

# SABIN VACCINE REPORT

the newsletter of the Albert B. Sabin Vaccine Institute at Georgetown University

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## Malaria Vaccine Development

*A comprehensive report on public and private efforts, including an editorial from the World Health Organization and a report from the National Institutes of Health's Fogarty Center on a study to quantify the global burden of malaria.*

*A scientist who is also a human being cannot rest while knowledge which might be used to reduce suffering sits on the shelf.*

Albert B. Sabin

The Albert B. Sabin Vaccine Institute is a non-profit institute dedicated to continuing the work and achieving the vision of Albert B. Sabin: to fully realize the potential of vaccination to prevent disease.

Founded in 1994, the Institute strives to prevent disease by promoting the development of new vaccines and delivery systems.

**Dedicated to Disease Prevention**

www.sabin.georgetown.edu

## Sabin Institute Scientist Honored

**Joseph A. Bellanti Receives Award**

BY JOHN CLYMER

Sabin scientist Joseph A. Bellanti, a Georgetown pediatrician and vaccine researcher, received the 1998 State University of New York at Buffalo Distinguished Medical Alumnus award in recognition of his long career as a teacher, researcher, and practitioner.

### A Most Prestigious Award

"I am both honored and humbled," Bellanti told medical school alumni, officials, and guests who gathered for a dinner in his honor in September on the Buffalo campus. "Medicine is about reducing human suffering. I hope that being selected for this award means that over the course of my career I have in some small measure helped to reduce human suffering, for that is this profession's highest achievement."

"The Distinguished Medical Alumnus is the most prestigious award given by the medical school and Medical Alumni Association," said Bertram A. Portin, assistant dean of alumni affairs at the SUNY-Buffalo School of Medicine and Biological Sciences. The pre-

ognizes a pioneer in translational medicine, a physician-scientist who has the rare skills to turn new medical knowledge into therapies and preventive measures that benefit patients. Joe Bellanti was a leading light in translational research long before the term 'translational research' was coined," Shepherd said.

In 1975, Bellanti founded the International Center for Interdisciplinary Studies of Immunology at Georgetown University Medical Center. Under his direction, more than 300 physicians from all over the world have received research and specialty training. He and his colleagues are prolific contributors to scientific literature, particularly in the area of vaccine development and immune response to infectious diseases.

"Perspective is essential," Bellanti commented. "No matter what one accomplishes in the laboratory, what is truly important is saving and improving the quality of human lives." ❖

## Peggy Johnston: You can go home again

BY PATRICIA THOMAS

The personalized plate on Margaret I. "Peggy" Johnston's car reads "HIV VAX." She got it in 1996, when she left a highly successful career at the NIH to become the first employee of a new organization called the International AIDS Vaccine Initiative (IAVI). Johnston took this dramatic step because she wholeheartedly endorsed IAVI's belief that HIV vaccines need to be made a top international priority. She was also convinced that her personal efforts could accomplish more within a small, single-minded outfit than within a sprawling federal bureaucracy.

Now, two and a half years later, the NIH has developed a new attitude toward AIDS vaccines, and Peggy Johnston is back. Having left as deputy director of the Division of AIDS (DAIDS), Johnston now occupies two other slots: assistant director for HIV/AIDS vaccines at the National Institute of Allergy and Infectious Diseases (NIAID) and associate director of the vaccine and prevention research program at DAIDS, which is part of NIAID. The former is a newly created post that moves HIV vaccines several rungs higher on the administrative ladder and gives Johnston a direct line of report to NIAID Director Anthony Fauci. She's been charged with linking NIAID's intramural and extramural vaccine research and making sure that everyone is pulling in the same direction.

### Running a global start-up

In a sense, what Johnston did while she was away from the NIH made it possible for her to return. After joining IAVI Johnston spent more time on airplanes than behind the wheel of her car. She was realizing the global ambitions of IAVI's parent organizations, which include the Rockefeller Foundation, the World Bank, and UNAIDS. By taking the vaccine message to scientific conferences, government meetings, and corporate boardrooms on nearly every continent, Johnston quickly became the group's public face, first as scientific director and later as vice president for scientific affairs. By mid-1998 IAVI had developed a high profile, a staff, a "blueprint" for speeding HIV vaccine development, and a growing endowment.

While Johnston was promoting AIDS vaccines as an urgent public health issue, NIH leaders were getting the message—not only from her, but also from other private groups such as the AIDS Vaccine Advocacy Coalition and the Sabin Vaccine Foundation (forerunner and parent of the present Sabin Vaccine Institute). "The government does listen," Johnston says, "as hard as it is for people to realize that sometimes. And it is responsive."

Public pressure and professional criticism of its AIDS activities caused the NIH to designate HIV vaccine

See JOHNSTON, page 3.



Pictured from left to right: John R. Wright, Dean; Jacqueline Bellanti; Joseph A. Bellanti; Elizabeth L. Maher, President, Medical Alumni Association.

sentation was made by John R. Wright, dean of the School of Medicine and Biomedical Sciences, and Elizabeth L. Maher, president of the Medical Alumni Association. Bellanti graduated from the medical school in 1958.

Bellanti began his teaching career at Georgetown in 1963. He is Professor of Pediatrics and Microbiology-Immunology. He recently became senior vice president of the Albert B. Sabin Vaccine Institute at Georgetown University. For most of the decade before Sabin's death in 1993, he and Bellanti worked side by side at Georgetown. Today, Bellanti continues research he began with Sabin, as part of a multinational effort to develop an intranasal measles vaccine.

Bellanti recently represented the Institute at the 1998 Consultative Group meeting at the Children's Vaccine Initiative (CVI) in Geneva, where he discussed the measles vaccine studies with colleagues from the United Nations Children's Fund (UNICEF), the World Health Organization (WHO), the Centers for Disease Control (CDC), and Mexican authorities. Plans are underway for an interdisciplinary meeting to discuss the current status of new delivery systems for respiratory tract immunization and the global eradication of measles.

H.R. Shepherd, chairman of the Sabin Vaccine Institute, said the Distinguished Medical Alumnus award is especially important "because this year it rec-

# Vaccine Diplomacy

by Joseph A. Bellanti

The effective use of vaccines strikes at the heart of one of medicine's greatest challenges for the 21st century: the prevention of infectious diseases. In order to achieve this, global scientific, political and economic cooperation are necessary. The biennial Children's Vaccine Initiative (CVI) Consultative Group Meeting November 9-10 in Geneva, Switzerland was based on this fundamental premise. The meeting was attended by representatives from multi-national immunization programs, the development assistance community, industry, non-government lay organizations, national governments, national and international health agencies, research institutes and academia, including the Albert B. Sabin Vaccine Institute.

The Institute is dedicated to building international cooperation needed to encourage research and distribution of vaccines to people in every corner of the world, to lift people from the suffering caused by disease. This was the dream of Albert Sabin and it is the Institute's guiding star.

