



**The U.S. Commitment to Global Health:
Recommendations for the Public and Private
Sectors**

Committee on the U.S. Commitment to Global Health;
Institute of Medicine

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THE U.S. COMMITMENT TO GLOBAL HEALTH

Recommendations for the Public and Private Sectors

Committee on the U.S. Commitment to Global Health
Board on Global Health

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

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Willing is not enough; we must do.”*

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Acronyms and Abbreviations

AAMC	Association of American Medical Colleges
ACT	artemisinin-based combination therapy
AIDS	acquired immunodeficiency syndrome
AITRP	AIDS International Training and Research Program
AMC	Advance Market Commitment
AMFm	Affordable Medicines Facility for Malaria
ASMQ	artesunate and mefloquine
BCG	bacille Calmette-Guérin (vaccine against TB)
BHGI	Breast Health Global Initiative
BMS	Bristol Myers Squibb
CDC	Centers for Disease Control and Prevention
CVD	cardiovascular disease
DALY	disability-adjusted life-year
DGPHCD	Division of Global Public Health Capacity Development
DHS	U.S. Department of Homeland Security
DNDi	Drugs for Neglected Diseases Institute
DOD	U.S. Department of Defense
DOTS	directly observed treatment, short-course (for TB)
EPA	U.S. Environmental Protection Agency

FACT	Fixed-dose Artesunate-based Combination Therapies
FCTC	Framework Convention on Tobacco Control
FDA	Food and Drug Administration
FELTP	Field Epidemiology and Laboratory Training Program
FETP	Field Epidemiology Training Program
FIC	Fogarty International Center
FRIND	Funds for R&D in Neglected Diseases
FY	fiscal year
GAVI	Global Alliance for Vaccines and Immunization
GBC	Global Business Coalition on HIV/AIDS, Tuberculosis, and Malaria
GDP	gross domestic product
GeoSentinel	Global Emerging Infections Sentinel Network
GHA1	Global HIV/AIDS Initiative (State Department)
GHC	Global Health Corps
GHS	Global Health Service
Global Fund	Global Fund to Fight AIDS, Tuberculosis, and Malaria
GNI	gross national income
GOARN	Global Outbreak Alert and Response Network
HHS	U.S. Department of Health and Human Services
HINARI	Health InterNetwork Access to Research Initiative
HPV	human papilloma virus
IANPHI	International Association of National Public Health Institutes
IDI	Infectious Diseases Institute
IDRC	International Development Research Centre
IEE	Independent External Evaluation
IHP+	International Health Partnership
IHR	International Health Regulations
IOM	Institute of Medicine
iOWH	Institute for OneWorld Health
LLIN	long-lasting insecticide-treated net
MDG	Millennium Development Goal
MDR-TB	multidrug-resistant tuberculosis
MIDRP	Military Infectious Diseases Research Program
MIT	Massachusetts Institute of Technology
MPHI	Mesoamerican Public Health Institute
NGO	nongovernmental organization

ACRONYMS AND ABBREVIATIONS

xix

NIH	National Institutes of Health
NPHI	National Public Health Institute
NSC	National Security Council
ODA	overseas development assistance
OECD	Organisation for Economic Cooperation and Development
OMB	Office of Management and Budget
PAL	Poverty Action Lab (MIT)
PDA	personal data assistant
PDP	product development partnership
PEPFAR	President's Emergency Plan for AIDS Relief
PHEIC	public health emergency of international concern
PhRMA	Pharmaceutical Research and Manufacturers of America
PPP	public-private partnership
Prep	pre-exposure prophylaxis
SAFE	surgery, antibiotics, face cleanliness, and environmental improvement
SARS	severe acute respiratory syndrome
STI	sexually transmitted infection
SWAp	Sector-Wide Approach
<i>T.b.</i>	<i>Trypanosoma brucei</i>
TB	tuberculosis
TDR	Special Programme for Research and Training in Tropical Diseases
TEHIP	Tanzania Essential Health Interventions Project
UCSF	University of California, San Francisco
UN	United Nations
UNDP	United Nations Development Programme
UNESCO	United Nations Educational, Scientific, and Cultural Organization
UNICEF	United Nations Children's Fund
USAID	U.S. Agency for International Development
WHO	World Health Organization

Summary

Global health is the goal of improving health for all people in all nations by promoting wellness and eliminating avoidable disease, disability, and death. It can be attained by combining population-based health promotion and disease prevention measures with individual-level clinical care. This ambitious endeavor calls for an understanding of health determinants, practices, and solutions, as well as basic and applied research on risk factors, disease, and disability.

In the United States, an area of study, research, and practice has emerged to contribute to the achievement of global health. The *U.S. global health enterprise* involves many sectors (both governmental and nongovernmental) and disciplines (within and beyond the health sciences) and is characterized by intersectoral, interdisciplinary, and international collaboration. U.S. leadership in global health reflects many motives: the national interest of protecting U.S. residents from threats to their health; the humanitarian obligation to enable healthy individuals, families, and communities everywhere to live more productive and fulfilling lives; and the broader mission of U.S. foreign policy to reduce poverty, build stronger economies, promote peace, increase national security, and strengthen the image of the United States in the world.

The U.S. government, along with U.S.-based foundations, nongovernmental organizations, universities, and commercial entities, can take immediate concrete action to accelerate progress on the urgent task of improving health globally by working with partners around the world to scale up existing interventions, generate and share knowledge, build human and institutional capacity, increase and fulfill financial commitments, and establish respectful partnerships.

SCOPE OF THE REPORT

The Institute of Medicine (IOM)—with the support of four U.S. government agencies and five private foundations—convened an expert committee to investigate the U.S. commitment to global health and articulate a vision for future U.S. investments and activities in this area. While global health encompasses the health of everyone (including U.S. citizens) and is a shared global aspiration that requires the work of many nations, this report focuses on the efforts of the United States, both its governmental and its nongovernmental sectors, to help improve health in low- and middle-income countries.

The committee examined whether the existing architecture, investments, and activities of the U.S. global health enterprise are optimally geared to achieving significant, sustainable, and measurable global health gains. This report communicates specific recommendations, not just for the U.S. government, but also for several nongovernmental sectors, including foundations, universities, nonprofit organizations, and commercial entities.

Because health is inextricably connected to the broader goals of hastening development and reducing poverty, the committee recognizes that any action taken by the United States to support global health should be tied directly to broader discussions of U.S. commitments to global economic and human development, as well as the environment. The committee also recognizes that while the United States has the opportunity to support and advocate for a global plan to improve health, ultimately individual countries—both governments and civil society—are responsible for putting in place the social and economic policies that protect the health of their populations.

U.S. CONTRIBUTION TO GLOBAL HEALTH IMPROVEMENTS

Health achievements in the last 50 years have been remarkable. Globally, life expectancy has increased more in this period than in the preceding 5,000 years. The creation, dissemination, and adoption of knowledge have been among the main drivers of these health gains, delivering marked improvements in low- and middle-income countries that have invested in sustainable and equitable systems to deliver proven, cost-effective interventions.

Both governmental and nongovernmental sectors in the United States have been an important source of global health knowledge, providing the scientific basis for many health successes worldwide through their research and capacity building efforts. The United States—in partnership with local communities, governments, and international organizations—has also played a critical role in the dissemination and adoption of knowledge by providing the financial and technical resources to expand public health infrastructure and access to health interventions in many countries, resulting in major public health achievements.

RECOMMENDATIONS FOR IMPROVED GLOBAL HEALTH

The United States now has an unprecedented opportunity to improve global health. The promise of potential solutions to global health problems has captured the interest of a new generation of philanthropists, students, scientists, healthcare professionals, private sector leaders, and citizens—all eager to make a difference in this interconnected world. At the same time, the U.S. government has made record financial commitments to global health programming, for which the support of the American people has been crucial.

Neither the U.S. government nor any one U.S. organization can achieve global health by acting alone. Progress toward this goal requires the collaboration of all countries, donors, and recipients of aid to develop, finance, and deliver essential and cost-effective health interventions. The United States can, however, lead by setting an example of meaningful financial commitments, technical excellence, and respectful partnership.

The committee examined many ways in which the United States, including the U.S. government and the nongovernmental sector, could contribute to advances in global health. The committee pursued those areas that draw on U.S. technical and scientific capabilities to generate knowledge; maximize growing involvement by the U.S. government, universities, foundations, and commercial entities; and address a significant deficiency in advancing global health. The committee identified five areas for action by the U.S. global health enterprise:

1. Scale up existing interventions to achieve significant health gains.
2. Generate and share knowledge to address health problems endemic to the global poor.
3. Invest in people, institutions, and capacity building with global partners.
4. Increase U.S. financial commitments to global health.
5. Set the example of engaging in respectful partnerships.

SCALE UP EXISTING INTERVENTIONS TO ACHIEVE SIGNIFICANT HEALTH GAINS

The global health community has reached a critical juncture. The knowledge, innovative technologies, and proven tools to help millions of people in need are within reach. Yet even with demonstrated success in tackling certain health issues, a wide gap remains between what *can* be done with existing knowledge and what *is* actually being done. Existing interventions are not widely used even though many are inexpensive and easy to administer.

Support the Millennium Development Goals by 2015

The globally recognized Millennium Development Goals (MDGs) were adopted by the Member States of the United Nations (UN) in 2000 to achieve

demonstrable reductions in poverty and improve specific health and social outcomes by 2015. Three of the eight goals pertain directly to health (Goal 4: Reduce child mortality; Goal 5: Improve maternal health; and Goal 6: Combat HIV/AIDS, malaria, and other diseases) and the other five, indirectly. While progress has been made, the MDG targets remain a distant goal for many countries, particularly in sub-Saharan Africa and parts of South Asia.

Recommendation 2-1. As part of a comprehensive approach to development and poverty reduction, the United States, both its governmental and its nongovernmental sectors, should support the UN's Millennium Development Goals. In particular, the United States should partner with countries to promote and finance the application of existing knowledge and tools to achieve the health-related MDGs by 2015 with special attention to areas that are lagging behind. (See Recommendation 5-1 for funding proposal.)

Prepare for Emerging Challenges of the Twenty-first Century

The timeless health problems associated with poverty are now coupled with new challenges. Infectious diseases are emerging at the historically unprecedented rate of one per year. With airlines now carrying more than 2 billion passengers annually and systems of trade more interconnected than in any time in human history, opportunities for the rapid international spread of infectious agents and their vectors have vastly increased. The recent spread of H1N1 influenza (swine flu) to more than 20 countries in the span of a few weeks highlights the speed at which new threats can travel. The rising tide of chronic diseases and injuries in low- and middle-income countries, where 80 percent of the world's deaths from chronic, noninfectious diseases now occur, also cannot be ignored.

Recommendation 2-2. The United States should partner with the global community to prepare for emerging challenges of the twenty-first century by increasing attention to pandemic infectious threats, noncommunicable diseases, and injuries. The U.S. government should demonstrate leadership in this area by adopting clear goals—such as improving global disease surveillance, decreasing deaths from tobacco-related illnesses, and reducing injuries from accidents—to guide U.S. global health investments. (See Recommendation 5-1 for a detailed funding proposal.)

Address Neglected Health Systems

The drive to produce results for the MDGs and other health goals has led many donors to focus on specific disease outcomes. Yet undermining all efforts to reduce disease burden is the stress on health systems in low- and middle-income countries. Functional health systems—including access to adequate financing;

public health infrastructure and programming; essential medical products, vaccines, and technologies; a well-performing health workforce; reliable and timely health information; and strategic policy frameworks to provide effective analysis, oversight, management, and governance—are sorely lacking in most low-income countries.

Given the emergency conditions prompting the initial global response to AIDS, for example, it is not surprising that donors chose to circumvent existing weak components of national health systems to set up programs devoted to immediate and demonstrable results. While this focus on specific diseases has led to significant health outcomes related to these diseases, the programs have sacrificed opportunities to strengthen local health systems.

Recommendation 2-3. When delivering health assistance, federal executive branch agencies and departments should work with Congress to make U.S. government global health programs less formulaic and more performance-based, to permit resources to be used more easily within unique national health systems with the explicit objective of promoting stronger national health systems and a better trained, more productive health workforce.

GENERATE AND SHARE KNOWLEDGE TO ADDRESS HEALTH PROBLEMS ENDEMIC TO THE GLOBAL POOR

One of the greatest contributions the United States can offer to the global campaign to improve health is to share America's traditional strength—the creation of knowledge—for the benefit of the global poor. The United States has a distinguished record in the generation of knowledge, spending more in this area than any other country. The United States and other wealthy nations focus the majority of their research resources on conditions that affect people within their own borders. As a result, diseases or conditions that are overwhelmingly or exclusively incident in low- and middle-income countries are often neglected.

While the U.S. research community—comprised of the U.S. government, universities, commercial entities, public-private partnerships, and other non-profit organizations—has increased its research contributions to benefit global health (especially to combat AIDS, malaria, and tuberculosis), it is not currently mobilized to reach its full potential. The growing number of public-private partnerships and university-based collaborative research models devoted to global health demonstrates the growing interest and untapped demand within the U.S. research community to engage with partners in addressing the health needs of the global poor.

Strengthen Knowledge on the Adoption and Dissemination of Existing Interventions

The systemic bottlenecks in the health systems of low- and middle-income countries (such as poor surveillance systems, bottlenecks in drug supply pipelines, and chronic deficits in the health workforce) prevent the full benefits of existing public health knowledge and technologies from being realized. Research on healthcare systems is required to mitigate these effects. Currently, few programs that deliver specific health interventions undergo rigorous evaluation. If U.S. efforts are to achieve sustainable and far-reaching outcomes, the importance of knowing what works is critical.

Recommendation 3-1. The U.S. research community should increase research and evaluation efforts to address the systemic bottlenecks in health systems in low- and middle-income countries that keep the full benefits of existing medical and public health knowledge and technologies from being completely realized.

(A) The U.S. research community should expand its research efforts through increased attention to health systems research (both for studies that can be generalized across countries and for operational and implementation studies that are culturally and contextually relevant).

(B) In addition to measuring inputs (such as dollars spent) and outputs (such as drugs delivered), Congress and other global health funders should require that efforts to deliver health interventions be accompanied by rigorous country- and program-level evaluations to measure the effect of global health programs on saving lives and improving health.

Continue Research to Develop Novel Health Technologies and Interventions

Global health would greatly benefit from developing and disseminating a variety of novel behavioral and biomedical prevention strategies to combat infectious diseases. Antiquated diagnostics and treatments also need to be improved to achieve sustainable results in the management and control of disease and to reduce drug resistance that results from misdiagnosis or poor adherence to treatment regimens.

One of the most promising approaches to bridge the enormous and widening gap in the availability of drugs, vaccines, and diagnostics to deal with the global disease burden is the advent of public-private product development partnerships (PDPs). This novel approach, coupled with U.S. expertise in science and biomedical research, strong U.S. financial commitments (through funding from the National Institutes of Health [NIH] and the U.S. biomedical and pharmaceutical industry), and the synergies that exist when the government works in partnership

with the nongovernmental sector, can yield technologies and interventions to revolutionize global health.

Recommendation 3-2. The U.S. research community, in collaboration with global partners, should leverage its scientific and technical capabilities to conduct research using state-of-the-art technology and innovative strategies to address health problems endemic to low- and middle-income countries.

(A) The U.S. research community should continue to examine new interventions for the prevention and treatment of global infectious diseases.

(B) The U.S. research community should expand its research efforts in global health with heightened attention to two purposes: (1) to study the basic mechanisms of diseases that disproportionately affect the global poor, and (2) to identify means to control communicable and noncommunicable diseases by adapting existing knowledge for low- and middle-income countries.

Share Knowledge that Enables Local Problem Solvers

Research on global health involves not only generating knowledge relevant to the context of low- and middle-income countries, but also effectively transferring such knowledge and technologies to these settings and ensuring that its intended beneficiaries can apply it on a sustained basis. With research increasingly conducted globally through virtual communities of geographically dispersed scientists, it is critically important that information exchange promote sustainable cross-country research partnerships and enable the timely dissemination of best practices.

Recommendation 3-3. The U.S. research community should promote global knowledge networks and the open exchange of information and tools that enable local problem solvers to conduct research to improve the health of their own populations.

(A) Funders of global health research should require that all work supported by them will appear in public digital libraries, preferably at the time of publication and without constraints of copyright (through open access publishing), but no later than six months after publication in traditional subscription-based journals. Universities and other research institutions should foster compliance with such policies from funding agencies and supplement those policies with institution-based repositories of publications and databases.

(B) The U.S. government, universities, and other research institutions should develop new methods—such as simplified web-based procedures

for executing agreements like materials transfer and nondisclosure agreements—to expedite the sharing of information and research materials with researchers in low- and middle-income countries.

(C) Scientists, clinicians, advocates, and other personnel involved in defined areas of global health should develop trustworthy websites that aggregate published literature, incorporate unpublished databases or clinical trial information, promote digital collaboration, and disseminate news and other information about common interests.

(D) Universities and other research institutions that receive federal and philanthropic funding to conduct research should adopt patent policies and licensing practices that enable and encourage the development of technologies to create products for which traditional market forces are not sufficient, such as medicines, diagnostics, and therapeutics that primarily affect populations in low- and middle-income countries.

INVEST IN PEOPLE, INSTITUTIONS, AND CAPACITY BUILDING WITH GLOBAL PARTNERS

Although the United States can offer partial solutions to help resolve the challenges that low- and middle-income countries face in delivering basic health services, these countries require capable local leaders, analysts, researchers, and practitioners to identify problems and solutions that work and are sustainable in their own countries. Unlike the United States, where academia, nonprofit organizations, and commercial entities play an important advisory role in domestic U.S. healthcare policy, in low- and middle-income countries, universities, science academies, and the research community are often absent from policy engagement. As a result, this community has been neglected as a partner by many external donors.

Expand Commitment to Institutional Capacity Building

The United States has an opportunity to address the neglect of universities and the research community in low- and middle-income countries by leveraging the growing involvement of U.S.-based universities, corporate entities, and foundations in global health by supporting institutional partnerships across nations. Such collaboration will not only strengthen capacity in leadership, research, teaching, and patient care for all the institutions involved, it will also create incentives for researchers and practitioners to stay in their home countries, by producing a workplace environment conducive to continuing education and enhanced career opportunities.

Recommendation 4-1. Federal executive branch agencies, along with U.S. private institutions, universities, nongovernmental organizations, and commercial entities, should provide financial support and engage in long-term and mutually advantageous partnerships with institutions—universities, public health and research institutes, and healthcare systems—in low- and middle-income countries with the goal of improving institutional capacity. These partnerships should enable local and global problem solving and policy engagement by

- Investing in training,
- Creating an enabling institutional environment,
- Funding a steady stream of diverse research grants,
- Generating demand for scientific and analytical work that influences public policy, and
- Contributing to the control of real and immediate health problems.

Rectify the Health Workforce Crisis

Institutional partnerships between organizations in low- and middle-income countries and the United States provide an opportunity to address the critical workforce deficits that hinder the achievement of health-related MDGs. Beyond the shortage of health workers, public health systems in these countries also lack capacity due to weak civil service and absenteeism, with limited incentives for good performance (including low salaries that lead to income supplementation strategies such as informal payments and dual-practice in the private sector). Underperforming market systems also typically have weak government capacity to regulate the quality of providers, leading to particularly insidious outcomes, such as price gouging and unnecessary or harmful care.

The same poor working conditions that have created disincentives for health workers to perform at the highest level have also pushed many health professionals in low- and middle-income countries out of the public sector. Many choose to emigrate to high-income countries that are experiencing a health workforce shortage. However, the committee finds that global migration is neither the main cause of, nor would its reduction be the main solution to, the worldwide human resource crisis in health. Attempts to merely increase the supply of workers by restricting emigration visas or reversing migration might have a modest effect on the numbers, but would not solve the problem and would put unnecessary restrictions on the right of workers to migrate.

National health resource plans that go beyond simply increasing the number of health workers and endeavor to understand and improve the dynamics of the labor market have been successful in stemming the tide of workforce migration and in recruiting and retaining labor for underserved areas. While such plans

require commitments by governments to construct and finance sound human resource plans, the success of these plans is often dependent upon external donor assistance and cooperation.

Recommendation 4-2. Federal executive branch agencies and departments, nongovernmental organizations, universities, and other U.S.-based organizations that conduct health programs in low-income countries should align assistance with the priorities of the national health sector human resource plans and should commit and sustain funding in support of these plans.

Recommendation 4-3. Congress should work with federal executive branch agencies and departments and U.S. universities to explore opportunities to leverage the U.S. workforce to contribute to solutions that partially address health workforce deficits in low- and middle-income countries. This exploration should include an inquiry into the willingness of Americans to participate in a global health service corps; a determination of whether this kind of assistance would be well received by recipient countries; and an examination of whether specific opportunities exist to help migrants from low-income countries return home to work temporarily or permanently.

INCREASE U.S. FINANCIAL COMMITMENTS TO GLOBAL HEALTH

Given the severe resource constraints in low-income countries, their progress toward meeting the MDGs by 2015 will require increased and sustained foreign assistance for health care from the advanced economies. Over the last decade, the U.S. government has made record commitments to global health. Between 2001 and 2008, global health programming through the U.S. Agency for International Development (USAID) and the State Department grew by nearly 350 percent. As a result, health now makes up a significantly larger portion of both the U.S. foreign affairs budget and the overall overseas development assistance (ODA) budget. The extraordinary increase in the percentage of U.S. aid for health was driven mostly by new models of assistance, such as the Global Fund to fight AIDS, Tuberculosis, and Malaria; the President's Emergency Plan for AIDS Relief (PEPFAR); and the President's Malaria Initiative.

In May 2009, President Obama announced the Global Health Initiative and requested that Congress provide \$63 billion in appropriations for global health over the next six years (2009-2014). The proposal calls for an increase in funding from \$8.186 billion in FY 2009 to \$8.645 billion in FY 2010.

Meet Existing International Aid Commitments

The committee commends the increased U.S. spending on global health. The U.S. commitment to overall ODA, however, is less impressive. It is less than the

efforts of other high-income countries in relative terms and is among the lowest levels of net ODA as a percentage of gross national income (GNI). Even when private giving is included, per capita spending by the United States does not approach the level of most other wealthy nations.

Meeting the MDGs would require advanced economies to devote 0.54 percent of their GNI to ODA, as determined by the UN Millennium Project. Accordingly, the committee estimates that the U.S. contribution to the health-related MDGs would be \$13 billion per year by 2012. This level of spending, although still below the capacity of the United States and the overall resources needed for health, is justified on the basis of international norms and commitments.

Additional resources will be required to respond to the contemporary challenges of chronic and noncommunicable diseases and injuries, which are responsible for more than half of the deaths below age 70 in low- and middle-income countries but are not captured in the health-related MDGs. Cost-effective strategies, such as tobacco control, hold the promise of averting millions of premature deaths in these countries.

Recommendation 5-1. The President and Congress should commit to investing \$15 billion in global health by 2012, with \$13 billion of this directed to the health-related MDGs and an additional \$2 billion to the challenges of noncommunicable diseases and injuries. (See Chapter 5 for more detailed recommendations.)

(A) While pursuing the goal of \$13 billion per year for the health-related MDGs, federal executive branch agencies should work with Congress to create balance in the traditional portfolio of global health spending that reflects the breadth of the health-related MDGs.

- (1) Congress should fulfill its implied commitments under PEPFAR reauthorization to global AIDS programs (\$7.8 billion per year), malaria (\$1 billion per year), and tuberculosis (\$800 million per year).
- (2) The U.S. government should use the remaining \$3.4 billion per year to support programs such as health systems strengthening, children and women's health, nutrition, family planning and reproductive health, and neglected diseases of poverty, all of which have been severely underresourced during the past decade.
- (3) Given concerns that PEPFAR costs could crowd out other equally important global health initiatives, the U.S. government should maintain funding for ARV treatment for individuals already supported by PEPFAR but should also act diligently to ensure that the program prevents as many HIV infections as possible.

(B) Federal executive branch agencies and departments—particularly the Centers for Disease Control and Prevention, the NIH, and USAID—

should work with Congress to identify specific ways to respond to the contemporary challenges of noncommunicable diseases and injuries and should commit to investing \$2 billion for this purpose by 2012.

Continue Strong U.S. Commitment to Fund Global Health Research

The appropriate mix of health spending for care delivery and for research should be weighed against the requirements of combating a particular disease and the unique health needs of a local population. However, including research in health assistance can only increase its effectiveness. In the spirit of the 2008 Bamako Call to Action on Research for Health (which urged international development agencies and major funders to allocate 5 percent of global health development assistance for health research), the committee recommends that aid be flexible and allow for the funding of research to be conducted through the foreign affairs budget as it supports improvements to health in low- and middle-income countries.

Recommendation 5-2. Federal executive branch agencies and departments should work with Congress to design a coordinated approach to funding global health research that leverages research subsidies through the Department of Health and Human Services budget and innovative funding mechanisms for novel vaccine, drug, and diagnostic procurement through the foreign affairs budget.

SET THE EXAMPLE OF ENGAGING IN RESPECTFUL PARTNERSHIP

The U.S. government—the largest funder of many international organizations and a significant donor of bilateral aid in some countries—carries considerable influence in shaping the global health environment. While the global health community faces many complex questions about governance that will not be resolved by any one country acting alone, many opportunities exist for the United States to be an effectual leader, respectful partner, and good steward for health at both the national and the global levels.

Support and Collaborate with WHO

The flourishing global health community is vast and diverse and is greatly in need of effective leadership. While the proliferation of new participants in this field, such as PDPs and foundations, is a welcome development that brings with it fresh resources and innovation, global health activities will remain ad hoc, duplicative, and highly fragmented unless the different initiatives and agendas are coordinated through effective leadership.

With so many committed partners based in different countries dedicated to improving global health, leadership would ideally be provided through a single

organization with a mandate for setting evidence-based norms on health-related technical and policy matters. Although not perfect, the World Health Organization (WHO) is such an organization, and if it did not exist, a similar one would have to be created—to lead a coordinated response to epidemic influenza, for example. The committee finds that the United States has much to gain from supporting WHO, despite the fact that many aspects of its current structure and function hinder its effectiveness.

Recommendation 6-1. The U.S. government should support WHO as a leader in global health by paying its fair share of the organization’s budget and providing technical expertise to WHO, as requested. However, it should also request a rigorous external review of the organization to develop future-oriented recommendations that maximize its effectiveness. (See Chapter 6 for more detailed recommendations.)

Align Aid with Country-Led Health Plans

The effects of the proliferation of new participants in global health are perhaps most acutely seen at the national level. Low-income countries typically receive aid from multiple global agencies, resulting in overburdened health ministries. Given that a majority of investments are delivered and managed through local nongovernmental organizations operating outside the recipient government’s budgeting system, many countries struggle to maintain control of their own health priorities. Countries with weak control of their health systems lose the incentive and ability to create and support their own sustainable plans.

Recommendation 6-2. To ensure that countries retain ownership and accountability for the health of their populations and to promote long-term sustainability, donors should support recipient countries in developing results-focused, country-led agreements that rally all development partners around one country-led health plan, one monitoring and evaluation framework, and a unified review process. Donors should also aim to build local capacity to regulate and integrate local private sector participants in the government’s health plan.

Recommendation 6-3. To reduce the burden on countries in coordinating donor efforts around a basic health plan, all funders of global health should strive to deliver a greater proportion of aid in support of technically and financially sound country-led health plans provided on the premise that the recipient government implements agreed-upon strategies in a transparent fashion.

CALL TO ACTION

At this historic moment, the United States has the opportunity to advance the welfare and prosperity of people within and beyond its borders through intensified and sustained attention to better health. Even as the U.S. economy is under pressure, attention to global health remains essential. The financial policies and practices of the wealthiest nations, including the United States, are having painful consequences in low- and middle-income countries. During economic downturns, the health of a country's population worsens due to lowered household income and reduced access to health care. Moreover, the poor in low- and middle-income countries are most affected because they pay a large portion of their healthcare costs out-of-pocket, without the benefit of social safety nets. It is therefore crucial for the reputation of the United States that the nation live up to its humanitarian responsibilities, despite current pressures on the U.S. economy, and partner with low- and middle-income countries in safeguarding the health of their most vulnerable members.

Global Health Is a Responsibility and an Opportunity to Be Seized

Health is a highly valued, visible, and concrete investment that has the power to both save lives and enhance the image of the United States in the eyes of the world. Through its policies and actions, the United States can take this opportunity to demonstrate that it fundamentally believes in the value of better health for all.

Recommendation 7-1. The President should highlight health as a pillar of U.S. foreign policy. The U.S. government should act in the global interest, recognizing that long-term diplomatic, economic, and security benefits for the United States will follow. Priorities should be established on the basis of achieving sustained health gains most effectively, rather than on short-term strategic or tactical U.S. interests.

Need for Coherent Strategy for U.S. Government Involvement in Global Health

If health is to hold a more prominent position in U.S. foreign policy, the U.S. government will need to increase coordination among the multiple agencies and departments engaged in global health. The 1997 IOM report *America's Vital Interest in Global Health* called for the establishment of a government Inter-agency Task Force on Global Health, led by the U.S. Department of Health and Human Services. The committee supports this recommendation in principle, but recommends that the interagency group be located more centrally, in the White House. Locating the effort in the White House, potentially within the National

Security Council (NSC) and reporting to the President through the NSC adviser, would give it convening authority among sometimes competing agencies and the ability to make policy recommendations directly to the President.

Recommendation 7-2. Within the first year of his administration, the President should create a White House Interagency Committee on Global Health to lead, plan, prioritize, and coordinate the budgeting for major U.S. government global health programs and activities. The President should also designate a senior official at the White House (Executive Office of the President, potentially within the NSC) at the level of deputy assistant to the President for global health to chair this interagency committee.

Call for Summit to Highlight U.S. Commitment to Global Health

Working with partners around the world and building on previous commitments, the United States has the responsibility and chance to save and improve the lives of millions; this is an opportunity that the committee hopes the United States will seize.

Recommendation 7-3. In recognition of the partnership needed to achieve global health, the President should call together world leaders for a summit meeting at the UN General Assembly General Debate and the meeting of the G20 in September 2009 to announce a commitment to the overall funding levels recommended in this report (\$15 billion spent annually by 2012) and to emphasize the importance of the closely related issues of food and water security. In the interest of sovereignty and sustainability, the President should also ask low- and middle-income countries to commit publicly to providing additional resources by 2012 to finance their own health initiatives.

1

Introduction

In 1997, an Institute of Medicine (IOM) report *America's Vital Interest in Global Health: Protecting Our People, Enhancing Our Economy, and Advancing Our International Interests* brought to the American public and policy makers an appreciation for America's direct stake in the health of people around the globe (IOM, 1997). More than a decade later, the IOM—with the support of four U.S. government agencies (the Centers for Disease Control and Prevention, Department of State, Department of Homeland Security, and National Institutes of Health) and five private foundations (the Bill & Melinda Gates Foundation, Burroughs Wellcome Fund, Google.org, Merck Company Foundation, and the Rockefeller Foundation)—convened an expert committee to revisit the U.S. commitment to global health and articulate a fresh vision for future U.S. investments and activities in this area. (See Appendix A for the official committee Statement of Task.)

To coincide with the U.S. presidential transition, the IOM committee prepared an initial report outlining its ideas for the U.S. government's role in global health under the leadership of a new administration, *The U.S. Commitment to Global Health: Recommendations for the New Administration* (released on December 15, 2008) (IOM, 2009). This is the committee's final report; it communicates specific recommendations, not just for the U.S. government, but also for several nongovernmental sectors, including foundations, universities, other nonprofit organizations, and commercial entities. (For more information on the committee's approach to the study process see Box 1-1.)

BOX 1-1

The Committee's Approach to the Study Process

The Institute of Medicine formed a 17-member committee in March 2008 to examine the U.S. commitment to global health and make recommendations for future action in this area. (Committee member biographies are provided in Appendix B.) The study process consisted of three committee meetings—two of which included outside speakers—and four public working group meetings in Washington, DC. Over the course of the study process, the committee heard public testimonies from 75 global health experts and received input from numerous organizations.

The first committee meeting, held in March 2008, featured the project sponsors and other eminent figures in global health to discuss the committee's charge and the role of the United States in global health broadly. At the second committee meeting in July 2008, the committee heard from a range of experts on opportunities to strengthen health systems in low- and middle-income countries. The third committee meeting was held in October 2008 in closed session to formulate recommendations and draft this report. (Public committee meeting agendas can be viewed in Appendix C.)

To provide more detailed input into the committee's deliberations, the committee formed four working groups to concentrate on key areas in global health: human and financial resources for global health; U.S. engagement in global health governance; gaps and priorities in U.S. contributions to global disease challenges; and the creation and diffusion of knowledge in global health. (Public working group meetings can be viewed in Appendix D.)

In June 2008, the human and financial resource working group held a public meeting on human resources for health in low- and middle-income countries, with presentations from experts on human resource migration and capacity building. The working group considered the effect of health sector human resource deficits on health outcomes and how the United States can support country efforts to implement human resource plans.

DEFINING GLOBAL HEALTH AND THE SCOPE OF THIS REPORT

Global health is the goal of improving health for all people in all nations by promoting wellness and eliminating avoidable disease, disabilities, and deaths. It can be attained by combining population-based health promotion and disease prevention measures with individual-level clinical care. This ambitious endeavor calls for an understanding of health determinants, practices, and solutions, as well as basic and applied research on disease and disability, including their risk factors. Although global health encompasses the health of everyone (including U.S. citizens) and is a shared global aspiration that requires the work of many nations, this report focuses only on the efforts of the United States, both its governmental and its nongovernmental sectors, to help improve health in low- and middle-income countries.

Also in June 2008, the global health governance working group convened a public meeting on the U.S. engagement in global health governance, with speakers representing major intergovernmental organizations such as the World Health Organization and the World Bank, as well as representatives from civil society, industry, public-private partnerships, and academia. Mr. Lawrence Gostin, Linda D. and Timothy J. O'Neill Professor of Global Health Law at Georgetown University Law School, was commissioned by the committee to provide a background paper on the state of global health governance (see Appendix E).

In July 2008, the working group on global disease challenges held a meeting on the gaps and priorities in U.S. contributions to global disease challenges, building on the work of the Disease Control Priorities Project. Meeting presenters included distinguished academics and practitioners to discuss prominent diseases and disabilities, and their risk factors, as well as the effect of weak health systems on delivering interventions.

In April 2009, the working group examining the creation and diffusion of knowledge hosted a public consultation to gather information on capacity building, knowledge sharing, and novel models of collaboration in global health research. Dr. Anthony So, director of the Program on Global Health and Technology Access at the Sanford School of Public Policy at Duke University, was commissioned by the committee to provide a background paper on sharing research knowledge for global health (see Appendix F).

As outlined in the study statement of task, the IOM commissioned the Program on International Policy Attitudes to conduct an opinion poll of the American public to understand its views on the U.S. commitment to global health. The results of the poll can be viewed at www.worldpublicopinion.org.

Findings from the public testimonies, commissioned works, and information provided to the committee by outside stakeholders and organizations informed the committee's deliberations, the content of this report, and the final recommendations for how the United States should invest in global health interventions, research, and capacity building over the coming decade.

Greater Opportunities for Meaningful Partnerships

Progress in global health and development has challenged the traditional thinking in foreign assistance. In the last century, and even today, it has been quite common to divide the world into “North” and “South” when referring to “developed” and “developing” countries. This nomenclature ignores major economic, demographic, and social changes of the last decades. In the past, there were two clear categories of rich and poor; today, some poor countries (mostly in Africa) have become poorer, while the majority of rich countries have become richer. However, several countries have since sharply improved their economic situation and acquired the label of “emerging economies,” rendering the earlier terms less relevant.

