

## LEADERS SUMMIT ON GLOBAL INFECTIOUS DISEASE: TOWARD AN L20?

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### Introduction

- **Statement of the Problem**

Though world health experts optimistically predicted a universal lengthening in life expectancies would flow from improvements in economies and targeted health interventions, the 1990s witnessed the opposite: *life expectancy gaps between the richest and poorest nations widened dramatically following the end of the Cold War*. Today the gap between the society with the greatest life expectancy (Japan) and the shortest (Zimbabwe, Sierra Leone and a short list of African nations) is nearly 50 years. Though the rich are living longer, this is also due to shrinking life expectancies in the poor world, *primarily due to infectious diseases*. Among the factors contributing to rising infectious diseases morbidity and mortality are rapid urbanization in poor nations, globalization of human and livestock movement, abysmal urban infrastructures, declining drug efficacy owing to microbes' resistance and suboptimal treatment due to resource scarcities and social issues.

Resentment is building in both middle income and poor nations, as the wealthiest nine nations become gerontocracies, while the poorest nations witness the evaporation of previous development gains, rising foreign debts and rising mortalities and the L20 are caught in the middle. Resentment can translate into support for anti-Americanism and anti-Westernism in many forms. The imams of northern Nigeria invoked fear of alleged American schemes in convincing mothers to eschew polio vaccination for their children – a successful campaign that has so far spawned resurgence of crippling polio epidemics in Nigeria and 16 other nations.

Existing institutions for addressing public health, at all tiers, lack resources sufficient to address the problems they face, and are hampered by structural impediments that have to date defied remedy through United Nations, national government, or G-8 mechanisms. They are precisely the sorts of problems that the UN's High-Level Panel on Threats, Challenges and Change considered when it concluded:

*“There still remains a need for a body that brings together key developed and developing countries to address the critical interlinkages between trade, finance, the environment, the handling of pandemic diseases, and economic and social development. To be effective, such a body must operate at the level of national leaders.”*

Barely five years ago, the health community scrambled to get crumbs for prevention and treatment of malaria, tuberculosis, HIV/AIDS, vaccine-preventable illnesses and a host of other killer diseases. With a mix of volunteerism, elbow grease and paltry funds public

health advocates the world over did their level best to hold back the rising gap in life expectancy between rich and poor nations, and control killer diseases. When epidemics of Ebola, Nippah, hantavirus and other deadly diseases emerged the World Health Organization and US CDC had to go begging for funds – literally – to buy plane tickets and laboratory supplies for disease experts to respond. Disease surveillance was haphazard, at best.

Thanks to United Nations Secretary General Kofi Annan’s 2001 call for billions (\$7-10B/year) of dollars annually to address some of these problems, and the G-8 leaders’ in-principle endorsement, the game shifted favorably, with monies dedicated to public health finally approaching the proper log scale, if not yet the correct multiplier. A Global Fund to Fight AIDS, Malaria and Tuberculosis was created, offering an independent, accountable mechanism for funneling money from the wealthy world to the poor.

But the entire effort, and the agencies and NGOs leading key health campaigns, are losing their way: Roll Back Malaria, Stop TB, the WHO 3 X 5 Campaign, the UNAIDS Programme, the Bush Administration’s PEPFAR effort, the Global Fund to Fight AIDS, Malaria and Tuberculosis and other such campaigns. Rivalries have emerged between health programs fighting over poor countries’ miniscule pools of health professionals; bogus generic drug makers are knowingly selling poor products; ministries of health are sitting on millions of dollars in unspent donor funds for vital programs. I have listened to program leaders’ rants about “too much money going to HIV” or “not enough for prevention”, and other such claims that pit one health drive against another, fighting over what remains an inadequate pool of funds for all. Questions of patent rights versus generics, abstinence vs. condoms, treatment vs. prevention, faith-based vs. secular initiatives, research vs. implementation and a host of other false dichotomies have overwhelmed health debates.

We don’t have our eyes on the right ball. *More people died of tuberculosis, malaria and HIV in 2003 than in any year in history.* Drug resistance threatens the successes of the 20<sup>th</sup> Century in battling a broad range of bacterial and parasitic diseases. Combined, these killers are literally reshaping societies, producing dramatic demographic changes that threaten local, regional and even global stability, with powerful impacts on the economic, military, governance, agricultural and social values components of afflicted areas.