The first half of the 20th century saw the entire world gripped by fear of the mysterious and deadly disease called paralytic poliomyelitis or polio. Children who happily ran and played suddenly could run no more, struck down by the greatly feared polio virus about which little was known. At the height of the polio epidemic in 1952, there were 52,768 new cases in the United States. It was Albert Sabin's indefatigable effort that led to the development of the oral polio vaccine that made possible a global campaign to eradicate the disease. The vaccine was to a large degree a product of Sabin's forceful character and his intervention to overcome geopolitical barriers to its development. The eradication campaign drove polio from the Americas and is on track for worldwide eradication in the year 2000. (Jonas Salk's injected vaccine became available five years earlier, however, it was more difficult to administer and provided less immunity.)

Not only did Sabin's vaccine provide the means to eradicate polio globally, his intuitive gift of prediction made him a trailblazer in the globalization of vaccine research and development. At the height of the Cold War in the late 1950s, it was Sabin and Soviet scientists who put aside their countries' considerable political differences to successfully test the oral polio vaccine in massive clinical trials in the Soviet Union and several Eastern bloc countries.

This history provides a backdrop for the Children's Vaccine Initiative's efforts to combat infectious diseases throughout the world. As World Health Organization Director General Gro Bruntland and several other speakers at the CVI meeting made clear, that mission has never been more urgent than it is today.

In our modern age, diseases that once stopped at the water's edge or took many months to be transported from one continent to another now spread around the world in a matter of hours. Armed with powerful vaccines, most of the developed world has conquered polio, measles, tetanus and other diseases that continue to kill or incapacitate millions of people in less developed countries. But malaria, tuberculosis, AIDS and other, less-publicized epidemics such as measles, ravage developing countries' human capital, consigning them to a persistent state of poverty and dependence. This situation threatens all people's health regardless of where we live, and it threatens our economic health by weakening the global market. Vaccines are the most humane and cost effective weapon in the medical arsenal to rectify this situation.

Delegates to the CVI meeting agreed that every child has a right to immunizations. Peoples of all countries face a moral and economic imperative to encourage the development and use of new vaccines and technologies to administer them more easily and cheaply. The scientists, public health officers, humanitarians, policy makers and advocates gathered for the CVI meeting are actively taking up this challenge in various ways.

For example, a major investigative effort of the Sabin Vaccine Institute relating to the aerosol administration of vaccines was discussed at the CVI conference. This effort is a continuation of Sabin's research on a measles vaccine that can be inhaled rather than injected. Measles is a silent human catastrophe. Although measles epidemics are rare in the U.S., thanks to injected vaccines, in 1993 measles killed nearly 1.2 million children and infected more than 45 million children worldwide. Albert Sabin reasoned that a more effective immunization strategy would be necessary to eradicate measles. Working in my laboratory until one month prior to his death, he was actively studying the optimal conditions for delivery of measles vaccine by aerosol. He reasoned that, as with his oral polio vaccine, this approach of administering the vaccine through an alternative route — in this case the respiratory system — would be more effective than parenteral administration (injection).

At the CVI meeting, I was able to confer with World Health Organization officials and public health authorities from the U.S., Mexico and other countries. We plan to meet in early 1999 at Georgetown University Medical Center to adopt specific strategies to accelerate development of a non-injected measles vaccine. This research on the respiratory route will stretch from our laboratories at Georgetown to California, to field tests in Mexico, South Africa and throughout the world to achieve Albert Sabin's dream. It also will involve efforts in New York, Washington, Brussels, Geneva and elsewhere to secure funding to distribute and administer the new vaccines as soon as they are available.

Scientific presentations at the CVI conference made it clear that the new understanding of microbiology and mapping of the human genome portend a revolution in vaccinology that will produce new and better vaccines at a pace unimaginable only a few years ago. Other presentations highlighted the roles of non-governmental organizations in making vaccines available so they are affordable to even the least wealthy nations. Social and behavioral research has improved our understanding of what motivates people to get vaccinated and suggests communication strategies to expand immunization.

The conference was itself an instrument of peace and an excellent example of "vaccine diplomacy." There was considerable momentum toward greater international cooperation evident in Geneva. The scientific and economic collaborations planned and underway align people from disparate backgrounds to halt deadly disease — the common enemy shared by people of all nationalities, beliefs and economic strata. ❖

*Joseph A. Bellanti is Senior Vice President of the Albert B. Sabin Vaccine Institute at Georgetown University and Director of the International Center for Interdisciplinary Studies in Immunology. He served more than 35 years on the Georgetown University Medical Center faculty as professor of pediatrics.*

## FROM THE EDITOR

The *Sabin Vaccine Report* showcases articles and reviews on the latest in vaccine research, development, and implementation, and is meant to serve as a resource for scientists in industry, government, and academia, as well as policy-makers and consumers of vaccines. The views expressed are not necessarily those of the Institute and reflect the opinions of the authors. We hope that you enjoy reading the *Sabin Vaccine Report*, and we welcome any comments or suggestions.

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## Traveler's Warning: Precautions for the adventurous

by Charlene A. Flash

A global economy, international corporate cooperation, and increasingly active foreign policy have greatly increased the volume of international travel. "Over 40 million people travel from the United States to international destinations each year," says Jane Johnson, clinical services director at a travel medicine clinic called SmarTravel. She and other experts note that venturing abroad requires special health precautions.

When heading off to far-flung destinations, the savvy traveler heeds guidelines for the necessary vaccinations and travels armed with medicine. In addition to the routine vaccinations that should be up to date, other vaccines may be necessary depending on the intended destination, duration of visit, living accommodations, and itinerary. This list may include, but is not limited to, an adult polio vaccine, meningococcal meningitis vaccine, measles vaccine, Japanese encephalitis vaccine, and malaria prophylaxis.

Vaccines for hepatitis A and B and an oral series of typhoid fever vaccine are recommended for travelers to developing countries, especially Africa, East Asia, Southeast Asia, the Middle East, Malta, the South Pacific Islands, and the interior Amazon region. The Centers for Disease Control website ([www.cdc.gov](http://www.cdc.gov)) is a good source for information on which countries require immunization against yellow fever. "Although many people are used to traveling for short periods of time, when longer trips are taken, special precautions must be made," says Linda Duquette-Petersen, a certified nurse practitioner at the International Health Travel Clinic at Georgetown University Medical Center (GUMC).

Some may favor spur-of-the-moment adventure;

however, safe international travel requires advance medical preparation. Vaccines must be obtained three months in advance for tetanus, diphtheria, polio, and measles, according to Duquette-Petersen. Yellow fever immunization should be given six to eight weeks before departure. Typhoid protection should be given one month in advance for an oral series or two months in advance for an injection. Moreover, malaria pills should be taken one or two weeks before departure, and immunization for hepatitis A and B and Japanese encephalitis require follow-up injections.

