical technologies, medical science, and competition and rivalry in science. By examining the complicated history of polio and the vaccine that was hailed as a "medical miracle" in the 1950s, the exhibition provides a better understanding of science, health and the impact of collective action on society.

Significant objects in the exhibition include a syringe used during the clinical trials 1954 and 1955 by Jonas Salk; an iron lung; a chest respirator; objects from disability activists Justin Dart, who was instrumental in passing the Americans with Disabilities Act and received the Presidential Medal of Freedom, and Ed Roberts, who integrated the UC Berkeley campus in the 1960s and was a founder of the independent living movement. Other exhibits include a gene synthesizer, equipment used today by vaccinators in India and Africa, and leg braces worn by President Franklin D. Roosevelt—the most famous polio survivor in America. A particularly intriguing object from the museum's collections is a piece of 70-year-old cake from one of the Birthday Balls held by the March of Dimes in honor of Roosevelt.

The Smithsonian website includes information related to the exhibit at americanhistory.si.edu/polio. The National Museum of American History is located at 14th Street and Constitution Avenue N.W., Washington, DC, with daily hours from 10 am to 5:30 pm, except Dec. 25.



Jonas Salk, MD (1914-1995) developed the inactivated polio vaccine licensed in 1955, a version of which is used in the United States today.



Albert Sabin, MD (1906-1993) developed the live attenuated oral polio vaccine licensed in 1962 and extensively used around the globe.

Vaccine Meetings on Pandemic Influenza, Rotavirus, Cancer Yield Insightful New Releases

Pandemic Influenza Threat Examined, Global Response Plan Explored in SVI Proceedings Report

Pandemic influenza outbreaks (when a novel strain emerges to which humans are not sufficiently immune) occur three or four times a century. In these early days of the new millennium, scientists are closely watching avian or “bird” flu outbreaks in Asia for signs of an impending catastrophe. The last great epidemic of 1918-1919, resulting in a worldwide death toll of between 40 million and 100 million people, is a grim reminder that history could repeat itself. Better understanding of novel influenza viruses and coordinated global health strategies may thwart or reduce the impact of another pandemic outbreak. These considerations are the subject of a new SVI publication, *Pandemic Influenza: Can We Develop a Global Vaccine Policy?*

An alarming trend in novel infectious diseases such as SARS in 2003 and increasing cases of avian influenza abroad has heightened the attention of the world’s scientific community to imminent pandemic. While SARS was relatively easily contained, its severity and newness surprised many. In recent months, avian influenza, once restricted to poultry and wild birds, has “jumped species” and is now known to have infected humans both through direct animal to human transmission and, most alarmingly, in probable human-to-human cases.

SVI convened the 11th Annual Vaccine Policy Colloquium in the fall of 2004, bringing together government officials, academic scientists and industry representatives to address and tackle key issues surrounding pandemic influenza. The expert group cautiously predicted



that a new pandemic is likely to occur in the not-too-distant future and called for a global response plan and vaccine policy to avoid the potentially overwhelming death toll that such a pandemic could pose. These leading stakeholders probed different aspects of pandemic planning, from initial source recognition and surveillance to the international coordination and political considerations of an emergency plan.

Proceedings of 2004 Cancer Colloquium Published

The *Proceedings of the Sixth Annual Walker's Cay Colloquium on Cancer Vaccines and Immunotherapy* are now available. The 70-page document is an edited commentary encapsulating the presentations and discussion which took place at the March 2004 international gathering of scientists from academia, industry, and government in the field of cancer vaccines.

Following a keynote address by Rolf Kiessling of the Karolinska Institute discussing the Her-2/neu oncogene, 27 presentations offer news of basic and clinical research, with lessons and insights applicable to future research and trial design. Reports range from basic ques-

tions in immunology to products in an advanced stage of development such as GVAX®, Provenge® and Theratope®. These presentations are grouped under session titles “Target Antigen Discovery and Validation,” “Platforms of Vaccine Development,” “Tolerance, Immunosuppression, and Tumor Escape Mechanisms,” “Adoptive T Cell Therapy

BOOK CORNER

These proceedings documents can be downloaded from www.sabin.org. Limited copies are available from the Sabin Vaccine Institute upon request.

and Dendritic Cell Based Therapies,” and “Clinical Trials and Immune Assessment of Response.” Also included are participants’ submitted abstracts and a glossary.

Rotavirus and Vaccine Development Appraised in Symposium Proceedings

The rapid introduction of safe, effective, and affordable rotavirus vaccines is urgently needed in developing countries, where nearly 500,000 children a year die from the disease, according to the most recent mortality estimates reported at the Sixth International Rotavirus Symposium. The symposium marked a watershed in the decades-long effort to bring such vaccines into use.