All the while, *new diseases, such as SARS and mad cow, continue to emerge*, and changing patterns of human behavior and trade – globalization – ensure many more microbial surprises lurk in our future. The emergence of humanly-transmissible strains of avian influenza pose the very real possibility of a 1918-type flu pandemic, which at that time killed 50 million people in 18 months. Though pharmaceutical improvements in treatment, coupled with vaccine possibilities, offer hope that such a deadly flu strain might be controllable, there are grave concerns: the drugs have very limited efficacy even under conditions of ideal use, and supplies are limited. Worse, the world can only manufacture enough vaccine, even under emergency conditions, to protect some of its wealthiest citizens, and most of the world lacks any capacity to manufacture vaccine. *In a pandemic the U.S., Canada and the EU would face the foreign policy implications of*

*denying vaccine to billions of people, while saving the lives of some of its own and witnessing the deaths of what experts predict would be well over 500 million people.*

In explaining the need for the L20, Canadian Prime Minister Paul Martin recently wrote that a key concern of the political leaders was, *“the inadequate state of the world’s public health systems. The SARS crisis and other outbreaks have demonstrated that even a relatively minor outbreak of infectious disease has the potential to overwhelm national and global public health systems. Experts keep warning that an influenza pandemic could kill millions and that the threat of deliberate bioterrorism cannot be discounted. Leaders in the L-20 could provide the political impetus to ensure that systems at the global, regional, and national level are adequately resourced and that there is sufficient communication, cooperation, and research to bolster the world’s defenses against infectious diseases.”*

Manmade horrors once thought the stuff of fantasy have in the last four years become realities in laboratories around the world. Since 9/11/2001 scientists have made artificial polio viruses that were built from the DNA up; made super-virulent strains of mouse, rabbit and cow pox viruses that kill 100% of infected animals in a matter of days; isolated the genes responsible for viral virulence and transmissibility and transferred those genes into different germ species; constructed a form of anthrax that is resistant to all known antibiotics. The list goes on.

The entire global surveillance team for new epidemics and manmade outbreaks at the World Health Organization – the Global Outbreak Alert and Response Network -- is five fulltime people.

### **Options Overview:**

The only way to effectively, and in a sustainable fashion, spend billions of dollars to reverse the course of the HIV pandemic and its companion epidemics of malaria, hepatitis, tuberculosis and pediatric illness associated with rising orphan numbers is to de-exceptionalize all of the illnesses and thoroughly integrate their prevention, diagnosis and care. There should not be stand-alone HIV prevention and care clinics. TB ought not be treated as a stigmatized outlier syndrome. The diagnosis and testing for all of these diseases ought to be matters of life-saving routine. Basic research should go hand-in-hand with treatment programs, not shoved to the side as an inconvenient impediment. Prevention and treatment of any particular disease ought not be segmented off from others because of the jurisdictional boundaries of a particular United Nations agency, U.S. federal bureaucracy or international program. Syphilis, gonorrhea, hepatitis C, pediatric dysentery – it must all come under one tent. And in building that tent the world needs to recall that nearly 75 percent of global wealth is now in the hands of just nine nations, according to recent World Bank data. *By necessity, building a health tent must mean attracting funds from the wealthiest nine nations to the needs of the poor, on a massive and sustained level.*

Given the scale of the challenge, coupled with the constant emergence of new disease threats and potential for manmade scourges, the L20 *must build alliances, work with existing multilateral agencies, reengage in treaty negotiations* and encourage all nations to cease taking go-it-alone approaches to global health and bioterrorism.

As a guiding principle the L20 should recognize that it will never be possible to create a disease-free world, or to eliminate the potential for emergence of new deadly microbes. Policies aimed at such goals will always fail. For example, we now understand that the Ebola virus is an ancient organism that has for centuries infected isolated individuals in central Africa. That cannot be stopped.

But we also now understand that Ebola, and now the Marburg, epidemics have occurred when individuals infected with the viruses entered desperately poor hospitals, where lack of sterilizing equipment and basic protective gear conspired to offer the microbes spectacular opportunities for transmission. Inadequately supplied hospitals act as disease amplifiers, rendering the harmless, isolated infection opportunity to become a full blown epidemic. The SARS epidemic offered the same lesson: from the most resource-scarce facilities in SE Asia to the well-endowed Toronto hospitals, medical settings offered opportunities for spread of the virus, and restoring safety to those environs proved remarkably difficult. *With very few exceptions the disease amplifiers in the world today are manmade, and therefore humanly controllable.* They include such things as lack of infection control in hospitals, reuse of syringes in medical and drug-injecting settings, unscreened blood supplies, exotic animal markets, unclean urban water supplies, lack of proper sewage systems and other points of clear intervention.

Policies aimed at limiting the amplifiers of disease – both at home and abroad -- have the greatest likelihood of preventing epidemics, whether they be natural or manmade occurrences.

