STANFORD UNIVERSITY School of Medicine



Gary K. Schoolnik, M.D. Professor Medicine (Infectious Diseases and Geographic Medicine) Microbiology and Immunology

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Maxmillian Angerholzer III Richard Lounsbery Foundation 1020 19th Street, NW, Suite LL60 Washington, DC 20036

Dear Max:

This cover letter is written to highlight and support a proposal that is submitted by Stanford University and entitled "Development of a National Tuberculosis Reference Laboratory in the Democratic People's Republic of Korea (North Korea)". The project described in this proposal will be led by Stanford University working in collaboration with tuberculosis experts from the San Francisco Bay Area tuberculosis consortium and with an NGO (Christian Friends of Korea) with over 15 years of on-the-ground experience in North Korea. Full implementation of this project will decrease the burden of tuberculosis in North Korea, strengthen the public health infrastructure of that county, prevent the regional spread of drug resistant strains of TB from North Korea into neighboring countries and initiate collaborations between Stanford scientists and scientists from North Korea. Because this project builds on a productive working relationship between American institutions and the North Korean Ministry of Public Health, it exemplifies global health democracy. Thus, a possible indirect outcome of this project is the creation of a forum for exchange and cooperation that could affect other areas of discourse between North Korea, its neighbors and the world community.

The attached proposal describes a four step developmental process: (1) establish the physical infra-structure of a modern TB laboratory in Pyongyang including the provision of equipment, modern plumbing and a continuous electrical supply; (2) train North Korean TB laboratory workers to carry out World Health Organization approved methods for the diagnosis of TB and for drug susceptibility testing; (3) obtain international certification that leads to its recognition by the World Health Organization as a National TB reference laboratory; and (4), initiate scientific collaborations between Stanford faculty, the North Korean Ministry of Public Health and faculty at Pyongyang School of Medicine.

- <u>Step 1</u> above has been achieved and, most impressively, this achievement occurred during a period of diplomatic instability and high tension on the Korean Peninsula. However, infrastructure alone, no matter how impressive, cannot save a single life or affect the TB epidemic in North Korea.
- Step 2, the most critical phase of the entire project, has begun. The Stanford led consortium has made five training visits to North Korea in the last 18 months. However, TB laboratory diagnosis and drug susceptibility testing is complex, demanding and subject to error if not carried out by highly trained laboratorians. Diagnostic errors at the level of the laboratory can adversely affect treatment outcomes. We estimate that another 12-18 months of training will be required if the laboratory is to reach international standards of competence. To achieve this critical step, it is now necessary to hire a full-time TB laboratory trainer, of exceptional skill and deep experience, who will work for extensive periods of time in North Korea, working each day with North Korean laboratory workers as they master the necessary skills. In short, periodic 1-2 week visits to Pyongyang by voluntary trainers, as has been our past practice, is not sufficient to achieve the required level of competence. Thus, we view the successful achievement of Step 2 as the critical go/no-go milestone for this project. If this request for funding is successful, funds from The Richard Lounsbery Foundation will be used to support a dedicated trainer who will drive this project to a successful conclusion. We have identified the ideal person for this position, Dr. Kathleen England, a TB laboratory expert who has already trained TB laboratory workers in Mongolia and China. Thus, we have developed the infrastructure, identified the trainer, specified the tasks and curriculum and defined the goal: prepare North Korean TB Laboratory technicians to reach a level of competency that meets international standards. Funds to support this critical go/no-go step are now required if the project as a whole is to succeed.
- <u>Step 3</u> will leverage the infrastructure provided by step 1 and the training provided by step 2 to achieve international accreditation for the North Korean National TB Reference Laboratory. The process of gaining international accreditation is rigorous and formal; it is carried out under the auspices of the World Heath Organization in conjunction with the WHO supra-national TB reference laboratory in Hong Kong. Achieving this status is very important: it will be the first time, we believe, that any public health laboratory in North Korea has achieved international recognition of this kind; it will mean that TB diagnostics in North Korea can be used confidently to treat patients and to support the North Korean TB control program; and, in effect, it will mean that TB public health workers in North Korea can join their counterparts on the world stage as equal partners.
- <u>Step 4</u> will use the accredited laboratory to catalyze research collaborations between Stanford faculty and their counterparts in North Korea. Examples of projects under consideration include: (1) microbial genotyping methods will be used to trace the possible flow of TB strains from North Korea into China and

beyond; (2) point-of-care rapid, accurate and cost-effective molecular diagnostic tests will be developed for TB that will accelerate and simplify the laboratory diagnosis of this disease in resource poor settings; and (3), the effect of malnutrition on the host immune response to TB will be measured.

What are the longer-term consequences of an internationally certified National TB Reference Laboratory in North Korea?

First, it means that the laboratory can directly affect patient care by providing critical information to the treating physicians.

Second, it means that it can be integrated into the North Korean TB control program, by, for example, monitoring TB drug resistance levels in the country, carrying out TB surveillance activities, identifying high risk populations and settings where TB transmission occurs at high levels, and monitoring the adequacy of treatment. Indeed this process is already occurring: Dr. Choe Kum-Song, a principal North Korean participant in the National TB Laboratory project, has just been promoted to lead the entire North Korean TB control program.

Third, it means that it will have the capacity to serve as a <u>Center of Excellence</u> within the country. By virtue of its advanced state, international recognition and superbly trained staff, it will very likely affect other aspects of the North Korean public health program, including the development of other critical laboratories. And, it will make it possible to carry out scientific collaborations between DPRK scientists and their counterparts at Stanford.

