

IHV Awarded \$50 Million to Combat HIV Crisis in Zambia

Grant comes as IHV reaches 1 million in HIV patient care overseas



Community workers gathering for an HIV prevention training in Zambia

The Institute of Human Virology (IHV) at the University of Maryland School of Medicine received a \$50 million five year grant from the President's Emergency Plan for AIDS Relief (PEPFAR) to support the program, "Stop Mother and Child HIV Transmission" in Zambia. PEPFAR is a \$48 billion initiative launched in 2004 by former President George W. Bush and continued by President Barack Obama. The announcement was made on the heels of IHV reaching the 1 million mark in care for HIV patients overseas.



Robert Sheneberger, MD

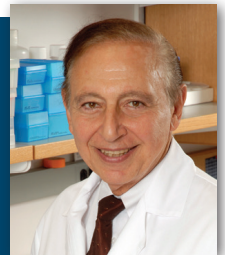
"This new funding will extend our reach and significantly grow the good work already being done by IHV's Robert Sheneberger, MD and his team to combat HIV and AIDS in Zambia," said Robert Gallo, MD, Director of the IHV, and most widely known for his co-discovery of HIV as the cause of AIDS and development of the HIV blood test. "We look forward to growing IHV's effective education, diagnostic and treatment training models with the support of Zambia's Ministry of Health."

Through the \$50 million five year grant, IHV will collaborate with the U.S. Centers for Disease Control to expand access and utilization of services for the Stop Mother to Child

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Director's Message:

*Was Albert Sabin
correct about an
HIV vaccine?*



Everyone knows the name of Jonas Salk and the Salk vaccine for polio—almost as famous was Albert Sabin. Their difference was how they approached the challenges of vaccines. Sabin wanted to use the more classical, live but presumably harmless, replicating variant of the disease-causing polio virus that in of itself would not be dangerous in causing disease, while Salk, was taking a newer approach which included inactivating the virus and using the inactivated virus as a vaccine. Many believe that the inactivation would lead to poor ability to induce the right kind of immune response. Nevertheless, both succeeded and their vaccines became used in different parts of the world and their names became virtually synonymous with success.

What about HIV?

Before Albert died, he wrote a letter in *Science* magazine in which he said that he finally came to the point of view that a vaccine against HIV was impossible.

Was he correct?

Up to now, we can say yes and no. No one has an effective vaccine against HIV, yet in some animal model studies

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Robert Redfield, MD

Transmission of HIV program, improve antiretroviral therapy coverage and effectiveness, enhance maternal child health services including the provision of better emergency obstetric and neonatal care, and lay the ground work for expanded community treatment of HIV within the Southern, Western, Eastern, and Lusaka provinces of Zambia.

“This grant funding creates the opportunity to demonstrate the impact of connecting every pregnant woman with a community worker to expand HIV testing into the community, promote early engagement in care, and improve retention” said Dr. Sheneberger, the IHV principal investigator implementing the PEPFAR program in Zambia.

“The targeted outcome is to eliminate transmission of HIV from mother to child, and improve maternal and infant survival.”

Under the direction of the IHV Associate Director and Director of the Clinical Care and Research Division, Robert Redfield, MD, Dr. Sheneberger will lead a team of experts and personnel based in both Baltimore and Zambia to implement the new grant. The team will also include a small consortium of local and international partners including the Elizabeth Glaser Pediatric AIDS Foundation, the Futures Group, the Church Health Association of Zambia, and the Zambia Ministry of Community Development, Maternal and Child Health.

“With each new grant, IHV’s leadership and excellence in implementing international programs is validated,” said Deus Mubangizi, IHV’s Director of International Programs in the Division of Clinical Care and Research.

The IHV will build upon its current work in Zambia including the establishment of the country’s first post graduate training programs in HIV medicine and infectious diseases, as well as providing technical assistance to numerous facilities providing integrated HIV care and treatment services.

The Zambia grant announcement comes as IHV reaches a monumental milestone of caring and treating for more than one million people infected with HIV overseas since 2004. Through PEPFAR, IHV has reached nearly four million people with prevention interventions and HIV testing, and trained 35,000 health care professionals throughout the program’s target countries that have, in turn, delivered more than 100 million doses of medication.

“My colleagues and fellow co-founders of the IHV, Bill Blattner and Bob Redfield comprise a select few of the country’s top PEPFAR recipients,” said Dr. Gallo. “Reaching 1 million in HIV care overseas is a tribute to their longtime dedication to fight this disease and their legacies will live on through the lives they have saved.”

Since 2004, the IHV has partnered with the governments of Guyana, Haiti, Kenya,



William Blattner, MD

Nigeria, Rwanda, South Africa, Tanzania, Uganda, and Zambia to address each country’s growing HIV/AIDS epidemics. The IHV led efforts to build public health infrastructures in each country via strategic international, national, and local collaborations through the design and implementation of unique education, training, and treatment programs addressing each country’s complex HIV/AIDS epidemics.

William Blattner, MD, IHV Associate Director and Director of the Epidemiology and Prevention Division, established an affiliate of the Baltimore-based IHV known as the Institute of Human Virology, Nigeria (IHVN). Since 2004, Dr. Blattner and IHVN have established 315 antiretroviral treatment programs in hospitals, 950 Prevention of Mother-to-Child treatment programs in local clinics, 193 TB centers, and 1,030 HIV testing sites throughout the country. Over 3.2 million have been tested for HIV in Nigeria and care and support has been provided to 283,000 HIV positive individuals. This HIV and TB clinical care capacity is a vital resource to Nigeria. IHV continues to provide technical assistance to support the Government of Nigeria and multiple local healthcare partners.

“The impact of this work touches the lives of individuals and their families in a broader context by adding to the quality of healthcare where our programs are implemented,” said Dr. Blattner. “This is IHV’s global legacy.”

Dr. Redfield led the implementation of PEPFAR programs in all nine countries, which resulted in linking more than 750,000 HIV positive patients into care.

“The PEPFAR program continues to have a profound impact on the lives of millions of people infected with and affected by the HIV epidemic,” said Dr. Redfield.

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Director's Message *(continued)*

and in at least one human clinical trial, there has been evidence of some success or at least it has been interpreted in such a way. There are of course many approaches toward an effective HIV vaccine. Some are very unconventional. For example, a recent report by Jean-Marie Andrieu from the University of Paris-Descartes, France suggests making the immune system tolerant to HIV proteins. His animal studies led to apparent success. This really unorthodox approach rests on the concept that keeping the immune system “quiet” would not open sufficient target cells for HIV to replicate because HIV needs an activated T cell system to reproduce itself. This study, now over two years old, begs for verification from other groups. One such study in the process now is led by Guido Silvestri at Emory University's Yerkes National Primate Research Center. Results from this study are awaited with great interest, at least from this quarter.

Most other studies have avoided the use of a killed whole virus (such as the Salk polio vaccine) because indeed the target that one wants to attack in a preventive vaccine is the surface envelope protein. That is certainly denatured by the current approaches for inactivation. Obviously we cannot use live, even attenuated, and presumably non-pathogenic HIV as Albert Sabin's polio vaccine because the possibilities may lead to extremely dangerous consequences. This is because we don't know of anything that modifies HIV to allow it to replicate without causing harm—it is just too enormously dangerous to approach it this way. Most of the field targets the envelope protein gp120. But additional component of the envelope is another glycoprotein but of molecular weight of 41,000 instead of 120,000, or so called gp41. There are studies that indicate areas of gp41 that when targeted can block infection, the most prominent of which includes a group led by Morgan Bomsel of Cochin Institute in France. She has a company designed now to develop a candidate vaccine for clinical trials. Her evidence indicates that she can induce broad antibodies that block virus infection, and her monkey studies are of considerable interest. This is a very interesting potential major advance, yet the downside is that no one else to date has obtained a similar result targeting gp41—at least not to my knowledge. Nonetheless, I think we need to pay close attention to her studies and attempt to duplicate them, and maybe to add to them by joining other vaccine approaches.