The growing importance of the G20 is one clear indication that countries

such as Brazil, India, South Africa, Egypt, and China should be playing a greater role in partnering with countries to improve health outcomes and reduce poverty. The emerging economies not only bring additional resources but also bring experience that may help bridge any gap in understanding between the wealthy and the least wealthy nations. These partners can bring creative thinking about how to deliver and develop interventions that are geared toward settings that may have limited infrastructure and human and financial resources. For this reason, the committee adopted the terms low-, middle-, and high-income countries to more appropriately portray the countries involved in global health progress.

Global Health Is Inextricably Linked to Broader Development Agenda

The modern era of global health is distinguished by the commonly accepted view that health is inextricably connected to the broader development and poverty agenda (Bloom and Canning, 2000). Policies that promote unsanitary living conditions and inadequate nutrition, limit access to clean water and quality health systems, stifle economic and educational opportunity, and disregard discrimination and inequity undermine individual and population health. The realization that policy choices in *all* sectors have the potential to affect health was the topic of an extensive study by the World Health Organization (WHO) to examine the social, economic, environmental, and political determinants of health. WHO's recommendations (see Box 1-2) are consequently far-reaching and require considerable investment, major change, and most importantly, political will, even as they draw attention to the need for a comprehensive multisector approach to global health that reaches well beyond the health sector (Marmot et al., 2008).

The IOM committee recognizes that any action taken by the United States to support global health should be tied directly to broader discussions of U.S. commitments to global economic and human development, as well as the environment (though these areas are beyond the scope of this report). The committee also recognizes that while the United States has the opportunity to support and advocate for a global agenda to improve health, ultimately individual countries—both governments and civil society¹—are responsible for putting in place the social and economic policies that protect the health of their populations (CSDH, 2008).

Global Health Inequities Persist Along with Dramatic Improvements

A failure on the part of governments, civil society, and global institutions to enact “healthy” policy choices has contributed to global inequities in health and

¹ To safeguard the health of their citizens, governments need to be supportive of civil society, which can play a powerful role in channeling the preferences and needs of a population (Blas et al., 2008). Civil society also has the potential to advocate for the underserved and neglected and to hold governments accountable for health inequalities (Lancet, 2008).

BOX 1-2
WHO Commission on the Social Determinants of Health

In 2005, WHO established the Commission on the Social Determinants of Health to “ensure that all people have the chance to lead healthy lives” (Friel et al., 2008) and to “marshal the evidence on what can be done to promote health equity and to foster a global movement to achieve it” (Marmot et al., 2008). The social determinants of health are “aspects of people’s living and working circumstances and . . . their lifestyles” that may initially seem outside the realm of health but, in reality, impact the burden of disease and cause of mortality across populations (WHO, 2003).

More than 350 researchers, practitioners, policy makers, civil society representatives, and representatives from 100 institutions in both high-income and resource-limited countries evaluated the impact made on the social determinants of health by the actions of governments, civil society, and international institutions (Blas et al., 2008). In August 2008, the commission identified the following three principles to guide governments, international agencies, and civil society in closing the health equity gap within the next generation:

1. *Improve daily living conditions.* Improve the well-being of girls and women, put major emphasis on early childhood development and education, improve living and working conditions, provide social protection policies, and create conditions for a secure life for the elderly. Policies to achieve these goals would involve civil society, governments, and global institutions.
2. *Tackle the inequitable distribution of power, money, and resources.* Address inequities, such as those between men and women, in the way society is organized. In addition to a committed and adequately financed public sector, this would require strengthened governance that provides legitimacy for civil society, rules for an accountable private sector, and support for people to invest in collective action in the public interest.
3. *Measure and understand the problem and assess the results of action.* National governments and international organizations, with the support of WHO, should set up national and global surveillance systems for routine monitoring of health inequity and should evaluate the health equity impact of their own policies and actions. This requires investment in the training of policy makers and health practitioners in understanding the social determinants of health and a strong focus on taking these determinants into account in public health research.

SOURCE: Adapted from the CSDH, 2008.

development both within and across countries. A girl born in Sierra Leone can expect to live only half the lifetime (42 years) of a girl born in Japan (86 years), and the chance of a child’s dying before age 5 in Angola is nearly 90 times higher than in Finland or Iceland (WHOSIS, 2008). Marked inequities in health can be seen even within wealthy countries such as the United States.

Yet despite the persisting health, social, and economic inequities worldwide, the committee finds that global health achievements in the last 50 years have been remarkable (Laxminarayan et al., 2006); global life expectancy has increased more in this period than in the preceding 5,000 years.² Average life expectancy—the age to which a newborn baby is expected to survive—was approximately 40 years in low- and middle-income countries in 1950; it is now about 65 years, having risen more than 60 percent (Levine, 2008; McNicoll, 2003).

Most of the improvements in life expectancy are derived from reduced health risks for young children. Since recordkeeping on child mortality began in 1960 (when 20 million children died annually, with 180 deaths per 1,000 live births), the number of children dying before their fifth birthday has been reduced by more than half, to 9.2 million in 2007 (72 deaths per 1,000 live births) (UNICEF, 2007, 2008).

Knowledge and Its Dissemination a Main Driver of Health Improvements

Contrary to expectation, increased wealth is not always the main driver for improved health outcomes. For example, levels of child survival in Niger and Eritrea are 74 and 91 percent, respectively, even though these countries have similar levels of gross domestic product (GDP) per capita (see Figure 1-1). India has the same child survival rate as Eritrea although its GDP per capita is three times higher. Vietnam has the same income per capita as India but a higher child survival rate (98 percent). Strikingly, the poorest 20 percent of Vietnam has higher child survival rates than the richest 20 percent of India (Gapminder, 2008). Economic well-being, then, is not a sound predictor of health status. In fact, economic growth has been shown to account for less than half of the health gains in low- and middle-income countries between 1952 and 1992 (Jamison et al., 2008; WHO, 1999).

Instead, technological innovation and the diffusion and adoption of knowledge have been the main drivers for improved and prolonged lives in even the most impoverished settings (Davis, 1956; Global IDEA Scientific Advisory Committee, 2004; Jamison, 2006; Jamison et al., 2008). Simple and cost-effective interventions such as the introduction and widespread use of vital vaccines and antibiotics, along with advances such as access to clean water, good sanitation practices, and improved nutrition, have been found to help save lives in countries around the world during any phase of economic development.

Globalization has greatly helped to diffuse knowledge about the best interventions, as well as the methods for their delivery. For example, diarrhea-related

² Gains in life expectancy are the result of an epidemiological transition—the shift from infectious (communicable) diseases to chronic noncommunicable diseases, which typically lead to death later in life than infectious diseases. This transition has allowed the aging of populations and reflects public health successes in the prevention and control of infectious diseases and child deaths (Beaglehole and Bonita, 2008; Mathers and Loncar, 2006).

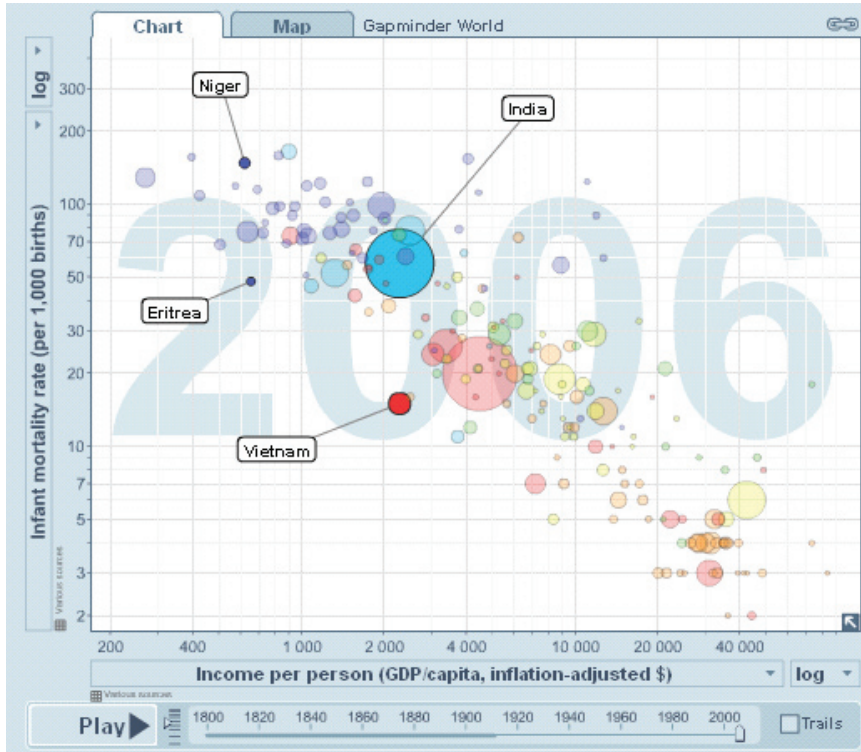


FIGURE 1-1 Infant mortality rates by income per person.

NOTE: This figure reveals the relationship between income per person (GDP per capita) and infant mortality rates (per 1,000 births) for 2006. Each circle represents a country, and the size of the circle is relative to its population size. For example, Niger and Eritrea have similar population sizes and income per person, but Niger’s infant mortality rate (148/1,000) is more than three times that of Eritrea (48/1,000). Vietnam and India have the same income per capita, but India’s population is much greater and its child mortality rate is quadruple that of Vietnam.

SOURCE: Gapminder, 2008.

deaths among children have fallen by several million a year, partly as a result of the development of oral rehydration therapy, much of which was the product of work from research laboratories in Bangladesh that was adopted on a global scale (see Table 1-1 for other examples) (Global IDEA Scientific Advisory Committee, 2004).

Research indicates that “the pace of such dissemination in a country, and the willingness and ability of those who live there to act on the information, governs the rate of health improvement much more than the level of income”

TABLE 1-1 Example of Science Contribution to Decline in Infectious Disease Mortality in the Twentieth Century

Condition and intervention	Annual deaths before intervention (reference year)	Annual deaths after intervention (reference year)
<i>Polio, diphtheria, pertussis, tetanus and measles</i> —immunization programs	~5,200,000 (1980)	1,400,000 (2001)
<i>Small pox</i> —eradication campaign	~3,000,000 (1950)	0 (1979)
<i>Diarrhea</i> —oral rehydration therapy	~4,600,000 (1980)	1,600,000 (2001)
<i>Malaria outside Africa</i> —residual indoor spraying and acute management	~3,500,000 (1930)	<50,000 (1990)
<i>Malaria in Africa</i> —limited use of residual indoor spraying and acute management	~300,000 (1930)	1,000,000 (1990)

SOURCE: Global IDEA Scientific Advisory Committee, 2004.

(Laxminarayan et al., 2006). A study examining infant mortality in 70 low- and middle-income countries revealed that even in periods of rapid economic growth, the diffusion of technology and educational improvements were far more important than income changes in explaining why infant mortality rates varied across countries (Jamison et al., 2004). These findings have been borne out by the experiences of European countries in the late nineteenth and early twentieth centuries and, more recently, of countries such as Bangladesh, Costa Rica, and Sri Lanka, where appropriate and timely policies have greatly reduced mortality even without high or rapidly growing incomes (Laxminarayan et al., 2006).

Therefore, while governments, civil society, and global institutions should continue to promote economic development, improve daily living conditions, and tackle inequity, the committee finds that immediate health gains (especially among the most disadvantaged populations) can be achieved by investing in sustainable and equitable systems to disseminate best practices, deliver cost-effective interventions, and develop future interventions. This report therefore focuses specifically on how the United States, by working with the governmental and nongovernmental sectors in low- and middle-income countries and with the international community, can advance global health by improving the delivery of effective interventions through the health sector.

BUILDING ON PRIOR SUCCESS AND NEW COMMITMENT TO STRENGTHEN GLOBAL HEALTH ACHIEVEMENTS

In the United States, an area of study, research, and practice has emerged to contribute to the achievement of global health. Termed the *U.S. global health enterprise*, it involves many sectors (both governmental and nongovernmental)

and disciplines (within and beyond the health sciences); it is characterized by intersectoral, interdisciplinary, and international collaboration. In preparing this report, the committee examined whether the existing architecture, investments, and activities of the U.S. global health enterprise are optimally geared to achieving significant, sustainable, and measurable global health gains.

Historically, the United States has contributed greatly to the achievement of global health gains, through both its governmental and its nongovernmental sectors, by working with partners around the world to develop and deliver cost-effective health interventions. While improving the health status for all people around the world will require a long-term and widely shared global commitment, the United States has the opportunity to take concrete steps toward this goal by building on past achievements, continuing successful partnerships, and leveraging new commitments to global health.

Significant U.S. Role in Global Health Progress

The United States has been an important source of global health knowledge, providing the scientific basis for many health successes worldwide through the research and capacity building efforts of its governmental and nongovernmental sectors. The United States has also played a critical role in the dissemination and adoption of knowledge to improve health in low- and middle-income countries, often in partnership with other countries and intergovernmental organizations.

Underlying several global health successes is the strong U.S. commitment to research, especially in the fields of science and medicine. The National Institutes of Health (NIH) and the National Science Foundation in collaboration with researchers at universities have provided the foundation for many public health and clinical discoveries that have a global impact. For example, the National Institute of Allergy and Infectious Diseases at NIH has supported scientists in conducting a broad portfolio of infectious disease research from diagnosing pandemic influenza to treating HIV/AIDS.

Another example of U.S. research with significant global benefit is the story of vitamin A. The distribution of this simple pill, which costs about 2 to 3 cents per capsule, as part of a supplementation program in low-resource settings was found to save the lives of millions, reducing child mortality by as much as 23 percent (Beaton, 1993; Fawzi et al., 1993; Glasziou and Mackerras, 1993; Sommer et al., 1983; Tonascia, 1993). Today, as a vital component of child survival strategy, more than 60 nations have vitamin A supplementation programs; many of these are supported by the U.S. Agency for International Development (USAID) (McCarthy, 2005). Research and programming by USAID have also contributed to other significant public health gains, such as the use of oral rehydration salts, which have reduced deaths from diarrheal dehydration by 82 percent among infants in countries such as Egypt (Levine, 2008; NRC, 2006).

The Centers for Disease Control and Prevention (CDC) has also played a historic role in global health progress, achieving remarkable successes such as

the worldwide eradication of smallpox and eliminating polio in many parts of the world, in partnership with other entities (Levine, 2008). In addition to its part in controlling and preventing infectious diseases, the CDC developed the Global Youth Tobacco Survey, in collaboration with WHO, to monitor tobacco use among youth in 140 countries. This surveillance system has played a key role in guiding national tobacco prevention and control programs in low- and middle-income countries (CDC, 2007).

The Department of Defense (DoD) is also an important player in infectious disease research and surveillance. The Military Infectious Diseases Research Program (MIDRP) develops vaccines and drugs to prevent and treat diseases that are important to the U.S. military, while the DoD-Global Emerging Infections Surveillance and Response System collects and analyzes epidemiological data to help control major infectious diseases in low- and middle-income countries. While currently engaged in the worldwide search for a malaria vaccine, MIDRP has already played a significant role in the development of several lifesaving vaccines (USAMRMC, 2007).³

A model of how cutting-edge science and regulatory activity can work to improve public health on a global scale was provided by the Food and Drug Administration (FDA) when a pharmaceutical ingredient (heparin) from China mysteriously caused hundreds of deaths worldwide (Blossom et al., 2008; Schwartz, 2008). The FDA worked with academic and industrial scientists to find the bacterial contaminant in Chinese heparin and moved quickly to ensure that the incoming supply was safe.

The U.S. commercial and nonprofit sectors have also been instrumental in achieving many global health successes. In an ambitious effort involving the pharmaceutical company Merck & Company, Inc., river blindness (onchocerciasis) has been virtually eliminated in West Africa. The program was led by WHO and included a host of countries and agencies, such as the World Bank, the Food and Agriculture Organization, and the United Nations Development Programme. Merck's donation of the drug Mectizan for 45 million people—combined with a grassroots effort by village volunteers and aerial spraying with environmentally safe insecticides—was critical to the program's success (Levine, 2008). This Mectizan Donation Program, now in effect for more than 20 years, is the largest ongoing disease-specific drug donation program in history (Colatrella, 2008; Merck & Co., Inc., 2008; Thylefors et al., 2008).

Similar efforts to eradicate disease in sub-Saharan Africa have been led by other U.S. organizations. The Carter Center leads an ambitious program to eradicate guinea worm disease (dracunculiasis), an affliction that has existed since ancient times and one that causes devastating disability, pain, and infection. The program is supported by the Bill & Melinda Gates Foundation and implemented through an international coalition comprising WHO, CDC, the United

³ Rubella (1969), adenovirus 4 and 7 (1980), tetravalent meningococcal bacteria (1981), hepatitis B (1981), oral typhoid (1989), Japanese encephalitis (1992), and hepatitis A (1995).

Nations Children's Fund (UNICEF), and several countries. The program—to provide clean water and health education and to contain and manage guinea worm cases—has already succeeded in reducing the prevalence of this disease in Africa by 99.7 percent (Levine, 2008).

Many other examples of success through partnership can be found, especially among vaccination programs. PolioPlus, the most ambitious program in the history of Rotary International, is the volunteer arm of the global partnership dedicated to eradicating polio (Rotary International, 2009). In the last 20+ years, Rotary (in partnership with UNICEF, WHO, and CDC) has vaccinated more than 2 billion children and prevented 5 million cases of paralysis (International Polio-Plus Committee, 2009). The Measles Initiative partnership (a collaboration of the American Red Cross, CDC, the United Nations Foundation, UNICEF, and WHO) is another example of a successful partnership that reduced measles deaths by 74 percent worldwide and by 89 percent in Africa (Measles Initiative, 2008).

As these examples demonstrate, U.S. government institutions have worked alongside U.S.-based foundations, nongovernmental organizations, universities, and commercial entities to provide the technical and financial resources necessary to expand public health infrastructure, increase access to health interventions, and improve health globally. These initiatives—often undertaken in partnership with local organizations, foreign governments, and intergovernmental organizations—are widely regarded as some of the most successful public-private health collaborations in the world.

Unprecedented Commitments to Global Health

The promise of potential solutions to global health problems has captured the interest of a new generation of philanthropists, private sector leaders, scientists, healthcare providers, students, and citizens—all eager to make a difference in this interconnected world. This attention is reflected in the record funding that global health has drawn in recent years, both from the U.S. government and from a variety of private sources, and in the growth and diversification of the U.S. global health enterprise.

U.S. Government Investment in Health at All-Time High

Over the last decade, the U.S. government has made record commitments to global health, in keeping with the nation's rising interest in the well-being of populations around the world. In 2009, U.S. global health funding reached an all-time high of \$8.186 billion (White House, 2009). This extraordinary increase was driven mostly by new models of assistance, such as the Global Fund to Fight AIDS, Tuberculosis, and Malaria (Global Fund) and the President's Emergency Plan for AIDS Relief (PEPFAR).

Between 2001 and 2003, the United States spent \$3.5 billion on the global fight against AIDS; since the inception of the Global Fund in 2002 and PEPFAR

in 2004, the United States has spent a combined total of more than \$25 billion on AIDS (PEPFAR, 2008, 2009). PEPFAR constitutes the largest commitment ever by any nation to a global health initiative dedicated to a single disease (White House, 2008). PEPFAR's achievement—bringing lifesaving drugs to 2.1 million people and more than quadrupling the number of HIV-infected people receiving treatment in sub-Saharan Africa in 2003 (PEPFAR, 2009)—demonstrated the success the United States is capable of achieving when it seriously commits to improving health outcomes.

Other major health initiatives by the U.S. government include two five-year programs: the President's Malaria Initiative, which earmarks \$1.2 billion to halve malaria-related deaths in Africa, and the Neglected Disease Initiative, which commits \$350 million to target tropical diseases, mainly through affordable treatment made possible by drug donations from manufacturers. Global health is also part of the U.S. government's Millennium Challenge Corporation, which aims to reduce global poverty through the promotion of sustainable economic growth.

U.S. investments in global health have come to form a prominent part of U.S. foreign policy. Repeated polls in the last few years have shown public support for this approach, with health now ranking among Americans' top priorities for development assistance—not merely to protect U.S. interests, but also as a way of promoting human development worldwide (Research!America, 2006; WorldPublicOpinion.org, 2009).

Increased Resources for Global Health from Philanthropy

U.S.-based grant-making institutions have a long tradition of making significant contributions to global health successes. The Rockefeller Foundation has launched programs since 1913 to address hookworm, malaria, and yellow fever, funding some of the earliest research on such diseases and establishing many of the world's first public health schools (Rockefeller Foundation, 2009). The Ford Foundation began making grants for welfare projects in 1936 (Ford Foundation, 2009).

Exceptional philanthropic commitments have recently been made to further combat disease and resolve healthcare delivery problems. Between 1995 and 2005, total charitable giving by U.S. foundations tripled (Garrett, 2007). Extraordinary wealth creation in recent years has produced a large number of extremely wealthy individuals with an interest in philanthropy that “involves using money for maximum impact by investing in potentially disruptive technologies⁴ . . . and

⁴ A disruptive technology or disruptive innovation is a technological innovation, product, or service that overturns the existing dominant technologies or products in a market by using a “disruptive” strategy (e.g., a pre-exposure prophylactic product to prevent HIV infection), rather than a “sustaining” strategy such as a latex condom to prevent HIV infection.

in social enterprises that can be scaled up as required”; the result has been “financial rigor as well as an appetite for risk” (Do it right, 2008).

The most notable example of private philanthropy has been the Bill & Melinda Gates Foundation. Now the world’s largest charitable organization (Garrett, 2007; Okie, 2006), this foundation has added unprecedented resources to the pool of available grant money. It nearly doubled its global giving between 2002 and 2004 to \$1.2 billion (Rose et al., 2008), but after a recent contribution from the financier Warren Buffett, it is expected to increase its total giving to \$3.8 billion, spending approximately half of this on global health programs (Gates, 2009).

Increasingly, many well-established foundations are turning their attention to global health; this is especially true for foundations focused on domestic science and health research, such as the Burroughs Wellcome Fund (1955) and the Doris Duke Charitable Foundation (1996). New foundations are also joining in existing global health efforts, such as the Google Foundation (2005) and the Clinton Global Initiative (2005).

Increased Resources from Growing Number of Nonprofits Involved in Global Health

Perhaps not surprisingly, the number of U.S. nonprofits engaged in global health has also increased. U.S. nonprofits spent an estimated \$1.9 billion on global health programs in 1995, of which approximately 70 percent (\$1.3 billion) was privately funded, with the remainder coming from the U.S. government. In 2005, U.S. nonprofits contributed \$5.7 billion to global health, of which 76 percent was privately funded (\$4.3 billion) (Rose et al., 2008). Of the 556 nonprofit organizations registered with USAID, 411 (or 74 percent) report working in global health (Rose et al., 2008).

Catholic Relief Services (1943), CARE (1945), and World Vision (1950) are a few examples of international nonprofits that have long served at the forefront of humanitarian efforts—aiding in emergency relief, food security, poverty reduction, and economic development. Yet many new nongovernmental organizations devoted to global health have emerged in the last decade; some of these organizations, such as GAIN (2002), are building public-private partnerships to counter specific problems such as malnutrition, while others have joined together with the ONE (2004) advocacy campaign to broadly fight preventable diseases and end poverty. A recent, private sector initiative called the Global Health Corps was created with the aim of building a pipeline of new global health leaders by funding promising young adults (applicants must be under 30 years of age) to work with selected partner organizations in low-income countries for one year (Global Health Corps, 2009).

Public-Private Partnerships for Innovative Financing

In the last decade, many new organizations have taken the form of public-private partnerships (PPPs), which have changed the landscape for global health and for infectious diseases in particular (Barr, 2007; Widdus, 2005). As of 2004, the database of the Initiative on Public-Private Partnerships for Health (at the Global Forum for Health Research) listed 91 international partnerships in the health sector, of which 76 are dedicated to infectious disease prevention and control, notably against acquired immunodeficiency syndrome (AIDS), tuberculosis (TB), and malaria (Nishtar, 2004). Two of the largest such PPPs are the Global Alliance for Vaccines and Immunization (GAVI) and the Global Fund to Fight AIDS, Tuberculosis, and Malaria (Global Fund).

GAVI is a partnership that includes low-, middle-, and high-income country governments, their vaccine industries, several research and technical institutes, civil society organizations, the Bill & Melinda Gates Foundation, WHO, UNICEF, and the World Bank. GAVI is committed to delivering stable aid flows, with a particular focus on reducing child mortality by increasing access to immunization in poor countries. While working with innovative finance mechanisms that link its diverse partners, GAVI also accepts direct contributions from industrialized countries, 67 percent of which are multiyear commitments with at least three-year terms (GAVI Alliance, 2009).

The Global Fund works in partnership with industrialized donor countries, recipient countries, private foundations, industry, and multilateral organizations to finance programs that support the prevention and treatment of AIDS, TB, and malaria. The U.S. government provided the founding pledge to the Global Fund in 2002, and it continues to provide nearly one-third of all Global Fund contributions through PEPFAR (Friends of the Global Fight, 2007). Although primarily supported by high-income countries, the Global Fund also receives funding from private foundations, as well as from innovative finance mechanisms.

Public-Private Product Development Partnerships to Tackle Neglected Diseases

One of the most promising approaches to address the enormous and widening gap in the availability of drugs, vaccines, and diagnostics to deal with the global disease burden is the emergence of a type of PPP known as a product development partnerships (PDP). Tapping philanthropic and government financing, PDPs create innovative business models that bring cutting-edge technology to bear on some of the world's most devastating scourges (Matlin et al., 2008; McKerrow, 2005). In many instances, PDPs are virtual pharmaceutical and biotechnology partnerships driven by the commitment to a single goal: the development of products for which there is little potential financial return on investment.

Several PDPs have emerged over the past decade to deal with global health challenges (Widdus, 2005), creating an infrastructure on which future investments can build. In 2007, nearly one-third of grants for biomedical research

for AIDS, TB, malaria, and other neglected diseases were routed through PDPs and other intermediary organizations, representing nearly 25 percent of product investments (\$577 million) (Moran et al., 2009).

Business Acumen for Global Health

The commercial sector is using these new models of collaboration to respond to opportunities to apply technology and business acumen to enduring social problems. Many companies have initiated socially responsible programs in the field of health. The importance of such corporate social responsibility or corporate citizenship has increased over the last decade, with a corporation's reputation increasingly under scrutiny by nongovernmental organizations and individual consumers.⁵ In 2007, 95 percent of CEOs surveyed by McKinsey & Company stated that "society now has higher expectations of business taking on public responsibilities than it did five years ago" (Franklin, 2008).

For example, (RED) is a business model that appeals to a consumer's social conscience to direct money to the Global Fund ((PRODUCT)RED, 2008). Prominent companies such as Gap and Starbucks pay (RED) a fee to carry the Product (RED) label on some of their products. In return for the opportunity to increase their revenue through sales of these products, a percentage of the proceeds is donated to the Global Fund.

Corporate social responsibility has resulted in greater financial and technical investments in global health research and programming by corporations. Between 2001 and 2003, the pharmaceutical industry increased its global health spending nearly threefold, from \$564 million to \$1.4 billion (PhRMA, 2003, 2004). Increasingly, other industries are also becoming engaged in this field. Two recent cases are ExxonMobil's establishment of the Africa Health Initiative in 2000 to fund and support activities related to the prevention, control, and treatment of malaria (ExxonMobil, 2008) and Procter & Gamble's initiative to provide safe drinking water to more than a million African children (Procter & Gamble Company, 2006). The Global Business Coalition on HIV/AIDS, Tuberculosis, and Malaria (GBC)—a nonprofit comprised entirely of businesses—applies its resources in partnership with other nongovernmental organizations, multilaterals, and governments (GBC, 2009).

New Business Models for Profit and for Global Health

Driven by the idea that society's most pressing social problems can be solved by innovative solutions using a sustainable business model, some businesses are combining profit with a social mission. The Grameen Danone Foods Social

⁵ Interestingly, the value of corporate citizenship to companies remains debatable: a meta-analysis of 167 studies over 35 years found a positive but weak link between social and financial performance (Margolis et al., 2007).

Business Enterprise in Bangladesh, for example, is a collaborative effort to bring nutrient-rich and affordable yogurt to low-income populations in Bangladesh, while also promoting a sustainable and socially conscious business model (Graameen Trust, 2006).

InnoCentive is a web-based platform that connects seekers faced with scientific challenges (such as governments, corporations, and foundations) to solvers (such as scientists, technologists, and businessmen). InnoCentive, with its network of 170,000 solvers from around the globe, helps to lower the transaction costs of product development. For example, InnoCentive brought together a seeker—the Global Alliance for TB—with a solver—a young man from India whose mother contracted TB when he was a child—to overcome a cost barrier in the product development process that would have prohibited the use of the TB drug in low- and middle-income countries (Bingham, 2009).

Global Health on the Academic Agenda

On American university campuses, the study of global health has flourished, with a globally oriented student body demanding a curriculum that reflects its interests and career aspirations. Unprecedented energy and enthusiasm for this field can be seen among students, as well as among medical residents and faculty. For example, data from the Association of American Medical Colleges (AAMC) show that the percentage of U.S. senior medical students participating in global health experiences increased from 8 percent in 1986 to 28 percent in 2008 (AAMC, 1986, 2008) and two-thirds of U.S. medical schools now provide courses in global health.

Universities are increasingly interested in global health efforts because the resulting initiatives are socially beneficial and foster institutional growth and development. Both learners and institutions gain from a greater awareness of global health issues that help them better understand issues in their own institutions and communities, which are becoming more global as the population continues to diversify (Kanter, 2008).

University global health programs range in scope from individual courses to comprehensive, multidisciplinary, multiprofessional initiatives that often include patient care, research, and education components. This interest is evident in university curriculums and in the many research alliances focused on global health initiatives spanning universities and research institutes. The larger initiatives include alliances with schools of public policy, engineering, law, environment, theology, and business, as well as partnerships with non-U.S. institutions (Kanter, 2008).

FUTURE COMMITMENTS TO GLOBAL HEALTH

Progress toward global health requires collaboration between many partners—donors, recipient country governments, and implementing agencies—to

develop, finance, and deliver essential and cost-effective health interventions. The United States can, however, lead by setting an example of meaningful financial commitments, technical excellence, and respectful partnership. By building on past achievements, continuing successful partnerships, and leveraging new commitments to global health, the United States has the opportunity to move the world closer to the ultimate goal of improved health for all.

The committee finds that progress in health over the last half-century can mostly be attributed to the creation, dissemination, and adoption of interventions to improve health. Simple and cost-effective interventions can help save lives in countries around the world during all phases of economic development. Immediate health gains, especially for the most disadvantaged populations, are therefore possible but will require investments in sustainable and equitable systems to deliver cost-effective interventions (and develop future interventions). Such investments should be made alongside the efforts by governments and civil society to monitor the social determinants of health within their countries to tackle inequity and improve daily living conditions.

This report focuses specifically on how the United States and the international community can work with the governmental and nongovernmental sectors in low- and middle-income countries to improve their healthcare sectors and so advance global health. The committee examined many ways in which the United States, including its governmental and the nongovernmental sectors, could contribute to these advances. The committee focused on areas in which the United States can draw on its comparative advantage, such as research, technology, or resources, to capitalize on the growing interest in its universities, foundations, and commercial entities to address significant bottlenecks in improving global health. The committee identified five areas for action by the U.S. global health enterprise:

1. Scale up existing interventions to achieve significant health gains.
2. Generate and share knowledge to address problems endemic to the global poor.
3. Invest in people, institutions, and capacity building with global partners.
4. Increase U.S. financial commitments to global health.
5. Set an example of engaging in respectful partnerships.

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2

Scale Up Existing Interventions to Achieve Significant Health Gains

The global health community has reached a critical juncture. Knowledge, innovative technologies, and proven tools to help millions of people are within reach. Yet despite demonstrated success in tackling certain health issues, the gap continues to grow between what *can* be done with existing knowledge, and what *is* actually being done in disadvantaged communities. Existing interventions are not widely used even though many are inexpensive and easy to administer (Bryce et al., 2003; Jamison, 2006). In the area of child mortality, for example, the tremendous gains made in child survival over the past half-century—due to interventions such as vaccinations and dietary supplementation strategies—have actually slowed or been reversed since the mid-1990s (Ahmad et al., 2000).

At the same time, chronic diseases such as diabetes and heart disease have joined the list of infectious diseases traditionally found in low- and middle-income countries, in an extraordinary global epidemiologic transition (Abegunde et al., 2007; Jamison, 2006; Laxminarayan et al., 2006; Omran, 1971). Steps are thus required to address this double burden of disease, as well as to combat emerging infectious threats such as pandemic flu. If the global community neglects its responsibilities at this critical moment, health outcomes for the most vulnerable populations will remain static or decline, progress achieved in poverty reduction thus far will be threatened, and the poorest countries will continue to be left behind.

ACHIEVE THE MILLENNIUM DEVELOPMENT GOALS BY 2015

The globally recognized Millennium Development Goals (MDGs) were adopted by Member States of the United Nations (UN) in 2000 to achieve demon-

strable reductions in poverty and improve specific health outcomes by 2015. Three of the eight goals pertain directly to health (Goals 4, 5, and 6); the other five, indirectly (see Box 2-1). Although progress has been made, as discussed below, the MDG targets remain a distant goal for many countries, particularly in sub-Saharan Africa and parts of South Asia (UNICEF, 2008).

MDG 4: Reducing Child Mortality

Global child mortality rates have dropped steadily over the last 50 years. Between 1960 and 1990, the rates of decline in worldwide child mortality averaged 2.5 percent per year. By contrast, from 1990 to 2001, the rates of decline averaged 1.1 percent per year. Although this deceleration might be expected in regions that had already achieved low mortality rates, such slowing has also occurred in high-rate regions (Black et al., 2003; Sepúlveda et al., 2006).

Between 1990 and 2006, about 27 countries—the large majority in sub-Saharan Africa—made little or no progress in reducing childhood deaths (see Figure 2-1) (UN, 2008b). In 2005, only 7 of the 60 countries that account for more than 94 percent of child deaths in the world were on track to reach MDG 4 (Bryce et al., 2006). While progress has been made in important areas—for example, deaths from measles fell by two-thirds between 2000 and 2006 due to dramatically improved vaccination programs covering 80 percent of children in

BOX 2-1

United Nations Millennium Development Goals

- Goal 1 Eradicate Extreme Hunger and Poverty
- Goal 2 Achieve Universal Primary Education
- Goal 3 Promote Gender Equality and Empower Women
- Goal 4 Reduce Child Mortality
 - Target 1: Reduce by two-thirds the under-5 mortality rate
- Goal 5 Improve Maternal Health
 - Target 1: Reduce by three-quarters the maternal mortality ratio
 - Target 2: Achieve by 2015 universal access to reproductive health
- Goal 6 Combat HIV/AIDS, Malaria, and Other Diseases
 - Target 1: Halt and begin to reverse the spread of HIV/AIDS
 - Target 2: Achieve, by 2010, universal access to treatment for HIV/AIDS for all those who need it
 - Target 3: Halt and begin to reverse the incidence of malaria and other major diseases
- Goal 7 Ensure Environmental Sustainability
- Goal 8 Develop a Global Partnership for Development

SOURCE: UN, 2008a.