Travel medicine has emerged as a discipline in its own right, accompanied by organizations dedicated to disseminating pre-travel health information such as SmarTravel, Passport Health, and the International Health Travel Clinic at GUMC. Although you should not completely forsake the advice of your primary physician, he or she may not be familiar with health hazards specific to your destination. For example, Duquette-Petersen notes that doctors sometimes contact her or direct patients to her clinic for current information on malaria. A travel medicine specialist can complement your primary care physician's advice with information about disease prevention, specialized supplies, and health hazards specific to your region of travel.

As global expansion continues in the business world and technological advances draw nations closer, international travel will continue to grow. Proper preparation can ease discomfort. Still, even the most conscientious traveler may return with symptoms of an infection acquired abroad. ❖

In the Next Issue...

What happens when you return from abroad with a fever, muscle aches, abdominal symptoms, or an infection?

## Four Hundred Linear Feet and Counting...

Just how much is 400 linear feet?

Imagine a box that holds letter-size papers and is about six inches thick. Take two of those and you've got a linear foot in archivist jargon. Now imagine 800 of these boxes full of correspondence, laboratory data, manuscripts of lectures and publications, microscope slides, and over 20 years' worth of hand-written laboratory notebooks — and it is *your* job to organize it all.

That is the formidable challenge facing archivist Maggie Yax, who is charged with the task of creating the Albert B. Sabin Archives at the Cincinnati Medical Heritage Center (CMHC) at the University of Cincinnati Medical Center. Sabin, who developed the oral polio vaccine that was instrumental in making global eradication of polio a possibility, donated his complete correspondence, laboratory materials, manuscripts, awards, and medals to the CMHC.

Almost halfway into the five-year project, Yax recently presented a progress report to several supporters of the project, which include the John Hauck Foundation and Heloisa Sabin, widow of the late Sabin. The Hauck Foundation — created in 1989 by Dr. Frederick A. Hauck, a great supporter of historic preservation — has established the Hauck Center for the Sabin Archives.

"The research value of the Sabin Collection goes beyond its obvious historical use," said Heloisa Sabin, who attended Yax's September talk. "Historians can use this resource to document the story of medical research in the 20th century and clinical researchers will find it relevant to their *current* projects." Such has already been the case when a scientist at the National Institutes of Health contacted Yax to learn the exact dates of the oral vaccine's administration; this information was essential to his research efforts. For more information, visit [www.aitl.uc.edu/cmhc/HAUCK/HCKHOM3.htm](http://www.aitl.uc.edu/cmhc/HAUCK/HCKHOM3.htm). ❖

Johnston, from page 1.

research as a top priority, to increase funding for these efforts, and to decide that developing vaccines for global use is the best way to guard Americans against AIDS. These changes, more than anything else, made Johnston say yes when the NIH asked her to come back.

### The fundamental things apply

Peggy Johnston has been coming and going from the Bethesda campus of the NIH for two decades. After receiving her PhD in biochemistry from Tufts University in 1977, she spent a year in Belgium and four years doing research as an NIH "lab rat" before leaving in 1982 to teach biochemistry and conduct immunochemistry studies at the nearby Uniformed Services University of the Health Sciences. In 1987, Johnston came back to join the NIH's fledgling AIDS program, which at the time was one year old and had about 21 staff members. Today, DAIDS has more than 120 employees, and Johnston supervises more than 30 of them.

As AIDS research mushroomed at the NIH, Johnston was first a program officer and then chief of the branch that coordinated drug discovery for HIV and opportunistic infections. She was an early proponent of both protease inhibitors and combination therapies, and she was interested in whether an HIV-damaged immune system could be reconstituted and whether gene therapy might be useful for AIDS. These remain hot research topics today. She rose rapidly through the ranks, and in 1993 she was promoted to deputy director of DAIDS.

Today, HIV vaccines are where treatment research was a decade ago. In each instance, it's important to "think big" — first defining the scientific issues and then figuring out how to pay for them. Experience has taught Johnston to focus on three fundamental questions: "Who are the right people? What is the right work? And how can we get the money into their hands?" Those are still the right things to ask.

### Forging more and better links

Johnston's research interests complement those of two other top players at the NIH. David Baltimore, chairman of the AIDS Vaccine Research Committee, has backed basic research projects that will theoretically lead to better vaccines in the future. Neal Nathanson, new director of the Office of AIDS Research, is promoting comparative animal studies as a means for understanding how vaccines work (see *Sabin Vaccine Report*, September 1998).

"I want to focus on moving products into the clinic," Johnston said. Each of these individuals will be trying to widen a different part of the pipeline that carries new products from the lab to the clinic.

She also aims to strengthen the NIH's ties to the Walter Reed Army Institute for Research, which has an important HIV vaccine research program, and with the Centers for Disease Control and Prevention, which is stepping up its HIV vaccine efforts and has experience with other forms of prevention.

She will also reinforce the NIH's newfound interest in developing vaccines active against strains of HIV found mainly in other countries. By traveling the world for IAVI, Johnston gained expertise that NIH officials highlighted when they welcomed her back. One of her overarching goals is to focus the energies of the NIH, corporations, and international investigators on the discovery, development, and field testing of HIV vaccines. "That's going to require linking public-sector dollars with private-sector expertise. That means linking domestic and international organizations that have clinical trial experience. It means linking agencies that work internationally so they can support research activities. It means linking vaccines with other prevention activities," she said.

### Rough spots ahead

When she's not thinking big, Johnston will also have some nuts-and-bolts problems to solve. Some of these involve implementing decisions that were made by others, such as pulling apart and reassembling the clinical infrastructure for testing vaccines and other prevention strategies. In the past, the NIH created one network for Phase I and II studies, which show whether a vaccine is safe and stimulates the immune system, and a separate one for Phase III trials, which can demonstrate efficacy. Although the government never used the latter system for a vaccine efficacy trial, it has been mobilized to study topical microbicides and other preventive measures.

The new plan calls for one network that will test vaccines from start to finish, with local investigators — instead of NIH scientists — setting the scientific agenda for these studies. Other types of prevention will be tested separately, which is a controversial proposal for some researchers and community activists. Johnston is optimistic about this reorganization, which she says will give investi-

gators more control over their work and result in a more unified approach to vaccine testing.

She will also administer several new programs intended to move potential HIV vaccines from the pre-clinical stage, when they are tested in animals, into early human studies. Promising vaccines sometimes languish at this point because their creators, who may be at a university or a start-up company, can't afford to do all the required experiments or to manufacture test batches of vaccine that the Food and Drug Administration can approve for human use.