But, back to gp120 and why it has been the major target: this is the first protein material that is seen by the cell. It is the outer part of the spike protein that is approaching cell surface receptors and interacts with the co-receptors CD4, and ultimately CCR5, on the surface of activated T cells to begin an infectious process.

So, why hasn't targeting gp120 led to a successful vaccine to date? What is so complicated about that? We can certainly

produce gp120 in quantity and have it in pure form, and it is not a dangerous molecule to inject into people. The difficulties come from a few different sources. One is that gp120 is very dynamic or a mobile molecule on the surface of the virus and becomes hard to target. Added to that is what has been called a glycan, or carbohydrate shield (sugar molecules in large chains that cover the surface of the protein, again making antibodies hard to get to key sites). A third problem is the great variation in gp120 from one isolate to another. Therefore, an effective vaccine of gp120 of one virus might not work against another. However, there must be common sites (conserved sites) and indeed there are several. These sites are conserved for a reason. They are involved in necessary functions of gp120 and its interactions with the whole cell to initiate infection and cannot be played with—they need to be fairly constant.

So why not target these sites? Well, the difficulties mentioned above including the glycan shield and the difficulty of the mobility of the gp120—a moving target. It is complicated by still another difficulty—the folding of the molecule so that some of these sites are not easily exposed but are in a more internal portion of the protein. The approach here at IHV is to expose those internal sites by an approach first developed and tested by IHV's Tony DeVico in the Division of Vaccine Research headed by George Lewis. The approach is meant to make a DNA construct that consists of gp120 of sequences



Anthony DeVico, PhD



George Lewis, PhD

that code for neutral amino acids (a short span) and this in turn connected to the sequence in coding the area of the CD4 molecule that binds gp120. When the protein is expressed, the proper folding occurs, so that the gp120 is in the form bound to CD4.

What's important about that? Well, when the normal infection events occur and HIV comes toward a CD4 positive T cell that is activated and also expressing CCR5 on its surface (the co-receptor)—that interaction causes gp120 to make a dramatic change in shape into a form that is able to interact with CCR5. So the vaccine candidate at IHV, called the Full Length Single Chain (FLSC), is in that form, the form which can interact with CCR5.

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Dr. Gallo meets with Nigerian health officials

In Guyana, IHV enrolled more than 2,443 patients in HIV care and initiated more than half into antiretroviral treatment. These efforts contributed to more than 30% of all HIV care and treatment enrolled clients in Guyana. Additionally, the program trained more than 200 healthcare professionals in the advanced management of HIV diseases and related illnesses. IHV established the nation's first and only internal medicine and infectious diseases post-graduate training residency program and revised the Infectious Diseases management curriculum for medical students at University of Guyana, including the training of more than 100 medical students. The IHV team also trained key staff of the Georgetown Public Hospital Corporation in grants management, which has enabled them to be eligible to be a recipient of grant funds from various sponsors.

Over the past 10 years, the IHV has been an instrumental participant in improving Haiti's quality of HIV and TB care to more than 15,000 patients beginning with AIDSRelief, and continuing through our partnership with the University of Notre Dame d'Haiti to provide post-graduate training specializing in HIV and Infectious Diseases for physicians and nurses. The IHV is a permanent member of the national cluster for HIV care, and Haiti now has a cadre of HIV experts who are trained onsite and are becoming leaders in the field of HIV care and research in Haiti. Due to an existing and strong presence in Haiti, the IHV was also instrumental in addressing the health crisis following the devastating 2010 earthquake in Port-au-Prince.

In Kenya, the IHV leads a team that is creating and implementing what has proven to be a paradigm shift in the health workforce of HIV related training, in partnership with Kenya's Ministry of Health and the University of Nairobi, by developing a National HIV Integrated training course. The onsite course replaced more than 20 disparate curricula, reducing time away from work for training. The course was piloted and is currently being rolled out

nationally, positioned to cut the unit cost of training by about 10 fold.

In Nigeria, in addition to the IHVN, the IHV Clinical Division successfully facilitated the operationalization of a local country organization, the Center for Clinical Care and Research Nigeria—CCCRN, to retain capacities previously built by the IHV, and also facilitated the launch of HIV/AIDS training hubs in 13 training institutions for nurses and community health extension workers and 44 military hospitals in Kaduna State. The IHV additionally incorporated HIV/AIDS topics in curriculum for MPH students, and launched a short course in HIV/AIDS for Doctors of the University of Nigeria.

The IHV's team in Rwanda supports the Rwandan Ministry of Health (MOH) to implement a decentralized clinical mentorship model in HIV care and treatment. This model is now implemented across 85 facilities and will be increased to 181 sites by the end of 2016. The IHV is a designated technical partner to the Rwandan MOH, aimed at improving oversight and quality assurance of public health programs in the country.

The IHV team in Tanzania provides technical assistance for quality HIV care at 101 healthcare facilities providing antiretroviral therapy and 521 Prevention of Mother-to-Child Transmission facilities in 3 regions of Tanzania. This project has enrolled 98,638 patients in care, out of which 76,187 were cumulatively started on treatment, and 41,198 were currently on treatment.

In Zambia, IHV's new grant will build on the work already done, including the implementation of post-graduate training programs at the University of Zambia School of Medicine in Masters of Science in HIV Medicine and Infectious Diseases, which have trained more than 15% of all practicing physicians in Zambia.



Graduates from a maternal-child health training group from the Stopping Mother and Child HIV Transmission (SMACHT) program in Zambia

Director's Message *(continued)*

It induces antibodies that interact with those regions which become exposed when in the course of virus infection the virus is binding CD4. These are referred to as CD4-induced epitopes (new sites on the gp120 molecule that the antibodies can now see).

But, let's get to the practical results with the IHV candidate vaccine. We have seen some success in primates in several experiments: we've been able to induce broad antibodies, meaning they react with a variety of viruses, and therefore with a variety of gp120's; we had sufficient titers of antibodies induced by the vaccine to be able to block infection, indicating maybe we had a decent vaccine candidate. Soon, however, we recognized that the antibodies were short-lived, but this is not novel. As we survey the literature, it seems that antibodies to gp120 are invariably short-lived; good responses lasting not much longer than 3 to 4 months. Even the modestly successful RV144 U.S. Army clinical trial in Thailand had the problem that the antibodies were short-lived. In an attempt to make them last longer with different adjuvants, or other additions to FLSC, we found that some of the additives led to increased T cell activation. We do need some T



Tim Fouts, PhD

cell activation because to make antibodies, B cells usually need what is called "help" from a T helper lymphocyte. But, too much activation provides new homes for HIV to replicate. And so, George Lewis, Tony DeVico and I have reported this in a perspective* in the *Proceedings of the National Academy of Sciences* (PNAS) and summarized the primate experiments principally with the work of our close collaborator, Tim Fouts at Profectus Biosciences LLC, an IHV spin-off company. Fouts, et al** reported the results which drive us to this conclusion—the conclusion being that you have to have very sharply balanced immune response. If you are going for the durability of antibodies the immune response must be in the proper range. There is not much room for too little or too much. This, to us, is the crux of our difficulties and we think that it can only be solved from studies of basic immunology related to antibodies against gp120.

