Leaders Summit on Global Infectious Disease: Toward an L20?
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Conjectural Communiqué by

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Summary

Global health deserves the attention of Heads of State, a fact which has been affirmed by the consistent attention given to the fight against infectious disease by the G8. A meeting of the Heads of State of the G20, however, could go further by offering an opportunity for donor and developing countries to make mutual commitments to issues of common concern. For each of the key challenges facing global public health, both the "North" and "South" will achieve more by using the occasion of a L20 summit to leverage specific commitments from the other party. A resulting L20 communiqué would be the following:

1. Strengthening Technical Assistance

1.1 We welcome increased domestic, bilateral and multilateral aid to developing countries to fight infectious diseases, particularly AIDS, tuberculosis and malaria, and we encourage the necessary technical assistance to make effective use of these resources in quickly scaling up proven methods to fight these diseases.

1.2 We reaffirm our commitment to United Nations agencies including WHO and UNAIDS to provide technical assistance and call on them to support a new initiative whereby L20 members will organize and finance "Global Health Corps" to provide "South-South" regional technical support among developing countries.

2. Expanding human capacity

2.1 We note with great concern the need for greater human resources, especially in Africa, to achieve the development goals set out in the Millennium Summit. Halting the brain drain and increasing local capacity should be a priority of donor and developing countries, multilateral organizations and other partners.

2.2 We encourage high-income countries to take steps to reduce the recruitment of health professionals from poor countries and to increase aid for bilateral recipients to fund health professional salaries. We encourage developing countries to urgently build new training facilities for healthcare workers, to maximize existing capacity by adapting health systems to leverage workers with less formal training, and to provide salary supplements to health professionals working in rural environments.

3. Ensuring access to medicines

3.1 We recognize the need to increase access to medicines in developing countries which, among other factors, depends on affordable prices. We welcome pharmaceutical companies' voluntary long-term commitments to providing essential medicines at substantially discounted prices to developing countries and strongly encourage further efforts, including supply competition. We also reaffirm the flexibilities offered by TRIPS and commit to ensuring the availability of these flexibilities by avoiding bilateral trade agreements with "TRIPS-plus" provisions.

3.2 As donor and recipient countries alike, we will take all steps necessary to prevent the diversion of medicines at discounted prices for developing countries – both generic and originator – away from the countries or regions for which they were intended. We will not use the preferential prices offered to the developing world as benchmarks for pharmaceutical products in high-income markets.

4. Increasing financial resources

4.1 We recognize the need for increased resources to ensure the provision of basic health care to individuals around the world and to achieve agreed international health targets, including the 2001 Declaration of Commitment on HIV/AIDS. We further recognize the necessity of increasing both bilateral and multilateral aid as well as domestic budgetary spending in developing countries.

4.2 As regional leaders of developing countries, we commit to increased national spending in our own countries and to working with others to ensure that, on average, domestic budgetary spending on health increases by one percent of gross domestic product by the end of 2007. As donors, we applaud this initiative and recommit to supporting the fight against disease with continued new financial commitments through both bilateral and multilateral channels.

5. Supporting vaccine development

5.1 To expand and accelerate efforts to develop vaccines for diseases affecting mostly developing countries ("neglected diseases"), we are committed to pilot an incentive system that would guarantee purchase of a vaccine, once developed, for a specified disease target at a fixed demand projection.

5.2 To support this project, those of us who are donors will provide the requisite financial resources for this pilot while those of us who are developing countries commit to preventing any encroachment on the intellectual property of firms pursuing vaccine research on the basis of the agreed incentive. We further commit to supporting this research by creating incentives and necessary regulatory systems to support clinical trials and affordable vaccine production.

Background

In wealthy countries including the members of the Group of Eight (G8), infectious diseases and other easily preventable causes of illness (maternal and prenatal conditions, respiratory infections and nutritional deficiencies) cause only six percent of all death and disability. Despite the ability of basic healthcare to marginalize these threats, these same conditions account for 44 percent of death and disability in developing countries, home to 85 percent of the world's population.

Across developing countries, more than one in three deaths – 17 million lives lost each year – are due to these inequitable health conditions. In Africa, the epicenter of global poverty, the burden of these diseases is 50 times greater than in wealthy countries, fundamentally impeding sustainable economic development.