### Efficacy trials still a challenge

In June of this year, a private California company, VaxGen, made history by launching the first efficacy trial of an HIV vaccine in the United States. Once this private trial was under way, the NIH announced that it would pursue a collaboration to beef up the laboratory research component. One of Johnston's first tasks has been to pick up negotiations on the details of this arrangement, which is as close as the NIH has come to an efficacy trial so far.

Because the rate of new HIV infections has fallen so low in the United States, many experts believe that this country is no longer a good place for large-scale testing. If experimental vaccines have protective effects, these will be easier to detect in areas of more rapid spread, such as parts of Africa, Asia, and Latin America. The NIH is poised for a first step in that direction, and Johnston arrived just as last-minute arrangements were being made for a trial in Uganda. "Because it's our first trial in Africa, it's very important that everybody be completely on board and everything be in place before we actually stick something into a person," she said, adding that she expects the trial to begin soon.

As she digs into her new duties, Johnston is mindful of something that the late AIDS vaccine advocate Jonathan Mann used to say. He complained that no one person at the NIH had the full-time job of being responsible for getting an HIV vaccine. "Getting a vaccine is where my head is going to be 100 percent of the time," Johnston says. "I consider it my responsibility. If other people also consider it their responsibility, that's fine." ❖

*Patricia Thomas has been writing about the AIDS epidemic since the early 1980s. In 1997, after nearly six years as Editor of the Harvard Health Letter, Thomas left Harvard Medical School to tell the story of the troubled search for an AIDS vaccine. Her book on this topic will be published by PublicAffairs.*



Peggy Johnston

“Who are the right people? What is the right work? And how can we get the money into their hands?”

## Children's Vaccine Initiative: Is Vaccination a Human Right?

Many of the world's leading experts in vaccines and vaccination come together every two years as partners in the Children's Vaccine Initiative (CVI), an 8-year-old organization that is determined to make universal childhood immunization not just a good idea, but a reality. Last month, members of the CVI Consultative Group met in Geneva to assess progress toward this goal. They talked about the newest vaccines emerging from laboratories, about the nuts-and-bolts of giving safe injections in remote areas, and about dozens of other topics. And, as the meeting progressed, the poignancy of opening remarks made by Sir Gustav Nossal deepened.

"We are meeting at a time of opportunity and challenge," Nossal had said when he welcomed 350 participants from 50 countries to the opening session. Opportunity takes the form of new vaccines "emerging at long-last from the research pipeline" and the challenge is that "in the 28 poorest countries of the world little progress has been made in the last decade," said Nossal, an emeritus professor of pathology at the University of Melbourne in Australia, who chaired the CVI meeting and is a trustee of the Sabin Vaccine Institute.

This lack of progress is reflected in World Health Organization (WHO) studies showing, year after year, that 20% of the world's children remain unprotected against polio, measles and other infectious diseases. This troubling finding hasn't changed in recent times, no matter what strategies public health officials have tried.

These vulnerable, unvaccinated children are concentrated in the world's poorest countries. These are places where traditional vaccines are underused due to widespread constraints on resources, such as shortages of money and manpower and grave difficulty deploying vaccines to children in remote areas. These same barriers will doubtless impede the use of new vaccines, which have the added complication of costing more than older products. Nossal's warning reverberated throughout the two-day CVI conference: as children in wealthy nations gain better protection thanks to scientific progress in vaccine design and delivery, the children of the developing world could fall farther behind. One of the greatest challenges in public health, speakers at the conference repeatedly said, is reaching the 20% of children who remain unvaccinated.

### Old and new arguments

Immunization is widely acknowledged as the most cost-effective of all public health interventions. If all the available vaccines were used as experts recommend, WHO estimates that 4 million lives could be saved each year. At a cost of pennies to a few dollars per dose, vaccines for pertussis, measles, hepatitis B, *Haemophilus influenzae* type B (Hib) disease, and others common infectious illnesses can save billions of dollars each year. Yet this isn't happening. Even though measles is largely preventable by immunization, for example, direct medical costs associated with this disease still total about US\$1.1 billion each year, much of it in industrialized countries that can afford the vaccine. When polio is finally eradicated, a long-elusive goal that is now almost within reach, worldwide health care savings will amount to an estimated US\$1.5 billion each year.

As impressive as these economic arguments are, the reality is that childhood immunization remains low on the priority list for many governments.

So at this year's meeting, CVI turned to moral suasion as a means for mobilizing political will in countries that lag behind.

### The right to vaccination

Humanitarian concerns were in the spotlight from the start, with the opening session devoted to presentations that portrayed vaccination as a right of every child. At least eight international conventions and treaties declare that children are entitled to protection against disease; one spells out immunization as a right while in the others this idea is implicit. One of the earliest and most explicit of these agreements is the 1988 "Protocol of San Salvador," a broad human rights document that specifies universal immunization as a right.

But the real cornerstone of the humanitarian line of argument is the Convention of the Rights of the Child (CRC), which clearly articulates the rights of children to health, and thus to vaccination (see box). After being adopted in 1989 by the United Nations General Assembly, the CRC was ratified more rapidly than any other human rights instrument ever has been. There are 191 signers and only two holdouts: Somalia, which lacks an internationally recognized government, and the United States. U.S. ratification has been complicated by political disagreement about the desirability of joining in an international agreement that addresses family life issues, as well as by other factors.

Although human rights agreements like the CRC have very weak enforcement provisions compared with conventions related to the conduct of war, they can be used to bring moral pressure to bear on governments. Once something is perceived as a right, governments have a perceived responsibility to provide it. If they fail to do so, they look bad on the international stage.

Even though the CRC lacks strong enforcement mechanisms, it is clearly a step in the right direction, according to Roy Widdus, coordinator of the CVI. The document emphasizes "that children are a special group in society" and holds governments morally and legally accountable for their protection. This strengthens campaigns waged by child health advocates within

each country, and leaves rogue nations open to censure by their peers.

### Life, death and accidents of birth

There is little doubt that children in poor countries need all the help they can get to attain a healthy maturity. According to the WHO, a child in Mozambique is 1,000 times more likely to die from measles than a child in Switzerland, where the per capita gross national product is 500 times greater than Mozambique's (US\$41,000 vs. US\$80).

Some speakers at the CVI conference warned

that such inequities may worsen in the future, as scientists develop exciting new vaccines that can shield children against a growing list of diseases. Recombinant hepatitis B vaccine is now recommended by the Centers for Disease Control (CDC) for all children in the United States; if this vaccine were used worldwide, it could prevent an estimated 800,000 deaths a year. If all children everywhere received the newly licensed rotavirus vaccine, WHO calculates that 600,000 and 800,000 lives would be saved each year.

### Rights, money are intertwined

Although Widdus believes that vaccine advocates are morally justified in using the language of human rights when they call for extended vaccination coverage for children, he also

recognizes that financially strapped countries are not going to divert funds from an airport construction project to a hepatitis B immunization campaign unless there are sound economic reasons for doing so.