#### **Diplomatic, Symbolic, No-cost and General Policy Options:**

- 1.) *Use health as a way to win hearts and minds in the world. Integrate health into foreign policy at all levels, including inside diplomatic missions.*

Most infectious diseases target children, and saving children's lives can translate into winning the affections of their mothers worldwide. Disease prevention and child survival ought to be American brands in the world. Every L-20 members' embassies and consulates should have staff knowledgeable about disease prevention and epidemic control. Greater expertise ought to be drawn into diplomatic missions as needed. Whenever and wherever outbreaks or epidemics threaten populations foreign service personnel ought to be adept at putting themselves at the forefront of global assistance efforts, working in partnership with local and WHO experts. Foreign missions ought also to be tasked to track hidden outbreaks and disease trends in countries that lack transparency. In L-20 members' missions, those individuals tasked with monitoring human rights abuses ought to include in their portfolio government or insurgent activities that deliberately imperil the health of ethnic groups, specific social groups or minorities.

- 2.) *Put health on the national security agenda. Put a scientist and/or physician well-versed in global health issues on the each L-20 nation's top security body, permanently.*

Putting a health expert on each nation's top security body, such as the National Security Council in the United States, would immediately elevate the import of health issues worldwide. Such a member would coordinate disease and outbreak information from multiple government sources and work closely with diplomatic and security sectors on efforts to mitigate such disease threats, and their economic and social impacts, to global and national interests.

- 3.) *Make influenza surveillance and disease transparency a key element in foreign policy engagement. Insert health priorities into all UN/Global conclaves and summits.*

For the foreseeable future the world will lack the capacity to manufacture sufficient supplies of flu vaccine and medicines to meet pandemic needs in a timely fashion. Influenza therefore poses a very real national security challenge to all of the L-20 States. The L-20 member-state's foreign ministries should work closely with their domestic public health and scientific agencies to develop and execute strategies for assisting in effectively dealing with influenza at the source levels in Asia. Such strategies might include inspections of large chicken and livestock operations in the region; further enhancement of CDC/counterpart operations in Bangkok, Beijing, Taipei and Hanoi; increased financial support for the global influenza surveillance network; direct scrutiny of chicken production in countries that are major exporters; beefing up sero-diagnostic laboratory capacity for flu strain identification in collaborative labs in Hong Kong, Guanzhou, Nanning and Beijing; aggressive, direct assistance programs between wealthy world disease control agencies and their local counterparts in southern China, Hong Kong, Vietnam, Cambodia, Laos, Thailand and Taiwan; development of clear direction within diplomatic missions regarding procedures for tackling lack of transparency on influenza matters, including possible triggers for official action. The L-20 should make it clear to influenza laboratories centers and UN agencies all over the world that all obstacles to full and speedy cooperation, including rapid sharing of flu samples and epidemiological information, must be identified and eliminated.

- 4.) *Support a major donors' meeting, to sort out the confusions, duplications and weaknesses in the current global health chaos, and set priorities.*

The L-20 should call for a summit, with the goal of issuance of a joint L-20 declaration. Invited summit parties should include major donor governments and private donors, such as the Bill and Melinda Gates Foundation. It should have a mandate to push for integration of health services in poor countries and a radical shake-up in the current mode of thinking and funding. Overall, those areas of health most closely linked to security – infectious diseases – ought to be funded and tackled in manners that are not linked to overall development schemes and avoid the corruption and pitfalls that commonly plague development programs.

5.) *Lift all political litmus tests that currently limit major donor funding and scientific engagements overseas.*

The wealthy world should be discouraged from placing moral and political restrictions on the use of its resources in poor countries, where the restrictions are derived primarily from the donor state's domestic disputes. Receiving states must be able to take ownership of their health programs, if such initiatives are to succeed and be sustainable. Imposing moral or political standards on recipients limits such ownership. For example, a donor state's domestic agenda may be rife with religious disputes: those issues ought not be imposed on that nation's foreign aid recipients. Further, in dealing with the World Health Organization, in provision of scientific expertise for technical support or outbreak control,

Scientists and physicians from the L-20 should maintain the longstanding WHO rule of thumb of "checking their flag at the door", offering scientifically, not religiously or politically, grounded consultation and support.