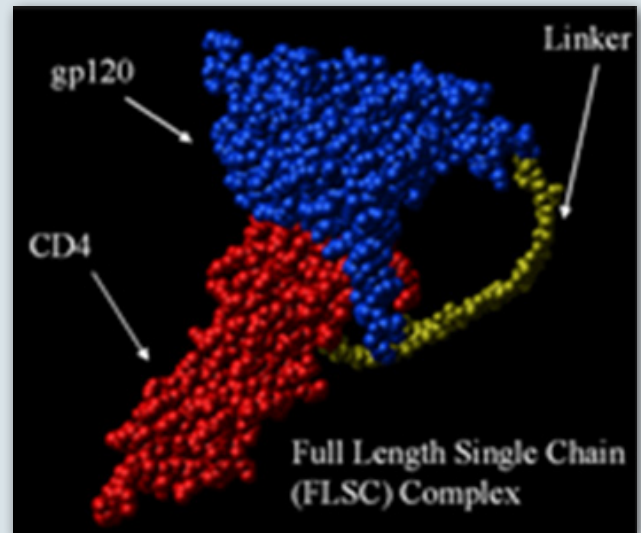
However, we are still going forward because we will gain knowledge impossible to gain from purely primate experiments with Phase 1

clinical trials initiated here at the Institute and led by my colleague Bruce Gilliam in the Division of Clinical Care and Research. These are limited to small Phase I studies for safety purposes. The clinical vaccine has already been rigorously tested in animal models according to FDA guidance to rule out potential safety issues. Following the Phase 1 trial, we plan to move to Phase 2 and study



Bruce Gilliam, MD

the kinds of immune responses we are getting and also attempt to do other studies designed to answer some of the key questions that we feel are essential in the field. Problems of durability and immune balance will be studied in monkey experiments by virtue of a grant submitted to the National Institute of Allergy and Infectious Disease (NIAID). We are also considering short clinical trials, which often referred to as Phase 1b or Phase 1c, that will be combine our FLSC protein with some other candidate vaccines of interest to the Human Vaccine Trial Network (HVTN) headed by Larry Corey in Seattle. We are grateful and happy to acknowledge that our work has been supported by the Bill and Melinda Gates Foundation and by NIAID and to a smaller extent the U.S. Army program. We are collaborating with these institutions as well as smaller collaboration with Sanofi Pasteur.



* Lewis GK, DeVico AL, Gallo, RC. Antibody persistence and T-cell balance: Two key factors confronting HIV vaccine development. *PNAS*, vol. 111(44); pp 15614-15621, 2014)

**Fouts TR, Bagley K, Prado IJ, Bobb K, Schwartz JA, Xu R, Zagursky RJ, Egan MA, Eldridge JH, LaBranche CC, Montefiori DC, Le Buanec H, Zagury D, Pal R, Pavlakis GN, Felber BK, Franchini G, Gordon S, Vaccari M, Lewis GK, DeVico AL, Gallo RC. Balance of Cellular and Humoral Immunity Determines the Level of Protection by HIV Vaccines in Rhesus Macaque Models of HIV Infection. *PNAS*. 2015 Feb. DOI10.1073/pnas.1423669112)



Erik de Leeuw, PhD

Human Defensins: Therapies for Victory and Tools for Defeat

Great military leaders are often remembered for brilliant war-time strategies, and for recognizing the balance between defensive and offensive tactics required to achieve victory. Ancient wisdom, offered by General Sun Tzu in the Chinese military

book *The Art of War*, suggests one has to know the enemy as well as one's self to achieve victory—advice that Dr. Erik de Leeuw, an Assistant Professor in IHV's Basic Science Division and the Department of Biochemistry and Molecular Biology of the School of Medicine, UMB, has been applying to studying a remarkably versatile group of small proteins, human defensins. Naturally-occurring antimicrobials, defensins are proving critical for initially fighting microbial infections, as well as modulating the immune system and killing host cells.

After obtaining his PhD in Molecular Microbiology from Free University of Amsterdam, the Netherlands, Dr. de Leeuw ultimately pursued biochemistry research at Oxford University, UK, where he studied targeting of compounds into, and across, bacterial membranes. There, he first became interested in the antimicrobial properties of a sub-group of defensins called alpha defensins—a family of six proteins, four made by human neutrophil cells (Human Neutrophil Protein (HNP) types 1-4) and two (human defensin (HD), types 5 and 6) by specialized, large intestine cells (Paneth cells).

His 2005 arrival at the IHV saw this interest transformed into basic research elucidating the functional, structural, and antimicrobial properties of alpha defensins. As part of their immediate, early stage roles in “front line” defense against invading organisms, alpha defensins provide innate immunity. “I became very interested in their natural roles in defending the body from harmful microbes, including bacteria, fungi, viruses, and protozoa,” says Dr. de Leeuw.

He began systematically exploring which amino acids and structural properties of alpha defensin (two sub-types) were involved in bacterial killing, binding certain bacterial toxins, interacting with host cells, and eventually, inhibiting the biosynthesis of an essential membrane component in Gram-positive bacteria—a molecule called Lipid II. In-depth

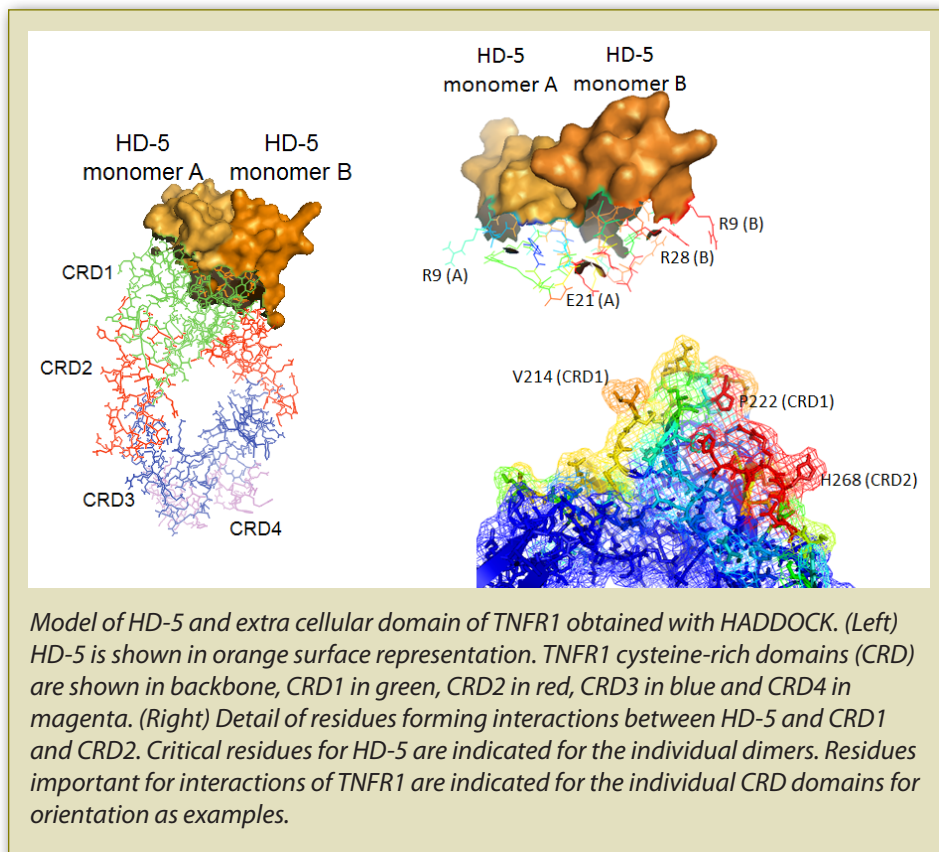
characterization of the 3-D interactions between HNP type 1 (HNP-1) and Lipid II, coupled with Computer-Aided Drug Design (CADD), has identified small molecule inhibitors of Lipid II, the first step toward novel, broad spectrum antibiotics.

Dr. de Leeuw's great success in “turning defense into offense,” as he fondly terms it, further fueled his interest in another alpha defensin—HD-5. Over the last six years, this intestinally-secreted human defensin has become of increasing interest to him, based on its modulation of host immunity and his own, unexpected observations. They would lead him to an application he never envisioned when he began—cancer therapeutics.

“Normally, HD-5 is present at low concentrations in the intestine, but in response to pathogens HD-5 concentration quickly and dramatically increases, acting like a bomb to kill pathogens, but also neighboring intestinal cells,” says Dr. de Leeuw. He wondered how HD-5 was killing these human cells lining the intestine—they were not bacteria!

When he looked at the effects of HD-5 on genes expressed in cultured, human colorectal (intestinal) cells, Dr. de Leeuw saw increased expression of three groups of genes associated with regulation of cell survival, pro-inflammation, and cell adhesion. Half these genes were known to be regulated by a “big player” molecule, NF- κ B (Nuclear Factor-kappa beta), famous in pro-inflammatory signaling pathways triggered by the binding of Tumor Necrosis Factor-alpha (TNF- α), Interleukin-1 (IL-1), and certain microbial peptides to TNF receptor on cell surfaces. In addition, HD-5 induced secretion of the pro-inflammatory protein interleukin-8 (IL-8), implying a role in induced immunity, via attracting immune cells.