Vaccine advocates can tap into the widespread belief "that it is in society's best interest to have healthy children because healthy children lead to a healthy society," Widdus said. In economic terms, this translates into a strong workforce and a growing economy. Although government officials may be responsive to the self-interested view that health is worth investing in because it paves the way to prosperity, Widdus believes this is a less

powerful than more humanitarian rationales for making child health a top national priority.

The relative merits of these arguments may depend on one's vantage point. An immunization program administrator from Thailand, for example, reported that the near-collapse of his country's economy has imperiled childhood immunization programs and made it much more difficult to compete for scarce government funds. When he has to go head-to-head with proponents for other government programs, the arguments that carry the day are hard facts about the cost-effectiveness of vaccination, not idealistic statements about human rights. Both arguments will doubtless be needed to narrow the gap that separates children in rich and poor nations, not just in Asia but in other parts of the globe as well. ❖

*This report was written by Erica Seiguer, editor of the Sabin Vaccine Report, and a research fellow at the Institute.*



Conference Chair Sir Gustav Nossal and Halldan Mahler, former executive director of the WHO.

### Excerpts from The Convention of the Rights of the Child

#### Article 24

1. States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. State Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services.

2. States parties shall pursue full implementation of this right and, in particular, shall take appropriate measures.

- a.) To diminish infant and child mortality;
- b.) To ensure the provision of necessary medical assistance and health care to all children with emphasis on the development of primary care;
- c.) To combat disease and malnutrition including within the framework of primary health care, through *inter alia* the application of readily available technology and through the provision of adequate nutritious foods and clean drinking water, taking into consideration the dangers and risks of environmental pollution...

### CVI F

**Mission:** The Children's Vaccine Initiative is a global effort that seeks to benefit all through the application of scientific advances into protecting children and simplifying vaccine delivery.

**History:** CVI was founded in 1990 during the World Children's Vaccine Initiative. Its cosponsors are the United Nations (UNICEF), the United Nations Children's Fund, the World Bank, the World Health Organization, and the Rockefeller Foundation.

**Participation:** Members represent international organizations, the vaccine industry, national immunization institutions, national immunization technical advisory groups, individuals and organizations.

**Activities:** The interests of the CVI Secretariat include:  
❖ accelerating the introduction of new vaccines  
❖ increasing global awareness of new vaccines  
❖ promoting and facilitating public-private partnerships



CVI Coordinator Roy Widdus.

## WHO Director-General Calls for New Solutions

If anyone at the Geneva conference doubted that the Children's Vaccine Initiative is a major player in the global health arena, then the presence of Gro Harlem Brundtland erased those doubts. In her message, the newly elected director-general of the World Health Organization celebrated the tremendous strides that have been made toward universal immunization while pointing up the hurdles that lie ahead.

"Prevention is not only cheaper than cure," she said, "it is certainly also better than cure. And with the development and introduction of new vaccines and technologies, some of the most powerful tools are within reach." A physician who is now one of the world's most prominent health policy-makers, Brundtland did not equivocate when she talked about vaccination's place in the grand scheme of things. "Immunization is simply the most cost effective health intervention we have available. There is no doubt in my mind," she proclaimed.

Brundtland's support for immunization adds momentum not only to the efforts of the CVI, but also to the Expanded Programme on Immunization

**“Immunization is simply the most cost effective health intervention we have available. There is no doubt in my mind.”**

(EPI). When the EPI was founded by WHO a generation ago, only 5% of the world's children received vaccines against polio, diphtheria, whooping cough, measles, and tuberculosis. Today, an estimated 80% of children worldwide have been immunized against these diseases. As successful as the EPI has been in expanding vaccination campaigns throughout the world, the next century will bring challenges that can only be met if new and different approaches are also used, Brundtland said.

### New products demand new strategies

Advances in laboratory science and clinical medicine now promise an entirely new generation of vaccines against some of the infectious diseases that now kill 17 million people each year, Brundtland said. But these new vaccines, many of which are products of the revolution in genetic engineering and recombinant technology, will cost more than traditional products—a factor that is sure to limit their use. For example, new vaccines against *Haemophilus influenzae* type B (Hib), pneumococcus, and rotavirus are expected to have a major impact on the health of children in industrialized nations, where their use is spreading quickly. Both the Hib and the pneumococcal vaccines prevent pneumonia, the number one killer of infants and children worldwide, while the rotavirus product protects against a virus that is a major cause of hospitalizations for diarrheal disease during the first two years of life. These vaccines can have an enormous impact on global health, so long as problems of affordability, acceptance, and infrastructure can be overcome.

It is never simple to introduce new vaccines to people who aren't familiar with their benefits and, in fact, may never have heard of them. "Several major challenges must be addressed before we can get maximum benefit," Brundtland noted. For example, epidemiological studies may be needed to demonstrate the burden of a disease, so that citizens and policymakers will take it seriously. Analysts will also need to figure out how a new vaccine can be integrated into existing immunization programs in a manner that is cost-effective and acceptable to both providers and patients. If technical assistance is needed to deploy a new vaccine, national or international experts may need to be called in. Finally, industry help and creative funding may be needed to bring new vaccines to the people who need them most, Brundtland said.

### A larger role for industry?

Given that the cooperation of vaccine manufacturers is needed if immunization programs are going to expand, it is a hopeful sign that pharmaceutical and biotechnology companies were well represented at the CVI conference in Geneva. CVI views industry as an integral partner in its efforts, along with scientific research institutions, national and international child health and immunization programs, government agencies and regulatory bodies, health-oriented private foundations, international donor agencies, and non-gov-

ernmental organizations. CVI's latest strategic plan, released last year, pays particular attention to industry's role in facilitating the "evaluation and production of vaccines of limited commercial interests."

This means vaccines for extremely rare diseases or those that mainly strike poor people who can't afford to buy such products, and who often live in parts of the world where transporting, storing, and administering them can be extremely difficult. There is unlikely to be a very profitable market for a vaccine against malaria, for example, because the people at highest risk usually live in poor countries. Brundtland pointed to development of these sorts of vaccines as one of the greatest challenges for advocates of prevention. The WHO and the CVI can play an important role here, by opening the dialogue with industry and looking for innovative ways to provide incentives for developing such products.

Although not every commercially unpromising vaccine can be this fortunate, scientific inquiry sometimes boosts the attractiveness of a product that had been going nowhere fast. For years, rotavirus was thought to be a major cause of serious, sometimes life-



G.H. Brundtland, Director-General of the World Health Organization.