6.) *Lend strong support to the Biological Weapons Convention efforts, especially for verification. Clearly define the extent and limits of "dual use" for public health, versus bioterrorism preparedness.*

First drafted in 1971 as a bilateral US/USSR agreement, the Biological Weapons Convention was a well-intended, but ultimately toothless document lacking in verification agreements. The Bush Administration withdrew from the BWC in August 2001. Since then, there has been a vigorous effort on the part of many nations to find a way to revitalize the BWC and fill the holes in its verification capacity. Key to the failures to date has been the concept of "dual use"; facilities designed for legitimate medical, scientific and public health purposes can also be deployed for bio-weapons research and development with few, if any, noticeable differences. As was demonstrated by the weapons inspections of Iraq following the 1991 Persian Gulf War, bio-weapons can be developed in facilities that are engaged in legitimate drug development, fertilizer manufacture, medical research and hospital care. In theory, therefore, every pharmaceutical company, university biology lab, hospital lab, biotechnology firm, beer brewery and agricultural products plant could be legitimate targets for international inspection – including thousands of such facilities inside the L-20 nations -- should an overseeing international body believe there is cause to suspect illegal terrorist or State actions were underway. For obvious reasons (including patent protection and research integrity) such BWC provisions are strongly opposed, particularly by the pharmaceutical industry.

The L-20 should consider BWC negotiations and ultimate ratification by their legislative bodies a top diplomatic priority, instructing their Ministries of Foreign Affairs to engage fully in negotiations. Those Ministries should actively seek input from government sectors that have special expertise in the growth, identification, surveillance and neutralization of microbes. Consideration should be given to the role the World Health Organization can play in disease surveillance, WHO's financial and expertise needs, and the import of having a body perceived to be neutral playing the lead role in identifying potentially deliberate releases of manmade microbes (see specific WHO recommendations below).

*8.) Support rapid development of the new International Health Regulations at the World Health Organization, and leverage pressure for their passage at the next World Health Assembly (May 2005).*

For more than 40 years the global community has operated under a set of International Health Regulations that is limited to a small list of infectious diseases, and seeks to enforce safety through vaccination verification cards. The list is out of date, and the nature of disease threats to the world has long since eclipsed any finite set of immunizations. For several years WHO has been trying to develop a new set of guidelines that not only expand the list of targeted diseases, but, as WHO puts it, “ensure maximum security against the international spread of diseases with a minimum interference with world traffic. The International Health Regulations are currently under revision to provide a responsive framework for WHO epidemic alert and rapid response activities, already being implemented in collaboration with Member States, to control international outbreaks and to strengthen global health security.”

Passage of new IHR is an essential first step not only to expansion of WHO capacity to respond to outbreaks of disease, but to any role the agency might play in bio-weapons surveillance.

As envisioned, these new regulations would give WHO the authority to monitor a broad range of international activities for potential disease threats and respond to outbreaks, or suspicions thereof, in a delineated set of ways. The L-20 should strongly support development of the new IHR, and implementation of the newly-passed regulations, tasking their Ministers of Health to engage in the process directly, leveraging diplomatic assets, where needed, to promote support for the IHR process worldwide.

*9.) The L-20 should take an HIV test on camera.*

Because HIV is asymptomatic, therefore invisible, throughout many years of infection afflicted individuals go untreated, and infect their sex partners, without ever knowing that they carry the deadly virus. Globally less than 5 percent of people who carry the virus are aware of their infection. In part this ignorance is due to lack of adequate testing facilities. But the real problem is stigma. HIV continues to be viewed as an especially terrible disease that originates in even more terrible personal behaviors. All over the world people who are infected are treated as social pariahs. In such a climate, nobody wants to be tested for infection. The cycle continues: stigma feeds ignorance; ignorance fuels dangerous behaviors; the behaviors result in infections; the infections go unnoticed, and then denied, for years because of the stigma.

This year several well known African leaders publicly took HIV tests in order to draw attention to the need to know an answer, and decrease the stigma associated with HIV. Among them were current Botswana President Festus Mogae, former Zambian President Kenneth Kaunda, current Zambian Vice President Nevers Mumba, a member of the Zambian cabinet and the leader of the South African Democrats Party, Patricia De Lille. If the L-20 publicly took a real-time HIV test (involving an oral swab and instant answer) it would make a powerful, profound statement to the global community, signaling the wisdom of routine testing, and the idiocy of HIV-associated stigma.

### **Low Cost Initiatives:**

- 1.) *Support direct mechanisms for corporations and the business community to get involved in health and urge them to do so with all their overseas operations.*

As the toll of HIV and its companion epidemics mount the corporate world is growing anxious, and is looking for ways to engage in the battle. The Global Business Coalition on HIV/AIDS, which currently boasts more than 180 members, has grown frustrated by the lack of clear avenues for its members' involvement in PEPFAR, the Global Fund or local efforts around the world. The L-20 should instruct their Secretaries of Commerce and Foreign Affairs to create joint offices that would liaise with interested corporations and businesses, representing their concerns to such international bodies as WHO and the Global Fund, and encouraging their engagement in global health issues.