What was very striking to Dr. de Leeuw was prior research on TNF- α , found in the intestine as well as in other locations throughout the body, showing that it, too, induced similar groups of genes and pro-inflammatory proteins, and could kill host cells. Building on these clues, combined with more detailed results from his studies of HD-5's effects on cell viability, cell-programmed death (apoptosis), and secretion of immunomodulatory molecules, Dr. de Leeuw began to



believe that HD-5 might work in two different ways. At low concentrations, it had minimal antimicrobial effects and functioned primarily as a pro-inflammatory molecule, while at high concentrations (during pathogen invasion) it worked as an antimicrobial and caused host cell death—by indirect and direct cellular interactions. The question was—how? Could TNF receptor really be mediating HD-5 effects?

Using genetic engineering tools, coupled with structural and functional studies, Dr. de Leeuw ascertained that HD-5 did bind to TNF Receptor type 1 (TNFR1), via interaction with an

extracellular TNFR1 region called PLAD (Pre-Ligand Assembly Domain)—a region distinct from TNF- α 's own binding site, but still crucial for facilitating binding of TNF- α . It was TNF- α 's binding to TNFR1 that mediated its role in immune regulation and chronic inflammatory disease, induction of apoptosis, and inhibition of tumor development and viral replication.

"Therapeutically, TNF- α can be either a 'good guy' or a 'bad guy,'" states Dr. de Leeuw, "depending on the disease condition. For inflammatory diseases, anti-TNF- α therapies (reducing inflammation) work, yet carry increased risk of malignancy. In cancer therapy

it causes apoptosis (cell death), yet is restricted in use by severe toxicity, likely because it increases inflammation." He began to consider the potential for HD-5 to somehow modulate TNF- α 's activity, and its possible therapeutic applications.

Dr. de Leeuw was also intrigued by observations of low or absent levels of HD-5 in numerous cancers, suggesting an association with HD-5 dysregulation (and inherently low apoptosis). He reasoned that, in the case of cancer, he might be able to turn the affinity of HD-5 for PLAD on the TNFR1 to his advantage, by developing compounds that mimic HD-5's interactions with PLAD and turn on apoptosis in cancer cells, while simultaneously preventing TNF- α from binding and exerting its toxic effects. "In my mind, HD-5 may act like a switch to turn TNFR on or off," he hypothesizes. It was once again time to switch from defense to offense—but this time for the big "C".

To that end, his on-going work seeks to characterize the critical amino acids and 3-D binding site interactions of HD-5 with the PLAD region of TNFR1, similar to his strategy for HNP-I and Lipid II in bacteria. Obtaining this 3-D "fingerprint" (a so-called pharmacophore) of the HD-5—TNFR complex will ultimately enable CADD screening for small molecules whose properties mimic these critical features, and which can be tested subsequently for their ability to kill cells without causing inflammation.

Dr. de Leeuw's long term goal is well in sight, namely, "to turn my past years of basic research into future therapies against cancer and infectious diseases." General Tzu would be quite proud.



Shyam Kottlil, MD, PhD

In April, Shyam Kottlil, MD, PhD, Co-Director of the Institute of Human Virology's (IHV) Clinical Research Unit and Associate Director for Clinical Research in IHV's Division of Clinical Care and Research, launched an outpatient hepatitis clinical program at the University of Maryland Medical Center Midtown Campus (UMMC Midtown Campus) which will focus on hepatitis C virus (HCV) research and treatment. This marks another milestone of the Institute of Human Virology's efforts to target viral infections which debilitate millions of people worldwide. Hepatitis C virus is the major cause of liver cirrhosis, liver cancer, and liver failure in the United States. HCV remains the main cause for liver transplantation and accounts for a significant percentage of liver transplants performed at the University of Maryland Medical Center (UMMC) each year. Dr. Kottlil, who is also a Professor in the University of Maryland School of Medicine's Division of Infectious Diseases of the Department of Medicine, intends to prevent long term consequences of viral hepatitis by eliminating the virus that causes liver disease. Treatment for hepatitis has rapidly evolved over the past few years and presently consists of a safe and well tolerated regimen consisting of pills for 8-24 weeks only.

"Up to 50% of those infected persons are unaware of the diagnosis because they were never tested. It means they're not

Kottlil Opens Hepatitis Clinic at UMMC Midtown Campus

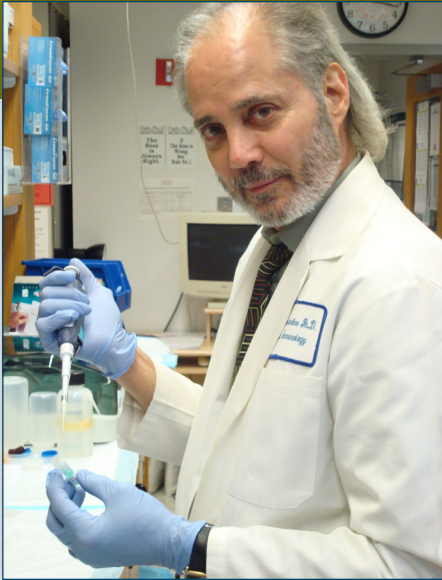
linked to care ... and in Baltimore and the Washington, D.C., area, it's an even larger problem," says Dr. Kottlil. "The treatment regimens we have are so effective that we are seeing patients infected with HCV cured of the virus with a short period of treatment, a simple treatment that includes taking just pills." Moreover, Human Immunodeficiency Virus (HIV) infection often co-exists in patients with HCV infection in the Baltimore and DC areas. Recent advances in the treatment of HIV infection have substantially diminished HIV-associated morbidity and mortality. However, the management of HIV-infected patients has become increasingly complex given co-morbid conditions that have an increasing impact on morbidity and mortality. Co-infection with HIV and HCV results in more rapid progression of liver fibrosis to cirrhosis, than patients with HCV mono-infection, and lower cure rates for HCV. Recent studies led by Dr. Kottlil and others, have demonstrated high efficacy of current HCV antiviral drugs in HIV/HCV co-infected subjects. The outpatient hepatitis program at UMMC Midtown Campus envisions screening for disease, linking to care, and providing state of the

art treatment for hepatitis C.

Dr. Kottlil is the Scientific Director of the DC Partnership for HIV/AIDS Progress (DC PFAP) Hepatitis Division which is funded by the National Institutes of Health (NIH) and operates in the following locations: (1) clinical partners within Washington, D.C. (2) NIH, Bethesda, MD and (3) IHV, Baltimore, MD. As part of the clinical aspects of the program, providers are embedded within established HIV clinics to augment and enhance subspecialty medical care for our region's high-risk population. Patients receive state-of-the-art care, and are offered opportunities to participate in clinical research, as appropriate. Within these subspecialty clinics, over 6,000 HIV infected patients and over 2,000 HCV patients have been linked to care, and over 200 patients have been cured of hepatitis C through treatment with novel directly acting therapy. Through direct linkage to care, effective treatment, and continual outcome measurement, this community based hepatitis program has developed an effective model for management of hepatitis C in an urban setting.



Constantine Lab Improves HIV Diagnostics



Niel Constantine, PhD, MT(ASCP)

Since the development and launch of HIV tests by IHV Director Dr. Robert Gallo and his colleagues Drs. M. G. Sarngadharan and M. Popovic (both currently with IHV) in 1984, diagnostics have continued to improve to address a number of issues. Beginning as ELISA tests for screening and Western blots for confirmation in 1986, new tests and testing algorithms have been introduced. Advances in HIV diagnostics include indirect immunofluorescence assays (for confirmation) and rapid tests that offer finger-stick and oral fluid as sample media (of value for Point of Care testing in outreach venues, and importance for use in resource-limited countries).

The newest addition for HIV diagnostics is the FDA approval of a rapid confirmatory test, called the Geenius HIV 1/2 Supplemental Assay (BioRad Laboratories). This test is similar to a Western blot but uses recombinant and synthetic peptide antigens to

detect specific HIV antibodies. The test requires only 20 minutes to perform and uses a reader for recording of results (eliminates subjectivity). The test can differentiate HIV-1 from HIV-2, and sample media can be whole blood, serum or plasma.