Photo courtesy of the WHO.

threatening diarrhea only for infants and toddlers in the developing world. And then, in an odd twist of fate, an epidemiological study found that rotavirus disease is actually quite widespread in industrialized countries. Suddenly, pharmaceutical companies were willing to invest in a vaccine that had previously been on the back burner. As a result of this effort, the world's first rotavirus vaccine was licensed by the Food and Drug Administration in August, 1998. The epidemiologist whose study sparked industry's interest, Roger I. Glass of the U.S. Centers for Disease Control, was co-recipient of the CVI Pasteur award presented at the Geneva conference. ❖

## CVI Presents Jenner, Pasteur and Lifetime Achievement Awards

This year, the CVI honored researchers and public health specialists from Australia, Japan, and the United States with its Jenner, Pasteur, and Lifetime Achievement awards. The awards were given at a ceremony during the 1998 Consultative Group meeting. Bjørn Melaard, the CVI Executive Secretary, presented the awards. The awards were created two years ago to mark the "Year of the Vaccine," commemorating the 200<sup>th</sup> anniversary of the first vaccine, for smallpox, discovered by British physicians Edward Jenner, and the 100<sup>th</sup> anniversary of the death of French vaccine pioneer Louis Pasteur. The awards honor individuals who have made exceptional contributions to vaccine development and immunization and in so doing have expanded protection against infectious diseases.

The Jenner Award laureate, Ralph H. Henderson, was cited for his visionary, single-minded leadership of the WHO's Expanded Programme of Immunization (EPI) from 1979-1989. During this decade of incredible growth, the EPI achieved what has been called "the greatest public health revolution of this century"—a revolution that brought vaccines to some 80% of the world's children and is continuing to do so every year, with an estimated saving annually of three million young lives. Before the EPI began, only about 5% of the world's children were receiving much-needed vaccines. Henderson is currently an adviser to Gro Harlem Brundtland, the Director-General of the WHO.

The Pasteur Award winners were cited for their pioneering work in the development of vaccines against rotavirus disease and in laying the foundations for the future application of these vaccines. The rotavirus claims

an estimated 600,000-800,000 children's lives each year. Ruth F. Bishop, a researcher at the Royal Children's Hospital in Melbourne, Australia, discovered the rotavirus in 1973 and, in so doing, opened an avenue of research that prepared the way for the development of the first experimental rotavirus vaccines. At the National Institutes of Health in Bethesda, Maryland, Albert Z. Kapikian, a leader in the field for the last 25 years, initiated development of what this year became the first rotavirus vaccine to be licensed for use in children. The third recipient, Roger Glass of the Centers for Disease Control (CDC) in Atlanta, Georgia, a student under Kapikian, produced the first clear evidence that rotavirus infections are prevalent not only in developing but also in industrialized countries. His work in this area became a major stimulus to epidemiological research on rotavirus disease throughout the world and has played a key role in the development of several experimental rotavirus vaccines.

The winners of the CVI lifetime achievement award, Yuji Sato and wife Kiroko Sato, developed the first acellular pertussis (or whooping cough) vaccine nearly twenty years ago, while working at the National Institutes of Health in Tokyo. This vaccine, which was widely used in Japan,

uses purified proteins of the pertussis organism, *Bordetella pertussis*, instead of the whole bacterial cell used for the traditional "whole-cell" pertussis vaccine. The newer acellular vaccines have about the same efficacy but fewer of the side-effects linked to the whole-cell vaccine, which has been almost entirely replaced in some industrialized countries. ❖



Pasteur Award recipients (from the left) Alfred Z. Kapikian, Roger I. Glass, and Ruth F. Bishop.

Photo by Erica Seliguer

This article is courtesy of the CVI Forum.

## Workplace-based Vaccination Programs Gaining in Popularity

BY ERICA SEIGUER

What's the secret to a healthy workforce? Many institutions, both public and private, are finding that on-site vaccination programs, most commonly during the flu season, are sure ways to decrease the number of sick employees, thereby improving profit margins and employee morale at the same time. It might seem obvious that healthier employees would save a company money. But there was little convincing proof that such vaccination programs could have a major impact until the *New England Journal of Medicine* published a placebo-controlled study demonstrating a 43 percent reduction in sick days among adults immunized for the flu. The National Coalition for Adult Immunization, an immunization advocacy organization, estimates that about 20 percent of the American population is infected during the flu season, with direct medical costs exceeding \$4 billion per year.

### Ahead of the game

The National Institutes of Health (NIH) has been offering flu vaccine to its employees for at least 18 years, according to trained virologist Robert W. McKinney, director of the NIH's Division of Safety, which operates the NIH Occupational Medical Service. Each year, the NIH provides the vaccine free to all employees, though the program places emphasis on healthcare providers, such as those who staff the NIH's Clinical Center.

The NIH's vaccination program is a huge undertaking; it attempts to cover more than 16,000 employees housed in over 7 million square feet of building space at several locations in suburban Maryland. In addition to on-site immunization, McKinney's staff provides all employees with information about other public immunization sites, such as those at local supermarkets and malls. Each year about 30 percent of employees elect to get vaccinated, but McKinney would rather see that number closer to 50 percent. "Immunization is of great

benefit not only for the individual, but for that person's family, and everyone they come in contact with," he said.

So what determines whether or not employees make it to the clinic? Each year, the Centers for Disease Control (CDC) in Atlanta, issues alerts about the various strains of flu for that season. Some years are worse than others, particularly if the flu vaccine does not contain the prevalent strains, which is what happened last season with the Sydney flu strain. "Compliance," McKinney said, "is correlated to how much the CDC scares the public into thinking it's going to be a particularly bad flu season."

### Corporate cost containment

In the private sector, news of the cost-saving benefits of employee immunization travels fast. And with this news, a cottage industry of companies that offer turnkey-style immunization programs has sprung up almost overnight. (See inset.) These companies provide on-site immunization programs—many times tailored to the individual needs of employees. For example, employees in work environments in which they might be exposed to blood products would have a different vaccination profile than employees working elsewhere.

The experience of the Kodak Corporation is a textbook example of the impact of immunization on the company's bottom line. For the past several years, Kodak's corporate medical director, Wayne M. Lednar, has been tracking the impact of the company's employee flu-vaccination program. The data from the three-year study are being prepared for publication. Lednar notes that Kodak's mature and long-standing epidemiology program enabled him to compare employee absences during the peak months of the flu season (December to May). The data confirmed that the greatest employee absences coincided with the highest levels

of virus in the community at large, according to community virological networks that observe the prevalence of the virus among the general population.

These data, along with the cost-benefit analysis, have convinced Lednar, and others, that employee immunization is a good investment in human capital. According to the pre-publication data, Kodak can expect to save at least \$1.5 million each year by vaccinating its employees against the flu, even with only 30 percent compliance. This is after subtracting the cost of the yearly program.