To achieve these goals we are asking the Lounsbery Foundation to provide \$86,934 to support the salary of Dr. Kathleen England for the first and most critical 10 months of her assignment to this project. The remaining 14 months of her tenure will be supported by a combination of funds from other sources. In particular, ZeroTBWorld, a South Korean foundation will provide the majority of funds for the last 14 months of the 24 month funding period. Note: Stanford has signed a MOU with ZeroTBWorld and this organization has committed \$100,000 USD during year 2 of Dr. England's participation.

In summary, the development of this laboratory project continued unabated during a period of high tension on the Korean Peninsula. During this process it has engaged in a kind of health diplomacy and begun to discuss scientific collaborations. But now it has reached a critical milestone on the path to national accreditation. Funds to support a full time laboratory trainer are urgently needed to achieve this critical go/no-go step. If successful in gaining national accreditation, this laboratory will be transformative: it will allow North Korea to join the international public health community of nations; and, it will serve as a center of excellence within North Korea, affecting other areas of the public health program.

As both a participant in the project and as an academic official of Stanford Medical School, I sincerely request your most careful review of this very worthy and unique project.

Sincerely,

Gary K. Schoolnik, M.D. Professor of Medicine, Microbiology and Immunology Associate, Dean, School of Medicine Associate Director, Institute of Immunology, Transplantation and Infection Senior Fellow, Freeman Spogli Institute for International Studies

Development of the National Tuberculosis Reference Laboratory Democratic Peoples Republic of Korea (DPRK – North Korea)

Stanford University

<u>Tuberculosis in the DPRK</u>: Tuberculosis (TB) is a contagious disease, caused by the bacterium, *Mycobacterium tuberculosis*, which preys on populations weakened by hunger and acute illness. Since the famine of the 1990's, rates of TB in North Korea (hereafter referred to as the Democratic Peoples Republic of Korea (DPRK)) have risen dramatically (an estimated 10% increase/year) to rank among the highest in the world and three times the rates in China and South Korea. A response to the DPRK TB epidemic is of global, regional and domestic public health importance.

North Korea, a country with 24 million people, has an estimated 100,000 TB patients per year, including 10,000 children. Without proper diagnosis and treatment, up to 50% of TB patients will die; and each untreated case can spread to 10-20 additional persons/year. Additionally, there are now an estimated 5,000 or more cases of multi-drug resistant TB (MDR-TB) in the DPRK. While the World Health Organization (WHO) listed the establishment of a National TB Reference Laboratory (NTBRL) in the DPRK to be a high priority and provided initial funding in 2006 towards this objective, political and security issues resulted in a subsequent loss of funding and a derailment of this effort. It was in this context that we were approached to help the DPRK – and in the process to contribute towards capacity-building and strengthening of the national TB treatment program, expand DPRK scientists' professional and scientific relationships and build trust.

<u>Our project</u>: The US-DPRK TB project was organized in 2008 to help establish the NTBRL for the DPRK, and to promote opportunities for professional and academic engagement with North Korea focused on mutual interests in TB control. The Project is led by Stanford University Medical School faculty working in collaboration with the Bay Area TB Consortium (BATC), an affiliation of TB physicians, epidemiologists and laboratory scientists from the Stanford School of Medicine and the California State Public Health Laboratory system. Stanford and the BATC work in collaboration with Christian Friends of Korea, a US NGO with more than 17 years of humanitarian engagement within the DPRK, including more than 15 years of TB-specific support in urban and rural areas of the country.

The goal of the NTBRL is to support the DPRK Ministry of Pubic Health (MoPH) in their efforts to conduct TB surveillance, develop national treatment and control guidelines, provide testing of individuals known or suspected of having drug resistant TB and provide training to regional peripheral laboratories. These are important disease-control goals, but in addition, we fully expect the NTBRL to serve as a center of excellence with the DPRK that will improve the capacity of other public health laboratories and initiate scientific collaborations between western and DPRK scientists.

<u>Our need</u>: Up until now, the development of the NTBRL project, including all training activities, has been carried out during periodic 1-2 week trips by Stanford faculty and volunteers from the California State Public Health TB Laboratory. In light of the still-expanding TB epidemic in the DPRK, and in order to achieve international accreditation of the NTBRL as soon as possible, it is urgent to hire a full-time, Ph.D. level mycobacteriologist to coordinate, develop and deliver training and assistance to the NTBRL over the next two years. We are asking the Richard Lounsbery Foundation to provide support for 10 months of salary and benefits for this position, enabling us to immediately hire an already-identified, highly qualified and experienced candidate to continue the present momentum of the project. The provision of 10 months of funding for this position will ensure that the most critical phase of training occurs without interruption; further, this funding will bridge a critical gap before funding by ZeroTBWorld, a South Korean Foundation, can begin.

Project History and the Step-wise development of the NTBRL: Despite considerable challenges in the external political and diplomatic environment coinciding with the timeline of our efforts over the last three years, we have completed the first of four planned steps and we are now well into the second step in the development of this laboratory: Step 1 – renovation of the infrastructure of the laboratory, including full electrification and delivery of equipment and supplies. Step 2 -- extensive training in support of international accreditation of the laboratory and scale-up to address the critical demands of the TB epidemic in the DPRK. Step 3 (use of the laboratory to enhance TB control efforts and inform the treatment of individual patients) and Step 4 (collaborative scientific projects between DRPK scientists and their western counterparts) will follow international certification of the laboratory.

The key historical landmarks for this project and described below.