For testing algorithms, the plan, according to BioRad, is to replace the HIV-1 Western blot and the rapid Multispot HIV 1-2 test (both used as confirmatory strategies) with the Geenius HIV 1/2 Supplemental Assay. Therefore, a screening test (EIA, CIA, or rapid test) will be the initial test followed by the rapid Geenius Supplemental Assay for confirmation and differentiation. Dr. Niel Constantine, Head of IHV's Laboratory of Viral Diagnostics in the Epidemiology and Prevention Division, is adopting this new testing strategy for application in the hospital clinical laboratories and for use in outreach programs associated

with the IHV. Not only will this new test decrease turn-around time for routine testing (same day confirmatory results), but it will have value in clinics and programs for those who test positive by rapid screening tests. In addition, a current effort of IHV's JACQUES Initiative, a novel program of the Clinical Care and Research Division, with the University of Maryland Medical Center to provide test results quickly for patients visiting the Emergency Department (ED) will benefit from the rapid turn-around times for confirmed results so that patients receive definitive results before leaving the ED (at present, the effort provides rapid turn-around results only for screening tests, but does not provide confirmatory results in a timely manner). This effort to rapidly identify HIV infected persons in the ED and link them to care is an important strategy to prevent the infection of others.



Geenius HIV 1/2 Supplemental Assay



Gallo Honored by Cameroonian Charity

In December, Dr. Robert Gallo was presented The Vincent Kewala Nyambi Foundation's 2014 Global Humanitarian Award during an eventful evening, where Dr. Gallo was also presented with full royal Cameroonian regalia – a unique honor. Dr. Eugen Ateh of IHV's Animal Models Division facilitated the recognition from the Foundation and IHV's Dr. William Blattner, Associate Director and Director of the Epidemiology and Prevention Division, provided a moving keynote presentation. Co-founded by Jude Nyambi, the Foundation has changed the lives of Cameroonian children orphaned by AIDS and/or infected with HIV. They do so by assisting, rehabilitating, stabilizing and empowering children by improving living conditions through formal education, vocational training and capacity building in order to make them become socio-economically independent.



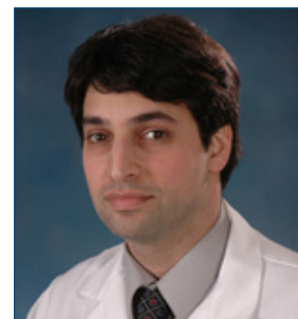
Alan Schmaljohn, PhD

Schmaljohn Joins IHV as Adjunct Professor

Alan Schmaljohn, PhD, a professor in the department of microbiology and immunology at the University of Maryland School of Medicine, has joined IHV as an adjunct professor in the Division of Vaccine Research. He will continue his interaction with members of the Division of Vaccine Research on the mechanisms of antibody-mediated protection against HIV-1. In addition, he is collaborating with Division of Vaccine Research members on a new project to define the mechanism of non-neutralizing antibody mediated protection against Ebola and Marburg viruses.

IHV Promotes Mahammad Sajadi

Effective in July, Mohammad Sajadi, MD of the Division of Clinical Care and Research was promoted to Associate Professor, non-tenure track in the Department of Medicine. Dr. Sajadi oversees the NVS cohort, HIV-1 infected patients who control viral replication in the absence of HIV therapy. He has studied the NVS and other HIV patients with low viral loads a model to study HIV humoral immunity. Working with IHV's Divisions of Basic Science and Vaccine Research, Dr. Sajadi oversees a project to directly sequence antibody from patient plasma, as well as studying the common characteristics of antibodies that mediate the neutralization response in HIV infection.



Mohammad Sajadi, MD



Riedel Receives Passano Foundation Award

David Riedel, MD, MPH, Assistant Professor of Medicine, Institute of Human Virology, received the 2015 Passano Foundation Clinician-Investigator Award. The honor is an annual award with a nomination process to promote the research career development of young faculty clinician investigators.

David Riedel, MD, MPH

IHV Promotes Alash'le Abimiku

Effective in July, Alash'le Abimiku, PhD of the Division of Epidemiology and Prevention was promoted to Professor, non-tenure track in the Department of Medicine. Dr. Abimiku is also Director of the Office of Laboratory Diagnostics and Research at the Institute of Human Virology, Nigeria. Her research focuses on using natural disease models in Africa to study the pathogenesis and prevention of HIV with focus on the mother: child model to investigate the transmitting subtype/s and role of natural protective factors in breast milk.

Alash'le Abimiku, PhD



Blattner Receives Alumni Achievement Award

On April 25, William Blattner, MD, Associate Director, Institute of Human Virology and Professor of Medicine, University of Maryland School of Medicine, received the Washington University Medical Center's Alumni Achievement Award as selected by the Alumni Association and presented during the School of Medicine's 2015 Reunion. The Washington University Medical Center Alumni Association honored Dr. Blattner as a pioneer in the epidemiological studies of human retroviruses and for his seminal contributions to the field of HIV/AIDS research, including understanding the cause of AIDS, its transmission, and methods of infection prevention. Dr. Blattner's work made a major impact on controlling and treating the disease on an international scale, greatly improving the human condition for millions.



The Washington University Medical Center Alumni Association President Dr. Linda Peterson, William A. Blattner, MD, and Washington University School of Medicine Executive Vice Chancellor and Dean Larry J. Shapiro, MD



Robert Gallo, MD

Gallo Gives Three Keynote Addresses

Robert C. Gallo, MD, Director, Institute of Human Virology, The Homer and Martha Gudelsky Distinguished Professor in Medicine, gave the keynote address — Journey with Blood Cells and Viruses—March 12 for Tulane University's Presidential Symposium on Translational Research in Infectious Diseases: From Microbes to Man. Dr. Gallo also gave the keynote address—Co-Founding the Institute of Human Virology and the State of HIV Research—at the Fulbright Enrichment Seminar sponsored by the U.S. State Department and hosted in Baltimore by the World Trade Center Institute on March 26 before an audience of 65 comprising Fulbright scholars from around the world, academia and public officials. And on April 9, Dr. Gallo gave the keynote address—Reflections on Some Lessons from the Past and Progress for the Future—for the University of Miami CFAR's annual HIV Symposium.

IHV Strengthens Ties with India



Robert Gallo, MD greets students in India

Last November, Institute of Human Virology (IHV) Director and Global Virus Network (GVN) Co-Founder and Scientific Director Dr. Robert Gallo visited India at the invitation of the Indian Medical Association (IMA) to participate in its 57th state conference of IMA Kerala in Trivandrum. The conference focused on the recent Ebola outbreak with a goal of developing training and awareness programs for IMA Members to tackle outbreaks of various viral diseases, including HIV. The IMA program is envisaged to help medical fraternity in the state, to stay updated on the emerging and re-emerging viral diseases, and to equip them to face emergencies. Following the IMA conference, Dr. Gallo traveled to Kochi, where he gave a presentation at Aster Medcity's conference on "New Horizons in Cancer Care." Aster Medcity, led by newly appointed GVN Board of Directors member Dr. Azad Moopen, is one of South Asia's most advanced quaternary care medical center and was founded to explore newer horizons and improving cancer management and care in India. Dr. Gallo was accompanied throughout the trip with newly appointed GVN Senior Advisor Dr. M.V. Pillai, who is Senior Medical Oncologist at Thomas Jefferson University and advises major medical organizations and the government in India.



Audience members listen during a keynote presented by Robert Gallo, MD

Over the course of a few days, Dr. Gallo presented five lectures on a variety of topics including, Viruses, Cancer, and Epidemics; HIV & AIDS: The Story of the Basic Science Advances and their Impact on Medical Research and Policy; Co-Founding the IHV; The Difficulty in Developing an HIV Vaccine; and, among other topics, the origins and need for the Global Virus Network (GVN).