In addition to the cost to the company of lost work days, there are other costs exacted by the flu that might not be so obvious. Lednar suggests that administrative costs and labor replacement expenditures are just the beginning. Illness due to preventable diseases can diminish the company's ability to perform optimally. For example, an employee ill with the flu who is at work on the assembly line might make a mistake that would lead to a defective product. Recalling a defective product is a very expensive proposition. In addition, the winter months are peak business activity months for Kodak, during which bookkeeping, business strategy, and new product launches demand a healthy workforce. Furthermore, the impact of employee-immunization programs on workforce morale can have far-reaching implications for worker productivity. For more information, visit the Sabin website at [www.sabin.georgetown.edu](http://www.sabin.georgetown.edu). ❖

### Workplace Vaccination Resources

The National Institutes of Health's "Foil the Flu" employee vaccination program.  
[www.cc.nih.gov/ccc/98flu](http://www.cc.nih.gov/ccc/98flu)

General Injectibles Vaccine, Inc.  
[www.giv.xom](http://www.giv.xom)

Vaccess Health  
[www.vaccess.com](http://www.vaccess.com)

#### A Moral Outrage

This 1994 Sabin Institute survey of immunization rates by self-funded employers was supported by the Aetna Foundation.

Available at [www.sabin.georgetown.edu](http://www.sabin.georgetown.edu)

## Sabin Institute Launches Revamped Website

BY ELIZABETH DE LA PAZ

The Sabin Vaccine Institute recently launched a completely revamped website on the World Wide Web. The user-friendly site can be found at [www.sabin.georgetown.edu](http://www.sabin.georgetown.edu). Additions to the website make it a valuable resource for anyone with an interest in vaccines—from concerned parents and cautious travelers to inquisitive scientists and researchers. The aim of the page is to provide visitors with the most current news and developments in vaccines, which are our best means of preventing the spread of disease worldwide.

Among the newest additions to the site are pages dedicated to specific diseases such as HIV, malaria, tuberculosis and others. The pages provide brief profiles on each disease and then links to the most current developments in vaccine research, development,

implementation, and public policy. For those visitors interested in becoming involved with vaccine public policy, links to various vaccine organizations with policy initiatives are only a click away from the site.

Newcomers to the site will learn about the history and mission of the Sabin Institute, as well as about opportunities available such as the Sabin-Hillman Fellows Program, which will provide summer internships to qualified high school students. Applications for the program will soon be instantly available via the site. The Sabin site is also eager to provide the public with current announcements on conferences on vaccines and links to publications providing in-depth articles.

The Institute plans to update the site often to keep visitors informed of the newest developments in the fight against disease. ❖



## sabin calendar

The following is a list of upcoming events, some of which are sponsored by the Sabin Institute. The Institute is not responsible for the content of non-Institute events listed here.

**December 15-17, 1998**

Cold Spring Harbor, NY

**From Bench to Bedside:**

A COLLOQUIUM ON TRANSLATIONAL RESEARCH  
Information available at the Sabin Institute website.

**March 28-30, 1999**

Bethesda, MD

SECOND ANNUAL CONFERENCE ON VACCINE RESEARCH

The conference will bring together the diverse disciplines involved in the research and development of vaccines and associated technologies for disease control through immunization to present and discuss current vaccine-related scientific data, results, and issues. In addition, the conference aims to encourage communication among vaccine researchers and developers, public health officials, and medical personnel who administer vaccines.

For details, visit [www.nfid.org](http://www.nfid.org)

**April 17-21, 1999**

Washington, DC

EXPERIMENTAL BIOLOGY '99

American Association of Immunologists Annual Meeting

The preliminary schedule is available at <http://www.scienceXchange.com/aai/>

**April 26-28, 1999**

Bethesda, MD

8TH ANNUAL MEETING OF THE NIAID INTERNATIONAL CENTERS FOR TROPICAL DISEASE RESEARCH

Information available at the website of the Division of Microbiology and Infectious Diseases (DMID) in the National Institute of Allergy and Infectious Diseases at the NIH.  
[www.niaid.nih.gov/research/Dmid.htm](http://www.niaid.nih.gov/research/Dmid.htm)

## Steere Awarded Albert Sabin Gold Medal for Pivotal Work on Lyme Disease

BY JOHN CLYMER AND TIMOTHY MAHONEY

Allen C. Steere, whose pivotal research on Lyme disease helped pave the way for development of a new vaccine to prevent it, has been awarded the sixth Albert B. Sabin Gold Medal. The award was presented to Steere on September 24 in Boston at a dinner in his honor organized by the Albert B. Sabin Vaccine Institute at Georgetown University, which sponsors the award. Heloisa Sabin, co-founder and a director of the Institute, and Joseph A. Bellanti, senior vice president of the Institute, made the presentation.

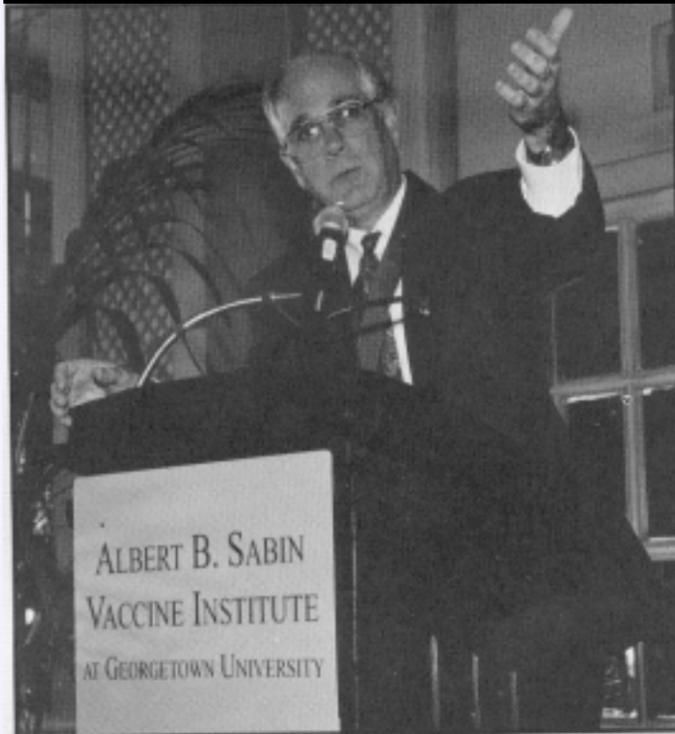
"Dr. Steere exemplifies medical research at its best," said H.R. Shepherd, chairman of the Sabin Vaccine Institute. "His work is an extraordinary example of translational research — that is, turning knowledge gained in the laboratory into a real product that spares patients enormous pain, suffering, and expense. From identifying Lyme disease as an infectious disease, through describing its pathogenesis and leading clinical trials of a preventive vaccine, Dr. Steere has contributed enormously to human health," Shepherd said.