- 2.) *Support limited, as needed DDT use to control malaria, dengue and other mosquito-transmitted diseases.*

We are losing the global battle against insect-borne diseases, particularly malaria. Numerous recent studies show that DDT is the most effective agent for killing mosquitoes that carry the malaria parasites, and it is affordable in poor countries. But DDT is also a persistent compound that does not biodegrade and has a host of demonstrable ill effects on the environment. Less toxic pyrethroid pesticides have been rendered virtually useless for public health purposes due to widespread misuse of the agents for agricultural purposes, resulting in widespread genetic resistance to the class of compounds. In 2003 a single season's use of DDT in a limited manner in Zambia reduced the number of human malaria cases by 55%, demonstrating the profound efficacy appropriate DDT use can have.

The L-20 members should instruct their environmental and public health agencies to review current policies regarding DDT use, in hopes of finding a balance appropriate both to the environmental and public health agendas.

- 3.) *Support scientific microbe identification missions, such as a search for the source of SARS.*

Currently there is no reliable funding mechanism in place for identifying the sources of newly discovered pathogens. Outbreaks that occur domestically are investigated by national disease control agencies. But internationally, funding for such research is haphazard, at best. Currently, for example, there is no clear funding stream in place to search for the origins of the SARS virus. The L-20 should support a permanent, modest funding line, creating a small office within the WHO, tasked to fund and coordinate such investigations, executed by scientists from disease control agencies and the academic community, targeted for on-the-ground research. Special attention should be paid to engaging local partners in countries wherein such investigations are underway, including encouraging co-authorship of any published results or discoveries.

- 4.) *Insist that UNICEF, WHO, charitable organizations and L-20 foreign aid agencies go to a 100% autodestruct syringe policy for administration of vaccines and medicines, and raise funds sufficient to cover the cost differential involved. Fund follow-up research aimed at determining how significantly such efforts reduce blood-borne disease transmission.*

It is estimated that every year some 19-20 *billion* injections are given for allegedly medical reasons, and worldwide more than half – in Asia, Africa and former USSR more than 70% -- involve dirty needles. Hepatitis C & B, HIV, malaria and a host of other microbes are being spread by the very medical institutions that are supposed to stop disease. This is intolerable, particularly given the availability of cheap autodestruct syringes that can only be used once.

Earlier this year the government of India announced that by early 2005, 100% of all vaccines delivered in that nation will involve auto-destruct syringes, guaranteeing the needles cannot be reused and thereby act as amplifiers of disease. In the long run the global community should aim to eliminate all inappropriate, non-sterile syringe use. As a first step in that direction all L-20 member states' funding for overseas vaccination and medical programs should stipulate that only autodestruct syringes may be purchased with their taxpayers' monies. This would directly affect support for UNICEF, WHO and foreign aid programs.

In addition, diplomatic missions located in countries that have exceptionally high prevalences of HIV, malaria or hepatitis ought to have plentiful supplies of such syringes both for the use of staff as needed for medical purposes, and for distribution to local government personnel and leaders with an aim towards promoting their use everywhere in the world.

There is an important caveat to any autodestruct syringes program: unit order rates. Currently ministries of health the world over order as many syringes as they can *afford*, not as many as they *actually need*. Health leaders know full well that the devices are being reused, often so many times that whet stones are kept at nurses' stations and clinics so that dulled needles can be re-sharpened. Introduction of autodestruct syringes on a unit-per-unit basis would be catastrophic, as millions of necessary injections would not occur. For this reason, appropriate implementation of an all-autodestruct campaign will be costly, not because the individual syringes are terribly expensive, but because the world needs hundreds of millions more syringes than it currently purchases.

- 5.) *Support the use of molecular epidemiology as a verification and surveillance tool and fund targeted global disease sampling and genome analysis.*

The genome revolution has handed public health an exciting new tool box for disease detective work, but it is largely going unused for lack of political and financial support. Scientifically it is now possible to find genetic fingerprints of strains of viruses or bacteria in the world and track their movements from one geographic place to another, one human subpopulation to another, one species to another. The actual genomic, laboratory work is comparatively easy, and relatively inexpensive. The more politically and financially sensitive labors involve collection of samples for that lab analysis.

In a sense, molecular epidemiology could be to disease (natural and manmade) verification what radiation and seismic detection are for nuclear verification. It could

prove a far more precise tool, offering a forensic trail that leads investigators right to the source of a new strain of virus or bacterium. But such detective work depends on gathering blood, animal, food or tissue samples, as appropriate to the disease, from targeted areas: a sensitive matter. For example, when SARS viruses returned in the fall of 2003 Chinese and Hong Kong scientists were able to immediately gather blood samples from people and animals in Guangzhou and submit them to genetic analysis, confirming the new strain was different from that which had caused the previous epidemic. Such work was impossible the previous year, however, because the Chinese leadership was denying the epidemic's existence. In another example, genomic analysis of HIV strains now circulating in southern Asia shows that nearly every strain is emerging from the region's heroin trail.