2007: DPRK's MoPH approaches the Center for International Security and Cooperation at Stanford University requesting assistance in developing the NTBRL.

2008: DPRK MoPH personnel including NTBRL staff visits Stanford and San Francisco Bay Area TB control programs and laboratories.

Initiation of the project is funded by Nuclear Threat Initiative (NTI) which provides monies for laboratory equipment.

2009: With permission by the US Department of Commerce, two sea containers of laboratory equipment are shipped from the United States to Pyongyang and multiple truckloads of materials, sourced in China, arrive at the TB Hospital #3 in

Pyongyang where the NTBRL is located. The US consortium, working with DPRK MoPH personnel install a generator, power conditioner, water system, electrical system, lighting, heating/AC, and other support infrastructure. Equipment including biological safety cabinets, incubators, freezers, refrigerators, cabinets and lab benches are also installed. Laboratory staff from Stanford University and BATC provides initial training on culture and susceptibility testing.

2010: Troubleshooting of equipment and infrastructure is completed, water and plumbing systems are completed, and a new transformer is installed supplying the hospital and the lab. The completed NTBRL is dedicated in a ceremony attended by the Vice Minister of Public Health, major donors/partners to the project, WHO and UNICEF representatives, and hospital/lab staff. A second round of training is provided by the US consortium. The need for the development of quality assurance systems is identified. This visit and 3 additional training visits in 2011 are funded in part by a one-time follow on grant (of \$100,000) provided by the Global Health and Security Initiative of NTI.

2011: Stanford, through funding provided by the Asia and Pacific Research Center (APARC), convenes a 2½ day workshop in Shanghai with a delegation from the DPRK's MoPH/NTBRL, the Shanghai CDC, and Fudan University regarding the role of a NTBRL in TB control systems. Three additional rounds of training are provided by the US consortium. The focus is on specimen processing and culture of *M. tuberculosis* and the development of standard operating procedures (SOPs). The need for the development of quality assurance systems is identified. The need for a full-time Senior Laboratory Scientist to coordinate accreditation training and volunteer efforts is identified.

<u>Current Status of the Laboratory</u>: The 1250 square foot, 13 room laboratory has been fully renovated to modern standards, and the NTBRL is equipped with state-of-the-art equipment. As detailed above, five training visits have been completed, coordinated via a pool of highly qualified US professionals working on a largely voluntary basis. Funding for travel costs have been pieced together from grants and private donors, including funds raised by some of the participants themselves.

The NTBRL project has established an operational laboratory facility capable of performing limited, but essential diagnostic evaluation for the detection of TB and determining drug resistance. However, the diagnostic capability of the NTBRL is still at an early stage of development: it can provide basic information necessary for a physician to treat and manage a limited number of patients. The laboratory has not yet reached international standards with respect to the validity of the results it provides, its capacity to function independent of the support and continued training by the US consortium or its ability to process a large number of samples that would impact the control of TB in DPRK.

In order for the DPRK NTBRL to be recognized by the global TB laboratory network it must undergo a formal accreditation process. Once accredited, global health authorities will acknowledge the lab as a global entity and recognize DPRK for its efforts in managing TB within its country. This will be a landmark event that will pave the way for further medical advances and integrating DPRK's TB control program into the international effort to address the emerging epidemic of drug resistant tuberculosis.

Role of an NTBL in TB Treatment: The overall direction of the project is to assist the MoPH in developing a strong and internationally recognized program for the management and care of the TB population within DPRK. The foundation for success lies in the ability to properly detect and diagnose TB and provide essential drug susceptibility assessments that will lead to an effective treatment program. Thus, the development of a high through-put NTBRL with quality diagnostics is imperative for the DPRK TB control program. Having a proper diagnosis and drug resistance profile will improve quality of care by ensuring that each patient receives the appropriate treatment regimen. Further, a NTBRL with sufficient diagnostic capacity will provide necessary information about the prevalence of drug-resistant TB in North Korea. This will result in more accurate information about the TB situation in DPRK, and foster support from international agencies including WHO, Global Fund and Green Light Committee. In turn, this will strengthen the supply of TB drugs; enhance the NTBRL diagnostic program; and lead to the development of TB treatment and management training programs.

The newly developed NTBRL plays a critical role in the country's strategic plan with WHO for TB control. With its full accreditation and demonstration of proficiency through international inspections, the MoPH will qualify for new drugs to treat MDR TB. Ultimately, the NTBRL will develop the capacity to test thousands of cases suspected of MDR TB per year. These test results will be provided to physicians and thus will affect the treatment of individual patients, based on criteria established by the tuberculosis control program. By establishing reference-level diagnostics and clinical consultation services, the NTBRL will serve as a "center of TB excellence" for all physicians and medical laboratories throughout the country; a model that can be replicated in other critical areas of need in the DPRK such as hepatitis and blood banking.

Steps Toward International Accreditation: The immediate goals for the project are to enhance the laboratory's capabilities both in the quantity and quality of its work leading to accreditation. The process of accreditation is long and arduous with many levels to achieve. To standardize this process, Stop TB partnership's Global Lab Initiative program has established a four phase strategy to assist TB laboratories in the accreditation process. We plan to adopt this strategy to achieve accreditation of the NTBRL.