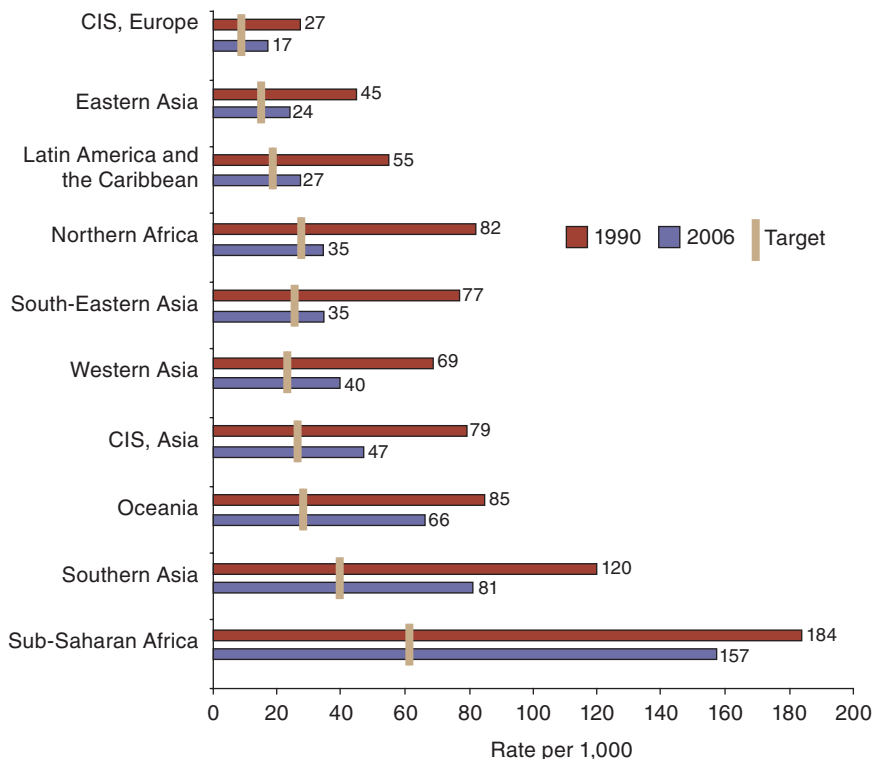


FIGURE 2-1 MDG 4: Deaths of children under 5 per 1,000 live births (1990, 2006, and 2015 target).
 SOURCE: UN, 2008b.

low- and middle-income countries (UN, 2008b)—the lack of well-functioning health systems in these countries severely constrains the delivery of many essential health interventions (Bryce et al., 2003). As a result, despite substantial attention from global health agencies, mortality of children less than 5 is projected to decline by only 27 percent between 1990 and 2015, substantially less than the MDG target of 67 percent (Murray et al., 2007).

While the causes of child death differ substantially from one country to another and therefore require a greater understanding of the epidemiology of child health at the country level (Black et al., 2003; Jones et al., 2003; Lawn et al., 2004), six causes account for 73 percent of the yearly deaths of children younger than 5: pneumonia (19 percent), diarrhea (18 percent), malaria (8 percent), neonatal pneumonia or sepsis (10 percent), preterm delivery (10 percent), and asphyxia at birth (8 percent); undernutrition is an underlying cause of more than half of all child deaths (Bryce et al., 2005). Diarrhea and pneumonia alone

account for 4 million child deaths each year, while an additional 11 million to 20 million children are hospitalized annually for pneumonia (Rudan et al., 2004).

At least one effective intervention is available for preventing or treating each main cause of death among children younger than 5 (apart from birth asphyxia) (Jones et al., 2003), and about 20 proven interventions available today are feasible for implementation in low-income countries at high levels of population coverage (Bhutta et al., 2008; Bryce et al., 2006; Darmstadt et al., 2005; Jones et al., 2003). Overall, existing health interventions could reduce child mortality by as much as 63 percent if they could reach those in need—children in the 42 countries that accounted for 90 percent of all childhood deaths in 2000 (Jones et al., 2003). These simple and cost-effective measures include promotion and support for breastfeeding; the management of diarrhea with low-osmolarity oral rehydration salts and zinc; the prevention of pneumonia and meningitis with *Haemophilus influenzae* type b (Hib) vaccine; the use of insecticide-treated bed nets; and supplementation with vitamin A, among others.

Achieving MDG 4 does not require a wait for new vaccines, drugs, or technology—although these should remain on the agenda in order to improve efficiency and effectiveness in the future; the requisite interventions are available now.

MDG 5: Improving Maternal Health

Outreach services can achieve impressive results when providing interventions such as vaccinations, but they offer little assistance in other medical cases such as childbirth or pregnancy complications, which require a functioning health service. Although maternal deaths represent only 1 percent of global mortality, 500,000 such deaths every year constitute a serious indictment of public health systems (Beaglehole and Bonita, 2008).

Maternal death rates are the largest inequity in health and vary enormously across countries, ranging from as low as 4 per 100,000 live births in Australia to 2,100 per 100,000 in Sierra Leone—a greater than five hundredfold difference (Beaglehole and Bonita, 2008; Gwatkin, 2004). Ninety-nine percent of maternal deaths occur in low- and middle-income countries (see Figure 2-2).

Progress has been slower for this MDG than for the others, especially in sub-Saharan Africa, suggesting that this issue is not yet firmly on the global agenda despite decades of effort (Shiffman and Smith, 2007). Only 47 percent of births in sub-Saharan Africa and 40 percent in South Asia are attended by a skilled professional. Meanwhile, progress in North Africa and Southeast Asia has been remarkable, demonstrating that substantial improvements are possible even in low- and middle-income countries (UN, 2008b).

Increasing the coverage of key maternal health provisions, including access to family planning services, skilled birth attendance, and obstetric services, would go a long way toward achieving MDG 5 (Ronsmans and Graham, 2006;

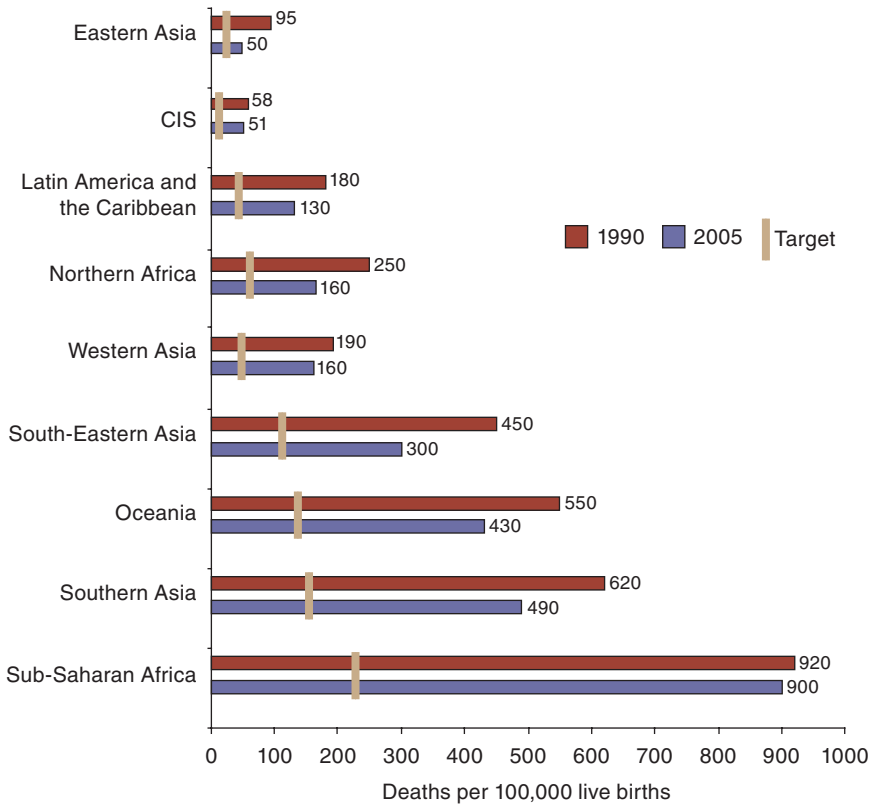


FIGURE 2-2 MDG 5: Maternal deaths per 100,000 live births (1990, 2005, and 2015 target).

SOURCE: UN, 2008b.

UN, 2008a). In low- and middle-income countries, about one-fourth of pregnancies are unintended (Haub and Herstad, 2002), highlighting the need for ways of avoiding them. Ensuring access to family planning and reproductive health for all women could help avoid up to 35 percent of maternal deaths (Belhadj and Touré, 2008). A commitment is also required to establish countrywide systems of qualified and adequately equipped personnel, along with an effective infrastructure that allows women to be referred and transported for emergency obstetrical care (Campbell and Graham, 2006; Ronsmans and Graham, 2006). Without these, one in six women living in the world’s poorest settings will continue to die from treatable or preventable complications in pregnancy and childbirth (Ronsmans and Graham, 2006).

MDG 6: Combating HIV/AIDS, Malaria, and Other Diseases

Recently, HIV/AIDS, malaria, and tuberculosis (TB)—often termed “the big three” because of their significant disease burden—have benefited from increased political commitments from the U.S. government’s bilateral program PEPFAR (President’s Emergency Plan for AIDS Relief); the international financing institution, the Global Fund to Fight AIDS, Tuberculosis, and Malaria (the Global Fund); and the World Bank’s Multi-Country HIV/AIDS Program for Africa, among others. A growing recognition of the enormous global impact of these three diseases has also led to an increase in research efforts, with philanthropies (such as the Bill & Melinda Gates Foundation) and U.S. government agencies (including the Centers for Disease Control and Prevention, the National Institutes of Health, and the U.S. Agency for International Development) galvanizing research that specifically targets the needs of populations in the world’s poorest settings.

HIV/AIDS Epidemic Continues to Be a Leading Cause of Death Worldwide

AIDS continues to be the leading cause of death in Africa and the sixth-largest killer worldwide (WHO, 2008b). Recent expansion of antiretroviral treatment for HIV-infected individuals through PEPFAR and the Global Fund, among others, has succeeded in reversing the direction of AIDS mortality; between 2005 and 2007, the number of people who died annually from AIDS declined from 2.2 million to 2 million (UNDP, 2008). However, in 2007, 2.7 million people were newly infected with HIV, signaling a failure to prevent the spread of the disease (UN, 2008b).

Despite the knowledge of successful, cost-effective strategies to prevent the transmission of HIV—condom use, reduction in the number of sexual partners, male circumcision, the prevention of mother-to-child transmission, and protection of the blood, organ, and tissue supply—the disease continues to spread at an alarming rate, especially among women in low- and middle-income countries (UNAIDS, 2008). Continued efforts to disseminate messages that motivate people to adopt these effective risk-reducing behaviors and interventions are critical (Coates et al., 2008; Potts et al., 2008; Wilson and Halperin, 2008).

New tools and strategies to prevent HIV infection through sexual transmission are also essential for halting the spread of the disease. Although condom effectiveness in preventing HIV transmission ranges from 80 percent (Weller and Davis-Beaty, 2002) to 94 percent (Hearst and Chen, 2004; Pinkerton and Abramson, 1997; Rutherford, 2008), sexual intercourse and condom use during the sex act are not always controlled by women. The development of HIV prevention products that do not require the cooperation or consent of one’s partner is thus critical (WHO, 2009c). Two experimental biomedical products that would greatly empower women (and men) to protect themselves and their

partners are microbicides—a compound that can be applied inside the vagina or rectum to protect against sexually transmitted infections, including HIV—and pre-exposure prophylaxis—a single drug, or a combination of drugs, to prevent infection (Lagakos and Gable, 2008). A vaccine to protect against HIV infection, while possibly decades away, would fundamentally alter the global response to the epidemic.

Malaria Results in One Million Deaths Every Year

Globally, more than 2 billion people are at risk of malaria each year (Snow et al., 2005). Despite dramatic reductions in malaria incidence and mortality in many parts of the world in recent years, approximately 500 million people still contract the disease, resulting in 1 million deaths annually (Greenwood et al., 2008). The threat of malaria has declined in many countries with high rates of infection due to the increased availability and accessibility of artemisinin-containing antimalarial drugs, and antimosquito measures such as long-lasting insecticide-treated nets (LLINs) and indoor residual spraying. A 2008 World Health Organization (WHO) report on the impact of LLINs and artemisinin-based combination therapies (ACTs) in four African countries found “strong initial evidence” in Rwanda and Ethiopia that the mass distribution of LLINs to children under 5 years of age, in combination with the distribution of ACTs nationwide, resulted in a dramatic decline of more than 50 percent in both in-patient malaria cases and malaria deaths (WHO, 2008d).

Nevertheless, new infections and re-infection continue, making a malaria vaccine of utmost importance. The vaccine candidate RTS,S has been found to reduce malaria incidence among children by more than 50 percent in two Phase II field trials.¹ This vaccine, which can be administered safely with other childhood immunizations, functions by halting malaria parasite replication in the liver (Abdulla et al., 2008; Bejon et al., 2008). Should the upcoming large-scale Phase III trials be successful, the RTS,S vaccine could be licensed by 2011 and available by 2012, providing a powerful tool in conjunction with additional malaria interventions (Engel, 2008).

Tuberculosis Demands Improved Prevention, Diagnostic, and Treatment Options

Despite the slow global decline in TB incidence per capita (less than 1 percent each year), the disease still kills 1.7 million people annually (WHO, 2008c). Between 1990 and 2003, the incidence of TB remained stable in all regions except Africa and the former Soviet republics and even rapidly declined

¹ The RTS,S vaccine was developed in 1987 by the Walter Reed Army Institute of Research and GlaxoSmithKline (Basu, 2007) and later received support from the PATH Malaria Vaccine Initiative and the Bill & Melinda Gates Foundation.

in emerging market economies such as Latin America and Central Europe (Dye et al., 2005; WHO, 2008c). Rates in Africa increased in part due to co-infection with HIV (Corbett et al., 2003), and in Eastern Europe due to economic decline and the general failure of health services (Dye and Floyd, 2006).

Since 2003, the number of new tuberculosis cases per capita has continued to fall worldwide. This decline can partly be attributed to the successful implementation of drug treatment programs (Dye et al., 2005). PEPFAR supported TB treatment for more than 395,400 HIV-infected patients through September 2008 (PEPFAR, 2009), while the Global Fund provided 4.6 million people with effective TB treatment through December 2008 (Global Fund, 2009). However, if global targets for tuberculosis control are to be met, Africa, China, and India—which collectively account for more than two-thirds of undetected TB cases—will have to improve both the extent and the timeliness of diagnosis of active TB and increase the rate of successful treatment (UN, 2008b). Successful diagnosis remains a major challenge in the control of tuberculosis; for example, the number of multidrug-resistant TB cases successfully diagnosed and notified in 2006 represented less than 5 percent of the nearly half million cases estimated to exist worldwide (WHO, 2008c).

The current class of TB drugs—the most recent of which was introduced in the 1960s—imposes a long and complex regimen on those burdened with the disease. Although effective, the treatment regimen itself is one of the greatest obstacles to controlling the disease. Because of the length of treatment and its negative side effects, patient compliance is often poor, ultimately resulting in drug resistance. A factor that vastly complicates diagnosis and treatment is the extremely drug-resistant form of tuberculosis, XDR-TB, which leaves patients (including many with HIV) virtually untreatable with currently available drugs (WHO, 2006c). TB treatment also involves considerable health system costs in terms of direct patient observation, amounting to more than \$4 billion a year worldwide. This further handicaps TB control programs, fueling drug resistance and preventing the systematic treatment of latent TB infection—the reservoir for the epidemic (see Box 2-2).

Neglected Diseases of Poverty Exacerbate the Burden of the Poor

AIDS, TB, and malaria are familiar names, but few U.S. citizens are acquainted with the other infectious diseases that commonly plague poor families in low- and middle-income countries. Often termed the neglected diseases of poverty, these scourges have afflicted the world's poorest since ancient times and continue to be common among the estimated 2.7 billion people living on less than \$2 a day. These conditions frequently result in long-term disability and poverty (Hotez et al., 2007) and carry disease burdens that are grossly underestimated and may be comparable to those of HIV, malaria, and TB (Hotez et al., 2006a, 2006b; Savioli et al., 2006).

BOX 2-2 **Drugs and Vaccines for Tuberculosis Research**

In 1995, the directly observed treatment, short-course (DOTS) control strategy for TB was launched (WHO, 2008f). DOTS is an inexpensive and highly effective means of treating patients already infected with TB, while preventing new infections and the development of drug resistance. In many low-income countries, DOTS costs only \$3 to \$7 for every healthy year of life gained (World Bank, 2003). The DOTS strategy provides diagnosis, patient registration, and a six-month multidrug treatment regimen, where the patient's compliance with treatment is "directly observed" even as he or she is free to work, go to school, and be with family. By combining individual patient outcome evaluation to ensure cure and cohort evaluation to monitor overall program performance, DOTS forms the core of the WHO's Stop TB Strategy (Floyd and Pantoja, 2008).

A shorter or otherwise simpler treatment regimen would greatly help to improve patient compliance and to lower toxic side effects, thereby increasing cure rates. A shorter treatment would also reduce the costs of TB treatment, both for patients and for health systems. New and faster-acting drugs could radically transform the fight against tuberculosis by accelerating DOTS, treating multidrug-resistant TB (MDR-TB), improving the treatment of latent infection, and reducing TB transmission. Effective treatment of latent TB is particularly important for patients co-infected with HIV (Bornemann et al., 2002).

The Global Alliance for TB Drug Development, a public-private product development partnership, has the primary goal of developing within a decade new anti-TB drugs that shorten and/or simplify treatment, are effective against MDR-TB, and address both active and latent forms of the disease. A central stipulation for any new drug is that it be accessible and affordable for all who need it (Bornemann et al., 2002).

No vaccine yet exists that is truly effective against adult pulmonary tuberculosis, the strain that accounts for most of the disease burden worldwide (Stop TB Partnership, 2009). The bacille Calmette-Guérin (BCG) vaccine, created in 1921, is currently the only available vaccine against TB. The vaccine is effective against severe forms of pediatric TB, but is unreliable against adult pulmonary TB. BCG is the most widely administered vaccine in the world, yet more than one-third of the world's population carries the disease (WHO, 2007b). A modern, safe, and effective vaccine is therefore urgently needed to prevent all forms of TB, including drug-resistant strains, in all age groups and particularly among people with HIV. In recent years, a number of new vaccine candidates for tuberculosis have been developed and shown promising results when tested in animals. Aeras TB, a nonprofit biotechnology company, has recently entered a new vaccine candidate human safety trial in South Africa (Aeras, 2009).

Two common groupings of these neglected infectious diseases are helminth infections and kinetoplastid infections (Hotez et al., 2008; Stuart et al., 2008). Helminth infections, caused by parasitic worms, are the most common clinical conditions among the "bottom billion"—the world's poorest people living on

less than \$1 per day (Collier, 2007)—and include parasites such as roundworm, hookworm, onchocerciasis, and schistosomiasis. Children and adolescents suffer the highest burden of worm diseases, experiencing growth and developmental delays that result in deficits in intelligence and cognition. Hookworm and schistosomiasis are common infections that cause anemia among women in their reproductive years. Because of their pronounced impact on maternal and child health, the disease burden caused by helminths is exceedingly high (Collier, 2007; Hotez et al., 2006b).

Kinetoplastid infections are caused by related parasites and include three diseases: trypanosomiasis, Chagas disease, and leishmaniasis. These infections are less common, but being vector-borne, they could increase as a consequence of climate change and other environmental influences (IOM, 2008b).

Neglected infectious diseases are often treated on a mass scale with various drugs; for example, mass administration of diethylcarbamazine and selective treatment or administration of diethylcarbamazine-medicated salt have succeeded in interrupting the transmission of lymphatic filariasis in the Pacific region (Ichimori et al., 2007). Vector control, followed by mass treatment with ivermectin, led to the control of onchocerciasis in 10 west African countries (Amazigo et al., 2006). Azithromycin treatment and the SAFE (surgery, antibiotics, face cleanliness, and environmental improvement) strategy have eliminated blindness-causing trachoma in Morocco (Cook, 2008), and multidrug treatment has eliminated leprosy as a public health problem in more than 93 countries (Molyneux, 2008).

The efficacy of mass treatment was confirmed in a systematic review of randomized controlled trials (Reddy et al., 2007). Because the major multinational pharmaceutical companies provide many of the drugs used for mass treatment free of charge, this approach is one of the most cost-effective global public health control measures (Hotez et al., 2007). The efficiency and effectiveness of mass treatment could be increased through the integration of several vertical disease control programs (Brady et al., 2006; Hotez et al., 2006b, 2007; Molyneux, 2008) since integration provides cost savings of almost 50 percent (Brady et al., 2006). In 2005-2006, a low-cost rapid-effect package of four drugs was developed to simultaneously target the seven major neglected tropical diseases (Hotez et al., 2006b, 2007). To launch an integrated global assault with the rapid-effect package, about \$2 billion to \$3 billion will be needed over the next five to seven years, or roughly 40 to 50 cents per person per year (Hotez et al., 2007, 2009).

New technologies and interventions developed for diseases that are found overwhelmingly or exclusively in low- and middle-income countries are usually serendipitous, as when a veterinary medicine developed by Merck (ivermectin) proved to be effective in the control of African river blindness (onchocerciasis) in humans (Campbell, 2005). Similarly, eflornithine—originally intended as a cancer treatment and also known to be highly effective against a strain of African sleeping sickness (trypanosomiasis)—was initially abandoned by drug manu-

facturers until it was discovered to be effective in preventing unwanted facial hair (see Box 2-3). Yet for many of these infections, genomes for the parasites and vectors have been completed; increased investment in the mining of these genomes could result in breakthrough discoveries of new diagnostic, drug, and

BOX 2-3 Human African Trypanosomiasis: Diagnosis and Treatment

Human African trypanosomiasis, or sleeping sickness, is spread by infected tsetse flies (*Glossina* genus). Although sleeping sickness is not fatal, it can be grossly debilitating by affecting the central nervous system, causing changes in personality, and creating difficulty in walking and talking. WHO estimates that there are currently 50,000 to 70,000 cases of African sleeping sickness, responsible for an estimated 1,525,000 disability-adjusted life-years (DALYs) (DNDi, 2008; WHO, 2006a).

Case detection requires major human, technical, and material resources, such as blood samples and spinal tap. Diagnosis becomes even more difficult because the disease primarily affects poor rural populations with little access to health facilities. New, accurate, and simple diagnostic tests that could determine the stage of disease are required, along with drugs that could be administered orally (CIPIH, 2006).

Currently there is no vaccine or drug available to prevent infection. While drugs to treat the disease are available, they are old, difficult to administer under poor conditions, and not always successful. Pentamidine is the first-stage treatment for the *Trypanosoma brucei* (*T.b.*) *gambiense* strain of African trypanosomiasis, and although it has a few side effects, it is generally well tolerated by patients (WHO, 2006a).

Eflornithine is a highly effective treatment for the *T.b. gambiense* strain of African trypanosomiasis, particularly in the late-stage disease. It is safer and more effective than other treatments, such as melarsoprol, but the dosing regimen is strict and the drug is expensive. It was originally intended as a cancer treatment, but was registered for African trypanosomiasis in 1989. Highly expensive, eflornithine was largely abandoned by drug manufacturers until it was discovered to be an effective treatment against unwanted facial hair. Due to extensive lobbying by *Medicins Sans Frontieres* in 2001, Sanofi-Aventis (formerly Aventis), the patent holder, agreed to provide \$12.5 million worth of the drug to WHO over five years. Now that this five-year period is over, Sanofi-Aventis has agreed to transfer the technology and assist other manufacturers that are willing to develop eflornithine; the Indian Institute of Chemical Technology (Hyderabad, India) and ILEX Oncology (Texas, USA) are both working on cheaper ways to produce the drug (CIPIH, 2006).

Targeted research on human African trypanosomiasis has revealed new and more promising treatments. A Phase III study—made possible by a public-private partnership—confirmed that eflornithine in combination with nifurtimox is a safe, effective treatment for stage 2 patients with the disease, and even more practical than eflornithine alone. This combination drug was added to the WHO Essential Medicines List in May 2009.

vaccine targets, leading to the development of new tools to combat them (Hotez et al., 2008; Stuart et al., 2008).

Determinants of Health and the Other MDGs

The remaining five MDGs do not deal exclusively with health issues, but are indirectly linked to health outcomes. The health sector should be a powerful voice in supporting governments and encouraging donors to give more funding to water and sanitation, nutrition, and other sectors that contribute to health outcomes.

Water and Sanitation (MDG 7c: Reduce by half the proportion of people without sustainable access to safe drinking water and basic sanitation)

More than 1 billion people—a sixth of the world's population—lack access to safe drinking water, and 2.6 billion people lack access to basic sanitation services (MDG 7) (Bartram et al., 2005). These figures have “hardly changed for almost two decades because any improvements in provision have barely kept up with population growth” (Lancet, 2008b). When both the direct (diarrheal illnesses) and the indirect (water-borne and water-related illnesses) health consequences are taken into account, 9.1 percent of the global burden of disease could be prevented by improving water, sanitation, and hygiene; in the 32 worst-affected countries, this figure jumps to 15 percent (Lancet, 2008a; Prüss-Üstün et al., 2008). One and a half million children die every year from preventable diarrheal illnesses, and many thousands more are disadvantaged by wide-reaching health and educational consequences because of these failings in water and sanitation services (Prüss-Üstün et al., 2008).

Poverty and Nutrition (MDG 1c: Reduce by half the proportion of people who suffer from hunger)

In low- and middle-income countries, one out of every four children under 5 years old is underweight due to lack of nutritious foods (MDG 1) (UN, 2008b). Undernutrition is caused by a poor dietary intake that may not provide sufficient nutrients and/or by common infectious diseases, such as diarrhea (Black et al., 2008). The attribution of more than one-third—3.5 million—of all child deaths and more than 10 percent of total global disease burden to maternal and child undernutrition demonstrates the huge importance of these prevalent risk factors to international health goals (Black et al., 2008; Horton, 2008). Malnutrition not only retards growth, but also leads to weak cognitive functioning, with consequences for the progress of whole societies. An estimated 200 million children under the age of 5 fail to reach their potential in cognitive development due to poor nutrition, poverty, and deficient care (Grantham-McGregor et al., 2007).

Unfortunately, there is no one technological intervention that can solve undernutrition. While one in seven people already suffers from food scarcity and 25,000 people die every day from hunger-related causes (including one child every 5 seconds) (Sheeran, 2008), the threat of climate change is further increasing the risk of crop failure, livestock losses, and subsequent food shortages (MDG 7) (FAO, 2008). In addition to improving consistent access to nutritious food, long-term investments in empowering women—in educational, economic, social, and political terms—can lead to sustainable improvements in maternal and child nutritional status and in the health of families more generally (Horton, 2008).

Educational, Economic, and Gender Inequity (MDGs 2 and 3)

Educational and economic opportunities are out of reach for many of the poor, especially young women. Among primary school-age children worldwide, more than 90 percent attend school, but 38 million children in sub-Saharan Africa do not (MDG 2). Low rates of school enrollment and attendance are especially devastating to girls because they are linked to their future income, personal health status, and the health status of their future children and families (MDG 3) (UN, 2008b; UN Millennium Project, 2005).

Gender inequality influences the health of both mothers and babies—“an influence that seems to continue many decades later” (Osmani and Sen, 2003). To avoid this intergenerational cycle of poor health and lack of education, gender gaps should be closed in all areas of development, such as primary and secondary education, women’s access to economic opportunities and health services, and equal participation in governance (Belhadj and Touré, 2008). The field of global women’s health has recently expanded to include a range of women’s health issues unrelated to reproduction, with a focus on identifying and correcting gender differentials and inequities in health (Buvinić et al., 2006). Overcoming the gender and power imbalance between men and women in communities and households around the world would yield rich rewards in terms of the health of millions of women and girls (and their children) (Belhadj and Touré, 2008).

Recommendation 2-1. As part of a comprehensive approach to development and poverty reduction, the United States, both its governmental and its nongovernmental sectors, should support the UN’s Millennium Development Goals. In particular, the United States should partner with countries to promote and finance the application of existing knowledge and tools to achieve the health-related MDGs by 2015 with special attention to areas that are lagging behind. (See Recommendation 5-1 for funding proposal.)

PREPARE FOR EMERGING CHALLENGES OF THE TWENTY-FIRST CENTURY

While the MDGs are useful guides for mobilizing and focusing aid resources, much more will have to be done to attain the goal of global health. Investments need to go beyond well-recognized infectious diseases such as HIV/AIDS and malaria and take a more comprehensive view of health in low- and middle-income countries.

Globalization and Urbanization—Opportunity and Barrier to Global Health

Dramatic changes have occurred in the last century: population growth; migration into previously uninhabited areas; rapid urbanization; environmental degradation; and the misuse of antimicrobials that has disrupted the equilibrium of the microbial world. Globalization has changed the way that nations should protect and promote health, in part due to the growing number of health hazards and solutions that increasingly cross national borders. While globalization has brought innumerable benefits to society, it has also generated resource depletion, environmental pollution, unhealthy living conditions, and the circulation of dangerous and unhealthy goods (Marmot et al., 2008).

Infectious diseases are now emerging at the historically unprecedented rate of one per year. With airlines now carrying more than 2 billion passengers annually and systems of trade more interconnected than in any time in human history, the opportunities for the rapid international spread of infectious agents and their vectors have vastly increased (WHO, 2007c).

Chronic diseases are also increasing as a result of globalization and urbanization (Dodgson et al., 2002; Lee, 2003; Lee et al., 2002). Cities are already home to half of the world's 6.6 billion people (Ash et al., 2008). City dwellers tend to have more expendable income than their rural counterparts; they live more sedentary lives and have easier access to low-cost, low-fiber, high-energy, high-fat food. Unhealthy imports, such as tobacco and processed foods, heighten the risk of many noncommunicable and chronic diseases (Dodgson et al., 2002; Lee, 2003; Lee et al., 2002). The nutritional transition that results from urbanization contributes to today's rapidly rising rates of obesity, with implications for the incidence of diabetes, heart disease, cancer, and stroke (Dye, 2008).

Climate Change to Play a Role in Global Health

Climate change poses a unique challenge to global health efforts and the "involuntary exposure" experienced in many societies and represents possibly the largest health inequity of our time (Patz et al., 2007). Ironically, in the last 30 years, the regions least responsible for causing greenhouse gas warming of the planet have been experiencing the greatest increases in diseases attributable to

temperature rise (Costello et al., 2009; Patz et al., 2007). Additionally, 88 percent of the disease burden attributable to climate change afflicts children under age 5—an innocent portion of the population. Not only is the health burden from climate change itself greatest among the world's poor, but some of the major mitigation approaches to reduce the degree of warming may produce negative side effects disproportionately among the poor. For example, competition for land for biofuel production can create pressure on food prices. Efforts to reduce the extent of global warming and its associated impacts should seek equitable solutions that first protect the most vulnerable populations (Patz et al., 2007).

Climate change was responsible for 5.5 million disability-adjusted life-years (DALYs) lost in 2000 when taking into account deaths caused by cardiovascular diseases, diarrhea, malaria, accidental injuries in coastal floods and inland floods or landslides, and the unavailability of recommended daily calorie intake (an indicator of malnutrition) (Costello et al., 2009). Infectious disease transmission patterns are altered by the effects of climate change (IOM, 2008b). In Africa, major contributors to child mortality, such as malaria and diarrhea, vary with temperature change and rainfall. Other vector-borne diseases, including schistosomiasis, yellow fever, sleeping sickness, and Rift Valley and East Coast fevers, are sensitive to seasons and other climatic conditions. Flooding increases the risk of water-borne diseases, while droughts force people and their animals to move to new environments, further increasing the risk of disease from microbes to which they have not previously been exposed (ILRI, 2008).

Infectious Pandemic Threats

Throughout human history, infectious diseases have threatened lives and livelihoods; increasingly, they challenge the health security of nations. Major pandemics such as the Influenza Pandemic of 1918-1919, which killed more people in 3 weeks than HIV/AIDS has killed in 24 years (HHS and CDC, 2006), demonstrate the potentially catastrophic impacts of emerging infections such as pandemic flu. Despite dire warnings, the global health arena currently faces a lack of specific effective antiviral agents and antibiotics (targeting emerging resistant bacteria), integrated health surveillance and management systems, and trained health personnel (IOM, 2005; WHO, 2007c). Even high-income countries are ill equipped to handle mass outbreaks of infectious diseases, including those that could arise from the intentional use of biological agents. The U.S. government has spent more than \$30 billion over five years to counter these threats, but so far, the drug development cycle for anti-infective drugs and vaccines has not kept pace with disease-response demands (Grotto and Tucker, 2006).

Emerging pandemic threats such as avian and H1N1 (swine) flu, which can spread with alarming rapidity in today's globalized world, need urgent preparation. Infectious disease outbreaks have significantly increased over the last several decades (IOM, 2003) and are dominated (60 percent) by zoonoses, or

diseases contracted from animals (Jones et al., 2008). This increase in the emergence of infectious diseases reflects many factors, including climate change (IOM, 2008b) and anthropogenic and demographic changes that increase and alter contact between humans and animals (Jones et al., 2008).

Zoonotic Disease Threats Are Increasing

Today, conditions for the development of zoonotic diseases that have the potential to become pandemics are already well entrenched (IOM, 2008a). Zoonotic diseases arise out of an expanding convergence of factors such as climate change, population growth, and consumer demand for food of animal origin—all of which increase the risks of disease transmission from wildlife to livestock and from both to humans (IOM, 2008a). Animal populations are reservoirs for several infectious diseases that infect humans, including West Nile virus (birds), Ebola hemorrhagic fever (bats), avian influenza (birds), and H1N1 influenza (pigs) (Grotto and Tucker, 2006). Since animals are more commonly affected by many zoonotic diseases than humans, in some instances they can provide an early warning of impending human epidemics (Rabinowitz et al., 2006). Unfortunately many health systems, including those of high-income countries, lack an integrated zoonotic disease surveillance system capable of monitoring both animal and human populations. Once zoonotic pathogens have developed into agents capable of human-to-human transmission, they can spread with alarming rapidity, striking with deadliest effect in less wealthy nations that are least equipped to monitor, control, and detect emerging diseases (IOM, 2008a).

In a matter of months between 2002 and 2003, more than 8,000 people in 26 countries became sick and 774 died (WHO, 2003) due to severe acute respiratory syndrome (SARS)—a zoonotic disease thought to have first been transmitted from bats to humans in south China (Lau et al., 2005). The global economic impact of this epidemic was estimated to be as much as \$30 billion (HM Government, 2008). Compared to outbreaks of other infectious diseases, this epidemic is considered to have been contained by one of the more successful international response efforts, owing to model multinational, collaborative, and coordinated surveillance, research, and containment measures (IOM, 2004). At the same time, the newness of the disease and the demonstrated speed of its global spread highlighted the need for vigilance and continued investments in integrated response systems against emerging diseases.

Two such response systems are the Global Outbreak Alert and Response Network (GOARN) and the Global Emerging Infections Sentinel Network (GeoSentinel). GOARN connects more than 115 organizations around the world; this network greatly aided WHO during the initial SARS outbreaks (IOM, 2004). GeoSentinel consists of travel and tropical medicine clinics around the world that monitor geographic and temporal trends in morbidity among travelers and other globally mobile populations; its rapid worldwide query-and-response function

electronically links providers around the world (GeoSentinel, 2008). A relatively new tool for tracking and predicting potential outbreaks is HealthMap—a freely accessible, automated real-time system that monitors, organizes, integrates, filters, visualizes, and disseminates online information about emerging diseases (Freifeld, 2009).