During his time in India, Dr. Gallo dominated media who were interested in his thoughts on Ebola, and in which he said, "The science of Ebola is not difficult and at present, there are at least 12 vaccines against Ebola, of which three or four are extremely promising. All it needs is more money and infrastructure for research." He reminded his audiences that HIV proved a far greater scientific challenge, killing more than a million each year, and that there is an urgent need to develop an HIV preventive vaccine for the world.

Dr. Gallo also met with top government officials, including Kerala's Chief Minister Oommen Chandy, who presented Dr. Gallo IMA's Medicine Millennium International Award during the IMA Conference for his "tremendous contribution towards medical sciences and developing medical facilities globally." In a private meeting with Drs. Gallo and Pillai, Mr. Chandy was optimistic about forging public-private partnerships in India to strengthen India's medical virology programs as well as to ignite a greater, leading role in the GVN.



Kerala Chief Minister Oommen Chandy presents Robert Gallo, MD with the IMA's Medicine Millennium International Award

Kerala is a region riddled with an impressive number of medical educational institutions which can—and should—take a global lead in the fight against viral epidemics. Second only to China in the world in its growing population of 1.2 billion people, India eagerly supports GVN and recognizes the country's vulnerabilities to viral outbreaks. Public-private entities in India will work with IHV scientists and the GVN in order to strengthen its ties with India's top medical virologists and position the country to take a global, leading role in furthering the missions of IHV and GVN.

Innovative Prevention Program in East Africa Seeks to Ensure Access to Care for Addicts with HIV



Clinic in Kenya

Heroin addiction is a growing problem in Kenya and Tanzania. Both countries are key transit points in the international heroin trade, and in recent years, increasing numbers of people in both countries are becoming addicted.

Because many of these users inject the drugs, they are at risk from HIV from shared needles and once infected less likely to receive the care they need to survive. HIV is a significant problem in Tanzania and Kenya. In these countries, around five percent of the general population has the disease (Kenya 6%, Tanzania 5%), a rate far higher than in the U.S. According to studies, HIV rates amongst injecting drug users (IDUs) are close to 20 percent. Nairobi, the capital of Kenya and its largest city, has roughly between 6,000 and 12,000 IDUs. Overall, the country could have as many as 30,000 heroin users, with the coastal cities being the major hot spots. The number is small compared to the U.S., but it seems to be growing rapidly. Researchers and health officials worry that in East Africa, IDUs could become a key driver of the HIV epidemic.

Now, a new project led by researchers at the Institute of Human Virology (IHV) and the Department of Psychiatry at the University of Maryland School of Medicine (UM SOM) is trying to reduce these numbers



Anthony Amoroso, MD

by treating heroin addicts in Kenya with antiretrovirals and methadone. The project is led by Anthony Amoroso, MD, an associate professor of medicine at the IHV, as well as Chief of the Infectious Disease Section at the Baltimore VA Hospital. Amoroso is working in partnership with a highly-experienced clinical team lead by Eric Weintraub, MD from the UM SOM Department of Psychiatry. The project is being developed in conjunction with



Clinical Team meeting

doctors at Mathari National Teaching Hospital, a district government teaching hospital in Nairobi. This program serves as a training and referral center, and the model of care has been refined to suit the unique environment.

Methadone is a synthetic opioid that is commonly used to help people reduce their dependence on heroin and other opioids. It reduces withdrawal symptoms and craving and with proper dosing blocks the effects of illicit opioids. It is taken by mouth, and can help addicted individuals reduce their illicit drug use and adhere to HIV treatment. It is widely accepted as a proven and effective public health strategy to curb infection amongst IDUs and their sexual networks, and most importantly, sustain HIV-infected individuals on HIV treatment.

“Heroin use is on the rise in Africa,” said Dr. Amoroso. “Access to appropriate care and treatment for these patients is really lacking because it is such a novel problem. In Nairobi, we have been working with the

city government to improve the quality of HIV care with particular focus on decreasing mother-to-child transmission for over 5 years. We felt it is time to continue pushing for better services for those most affected and marginalized in these health systems. The University of Maryland School of Medicine has years of experience working with patients with IV drug addiction issues, including opioid addiction, concurrent mental illnesses, HIV infection and other infectious diseases, health policy, and social services. With the Department of Psychiatry engaged in our programming, we know we can make a real impact on helping countries struggling with emerging epidemics of IDU and HIV. The hope is that an effective demonstration will lead to scaling of services and ultimately make an impact on HIV prevention in key cities.”

The program, which is known as Medication-Assisted-Treatment for Opiate Addiction (MAT), began in September 2013. However, it was a struggle to initiate patient care due to a withering list of challenges. But finally in December 2014, the first patients were enrolled. Over the next several months the program will help around 1,400 patients and expand to create one additional clinic in Nairobi city. Over three years, the program will receive \$2.2 million in funding from the U.S. Centers for Disease Control and Prevention (CDC) as part of a larger HIV care and treatment grant that Dr. Amoroso has been leading in Nairobi since 2010.



Therapeutic group meeting

HIV/AIDS Presents an Unprecedented Challenge to Developing a Vaccine

As the world focuses on Ebola, we must not forget that HIV/AIDS presents a far greater challenge in the world of vaccines.

Thirty years ago this past April, my colleagues and I reported that a new retrovirus, now known as HIV, was the agent causing AIDS. At the time, it was a pandemic with far greater mortality and morbidity than Ebola -- and one with greater implications including life-long infection with sure death along with a tainted global blood supply -- neither of which are the case with Ebola. Furthermore, Ebola seems to be straightforward, on the fast track to a successful vaccine, which have already been effective in monkeys.

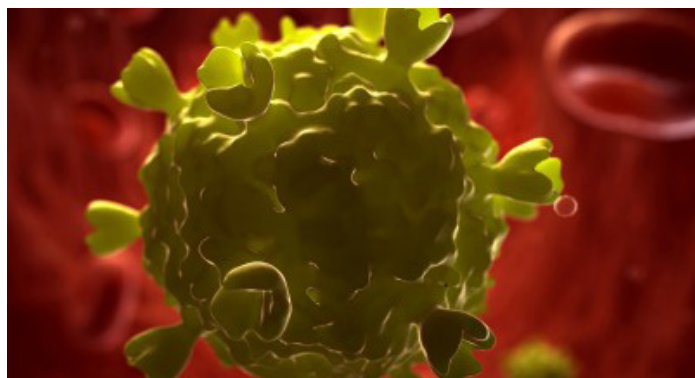
It is often reported erroneously by media that during this press conference U.S. Health and Human Services Secretary Margaret Heckler said that there would be a vaccine in two years. One can verify in public transcripts of the press conference that this is not what Secretary Heckler said, though she is forever criticized and falsely attributed to this made-up quote. What Secretary Heckler did in fact say was that we could now grow the virus permanently in cell line culture, which was one of the substantive advances we made that allowed us to get the blood test. This new biotechnical advance also allowed others to test and develop HIV medicine, including the first successful drug therapy, AZT.

Secretary Heckler concluded the press conference saying that because of this new advance, a vaccine could be tested in a couple of years, which was in fact the case. No one expected to have an effective vaccine out of the gate. In fact, developing an effective HIV preventive vaccine has turned out to be a huge, complex challenge.

As written by my colleagues, George Lewis and Anthony Devico, and me in a perspective published Monday by the Proceedings of the National Academy of Sciences, we outline the unprecedented challenges facing the field, and one particularly that does not get much attention but we believe is the key to solving the vaccine problem.

Unlike Ebola, at the heart of the challenge is that HIV is a human retrovirus, and by nature irreversibly infects an individual permanently in a few days. Thus, unlike viruses for which we have successfully developed vaccines, such as polio, the immune system has no time to recognize HIV and produce antibodies to fight it. HIV has already begun inserting its genes into its human host's genome. We believe an effective vaccine must achieve "sterilizing immunity," or the ability to completely block infection at the entry point.

Previously, five large HIV vaccine trials failed to do this, including one that increased risk for HIV infection. However, a sixth large HIV vaccine study, the U.S. Army RV144 Thailand vaccine trial succeeded in 2009 to show modest



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antibody-associated protection in the first few months of infection. But, similar to our Institute's HIV vaccine candidate results in monkey tests, as the particular protective antibodies faded in the U.S. Army vaccine trial, so did protection. In reviewing the literature, there is a common theme which has gone unnoticed -- these antibodies uniformly don't persist.