In order to accomplish our current goal, the project now requires a full-time TB laboratory expert to guide it through all the steps and processes necessary to achieve accreditation. Without this individual, progress will stall, the laboratory program will not be accredited and persons with TB will receive sub-optimal treatment. Without a solid and globally recognized TB diagnostic program in the DPRK, it will not be possible to formulate an effective treatment program and the drug-resistant TB epidemic will grow. This has far-reaching implications that extend beyond the country's borders, especially if drug-resistant strains spread regionally to other countries in Northeast Asia. By contrast, the successful accreditation of this laboratory will provide a plethora of benefits that extend beyond TB care. An internationally accredited NTBRL would constitute a "Center of Excellence" within the DPRK for the improved diagnosis, treatment and control of other infectious diseases. Further, we believe that an accredited NTBRL will lead to improvements in medical education and clinical training and the strengthening of biomedical research within the country.

WHO recommends one laboratory for the isolation and culture of *Mycobacterium tuberculosis* for every five million population and one laboratory capable of testing for drug susceptibility of *M. tuberculosis* for every ten million population. The present laboratory is the only one in the DPRK. This laboratory will serve as a model for others that will need to be to be developed and as a source of trained laboratory staff for those laboratories.

<u>Past Funding Sources and Current Needs</u>: The initial funding for equipment (\$230,000), and one follow-on grant (\$100,000) to support training efforts in 2010 and 2011 from NTI, have been exhausted.

This proposal to the Lounsbery Foundation seeks funds to support a full-time Senior Laboratory Scientist for 10 months to lead and coordinate training efforts within the DPRK. Following this10 month period, continued funding of this position will come from ZeroTBWorld, a South Korean Foundation that will provide funds in 2013. Thus, funds to support this position for the next 10 months will address this funding gap and will allow training to proceed at a critical time in the development of this project. The use of these funds is described below.

We are requesting a total of \$86,934 from the Richard Lounsbery Foundation to support 10 months of salary and benefits for the Senior Laboratory Scientist. (The Biography of the highly-qualified, experienced and currently available candidate, Dr. Kathleen England, is provided at the end of this proposal). Ideally, this position would be based in the DPRK assisting local laboratory staff for months at a time. However, this is not possible at this time because of the political/diplomatic environment. Instead, working within the present constraints, the Senior Laboratory Scientist will make regular (3 week-long) visits to the DPRK for a total of eight visits over two years. When not in the DPRK, this person will be based at Stanford University and will focus on follow-up activities from the previous visit, preparations for the next visit, ongoing curriculum

development, coordination of volunteers, interaction with the international TB/health community, and other related activities.

<u>Scientist</u>			
Salary for			
Laboratory			
Scientist	10 months	\$80,000/year	\$66,667
Fringe			
Benefits for			
Lab Scientist	10 months	\$24,320/year	\$20,267
Total Request			\$86,934

Proposed 10-month salary/benefits budget for the position of Senior Laboratory Scientist

Please note that Stanford University will waive all administration and overhead costs related to the position, and will also provide office/laboratory accommodation and support to the position.

Global, Political and Scientific Impact: Because of diplomatic isolation, DPRK remains "off-the-radar" for internationally funded MDR scale-up programs, even though it is well established in the global health community that all countries, regardless of political systems, are eligible for basic TB drugs. The presence of an established and accredited NTBRL in DPRK will have significant consequences. They will join other countries in the global effort to combat TB. Further, the presence of an internationally accredited laboratory in the DPRK will foster international professional relationships that can lead to the development of regional disease surveillance programs, improve public health infrastructure, encourage professional development, and provide opportunities for technical exchanges. Regional partnerships with bordering countries (Mongolia, China and Russia) will strengthen the Northeast Asia TB Control program. In this connection, the project has already led to a 2 day, Stanford-sponsored workshop between the DPRK and Shanghai departments of public health. A second workshop in Shanghai is planned for October, 2012, again sponsored by Stanford University.

The project has already generated significant interest in the scientific and diplomatic communities and articles have been published in *Science*, *On Korea* (Korea Economic Institute Journal), and *Lancet* (please see the Appendix for a copy of an editorial in *Science* about this project).

<u>Acronyms</u>

BATC	Bay Area Tuberculosis Consortium	
CFK	Christian Friends of Korea	
DPRK	Democratic Peoples Republic of Korea	
GLI	Global Laboratory Initiative	
MoPH	Ministry of Public Health	
NTI	Nuclear Threat Initiative	

NTBRLNational Tuberculosis Reference LaboratorySRLSupranational Reference Laboratory

Biographies of Key Participants

<u>Gary K. Schoolnik, M.D.</u> Professor, Medicine, Microbiology and Immunology Attending Physician, Stanford University Hospital Associate Dean, Stanford Medical School Associate Director, Institute of Immunology, Transplantation and Infection Senior Fellow, Freeman Spogli Institute of International Studies

Dr. Schoolnik was trained in internal medicine at the Massachusetts General Hospital where he served as Chief Medical Resident; and in microbial physiology and biochemistry at The Rockefeller University. For the past 25 years he has worked as a biomedical scientist and infectious disease clinician at Stanford Medical School, focusing on the pathogenesis of tuberculosis and cholera. He has served in a variety of national and international scientific advisory roles including a 5 year term as a member of the National Advisory Allergy and Infectious Diseases Council of the National Institutes of Health; and as a current standing member of the FDA Advisory Panel on Vaccines. He was a participant in three Gates Foundation Grand Challenges in Global Health projects in which he served as head of the TB genomics program; he is the Principal Investigator of the Gates funded TBDatabase project <TBDB.org>; and he is the Principal Investigator of a 5 year, 20 million dollar NIH funded TBSysBio contract. His work has been recognized by his election to the American Society for Clinical Investigation and the American Academy of Microbiology. He has numerous international advisory responsibilities: he is a member of the Fudan University International Scientific Advisory Board and he provides advice to the Shanghai CDC TB control program. With Chris Higgins he founded the journal Molecular Microbiology; he was Associate Editor of the Journal of Clinical Investigation; and he current serves on the editorial board of Journal of Microbes in Infections (Chinese).