Food-Borne Diseases Demand Attention

Globalization of the food supply further exposes a greater proportion of people to the risk of food-borne diseases. Although preparing nations to address natural and intentional biological threats is a formidable challenge, understanding these twin threats and the characteristics they share encourages shared strategic preparations for surveillance, diagnosis, outbreak investigation, and medical response systems (IOM, 2006).

Food-borne diseases have wide-ranging repercussions for consumers, governments, and the food industry. They can arise both unintentionally and through deliberate contamination. Outbreaks of food-borne illness damage trade and tourism, lead to loss of earnings, destroy the commercial credibility of suppliers, and affect consumer confidence (FAO, 1999). Despite the risk of terrorist attacks on food supplies, the likelihood of accidental food-borne illnesses surpasses intentional contamination by approximately 10,000 to 1 (IOM, 2006).

Since the late 1990s, the incidence of various illnesses associated with food-borne microorganisms in the United States has remained steady or decreased. However, challenges in food inspection, sampling, and surveillance abound and demand further progress (HHS and FDA, 2007). As new food sources increase, production and distribution methods advance, and imports respond to growing consumer demand, food protection strategies should adapt to these changes. Among the challenges are establishing internationally standardized food safety systems, particularly in low- and middle-income countries, not only because food exports from these countries are on the increase (with approximately 15 percent of the overall U.S. food supply volume now imported) (HHS and FDA, 2007), but also because the introduction of debilitating food-borne pathogens from advanced economies has increased in low- and middle-income countries.

International Health Regulations Strive for Early Detection of International Threats

The revised International Health Regulations (IHR), which entered into effect in June 2007, bind 192 countries across the globe and help the international community to report and respond to major epidemics in an integrated, harmonized, and holistic way. The IHR expand the focus of collective defense from just a few quarantinable diseases to include any emergency with international repercussions for health, including outbreaks of emerging and epidemic-prone diseases,

outbreaks of food-borne diseases, natural disasters, and chemical or radionuclear events, whether accidental or deliberate (Fidler and Gostin, 2006).

In a significant departure from the past, the revised IHR call for a strategy of proactive risk management, rather than a focus on passive barriers at borders, airports, and seaports. The new strategy is aimed at detecting an event early, before it has a chance to become an international threat, and stopping it at its source (WHO, 2007c). It calls for notification of WHO within 24 hours of any event that has the potential to become a public health emergency of international concern (PHEIC). The term PHEIC now more broadly covers accidental or deliberate releases of biological, chemical, or radiological agents that could harm more than one country. The IHR also mandate that all participating countries work closely with partners and strengthen national core capabilities for public health surveillance and response within five years (WHO, 2005a).

More private sector involvement is needed to improve the quality of early-warning systems for the detection of disease outbreaks and to support advancing biomedical research in the development of safe, cost-effective vaccines capable of treating a broad spectrum of infectious diseases (Grotto and Tucker, 2006). Public-private partnerships can play a pivotal role in developing new antibiotics, diagnostics, and other means of combating infectious disease. Such partnerships could also help to establish regional networks and build appropriate infrastructure to implement the global health standards mandated by the IHR (Kimball et al., 2008).

Chronic and Noncommunicable Diseases

The rising tide of chronic and noncommunicable diseases in both high-income and low- or middle-income countries cannot be ignored any longer. In an extraordinary global epidemiologic transition, chronic conditions such as cardiovascular disease and diabetes have joined the list of infectious diseases traditionally seen in less affluent regions (Laxminarayan et al., 2006; Omran, 1971). Remarkably, 80 percent of chronic disease deaths now occur in low- and middle-income countries (WHO, 2005b). In 2001, cardiovascular disease had become the leading cause of death in low- and middle-income countries (as it had been in industrialized countries since the mid-1990s) (Mathers et al., 2006). Smoking, which greatly increases the risk of acquiring conditions such as heart and lung disease and many cancers, is an increasingly common addiction in many low- and middle-income countries. Unless large numbers of adults quit, smoking will account for 1 billion deaths this century (Jha et al., 2006).

Increased mortality from chronic disease is not merely a result of fewer deaths from infectious disease. In East Asia and the Pacific, for example, the anticipated increase in death rates from chronic disease will be more than five times the predicted decrease in mortality rates from infectious disease (Stuckler, 2008). Both emerging infectious threats and chronic diseases are increasing glob-

ally, resulting in the so-called dual burden of disease, whereby significant infectious and chronic diseases burden the same country or region (see Figure 2-3). For example, some low- and middle-income countries are experiencing a protracted and polarized epidemiologic transition with high levels of malnutrition alongside high levels of obesity (Frenk et al., 1989). This mix of health challenges demands new approaches that integrate both infectious and chronic disease interventions.

The prevention and treatment of chronic and noncommunicable diseases should therefore become a priority in global health. Chronic diseases have received significant research attention in the United States, resulting in important advances that focus on individual risk factors and specialized treatments. However, the scale and urgency of these diseases in low- and middle-income countries require solutions that are tailored to a different, much less understood reality, encompassing cost-effective and population-based methods, rather than individualized ones (Batniji, 2007). Although noncommunicable diseases are not included in the MDGs (Fuster and Voûte, 2005), WHO has called for a global commitment to reduce chronic disease death rates by an additional 2 percent annually, or to 36 million deaths by 2015 (Strong et al., 2005).

Cardiovascular Disease Is Increasing in Low- and Middle-Income Countries

Cardiovascular disease (CVD) is the leading cause of death worldwide. At the beginning of the twentieth century, CVD was responsible for less than 10 per-

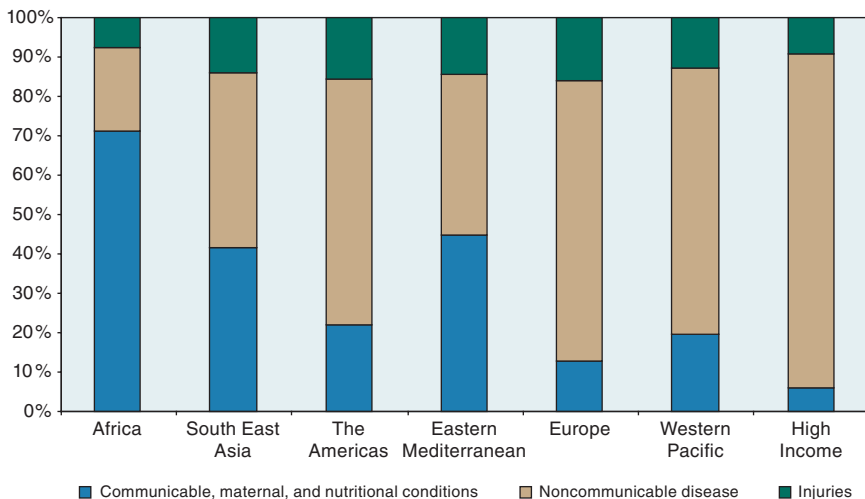


FIGURE 2-3 Burden of disease in disability-adjusted life-years (DALYs) by cause and WHO region (2004).

SOURCE: Committee's calculations based on WHO, 2008b.

cent of all deaths, but by 2001 the figure was 30 percent. About 80 percent of the global burden of CVD deaths occurs in low- and middle-income countries. And while other causes of death, such as injuries, respiratory infections, nutritional deficiencies, and HIV/AIDS, collectively still play a predominant role in certain regions, CVD is now a significant cause of mortality in all regions. Nearly 50 percent of all deaths in high-income countries and about 28 percent of deaths in low- and middle-income countries are the result of CVD (Gaziano et al., 2006; Mathers et al., 2006).

Working-age adults account for a high proportion of the CVD burden in low- and middle-income countries. Premature deaths in this population have a significant social and economic impact on societies, especially in already impoverished settings (Gaziano et al., 2006; Greenberg et al., 2005).

Cancer Should Be Raised onto the Global Health Agenda

Cancer receives less attention on the health agendas of low- and middle-income countries than it does in high-income countries, even as other chronic diseases have gained attention. Yet cancer is common everywhere and growing as a share of the burden of disease. Of the 11 million cases of cancer that occur annually worldwide, 6 million are in low- and middle-income countries, where they cause 4 million deaths (1 million more than from AIDS) (IOM, 2007). Very recently, a vaccine against oncologic strains of human papilloma virus (HPV)—the leading cause of cervical cancer—was developed and is being delivered in the United States and other advanced economies. Its use in low- and middle-income countries—home to more than 80 percent of cervical cancer deaths—could save the lives of millions of women (see Box 2-4).

Whereas the majority of cancers in high-income countries are those associated with more affluent lifestyles—cancers of the lung, colon and rectum, breast, and prostate—cancers related to infectious agents are more common in low- and middle-income countries—cancers of the liver, stomach, esophagus, and cervix. Investments in cancer diagnosis and treatment, however, should vary depending on resources available in the country. A temptation that high-income countries should resist is focusing on exporting the latest, most expensive technologies that may be appropriate for wealthy countries, but for which alternatives exist that may be preferred in low- and middle-income countries. Partnerships are needed between high-income and other countries in developing resource-appropriate strategies (IOM, 2007).

Diabetes Reaching Epidemic Levels

Obesity is escalating worldwide at an alarming pace, along with rates of type 2 diabetes, hypertension, and lipid abnormalities associated with obesity. More than 1 billion adults are now overweight, and 300 million are clinically obese

BOX 2-4 Cancers That Affect Only Women

Breast cancer is the most common cancer among women worldwide. Its incidence is much higher in high-income countries, where more than half of all cases are diagnosed. However, breast cancer is increasing everywhere, even more so in places where rates have historically been low. Between 1990 and 2002, the global increase was about 0.5 percent per year. In China, however, annual increases of 3 to 4 percent are reported. If these rates are representative, 1.5 million cases of breast cancer are expected worldwide in 2010 (IOM, 2007).

The Breast Health Global Initiative (BHGI) is an ongoing international collaboration that produces detailed guidelines for low- and middle-income countries to improve breast health outcomes, from early detection through palliative care. BHGI has begun to work with low- and middle-income partners to develop experience in adapting and applying policy and programmatic guidelines (IOM, 2007), including effective communication interventions for early detection through breast self-examination and timely diagnosis (BHGI, 2009).

Cervical cancer is the second most common cancer among women. More than 493,000 women are diagnosed each year, and approximately 274,000 women die annually from this disease (Ferlay et al., 2004). More than 80 percent of these deaths occur in low- and middle-income countries (Stewart and Kleihues, 2003; WHO, 2006b). Most women in low-income countries do not have access to care that can prevent the onset of cervical cancer; once diagnosed, few can afford the lifesaving surgery and radiotherapy. Cervical cancer incidence and mortality thus disproportionately burden women in less affluent settings. The continuing high mortality rate demonstrates a lack of awareness and advocacy aimed at this disease.

WHO (2006b) developed the *Comprehensive Cervical Cancer Control: A Guide to Essential Practice* report as a “how-to” manual for cervical cancer, aimed at low- and middle-income countries in terms of the technologies addressed (IOM, 2007). The report gives recommendations that are feasible in less affluent settings, including visual screenings and availability of appropriate medications (WHO, 2006b). Deployment of the recently developed HPV vaccine, now used in high-income countries, would go a long way toward stemming cervical cancer disease burden in these low- and middle-income countries.

(Gaziano et al., 2006). As some low- and middle-income countries undergo rapid urbanization, childhood obesity has increased dramatically, while the prevalence of type 2 diabetes has reached epidemic levels and is expected to increase in East Asia and the Pacific (Narayan et al., 2006). Because the health consequences of this epidemic threaten to overwhelm health systems in these regions, action is urgently needed to encourage lifestyle changes (Yoon et al., 2006). Studies such as the Diabetes Prevention Programme (Knowler et al., 2002), Da Qing study (Pan et al., 1997), Finnish Diabetes Prevention Study (Tuomilehto et al., 2001),

Japan lifestyle study (Kosaka et al., 2005), and Indian Diabetes Prevention Programme (Ramachandran et al., 2006) have shown that lifestyle changes and some medications are effective in preventing type 2 diabetes in at-risk individuals. Public health strategies aimed at prevention of weight gain and obesity will be more cost effective than treatment of the consequences of these conditions such as diabetes (Yoon et al., 2006).

Mental Health—Great Source of Disability Globally

Mental disorders affect millions of people worldwide; about 14 percent of the global burden of disease has been attributed to neuropsychiatric disorders, mostly due to the chronically disabling nature of depression and other common mental disorders, alcohol use and substance use disorders, and psychoses. Although most of the burden attributable to mental disorders is disability-related, premature mortality from suicide is also significant. Further, mental disorders increase the risk for communicable and noncommunicable diseases and contribute to unintentional and intentional injuries. Conversely, many health conditions increase the risk of mental disorder, and comorbidity complicates help seeking, diagnosis, and treatment (Prince et al., 2007).

Most mentally ill people are not treated (Kohn et al., 2004; Wang et al., 2007). It has been estimated that among severe mental disorders such as schizophrenia, one out of three people does not receive any treatment at all, while for less severe disorders, one person out of two is not treated. In low- and middle-income countries, 90 percent of mental illness is untreated (Maselko, 2008).

Resources for mental health are scarce, inequitably distributed, and inefficiently allocated, with most being spent on psychiatric hospitals and institutional care rather than primary and community care. Scaling up a package of cost-effective treatments for a core group of three mental disorders (schizophrenia, depression, bipolar affective disorder) and one risk factor (hazardous alcohol use) would cost about \$2 per person per year in low-income countries and \$3 to \$4 per year in lower-middle-income countries (Chisholm et al., 2007). However, one-third of low- and middle-income countries have no mental health budget at all. Of those that do, 20 percent spend less than 1 percent of their health budget on mental health—and this almost entirely on psychiatric hospitals in urban areas (Saxena et al., 2007).

Finally, health services are not provided equitably to people with mental disorders, and diagnosis with mental disorder can influence prognosis. Psychosocial interventions that can be integrated into infectious and noncommunicable disease management need to be developed and evaluated (Prince et al., 2007). The shortage of mental health professionals, the low capacity and motivation of nonspecialist health workers to provide quality mental health services, and the stigma associated with mental disorder are some of the key challenges to addressing mental health needs (Patel et al., 2007).

Injuries and Violence Are on the Rise

Other health hazards (beyond diseases), such as intentional and unintentional injuries, are also more prevalent in low- and middle-income countries. Together, unintended injuries and violence kill more than 5 million people worldwide and harm millions more each year (Hyder et al., 2009; WHO, 2009a). Injuries and violence account for 9 percent of global mortality and are a threat in every country of the world (WHO, 2009a).

Morbidity and mortality from injuries are on the rise. Eight of the fifteen leading causes of death for people age 15 to 29 are related to injuries, through road traffic accidents, suicides, homicides, drowning, burns, war, poisonings, and falls (WHO, 2008a). Unintentional injuries are the leading cause of childhood death after the age of 9; 95 percent of these child injuries occur in low- and middle-income countries (WHO, 2008e). Yet proven interventions for preventing child injuries exist, such as car seats, cycling helmets, child-resistant packaging for medications, fencing around swimming pools, hot water tap temperature regulation, and window guards (WHO, 2008g). Other cost-effective interventions to prevent deaths and injuries include motorcycle helmets, seat belts, and enforcement of alcohol and driving limits, and speeding laws (Beaglehole and Bonita, 2008).

Traffic accidents have increased dramatically with the increase in motor vehicles in low- and middle-income countries. They now claim 1.2 million lives each year (Morris, 2006) and are the leading cause of death among young people between 10 and 24 years (Toroyan and Peden, 2007). The greatest burden of such injuries and fatalities is borne disproportionately by poor people in low- and middle-income countries, mostly pedestrians, cyclists, and the passengers of buses and minibuses (Nantulya and Reich, 2002). For every death, it is estimated that there are dozens of hospitalizations, hundreds of emergency department visits, and thousands of doctors' appointments. A large proportion of those who survive their injuries incur temporary or permanent disabilities (WHO, 2009a). Roadway improvements and better onsite emergency response systems can help prevent deaths from traffic accidents (Beaglehole and Bonita, 2008).

Violence is another problem worldwide, resulting in the death of more than 1.6 million people each year (WHO, 2002). Almost half of these deaths, about 800,000 annually, result from suicide; additionally, 35 percent are due to interpersonal violence and 11 percent to collective violence, which can include organized violence, forms of war, and gang violence (IOM, 2008c; WHO, 2002). For women, in particular, the prevalence of lifetime physical or sexual violence (or both) by an intimate partner ranges from 15 to 71 percent (WHO, 2005c). Women's health suffers further from a persistent violation of their rights through harmful practices on the basis of gender, such as female genital mutilation or cutting, early marriage, sexual violence, or forced prostitution.

Violence is heightened and health is negatively impacted during conflicts

(Belhadj and Touré, 2008). Aside from the immediate effects of armed conflict, death, and injuries, war threatens the future of public health through “the displacement of populations, the breakdown of health and social services, and the heightened risk of disease transmission” (Murray et al., 2002). In Liberia, 14 years of civil war devastated the government’s health system and left more than a million people without running water, electricity, or sanitation systems (Huerga et al., 2009). In particular, conflicts that involve genocide result in higher rates of post-conflict death and disability (Hoddie and Smith, 2009), and war has acutely detrimental effects for child development (CSDH, 2008).

Recommendation 2-2. The United States should partner with the global community to prepare for emerging challenges of the twenty-first century by increasing attention to pandemic infectious threats, noncommunicable diseases, and injuries. The U.S. government should demonstrate leadership in this area by adopting clear goals—such as improving global disease surveillance, decreasing deaths from tobacco-related illnesses, and reducing injuries from accidents—to guide U.S. global health investments. (See Recommendation 5-1 for a detailed funding proposal.)

ADDRESS NEGLECTED HEALTH SYSTEMS

A functioning health system, as defined by WHO, should include access to adequate financing; essential medical products, vaccines, and technologies; a well-performing health workforce; reliable and timely health information; and strategic policy frameworks to provide effective analysis, oversight, and governance (WHO, 2007a). Many low-income countries lack such a system, undermining progress toward the health-related MDGs and other health outcomes (Travis et al., 2004; UNICEF, 2008).

Because health systems are highly context-specific, no single set of best practices can be put forward as a model for improved performance. In fact, many low-income countries today have two health systems running parallel: a government delivery system and a privately financed market system. The relative proportions of care delivered by each system vary significantly by country. Yet health systems that function well have certain shared characteristics. They have procurement and distribution systems that deliver interventions to those in need. They are staffed with sufficient health workers having the right skills and motivation. They also operate with financing systems that are sustainable, inclusive, and fair, and do not impose costs that force impoverished households even deeper into poverty (WHO, 2007a).

Most government systems were created in the last century and are characterized by centralized budgeting and planning, civil service staffing, and publicly owned infrastructure. In many countries, these public systems have been inad-

equately resourced (Lagomarsino and Kundra, 2008). Government assistance for health in low-income countries is only 29 percent of the total expenditure on health compared to 65 percent in high-income countries; in fact, the poorer the country, the lower the proportion of government money devoted to health (Gotret and Schieber, 2006).

In general, giving more money to health systems requires a reallocation of funds from different government sectors, which can encounter political resistance (WHO, 2007a). In addition, public delivery systems tend to have weak governance structures that can lead to “political influence on decisions, weak incentives to work for the benefit of the poor, lack of transparency in financial and procurement processes, and corruption” (Lagomarsino and Kundra, 2008). As a result, public systems have been shown to allocate resources poorly. For example, studies of African health expenditures have shown that public health funds disproportionately benefit wealthier populations (Lagomarsino and Kundra, 2008; Preker and Carrin, 2004).

Individuals who do gain access to public health care are often confronted by a shortage of quality medical personnel and essential drugs (Mills, 2007). For example, WHO estimates that 57 countries (36 of which are in sub-Saharan Africa) have critical health workforce shortages (WHO, 2006d) and nearly 2 billion people do not have regular access to essential medicines (WHO, 2004). These shortages often stem from larger policy failures, such as a lack of capacity to train, recruit, and retain health workers; manage a drug supply system; or anticipate healthcare needs (Mills, 2007).

The lack of reliable and timely statistics on births and deaths (including the medical causes of death) poses a serious obstacle to planning and decision making to improve health systems (AbouZahr et al., 2007). Most people in Africa and Asia are born and die without leaving any legal records or official statistics (Setel et al., 2007; Szreter, 2007). Each year, nearly 50 million births are not registered worldwide (UNICEF, 2005), and half of the countries in Africa and Southeast Asia record no “cause-of-death” data at all (Mathers et al., 2005; Setel et al., 2007). This lack of information, coupled with a general dearth of managerial capacity at all levels of health systems, increasingly threatens the achievement of the MDGs and other health outcomes (Egger et al., 2007).

In the face of such inefficiencies in public systems, market systems offering health care have evolved in many countries. Yet even as these private systems offer solutions to patients for some of the problems of public delivery systems, such as lack of convenience and availability, they create a host of additional challenges that exacerbate the inequities in health outcomes in low- and middle-income countries. Underperforming market health systems are characterized by a lack of incentives for quality and for serving the poor, asymmetries of information between providers and patients—a characteristic of health systems everywhere—and weak government capacity to regulate the quality of providers (Lagomarsino and Kundra, 2008; Sekhri and Savedoff, 2006; WHO, 2007a).

These conditions lead to particularly insidious outcomes such as price gouging and unnecessary or harmful care. An “inadequate pooling of risk and the lack of subsidies for the poor, combined with high prices for private sector services, lead to high (often crippling) out-of-pocket payments” (Lagomarsino and Kundra, 2008). Such payments represent the most inequitable type of financing because they disproportionately hurt the poor and provide no protection from the costs of catastrophic illness (Gottret and Schieber, 2006).

Countries facing the complex challenges of a mixed healthcare system have a number of policy choices as they attempt to strengthen their health financing and delivery, though the appropriate role for each of these sectors remains controversial (Hanson et al., 2008). For some, it may make sense to focus on introducing reforms to strengthen their publicly financed government systems, but many low- and middle-income countries have already evolved toward disproportionately “marketized” systems, with a large portion of health expenditures financed privately and many services delivered by private providers. In India, for example, more than 80 percent of the country’s total expenditure on health is comprised of out-of-pocket payments (Mahal et al., 2001).

In some instances, healthcare service delivery has been improved by using public funds to contract with nonstate entities, such as nongovernmental organizations, universities, or private providers. A review of programs to contract out the delivery of primary care demonstrates that the practice has potential and should be explored further, but no robust conclusions to influence policy makers can be drawn without more extensive and higher-quality evidence (Liu et al., 2008; Loevinsohn and Harding, 2005; Patouillard et al., 2007).

Although social insurance constitutes less than 2 percent of total spending in low-income countries (Gottret and Schieber, 2006), several countries have implemented expanded or universal insurance programs with positive results. In Thailand, a gradual program to expand subsidized—and eventually free—social insurance resulted in a significant reduction of child mortality rates and reduced inequalities between child mortality rates of the rich and poor by 50 percent (WHO, 2007a). Results from three studies evaluating the effect of universal health insurance in Colombia reported a significant increase in access to and use of health care and lowered catastrophic health spending (Giedion and Uribe, 2009). The Dutch nongovernmental organization PharmAccess is currently developing low-income health insurance products for a variety of low-income workers in about 30 African countries (Gaag and Gustafsson-Wright, 2007). The evaluation of the effectiveness of community- and employer-based insurance models in improving quality and access to health care in low-income countries is still too sparse to inform widespread policy.

Leverage Disease-Specific Programs to Build Health Systems

In response to the weak performance of many public and private health systems in low-income countries, the global health community has long debated the most effective approach to strengthening health systems and delivering health aid (Sepúlveda, 2006). While the Alma Ata declaration of 1978 promoted a comprehensive approach to improving health with an emphasis on building health systems “from the bottom up” through primary health care, this vision was challenged by those who argued that to achieve a measurable effect, it was necessary to focus on a limited number of cost-effective interventions (Travis et al., 2004; Wagstaff and Claeson, 2004). This debate—between horizontal and vertical,² comprehensive and selective, and top-down and bottom-up approaches—has been a major topic in global health, with few programs or agencies bridging the gap and insufficient evidence to distinguish either approach as more valuable than the other (Lawn et al., 2008).

Over the past decade, the drive to produce results for the MDGs has led many donors to focus on their disease priority first and to adopt vertical—disease-specific or service-specific—initiatives that focus on a limited number of interventions. Given the emergency conditions prompting the initial global response to AIDS, for example, donors even chose to circumvent existing weak components of national health systems to set up programs devoted to achieving immediate and demonstrable results. Given the need to expand antiretroviral (ARV) treatment, voluntary counseling and testing, and other HIV/AIDS interventions rapidly in the face of poor data, weak supply chains, and human resource constraints, AIDS donors chose—some more purposefully than others—to set up separate systems to achieve their programmatic goals. For example, the three global AIDS donors—PEPFAR, the Global Fund, and the World Bank’s Multi-Country HIV/AIDS Program for Africa—decided to support procedures for provision of ARVs that are separate from those for other essential medicines because of the critical importance of avoiding shortness of ARV drugs and the weaknesses in national drug distribution systems (Oomman et al., 2008).

While the focus on specific diseases has led to significant improvements in health outcomes related to these diseases, the programs may have sacrificed opportunities to strengthen local health systems. Within the disease-specific programs, an implicit assumption exists that the implementation of targeted interventions will strengthen the system more generally. However, experience suggests that if health systems are “lacking capabilities in key areas such as the health workforce, drug supply, health financing, and information systems,” they may

²Vertical approaches refer to focused, proactive, disease-specific interventions on a massive scale that often use planning, staffing, management, and financing systems that are separate from other existing services, whereas horizontal programs refer to more integrated, demand-driven, resource-sharing health services that work through existing health system structures (Sepúlveda, 2006; Travis et al., 2004; Wagstaff and Claeson, 2004).

not be able to respond adequately to opportunities to be strengthened through disease-specific programs (Travis et al., 2004).

Furthermore, “already weak systems may be further compromised by over-concentrating resources in specific programs,” leaving many other areas further under-resourced (Travis et al., 2004). For example, a study of overall care for pregnant women before and after implementation of targeted HIV programs illustrates the dilemma perfectly. In this study, antenatal syphilis testing rates actually declined when prevention of mother-to-child HIV transmission programs were instituted, due to swamping of nurses whose workloads rose for HIV prevention without adequate support to maintain their prior duties such as syphilis screening. These results highlight the need for health policy makers and researchers to plan explicitly for how targeted programs can have a broader primary care impact (Potter et al., 2008).

Unfortunately, we cannot now be sure how the increase in resources for disease-specific programs, such as those to prevent and treat HIV/AIDS, might or might not be affecting health system capacity because little is known about how the programs are interacting with parts of existing health systems. A lack of such factual knowledge limits our ability to investigate the cause and effect of vertical programs on health system strengthening (Oomman et al., 2008). The choice between vertical and horizontal is itself a false dilemma. In reality, few interventions are delivered through totally stand-alone or totally integrated approaches, with most operating through a complex patchwork of arrangements (Sepúlveda, 2006; Travis et al., 2004; Wagstaff and Claeson, 2004). Donors should move beyond the horizontal-versus-vertical debate and focus on leveraging both approaches to improve and sustain health outcomes.

One way to make improved outcomes sustainable through health systems’ strengthening is for donors to take a disease-specific approach without creating a parallel structure for care delivery. As an example, donors could coordinate information systems by having their own information needs flow through national health management information systems. By strengthening the health information systems of the government, donors could reduce information system fragmentation, minimize duplicative and burdensome reporting for scarce health sector staff, and improve local data quality and analysis. Similarly, donors could use their programs to strengthen local health systems by utilizing national supply chains and strengthening human resources employed by the public sector (Oomman et al., 2008).

The committee contends that donors should make existing global health programs less formulaic and more performance-based, to permit resources to be used more easily within individual national health systems. This would require disease-specific strategies to explicitly take care to strengthen health systems. Having an explicit “health systems” strategy does not mean abandoning priorities, losing a focus on outcomes, or trying to do everything at once. It simply

means recognizing that health systems are vital not only to achieving health outcomes but also to sustaining them (Mills, 2007; Travis et al., 2004).

Successful models do exist and there are opportunities to learn from these experiences. “Child Health” days, which began as an important approach to reach rural or other marginalized families with polio immunization, have now been expanded in many countries to include other immunizations as well as different interventions, such as deworming, family planning, and health education messages (WHO, 2009b).

Likewise, countries have used a selective set of programs, initially focused on child health, to build a pathway to a more comprehensive health system (Rohde et al., 2008; Sepúlveda et al., 2006). For instance, the Tanzania Essential Health Interventions Project was instituted to test innovations in planning, priority setting, and resource allocation at the district level, in the context of the reform and decentralization of Tanzania’s healthcare system (IDRC, 2009). Improved local health system planning and priority setting, together with modest investments in health services and increased coverage of key child-survival interventions, contributed to significant reductions in infant and child mortality in Tanzania (Bennett, 2007). The most recent demographic and health survey in 2005 showed a 24 percent improvement in child survival, with mortality rates among children younger than 5 down from 147 deaths per 1,000 for 1994-1999 to 112 deaths per 1,000 for 2000-2004 (Masanja et al., 2008).

For the U.S. government, this would mean that even disease- and intervention-specific programs, such as PEPFAR and the President’s Malaria Initiative, should contribute to wider health outcomes by working with countries to incorporate programmatic best practices into health service delivery. The committee commends the language in the 2008 reauthorization of PEPFAR, which calls for expanded efforts to strengthen health systems and human resources and to collaborate with other programs, such as child and maternal health, clean water, food and nutrition, and education (PEPFAR, 2008). Leveraging the successes in implementing PEPFAR to support broader national health priorities would go far in making even greater improvements in health outcomes.

Ultimately, this approach would allow U.S. health investments to go beyond merely treating a patient for a single disease and support the delivery of more comprehensive primary health care. When a woman brings her child with acute malaria to see a health worker for treatment in Zambia, for example, appropriate treatment will usually prolong the child’s life. However, a comprehensive approach to care—by using that same health worker and drug supply chain to provide malaria treatment as well as preventive measures such as oral rehydration salts, deworming, and inoculation against polio and measles—can immeasurably improve the child’s health. Strengthening primary health care to include services for the mother can extend the benefits even further: the mother visiting a health clinic because of her sick child could gain access to cervical cancer screening,

antenatal care, family planning, treatment for sexually transmitted infections, and HIV testing and counseling.

Recommendation 2-3. When delivering health assistance, federal executive branch agencies and departments should work with Congress to make U.S. government global health programs less formulaic and more performance-based, to permit resources to be used more easily within unique national health systems with the explicit objective of promoting stronger national health systems and a better-trained, more productive health workforce.

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3

Generate and Share Knowledge to Address Health Problems Endemic to the Global Poor

One of the greatest contributions the United States can offer to the global health campaign is to share America's traditional strength—the creation of knowledge—for the benefit of the global poor. With its extensive expertise in science and research, the synergistic partnership between its public and nongovernmental sectors, and its strong financial commitments, the United States can do much to redress the imbalance in knowledge about high-income-country and low-income-country diseases, conditions, and health systems. The U.S. research community, in collaboration with its global partners, should leverage its scientific and technical capabilities to study health problems endemic to poor countries, more rigorously evaluate programmatic efforts to improve health, and promote global knowledge networks to enable low- and middle-income-country researchers to improve the health of their own populations.

GENERATE KNOWLEDGE TO BENEFIT THE GLOBAL POOR

As previously discussed, progress in global health over the last half-century has been remarkable and can mostly be attributed to the creation, dissemination, and adoption of novel interventions to improve health. In the public mind, scientific innovation to improve global health is often associated with the discovery of exciting medical tools such as vaccines or pharmaceuticals. In reality, however, such innovation also extends to activities that allow these tools to be utilized successfully. These include novel public health programs and healthcare delivery strategies, as well as population-based measures such as innovative epidemiological surveillance models to track disease within communities.

Indeed, most public health advances are the result of a comprehensive

research strategy that incorporates a variety of tools and interventions spanning prevention, diagnosis, and treatment. The recent eradication of smallpox provides a concrete example of how such a comprehensive strategy dramatically altered disease burden (see Box 3-1). Without a series of research advances, coupled with the political will and financial commitments of national governments, donors, and intergovernmental agencies to invest in this research and its subsequent adoption, it is highly unlikely that smallpox eradication would have succeeded.

Today the world faces many enormous challenges in global health, including halting the spread of HIV, eradicating polio, controlling the use of tobacco products and the onset of chronic noncommunicable diseases, and bringing basic

BOX 3-1
Smallpox Eradication Made Possible by a
Series of Research Discoveries

In 1967, when the World Health Organization (WHO) “launched an intensified plan to eradicate smallpox, the ancient scourge threatened 60 percent of the world’s population, killed every fourth victim, scarred or blinded most survivors, and eluded any form of treatment” (WHO, 2009a). Yet why did this commitment to eradicate smallpox come more than 170 years after Edward Jenner had successfully vaccinated people against the disease in 1798 (Fenner et al., 1988)?

Global eradication could become a practical objective only after the development in the 1950s of a vaccine that did not require cold storage and could be produced on a massive scale (Tucker, 2001). The bifurcated needle—a marvel of simple technology that reduced costs (1,000 needles for only \$5)—also made vaccinating easier, allowing village health workers to be trained in proper delivery in only 15 minutes (Levine, 2008a). Another key element in the eradication effort was the discovery that most effective control could be achieved by selective vaccination using an innovative surveillance-containment strategy (Foege, 1998), resulting in the interruption of smallpox transmission much sooner than anticipated (Foege et al., 1975).

Other research initiatives that enabled the success of smallpox eradication included field studies, which revealed the epidemiology of the disease to be different from that previously believed, allowing modification of basic field operations; the discovery that the duration of vaccine efficacy was far longer than was earlier thought, making revaccination efforts much less important; operations research, which facilitated more efficient vaccine delivery and case detection; and studies that conclusively demonstrated there was no animal reservoir to obstruct eradication (Henderson, 1999).

Without the follow-on innovation and research to build on the work of Edward Jenner, the eradication of smallpox would not have been feasible. It required the collaborative efforts of researchers working both in laboratories and on the ground to devise a successful containment strategy, and the political will and financial commitment of governments, international organizations, and local communities to adopt the interventions and make eradication a reality.

health provisions to the most disadvantaged populations. Like smallpox, today's challenges will be met only by comprehensive research and delivery strategies that include the successful development and deployment of novel biomedical tools, new behavioral and public health programs, and impact evaluation to improve our understanding of what works and of how simple and cost-effective interventions can be delivered successfully in even the most resource-deprived settings.

Asymmetry in the Creation of Knowledge to Benefit the Global Poor

While the creation of knowledge through a comprehensive research strategy is critical for improving health in all countries, the capacity to undertake research varies sharply across countries. Representing only one-fifth of the world's population, high-income countries are home to more than two-thirds of the world's researchers, command three-quarters of the gross expenditure on research and development, and originate more than 90 percent of the patents granted in Europe, the United States, and Japan (UNESCO, 2005). High-income countries focus the majority of their research on conditions that affect people within their own borders. As a result, diseases or conditions that are overwhelmingly or exclusively incident in low- and middle-income countries are often neglected (WHO, 2001b), and little energy is devoted to research on how to improve healthcare systems to deliver interventions in these settings.