There is something about the virus' envelope protein -- not unique in biology but unusual that the antibodies last less in time. This is the crux of one of the chief problems in the field.

How do we solve this so we can save people from HIV infection? One approach to solving this problem is to boost repeatedly when antibody levels decrease below protective levels. However, there are serious problems with this approach. First are logistics. For example, one cannot go to every village in a resource-poor country, recruit people and then continually boost them. Second, HIV variants emerge and as this happens, we cannot be sure that boosting will work on those variants. Moreover, in the literature there is evidence that constant boosting alters the function of antibodies by diminishing them. And, if that's not enough, incessant boosting activates T cells, which are the necessary targets of HIV infection. So you make more of these T cells and HIV says, bravo, thank you. Herein lays a fundamental immunologic challenge, while we try to make antibodies long-lasting we are destroying the efficacy of the vaccine because more target cells are produced. We must solve this challenge, to solve the AIDS problem.

Robert C. Gallo, MD directs the Institute of Human Virology and is a professor at the University of Maryland School of Medicine in Baltimore and is co-founder and Scientific Director of the Global Virus Network. He is best known for his co-discovery of HIV as the cause of AIDS and development of the HIV blood test.

Follow Robert C. Gallo, MD on Twitter: www.twitter.com/DrRobertCGallo

Wang Takes New Position at UM College Park

This year, Lai-Xi Wang, PhD, took a position with the department of chemistry and biochemistry at the University of Maryland, College Park where he will serve as professor and dedicate a significant effort to teaching and training undergraduate and graduate students. Dr. Wang joined the Institute of Human Virology (IHV) as a tenure track assistant professor in 2000 and was subsequently promoted to full professor with tenure in 2009. Over the 14 years as a member of IHV's faculty, Dr. Wang's research centered on two fronts: Developing new chemoenzymatic methods for making well-defined homogeneous glycoproteins for functional studies and therapeutic applications, and characterizing oligosaccharide and glycopeptide neutralizing epitopes on HIV-1 envelope for vaccine design. His chemoenzymatic method for glycoengineering of monoclonal antibodies has a great potential for improving the therapeutic efficacy of those monoclonal antibodies and also provides a novel approach for making antibody-drug conjugates.

“What a huge loss for us,” said Dr. Robert Gallo, Director of the IHV. “We all will miss his many scientific gifts and his collegiality. He was and remains a friend, and one we are proud of.”



Lai-Xi Wang, PhD

In addition to working with undergraduate and graduate students in his new position, Dr. Wang is developing a new course on Chemical Biology and will also teach organic chemistry. According to Dr. Wang, education and training of younger generations of scientists and scholars is always a dream that he wanted to pursue. Meanwhile, Dr. Wang will expand his research in bioorganic chemistry and chemical glycobiology by initiating new research projects on synthesis, structure and function of glycans and glycoproteins. He was also charged to establish a new chemical biology center on the campus.

Dr. Wang continues to work together with faculty members at IHV. For example, he is working with IHV Associate Director of Faculty Development David Pauza, PhD on HIV vaccine research; and with IHV Basic Science Division Co-Director Eric Sundberg on the structure and engineering of endoglycosidases. In addition, Dr. Wang continues to work with IHV Vaccine Research Division Director George Lewis, PhD and IHV's senior scientist Tony DeVico, PhD on monoclonal antibodies and on exploring new methods for making antibody-drug conjugates.

Dr. Wang says, “I always feel appreciative to Dr. Bob Gallo for the opportunity to work at IHV. Bob recruited me as a “chemist” from MIT, and when I told him that I knew nothing about virus and virology, which was before I accepted the offer, I remember that he said that was not a problem, so long as you are smart. That year, four of us, including Drs. Pauza, Maria Salvato, Wuyuan Lu, and I were recruited to IHV's Basic Science Division, and we all started on July 1, 2000. It has been extremely fun and exciting to work together with so many extraordinary scientists and clinicians at IHV. Those are the very good old days...”



announces its 2nd Annual Short course: **“GVN: Virology”** A SHORT COURSE FOR EMERGING LEADERS IN MEDICAL VIROLOGY

Experts will explore state-of-the-art basic science, clinical, and translational aspects of viruses of great importance to human health in a small group setting designed for discussion and interaction.

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- DIANE GRIFFIN
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- AB OSTERHAUS
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- CONNIE SCHMALJOHN
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Terry Lierman

Board of Advisors Chairman's Message

This is a time of CHANGE for the Institute of Human Virology (IHV)!!

While we still receive millions of dollars in federal research grants, those funds are not as plentiful as they once were and there is no flexibility for discovery

within the parameters of the grants, and yet, the need for the kind of work done by IHV continues to grow.

Case for IHV:

According to the U.S. Centers for Disease Control, 35 million people worldwide are living with HIV/AIDS with 1.5 million people dying from HIV-related infection in 2013 alone; cancer causing viral infections such as hepatitis B, hepatitis C, human T cell leukemia virus-1, and human papilloma virus are responsible for up to 20% of cancer deaths in low- and middle-income countries; and 130-150 million people worldwide have chronic hepatitis C infection.

IHV is poised to take the NEXT STEP on the path to discovery and hope. In order to do that, we have taken the leap into private revenue fundraising. As you'll see in the corresponding interview, Lori Piccolo is our new Director of Development. Working closely with IHV's Board of Advisors she is guiding us in our fundraising effort.

Because public relations and government affairs are so closely linked to fundraising, we've launched three new Board subcommittees concurrently.

I've often said that IHV is the best kept secret in Maryland, if not the United States! We no longer want that to be the case. Our public relations subcommittee is strategizing on ways to enhance IHV's public relations and outreach program, the development subcommittee, with the help of all Board Members, is identifying funding sources, and the government relations subcommittee is actively seeking new sources of funding within the city, state, and federal governments.

Much like the development subcommittee works closely with Ms. Piccolo, the public relations and government affairs subcommittees draw on the expertise of IHV's Public Relations Director Nora Grannell.

Listed below are the Board Members for our three new subcommittees.

Fundraising Subcommittee

John Evans
Mark H. Kaplan, MD, FACP
Terry Lierman
Franco Nuschese
Steven Wozencraft

Public Relations Subcommittee

John Evans Ellen Ratner
Sheilah A. Kast Raj Shah
Terry Lierman Jeffrey B. Trammell
James Pinkerton Steven Wozencraft

Government Relations Subcommittee

John Evans The Honorable Kathleen
Terry Lierman Kennedy-Townsend
Franco Nuschese Jeffrey B. Trammell
James Pinkerton Steven Wozencraft
Raj Shah

If you have suggestions, ideas, or thoughts regarding all of these new initiatives, PLEASE feel free to contact me at any time at tlierman@ihv.umaryland.edu.



Lori Piccolo

IHV Recruits Piccolo as New Development Director

Lori Piccolo has more than 20 years of fundraising experience in a range of Washington DC-based organizations. Before coming to IHV, Ms. Piccolo spent three years as director of development for DC's Children's Law Center where she presided over 35% growth

in private revenue fundraising and guided the participation of the board of directors and senior leadership in fundraising efforts. Prior to that, she spent 14 years with the Washington Office on Latin America (WOLA) where she created a major gifts program and launched WOLA's annual benefit gala. She also worked as a foundation specialist with People for the American Way and began her fundraising career at Public Citizen in 1991. She has been a member of the Executive Committee of the Chicago-based Brian Piccolo Cancer Research Fund since 1982 and in 1994, became a founding director of Human and Civil Rights Organizations of America. Ms. Piccolo graduated from Wake Forest University in 1987 with a BA in economics.

Why IHV?

I have long had a passion for medical research and science, which goes back to my father's battle with cancer. I learned at a young age the powerful way that fundraising and research can come together against diseases. When I was offered the opportunity to raise funds for a place like IHV that is making such a tremendous difference in the lives of people living with virus-linked diseases like HIV/AIDS and some types of cancer, I jumped at the chance.