Kathleen England, Ph.D. Designate: Senior Scientist, Stanford Medical School

<u>Dr. England</u> received her Ph.D. in Microbiology from Colorado State University (working in the area of TB drug development); served as a post-doctoral fellow at the TB research Unit of the NIH; served as laboratory supervisor for the Doctors Without Borders National TB Reference Laboratory project in Mongolia; and trained TB laboratory personnel in China and in South Korea. She also served as a WHO Fellow in Geneva training in the area of Global Response to Emerging Infectious Disease Threats. Sharon Perry and Gary Schoolnik are executive director and medical director, respectively, of the Stanford DPRK Tuberculosis Project. E-mail: shnperry@ stanford.edu (S.P.).

Heidi Linton is executive director of Christian Friends of Korea.

Tuberculosis in North Korea

TENSIONS ON THE KOREAN PENINSULA ARE HIGH. HOW SOUTH KOREA, THE UNITED STATES, and other countries, including China, engage North Korea remains a sensitive issue, as policies tying aid to denuclearization are debated. This month, the United States, South Korea, Japan, and China have been discussing the situation, including a meeting between Chinese President Hu Jintao and U.S. President Obama in Washington. These conversations, focused on conventional security concerns, would benefit from the articulation of mutual humanitarian goals.

Although North Korea's nuclear ambitions are the focus of international security concerns, the global community has also recognized that this nation of 24 million people is plagued by crippling food, medical, and energy shortages. Aid from the United Nations and nonprofit groups has largely aimed at reducing malnutrition and communicable disease in a near-starving population. Since the famines of the 1990s, rates of tuberculosis (TB), a disease that exploits

malnutrition and other immunocompromising conditions, have risen dramatically. Based on World Health Organization (WHO) estimates for 2009, the country's TB incidence rate of 345 cases per 100,000 people is among the highest in the world outside of sub-Saharan Africa, being more than three times the TB rates for South Korea and China.*

For the past 2 years, the Stanford School of Medicine, the Bay Area TB Consortium, and Christian Friends of Korea (CFK) have worked with the North Korean Ministry of Public Health to develop the country's first modern TB laboratory. With funding from the Global Health and Security Initiative (administered by the Nuclear Threat Initiative, an international nonprofit organization), equipment was selected based on a standard WHO inventory and then approved for export by the U.S. Department of Commerce. Since the spring of 2009, Stanford-CFK teams have completed seven visits to the site to install the lab and conduct training workshops with North Korean physicians.

These efforts were supported by the Ministry of Public Health and other government officials. The new facility enables public health officials to carry out drug susceptibility testing for the first time. Presently, the extent of drug resistance in North Korea is unknown but is believed by WHO experts to be substantial,† based in part on reported retreatment rates, a well-known proxy for drug resistance risk.

The successful collaboration of a major U.S. medical institution, a U.S. nongovernmental organization (CFK), WHO, and North Korean public health officials stands in sharp contrast to the downturn in North Korea's diplomatic relations with the West, now at their lowest level in 20 years. Why should we care about controlling an infectious disease in North Korea? TB is a lethal disease: Untreated TB kills 50% of its victims, and each case produces 10 to 20 additional cases. In the pre-drug era, TB epidemics could rage for centuries. In the antibiotic era, conditions that foster economic isolation and disrupt drug supplies can ignite "hot zones" of drug-resistant disease. Thus, for example, drug-resistant strains may have emerged during the period of economic destabilization that accompanied the collapse of the Soviet bloc in the 1980s.‡ In parts of western Russia today, as many as 25% of TB patients harbor multiple drug–resistant TB (MDR-TB) strains. Since the end of the Cold War in Europe, drug-resistant strains emanating from this epicenter have been tracked into Western Europe, the Middle East, and South Africa.

The modern MDR-TB epidemic reminds us that the loss of TB control leaves costly legacies, for which the world community is ultimately responsible. As discussions continue about how to deal with North Korea, it is important to remember that decisions made in a narrow security arena can have far-reaching global health consequences. Efforts such as the TB laboratory project are evidence that engagements based on mutual health interests are not only possible, but also crucial to sustain. **– Sharon Perry, Heidi Linton, and Gary Schoolnik**

10.1126/science.1201892



20, 2011

^{*}WHO, www.who.int/tb/publications/global_report/2010/gtbr10_a2.pdf (accessed 1/10/2011). †WHO, http://whqlibdoc.who.int/publications/2010/9789241599191_eng.pdf (accessed 1/10/2011). ‡O. S. Toungoussova *et al., Tuberculosis* **86**, 1 (2006).





American Society for Microbiology **"Building Science Policy for Public Health in Burma"** A Proposal to the Richard Lounsbery Foundation March 30, 2012

Project Summary:

This project aims to strengthen evidence based policy making in Myanmar (Burma), specifically in the area of public health. Through a series of collaborative interactions between American and Burmese scientists, including both young scientists and senior investigators, the <u>American</u> <u>Society for Microbiology</u> (ASM) will provide stewardship on how to collect data, organize peerreview, publish and present scientific information to better inform policy makers. As the oldest and largest life science membership society in the world, ASM will leverage its vast network of scientists, as well as the experience of its institutional leadership to provide mentorship to nascent institutions in Myanmar. This project will build directly upon the previous work of AAAS in Myanmar, and will specifically deliver items identified as next steps. This project will not only provide Burmese scientists the tools needed to better collect and interpret scientific data it will also provide linkages to the broader international scientific community at a critical stage of development for Myanmar.