Bacterial examples of the utility of this approach abound, particularly for tuberculosis, staphylococcus and streptococcus. Drug resistant forms of these microbes, which are spreading globally with dire results, have been traced to their source using molecular epidemiology. For example, it is now known that the 1991 outbreak of highly drug resistant tuberculosis that swept through New York City actually originated in a jail in Siberia. A particularly insidious form of drug resistant strep now found in hospitals worldwide has been traced to origins in Papua New Guinea. Learning the origins of such deadly microbes can greatly enhance prevention efforts.

Some forms of drug resistance mutation are inherited, meaning the organism's chromosomes have mutated and all progeny of the mutant will have the new trait. Other forms of drug resistance (or other bacterial characteristics) are carried on floating bits of DNA called plasmids or transposons, which microbes freely swap, even between rival bacterial species. The easiest way to genetically engineer a bacterial organism is by putting the desired traits in a manmade transposon or plasmid.

A truly 21<sup>st</sup> C approach to disease surveillance, preparedness and potential bio-weapons/terrorism monitoring would draw from the tools of molecular epidemiology, as a matter of routine. The L-20 should provide support for creation of large genetic databases and sample collection from all over the world. Such a database already exists for HIV --- located at Los Alamos National Laboratory -- but it passively receives samples, and has no funds to actively pursue sample collection from suspicious or dicey parts of the world. No centralized database exists for transposons, plasmids, or a list of key pathogens. The L-20 should discuss the politically sensitive question of where such databases ought to be situated, and under whose management.

### **Moderate Cost Initiatives:**

#### *1.) Radically beef up global surveillance and WHO emergency response capacity.*

As described above, WHO is woefully understaffed for handling global disease surveillance and response. The L-20 should directly support improvements in WHO's capacity. Recently an emergency operations center was constructed inside WHO HQ in Geneva. That is a start. But the center must be staffed fully with top flight epidemiologists, physicians, multilingual crisis communications experts, IT support and a lead team of outbreak investigators ready to travel to any location in the world with 12 hours notice. The response team should draw from the world's pool of experienced

epidemic responders, and between them represent not only a range of scientific skills, but also linguistic and cultural experiences.

On an ongoing basis disease monitoring capacity and routine surveillance requires significantly increased support, pushing it to the highest possible standards of professionalism. Surveillance data should be online, accessible through password protected means to disease detection agencies worldwide. WHO should convene regular technical meetings of scientists to assess the quality of acquired data and determine ways to improve its collection on the ground, verification and reporting to Geneva.

In addition to the above-described microbe, plasmid and transposon database systems WHO should have a global system in place modeled after the New York City Department of Health's Syndromic Surveillance System, which identifies unusual trends of admissions to emergency rooms citywide. The system triggered recognition in 1999 of an unusual cluster of encephalitis cases – the first hint of invasion by the West Nile Virus.

The L-20 members should instruct their Ministries of Health to develop outlines of a model set of WHO surveillance systems, including projected staffing and funding needs. The analysis should be presented to the G-8 Summit for discussion and financial commitment.

2.) *Safe needles save lives: allow needle exchange for domestic and foreign users.*

Despite mountains of research demonstrating that needle exchange programs stem the spread of HIV, hepatitis and other microbes between IV drug users, political and religious leaders the world over continue to oppose such programs at home or abroad. The L-20 members should instruct their Ministers of Health and Human to compile the mountains of evidence and formally present them to their legislatures, along with a call to promote access to safe needles for IV drug users, in order to curb spread of HIV and other blood borne diseases.

3.) *Support mechanisms for generic manufacture, inspection and purchase of life-saving medications and vaccines for HIV, malaria, tuberculosis, hepatitis B & C.*

There is a market failure in pharmaceuticals. The classic capitalist credo is that supply will follow demand, but such is not the case with medicines: The world demands medicines and vaccines for infectious diseases, but the pharmaceutical marketplace, driven by extraordinary profit demands on the part of investors, addresses the exclusive needs of the wealthiest world. Worse, the market failure now extends to ignoring the medicinal needs even of poor-to-moderate income residents of the wealthy world. In light of failures to produce flu vaccine in a timely fashion during the summer/fall of 2004, it is now obvious that in a disease crisis the pharmaceutical industry could not be relied upon to provide life-saving vaccines or drugs on an urgent timeline.