Remarkably, if wealthy and developing countries together marshaled roughly $34 per person per year for health care, education and sanitation, eight million lives could be saved each year by as early as 2010 – with direct and indirect economic benefits totaling $360 billion annually.

AIDS, tuberculosis and malaria exemplify the inequities of the burden of disease and of access to care. These three diseases killed six million men, women and children in 2003, and this annual death toll is rising rapidly. Already, 40 million people are living with HIV around the world, but this pales in comparison to the projection of 45 million new infections in just five countries by 2010 – by which time AIDS orphans will total 25 million. Across Africa today, only four percent of the more than four million people who need AIDS treatment receive the medicines they need to survive. Two in five adults are infected in some countries, making it clear why the United States Secretary of State regards AIDS as "more destructive than any army, any conflict, any weapon of mass destruction."

And yet every case of AIDS, tuberculosis and malaria can be prevented and treated. The science and tools exist to fight back effectively and affordably – in order to save lives, to stimulate development and ultimately to reinforce global security. The same is true of other inequitable causes of illness, from measles to diarrhoeal diseases.

Money is critical to this response, but beyond the price tag is the greater challenge of making money work. For example, to sustain basic health interventions on the continent, Africa needs to more than double its number of health care workers by 2010, even as a severe and ongoing "brain drain" bleeds countries of physicians and nurses more quickly than they can be recruited and trained. And at the international level, increased resources must be matched by technical assistance to enable the use of bilateral and multilateral aid, by consistent leadership on trade to ensure access to affordable medicines and by a strategy that balances the delivery of known interventions with research and development to improve the global response, in particular by pioneering vaccines that can prevent infection.

Leadership summits are appropriate and important occasions to advance the fight against disease. The G8 have increasingly prioritized global health over the past few years, using G8 Summits to affirm visible and senior political commitment to issues that need championing (as when the G8 set its site on AIDS, tuberculosis and malaria in Okinawa in 2000), to pledge resources (more than $1 billion to the Global Fund to Fight AIDS, Tuberculosis and Malaria at Evian in 2003) and to commit to concrete policies or collaborative projects (the Global HIV Vaccine Enterprise in Sea Island in 2004). When the G8 last met, two of the 16 final documents focused exclusively on global health, and an additional five discussed global health as part of broader topics.

Though the G8's focus is critical, a leaders' summit of the G20 could go further. Donors have substantially increased development assistance for health in the past five years, and they are keen to see their resources leverage greater leadership, action and local investment by recipients. A L20 summit which focused on the challenges facing global health would allow key representatives of developing countries to meet this need, and in so doing advance their own interests by encouraging donors to provide greater resources on the basis of greater confidence and shared responsibility. However, a L20 communiqué is only relevant insofar as it expresses mutual commitments by both "sides" of this set of nations.

Issues and Recommendations

The agenda of a L20 summit should focus on issues with maximum impact on the fight against inequitable diseases, namely technical assistance, human capacity, access to medicines, financial resources and vaccine development. For each issue, consensus across the L20 on ways forward will be predicated on mutual commitments by the "North" and "South". In the case of global health, the position of the South will be based on the leadership of large developing nations, particularly Brazil, China, India, Russia and South Africa. Cooperation of these L20 leaders will be critical to negotiate effectively with the leaders of the G8 (in fact, the G7 plus the European Union). In offering regional leadership in the fight against diseases, these L20 leaders will set a precedent for sustained collaboration – necessary both to execute on commitments made at the L20 level but also useful in increasing local ownership of the fight against global disease, from implementation to research.

Technical Assistance

Despite substantial new funding from the Global Fund and other sources, including the United States President's Emergency Plan for AIDS Relief (PEPFAR), the international community will likely fall short of the World Health Organization's (WHO) target to have three million people on AIDS treatment by the end of 2005. This does not reflect a lack of resources or political will, but instead the challenge of large-scale, accelerated implementation of public health programs in resource-poor settings.

Experts agree that technical assistance (TA) is critical to enabling the implementation of health programs, but technical assistance varies from normative guidelines to

management expertise to procurement support to assistance in data monitoring. Donors have been keen to fund TA, but thus far the focus of TA has been on bilateral and multilateral agencies which may or may not have expertise or capacity in all of these areas. While their contributions are essential, there is untapped potential for South-South cooperation.