Cost:

ASM respectfully requests **\$64,860.00** from the Richard Lounsbery Foundation to deliver a set of institutional capacity building activities in Myanmar in science policy and public health. Funding supports a six person team of experts to provide a 5-day interactive workshop and training event; physical resource center (small library and computer interface); clinical lab assessment; and the development of a long-term collaborative framework (MOU) to facilitate student exchange and foster institutional mentorship. Funds provided would specifically build upon previous Lounsbery Foundation activities in Myanmar, leverage significant funding and resources from ASM, and deliver concrete action items requested by Myanmar.

Background: Richard Lounsbery Foundation and Burma

Two recent delegations to Myanmar, led by AAAS (American Association for the Advancement of Science) and funded by the Richard Lounsbery Foundation, affirmed that public health systems development and science policy are among the highest priorities and of greatest interest for collaboration between Myanmar and the U.S.. These teams delivered some of the first conversations with the previously closed Burmese Government, uncovering an enthusiastic partner in Myanmar. Thanks to recent political reforms, this government is eager embrace the U.S., particularly in health, where Myanmar faces an enormous disease burden and cuts to the Global Fund this year will compound their problems. AAAS also found that Myanmar has little domestic capacity to take advantage of the political reforms, with a total absence of any evidence-based policy making systems. Myanmar asked specifically for help that would allow





government agencies to draft and enforce new policies based on scientific data rather than the previous system of political corruption led by a military junta, particularly in the area of health.

The Richard Lounsbery Foundation's previous grant to AAAS was timed perfectly, sending teams of "science diplomats" just before and just after Burma's break-through general election in 2011 (as well as the visit of U.S. Secretary of State, Hillary Clinton). The AAAS team was instrumental in uncovering Myanmar's interest in developing evidence based policy systems, and met with key health officials to outline next steps. ASM joined AAAS in the most recent delegation to Burma, where the response for the Ministry of Health was so great, separate workshop events were developed; ASM played a key role in the discussion around the value of scientific associations, policy making and health systems development. The Lounsbery Grant was essential in allowing this dialogue, as U.S. Government delegations are still prohibited (despite the Secretary's visit). It may be years before sanctions and restrictions are lifted. While the new Myanmar government understands this, they also know the window is now open and without making progress, things can and will quickly return to the closed system of the military junta. Engagement and progress via the Lounsbery Foundation, is a critical ingredient for delivering on the U.S.-Myanmar dialogue, and the road to democracy. Further Lounsbery funding will deliver on action items and lay the tracks, in a meaningful and important way, for the onslaught of U.S. Government programs that are sure to come in the years ahead.

Rationale for the Grant:

In the recent AAAS-led trip to Myanmar, the new Government of Myanmar, while enthusiastic, was outspoken about not being prepared for the sudden political changes or the enormous task ahead. Accordingly, they are eager to build domestic capacity in basic governance, particularly in the area of evidence based policy in their health systems. During the trip, ASM helped deliver on Myanmar's interests providing initial feedback during meetings with health officials and nascent scientific associations. During these discussions, Myanmar requested two specific items as next steps:

First, assistance on how to establish science-policy oriented organizations. The round-table with locally organized scientific associations highlighted the fact that Myanmar lacks an unbiased source of information, particularly around health related issues, in the public policy ecosystem. This request was repeated throughout the trip.

Second, a request for assistance on health systems strengthening, specifically, by ministry officials, eager for new collaboration with ASM members and institutions (such as the Johns Hopkins University) to provide models in rebuilding their health systems.

To deliver on these two requests, ASM will assemble a team, led by veteran science policy experts as well as young scientists in the field of health policy to visit Myanmar and hold a collaborative workshop and launch a series of activities. The workshop will provide mentorship to the new government, as well as young university scientists in Myanmar. The team will





continue the ongoing dialogue around the issues of science for policy and health systems strengthening. A key element of the workshop will be interactive break-out sessions where young scientists from both sides collaborate over several days, giving joint presentations on their findings. The team will also make trips outside Rangoon, to visit field sites, including clinical laboratories, to better understand the current situation in Myanmar, and provide more targeted advice and follow on assistance. Finally, ASM will open a "Bio Resource Center" at a strategic location in Myanmar, providing access to clinical information and thousands of health related scientific publications. This center will allow virtual trainings and webinars in the future, a program ASM has used world-wide in resource constrained settings.

This proposal will take concrete steps in filling critical gaps in Myanmar, by empowering scientists and scientific societies to organize and connect with policy makers in mutually beneficial ways. This proposal specifically build upon previous work of AAAS (and the Richard Lounsbery Foundation), and delivers next steps requested by Myanmar.

Key Team Members:

<u>Dr. Jason Rao</u>, current Director of International Affairs at ASM and former Senior Policy Advisor to President Obama, Office of Science and Technology Policy. Dr. Rao is a Graduate of the Johns Hopkins School of Medicine, with a decade of service as a diplomat for the U.S. Department of State.

<u>Dr. Peter Hotez</u>, (tentative) is a renowned physician known for defining "Neglected Tropical Diseases" or NTD's and a leading advocate in low-cost vaccine production capability in developing countries. Dr. Hotez is the Dean of Baylor College of Medicine and leader of the Sabin Vaccine Institute, funded by Bill and Melina Gates Foundation. (Hotez will lead site visits to clinical labs, and assess potential for vaccine work).