Health research in low- and middle-income countries, especially in the emerging market economies, has increased in recent years. Between 2000 and 2006, the average annual growth rate in the number of patent filings originating from China and India far outstripped that of all reported countries in Europe and North America (WIPO, 2008). Many countries, such as Brazil, Egypt, and South Africa, are now reaping the benefits of decades of investment in education, health research infrastructure, and manufacturing capacity. These countries are beginning to control endemic diseases and conditions by developing their own interventions, with only modest technical or financial assistance from high-income countries (Morel et al., 2005). For example, Brazil—which has the second-highest rate of leprosy in the world—contributed more than a quarter of the total funding for research on the disease (Moran et al., 2009).

Despite these developments, the U.S. research community—comprised of universities, U.S. government agencies, commercial entities, and nonprofit organizations—continues to play a prominent role in health research worldwide. The U.S. research community conducts 50 percent of all health research (Research!America, 2006) and generates almost twice as many scientific publications (32.7 percent of the world total) as low- and middle-income countries combined (17.6 percent) (UNESCO, 2005). Over the last decade, this commitment to health research has expanded its focus to include global health issues.

A significant portion of global health research is financed, managed, or

conducted by American-based universities, public-private product development partnerships (PDPs), and U.S. government agencies that work in partnership with research institutions in low- and middle-income countries. Indeed, the emergence of university research consortiums and global PDPs dedicated to global health demonstrates the extraordinary interest and untapped potential within the U.S. research community to address the health needs of the global poor. By tapping more fully into this energy, the United States can further complement the expanded health research efforts of low- and middle-income countries and hasten the discovery and delivery of lifesaving knowledge.

Strengthen Knowledge on the Adoption and Dissemination of Existing Interventions

Attention is required to address the systemic bottlenecks in health systems and policy making in low- and middle-income countries that keep the full benefits of existing medical and public health knowledge and technologies from being completely realized. Surveys of deaths among children under 5 years of age in 42 low-income countries revealed that while improved technology could potentially avert 22 percent of deaths, improved utilization of existing methods could avert 63 percent of the deaths (Leroy et al., 2007).

Although most research focuses on interventions—97 percent of the grants awarded by the two largest research funders in recent years were for the development of new technologies (Leroy et al., 2007)—little is known, for example, about the characteristics of delivery strategies that could achieve and maintain high coverage for specific interventions in various epidemiological, health system, and cultural contexts. Systematic studies that help answer questions about how best to scale up and deliver existing interventions are urgently needed (Bryce et al., 2003; Mills, 2007; Walley et al., 2007). Unfortunately, few programs that deliver specific health interventions undergo the type of rigorous evaluation that improves our understanding of what works and where improvements should be sought.

Greater Attention to Health Systems Research

Health systems research is “the production and application of knowledge to improve how societies organize themselves to achieve health goals,” taking into account not only how activities are planned, managed, and financed, but also the roles, perspectives, and interests of different stakeholders. Health systems research is a continuum from rigorous and more generalizable scientific research on major issues facing policy makers, such as how to improve the effectiveness of human resource management, to operational or implementation research, which tends to be highly context-specific (Mills, 2008).

The Alliance for Health Policy and Systems Research conducted a biblio-

metric survey and found that over a period of 12 years (1991-2003), 1.8 million publications were indexed with at least one major subject heading in the field of health systems research, but only 5 percent of these were concerned with low- and middle-income countries, and an even smaller proportion were produced by low- and middle-income country researchers themselves (Alliance for Health Policy and Systems Research, 2004). While recent years have seen an increasing number of systematic reviews of particular areas of health systems research, in general, they have not yielded information that has dramatically influenced public policy. For example, although several studies have examined the effectiveness of working with private providers to improve equity in health for the poorest individuals, no robust conclusions to influence policy makers can be drawn without more extensive and higher-quality evidence (Patouillard et al., 2007).

Health systems research, when of high quality and when conducted through a number of comparative studies in different countries on a particular theme, is a particularly important method for identifying promising and generalizable interventions for health systems delivery (Mills, 2008). For example, health systems research has led to some influential practices, such as integrating the management of childhood illnesses (Arifeen et al., 2004; Armstrong Schellenberg et al., 2004) or rethinking the desirability of user fees (a nominal fee charged for health services) (Holla and Kremer, 2009) or charging for bed nets or other health goods (Ashraf et al., 2007; Hoffmann et al., 2009).

The Poverty Action Lab (PAL) at MIT tested the widely held belief that unless people pay for a product—in this case, for a bed net—they will neither value nor use it. One PAL study in Kenya tested this theory and found no evidence that paying for a bed net will increase its use (Cohen and Dupas, 2009; Dupas, 2009). Interestingly, another study in Uganda showed that if you charge for a bed net, it is more likely to be used by the highest-income earner; but if you give it away for free, it is more likely to be used by mothers and small children, who are most vulnerable to malaria (Hoffmann, 2007, 2008).

Health systems research is critically important for addressing pressing concerns such as human resource constraints and can offer approaches for delivering care in more efficient and creative ways (Bjorkman and Svensson, 2007). For example, in studies in India, giving a kilogram of lentils every time a child was immunized (and a set of plates with each additional dose) both increased immunization rates by 3 percent and reduced the cost per immunization. By placing a nurse—a limited resource and the greatest administrative expense—in one location with bags of lentils, people were willing to walk up to 6 miles to get the lentils (and their child immunized) (Banerjee et al., 2008).

Operational or implementation research tends to be more context-specific and focuses on promoting “the uptake and successful implementation of evidence-based interventions and policies that have . . . been identified through systematic reviews” (Sanders and Haines, 2006). Increased support for operational and implementation research would help to resolve many of the context-

specific barriers to deploying existing interventions more routinely (Madon et al., 2007).

For example, strategies and drugs to prevent mother-to-child transmission of HIV, such as oral nevirapine prophylaxis, exist.¹ Yet while the prevention of this mode of HIV transmission has proved highly efficacious in tightly controlled clinical trial settings, its effectiveness in real-world settings—and thus its usefulness—is significantly diminished. Few women in low- and middle-income countries can access the required drug because the health systems in these countries lack the necessary components—human resources, physical infrastructure, laboratory capacity, procurement and supply systems, and fiscal management—to provide universal access to the drug (WHO, 2006). Operational research is urgently required for the uptake of this drug since vertical transmission of HIV/AIDS from parents to children continues to infect more than 400,000 children with the disease each year (UNICEF, 2008). Similarly, other simple interventions with proven benefits, such as the provision of potable water, polio vaccines, and bed nets, also await operational research that can allow their benefits to be widely available.

Operational and implementation research that includes cost-benefit analysis and acceptability studies will also be crucial before the scale-up of new interventions, such as the human papilloma virus vaccine to prevent infection and ensuing cervical cancer or male circumcision to reduce the likelihood of HIV infection. Policy makers in low- and middle-income countries will need to decide whether and how to add these interventions to their health programs, based on an array of factors including their cost-effectiveness and acceptability, but also larger issues such as disease burden and strain on the health system (Brooks et al., 2009; Saxenian, 2007).

The committee finds that too often, research efforts fail to address breakdowns in public health infrastructure and health systems delivery, such as poor surveillance systems, bottlenecks in drug supply pipelines, and chronic deficits in the health workforce. While additional research focused on cultural- and context-specific settings could allow the deployment of new interventions, it could also improve the deployment of several interventions already in use. The U.S. research community should support areas of study using operational, policy, and systems research to identify the desirable characteristics of interventions from the perspective of end users and to influence policy making, thus enabling innovations to be disseminated and used globally.

¹ A 1999 landmark randomized trial in Uganda testing the safety and efficacy of a single dose of oral nevirapine prophylaxis—given to mothers at the onset of labor and to infants within 72 hours of birth—showed a 50 percent reduction (compared to zidovudine) in perinatal HIV transmission in breast-fed infants, who were followed up to age 14-16 weeks (Guay et al., 1999). Subsequent studies following these babies up to age 18 months demonstrated the drug's continued efficacy, with a 41 percent reduction in vertical transmission of HIV seropositivity (Jackson et al., 2003).

Measure Impact of Programmatic Investments in Health

Not only has research on healthcare systems been underutilized generally, but few programs that deliver specific health interventions undergo rigorous evaluation. This is a significant missed opportunity to understand how to improve programmatic efforts, for example, to understand why some households do not use newly installed water purification systems in spite of life-threatening disease or why children continue to fall ill to water-borne disease even after this service is provided. An assessment that only tracked the number of households that used water purification systems would not reveal that misuse of the water in the home perpetuated high rates of diseases.

The importance of knowing what works is critical if U.S. health efforts are to help countries achieve sustainable and far-reaching outcomes. Evaluation should thus form an essential component of U.S. global health programs. Yet with the exception of the Millennium Challenge Corporation, a U.S. government corporation established in 2004 to reduce global poverty through the promotion of sustainable economic growth, there has been little emphasis on evaluating impacts. Recent trends—including the reorganization of foreign assistance under the State Department and the implementation of the President's Emergency Plan for AIDS Relief (PEPFAR)—have focused significant attention on creating indicators for recording and monitoring purposes, such as the number of health workers trained or the number of pregnant women receiving HIV testing and counseling (PEPFAR, 2007). Although such data on inputs (such as dollars spent) and outputs (such as vaccines delivered) are necessary for timely managerial decisions and accountability for the use of resources, they do not provide any useful information on the *effect* of U.S. interventions on saving lives and improving health.

As a result, the United States has lost the opportunity to learn what kinds of programs are most effective and should be disseminated to other settings and which ones are yielding fewer benefits than they could. For example, an Institute of Medicine (IOM) evaluation of PEPFAR found that some of the indicators collected did not provide appropriate information on the progress being made toward the ultimate goal of controlling the AIDS epidemic. In its early stages, most of the results reported were for targets that could be measured only in the short term and therefore revealed more about the process of implementation than the impact of the program (IOM, 2007). In response, the PEPFAR reauthorization calls for impact evaluation to examine the effect of PEPFAR programs on indicators such as incidence, prevalence, and mortality.

In addition to asking for measurement of inputs and outputs, Congress and other donors should require that program efforts be accompanied by rigorous country- and program-level evaluations to measure the effect of global health investments. Independent and rigorous evaluation, accompanied by careful study of the implementation process, is the recommended means of addressing policy questions of enduring importance. Beyond counting the number of vaccines

administered or health workers trained, it is important to ask tough questions such as, Are we preventing HIV infections in adolescent women? Do our efforts lead to sustained reductions in child mortality? Critical questions like these should inform future U.S. investments by improving knowledge of what does or does not work. For example, such questions could help the authorizers of PEPFAR go beyond simply knowing the sheer number of individuals who undergo HIV counseling to understand whether or not the program is actually lowering the rate of HIV infection within a target population.

In order to arrive at this level of information, along with program-level evaluation, investments are needed for the expansion of country-based, reliable, transparent, and long-term systems for recording health information. These should include complete (as far as possible) registration of births and deaths, along with details on the causes of death, and focused surveillance systems for infectious diseases. Indeed, such systems form the backbone of any rapid global response to new diseases and pandemics, such as severe acute respiratory syndrome (SARS) and influenza, and will be needed to track sustained health gains in preventing infections such as HIV. Improved country-level tracking would also greatly enhance the success of partnerships with the Centers for Disease Control and Prevention, which has played a historically important role in surveillance (Levine, 2008b).

Recommendation 3-1. The U.S. research community should increase research and evaluation efforts to address the systemic bottlenecks in health systems in low- and middle-income countries that keep the full benefits of existing medical and public health knowledge and technologies from being completely realized.

(A) The U.S. research community should expand its research efforts through increased attention to health systems research (both for studies that can be generalized across countries and for operational and implementation studies that are culturally and contextually relevant).

(B) In addition to measuring inputs (such as dollars spent) and outputs (such as drugs delivered), Congress and other global health funders should require that efforts to deliver health interventions be accompanied by rigorous country- and program-level evaluations to measure the effect of global health programs on saving lives and improving health.

Continue Research to Develop Novel Health Technologies and Interventions

Global health would greatly benefit from the development and dissemination of a variety of novel behavioral and biomedical prevention strategies to combat infectious diseases. Antiquated diagnostics and treatments also need to be

improved to achieve sustainable results in the management and control of disease and to reduce drug resistance that results from misdiagnosis or poor adherence to treatment regimens (Dowdy et al., 2008). These steps are especially important given that new vaccines against the three major infectious diseases seem unlikely to be deployed for another decade or more.

The research process involved in discovering, developing, and deploying a new biomedical technology is termed the “innovation cycle” by the World Health Organization (WHO) Commission on Intellectual Property Rights, Innovation and Public Health. It spans activities from basic science to translational studies; involves experts from multiple disciplines within and beyond the health and life sciences, such as behavioral scientists, chemists, engineers, and economists; and is conducted in partnership between local and global researchers, with the participation of the endemic communities. Its goal is to deliver good-quality interventions that are effective, culturally appropriate, accessibly priced, and made available in sufficient quantities (see Box 3-2) (CIPIH, 2006). While the innovation cycle runs quite smoothly in high-income countries, it often breaks down in low- and middle-income countries due to gaps and inefficiencies at each stage (discovery, development, and delivery). The U.S. research community should both conduct and fund research to help fill these gaps and should create norms for sharing that make it easier to access the information and tools necessary for research in low- and middle-income countries.

Continue Support of Product Development Partnerships to Deliver New Technologies

One of the most promising approaches to bridge the enormous and widening gap in the availability of drugs, vaccines, and diagnostics to deal with the global disease burden is the creation of public-private product development partnerships. Tapping innovative philanthropic and government financing, PDPs combine cutting-edge technology with traditional product development to create new business models that address some of the world’s most devastating scourges (Matlin et al., 2008; McKerrow, 2005). PDPs have brought together participants from the public and private sectors, maximizing their skills and resources to tackle complex issues of drug, vaccine, and diagnostic development and distribution (Meredith and Ziembra, 2008). In many instances, PDPs are virtual pharmaceutical and biotechnology companies, made operational by the commitment to achieve an important aim that would not be possible for any one partner acting alone: the development of products for which there is little potential financial return on investment.

Although PDPs came into being only in the last 10 years, the global health field has already benefited enormously from their growth. One study found that the PDP approach, compared to when the commercial or public sectors act alone, was the most cost-efficient and delivered the best health outcomes for low- and

BOX 3-2 Identifying Promising Interventions

The WHO Commission on Intellectual Property Rights, Innovation and Public Health identified an analytical framework laying out the four interrelated components that together define “the right to health interventions and technologies.” According to this framework, interventions should be available, acceptable, accessible, and of quality, as detailed below.

Available in sufficient quantities. To be available, the right kinds of interventions must exist. If they do not, the principal challenge is to spur innovation to create a product that fills the need. Where a suitable intervention already exists but is unavailable in adequate supply, solutions should be sought through research, such as the creation of a synthetic version of artemisinin, the antimalarial drug, because the natural product is in limited supply. Alternatively, an existing intervention may be suboptimal, such as current tuberculosis treatments that require six months of use and are cumbersome to administer. Then, too, an intervention may require effective procurement of existing products, the financing or subsidizing of production and distribution, or establishing effective delivery infrastructures.

Acceptable, in terms of both their usability and their appropriateness, given cultural and other factors. This requires the right kinds of products, tailored to the specific technical and social needs of the group that will use them. Knowledge is a critical element of creating acceptable interventions, such as knowledge of existing gaps in scientific know-how and clinical outcomes and of behavioral and cultural norms. This sort of knowledge requires its own kind of research and usually relies on epidemiological or social anthropological studies to understand the scale of the impact of a disease on a community or of the means required to achieve uptake of an intervention. Education and health systems research can play an important role.

The lowest possible cost to facilitate access. This requires the financing of research, and the availability of finance often drives the direction of research (HIV/AIDS, for example, has greatly benefited from the active involvement of public sector institutions); affordable pricing of medicines; the financing of procurement that can help to scale up and manufacture new products; and access to existing products.

Effective and of good quality. This requires standards for testing new products, as well as incentives to conduct clinical trials in key populations. Particular ethical and technical challenges need to be resolved for the testing of products on pregnant women and very young children, particularly those who are poor, marginalized, and often most at risk.

SOURCE: Adapted from the Commission on Intellectual Property Rights, Innovation and Public Health, 2006.

middle-income country patients. PDP drug development trajectories matched or exceeded industry standards and were significantly faster than government drug development (Moran, 2005). The unique strengths of PDPs—their ability to galvanize sectors and research networks to identify the strongest selection of drug, vaccine, and diagnostic candidates; negotiate intellectual property, licensing, and pricing agreements early in the discovery process to ensure access and affordability for effective interventions; and react nimbly to opportunities within the research community—have laid the groundwork and provided lessons for future research endeavors across sectors and countries.

The committee finds that continued investment in PDPs is essential. Several PDPs are now moving promising products into large-scale clinical trials; additional and diverse funding will be needed to see these products through to development and to determine the best ways to deliver successful interventions. The U.S. government and private foundations should continue to support PDPs and other innovative research models that best address the unmet health needs of poor countries. The U.S. research community should continue to explore cross-sectoral collaboration to focus a diverse set of expertise on the discovery, development, and delivery of the new generation of cutting-edge biomedical advances that have the potential to revolutionize global health.

Study the Basic Mechanisms of Diseases That Disproportionately Affect the Global Poor

Most of the research being conducted on global health by the U.S. research community is biomedical research directed to just three diseases: AIDS, malaria, and tuberculosis (TB). This research is itself heavily biased toward vaccine and drug development and largely neglects diagnostic and platform technologies (technologies on which other technologies or processes are built) (Moran et al., 2009). However it is critical to develop and leverage both cutting-edge research tools and platform technologies because they facilitate innovation and attract the interest of leading research teams seeking breakthrough interventions, especially against the most neglected tropical diseases that have received little investment but place a high burden on low- and middle-income countries.

These technical research tools are immensely valuable at every step of the discovery process, for example, in developing suitable animal models, identifying biomarkers, and validating surrogate end points for treatment. Platform technologies such as proteomics, microarray, and high-throughput screening increase the efficiency of product development and allow researchers to make early decisions on whether or not to proceed with a promising lead. This is especially important given the high cost of biomedical research and the finite resources available for global health.

High-throughput screening—a search for chemicals that act on a particular molecule—is an example of a technology that enables drug developers to quickly test thousands of different compounds using robotic handling systems and automated analysis of results. Such screening, along with computer-based screening using molecular docking,² is commonly used by industry and, more recently, by the academic community. Increasingly, these techniques are also being applied to neglected diseases, with compound libraries in the public and private sectors being queried for drugs against conditions such as African sleeping sickness, leishmaniasis, Chagas disease, and schistosomiasis (McKerrow, 2005; Renslo and McKerrow, 2006).

In one such example, the Sandler Center for Basic Research in Parasitic Diseases at the University of California, San Francisco (UCSF), established a consortium of core laboratories to develop new drugs for global parasitic diseases that have been ignored by the pharmaceutical industry. Initial work at the center focused on a drug lead for Chagas disease, which kills more people in Latin America than even malaria. A promising drug compound for Chagas was discovered by the UCSF team, with support from the National Institute of Allergy and Infectious Diseases at the National Institutes of Health (NIH), and developed further by the Drugs for Neglected Diseases Institute (DNDi), a PDP, and the Institute for OneWorld Health, a nonprofit pharmaceutical company.

Several other new technologies also hold the promise to unlock the secrets of biological questions and dramatically impact the way we prevent, diagnose, and treat illness on a global scale. Virus chip technology, a tool using DNA sequences to quickly identify disease agents (Wang et al., 2002), played a critical role in identifying SARS in 2002 (Frankish, 2003). Nutrigenomics—the study of gene-nutrient interactions—indicates that “dietary imbalance” can increase the risk for noncommunicable diseases (Kaput and Rodriguez, 2004), showing the way to public health applications such as the response to chronic disease through dietary interventions. Genomics—the study of gene sequencing in living organisms—is expected to yield new preventive and therapeutic approaches to the treatment of global health diseases and to promote enduring food security in low- and middle-income countries. Genomics has already yielded an antimalarial drug that went into clinical trial in less than two years (Pang, 2002).

In addition to the work being done to identify new drug targets, state-of-the-art technologies such as reverse vaccinology are revolutionizing the vaccine field (Bambini and Rappuoli, 2009; Serruto et al., 2009). Researchers are now using reverse vaccinology to help identify a serotype-independent vaccine to address pneumococcal disease. The compelling need for this vaccine has prompted several governments and other donors to fund an “Advance Market Commitment” to further draw the commercial industry and nonprofit research institutes into apply-

² Molecular docking is a collective term that refers to theoretical methods and computational techniques to model or mimic the behavior of molecules.

ing the latest technological advances to develop a vaccine that would be conducive to fighting the disease in low- and middle-income countries (see Box 3-3).

The application of cutting-edge science to the search for promising products to address neglected poor-country diseases is now occurring in labs at universities and research institutes across the United States. The committee finds that increased support for basic research, with heightened attention to using cutting-edge research tools and platform technologies, is possible, timely, and indispensable. Investments in basic research, particularly for diseases and conditions that disproportionately affect poor populations, will generate the knowledge upon which lifesaving medical interventions can be developed. Universities

BOX 3-3
An Advance Market Commitment (AMC)
for Pneumococcal Vaccine

Pneumococcal disease can cause severe infections and pneumonia; it kills close to 1 million children under 5 years of age worldwide every year (mostly in low- and middle-income countries) (CDC, 2007; WHO, 2007). These deaths tell only part of the story; an additional 11 to 20 million children are also hospitalized each year for pneumonia (Rudan et al., 2004). The pneumococcal vaccine routinely administered in the United States covers 65 to 80 percent of the serotypes associated with invasive pneumococcal disease among young children in Western industrialized countries. Serotypes vary by region, however, and this coverage is lower in many low- and middle-income countries (WHO, 2007). Because existing vaccines for pneumococcal disease are too expensive and not the right serotypes for low- and middle-income countries, they are rarely administered. Why isn't there a serotype-independent pneumococcal vaccine? Addressing this question could go a long way toward helping to avoid the more than 10 million child deaths each year.

The Pneumococcal Advance Market Commitment is an innovative finance mechanism that aims to stimulate faster progress in developing vaccines for pneumococcal diseases. Simply, an AMC guarantees innovators that there will be a market for their product if they commit the research and development necessary to produce it. In the pilot AMC program for pneumococcal vaccines, donors (including the Bill & Melinda Gates Foundation and Canada, Italy, Norway, Russia, and the United Kingdom) have committed \$1.5 million to speed the development and availability of an effective vaccine. When such a vaccine becomes available, GAVI (Global Alliance for Vaccines and Immunization) and donor funds will help recipient countries purchase it at high prices for a guaranteed period of time. GAVI slowly phases out its co-financing, and when donor funds are depleted, recipient countries are responsible for buying the vaccine at a lower price without outside assistance. The design of the AMC assures vaccine developers that there will be an initial market at high prices for their product, under the agreement that after donor funding runs out, the vaccine will be available at lower, affordable prices (AMC, 2007).

and research institutes undertaking such research should be strongly supported through grants from philanthropies and the U.S. government.

Adapt Existing Knowledge for Low- and Middle-Income Countries

While many areas require further research to identify novel technologies to address the health conditions of the global poor, additional attention is also required to adapt existing tools and interventions to better serve the global poor. Even when interventions for disease already exist, deploying them more widely and effectively in low- and middle-income countries and in distinct sociocultural settings can be very difficult, hampering global health progress (GFHR, 2004). Increasing utilization can often be achieved through adaptations to technologies and interventions—for example, by developing vaccines that do not require cold storage or modifying a behavior change program to adapt to the local context. Relatively minor adaptations can improve the effectiveness of certain interventions, such as combining drug regimes to improve clinical performance and combat drug resistance.

An example of such a modification can be seen in the treatment of malaria. At a time when malaria mortality and morbidity were on the rise due to widespread resistance to antimalarial drugs, a new combination of artesunate with another antimalarial drug was seen to confer significant clinical benefit (White et al., 1999). While such artemisinin-based combination therapies, or ACTs, are currently the most effective medicines for malaria, they are typically much more expensive than traditional malaria treatments (Garner, 2004; WHO, 2001a). In response, a variety of public-private initiatives have arisen to lower the barriers to producing ACTs and making them widely available. WHO entered into a special pricing agreement with Novartis (the manufacturer of the first ACT to be prequalified by WHO) to provide drugs at cost to governments in malaria-endemic countries; a pediatric, cherry-flavored tablet that dissolves in water or breast milk and tastes like fruit juice has now been devised to improve the drug's acceptability (Novartis, 2009). Another combination therapy using two off-patent and thus cheap drugs, artesunate and mefloquine, was formulated under DNDi's Fixed-dose Artesunate-based Combination Therapies project in collaboration with Brazil's Farmanguinhos/Fiocruz to treat patients in Latin America and Southeast Asia (DNDi, 2008). To further ensure the widespread availability of ACTs, the Affordable Medicines Facility for Malaria was initiated in 2009. This partnership—originally suggested in the 2004 IOM report *Saving Lives, Buying Time*—aims to negotiate lower prices and provide copayments for ACTs to expand access to successful malaria treatment and reduce the drug resistance that can occur with less effective treatments (IOM, 2004).

Adapting vaccines to suit low- and middle-income countries would be another way to increase the use of an existing intervention. According to WHO, vaccine-preventable diseases such as measles, hepatitis B, and *Haemophilus*

influenzae type b (Hib) disease cause an estimated 2.7 million deaths each year. However, vaccine delivery in low- and middle-income countries is hindered by the need to provide refrigerated transport and storage, multiple doses over the course of months or years, and the use of injections, which are unacceptable in some cultures. Improvements in vaccine delivery were identified as one of the Gates Grand Challenges (Grand Challenges in Global Health, 2008); scientists are exploring various alternatives to needle-based delivery of vaccines that are not dependent on refrigeration and that can be delivered in conjunction with other major vaccines (Juma and Yee-Cheong, 2005).

The need to adapt existing technologies for use in low- and middle-income countries goes well beyond the arena of infectious diseases and biomedical tools. Noncommunicable diseases such as heart disease and cancer have increased dramatically in low- and middle-income countries, but the pace at which proven therapies and preventive measures for these diseases are adapted and deployed there is not commensurate with the extent and public health impact of this epidemiological transition. Several lifesaving medicines are now available generically and can be produced cheaply, providing an opportunity to save lives in low- and middle-income countries.

Evidence suggests that a “polypill” combining three blood pressure lowering drugs (a statin, aspirin, and folic acid) in low doses could reduce cardiovascular events by more than 80 percent in healthy individuals (TIPS, 2009). The patients studied were middle-aged (45-80 years) Indian men and women without previous cardiac disease, but with at least one cardiovascular risk factor: high blood pressure, obesity, high cholesterol, diabetes, or smoking (Cannon, 2009). This polypill strategy may provide important insights into adapting and delivering existing therapies to tackle growing chronic diseases in settings where access to physicians and healthcare providers is sporadic or difficult (Cannon, 2009). The idea of prescribing a single pill without lifestyle changes (such as smoking cessation) to prevent cardiovascular diseases, however, is controversial. Opponents argue that it could lead to excessive medication and mask the major causes of cardiovascular mortality, such as those related to lifestyle or socioeconomic status (Costantino et al., 2007).

Behavioral interventions to combat noncommunicable diseases also need to be adapted to low- and middle-income-country settings, since several of the most prominent noncommunicable diseases—lung cancer, hypertension, and diabetes—can be mitigated by behavioral change. For example, smoking prevention and cessation programs have been tested extensively in high-income countries as strategies against lung cancer. The implications and extrapolation of these results to low- and middle-income countries are less understood and require appropriate behavioral trials in local settings (Buekens et al., 2004).

The committee finds the need to devote immediate attention to our continued inability to bring existing and future promising health interventions to the most disadvantaged populations. The U.S. research community has not yet fully

capitalized on opportunities to adapt existing technologies and interventions to low- and middle-income countries.

Recommendation 3-2. The U.S. research community, in collaboration with global partners, should leverage its scientific and technical capabilities to conduct research using state-of-the-art technology and innovative strategies to address health problems endemic to low- and middle-income countries.

(A) The U.S. research community should continue to examine new interventions for the prevention and treatment of global infectious diseases.

(B) The U.S. research community should expand its research efforts in global health with heightened attention to two purposes: (1) to study the basic mechanisms of diseases that disproportionately affect the global poor, and (2) to identify means to control communicable and noncommunicable diseases by adapting existing knowledge for low- and middle-income countries.

SHARE KNOWLEDGE THAT ENABLES LOCAL PROBLEM SOLVERS³

Research on global health involves not only generating knowledge relevant to the context of low- and middle-income countries, but also effectively transferring such knowledge and technologies to these settings and ensuring that the intended beneficiaries can apply them on a sustained basis. All of this requires the involvement of researchers on the ground in low- and middle-income countries. With research increasingly conducted globally through virtual communities of geographically dispersed scientists, it is critically important that information be made available to in-country researchers through a global network to exchange ideas and scientific tools, promote sustainable cross-country research partnerships, and enable the timely dissemination of best practices for local problem solvers.

Opportunities for more productive collaboration have been made possible by novel technologies, especially those in the biological and medical sciences, with dramatic benefits in how medical research is conducted; how new information is published, stored, retrieved, and used; how scientists and clinicians communicate with each other; how diseases are monitored and tracked; and how medicine is practiced. However, these developments also present their own set of challenges. Several factors affect the sharing of knowledge, such as the nature of the knowledge and the norms for scientific exchange. For example, even as information

³In preparing this section of the report, the committee drew heavily on the background paper prepared by Dr. Anthony So and Mr. Evan Stewart (see Appendix F).

technology has changed the speed and marginal cost of disseminating knowledge, intellectual property rights can make such knowledge costly to acquire. Even in the absence of patents, a technology that is new to low- and middle-income countries—such as conjugation technology for vaccine production—may not easily transfer without technical assistance. Norms related to the ownership of knowledge also influence the sharing of knowledge. These norms are rooted in statutes and regulations such as the Bayh-Dole Act, prevailing practices among research institutions and competing scientists, and guidance provided by funding agencies (So and Stewart, 2009).

Access to the Building Blocks for Research

In the path from bench to bedside (laboratory discoveries to medical treatments), the research continuum consists of inputs and outputs, each of which depends on the sharing of knowledge. Three stages in this continuum warrant closer scrutiny because decisions at these points significantly affect what knowledge can later be shared within the scientific community (So and Stewart, 2009). The three important elements relating to these stages are (1) access to scientific publications, (2) the norms for data and material sharing, and (3) patenting and licensing practices. Characterizing the obstacles to and opportunities for each can help point the way to paths that lower the barriers to sharing knowledge and improve the scientific community's ability to respond to health challenges.

Access to Scientific Publications

One of the challenges to sharing knowledge through scientific publications is that the subscription price of journals is often unaffordable for researchers in low- and middle-income countries. Mailing hard copies of journals to these countries is also prohibitively expensive for research institutes in the advanced economies. Several strategies have been deployed to ensure greater access to such publications, such as tiered pricing or the pooling of published research in open access journals or repositories. With the advent of the Internet, much of this access can now be offered electronically, provided that health workers and researchers are equipped with computers and high-speed access to the Internet (see Box 3-4).

The WHO-led Health InterNetwork Access to Research Initiative (HINARI) is one example of a tiered-pricing approach for enabling online access to scientific publications. Launched in January 2002, HINARI seeks to provide tiered access to more than 6,200 major journals in biomedicine and related social sciences. In collaboration with participating publishers, HINARI divides low- and middle-income countries into two groups: (1) countries with a gross national income (GNI) per capita from \$1,250 to \$3,500 per year, whose institutions can receive access for \$1,000 per year, and (2) countries below this GNI level whose institutions receive free access. HINARI has claimed that between 2002 and

BOX 3-4
Improving Connectivity in Low- and Middle-Income Countries

In an ideal world, everyone in the field of global health would have access to the digital tools needed to benefit from global research advances. In reality, of course, low- and middle-income countries lag far behind the advanced economies in access, despite some improvements, such as the use of the Internet and mobile technologies. For example, only 4 percent of the sub-Saharan African population uses the Internet, as opposed to 74 percent in North America (World Bank, 2007). Continued commitments are clearly needed for long-term investments in infrastructure to bring more people around the world “online.” A unique opportunity now exists for the U.S. government and other donors to invest in information technology and infrastructure that would encourage more efficient communication among the multiple players in the global health arena. The following actions are required to facilitate such connectivity:

- Industries, governments, and universities that control routes of communication over the Internet through cables or satellites should develop procedures for sharing these routes with global health programs and activities that have inadequate resources, especially in countries with weak digital infrastructure.
- Funders of global health programs and activities should ascertain the digital support available to personnel and repair any deficiencies that impede communication or performance.
- Research teams, global health practitioners, and meeting organizers should support virtual collaboration and strive to take advantage of Internet-based convening opportunities, such as Webinars and interactive websites, to reduce the time and expense involved in traveling to meetings.
- The U.S. government and other funders of research should provide incentives for the adoption of available technologies that allow connectivity between the field and medical personnel for diagnosis, surveillance, and delivery of health care. They should also aggressively support the research and development of transformational technologies that would help close the digital divide by allowing data transfer to benefit public health.

2006, researchers in HINARI countries increased their rates of publication by 63 percent, while those in non-HINARI nations saw only a 38 percent increase (Nightingale, 2008).

The pooling of published research in open access journals or repositories is an alternative method of increasing access in low- and middle-income countries. Open access journals provide articles online without charging subscriber fees because they raise their revenue from other sources, such as upfront author fees. Several studies show that this free online access corresponded to higher mean citation rates in disciplines ranging from electrical engineering to mathematics

(Antelman, 2004; Eysenbach, 2006; Hajjem et al., 2005; Lawrence, 2001). Notably, the impact of public access publication on citations in journals was twice as strong in low- and middle-income countries (Evans and Reimer, 2009).

Several health research funding agencies require investigators to make their publications accessible following publication. The NIH Public Access Policy requires investigators to submit final, peer-reviewed journal manuscripts arising from NIH funding to PubMed Central upon acceptance for publication. The Wellcome Trust requires submission of scientific publications resulting from its grants into UK PubMed Central within six months of the publication date, and even provides funding for the upfront fees associated with publishing in truly open access journals that make content freely available immediately upon publication (Wellcome Trust, 2007). Investigators in the Howard Hughes Medical Institute also face a similar requirement to deposit publications in PubMed within six months of publication (Howard Hughes Medical Foundation, 2007).

By retaining copyright and granting a nonexclusive license to journals, authors can also self-archive their work, oftentimes on their own websites or in a university repository. For example, in early 2008, the Faculty of Arts and Sciences at Harvard University adopted its own public access mandate whereby members submit electronic copies of all completed articles to an institutional repository that will eventually be accessible worldwide via the Internet (Guterman, 2008). This practice has spread: Harvard Law School and Harvard's Kennedy School of Government recently adopted their own public access initiatives, as have the Stanford University School of Education, Boston University, and the Massachusetts Institute of Technology (Gavel, 2009; Jahnke and Ullian, 2009; Suber, 2008; Taylor, 2009).

Access to Research Data and Materials

The sharing of data and other research materials enables the scientific community to confirm study findings and also to build upon the work of others. Aggregating efforts thus lowers the transaction costs by sharing the building blocks of research. Unlike the electronic distribution of journal articles or data, the marginal cost of disseminating research materials may not be negligible, creating barriers to sharing. Competing public policy concerns can also sometimes set limits on their sharing; for example, some data may risk the personal privacy of human subjects or compromise the confidentiality of privileged proprietary information (So and Stewart, 2009). Dual-use technologies—developed for military purposes but adapted for industrial or consumer uses—have the potential both to advance scientific knowledge and to pose threats to public health or the environment; such research activities as well as resulting data and materials thus require government or institutional oversight (Davidson et al., 2007).