Some countries are already making progress in this front. Brazil recently launched its International Center for Technical Cooperation on AIDS (which could serve as a model for a larger effort). Cuba has made available thousands of healthcare workers to travel to Africa to support AIDS training programs. Other countries like Thailand and Uganda, who have been successful in their AIDS programs, could also usefully share their expertise with regional neighbors struggling to replicate their success. As new programs make strides forward, documenting and disseminating what works will become ever more important. For example, the experience of Rwanda and Botswana offers lessons for AIDS treatment in Africa, as does the experience of private providers like Anglo American.

Regional leadership in this task could be facilitated by a L20 dialogue. For a nation like India which is looking to assert itself in the international arena – including making a bid for a permanent Security Council seat – a leadership role would be appealing. The South may also see an advantage if the dialogue encourages greater funding by the North. For donors, regional efforts to extend technical assistance will help make better use of existing investments. Also, South-South TA could also help to affirm the expansion of salubrious domestic policies (eliminating tariffs on public health products) which maximize the use of donor resources.

Therefore a L20 summit should encourage South-South TA, possibly through a concrete collaborative project that is funded by the North. A L20 summit could propose regional "global health corps" of governmental and nongovernmental healthcare workers and project managers, who would be available to work in other developing countries to share best practice. Regional leadership of the project would be by a L20 member, with the United Nations providing administrative support and the donors of the L20 providing the financing.

This proposal could be reflected by the following language in a L20 communiqué:

1. Strengthening Technical Assistance

1.1 We welcome increased domestic, bilateral and multilateral aid to developing countries to fight infectious diseases, particularly AIDS, tuberculosis and malaria, and we encourage the necessary technical assistance to make effective use of these resources in quickly scaling up proven methods to fight these diseases.

1.2 We reaffirm our commitment to United Nations agencies including WHO and UNAIDS to provide technical assistance and call on them to support a new initiative whereby L20 members will organize and finance "Global Health Corps" to provide "South-South" regional technical support among developing countries.

Human Capacity

AIDS treatment targets and the Millennium Development Goals (MDGs) cannot be met without more skilled health professionals in developing countries. Lack of skilled personnel is emerging as a major if not the major obstacle to the scale-up of AIDS treatment, as well as other services. For example, staffing problems are hampering the ability of 17 of 22 of the countries with the highest tuberculosis burden from reaching 2005 targets.

The need for more capacity is aggravated severely by an ongoing brain drain that is diminishing the ranks of current healthcare workers. This problem is most severe in Africa. Zambia's public sector has retained only 50 of the 600 physicians that were trained in the country's medical school from approximately 1978 to 1999. In 1999, about 328 nurses emigrated from Ghana, equivalent to the country's entire annual output of nurses at the time. During the 1990s, 1,200 physicians were trained in Zimbabwe; only 360 were still practicing in Zimbabwe and 2001.

A study to be published in December estimates that Africa needs to more than double its healthcare workforce by adding about one million healthcare workers by 2010. This goal will require substantial political leadership, with an as yet unprecedented focus on human resources. In addition to resources to train, recruit and retain healthcare workers, it will also require policy shifts to maximize available capacity. (For example, the capacity of physicians in Botswana is unnecessarily spent on phlebotomy, a task that cannot be relegated to nurses by law. Similarly, nurses perform the tasks that could be performed by other cadres of workers with less formal training.) But increasing capacity will also require a reduction in the outflow of capacity to high-income countries, and this demands leadership from donors. Given this dynamic, the issue is an appropriate one to consider at a L20 summit. It is particularly ripe as it involves largely uncontroversial political commitments and is tied directly to existing international goals, including the MDGs.

A L20 summit should at a minimum lend affirm senior political commitment to this issue, preferably with early commitments to supportive public policies in both the North and South. A communiqué could therefore state:

2. Expanding human capacity

2.1 We note with great concern the need for greater human resources, especially in Africa, to achieve the development goals set out in the Millennium Summit. Halting the brain drain and increasing local capacity should be a priority of donor and developing countries, multilateral organizations and other partners.

2.2 We encourage high-income countries to take steps to reduce the recruitment of health professionals from poor countries and to increase aid for bilateral recipients to fund health professional salaries. We encourage developing countries to urgently build new training facilities for healthcare workers, to maximize existing capacity

by adapting health systems to leverage workers with less formal training, and to provide salary supplements to health professionals working in rural environments.