<u>Dr. Joseph M. Campos</u>, PhD, DAPMM, FAAM, is the director of Laboratory Informatics and Molecular Diagnostics in the Division of Laboratory Medicine. Dr. Campos has published nearly 100 papers and more than 60 abstracts, and authored more than 35 book chapters. Since 1980, he has given more than 400 lectures nationwide on microbiology, virology, infectious disease diagnosis, and quality improvement. Dr Campos serves as ASM's Secretary, the most senior ranking volunteer official in the organization. (Campos will develop an MOU for ASM and counterpart organization, and lead clinical network sessions).

<u>Dr. James McGlothlin</u>, is a pioneering clinical microbiologist based at Stanford University with more than 40 years health systems experience in the developing world. Most notably, Dr. McGlothlin assisted Cambodia in developing critical clinical infrastructure, with measured impact on health outcomes over more than a decade of on the ground training and education. (McGlothin will provide training on disease surveillance, and lab capacity building).





<u>Darya Pilram</u>, an MPH student, planning to graduate this May from the GW School of Public Health, focusing on monitoring and evaluation in global development. Darya is a rising star, having already served on the U.S. Mercy hospital ships, measuring impact of DoD's Health Diplomacy in the field. (Pilram will lead student working group on monitoring and evaluation, and assist with the Resource Center).

<u>Sarah Diamond</u>, MPH, recently graduated GW School of Public Health and was awarded a Presidential Management Fellowship. Sarah's area of expertise is monitoring and evaluation for improved outcomes. Her Fellowship will focus on food Security at USAID. (Diamond will lead student working group on Public Health policy initiatives).

Local Counterparts*:

Key contacts in Myanmar that will participate in this work include:

<u>Dr. Myo Khin</u>, Director General, Department of medical research Myanmar Ministry of Health. Dr. Khin is a Johns Hopkins University Alumni, and champion of health systems reform in Burma.

<u>Dr. Ko Ko Naing</u>, Director International Health Division, Ministry of Health. Responsible for donor coordination and eager participant in AAAS discussions on science policy.

<u>Dr. Myint Htwe</u>, Director, Global health, Ministry of Health and 20 year representative to WHO for Burma. Johns Hopkins MPH alumni, now working to reform Myanmar's Ministry operations, monitoring and evaluation.

<u>Professor Khin Maung Cho</u>, Director Myanmar NGO's Network, faculty at Myanmar State University Yangon. Thought leader in developing new member-based scientific societies in Myanmar.

*ASM collected more than 50 contacts in the Ministry of Health during the AAAS trip to Burma. Dr. Rao has maintained correspondence with dozens of key health officials who are eager to proceed with next steps discussed here.

Institutional Support:

Richard Lounsbery Foundation funding will leverage additional ASM support for this work:

- All materials for the Bio Resource center, including more than 100 text books, and free on-line access to scientific journals and clinical microbiology portal.
- ASM will provide free membership to all interested Myanmar scientists.
- ASM will provide staff time, and provide a senior clinical microbiologists on the trip.





Partners:

ASM will partner with both U.S. and local organizations in Myanmar, including <u>U.S. Collections</u>, with dedicated presence in Burma, operated by Burmese nationals and the "Myanmar NGO Network" a small organization that fosters scientific society development in Myanmar. Myanmar is also starting its own Society for Microbiology, which ASM will engage as a sister-society and explore the development of an MOU. ASM will leverage its close connection with the Johns Hopkins University, and George Washington University to become involved in and ensure further steps are taken to sustain the relationships forged under this grant. Further, this work is designed to encourage future sessions, under a shared fame work. Given the pending interest form the U.S. and global community in working with Myanmar, and keeping in mind that Myanmar will be the next chair to ASEAN (2013), this event will be established as the first of many, with the goal of future funding coming from international donors, as well as the U.S. and government of Myanmar.

Further Geopolitical Context and Background:

Myanmar has suffered from years of economic mismanagement and political oppression, leaving it decades behind its immediate neighbors, India, China and Thailand in terms of overall development. The U.S. and much of the developed world, has been critical of the Burmese Military Junta, attaching economic sanctions that have crippled the country, and isolated its people. Notably, China has largely ignored the human rights violations of the Burmese regime, investing and benefitting heavily from Myanmar's rich natural resources. China remains a strong influence to Myanmar, though recent elections and reforms create space for other western influences. With recent elections and political gestures, Myanmar is beginning to open, and the U.S. has responded. Secretary of State Clinton recently visits Myanmar, as well as several other U.S. officials, with the promise of lifting economic sanctions and increasing much needed aid.

With more than 60 million people, Myanmar is now poised to be the next great economy in Southeast Asia. The business community, which has resisted investing due to the optics of supporting a corrupt regime, is eager to engage. Like the U.S. government, many other countries are now beginning significant dialogue with Myanmar, with economic development and assistance in mind.

After decades of benign neglect, the Myanmar Government is simply not prepared to take on the rapid change that has thrust them into the international community. A recurring theme in engagement with government ministry officials was the need for basic, democratic governance and education models, with particular need to engage Myanmar's youth.