At the same time, emerging infectious diseases have highlighted the need for a more rapid and free exchange of information and materials. During the 2003

SARS outbreak, WHO's Global Influenza Surveillance Network played a key role in linking the world's leading laboratories and experts with real-time information (Heymann and Rodier, 2004). In the race to identify the coronavirus as the cause of SARS, 11 laboratories recruited by WHO regularly and voluntarily shared samples of the unknown virus and held conference calls to discuss their results (Surowiecki, 2004). Without this level of collaboration and sharing, the transmission of SARS might not have been halted within four months.

In times of public health crises, data sharing is crucial but can also lead to conflict over the ownership of information. To study the avian flu virus, researchers in high-income economies are dependent upon low- and middle-income countries to supply them with wild virus samples. However the patenting of avian flu wild virus samples sent to laboratories in the advanced economies and the likely high costs of any resulting vaccines recently created friction in the Global Influenza Surveillance Network. The refusal of Indonesia to share virus samples with WHO Collaborating Centers without an assurance of sharing in later benefits highlighted the importance of a bidirectional flow of benefits in the sharing of data and materials (Khor and Shashikant, 2008).

Advances in mobile phone and Internet technologies have an increasingly vital role in disease surveillance. Text (or SMS) messages can be used as an alert system for the public, and personal data assistant phones can help physicians improve critical response times (Park et al., 2008). Today, more than half of the disease outbreaks investigated by WHO have come to its attention from informal sources such as news media, press reports, chat rooms, and blogs (Heymann and Rodier, 2001). Automated systems such as HealthMap (see Figure 3-1) seek to expedite health surveillance strategies by integrating web-based information around the globe into one tracking system that reports disease outbreaks in real time (Freifeld, 2009).



FIGURE 3-1 All diseases reported to HealthMap from January 14 to February 12, 2009.
SOURCE: Freifeld, 2009.

Despite the significant challenges to creating repositories and sharing the knowledge from them, some promising developments can be seen in different but complementary approaches to broadening access to compound libraries used to find new treatments for neglected diseases. Tackling a range of neglected diseases, the Special Programme for Research and Training in Tropical Diseases (TDR) has launched a web portal, TDR Targets, to bring together data and annotation in a publicly accessible database on tropical disease pathogens. Users can undertake searches ranging from genomic or protein structural data to target drug ability on neglected diseases, or they can find information on diseases such as leprosy, filariasis, and Chagas disease. In the first 16 months since the launch of the database, the site has logged more than 10,000 visits, with more than 30 percent coming from low- and middle-income countries or regions where these neglected diseases are endemic (Agüero et al., 2008). This web-based initiative complements other efforts to bring together the partnerships and multidisciplinary networks needed for drug discovery for neglected diseases (Senior, 2007).

Funding agencies have again played an important role in setting norms for sharing data and materials. The U.S. Department of Health and Human Services has developed a clinical trial registry (ClinicalTrials.gov) and data bank for the results of both federal and privately supported clinical trials conducted around the world. The Food and Drug Administration (FDA) Amendments of 2007 strengthened reporting requirements by requiring that clinical trial results completed before product approval be submitted to ClinicalTrials.gov no later than 30 days after the drug or device has received FDA approval (United States Code, 2007). Building upon the momentum of these efforts, WHO has sought to provide a forum for developing best practices for clinical trial registration, and a number of countries now maintain prospective trial registries (WHO, 2009b).

Access to Patented Inventions

The patenting and licensing of inventions significantly influences the sharing of knowledge. The patenting of knowledge enhances its potential commercial value by rewarding the inventor with time-limited market exclusivity and can help mobilize needed private sector resources for further research and development. The approach to licensing the patent shapes the conditions of access and the sharing of knowledge (So and Stewart, 2009).

Tiering can be applied to patents and their licensing in the same way it applies to scientific publications, data, and material transfers. By setting limits of geography or use, licenses may offer royalty-free rates for the invention's application in low- and middle-income countries. For example, in 2002, the TB Alliance signed an agreement with Chiron Corporation (now part of Novartis) for an anti-TB compound, PA-824. Chiron owned all the patents, know-how, and data for PA-824, as well as hundreds of its chemical analogues. The license agreement granted the TB Alliance exclusive worldwide rights for the development of

TB drugs, and in an unprecedented move for a pharmaceutical or biotechnology company, Chiron agreed to take no royalty payments in low- and middle-income countries. Such licenses often promise little revenue return from these countries, but by reserving rights for application in the advanced economies, revenues from paying markets remain possible.

The role of academic licensing in global access visibly surfaced in 2001 at Yale University in the case of the AIDS drug Zerit. The compound d4t had been discovered by two Yale researchers with funding from NIH and Bristol Myers Squibb (BMS) in the early 1990s. In exchange for the funding, as is common practice in most U.S. academic institutions, BMS was granted an option to claim broad patent protection for the compound, which it subsequently exercised. In 2001, however, Doctors Without Borders requested a waiver of the South African patent. BMS rejected this request, leading to student protests on the Yale campus and increased public attention to the critical importance of the drug to thousands in South Africa. BMS then agreed not to assert its rights.

This led to an awakening on university campuses across the United States. Several universities have since taken measures to ensure that their research is accessible to researchers in low- and middle-income countries. For example, Boston University has made the decision to ask its faculty not to assert intellectual property rights on their patents when the intervention is used by global public health organizations, such as WHO or the United Nations Children's Fund, to enable access in publicly funded programs in low- and middle-income countries (Stevens, 2009).

Funders have also sought to mitigate the concerns over exclusive licensing of inventions by establishing patent policies and requiring access provisions. Various foundations have issued guidance that encourages greater sharing of inventions resulting from their research, sometimes incorporating such conditions into their grant agreements. In funding point-of-care diagnostics for monitoring AIDS, the Doris Duke Charitable Foundation assessed how preexisting intellectual property affected the ability of its grantees to make good on the charitable objective of ensuring the technology's availability at an affordable cost in low- and middle-income countries. The grant agreements also allowed the foundation to retain a nonexclusive, royalty-free license to any patents filed in these countries, giving it the ability to sublicense rights to make and distribute the product if the grantee failed to deliver on the charitable objective (Doris Duke Charitable Foundation, 2004).

Pooling patents can also help lower the transaction costs associated with assembling the tools needed to conduct research on a health technology. GlaxoSmithKline recently developed a patent pool, or an agreement among organization to share patents, through which it contributed more than 80 current and pending patent families (GlaxoSmithKline, 2009). This voluntary patent pool makes available the patented knowledge it uses to develop medicines for neglected diseases to other drugs companies, governments, and nongovernmental

organizations. In order to enhance access to any drugs that are developed through the patent pool in low-income countries, GlaxoSmithKline has promised to cap the prices of these drugs at less than 25 percent of their potential price in high-income nations.

Recommendation 3-3. The U.S. research community should promote global knowledge networks and the open exchange of information and tools that enable local problem solvers to conduct research to improve the health of their own populations.

(A) Funders of global health research should require that all work supported by them will appear in public digital libraries, preferably at the time of publication and without constraints of copyright (through open access publishing), but no later than six months after publication in traditional subscription-based journals. Universities and other research institutions should foster compliance with such policies from funding agencies and supplement those policies with institution-based repositories of publications and databases.

(B) The U.S. government, universities, and other research institutions should develop new methods—such as simplified web-based procedures for executing agreements such as materials transfer and nondisclosure agreements—to expedite the sharing of information and research materials with researchers in low- and middle-income countries.

(C) Scientists, clinicians, advocates, and other personnel involved in defined areas of global health should develop trustworthy websites that aggregate published literature, incorporate unpublished databases or clinical trial information, promote digital collaboration, and disseminate news and other information about common interests.

(D) Universities and other research institutions that receive federal and philanthropic funding to conduct research should adopt patent policies and licensing practices that enable and encourage the development of technologies to create products for which traditional market forces are not sufficient, such as medicines, diagnostics, and therapeutics that primarily affect populations in low- and middle-income countries.

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4

Invest in People, Institutions, and Capacity Building with Global Partners

While the United States can offer low- and middle-income countries partial solutions to help resolve the challenges they face in delivering basic health services, these countries require capable local leaders, managers, analysts, and researchers to identify solutions that work and are sustainable in their own countries. Capacity building efforts that help produce a critical mass of leaders, researchers, practitioners, and educators; create an enabling institutional environment through improved infrastructure and professional support; and fund a steady stream of diverse grants to sustain the efforts of researchers would benefit health in low- and middle-income countries and begin to address the severe deficits in their health sector workforce.

LONG-TERM INSTITUTIONAL CAPACITY BUILDING

Much of the international community's work in building the capacity of public health practitioners and researchers in low- and middle-income countries has borne noticeable results. Once dominated by health experts from advanced economies, the field of public health now reflects a more diverse and globally representative group of experts and organizations. Twenty-five years ago, global health experts gave guidance to health officials in low-income countries; today, the relationship is more a partnership than a tutorial. Low- and middle-income countries have health experts of their own who not only occupy a seat at the same table, but are often better informed about the health status and specific needs of their country or region than their international partners.

U.S. government agencies, such as the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC), have long-standing

capacity building programs aimed directly at strengthening researchers and public health practitioners in low- and middle-income countries (see Box 4-1). Universities, pharmaceutical companies, and more recently, public-private product development partnerships (PDPs) have trained the workforces of low- and middle-income countries in good research, laboratory, and clinical practices as a secondary outcome of their clinical trial work. While such efforts have helped to provide trained health workers and researchers, a lack of institutional support within these countries has often driven away the most promising and well-trained practitioners and researchers.

While many existing and new global institutions have received increased funding, research institutions in low- and middle-income countries (such as universities, public health schools, science academies, and research centers)

BOX 4-1
Building Capacity of Researchers: The Role of
U.S. Federal Executive Branch Agencies

U.S. government agencies have successfully contributed to building the capacity of international partners in health research. Two noteworthy efforts are those of the NIH's Fogarty International Center and the CDC's Field Epidemiology Training Program.

NIH's Fogarty International Center

The Fogarty International Center (FIC) at NIH runs a highly successful AIDS International Training and Research Program (AITRP) that brings scientists from low- and middle-income countries to the United States to train in multidisciplinary biomedical and behavioral research in HIV/AIDS and the related epidemic of tuberculosis in their countries.

AITRP trainees are sponsored for a master's or doctorate degree or hold postdoctoral positions. The program uses several scientific, political, and economic strategies to encourage scientists to return to their home countries after training. By focusing on research that is responsive to priorities in the home country—and maximizing the amount of training conducted there—trainees are better equipped to find jobs or funding in their home countries once training is complete. A trainee may be allowed to retain an e-mail address and access to journals through the U.S. host institution even after training. Trainees come to the United States under nonimmigrant temporary visas; some sign agreements that require them to reimburse their training costs if they do not return to their home country (Kupfer et al., 2004).

A 2002 survey of five of AITRP's longest-funded programs showed an average return rate of 80 percent among their 186 long-term trainees (Kupfer et al., 2004). An evaluation of the entire program this past year showed an 85 percent rate of return among trainees over 15 years (Kupfer, 2009). FIC recently built on the AITRP model and designed the Millennium Promise Awards to extend research

have not experienced commensurate growth or been sufficiently engaged in the global health arena. In the United States, academia, nonprofit organizations, and commercial entities play an important advisory role in domestic U.S. healthcare policy, but in resource-limited nations, indigenous scientific expertise is rarely sought when shaping national policies. As a result, research institutions in these countries are often neglected and bypassed as working partners by many external donors.

Yet the challenges faced by these nations in delivering quality and equitable health services require capable leaders, managers, analysts, practitioners, and researchers to identify problems and solutions that can influence public health policy. Many low-income countries have neither a critical mass of researchers and health workers nor sufficiently funded institutions to conduct the research

capacity to cancer, cerebrovascular disease, lung disease, obesity, lifestyle factors, and genetics as related to chronic diseases (FIC, 2008).

CDC's Field Epidemiology Training Programs

The Field Epidemiology Training Program (FETP) and the Field Epidemiology and Laboratory Training Program, which offers an added laboratory component, are applied epidemiology programs offered by the CDC's Division of Global Public Health Capacity Development (DGPCHD). Both programs help countries develop and implement dynamic public health strategies to improve their health systems and infrastructure.

An in-country resident adviser is assigned to provide training and technical assistance for four to six years. The curriculum of both two-year programs is modeled on CDC's Epidemic Intelligence Service, typically involving classroom instruction (25 percent) and field assignments (75 percent). In class, trainees take courses in epidemiology, communications, economics, and management, while learning quantitative and behavior-based strategies. In the field, trainees conduct epidemiologic investigations and field surveys, evaluate surveillance systems, perform disease control and prevention measures, report their findings to decision makers, and train other health workers.

Since 1980, DGPCHD has helped to establish 30 field epidemiology training programs that have produced more than 1,000 graduates. In 2008, the programs had 276 active trainees; together, trainees and graduates conducted more than 300 outbreak investigations and gave 280 presentations at international conferences. As of April 2009, 17 resident advisers for epidemiology and laboratory were supporting 12 programs in Central America, Asia, the Middle East, and Africa. Located at CDC's headquarters in Atlanta, Georgia, DGPCHD staff provide additional scientific support and advice to sustain FETPs and related programs around the globe. This division of CDC also supports the technical components of five other mature programs in Brazil, Egypt, Jordan, Saudi Arabia, and Thailand. Plans for the establishment of new programs are under way in 14 countries, including Afghanistan, Central Africa, Iraq, and Yemen (CDC, 2008).

and analytical work needed to find solutions (not to mention inform policy) to address the health problems endemic to their countries.

For example, universities in low-income countries—vital to human resource development—often face a host of problems. They suffer from lack of funds, weak infrastructure, outdated or misaligned training programs, overcrowded classrooms, and overburdened and underpaid staff (Dovlo, 2003; Tettey, 2006). In recent years, many health science schools in sub-Saharan Africa have been asked to double or even quadruple the number of students without concomitant increases in their budgets and despite significant staff vacancies (Effah, 2003; Houenou and Houenou-Agbo, 2003; Jibril, 2003; Taché et al., 2008). For students, the shortage of teachers means a lack of mentorship and academic support. Students often graduate without being equipped to address critical tasks pertinent to the burden of disease and epidemiologic scenarios for which their service is needed (Taché et al., 2008). Health practitioners are often unprepared to deal with the challenges of working in underresourced clinics and hospitals (WHO, 2006). Both researchers and faculty struggle to find resources for substantive research projects. The consequent overall lack of opportunity and career advancement results in low morale, providing little incentive to work in academia or the public sector or to remain in the country.

The committee finds that strengthening universities, research centers, and government institutes in low- and middle-income countries could have a direct impact on the ability of these countries to muster the internal resources needed to address their own health problems. In particular, the committee finds that by supporting these institutions, the United States can help to develop an environment of inquiry, entrepreneurship, and experimentation that brings together researchers, practitioners, and policy makers, across disciplines and borders, to solve some of the pressing health problems facing less wealthy nations.

Expand Commitment to Institutional Capacity Building

The United States still has much to contribute in building academic and research capacity in low- and middle-income countries, given its expertise in research, science, and technology. A global health field has recently emerged that has been defined as an area for study, research, and practice that places a priority on improving health and achieving equity in health for all people worldwide. The global health field emphasizes transnational health issues, determinants, and solutions; involves many disciplines within and beyond the health sciences; promotes interdisciplinary collaboration; and is a synthesis of population-based prevention and individual-level clinical care (Koplan et al., 2009). By building on successful programs and leveraging the growing involvement of U.S.-based universities, commercial entities, and foundations in global health, the United States has an opportunity to help redress the neglect of universities and other research and public health institutions in resource-limited settings.

Unprecedented energy and enthusiasm for global health now exist among students and medical residents in U.S. universities (Drain et al., 2007). U.S. academic institutions have a vast untapped potential to work with academic institutions in low- and middle-income countries to advance the academic environment in both sets of institutions by strengthening faculty and improving training programs and curriculums. Many examples in the past several years also illustrate the interest in the commercial sector and among professional associations in sharing their business and technical acumen for the greater social good.

Several U.S.-based foundations, such as Rockefeller, Carnegie, and Pew, were some of the first organizations to embark on capacity strengthening programs in low- and middle-income countries. For example, the Rockefeller Foundation—which contributed \$25 million in 1921 (equivalent to \$357 million today) to establish 21 schools of public health in cities such as London, Tokyo, Calcutta, and Sao Paulo—today continues to support many institutions and fellowship programs for health scientists worldwide (Fosdick, 1989).

U.S. philanthropies and the U.S. government should continue the tradition of funding capacity building initiatives and expand this commitment to leverage the growing interest of academia, nonprofit organizations, and commercial entities. With increased support, research institutes could adopt innovative methods and technologies for distance learning and collaboration and, thus, help to reshape education and research in global health.

Support Long-Term and Mutually Advantageous Institutional Partnerships

The committee finds that the United States can support institutional capacity building in low- and middle-income countries by funding and participating in long-term and mutually advantageous institutional partnership compacts. Through sustained partnerships, U.S. government agencies, universities, corporate entities, and foundations can strengthen the local capacity of researchers, practitioners, and policy makers, as well as their respective institutions, in low- and middle-income countries.

Many examples of capacity building partnerships among institutions exist, with different arrangements and varying benefits for participants. Traditionally, these partnerships have involved an institution from a high-income country and an institution from a low- or middle-income country (sometimes referred to as “twinning”), but increasingly, the partnerships involve partners from low- and middle-income countries only. For example, under the leadership of the Mexican government, the Mesoamerican Public Health Institute was established to support a virtual network of academic and research institutes in the Central American region (López, 2008). Both models have their advantages; in a partnership involving high-income countries, the high-income institution brings valuable expertise to the table but can overshadow the other partner, while a partnership between

low- and middle-income institutions tends to be more equitable and less costly but offers fewer opportunities to transfer expertise.

Given the importance of the emerging economies, another type of partnership called “triangulation” has been suggested to leverage the strengths of institutions from all three levels of economies: high, middle, and low income. The United States might, for example, establish a partnership with both Brazil and Mozambique. The International Association of National Public Health Institutes (IANPHI) is exploring this exact partnership, among others, in an attempt to build the capacity of public health institutes globally (see Box 4-2).

Such partnerships often result in the establishment of Centers of Expertise that serve entire regions. Centers of Expertise are promising, especially in the initial stages of capacity building, because they afford some coordination among multiple, differentiated institutions, which can help to propel and sustain entire professional fields.

BOX 4-2
National Public Health Institutes: Integrating Vertical Programs and Enhancing Public Health Capacity

National Public Health Institutes (NPHIs) are science-based governmental organizations, such as the CDC in the United States, FIOCRUZ in Brazil, RIVM in the Netherlands, and CDC in China, that provide expertise and leadership for core public health functions, including research, disease surveillance, outbreak investigation, laboratory science, policy formulation, and health education and promotion.

Coordinating core public health functions through an NPHI can result in a more efficient use of resources, improved delivery of public health services, and increased capacity to respond decisively to public health threats and opportunities. NPHIs are particularly beneficial in low-resource countries, where they provide public health professionals with a group of technically oriented colleagues and a prestigious career path, helping to stem the tide of experts leaving government service for higher-paying jobs with international nongovernmental organizations. NPHIs in low-resource countries also encourage governments to set science-based public health priorities and policies, better integrate and leverage funds from numerous vertical programs, and plan strategically and systematically for future human resource and infrastructure needs.

NPHIs vary in scope, function, and size along a continuum from fledgling institutes to organizations with comprehensive responsibility for research, programs, and policy for almost all public health threats. Most NPHIs, including the U.S. CDC, began as very focused public health or research institutes charged with identifying and combating infectious disease threats. Over time, CDC and many other NPHIs in mid- to higher-resource countries have evolved and expanded to meet new public health challenges, including death and disability from chronic diseases, environmental and occupational threats, and injury prevention. The growth of NPHIs over the years—including their successes and failures—provides

The committee finds that partnerships among institutions in advanced and emerging economies and resource-limited nations are a promising practice and should be expanded. Institutional partnerships—whether twinning, triangulation, or establishing Centers of Expertise—have proved an effective way to build capacity when they are conceived as a long-term commitment and based on an equitable relationship among participants. Numerous institutions in low- and middle-income countries have been able to take advantage of long-term partnerships to build their institutional capacity. Makerere University in Uganda is an example of an institution that has leveraged multiple partnership compacts with universities, commercial industry, foundations, and PDPs to reestablish the university as a leading institution in sub-Saharan Africa (see Box 4-3).

Although there has been little rigorous evaluation to parse the most promising aspects of the institutional partnership model, some lessons can already be

an important frame of reference for those with more limited current capacity as they consider how to move forward. Such a “road map” is invaluable not only to lower-resource economies, but also to countries such as the United Kingdom, Hong Kong, and Canada, which have created NPHIs only recently in response to public health challenges such as bovine spongiform encephalitis and severe acute respiratory syndrome.

Moving NPHIs forward along the continuum toward more technical depth and comprehensive capacity is the primary goal of the International Association of National Public Health Institutes, which serves as a professional organization for NPHI directors, assisting them in their professional and institutional growth through scientific meetings, leadership development activities, and seed grants for research and training. IANPHI’s fundamental philosophy is that the collective history, knowledge, and scientific expertise of its member institutes is a powerful force for transforming public health systems in low-resource countries.

IANPHI is collaborating with nine low-resource countries to create new NPHIs or to substantially increase capacity at fledgling institutes. IANPHI’s nine long-term NPHI development sites include Burkina Faso, Ethiopia, Guinea Bissau, Mozambique, and Tanzania, with projects being explored in Bangladesh, Cambodia, Central America, and Ghana. In addition to its strategic investments of up to \$670,000 in each of the nine long-term project sites, IANPHI leverages substantial strategic planning and organizational design expertise, scientific technical assistance, and public health training for each project from other IANPHI members. For example, Guinea Bissau received technical assistance and training from Brazil; Finland is providing technical assistance and training to Tanzania; the Netherlands and Norway have committed to providing assistance to Ethiopia; and Morocco has pledged technical assistance and training to Burkina Faso. In addition, IANPHI links into each project the specialized expertise of other partners, including WHO, and links with key funders and programs, including the Health Metrics Network, the Global Fund, bilateral aid groups, and the U.S. government.

BOX 4-3

Rebuilding Uganda's Makerere University Through Institutional Partnerships

Makerere University, established in 1922, is one of Africa's oldest universities. It has 30,000 undergraduate and 3,000 postgraduate students. Through international collaborations with a number of institutions, Makerere has established itself as a global center for research, especially on HIV-related health outcomes. Once reputed as the preeminent research institution in sub-Saharan Africa, Makerere University faced financial and institutional collapse during the late 1980s. The restructuring of administration, increases in enrollment, and a reallocation of private funding have been instrumental in rebuilding Makerere University as an example for surrounding institutions suffering similar infrastructure collapse (Task Force on Higher Education and Society, 2008).

Among the university's more notable collaborations has been its partnership with Johns Hopkins University in the United States to establish a College of Health Sciences. A two-year initial phase includes a needs assessment plan written by students and led by Makerere faculty members with support from Johns Hopkins, building on a long history of Johns Hopkins' collaboration with Makerere University. The plan will include an evaluation of how Makerere University might most effectively promote local health initiatives involving HIV; test innovative strategies such as voucher systems; and support implementation of health programs based on research—for example, the Makerere University finding that circumcision can reduce the risk of acquiring an HIV infection by 48 percent. Over the next eight years, a strategic plan will be implemented jointly by an advisory panel (made up of deans from Makerere's College of Health Sciences and Johns Hopkins faculty) and an advisory council drawn from Ugandan government and civil society. After identifying Uganda's health needs and drawing up a plan to meet them, Makerere University will expand its capacity to improve health outcomes in Uganda and East Africa (Gebel, 2009).

In another successful collaboration, Makerere University partnered with Pfizer Inc., Accordia Global Health Foundation, and the Academic Alliance to establish the Infectious Diseases Institute (IDI) in 2004. African-owned and African-led, IDI is now a preeminent center for infectious disease research, training, and treatment. By enhancing the stature and recognition of the Faculty of Medicine at Makerere University, IDI is helping to reverse the trend of African healthcare professionals' pursuing career opportunities abroad. The IDI model has proven extraordinarily productive, with far-reaching applications for similar disease-fighting efforts elsewhere in Africa (Accordia Global Health Foundation, 2009a).

Another collaborative effort by Makerere University, the IDI-based Sewankambo Scholarship Program, aims to build the next generation of academic medical researchers in Africa. The program couples outstanding African clinicians with at least one internationally recognized investigator who commits to providing five years of substantive, ongoing mentorship in a rigorous research program. During this process, scholars also develop their own research teams and mentor, in turn, another generation of young Ugandan investigators, thus expanding "in-country" clinical and applied research with little assistance from Western institutions (Accordia Global Health Foundation, 2009b).

learned from partnerships undertaken in health and other fields such as agriculture and science. Institutional partnerships should do the following:

- Represent a long-term financial commitment (5 to 10 years or more) with a focus on sustainability and creating self-reliance (Crisp et al., 2000; Drain et al., 2007; ODI, 2009).
- Be based on trust, ethical principles, transparency, and equity in exchange and ownership, where all partners find the relationship mutually advantageous and respect and understand differences in cultures and perspectives (Jones and Blunt, 1999; KFPE, 1998; Ofstad, 1999; Tsibani, 2005).
- Have leadership commitment from their respective Ministries of Health and Higher Education (among others) (Crisp et al., 2008; Nuyens, 2007).
- Focus on strengthening the institution and not a particular individual, paying attention to the crucial need for improving the institutional environment to enable problem solving and policy engagement.
- Incorporate an interdisciplinary approach that goes beyond the medical and health science schools and includes disciplines such as public health and policy, business, engineering, agriculture, and economics.
- Define goals and metrics of success at the beginning of the partnership; all parties involved must commit to evaluate the model and remain flexible to adjust as needed (Crisp et al., 2000; Ijsselmuiden et al., 2004; KFPE, 1998; ODI, 2009).
- Reach agreement at the start regarding the ownership of data, specimens, and intellectual property, as well as how information should be shared, given the existing information-sharing infrastructure.

While institutional partnerships should be flexible in order to build upon the strengths of their participants, they should endeavor to engage in the following five important and focused activities:

1. *Invest in training to help build a critical mass of researchers, practitioners, and educators.* Institutional partnerships should play an explicit role in helping to educate and train leaders, researchers, teaching faculty, health workers, and professionals (such as managers, public health practitioners, and policy analysts). Training must be based on a comprehensive approach to build long-term, sustainable, and independent leadership, research, and teaching capacity and should include investment in master's and doctoral training programs (Maziak et al., 2004; Nchinda, 2002). Adequately staffed universities, health science schools, and teaching hospitals will go a long way toward training leaders and managers while addressing the critical shortage in the health workforce (Crisp et al., 2008).

2. *Create an enabling institutional environment to rectify a development paradox.* Better training can lead to a depleted workforce if trained workers emigrate (Arah et al., 2008). Significant and long-term investments will be required to rectify the “push” factors that drive the health workforce out of underserved areas and discourage professionals from serving the public good. Investments in infrastructure (such as properly equipped labs and increased access to research tools and scientific journals) and professional support will help retain trained health workers among underserved populations (Dovlo, 2004). Examples of such support are compensating professionals for mentoring activities and providing opportunities for their career advancement through faculty development and exchange programs.

3. *Fund a steady stream of diverse grants to sustain the efforts of researchers.* To further support and sustain institutions, institutional partnerships should work to ensure a steady stream of grants to generate and share knowledge that can inform health policy. Grants could be directed to underfunded research areas, such as health systems research, and focus on critical needs such as improving the delivery of existing interventions.

4. *Generate demand for scientific and analytical work to influence public policy.* Once best practices are identified in relevant health areas by institutional partnerships, country leaders can take up the task of bridging the knowledge-action gap in their societies and create evidence-based guidelines to inform good practice for health workers, policy makers, leaders, professionals, and academicians.

5. *Build credibility by contributing to real and immediate health policy challenges.* By contributing to solving some of the most pressing global health challenges through a specific focus on, for example, human resource capacity issues, partnerships can have a meaningful and real-time effect on the ongoing delivery of care within a particular country or region. This will enhance the credibility of the local institution, both with local policy makers and with external donors who may be skeptical of the benefits of long-term capacity building investments, and offer opportunities to partner with service delivery programs such as the President’s Emergency Plan for AIDS Relief or President’s Malaria Initiative.

Recommendation 4-1. Federal executive branch agencies, along with U.S. private institutions, universities, nongovernmental organizations, and commercial entities, should provide financial support and engage in long-term and mutually advantageous partnerships with institutions—universities, public health and research institutes, and healthcare systems—in low- and middle-income countries with the goal of improving institutional capacity. These partnerships should enable local and global problem solving and policy engagement by

- Investing in training,
- Creating an enabling institutional environment,
- Funding a steady stream of diverse research grants,
- Generating demand for scientific and analytical work that influences public policy, and
- Contributing to the control of real and immediate health problems.

RECTIFY THE HEALTH WORKFORCE CRISIS

Many countries face critical health workforce deficits that directly affect health outcomes. National health resource strategies that go beyond simply increasing the number of health workers and endeavor to understand and improve the dynamics of the labor market have been successful in stemming the tide of workforce migration and in recruiting and retaining labor for underserved areas. While such strategies require commitments by governments to construct and finance human resource plans, the international community, too, needs to play an important role in supporting and financing these country-led plans.

Global Health Workforce Deficits Are of Crisis Proportions

Human resources are critical to improving global health. The density and quality of the health sector workforce directly affects health outcomes, with increased density being associated with reductions in maternal, infant, and under-5 child mortality (Anand and Barnighausen, 2007; Chen et al., 2004). On average, countries with fewer than 2.5 healthcare professionals (counting doctors, nurses, and midwives) per 1,000 people failed to achieve an 80 percent coverage rate for measles immunization or for deliveries by skilled birth attendants (Chen et al., 2004).

Such statistics have led the World Health Organization (WHO) to recommend that a country maintain a health workforce density of no less than 2.28 workers per 1,000 population (or 1 health worker for every 400 people) to achieve desired levels of key health intervention coverage (WHO, 2006). Based on this measure, the world has a global shortage of 2.4 million doctors, nurses, and midwives; when other health service providers such as medical technicians are included, the global shortage reaches 4.3 million health workers (WHO, 2006).

WHO estimates that 57 countries (36 of which are in sub-Saharan Africa) have critical health workforce shortages, making it difficult (if not impossible) for them to achieve the health-related Millennium Development Goals (MDGs) (WHO, 2006). For example, sub-Saharan Africa would need to increase its health workforce by 140 percent to support attainment of the MDGs (UN, 2008). A study to assess the human resources required to achieve the MDGs in Tanzania and Chad found that by 2015, Tanzania would require 98,000 full-time health workers, but would have only 36,000; in Chad the situation would be even worse,

with 19,000 workers required, but only 3,500 available—a deficit ratio of more than 5 (Vujcic, 2005).

Beyond the shortage of health workers, issues of productivity, absenteeism, and “ghost” workers exacerbate the problems of the health workforce. Public health systems are often characterized by a lack of capacity due to weak civil service and limited incentives for improving performance. Poor labor conditions such as low salaries, supply shortages, and work overload contribute to unsatisfactory working conditions that drive health workers out of government service—especially in underserved areas—and minimize the impact of those workers who do remain (Marchal and Kegels, 2003).

Low compensation leads to income supplementation strategies such as informal payments and dual practice in the private sector. Research on absenteeism has revealed “ghost” doctors—physicians absent from their salaried posts due to private sector obligations or higher-paying opportunities elsewhere (Chaudhury and Hammer, 2004; Chaudhury et al., 2006). A recent survey of six countries (Bangladesh, Ecuador, India, Indonesia, Peru, and Uganda) shows an average absence rate of 35 percent among healthcare providers. In Peru, for example, 48 percent of doctors reported external income from private practice in addition to public sector work; not coincidentally, these providers also showed a higher absence rate compared to other practitioners (Chaudhury et al., 2006). High absentee rates often result in the diversion of patients to more accessible private providers, subjecting patients to care that is often costly and delivered by poorly or undertrained providers (Lagomarsino and Kundra, 2008).

The same poor working conditions that prevent health workers from performing at the highest level have also “pushed” many health professionals in resource-poor settings out of the public sector entirely, with many choosing to emigrate to higher-income countries that are experiencing a health workforce shortage (Aiken et al., 2004; Arah et al., 2008). An analysis of African-born nurses and doctors working domestically and abroad revealed that one-tenth of nurses (~70,000) and one-fifth of doctors (~65,000) were working overseas in a developed country in 2000 (Clemens and Pettersson, 2008). The fraction of health professionals abroad varied enormously across African countries. In the Gambia, for example, for every professional nurse working in the country, about two live in a developed country overseas (Clemens, 2007). While Niger has a tiny physician diaspora, Ghana’s is enormous (Clemens and Pettersson, 2007). Overall, 47 percent of the African countries sampled have lost more than 40 percent of their physicians, while nearly one-third of the countries lost more than 20 percent of their nurses (Clemens, 2007).

Given these migration statistics, it is not surprising that terms such as “brain drain” and “poaching” have become popular to characterize the health sector’s human resource crisis in poor countries. Low-income countries subsidize professional education to generate much-needed skilled professionals, but labor and credit market failures often prevent these professionals from being paid their

marginal social product. If they departed for countries where their private gain better reflects their contribution, they would be lost (brain drain) and a public good—the government-funded education of a health worker—would become a private good (poaching).

Health Workforce Plans Depend on Donor Support

To address the health workforce crisis, many countries have set out to establish human resource plans to deal with clinical workforce deficits, as well as shortages of administrators, managers, policy analysts, public health specialists, and academicians in higher learning institutions—all of whom are key to ensuring a well-functioning health system (see Box 4-4). Although the opportunities for donors to improve the health workforce in low- and middle-income countries are marginal, there is mounting recognition that without urgent attention to workforce shortages, other initiatives in global health will suffer. According to the *2006 World Health Report*, national strategies on their own (however well conceived) are insufficient to deal with the difficulties of health workforces today and in the future (WHO, 2006).

In many instances, severely resource-constrained countries are dependent upon donors to assist in supporting and financing country-owned human resource strategies (Crisp et al., 2008). The United States should work to improve the global human resource crisis in the health sector by first doing no harm; helping to finance “sound” country-owned plans to improve human resources for health; and considering partial solutions that leverage the U.S. workforce to address immediate workforce needs in low-income countries.

Donors Should First Do No Harm

Well-intentioned donor financing and programming can sometimes have unintentional consequences that undermine country-led efforts to improve the health workforce. For example, well-meaning foreign assistance often comes in the form of a large number of training workshops and short courses of study meant to improve the workforce. Too often, these short courses are not effective and lack evaluation or even a coherent or long-term strategic purpose. The trainers often fail to consider how, when, and where to conduct courses in order to minimize the disruption of care delivery. As a result, health workers are often pulled out of the care delivery setting in order to attend training courses, leaving clinics, hospitals, and teaching facilities further depleted.