Scientists from the National Institutes of Health, Centers for Disease Control and Prevention (CDC), and leading academic institutions joined Lyme disease patient advocates and public officials in endorsing Steere's selection as a Sabin Gold Medalist. Governor John Rowland declared September 24 as "Allen C. Steere Day" in Connecticut. John Livengood, director of the CDC Epidemiology Surveillance Division, David S. Krause, vice president and director of clinical re-

search and development and medical affairs at SmithKline Beecham Pharmaceuticals, and Robert S. Schwartz, deputy editor of the *New England Journal of Medicine* and distinguished physician at New England Medical Center, addressed the dinner audience at the Four Seasons Hotel-Boston. They praised Steere's accomplishments as a scientist, his care and concern for patients, and the benefits of the new LYMERix vaccine. The vaccine was developed and is manufactured by SmithKline Beecham.

Lyme disease is the second most prevalent emerging infectious disease in the United States, according to the CDC. It is spread by ticks when they bite their victims. It is not fatal, but it can be very debilitating. It can affect a patient's skin, joints, heart, and nervous system. Its symptoms can include facial muscle paralysis, meningitis, inflammation of the heart, and abnormal cardiac rhythm.

Steere holds the Natalie V. & Milton O. Zucker Endowed Chair in Rheumatology and Immunology at Tufts University School of Medicine. He also is chief of rheumatology/immunology at the New England Medical Center in Boston. ❖



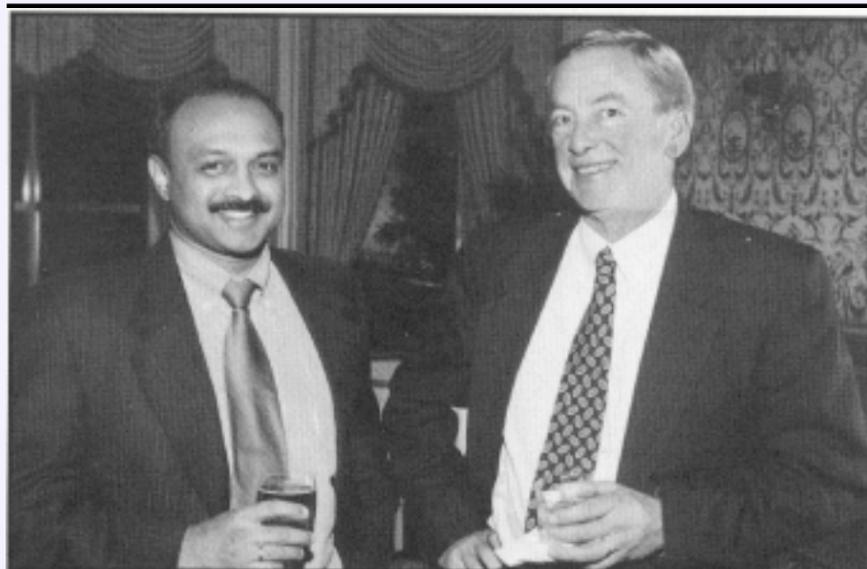
*Allen C. Steere accepts the sixth Albert B. Sabin Gold Medal. Steere called attention to the numerous physicians, scientists, and patients who contributed to understanding Lyme disease and developing a vaccine to prevent it.*



*Sabin Vaccine Institute Senior Vice President Joseph A. Bellanti and Director Heloisa Sabin congratulate Albert Sabin Gold Medal recipient Allen Steere. SmithKline Beecham Vice President David S. Krause applauds Steere.*



*Albert Sabin Gold Medalist Allen C. Steere and Sabin Vaccine Institute Chairman H.R. Shepherd discuss research on immunotherapies for rheumatic diseases such as arthritis.*

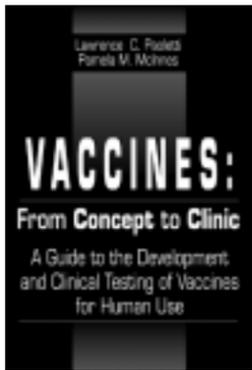


*Ariyapadi Krishnaraj, Senior Product Manager for SmithKline Beecham's Lyme disease vaccine and American Lyme Disease Foundation Executive Director David Weld toast the development of a vaccine to prevent the debilitating and painful disease.*

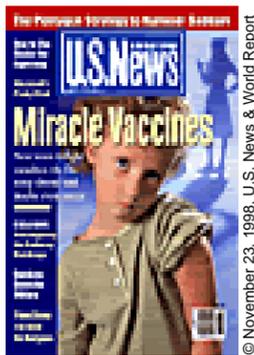
## NEW AND NOTEWORTHY

❖ **Vaccines: From Concept to Clinic**  
*A Guide to the Development and Clinical Testing of Vaccines for Human Use*

by Lawrence C. Paoletti and Pamela McInnes  
*CRC Press, August 1998.*



❖ **Miracle Vaccines**  
 US News & World Report  
 November 23, 1998



❖ **Vaccines: Emerging Technologies, Trends and Market Opportunities.**

by Pamela Bassett, DMD, MBA  
*D&MD Reports, November 1998.*

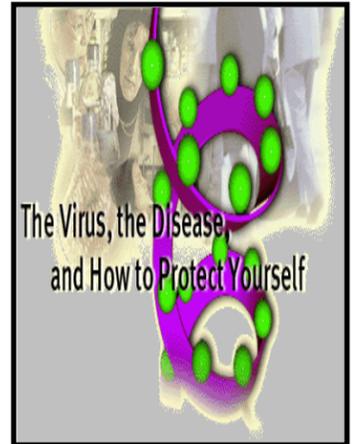


❖ **Vaccines for the 21<sup>st</sup> Century**  
*A Tool for Setting Priorities*

Kathleen R. Stratton, Jane S. Durch, and Michael A. Stoto, Editors  
 Committee to Develop Priorities for Vaccine Development, The Institute of Medicine  
*National Academy Press, Spring 1999.*

❖ **Influenza:**  
*The Virus, the Disease and How to Protect Yourself*

by William J. Martone, M.D.  
<http://www.nfid.org/library/influenza/>  
 Supported by a grant from the National Foundation for Infectious Diseases and Paster Merieux Connaught, this is a well-written guide to influenza. William J. Martone, currently of the National Foundation for Infectious Diseases, Bethesda, MD is the former Director of the Hospital Infections Program, Centers for Disease Control and Prevention, (CDC) and is a specialist in infectious diseases.



❖ **Needle Tips & the Hepatitis B Coalition News, Fall/Winter 1998-1999**



Margaret Vaillancourt and Deborah L. Wexler of Needle Tips.

Published by the Immunization Action Coalition (IAC) for individuals and organizations concerned about vaccine preventable diseases, *Needle Tips* provides valuable information reviewed by the Centers for Disease Control (CDC). Co-editors Deborah L. Wexler and Margaret Vaillancourt describe the IAC as a "grass-roots" organization which, through its newsletter publication and website, provides practical information for health professionals and consumers of vaccines.



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