What do you hope to achieve in your new role as IHV Development Director?

I have been in fundraising for a long time and one of my absolute favorite things is building a fundraising program where there hasn't been one before. IHV has had remarkable success in securing government research grants and even some private revenue grants like the Bill and Melinda Gates Foundation's support of IHV's HIV vaccine research, but there is so much more fundraising potential here. We are building a private revenue fundraising program here that will involve individuals, corporations, and private foundations.

What are IHV's fundraising priorities and objectives?

We have a lot of fundraising priorities but I'd say at the top of the list are an endowed distinguished professorship named in honor of Dr. Gallo and two endowed professorships named in honor of Dr. Blattner and Dr. Redfield. These professorships are so important to IHV's future in that they will allow us to attract and retain leading physicians and scientists to further advance IHV's cutting edge research and clinical care.

How do you plan to meet these priorities and objectives?

IHV's board of advisors, particularly the board development committee led by Board Chair Terry Lierman, are my partners in this fundraising effort. I've also started working with IHV staff and faculty on outreach and because IHV is part of the University of Maryland School of Medicine, I get to draw on the expertise of the School of Medicine's Development Team. Together we are starting to have conversations and meetings with prospective donors, we will launch an annual giving effort later this year, and we will begin to have a series of small-scale substantive events in the fall that will introduce people to the amazing work of IHV.



The Honorable Robert K. Gray Bequests \$1M Towards Gallo Endowment



The Honorable Robert K. Gray

Last year, one of IHV's original Board Members, who remained deeply engaged with the Institute all these years, died. The Honorable Robert Keith 'Bob' Gray was a stalwart supporter of the Institute, an HIV/AIDS leader in Florida after he retired from a distinguished and prominent career in Washington and national political life, and an enduring and loyal friend to all the founders of IHV

but especially Dr. Robert Gallo. His professional and personal relationship with Dr. Gallo even preceded the founding of IHV by many years. We are so pleased and grateful to announce that Bob Gray left the Institute a generous gift of \$1.0 million to establish an endowed distinguished professorship to honor his special friendship with Dr. Gallo. For Bob Gray the highest personal value was loyalty to the people and causes that gave meaning to his life. We are honored by this bequest and how his devotion to the Institute will live on.

Fischell Joins IHV Board of Advisors

Dr. Robert E. Fischell joined the IHV Board of Advisors. He received his BSME degree from Duke University and MS and ScD (honorary) degrees from the University of Maryland. Dr. Fischell was employed at the Johns Hopkins University, Applied Physics Laboratory for 25 years where he actively developed more than 50 spacecraft. Starting in 1969, Dr. Fischell began the formation



Robert E. Fischell, ScD

of 15 private companies that licensed his patents on medical devices including heart pacemakers, defibrillators, coronary stents, and devices to treat epilepsy and migraine headaches. Dr. Fischell is a prolific inventor with over 200 issued US and foreign patents many of which have started 15 new medical device companies. He is a Trustee of the University of Maryland, College Park Foundation, a member of the Board of Visitors for the College of Engineering, a member

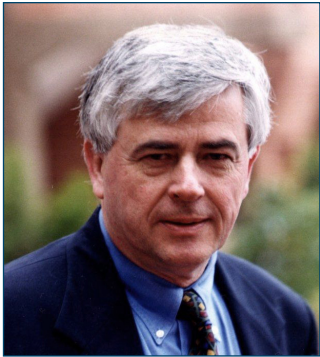
of the Board of Visitors of the University of Maryland School of Medicine and a Director of the University System of Maryland. Dr. Fischell's honors include Inventor of the Year for the USA in 1984, election to the National Academy of Engineering in 1996, and several medals for distinguished accomplishments in science, engineering and innovation. In 2004 Discover magazine gave Dr. Fischell their annual award for Technology for Humanity. In 2005 he received the TED award (with a \$100,000 prize) for contributions to medical technology. Also in 2005 Dr. Fischell provided a philanthropic gift of \$30M to create and fund the Fischell Department of Bioengineering in the Clark School of Engineering. In 2007 he received the prestigious Woodrow Wilson Prize for Public Service from the Woodrow Wilson Society for Scholars. In May 2008 he received an honorary degree as Doctor of Humane Letters from the Johns Hopkins University in recognition of his many contributions to betterment of mankind.

Lowé Receives Jamaica's National Medal for Science



Henry Lowe, PhD

Last November, Dr. Henry Lowe, a member of IHV's Board of Advisors, was awarded Jamaica's National Commission on Science and Technology's National Medal for Science, Technology and Innovations by Prime Minister Portia Simpson-Miller. Lowe pledged to match the \$1.5 million cash award received and made a donation towards a fund for the development of the island's nutraceutical sector. Lowe was honored for his contributions, which spans over 50 years in the fields of science and technology, energy, the environment, wellness and health sciences both nationally, and internationally.



Max Essex, DVM, PhD

Essex Receives My Hero Award

Dr. Max Essex, a member of IHV's Scientific Advisory Board, this past fall received the My Hero Award during the My Hero Gala hosted by AID FOR AIDS. He received the Award alongside longtime IHV friend Dr. Jose Esparza at the Metropolitan Museum of Art in New York City. AID FOR AIDS collects

medication that would otherwise be discarded and ships it to people in 43 countries in the developing world, particularly in regions of the world that remain largely overlooked in the fight against HIV: Latin America and the Caribbean. Dr. Essex is the Mary Woodward Lasker Professor of Health Sciences and Chairman of the Harvard School of Public Health AIDS Initiative and also recipient of IHV's Lifetime Achievement Award for Scientific Contributions in recognition of his work on animal and human retrovirus research and his leadership and great impact in the public health of Botswana.



Raj Shah

Shah Gives Back to Inova Fairfax Hospital

IHV Board Member Raj Shah, a transplant recipient three years ago, is donating more than \$1.4 million by 2016 to Inova Fairfax Hospital. The donation will increase patient educational services and resources to enhance staff education and will support research to help improve the outcomes of advanced heart failure/transplant patients. Mr. Shah is CEO of CTIS, Inc.

and is dedicated to contributing to the improvement of the health industry, specifically committed to finding individualized health solutions for the chronic disease population, especially within the global "communities in need" afflicted with health disparities. His vision is to provide integration of processes for better collaboration and performance at the point of care in order to supply the safest and most cost-effective patient care. His strategy is to integrate information, technology, process, best practice, and standards through the use of health informatics solutions for providers and physicians that support patient need for prevention, early disease detection, care management, and research.

Moynahan Inducted into Post University Hall of Fame



Timothy C. Moynahan, Esq.

IHV Board of Advisor Member and Global Virus Network Board Vice Chairman Timothy C. Moynahan, Esq., with legal practices in Waterbury and Southbury, Connecticut, was inducted April 9 along with a dozen honorees into Post University's new Hall of Fame as part of the school's year-long 125th anniversary celebration. The inaugural group of 12 inductees represent the "best of the best" of Post's alumni, faculty and staff, and supporters, and were selected from more than 50 nominations received from the public in late 2014.



Franco Nuschese

Nuschese Honored with First Saint Pio Award

IHV Board Member Franco Nuschese will receive the 1st Saint Pio Award presented by the Saint Pio Foundation during a ceremony on May 22, 2015 in Washington, DC. Mr. Nuschese will receive the Award alongside Tony and Emmy-winning actor, producer, writer and director Joe Mantegna. The Saint Pio Award has been established to recognize

the selfless and outstanding contribution to the Catholic Church of those individuals who have strongly committed to support the Saint Pio Foundation and its vision. The Saint Pio Foundation is a non-profit national charity organization dedicated to the promotion of the spiritual charism of Saint Pio of Pietrelcina, universally acclaimed as one of the most venerated contemporary saints of the Catholic Church.

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Dr. Robert C. Gallo, Director, Institute of Human Virology

Please visit WWW.IHV.ORG for more information on the program, registration and abstract submission.



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The Institute of Human Virology is a center of the University of Maryland School of Medicine and is affiliated with the University of Maryland Medical Center.

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