Numerous examples of wage distortion can be found when health sector employment is financed internationally rather than locally (McCoy et al., 2008). In Malawi, a survey of local and international nongovernmental organizations in 2005 showed that the average salaries paid by international organizations were substantially higher than those paid by local ones (Imani Development,

BOX 4-4
**Health Sector Human Resource Strategies
to Address the Workforce Crisis**

Workforce policies focused on simply increasing the number of health workers to address health needs (without understanding the dynamics of the labor market, such as supply and demand) often fail to achieve their objectives (Glassman et al., 2008; Vujicic and Zurn, 2006). Policies that incorporate more explicitly the behavior of those who supply labor (doctors, nurses, midwives, and other providers) and those who demand labor (local governments, the private sector, and foreign governments) and endeavor to understand how each group responds to incentives can be successful (Vujicic and Zurn, 2006).

The supply of healthcare professionals at the country level can be thought of as the number of individuals with the necessary qualifications who are willing to work in the healthcare sector. Supply is influenced by opportunities to migrate, as well as access to training, labor conditions, and wages. By understanding how these factors influence the supply of viable healthcare professionals, countries can create public policies to address their health workforce shortages (Vujicic and Zurn, 2006).

Given that resources are limited, what is desirable or needed is not always feasible. Thus, the demand for healthcare services—the quantity of healthcare services that individuals or governments are willing to pay for—does not always correspond to healthcare needs. For example, in many cases, hospitals *need* more doctors and nurses to achieve the desired level of health service delivery, but do not have the resources to pay their wages and thus *do not demand* more healthcare providers. Other factors, such as the length of time required to educate physicians, can delay changes in the available supply, thus delaying balance in the labor market (Zurn et al., 2004).

Providing Educational Incentives

Targeted subsidies, grants, and scholarships are examples of incentives that can be used not only to attract more students, but also to retain students who are more likely to remain in the country and work in underserved areas (Marchal and Kegels, 2003). Thailand provides an example of such incentive-based placement of doctors to address urban and rural healthcare disparities (Wibulpolprasert and Pengpaibon, 2003). Another measure to retain health workers could be to identify,

2005; McCoy et al., 2008). Another study has found that in several countries the Global Fund has contributed to an exodus of employees from health ministries by paying higher salaries than the government (Drager et al., 2006). While wage discrepancies between locally financed positions and internationally financed positions exist and may be especially problematic in areas that receive significant international funding for programs such as HIV/AIDS (Shiffman, 2008), the

at the time of entry to health worker education, those candidates who are likely to stay in their country and work where they are most needed (Marchal and Kegels, 2003). A Ugandan study of nursing students found that those wanting to emigrate would be least likely to work in rural areas (Nguyen et al., 2008). Governments could then create incentives to target the students who do not aspire to migrate as being the most inclined to work in rural and underserved areas.

Improving Working Conditions

Wage increases, additional benefits, and flexibility in working hours are other examples of commonly used incentives to attract or retain workers. Yet recruiting and retaining health staff requires an *overall* conducive environment that offers opportunities and favorable working conditions. Health personnel working in underserved areas require special incentives that go beyond educational incentives and reasonable salaries, such as hardship and transportation allowances; subsidized school fees for children and housing; and opportunities for continued education and career development. Reducing the brain drain within countries among doctors requires “clear-cut, merit-based career structures that offer attractive posts in clinical or research fields, accompanied by adequate remuneration” (Marchal and Kegels, 2003).

Reforming the Skill Mix

In some instances, resource-limited countries are making greater use of mid-level health workers, such as assistant medical officers, clinical officers, and surgical technicians (Heller and Mills, 2002; Marchal and Kegels, 2003). These workers supplement the work of doctors and nurses to provide medical, obstetrical, and surgical care in underserved areas. Midlevel workers can provide quality care if appropriately trained, monitored, and given the opportunity to attend continuous skill improvement courses (Dovlo, 2003; Vaz et al., 1999).

Overall, such incentives and policies can bring more workers into the public health system and improve its effectiveness. National policies that improve labor conditions by offering a mix of these incentives have been successful, but they require a commitment by governments to formulate health resource plans. These plans should be led by countries because the policies to address the local labor market must be planned, implemented, and owned within national settings (Chen et al., 2004).

evidence in this area is still sparse and requires further evaluation to understand how international nongovernmental organizations and donor programming affect the health sector labor market. Donors should be cognizant of the potential effect their efforts to recruit health workers and professionals may have on local public health recruitment efforts.

The demand for health workers in the United States and other advanced

economies is also a factor that can contribute to the recruitment of health workers away from underserved areas in low- and middle-income countries. Trends over the last 25 years show that the number and percentage of foreign-trained nurses and doctors have increased significantly in most high-income countries (Dumont, 2007). For example, nurse immigration to the United States has tripled since 1994 to almost 15,000 entrants annually. In 2007, about 8 percent of all registered nurses were estimated to be foreign educated; of these, 80 percent were from lower-income countries (Aiken, 2007).

This has prompted many organizations to call for increased measures both to limit the recruitment of healthcare professionals from other countries, especially from countries most affected by human resource shortages, and to reduce U.S. dependency on an immigrant workforce in the health sector. An examination of U.S. migration, workforce, and training policies was not within the purview of the committee's charge.

The committee did consider the effect of migration of health workers on health outcomes in low- and middle-income countries and finds that global migration is not the main cause of the human resource crisis, nor would its reduction be the main solution, even though it does exacerbate the acuteness of the problem in some countries. Attempts to merely increase the supply of workers by restricting emigration visas or reversing migration might have a modest effect on the human resource crisis, but would not solve the problem and would put unnecessary restrictions on the right of workers to migrate. For example, the need for human resources in low-income countries, as estimated by WHO, largely outstrips the number of immigrant health workers in the United States and elsewhere (Dumont, 2007).

Moreover, at least one study examining the emigration of African physicians and nurses found no evidence that migration substantially affected the 11 indicators of mass primary care availability and public health outcomes (Clemens, 2007). If physicians or nurses abroad substantially degrade basic public health conditions, one would expect to see a positive correlation between the number of physicians abroad and childhood mortality. Yet the study found the exact opposite. Countries with higher migration tend to have lower mortality rates. Another analysis found similar results; higher physician migration density was significantly associated with relatively "higher wealth and less poverty, higher health spending, better development, and higher population health status" (Arah et al., 2008).

Therefore, the committee finds that while migration is a highly visible and volatile topic, it is a sign that even as a country is training internationally valuable resources, it is not providing enough incentives to prevent these resources from finding more promising opportunities elsewhere. Migration is a symptom of more serious issues of chronic lack of reinvestment in the health workforce and health systems of low- and middle-income countries that encourage workers to migrate to wealthier countries. Addressing the human resource crisis in the health sector

will require reversing deficits in capacity, infrastructure, and leadership within the health sectors of resource-limited countries.

Support Country-Led Health Sector Workforce Plans

The committee also finds that while low-income countries are the owners and drivers behind national strategic plans to improve the health workforce, in many instances, the success of these plans is dependent upon external donor assistance (HRET, 2007; JLI, 2004; WHO, 2006, 2008). As much as 50 to 85 percent of the recurrent healthcare budget of some countries in sub-Saharan Africa is consumed by salaries for healthcare providers (Vujicic, 2005). Large increases in funding, no matter what the source, are therefore necessary to scale up human resources for health.

The current model of donor assistance does not support the long-term, country-led investment that is required to help finance nationally owned strategies for developing human resources for health. Development assistance and donor grants tend to be unpredictable, volatile, and short term, making it difficult for recipient governments to make long-term investments or to plan budgets using external assistance (Lane and Glassman, 2007). Funds for hiring workers need to be stable and long term in order to cover recurrent costs, such as salaries. Governments, therefore, may not wish to expand their health workforce any faster than is sustainable in the long term with domestic resources (Vujicic, 2005).

In an interesting case in Malawi, a careful analysis of the health labor market found a mismatch between the government's great need for health workers and a large available pool of skilled workers in the private sector who were unwilling to work for public sector salaries. With assistance from the United Kingdom, the Malawi government initiated a six-year plan to increase salaries in the health sector by 50 percent (Glassman et al., 2008). Preliminary assessment of the Malawi program in its first three years of implementation shows an increase in practicing health professionals in the public sector. In 2007, the physician and nurse workforces increased 40 and 30 percent, respectively, compared to 2003. Medical training infrastructure also improved—observable in the quadrupling of medical training facilities between 2003 and 2006. To continue improvement in retention and recruitment in the priority health fields, the Malawi plan aims to improve incentives by offering a 52 percent salary increase (WHO and GHWA, 2008).

Recommendation 4-2. Federal executive branch agencies and departments, nongovernmental organizations, universities, and other U.S.-based organizations that conduct health programs in low-income countries should align assistance with the priorities of national health sector human resource plans and should commit and sustain funding in support of these plans.

Consider Partial Solutions for Leveraging the U.S. Workforce

Given the overwhelming interest in global health, a relatively small number of U.S. health professionals currently work in low- and middle-income countries. Many health professionals volunteer with faith-based or secular nongovernmental organizations, while several universities and corporations support health personnel in low-income countries through global health programs or research projects. The U.S. government also sends small numbers of health professionals through CDC and U.S. Agency for International Development projects (Mullan, 2007).

This relatively modest level of mobilization begs the question: If the resources were made available, would a greater number of Americans in medicine, nursing, public health, and the nontraditional health fields commit to service overseas? An equally important question is whether or not an increase in U.S. expatriates and volunteers would be a welcome resource in low-income countries. The level of analysis necessary to answer both questions requires further investigation.

A 2005 study of nongovernmental organizations in sub-Saharan Africa found a variety of volunteer opportunities ranging from two weeks to more than two years at an estimated cost between US\$36,000 and US\$50,000 per expatriate volunteer per year (Laleman et al., 2007). In general, the study found that most country experts had experienced some interaction with hard-working, highly motivated, and committed expatriate volunteers, who were willing to live and work in remote areas. However, the study also found that volunteers tended to be junior, inexperienced, and ill prepared to work in low-income countries for both cultural and professional reasons. The use of volunteers in low-income countries may require a more coordinated approach if this type of support is to provide a partial solution to the human resource crisis in the global health sector.

The 2005 Institute of Medicine report *Healers Abroad: Americans Responding to the Human Resource Crisis in HIV/AIDS* recommended that the federal government create and fund an umbrella organization called the United States Global Health Service (GHS) to mobilize the nation's best healthcare professionals and other experts to help combat HIV/AIDS in severely affected African, Caribbean, and Southeast Asian countries. With a goal of building the capacity of targeted countries to fight the pandemic over the long run (IOM, 2005), the GHS would include, among several elements, a pivotal "service corps" made up of full-time, salaried professionals. Other GHS staff would be stationed on the ground to provide medical care and drug therapy to affected populations, while offering their local counterparts training and assistance in clinical, technical, and managerial areas.

The committee finds that if a global health service model is deployed, the mandate of the program should be broadened to include global health issues beyond HIV/AIDS, emphasize training over service provision in the context of providing patient care, and support bidirectional engagement (with U.S. professionals going abroad but also having professionals from low-income countries come to the United States). Given that this type of program would require signifi-

cant resources, the committee considered whether or not scarce U.S. development assistance dollars could be better spent supporting local country staff. While such an investment would be an important opportunity for bidirectional knowledge transfer, the committee recommends more detailed studies to determine the demand for such a program (would mid- and advanced-career professionals be willing to commit to a multiyear program?) and the degree of public health benefit in recipient countries (would this type of support be well received by recipient countries and would it be the most appropriate use of U.S. resources to address the human resource crisis and improve global health outcomes?).

Another partial opportunity to address the global health resource crisis is by considering the possibilities of “circular” migration as part of the solution. Many migrants feel a strong sense of responsibility to their homelands and, having spent some time abroad, would like to return home, perhaps temporarily, if conditions for their return were right (International Organization for Migration, 2003). The International Organization for Migration (2001) has implemented several voluntary return programs in Europe, Latin America, and Asia. In Africa, a program called the Return and Reintegration of Qualified African Nationals successfully stimulated the selective return of 2,565 urgently needed professionals in many disciplines between 1983 and 1995. This still-fashionable paradigm continues to tap into the skills and resources of the African diaspora by hiring emigrants for short-term assignments and development activities in their home countries (International Organization for Migration, 2001, 2002, 2003).

Policy barriers now limit the ability of health workers in the United States to return to their country of origin to either train or practice their professions. These barriers include the process of acquiring residency and naturalization and the lack of portability of benefits, pensions, and insurance (Agunias, 2008). Yet there is a desire on the part of migrants to see more temporary and circular migration. The United States should consider more comprehensive policy options to encourage circular migration to benefit both the countries that need labor and the countries from which the workers come. A recent public opinion poll found that 81 percent of Americans surveyed would support such a policy (WorldPublicOpinion.org, 2009).

Recommendation 4-3. Congress should work with federal executive branch agencies and departments and U.S. universities to explore opportunities to leverage the U.S. workforce to contribute to solutions that partially address health workforce deficits in low- and middle-income countries. This exploration should include an inquiry into the willingness of Americans to participate in a global health service corps; a determination of whether this kind of assistance would be well received by recipient countries; and an examination of whether specific opportunities exist to help migrants from low-income countries return home to work temporarily or permanently.

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5

Increase U.S. Financial Commitments to Global Health

FINANCE THE GLOBAL HEALTH FUNDING GAP

A financing gap contributes to the difficulties that low- and middle-income countries face in addressing the health needs of their populations. New threats such as pandemics and chronic diseases have altered the disease burden of these countries, even as the financial crisis has weakened their economies further. External assistance from donors will be essential if low-income countries are to reach the globally recognized Millennium Development Goals (MDGs) and if the global community is to address the emerging challenges of the twenty-first century.

Basic Health Needs of the Global Poor

The global community uses one of two benchmarks to quantify the basic health needs of poor countries: (1) the cost of scaling up to meet the health-related MDGs, estimated at \$20 billion to \$70 billion annually (Wagstaff et al., 2006) or (2) the price estimate of \$34 per capita per year for an essential health benefit package, as assessed by the World Health Organization's (WHO's) Commission on Macroeconomics and Health (WHO, 2001). While low-income countries bear a large portion of the total disease burden, they contribute only 2 percent of worldwide health spending (\$7 billion annually or 5.3 percent of their gross domestic product [GDP]) (Gottret and Schieber, 2006).

Low-income country revenues amount to only 18 percent of their GDP (compared to 32 percent in high-income countries), severely limiting their ability to finance essential health services (Gottret and Schieber, 2006). For a country

such as Burundi, with a GDP per capita of \$341 (World Bank, 2007a, 2007b), revenues are expected to deliver \$61 per capita to spend on all public needs such as education, health, and infrastructure. If \$34 of this were spent on the essential health benefit package as prescribed by WHO, more than half of government revenue would be consumed by basic health services alone.

To meet their basic health needs, low-income countries have been asked to raise an additional 1 to 4 percent of GDP in public revenue (UN Millennium Project, 2006; WHO, 2001). The committee supports the call for increased health spending by low-income countries, but recognizes that revenue performance over the past few years has been disappointing and even stagnant in some regions (Gupta et al., 2004).

Increasing spending for public health is made especially challenging by the global economic recession. Countries relying on revenue from commodity exports and foreign direct investment will need external assistance and concessional borrowing as export prices plummet and foreign direct investment dries up. With governments unable to maintain critical expenditures on social safety nets, human development, and critical infrastructure, the plight of the poor in low- and middle-income countries is set to worsen. Falling employment and wages further impede households' ability to pay for essential food and health services (see Box 5-1) (World Bank, 2009b).

Without substantial economic development and debt relief, it will be difficult for low-income countries to scale up health spending on their own, at least in the immediate future. Even if low-income countries were able to mobilize an additional 1 to 2 percent of their GDP to finance health, it would amount to only \$12 billion to \$24 billion, which is insufficient to meet the MDG funding gap. Likewise, if the aim were to deliver the \$34 per year benefit package, low-income countries would need to increase their health spending by more than 40 percent, which is an unlikely prospect (Schieber et al., 2007). Low-income countries will clearly not be able to make significant progress in delivering basic health provisions to their populations without external assistance (Gottret and Schieber, 2006; UN Millennium Project, 2005; WHO, 2001).

Finance the Global Health Funding Gap

If low-income countries are to move closer to meeting the MDGs and delivering essential health services, foreign assistance for health from advanced economies will have to increase and be sustained over the coming decade. These countries already depend greatly on external assistance to fund health programming. In some 30 African countries, 30 percent of health spending comes from donors and international nongovernmental organizations (Gottret and Schieber, 2006); in Rwanda's 2008 work plan, this figure was as high as 83 percent and is expected to remain above 67 percent until 2020 (WHO et al., 2008).

BOX 5-1 **Health and Poverty During Economic Downturns**

Mobilizing financing for the health sector is especially crucial during economic downturns and subsequently lowered household earnings. The poor in low-income countries are most affected at such times because they pay a large portion of their health care costs out-of-pocket, without the benefit of social safety nets (Gottret and Schieber, 2006; Hopkins, 2006). The health of a country's population thus significantly worsens during a downturn due to reduced access to health care (Hopkins, 2006; Pongou et al., 2006; Waters et al., 2003) and poor nutrition.

The current global economic crisis is dramatically increasing the number of people trapped in poverty in low-income countries. New estimates for 2009 suggest that 46 million more people will be living on less than \$1.25 a day than was expected prior to the crisis. An extra 53 million will be trapped on less than \$2 a day. This is in addition to the 130 million to 155 million people already pushed into poverty in 2008 because of soaring food and fuel prices (World Bank, 2009a).

These new forecasts highlight the serious threat to achieving the MDGs by 2015. Sub-Saharan Africa, one of the regions hit hardest by rising food prices, could be further affected if foreign direct investment and aid flows now decline (World Bank, 2008). New research shows that child mortality rates are set to soar if the crisis persists, with preliminary estimates for 2009 to 2015 suggesting an average of 200,000 to 400,000 more child deaths a year (amounting to a total of 1.4 million to 2.8 million deaths) (World Bank, 2009a). Some hard-won advances of the past few years in poverty reduction and health could thus unravel.

In today's market crisis, the financial policies and practices of the high-income nations, including the United States, are seen as the cause of painful economic spillovers in low- and middle-income countries. It is therefore crucial for the reputation of the United States that the nation live up to its humanitarian responsibilities, despite current pressures on the U.S. economy, and assist low-income countries in safeguarding the health of their poorest members. It is equally important that the entire global community uphold its commitments and remain focused on the MDGs (UN, 2008).

For low-income countries to see significant improvements in health, large grants from external donors will have to be sustained for long periods. A study in Ethiopia and Tanzania found that a doubling of aid as a percentage of GDP would require grant financing for 20 years before these grants could be replaced by additional tax revenue under reasonable assumptions of increased domestic growth (Foster et al., 2003; Gottret and Schieber, 2006). The level of investment needed to deliver individual-level and population-based care, to build institutions and systems, and to conduct health research will require both significant and sustained investment by bilateral and multilateral agencies and greater exploration of innovative financing models.

Increase U.S. Commitments to Achieve Health-Related MDGs

In 2002, the United Nations (UN) Millennium Project estimated that total overseas development assistance (ODA) volumes would need to rise to 0.54 percent of high-income country gross national income (GNI) by 2015 if low- and middle-income countries were to meet the MDGs (UN Millennium Project, 2006). Although global ODA directed to health has increased significantly, from 4.6 percent of total ODA in 1990 (Schieber et al., 2006) to 16 percent in 2006 (OECD, 2008a), the overall level of ODA commitment is still too low to meet the MDG funding needs of low- and middle-income countries.

Over the last 10 years, U.S. ODA has grown from \$8.8 billion to \$26 billion (a 196 percent increase) (OECD, 2009). Between 2001 and 2008, U.S. Agency for International Development (USAID) and State Department global health programming grew by nearly 350 percent. As a result, health now makes up a larger portion of both the U.S. foreign affairs and the overall ODA budgets. In 2006, health aid comprised 23 percent of U.S. allocable aid; this is more than the average proportion of spending on health aid by other advanced economies (see Figure 5-1) (OECD, 2008b).

President Obama announced the U.S. government Global Health Initiative in May 2009 and requested that Congress support \$63 billion in spending on global health between 2009 and 2014; this is an average of \$10.5 billion per year over the next six years. Under the initiative, the President’s Emergency Plan for AIDS

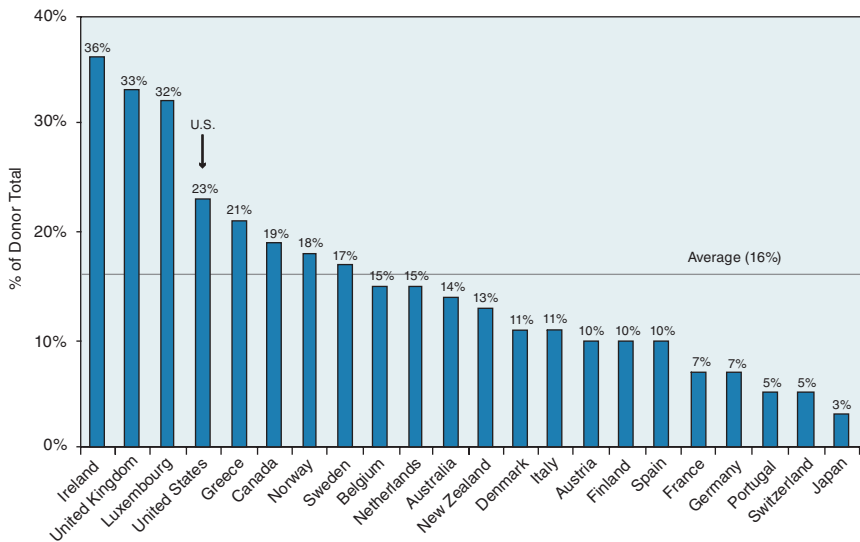


FIGURE 5-1 Allocable aid for health (2006).

SOURCE: Committee’s calculations based on OECD, 2008b.

Relief (PEPFAR) would receive \$51 billion over six years. The proposal calls for an increase in funding from \$8.186 billion in 2009 to \$8.645 billion in 2010 (White House, 2009).

The committee commends the recent increases in spending on global health but finds that an even greater commitment by the U.S. government is required to demonstrate leadership in both global health and global economic and human development. Despite dramatic increases in spending for global health—and in the proportion of ODA allocated to health—over the past decade, the U.S. commitment to overall ODA has been below the efforts of other high-income countries in relative terms. So even though the United States was the largest aid donor in absolute dollars (\$26 billion) in 2008, it has one of the lowest levels of net ODA as a percentage of GNI: 0.18 percent (see Figure 5-2). This is well below the UN target of 0.54 percent and the Development Assistance Committee average of 0.45 percent.

Even when private giving is included, the United States does not come close to the level of most other high-income countries' ODA. The U.S. government contributes only 25 cents per day per person, with an additional 10 cents per day being given by private U.S. donors. Sweden and Denmark, by comparison, give \$1.00 and \$1.07 per day per person, respectively, in public aid alone (Roodman, 2007).

If the U.S. government is to meet its obligations to support all of the MDGs, it will need to reach the UN target of 0.54 percent of GNI and commit to spending

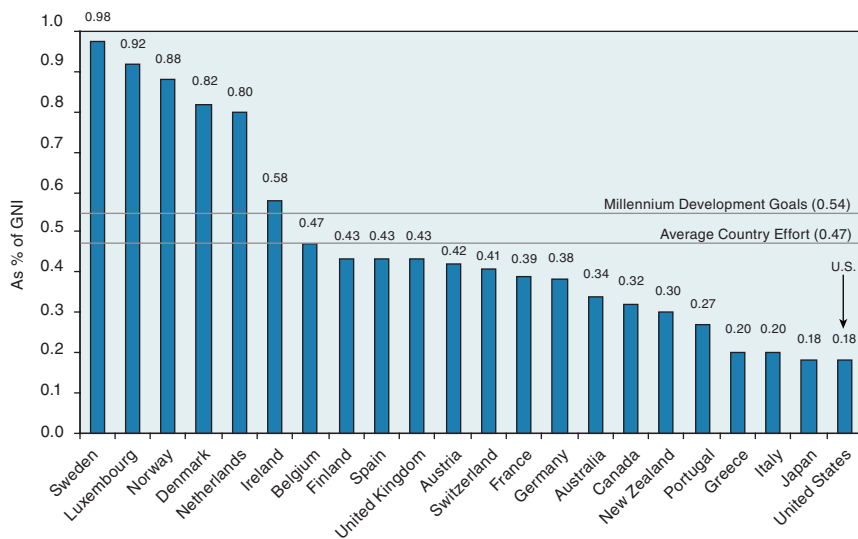


FIGURE 5-2 Net official development assistance (2008).

SOURCE: OECD, 2009.

approximately \$81 billion per year on development assistance by 2012. Given that three of the eight MDGs are directly related to health (Goals 3, 4, and 5), a portion of any increase in development assistance should be allocated for health programs and research activities. Within this greater commitment to foreign assistance, the committee recommends that the U.S. government investment in global health match the average proportion of ODA for health (16 percent in 2006) for countries belonging to the Organisation for Economic Cooperation and Development (OECD).

By 2012, the President and Congress should commit to spending a minimum of \$13 billion annually on development assistance for health in support of the health-related MDGs. (This number is the product of the UN goal of 0.54 percent of GNI; the estimated GNI for the United States in 2012 [\$15 trillion]; and the average proportion of ODA for health [16 percent] in OECD countries in 2006.) This level of spending, although still below the capacity of the United States and the overall resources needed for health, is justified on the basis of international norms and commitments.¹

Balance the Traditional Portfolio of U.S. Investments in Global Health

Increased finances would provide an opportunity to balance the portfolio of U.S. government investments in global health to reflect the breadth of the health-related MDGs. Allocations over the last eight years have been heavily skewed in favor of HIV/AIDS, which received more than 70 percent of USAID and State Department global health funds in 2008 (Salaam-Blyther, 2008). Between 2004 and 2008, projects to combat HIV/AIDS, tuberculosis (TB), and malaria received \$19.7 billion, far outpacing support for other health programs. This dramatic increase was a result of new commitments to the Global Fund to Fight AIDS, Tuberculosis, and Malaria (the Global Fund) and PEPFAR. During the same period, USAID programs for children and women's health received only \$4.6 billion, representing little or no increase in real terms (see Figure 5-3) (Salaam-Blyther, 2008).

The committee strongly recommends that Congress balance the traditional portfolio of global health aid while pursuing the goal of \$13 billion per year for the health-related MDGs. The U.S. government should fulfill its implied commitments under PEPFAR reauthorization to global AIDS programs (\$7.8 billion per year), malaria (\$1 billion per year), and TB (\$800 million per year). The remaining \$3.4 billion per year would roughly double current spending levels for pro-

¹ Beyond reaching the goal of 0.54 percent of GNI by 2012, it is important to note that in a 1970 General Assembly Resolution, UN Member States declared a minimum target of 0.7 percent of each economically advanced country's national income for ODA to developing countries. The 0.7 percent target was reconfirmed by all countries in the 2002 Monterrey Consensus, of which the United States was a signatory (UN, 2003).

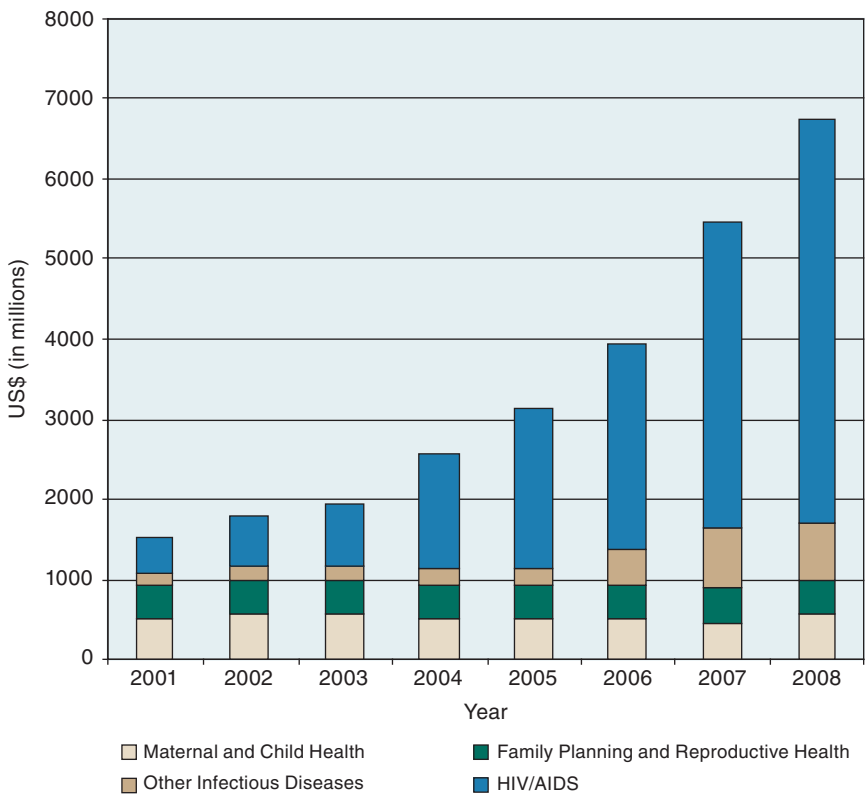


FIGURE 5-3 State Department Global HIV/AIDS Initiative (GHAI) and USAID spending on global health (2001-2008).
SOURCE: Committee’s calculations based on Salaam-Blyther, 2008.

grams in support of health systems strengthening, children and women’s health, nutrition, family planning and reproductive health, and neglected diseases of poverty, all of which have been severely underresourced during the past decade.

The U.S. government should also adopt health goals that support the targets of the health-related MDGs to guide the allocation of the recommended \$13 billion in funds. Expenditures should include the scale-up of proven clinical and public health interventions and policies to reduce avoidable deaths, as well as research efforts to explore new technologies and identify improved methods for delivering existing tools. Where feasible, funding should support multilateral efforts aimed at addressing the MDGs, such as the Global Alliance for Vaccines and Immunization, the Safe Motherhood Initiative, and the Global Fund.

Allocate Additional Funding for Noncommunicable Disease and Injuries

Although the recommended \$13 billion per year for global health would support the health-related MDGs, additional resources will be required to meet the global burden of disease for the twenty-first century. Even though chronic diseases account for nearly half of the disease burden in low- and middle-income countries (Beaglehole et al., 2007), virtually no USAID programs address chronic or noncommunicable diseases (Greenberg et al., 2005). Injuries, which accounted for an additional 16 percent of deaths in 2001, also receive little U.S. attention (Lopez et al., 2006b). When comparing the disease allocations in U.S. government global health spending as estimated by the Kaiser Family Foundation for 2008 (Kates et al., 2009) to the top seven causes of death in low- and middle-income countries for those under age 70 (Lopez et al., 2006a), the lack of attention to noncommunicable disease and injuries is striking (see Figure 5-4).

Preventive and low-cost treatment measures specially tailored to low-resource areas can help reduce the burden of chronic disease and injuries (Beaglehole et al., 2007; Lagarde, 2007), which threatens to overwhelm health systems in these countries (Adeyi et al., 2007; Norton et al., 2006). Cost-effective strategies—such as higher tobacco taxes, reduction of salt in processed foods, and the administration of a multidrug regimen to treat and prevent cardiovascular disease—hold the promise of averting 32 million premature deaths from noncommunicable diseases in these countries (Asaria et al., 2007; Lim et al., 2007).

The committee finds that an additional \$2 billion to expand the U.S. portfolio to address noncommunicable disease and injuries would be appropriate. Federal executive branch agencies and departments—particularly the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and USAID—should work with Congress to identify specific ways to respond to the contemporary challenges of noncommunicable disease and injuries. The U.S. government should adopt clear health goals, such as lowering deaths from smoking or reducing injuries from domestic violence and accidents, to guide the allocation of the recommend \$2 billion in funds. Expenditures should include the scale-up of proven interventions and policies to reduce avoidable deaths, as well as research efforts to translate existing knowledge (often individualized treatment) into population-based interventions that are cost-effective in low-resource settings with large at-risk populations.

Address PEPFAR and Long-Term AIDS Strategy

Concerns have been raised that PEPFAR commitments have already created a new global “entitlement” that could prevent an increase in funding for other initiatives. This entitlement exists in the form of an open-ended commitment to provide AIDS treatment in countries receiving PEPFAR money that would be very difficult to halt. (Treatment costs are themselves set to escalate, mainly

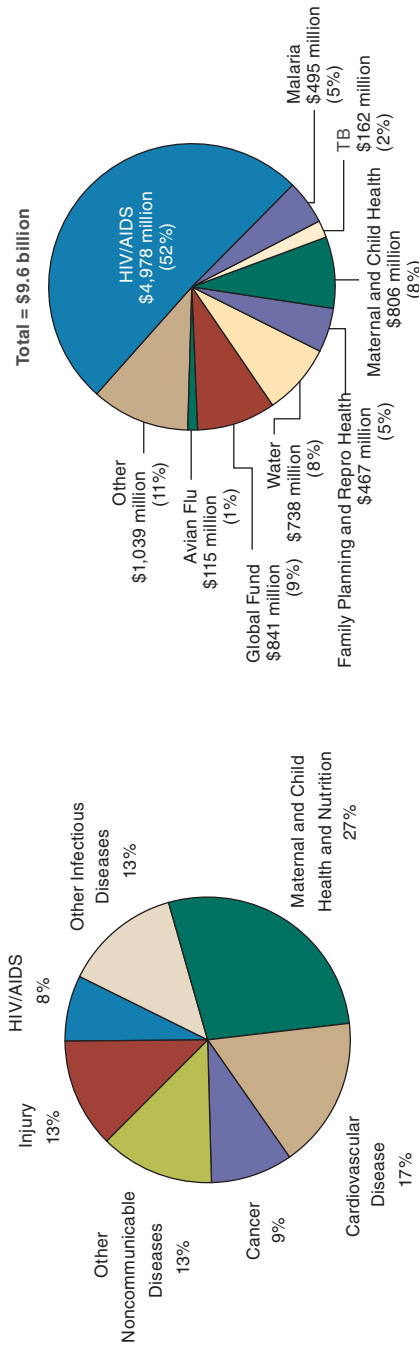


FIGURE 5-4 *Left:* Top seven causes of death below age 70 in low- and middle-income countries (2001). *Right:* U.S. government funding for global health by major subsector and for the Global Fund, FY 2008.
 SOURCES: *Left:* Committee's calculations based on Lopez et al., 2006a. *Right:* Committee's calculations based on Kates et al., 2009.

due to three factors: antiretroviral [ARV] drugs have successfully prolonged the lives of AIDS patients who now require lifelong treatment; new HIV infections continue to outpace the number of people receiving treatment, due to inadequate prevention; and many of those on first-line drugs, for which dramatic price reductions have been attained, will require more costly second-line therapies as they become resistant to first-line treatments [Over, 2008].)

PEPFAR provided 77 percent of declared external AIDS funding in 2005 to 15 countries and is responsible for the large majority of increases in AIDS funding since 2004 (Over, 2008). By 2006, PEPFAR money constituted 62 percent of HIV/AIDS resources in Zambia, 78 percent in Uganda, and 78 percent in Mozambique, 3 of the 15 countries that receive PEPFAR funding (Oomman et al., 2008). With PEPFAR usually providing more than three-quarters of the total external AIDS spending, and presumably at least as large a share of treatment spending in any recipient country, AIDS treatment entitlements are incumbent upon the United States more than on any other donor or group of donors (Over, 2008). It is unlikely that even relatively well-off countries with high HIV prevalence rates will be able to absorb the costs of universal or widespread ARVs. Among the 15 PEPFAR countries, “South Africa is the only one to fund a sizable share of the costs of its AIDS interventions from its own budget” (Over, 2008).