The pharmaceutical industry's life expectancy is limited. It is inconceivable that the world will continue paying such high prices for health in the wealthy world, while having no access to life-saving drugs in most of the rest of the world. A decade ago industry insiders predicted that the genomic revolution would spawn a new age in drug discovery

and a complete transformation in the practice of medicine. But time has revealed that biologically, rather than chemically, based drugs are difficult to manufacture safely, are costly, and prone to the same range of contamination issues seen with live vaccine production. Industry leaders now say their research pipeline is running dry, and product liability claims are skyrocketing, chiefly targeting pharmaceuticals that were licensed during the last eight years.

Simplistic changes, or a continuing series of fine tweaks in drug reimbursement plans, will fail to stem the overall problem. The L-20 should seek far-reaching solutions to this problem, overseeing an expert analysis of this question: How can North America and Western Europe continue to be the primary sources of the world's pharmaceutical innovation, develop drugs that address the needs of the *global* population at affordable prices, manufacture vital vaccines on an urgent and mass scale as needed, and maintain a for-profit industry?

- 4.) *In a multilateral donor effort, assist WHO to develop PUSH Packs for global use, to be located in a handful of key regional centers.*

One of the most significant steps taken domestically to prepare for outbreaks and natural disasters was the creation of so-called PUSH Packs: stockpiles of medicines, medical supplies and vaccines that are strategically located to ensure delivery within 24 hours is possible for any site in the 50 United States. The U.S. and L-20 should work with other nations to develop similar PUSH Packs positioned around the world, and maintained by WHO. Investment should be sufficient to cover on-going maintenance of the supplies, replenishment as needed, deployment and delivery. The target should be to have PUSH Packs deliverable to any outbreak, refugee crisis, catastrophic natural disaster or other crisis situation deemed to be a likely source of global health concern, within a 48-hour time window..

#### **Costly, but Nevertheless Vital Initiatives:**

- 1.) *Radically increase support for the Global Fund not only with money, but also U.S. expertise.*

In 2001 Secretary-General Kofi Annan estimated that the Global Fund needed \$10 billion annually in order to put up a decent fight against AIDS, TB and malaria, yet the Fund has never topped ten percent of that target since its formation, and commitments for the remainder of this decade offer a dismal dwindling of fiscal resources, even as the AIDS death toll will mount. The U.S. Congress stipulated in 2003 that American contribution to the Global Fund ought not exceed a third of all donations received for the program in a given year, and in 2005, charging global donations had sagged, the U.S. reduced its contribution to the Fund. This is impermissible. The L-20 should challenge all developed nations to commit to a rapid and sustain scale-up in support for the Fund. At a minimum, the G-8 leaders should agree to jointly pony up \$6 billion/year. The L-20 should commit to raising minimally an additional \$1 billion annually for the Fund.

The L-20 should call upon the global community to respond not only on behalf of the ailing victims of these diseases, but also for the orphaned children they leave behind, a pool estimated to reach 22 million by the end of the decade. The social destabilization expected in countries with exceptionally large orphan populations is staggering.

In addition to direct cash commitments to the Fund the L-20 members should instruct their Ministers of Health, Commerce and Foreign Affairs to second expertise to the Fund as needed to enhance the Fund's fiscal, scientific and management operations.

- 2.) *Radically increase support for appropriate technology R&D into diagnostics, vaccines, medicines and computer IT of health and inventory management.*

Despite a FY 2004 budget of nearly \$28 billion the U.S. National Institutes of Health funds almost no research aimed at the diagnosis and treatment of disease in poor countries. Historically the NIH was focused on the leading diseases afflicting Americans: cancer, heart disease, mental illness. But in light of changing understandings of the links between global health crises and U.S. security it seems imperative that NIH – and its counterpart scientific research agencies the world over -- add to its research agenda the search for cost effective methods of treating and diagnosing key diseases afflicting poor countries.

Discovering cheap, effective means of diagnosing and treating diseases is only the first step: getting such things into the manufacturing pipeline is quite another. Suggested means for facilitating pharmaceutical industry interest in said development should be part of the L-20 review of the industry, as described above.

- 3.) *Regulate use of antibiotics in U.S. food and livestock far more tightly. Back EU restrictions, and instruct agriculture and drug regulation agencies to develop rational schemes for deciding which compounds too closely resemble human use ones, and therefore limit or ban their use in agriculture.*

On a daily basis more and more microbes are acquiring resistance to the world's available antibiotics. Drug resistant bacteria pose a genuine threat already, with increasing numbers of world citizens becoming infected with such killer microbes in the community, or while hospitalized. The outcome is a steady increase in hospitalization costs and deaths. At the current pace of bacterial resistance-acquisition many infections – notably those involving streptococcus and staphylococcus – could within a decade pose precisely the same threats to human beings as they did during the early 20<sup>th</sup> Century. While it would be nice if a laboratory came up with a breakthrough invention that could solve all of this, such a miracle is unlikely, at least for the near future. Instead, *the L-20 must seek policy solutions that can minimize the pace of resistance-acquisition in the microbial world.*

The clearest target is the conflict between livestock and agricultural use of antibiotics versus their use to protect human health. By a logarithmic factor far more antibiotics are used in agriculture than for human or veterinary medicine. Most of this agricultural use is for growth promotion, with antibiotics routinely added to livestock feed, aquaculture waters, seed stocks and on trees and vines. The result is larger animals, fish and fruit, though nobody is certain why the antibiotics have this effect. In agriculture “larger”

generally equals more profitable, and the industry is loathe to alter its use of these products.