Access to Medicines

The international debate over the past five years about the impact of global trade rules on public health and access to medicines has been driven in large part by concerns about the price of antiretroviral therapy for AIDS treatment in developing countries. During this period, the price of a commonly prescribed triple combination "cocktail" has fallen from approximately $15,000 per person per year to less than $150 per person per year. This reflects the confluence of international public pressure, concessional pricing by manufacturers who hold patents on pharmaceuticals, and generic competition.

Generic competition is widely regarded as a critical mechanism to systematically and sustainably bring down the prices of medicines. Patent and other intellectual property rules determine when generic competition can commence.

The World Trade Organization (WTO) Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) sets out minimum standards for IP protection that must be met by all WTO Members within specific timeframes. In 2001, at the WTO Ministerial Conference in Doha, Qatar, WTO Members unanimously adopted a Ministerial Declaration on the TRIPS Agreement and Public Health (the "Doha Declaration"), which reaffirmed some of the key flexibilities in the TRIPS Agreement – such as compulsory licensing and parallel importation – and obligated countries to interpret and implement the treaty "in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."

Some countries have started to make use of TRIPS flexibilities to overcome patent barriers and promote access to generic medicines, both within their own countries and among other developing countries. Some donors, like Canada, have gone so far as to allow generic manufacturers in high-income countries to export to developing countries. Similar legislation is being considered by the European Union, which has been careful to explicitly prohibit reimportation of generics back into Europe.

Other donors, including the United States, have been criticized for undermining the ability of countries to implement the Doha Declaration, principally by attempting to restrict the scope of diseases covered by the Declaration as well as by negotiating regional and bilateral free trade agreements, which contain intellectual property (IP) provisions that go far beyond those required in TRIPS ("TRIPS-plus"). TRIPS-plus provisions include, for example, those that extend patent terms beyond 20 years, allow for second-use patents, provide five years or more of exclusive protection over pharmaceutical test data, link marketing approval of drugs with patents status and limit compulsory licensing.

Independently of donor policy, experts warn that WTO members may face challenges to the production and export of generics as they become TRIPS compliant. Indian

generic manufacturers, for example, have relied on a current system of process rather than product patents to reverse engineer pharmaceutical products. But a "mailbox" full of 6,000 product patents awaits the moment that India becomes TRIPS compliant in 2005. This could impede generic manufacturing unless the flexibilities of TRIPS are fully affirmed and realized.

Given the need for continued political endorsement of these flexibilities, as asserted in the Doha Declaration, access to medicines should also be a topic addressed by the L20. Beyond what would otherwise be possible with the G8 (which has consistently addressed this topic in their own communiqués), a L20 summit would give leading developing countries an opportunity to assert their commitment to preventing reimportation of generics into high-income countries. A communiqué could offer a shared political signal in this regard with the following assertions:

3. Ensuring access to medicines

3.1 We recognize the need to increase access to medicines in developing countries which, among other factors, depends on affordable prices. We welcome pharmaceutical companies' voluntary long-term commitments to providing essential medicines at substantially discounted prices to developing countries and strongly encourage further efforts, including supply competition. We also reaffirm the flexibilities offered by TRIPS and commit to ensuring the availability of these flexibilities by avoiding bilateral trade agreements with "TRIPS-plus" provisions.

3.2 As donor and recipient countries alike, we will take all steps necessary to prevent the diversion of medicines at discounted prices for developing countries – both generic and originator – away from the countries or regions for which they were intended. We will not use the preferential prices offered to the developing world as benchmarks for pharmaceutical products in high-income markets.

Financial Resources

There is universal agreement among donors that greater resources are required to improve public health in developing countries. While few have attained (and some dispute) the Monterrey commitment to dedicate 0.7 percent of GDP to development assistance, donors have substantially increased aid flows in the past few years. Spending on AIDS has roughly doubled, for example. The G8 Summit has been used repeatedly to draw attention to the need for resources and to commit new resources. Such will be the case again in 2005 during the United Kingdom's presidency of the G8, which will focus next year on eradicating global poverty. New resources are expected both through traditional Official Development Aid (ODA) accounts as well as through new mechanisms, including the International Finance Facility (IFF).

Adequate spending for health, however, will depend greatly on commensurate increases in national spending by developing countries. The Commission on Macroeconomics and Health recommended that spending in developing countries reach $34 per person in 2007. But spending among least developed countries at the

turn of the century totaled only $11 – $4 in domestic spending by the government, $5 in domestic out-of-pocket expenditure, and $2 in donor support. The ration of the recommended $34 is $15 domestic to $19 of international aid. Overall, budgetary spending on health, it is recommended, must increase by an additional one percent of GDP in developing countries by 2007.