The ASM Network:

<u>ASM</u> (www.asm.org) is the oldest and largest society of health scientists in the world with more than 40,000 members representing every branch of biological science. ASM publishes 13 of the most subscribed scientific Journals and state-of-the-art Magazines, and provides major





platforms for information exchange through ASM's internationally-recognized and attended annual meetings. ASM implements a substantial global outreach program, with education, mentorship and laboratory capacity building as core elements. ASM's Global Ambassador network, of more than one hundred senior scientists, is used to empower local scientific societies and associations by increasing visibility and advocating for individual scientists and as well as institutional capacity building.

Budget:

CATEGORY	AMOUNT
Airfare (coach class/per person)	\$3,250
Total Airfare (6 people, coach)	\$19,500
Hotel (10 nights/per person)	\$2,000
In Country Travel	\$400
Meals (Per Diem 10 days)	\$1000
Total Expense for 6 Person Team:	\$39,900
Local Training Venue (includes participant meals 5 days)	\$6,500.00
Travel/Lodging/Supplies for Local Participants (5 days)	\$5,000.00
Training Materials and Bio-Resource Center	\$3,000.00
Post-Trip Report (Printing/pub)	\$2,000.00
Total Direct Costs:	\$56,400.00
Overhead (15%)	\$8,460.00
Total Request:	\$64,860.00

Deliverables:

- A 5-day training workshop, with specific learning objectives in evidence based policy making, and monitoring and evaluation for improved health outcomes delivered to ministry of health officials. Three interactive sessions with university students on topics of shared interest in public health.
- A permanent "Bio-Resource Center" will be established at the local host institution, to provide a site for virtual trainings and webinars, as well as access to current health science publications, reference materials and clinical portal.
- Establish memoranda of understanding to support a direct institutional mentorship program between ASM and Myanmar counterpart organization(s).
- A final report on workshop findings, outcomes and next steps.





- Site visits and technical evaluation of clinical network capacity at sites visited.
- Establishing an ongoing framework for future collaboration between young university scientists in the U.S. and Myanmar in the area of public health; sponsor first exchange through Johns Hopkins and GW. (Follow on funding from Universities, ASM and USAID)
- Human resources: initial training and follow on mentorship will both identify and assist the next generation of leaders in Myanmar needed to develop evidence based policy frameworks.

Next Steps:

RTF funding under this project will open the door to substantial follow on activity, long after the funds are exhausted; particularly with regard to bringing Myanmar into the ASM global network of health scientists. Specifically:

- ASM provide long-term/permanent "Institutional Mentorship" to its counterpart
 organization in Myanmar, under the MOU established. This means assisting Myanmar
 to create a self-sustained, member-based organization, with publications, annual
 meetings, and a policy voice for domestic scientists. ASM has a proven track record in
 this role, assisting similar organizations in Southeast Asia, Africa and Latin America.
- ASM will hold periodic trainings and webinars through the newly established "Bio Resource Center". ASM will bring its virtual training platform to Myanmar, through the Bio resource Center portal established under this grant. This will allow speakers and virtual seminars on topics of interest to the health community, to interact with Myanmar scientists in real time. Topics range from biosafety and disease surveillance, to publishing a scientific paper.
- ASM will expand its <u>Global Outreach</u> programs to Myanmar, leveraging the MOU established under this grant activity. The MOU will provide a mechanistic framework for student exchange, <u>fellowship programs</u>, and <u>Ambassador Network</u>, which provide world-class education and capacity building to resource constrained countries.
- ASM will directly support annual scientific exchange with Myanmar, including sponsorship of visiting Myanmar scientists to visit and speak at university labs, conferences and training events in the U.S.
- ASM will leverage this work to secure outside funding for continued exchange with Myanmar, with the (minimal) goal of holding an annual public health stakeholders meeting in Myanmar on topics of shared interest.
- The team will leverage the outcome report of this grant to educate relevant NGOS and USG policy officials in Washington, in an effort to inform U.S. assistance programs considering work in Myanmar.
- The team will make a dedicated effort to assist Myanmar counterparts to leverage outside funding sources for follow on ideas; this will include assistance with grant writing, and facilitation of partnership with specific U.S. scientists and institutions in the ASM network.





Project Director, ASM Point of Contact:

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Dr. Jason Rao Bio:

Dr. Jason Rao is currently the Director of International Affairs at the American Society for Microbiology, where he oversees policy, programs and global outreach to more than 40,000 members. Dr. Rao recently served as Senior Policy Advisor for Global Science Engagement in the White House Office of Science and Technology Policy, where his responsibilities include President Obama's Global Engagement initiative, aimed at renewing science and technology partnerships to meet grand challenges around the globe.

Dr. Rao previously served in the U.S. Department of State for nearly a decade, where he was responsible for a range of foreign assistance programs aimed at enhancing scientist engagement as well as global health security. Over a decade of service, Dr. Rao created and launched two novel, multi-million dollar foreign assistance initiatives, working across Southeast Asia, Middle East, North Africa and Latin America. He lived in Russia, Georgia, Indonesia and Pakistan. In 2009 Dr. Rao became a Brookings Legislative Fellow in the 111th Congress, working with both the Senate Foreign Relations and Homeland Security and Government Affairs Committees, contributing to new legislation on international science cooperation.

Dr. Rao holds a Ph.D. in Biochemistry, Cellular and Molecular Biology from the Johns Hopkins University School of Medicine and earned his bachelor's degree from the University of California at Santa Cruz. He was awarded an American Association for the Advancement of Science (AAS) Diplomacy Fellowship, and worked in the pharmaceutical industry and as a research fellow at the National Institutes of Health. He currently lectures at Georgetown University and is adjunct faculty member with both Cornell University and the George Washington University.