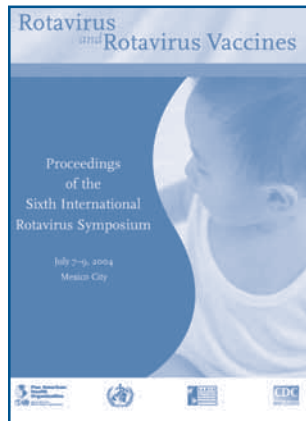
The *Proceedings of the Sixth International Rotavirus Symposium* describes how, for the first time, scientists, policy makers, economists, public health experts and the donor community together tackled the scientific, social,

and economic issues that must be resolved for rotavirus vaccines to become widely accessible to the children who need them most—those living in impoverishment or in developing nations.

First discovered by Dr. Ruth Bishop in 1973, rotavirus is described as a “democratic infection” afflicting nearly all children, whether rich or poor, by the age of 5. Yet it is the world’s poorest children who are most likely to die from

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rotavirus. More than 80 percent of rotavirus deaths occur in developing countries where resources are scarce and health care systems inadequate. By breaking with past practices and focusing clinical trials and licensure efforts in middle- and low-income countries, the global health community would save and change the lives of children too chronically sick and weak even to attend school.

With a new vaccine just having entered the market and another nearing completion of clinical trials, the global rotavirus community finds itself at a pivotal juncture in the effort to overcome the devastating mortality caused by rotavirus. Successful, widespread introduction of these vaccines will hinge on the answers to three fundamental questions: **1. Efficacy:** will the new vaccines work equally well for children in lower income countries as in upper- and middle-income countries? **2. Safety:** will a few adverse events lead to the withdrawal of the vaccines? **3. Cost:** will the new vaccines be priced and financed in a way to ensure long-term affordability and sustainability?

In a declaration signed by health officials from 16 Latin American countries during the symposium, delegates agreed “to continue to support immunizations in the region as a common good in the region, as the highest political priority” and “to facilitate the introduction of the rotavirus vaccine, as soon as it becomes available at affordable prices for the countries in the region.”

SABIN CALENDAR

APRIL-SEPTEMBER 2005

April 18 – 20 *Arlington, Virginia*
Bio-Chem Defense Vaccines and Therapeutics

www.infocastinc.com/biovac.html

April 19 – 20 *Montreal, Canada*
World Vaccine Congress Montreal 2005
www.lifescienceworld.com/2005/wvcm_CA

April 24 – 30 *USA Nationwide*
2004 National Infant Immunization Week

www.cdc.gov/nip/events/niiw

May 1 – 5 *Lisbon, Portugal*
International Society of Travel Medicine Conference 2005

www.istm.org

May 9 – 11 *Baltimore, Maryland*
Eighth Annual Conference on Vaccine Research

www.nfid.org/conferences

May 10 *Baltimore, Maryland*
Albert B. Sabin Gold Medal Ceremony

www.sabin.org/awards_gold.htm

May 12 – 13 *Mainz, Germany*
Cancer Immunotherapy 2005

www.c-int.org

May 23 – 25 *Amsterdam, Neth.*
Phacilitate Vaccine Forum Spring 2005

www.phacilitate.co.uk

June 1 – 2 *Rockville, Maryland*
Advisory Commission on Childhood Vaccines (ACCV) Meeting

www.hrsa.gov/osp/vicp/accv.htm

June 1 – 3 *North Bethesda, Maryland*
Accelerating Anticancer Agent Development and Validation Workshop
www.acceleratingworkshop.org

June 7 – 8 *Washington, DC*
National Vaccine Advisory Committee Meeting www.hhs.gov/nvpo

June 8 – 10 *Prague, Czech Rep.*
Plant-Based Vaccines & Antibodies
www.meetingsmanagement.com/pbva_2005

June 14 – 15 *San Diego, California*
From Innate Immunity to Vaccines
www.infocastinc.com/vac.html

June 15 - 18 *Lisbon, Portugal*
12th International Congress on Infectious Diseases
www.isid.org

June 21 – 24 *Cold Spring Harbor, NY*
7th Annual Sabin Colloquium on Cancer Vaccines and Immunotherapy
www.sabin.org/pub_cancer.htm

June 27 – 29 *Bethesda, Maryland*
2005 Annual Conference on Antimicrobial Resistance
www.nfid.org/conferences/resistance05

June 29 *New York, New York*
Sabin Awards Celebration
The University Club
www.sabin.org/awards.htm

June 29 – 30 *Atlanta, Georgia*
Advisory Committee on Immunization Practices (ACIP)
www.cdc.gov/nip/acip

July 12 – 15 *Boston, Massachusetts*
NACCHO-ASTHO 2005 Joint Meeting
www.astho.org

September 5 – 7 *Lisbon, Portugal*
Cancer Vaccines/Adjuvants/Delivery
www.meetingsmanagement.com/cvadd_2005



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