Many of the products now used as growth promoters around the world are identical to medicinal antibiotics. Many more are chemically so close to their sister antibiotic products as to inspire identical resistance mechanisms in microbes. The world must radically rethink how such growth promoters are used, possibly banning their agricultural sales.

The European Union has taken steps in this direction, greatly reducing and even banning the use of certain growth promoters. The result in most cases has been a marked decline in related types of antibiotic-resistant disease in human beings. Many American chicken manufacturers, sensing a shift in consumer concerns and European import bans, have recently abandoned antibiotic use and so-label their products. No serious international standards for the use of these products exist.

The L-20 should request formation of a joint WHO/FAO commission assigned to review *all* growth promoters with an eye to identifying those most likely to play a role in increasing drug resistant disease in human beings. As a first step the L-20 members should ban *all* agricultural/livestock uses of growth promoters that are chemically identical to medicinal products. As a second step, the Joint Commission should review the efficacy of the EU regulations and consider their adoption. Additionally the Joint Commission should systematically review the chemical homology between antibiotics and all licensed growth promoter products used in agricultural production. The Joint Commission should also conduct an extensive literature review of all studies demonstrating links between human drug-resistant bacterial diseases and animal or plant growth promoter use. The Joint Commission should identify areas requiring further study and/or surveillance.

- 4.) *Stop the brain drain and poaching of health care workers from poor countries by instructing wealthy world domestic agencies to develop mechanisms to decrease domestic demand of foreign health care workers thru promotion of local nursing training and pay incentives.*

The world faces a severe shortage in trained nurses and doctors, aggravated by rising demand for long term and assisted living care in the aging, wealthy countries. Hospitals and recruiters are actively luring health care workers from more developed countries, such as the Bahamas, South Africa, the Philippines, Thailand and Hong Kong. Those areas are, in turn, poaching health care workers from neighboring, poorer nations. The result is a historic brain drain that threatens to shove poor nation health systems into complete collapse. This drain of talent threatens to undermine relations between nations, and aggravate hostilities towards the United States, Australia, Canada, New Zealand and Europe. It simply cannot persist, much less expand. But there are concrete reasons why fewer young adults in the wealthy countries are interested in pursuing careers in nursing, medical technician work or other vital clinical professions: training, status, pay, work hours and career advancement. Overall, nurses and their health colleagues complain that they are overworked, underpaid, have little opportunity for advancement, work under severe stress due to understaffed hospital and care settings and are treated poorly in the medical hierarchy.

Rather than continuing to poach personnel from poorer countries, the wealthy world should grow the professions domestically. This would mean funding improvements in nursing schools, increasing salary levels for federally employed nurses and offering tax incentives to hospitals that create incentives to retain indigenously-trained health professionals. They should also fund fellowships for nurses and medical laboratory professionals who opt to spend one to three years working in poor countries through their foreign service agencies.

- 5.) *Current funding for prevention of spread of HIV is abysmal. It must rank as a top global priority and receive urgent funding support.*

The global support for HIV vaccine research in 2004 – both public and private spending – was a mere \$680 million, or just 1 percent of all HIV/AIDS spending. Efforts to find a vaccine are stymied by both inadequate funding and enormous intellectual challenges. Similarly, spending on vaginal microbicide research is meager. Globally, commercial sector spending on HIV vaccine and microbicide R&D is less than \$60 million. These figures guarantee an ultimate solution to the spread of HIV will not be found for decades, if at all. While well orchestrated campaigns to control HIV in some countries have yielded significant success – particularly in Thailand – it is inconceivable at this time that HIV can be stopped without female-controlled, affordable technologies (microbicides) and an effective vaccine.

The L-20 should strongly support vaccine and microbicide development through a diverse set of mechanisms, including radically increased funding of their own countries' R&D programs, support for research in hard hit countries, greater support for the International AIDS Vaccine Initiative and the Vaccine Enterprise program, and review of mechanisms for promoting engagement by the commercial pharmaceutical industry (see above).

In addition, L-20 leaders must make very clear in all statements regarding HIV that treatment and care issues are important, but must not be allowed to override prevention efforts.