While G8 summits provide a setting to make new commitments to donor aid, occasions for developing countries to commit to increased domestic spending are less obvious. A L20 summit could offer such an opportunity, with actual commitments by leading developing countries which are members of the L20 and, importantly, leadership from them to ensure that other developing countries follow their example. A visible sign of increased spending by developing countries themselves will affirm the additionality of donor funds and will encourage high-income countries to give more. From these countries, it is likely that a L20 would provide an opportunity for continued political commitment to the goal of increased resources.

A communiqué could therefore read:

4. Increasing financial resources

4.1 We recognize the need for increased resources to ensure the provision of basic health care to individuals around the world and to achieve agreed international health targets, including the 2001 Declaration of Commitment on HIV/AIDS. We further recognize the necessity of increasing both bilateral and multilateral aid as well as domestic budgetary spending in developing countries.

4.2 As regional leaders of developing countries, we commit to increased national spending in our own countries and to working with others to ensure that, on average, domestic budgetary spending on health increases by one percent of gross domestic product by the end of 2007. As donors, we applaud this initiative and recommit to supporting the fight against disease with continued new financial commitments through both bilateral and multilateral channels.

Vaccine Development

Vaccine development is another goal that could be advanced significantly by mutual commitments by the North and South. It is well know that 10 percent of global research and development is aimed at the diseases which affect 90 percent of the world's population. It is also widely accepted that vaccines – which face the further economic disincentive from therapeutics of one-time rather than repeated use – are a proven technology which could substantially impede the spread of diseases like AIDS, tuberculosis and malaria, just as they have for polio and diphtheria.

There has been some progress in improving vaccine development for diseases affecting mostly developing countries. The International AIDS Vaccine Initiative, the Tuberculosis Vaccine Collaboration and the Malaria Vaccine Initiative are good examples. All have benefited greatly by private investment through the Bill &

Melinda Gates Foundation, which has also made available unprecedented resources for vaccine research into other neglected diseases (rotavirus, pneumococcus and meningococcus to name but a few). Developing countries have also made strides forward by expanding their own research initiatives. For example, an International Vaccine Institute has been launched in South Korea to pool scientists for research relevant to neglected diseases in Asia. Thailand has been cited by the Wellcome trust as a leader in clinical research for malaria therapeutics.

Investment by pharmaceutical and biotechnology firms, however, remains limited due to the lack of a concrete financial incentive. This is despite previous statements by Heads of State, including the G8 commitment in 2003 to "encourage research into these diseases, in our countries... by providing appropriate incentives." Specific and tangible action is required to substantiate this intention. Recommendations have been made, for example, to extend orphan drug legislation to international neglected diseases, in order to provide tax breaks and government subsidies to pharmaceutical and biotechnology companies to pursue relevant research.

There is increasing interest in creating mechanisms to guarantee purchase of vaccines, once developed, to allow firms to invest fully in research and development for specific vaccine targets. These mechanisms would draw on donor governments – and other investors – and entail binding commitments.

An L20 summit could provide an ideal occasion to launch such a project given the mutual commitments necessary of both donor and developing countries to make such an initiative work. In addition to the resources required from donors, developing countries should explicitly commit to respecting the patents of any firms which develop a vaccine based on the promise of fixed demand. While this would likey be a contractual element of the incentive system, political commitment in countries with strong generic industries (including Brazil and India) would be helpful. Developing countries could also mitigate costs and accelerate the timeframe of research efforts by committing their own resources to local clinical research of vaccine candidates and by offering appropriate incentives for firms to quickly and affordably establish production capacity in developing countries. These commitments could be reflected by the following text in a communiqué:

5. Supporting vaccine development

5.1 To expand and accelerate efforts to develop vaccines for neglected diseases, we are committed to pilot an incentive system that would guarantee purchase of a vaccine, once developed, for a specified disease target at a fixed demand projection.

5.2 To support this project, those of us who are donors will provide the requisite financial resources for this pilot while those of us who are developing countries commit to preventing any encroachment on the intellectual property of firms pursuing vaccine research on the basis of the agreed incentive. We further commit to supporting this research by creating incentives and necessary regulatory systems to support clinical trials and affordable vaccine production.