In the meantime, the importance of HIV prevention—as both a public health and a fiscal imperative—cannot be overemphasized. The U.S. government should maintain funding for ARV treatment for individuals already supported by PEPFAR, but it should also act diligently to ensure that the program prevents as many HIV infections as possible, especially among young women in Africa (who are three times more likely to be infected than men of the same age in many high-burden countries) (UNAIDS, 2008). The committee supports the 2007 Institute of Medicine (IOM) committee findings on PEPFAR implementation, which state that in order to help countries make gains against the HIV/AIDS epidemic, PEPFAR will need to emphasize effective, evidence-based prevention with the same urgency and intensity it has focused on treatment (IOM, 2007). Without a stronger focus on prevention, PEPFAR costs could crowd out other equally important global health initiatives (Over, 2008).

Provide Incentives for Better Health

To ensure that global health financing in all areas—HIV/AIDS, maternal and child health, and health systems strengthening, among others—is contributing to significant, measurable, and sustainable health gains, the U.S. government should consider novel approaches to delivering aid that is effective. Results-based financing—one of several routes to improving health outcomes and systems performance—relies on a government or donor providing material rewards when, and only when, particular results are achieved. Ideally, these extrinsic incentives are offered as an add-on at the margins to complement reliable resources for basic service delivery and are introduced in ways that reinforce good perfor-

mance. Applied at the highest level, donors link the release of additional funds to improved health-related indicators, based on *ex ante* agreements negotiated with the recipient government around a set of shared goals. At a lower level, rewards can be granted to districts, health facilities, or even individual health workers, based on performance. At the microlevel, mothers (or others who make household-level decisions about health care) are rewarded on the basis of documented health-related behaviors, such as taking children for well-child visits for vaccinations or maintaining prolonged treatment for conditions such as TB.

For example, under a currently operating USAID-funded scheme in Haiti, nongovernmental health providers agree to reach certain targets such as the proportion of children fully immunized, the proportion of new mothers with assisted deliveries, and the proportion of pregnant women receiving prenatal care. Ninety percent of the payment to the health providers is fixed, but the remainder is made on the condition of good performance. In the seven years of operation, the program has achieved remarkable improvements in key health indicators. Nongovernmental health providers now reach about one-third of the population (3 million people), providing essential services in a complicated environment of violence, poverty, and limited government leadership. Full immunization coverage has increased by 13 percent per contract period, and assisted deliveries have increased by 19 percent (Eichler and Levine, 2009).

The results measured are usually expressed in terms of outputs, such as the number of health workers trained or immunizations delivered. However they can also be assessed from the wider perspective of health outcomes, such as a program's impact on saving lives or reversing the trend of malaria infections in its target population.

Results-based financing is thus a tool to address persistent problems or bottlenecks in the functioning of a health system, including inadequate services or low utilization of services, particularly by the poor, while also increasing the total amount of resources available for service improvement. A broad sectoral understanding of the causes of such problems is essential to determining whether results-based aid will work in a particular context. An assessment of institutional arrangements, such as mechanisms for the flow of funds, is also important in judging whether these can facilitate or impede "paying for results." Design and operational considerations for such programs include, but are not limited to, careful choices about the targets, indicators, incentives, contractual details, and information sources. Strong information systems, complemented by credible verification and validation mechanisms, are critical to these programs.

To date, results-based aid has mostly been tried in two types of contexts: first, in fragile or post-conflict states such as Haiti and Afghanistan, where donors make results-based arrangements with nongovernmental organizations, sometimes through the contracting units of health ministries; and second, in states such as Rwanda and Zambia, where results-based financing is a part of major reforms in health financing and organization to change the way business is done and accelerate progress toward health goals. Demand-side incentives have been

used in a wide range of settings, from Latin America to the former Soviet Union to Bangladesh (Eichler and Levine, 2009).

Increasingly, interest in results-based approaches is being expressed by national and local governments. The World Bank and other agencies report quick responses from governments to their requests for proposals, participation in workshops, or information. Apart from the expected interest among donor partners and recipient country officials, an independent trend in support of performance incentives can also be seen among thought leaders in low-income countries.

Evidence from results-based financing suggests that these programs have led to important improvements in health and health system functioning. The process of negotiating a common set of indicators to assess performance (and appropriate incentive payments) has the effect of rallying participants around a larger agreed-upon objective and presents opportunities for several important benefits: (1) integrating “vertical” donor funding streams that are focused on one specific disease, such as HIV/AIDS, to adopt a more comprehensive approach to health care; (2) aligning the priorities of government, target community, and donor; and (3) harmonizing donors in a country by avoiding duplication of their efforts and capitalizing on synergies. As this agenda goes forward, important operational questions remain about how performance-based programs can be made more cost-effective and how certain risks can be mitigated—for example, undue attention directed toward the rewarded services, participants attempting to game the system, and erosion of the integrity of information systems (Eichler and Levine, 2009).

Be Open to Innovative Financing

Innovative finance for health offers new opportunities for multilateral financing of global health initiatives and includes new or newly applied financial instruments as well as the institutions developed to implement them. Many of these initiatives are partnerships between funding and recipient countries, industries, intergovernmental organizations, and foundations that allow for donor coordination and harmonization, as well as long-term predictability (Ferranti et al., 2008).

Within the last decade, several innovative finance mechanisms have been developed to counteract the current trend of unpredictable, volatile, and short-term aid. Innovative finance initiatives are proposed solutions that may be applied to various goals such as increasing access to existing vaccines and medicines by creating procurement funds or creating incentives for the development of new technologies (Ferranti et al., 2008).

UNITAID, for example, is an international drug purchase facility that is funded primarily by a revolutionary tax on air travel. The predictability of airline travel and the continuous upward trend in fares provide a constant source of funding for UNITAID that allows the purchase of bulk medicines and contributions to the Global Fund. In 2006, France enacted the airline solidarity tax, followed

by Chile, the Republic of Korea, and several African countries. The concept of the tax is flexible, and each government determines the details of its own tax. For example, the tax can be applied to domestic flights, international flights, or both, and the tax can vary depending on the class of service.

Opponents argue that the tax may affect the market for airline travel or force consumers to contribute to a cause they may not feel passionately about. Supporters of the tax praise the idea as the first progressive tax to target a global public good and note that the cost of the tax is low compared to the price of an airline ticket. A recent opinion poll of the American public found that 57 percent thought the United States should join these countries and would support charging an additional \$1 to \$2 on international flights to support UNITAID (WorldPublicOpinion.org, 2009).

While U.S. academics and institutions have been the intellectual drivers behind many of these innovative funding models, such as Advance Market Commitments and Affordable Medicines Facility-Malaria, the U.S. government has been reluctant to fund these endeavors. Congress and federal executive branch agencies should be open to supporting these mechanisms as an opportunity to address long-term funding needs and work in collaboration with the private sector. Where it finds a lack of evidence to warrant a full commitment to any particular funding model, the U.S. government should fund pilot projects that could provide a proof of concept.

Recommendation 5-1. The President and Congress should commit to investing \$15 billion in global health by 2012, with \$13 billion of this directed to the health-related MDGs and an additional \$2 billion to the challenges of noncommunicable diseases and injuries.

(A) While pursuing the goal of \$13 billion per year for the health-related MDGs, federal executive branch agencies should work with Congress to create balance in the traditional portfolio of global health spending that reflects the breadth of the health-related MDGs.

- (1) Congress should fulfill its implied commitments under the PEPFAR reauthorization to global AIDS programs (\$7.8 billion per year), malaria (\$1 billion per year), and tuberculosis (\$800 million per year).
- (2) The U.S. government should use the remaining \$3.4 billion per year to support programs such as health systems strengthening, children and women's health, nutrition, family planning and reproductive health, and neglected diseases of poverty, all of which have been severely underresourced during the past decade.
- (3) Given concerns that PEPFAR costs could crowd out other equally important global health initiatives, the U.S. government should maintain funding for ARV treatment for individuals already supported by

PEPFAR but should also act diligently to ensure that the program prevents as many HIV infections as possible.

(B) Federal executive branch agencies and departments—particularly CDC, NIH, and USAID—should work with Congress to identify specific ways to respond to the contemporary challenges of noncommunicable diseases and injuries and commit to investing \$2 billion for this purpose by 2012.

(C) The U.S. government and the private sector, including industry and philanthropy, should continue to support and further explore novel incentives and innovative funding mechanisms to ensure sustainability for (1) research and product development for neglected conditions and diseases that disproportionately affect poor populations, and (2) procurement and delivery of these products.

ADDRESS THE GLOBAL HEALTH RESEARCH FUNDING GAP

Given the reality of limited funds, a difficult balance must be struck between investing in the improved uptake of existing knowledge and practices and investing in research that could lead to new interventions—and even scientific discoveries—in the future. Investments in the health of people today (through better delivery of existing approaches) and in the health of people tomorrow (by making new discoveries to understand and combat disease) are both needed; the appropriate mix of health spending for care delivery and research should be weighed against the urgency of combating a particular disease and the unique health needs of a local population. However, excluding research from health assistance can prove short-sighted and limit its effectiveness.

Provide More Adequate Funding for Health Research to Benefit the Global Poor

While investments in research have saved, improved, and prolonged lives even in the most impoverished settings in the world, governments and the commercial sector—the two largest funders of health research—spend relatively little on solutions for conditions of the global poor. For example, biomedical research and development to combat infectious diseases that infect people living in low- and middle-income countries represented only about 1.6 percent of worldwide investments in health research.²

²One study estimated that just over \$2.5 billion was invested into research and development of new neglected disease products in 2007 (Moran et al., 2009). The Global Forum for Health Research estimated that the global expenditure on health research was \$160.3 billion in 2005. Therefore, an estimated 1.6 percent of global expenditure on health research was devoted to diseases and conditions that primarily affect low- and middle-income countries.

This low allocation to address diseases that disproportionately affect the poor is driven by two factors: (1) market failure and (2) the lack of resources or political will within low-income countries to invest public funds in health research. There are inadequate commercial incentives for the private sector, in any country, to undertake research on diseases whose cures will have little or no viable financial market. In the absence of lucrative sales for drugs, vaccines, and diagnostics for such diseases, the pipeline for any new interventions has virtually dried up during the past three decades (Trouiller et al., 2002). Two studies of drugs developed between 1975 and 2004 found that tropical diseases and TB accounted for only slightly more than 1 percent of new products (Chirac and Torrelee, 2006; Trouiller et al., 2002).

In the United States, there are similar market failures for diseases that do not have a viable commercial market. However, the U.S. government provides financial incentives to invest in these diseases through the Orphan Drug Act of 1983, which encourages pharmaceutical companies to develop drugs for rare conditions affecting fewer than 200,000 people by offering tax incentives and allowing sales without competition for seven years. While low- and middle-income countries have limited financial capacity to offer such incentives to the commercial sector, investments by governments are crucial in the absence of market incentives to reward health research.

Although low- and middle-income countries increased spending on health research by 42 percent between 1998 and 2005 (GFHR, 2008), their contribution amounted to just 3 percent of the global funding for health research in 2005 (Schneegans, 2008). Research undertaken by the emerging economies has gone some way toward reducing the asymmetry in knowledge generation between wealthy and less wealthy nations. In November 2008, representatives from 62 countries met in Bamako, Mali, and committed to spending 2 percent of government health budgets on health research in the Bamako Call to Action (Bamako Call to Action, 2008).

The committee endorses the recommendation that all countries devote some significant portion of public funding for health research—especially research that benefits underserved populations—and include health research in their overall national strategic health and poverty reduction plans, but it also recognizes the limitations faced by low-income countries in allocating significant sums for health research.

For now, research to benefit the global poor remains primarily the realm of high-income-country public and philanthropic donors. According to a study conducted by the George Institute, around 90 percent of global biomedical R&D funding for neglected diseases in 2007 was financed by public and philanthropic donors. Four out of the top five funding organizations contributing to biomedical research for neglected diseases that affect low- and middle-income countries were based in the United States (NIH, the Bill & Melinda Gates Foundation, the U.S. Department of Defense, and USAID) (see Table 5-1). After the Gates Foundation

TABLE 5-1 Top 12 Organizational Funders of Neglected Diseases

Organization	Amount (U.S.\$)	Percent
U.S. National Institutes of Health	1,064,859,791	41.6
Bill & Melinda Gates Foundation	452,102,715	17.7
European Commission	121,366,882	4.7
U.S. Department of Defense	86,914,578	3.4
U.S. Agency for International Development	80,600,336	3.1
Wellcome Trust	59,985,371	2.3
U.K. Medical Research Council	51,716,968	2.0
U.K. Department for International Development	47,565,987	1.9
Dutch Ministry of Foreign Affairs	33,951,646	1.3
Institut Pasteur	31,617,540	1.2
Irish Aid	24,271,557	0.9
Swedish International Development Agency	21,529,014	0.8
Subtotal top 12 funders	2,076,482,385	81.1
Total R&D funding	2,560,068,749	100

SOURCE: Moran et al., 2009.

and NIH—representing 59.3 percent of the total investment made by the top 12 funders in global health research—the third-largest funder of biomedical R&D on neglected diseases was the private sector, providing 9.1 percent of funding (Moran et al., 2009).

The majority of global biomedical research and development funding (76.6 percent) for neglected diseases is focused on the big three: HIV/AIDS, malaria, and TB. Other diseases have received less attention, even though they pose a significant disease burden (Moran et al., 2009).

U.S. Government—The Largest Investor in Biomedical Research on Neglected Diseases

The U.S. government provided nearly three-quarters of global public spending on neglected disease biomedical research, with an investment of \$1.25 billion. While NIH is a significant contributor to global health research, the agency spends less than 1 percent of its budget to fund research that tackles parasitic and bacterial diseases, such as malaria, sleeping sickness, leprosy, and lymphatic filariasis (NIAID, 2008), which are virtually unknown in the United States but are among the most common infections for the world’s poorest billion people (Hotez et al., 2007).

The exact amount that the U.S. government devotes to global health research is unknown because it is difficult to isolate funds dedicated to global health from domestic health research investments. For example, issues arise when counting research on diseases that are shared by the United States and low- and middle-income countries, such as AIDS and noncommunicable dis-

eases, or when counting basic research, which may not be related to any particular disease.

Beyond biomedical R&D, the U.S. government and foundations invest in other forms of research that benefit health, such as economics, social and behavioral sciences, and public health. To the committee's knowledge, no studies have been conducted to quantify the level of commitment in these areas, although it is reasonable to believe that the investment is significantly smaller due to the difference in cost between biomedical and nonbiomedical research.

As a result, the total government expenditure applied to research relevant to all the health problems of low-income countries cannot be estimated with any meaningful degree of accuracy. Nonetheless, the committee finds that the investment by the United States in global health research is important, even though it represents a miniscule fraction of the overall research budget for domestic health research.

Public-Private Product Development Partnerships—Significant Recipients of Research Funding

Notably, a significant portion of this research (23 percent) is managed by public-private product development partnerships (PDPs) (Moran et al., 2009). The benefits of this investment in PDPs are starting to be realized. Several products are in the pipeline with some entering late-stage clinical trials. It has been estimated that \$1 billion per year over the next 10 years will be required to put the experimental treatments and vaccines currently in the PDP pipeline through large human trials and file them with regulators (Herrling, 2009). While this is more than the nearly \$600 million that was invested in PDPs in 2007 (Moran et al., 2009), several innovative public-private financing proposals are now under consideration.

For example, FRIND—the Fund for R&D in Neglected Diseases—would pool money from governments, foundations, and other sources to finance the movement of potential treatments through the pipeline. Donors would only fund drugs through one stage of the pipeline at a time, requiring regular feedback before providing further money. In exchange for funding, the originator of the drugs would grant exclusive licensing to the fund to use his or her product to treat neglected diseases; such products would be priced affordably for low- and middle-income countries. The originator would also hold a patent, retaining the right to use compounds or elements of the discovery for different drugs in the future (Herrling, 2009).

Continue Strong U.S. Commitment to Fund Global Health Research

The Bamako Call to Action urged international development agencies and major funders of global health activities to allocate 5 percent of health devel-

opment assistance toward health research (Bamako Call to Action, 2008). The appropriate allocation of foreign aid to care delivery and research depends on the unique characteristics of particular diseases and their existing treatment and prevention mechanisms, as well as the health needs of particular populations. For example, in areas such as child survival, many interventions to prevent premature death and disability already exist (Jones et al., 2003), but health systems research is needed to determine how best to scale up and sustain delivery of these interventions (Bryce et al., 2003). Designating a portion of health aid to fund health systems research, along with impact evaluations, is important for improving the delivery of existing interventions. In some areas such as TB, however, health outcomes would benefit from greater attention to finding novel tools and interventions appropriate for improving care in low-income settings.

Research breakthroughs to address the needs of the world's poorest populations can be promoted in several ways, most of which can be classified under two complementary categories: "push" and "pull" mechanisms. A push mechanism is the traditional mode of encouraging research, using direct funding to accelerate the development of a vaccine, drug, or diagnostic by reducing the risks and costs of R&D investment. Most of the U.S. government investment in global health research is through push mechanisms, particularly through the NIH, and to a lesser extent, through contributions to public-private PDPs.

A pull mechanism is a more novel mode of funding, in which the purchasing power for particular types of vaccines, diagnostics, and drugs serves as an incentive for commercial pharmaceutical firms to invest in the R&D required to produce it. Pull mechanisms thus provide a market incentive for the same result as a push mechanism, but with money being paid out only when a product has been developed. Together, if designed in a coordinated fashion, the *push* through NIH and the Department of Health and Human Services budgets can act in synergy with the *pull* provided by a donor to produce a vaccine or other product.

Existing support for global health research should be maintained, and as investments in health research increase, so should investments in research that has a global impact. In the spirit of the Bamako Call to Action, the committee recommends that funding of research also be conducted through the Foreign Operations budget—because it supports improvements to health in low- and middle-income countries. This level of flexibility would allow the U.S. government to leverage two types of approaches—push and pull mechanisms—to fund global health research.

One way to do this is through a formal Advance Market Commitment (AMC), such as the pilot AMC that has been developed for a vaccine against the strains of pneumococcal disease prevalent in Africa and Asia. Although, in the past, donor aid programs did not procure patented products on a large scale and the low- and middle-income-country pharmaceutical market was not commercially attractive, in recent years, donors have been willing to procure patented products (ARVs, vaccines, antimalarials) at prices far higher than the pennies-per-dose customary

in earlier donor programs. This trend has served to accelerate the introduction and uptake of cutting-edge medical products, bringing with it an opportunity to use procurement strategy as a commercial incentive to encourage research into new tools to address global health. Other pull mechanisms could also be developed as a way to use development assistance for health to “prime” the pharmaceutical market, by providing credible signals to potential developers and manufacturers about the volume and prices to be paid for new and effective products. In one attempt to stimulate R&D for neglected diseases, the U.S. Food and Drug Administration (FDA) developed a priority review voucher for neglected diseases. The FDA will award a priority voucher to a company that wins FDA approval for a drug for a neglected disease. The vouchers are intended to stimulate R&D for neglected diseases by creating an incentive for pharmaceutical companies to bring drugs in late-stage development to the market. Like AMCs, the priority vouchers do not require upfront investment by the government, but the ultimate costs of the vouchers are uncertain. A voucher can cut in half the time it takes to get a new drug approved, which can result in hundreds of millions of dollars in profits for a company with a blockbuster drug—these profits ultimately come from the purchasers of the drugs, both private consumers and governments (Waltz, 2008).

Recommendation 5-2. Federal executive branch agencies and departments should work with Congress to design a coordinated approach to funding global health research that leverages research subsidies through the Department of Health and Human Services budget and innovative funding mechanisms for novel vaccine, drug, and diagnostic procurement through the foreign affairs budget.

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6

Set the Example of Engaging in Respectful Partnerships

The profusion of new players in the field of global health—such as philanthropies, nongovernmental entities, and public-private partnerships—has brought great energy, resources, and innovation to the field. Yet without global leadership and a coherent, unifying strategy to guide the actions of all these participants, a critical opportunity to improve global health could now be missed. The governance challenges involved are complex and cannot be addressed by any one country acting alone. However, the United States can do much to shape the health environment—for example, by setting norms to define the partnership between donors and recipients and improving coordination across all parties working on the ground to avoid burdening recipient countries with a proliferation of uncoordinated initiatives.

GLOBAL HEALTH GOVERNANCE¹

The global health community—comprising more than 40 bilateral donors, 26 United Nations (UN) agencies, and 20 global and regional funds, all supporting more than 90 global health initiatives—is now burgeoning with the entry of many new organizations engaged in global health (Alexander, 2007). Powerful new philanthropies and other nonstate organizations are affecting the direction of global health programs and policies in dramatic ways. The Gates Foundation, which has firmly established its place on the global health governance map by mobilizing resources for innovative financing mechanisms and product develop-

¹In preparing this section of the report, the committee drew heavily on the background paper prepared by Mr. Lawrence Gostin and Ms. Emily Mok (see Appendix E).

ment, has already spent approximately \$9 billion on health projects since 1998 (McCoy et al., 2009).

States and intergovernmental organizations have sometimes joined forces with nongovernmental organizations (NGOs) to address global health problems, forming public-private partnerships (PPPs), or “hybrid” organizations. About 75 to 100 global health PPPs focused on both implementation and research now exist worldwide (High-Level Forum on the Health MDGs, 2005; WHO, 2007a). Two PPPs that are changing the global health landscape and using new financing mechanisms to generate a large percentage of new funds for global health are the Global Fund to fight HIV/AIDS, Tuberculosis, and Malaria (the Global Fund) and the Global Alliance for Vaccines and Immunization (GAVI).

All these participants in global health bring considerable resources to bear on the direction of global health policy. Yet because they answer to different stakeholders, their approaches are tied to institutional preferences, orientations, or biases and are often inconsistent with each other. Although there is now an emerging practice of establishing systems to monitor and evaluate their actions, the various organizations engaged in global health generally participate on a voluntary basis, with no mechanisms to enforce the achievement of goals. Coordination, accountability, and the most effective use of resources to support global health thus remain serious concerns, underscoring the need to think anew about strategies for global health governance (Gostin and Mok, 2008).

The traditional system of international health governance, relying primarily on nations and intergovernmental organizations, is clearly inadequate in the new global health context (Dodgson et al., 2002). Organizations such as the World Health Organization (WHO) and the UN are comprised of member countries; while nonstate participants are recognized and engaged to some degree by both, they cannot vote in formal decision-making processes. At the country level, traditional mechanisms of bringing together external donors have neglected to engage NGOs and private sector providers, even though they play a crucial role in financing and delivering care. A space needs to be created for all relevant NGOs—including civil society and private entities—to be part of legitimate agenda-setting processes at the global and national levels (Gostin and Mok, 2008).

While this proliferation of new participants is a welcome development that brings potentially great wealth and creativity into the global health arena, the response to vital challenges will remain ad hoc and highly fragmented unless their different initiatives and agendas are coordinated through effective global health leadership. The United States is well positioned to promote such coordination by taking the steps detailed below. Indeed, if the goals of U.S. global health investments are to be realized, such U.S. collaboration with the global health community will be essential.

GLOBAL PARTNERSHIP

The U.S. government interacts with multiple UN agencies and other inter-governmental bodies on issues related to health, including the World Bank, the International Monetary Fund, GAVI, the Global Fund, UNITAID, the United Nations Children's Fund (UNICEF), and UNAIDS, and wields considerable influence in virtually all multilateral institutions, through both offering (or withholding) dues and voluntary contributions and deploying its political and technical stature. The committee finds that the United States has much to gain from supporting WHO and sees a unique opportunity for U.S. leadership in strengthening this global body.

For achieving a large set of global health goals, WHO is the most important multilateral agency with which the United States has a relationship. WHO is widely seen by low- and middle-income country health officials as the authoritative source for technical guidance, and it is the "home base" for generation of a broad set of health-related global public goods, from the International Health Regulations (IHR) to support for disease surveillance to collection and dissemination of data about health system performance. What WHO says and does matters greatly for health in resource-limited nations, and what the United States says and does in its governance role and as a major funder of WHO matters greatly for that institution. Thus, one of the key U.S. assets in advancing global health is its relationship with WHO.

Support and Collaborate with WHO

WHO is uniquely positioned to provide global health leadership by virtue of its role in setting evidence-based norms on technical and policy matters, highlighting best practices that improve health globally, and monitoring and coordinating action to address current and emerging global health threats. Examples of these can be seen in many areas.

WHO played a crucial role in the response to the global tobacco epidemic. The agency adopted the Framework Convention on Tobacco Control (FCTC) in 2003, raising worldwide awareness of the dangers of tobacco. Although the United States has yet to ratify the convention, 164 countries have done so and have taken significant steps to reduce tobacco usage globally.

WHO's work in this area has influenced governments as well as independent philanthropic organizations within the United States, guiding their investments in sound and cost-effective health strategies. When New York City Mayor Michael Bloomberg recently joined forces with the Gates Foundation to commit \$500 million to WHO's program to reduce smoking in 15 countries where more than two-thirds of the world's smokers live, his philanthropic program selected countries per the FCTC's protocol and adopted its first six initiatives (Myers, 2008). In this

case, WHO's evidence-based norms on technical and policy matters successfully guided private investment for greater impact.

WHO also plays a vital role in global health governance by monitoring and coordinating action to address current and emerging global health concerns. Once threats have been identified, WHO provides evidence-based advice on technical and policy matters, such as the IHR, which countries must follow to identify and control disease outbreaks. To many countries in Africa, Asia, and South America, WHO is a trusted and invaluable resource for ongoing technical advice on current health issues.

If this international agency did not already exist, it would have to be created. Unfortunately, however, the primacy of this organization has declined in recent decades. At the same time, other intergovernmental organizations, such as the World Bank, the World Trade Organization, UNICEF, and the United Nations Development Programme (UNDP), have emerged as important participants in the realm of global health (see Box 6-1) (Dodgson et al., 2002).

WHO was created 60 years ago, in a very different era. Today, many aspects of the organization's structure and function hinder its ability to provide effective leadership. Improving these mechanisms may require collaboration at the highest levels of the UN to clearly articulate the division of power among the numerous agencies working on global health, such as the World Bank and the United Nations Population Fund (UNFPA), and demonstrate commitment to WHO as the leading technical agency in global health. The creation of UNAIDS and UNFPA as UN priority initiatives outside the WHO structure demonstrates a lack of confidence in WHO to lead across UN agencies.

So while many multilateral organizations are also crucial players in the health arena, the United States, along with the international community, should support WHO's leadership position in global health. To this end, the United States should pay its fair share of the organization's core budget and provide technical expertise, while also requesting a rigorous external review of the agency.

Support Rigorous External Review

The UN is currently undergoing a reform process, initiated in 1997 by then Secretary-General Kofi Annan and continued by his successor, Secretary-General Ban Ki-moon. This self-assessment is an important effort to "breathe new life and inject renewed confidence into a strengthened United Nations . . . which is effective, efficient, coherent and accountable" in facing today's growing humanitarian, health, and environmental challenges (UN, 2008). Yet at a time when WHO is struggling to work with more and more nongovernmental participants, coordinate its activities over multiple UN agencies, and reassert control over the global health agenda, it needs strengthening that goes beyond an internal assessment.

Although this report is not prescriptive of a role for WHO, it does recommend an honest reassessment of the agency's role and comparative advantages.

BOX 6-1
Strengthen the World Bank's Comparative Advantage

Recognizing the connection between public health and its own mission of reducing poverty by investing in people in low- and middle-income countries (Abbasi, 1999), the World Bank moved beyond its core financier operations and launched the implementation of “a whole array of health initiatives . . . bringing new money and fresh ideas to tackle disease” (Gostin and Mok, 2008; Yamey, 2002).

The combination of the World Bank's financial power with aggressive health initiatives led many observers to believe that the World Bank would displace WHO as the “premier global health agency” (Yamey, 2002). During the 1990s, this seemed possible because WHO had become stagnant in its international role. WHO did come to be sidelined, playing only a supporting role by providing medical expertise and technical support, while the World Bank worked on health initiatives with the ministries of health, finance, and planning in low- and middle-income countries (Abbasi, 1999; Gostin and Mok, 2008).

In an attempt “to find its footing on shifting ground in global health” (Levine and Buse, 2006), the World Bank reevaluated its health sector strategy in 2007. The new strategy aims to enhance the World Bank's capacity toward its comparative advantages and the less popular global health issues—such as health system strengthening at the country level, including financial sustainability, regulatory frameworks, and good governance in the health sector—as areas in which it has strengths to generate knowledge, provide policy and technical advice, and provide funding (Levine and Buse, 2006; Ruger, 2007). The strategy also reinforces recent attempts by UN agencies at a collaborative division of labor with global partners, leaving functions such as the technical aspects of disease control and human resource training in health to organizations such as WHO, UNICEF, and UNFPA (Gostin and Mok, 2008; Ruger, 2007).

The United States should support the World Bank's strategy of narrowing its focus to its traditional strengths in advising governments on strategic planning and health sector priorities, especially in light of the recent economic downturn. The World Bank is best positioned to assist low-income countries by maintaining and increasing spending in the health sector. In response to the current economic crisis, the agency is planning to triple its health loans from the \$950 million approved in 2008 to about \$3 billion in 2009, while advising countries to spend on specific programs (such as nutrition for pregnant women and child immunization) aimed at populations that are most vulnerable during economic downturns.

The committee advocates an early review of the organization and its six semi-independent regional offices, all of which have different strengths and weaknesses. The U.S. government should support a rigorous, multinational, external review of WHO, with a view to producing future-oriented recommendations as part of broader UN reforms to ensure that the organization is appropriately structured and funded to meet the global health challenges of the twenty-first century.

The goals of such a review would be to strengthen WHO's normative role and to encourage WHO to play a larger role in ensuring coherence within the UN system as it relates to global health.

Recommending such an independent, external review of a UN agency would not be unprecedented. In 2005, the Food and Agriculture Organization (FAO) agreed to undergo an Independent External Evaluation (IEE) to ensure that the agency was able to respond to the global food and agriculture needs of the twenty-first century. The evaluation was undertaken by a team of independent consultants, with oversight provided by a committee of the FAO Council for the IEE (FAO, 2007). A similar review could assist WHO in transforming itself into a global health leader that is well prepared for the challenges of the twenty-first century. The review could also include a broader investigation of WHO's role within the UN and the potential for increased attention to health within the UN Office of the Secretary General.

Pay Fair Share of WHO Budget

WHO is woefully underresourced. The agency's core budget—decided on by member states through democratic mechanisms—has been declining in real terms for almost a decade (Levine, 2006). At the same time, WHO faces a growing need to compete with other international agencies for the financial support of member nations and the nongovernmental and commercial sectors. The ongoing practice by member states of primarily funding outside the WHO core budget—which receives only 28 percent of non-earmarked funds, while 72 percent goes into specific programs² that donors can control and claim credit for—has transformed WHO into a very “donor-driven” organization with increasingly fragmented and compartmentalized programs (Gostin and Mok, 2008; WHO, 2007b). This has also led to “unhealthy competition among departments within the WHO” (People's Health Movement et al., 2008) and restricted the organization's ability to direct and coordinate a forward-looking agenda (Burci and Vignes, 2004).

Given all of these factors, WHO's financial struggle hinders its ability to promote institutional leadership against the pressures of state sovereignty and to advance the application of its legal powers (Gostin and Mok, 2008; Taylor, 2004). Without the economic power to ensure funding of its core mission and functions, WHO will not be able to fulfill its broad mandate.

Even though U.S. financial commitments to WHO are already lower than

² A recent study by Stuckler et al. (2008) revealed that WHO's general budget “was much more closely aligned with the actual global burden of disease than were the extra-budgetary funds.” WHO's general budget (2006-2007) allocates 61 percent to infectious diseases, 38 percent to noncommunicable diseases, and about 1 percent to injuries. On the other hand, WHO's extra-budgetary funds for the same year allocate 91 percent to infectious diseases, 8 percent to noncommunicable diseases, and about 1 percent to injuries (Gostin and Mok, 2008; Stuckler et al., 2008).

those of other industrialized countries as a share of gross domestic product, the U.S. government has consistently declined to meet its commitments in a timely manner. As of November 2008, the United States owed more than \$140 million in back dues for 2007 and 2008 (Smith, 2008)—a significant share of the \$900 million that constitutes WHO's core budget. Prompt payment of U.S. commitments would help WHO's budgetary cycle and also set an example for other countries in their relationship with WHO. The U.S. government should go further and propose an increase in *assessed (non-earmarked) contributions* to WHO's budget (as compared to voluntary contributions, which are earmarked and today constitute almost 80 percent of the agency's budget). Assessed contributions have been more or less frozen for the last 15 years. An increase in these non-earmarked contributions would change the budget structure of WHO, allowing it the flexibility to implement the most important global health priorities.

Support WHO with Technical Know-How, Remove Political Interference

WHO is dependent on member states and external funders for financing and therefore vulnerable to pressure from these stakeholders, whose broad agreement it needs to support its mission and priorities. However, the agency's function as a scientific clearinghouse can be jeopardized by undue interference from different countries (Levine, 2006). WHO scientific guidance must be protected from political pressures and competing political philosophies so that it can be trusted as a source of technically sound advice.

The U.S. government should continue to support WHO headquarters and its country and regional offices with technical expertise as requested. For 50 years, the Centers for Disease Control and Prevention's (CDC's) tremendous concentration of technical expertise in public health has been a key source of input and support to a range of bilateral and multilateral organizations, with CDC staff being placed at WHO headquarters and in individual nations. This important in-country presence during the design, implementation, and evaluation of health initiatives has contributed to numerous programmatic successes. For example, in the late 1960s and 1970s, CDC staff—in partnership with WHO—helped lead the successful eradication of smallpox (Levine, 2008). The United States should build on this impressive record by continuing a high-level exchange and sending leading technical and policy experts from agencies such as CDC, the National Institutes of Health (NIH), and the Food and Drug Administration (FDA) to engage in WHO's tasks as requested.

Recommendation 6-1. The U.S. government should support WHO as a leader in global health by paying its fair share of the organization's budget and providing technical expertise to WHO, as requested. However, it should

also request a rigorous external review of the organization to develop future-oriented recommendations that maximize its effectiveness.

(A) The U.S. government and global health enterprise, along with the international community, should support a rigorous, multinational, external review of WHO, with a view to producing future-oriented recommendations as part of broader UN reforms to ensure that the organization is appropriately structured and funded to meet the global health challenges of the twenty-first century.

(B) Following the outcome of the external review and movement by WHO to enact the recommendations, Congress should propose an increase in assessed (non-earmarked) contributions to the WHO budget.

(C) Federal executive branch agencies and departments—such as CDC, FDA, NIH, and the U.S. Agency for International Development—should continue to send leading technical and policy experts to engage in WHO’s tasks as requested.

LOCAL PARTNERSHIP

Beyond the recommendation for strengthened governance at the global level, greater leadership and coordination are also required at the country level. The multitude of new participants in health should not obscure the reality that national governments should ultimately hold responsibility for providing health services to their own populations.

Low- and middle-income countries typically receive health assistance from numerous channels: bilateral and multilateral donors; intergovernmental organizations, such as the World Bank, UNICEF, and UNDP; and international NGOs, such as CARE and Save the Children. The arrival of new organizations like philanthropies and PPPs has increased and diversified the financial resources available to countries, but it has also had a crippling effect by confronting governments with a bewildering array of global agencies from which to elicit support. Efforts to write proposals and reports for donors whose interests, activities, and processes sometimes overlap, but often differ, typically overburden health ministries (Bloom, 2007). Even when working with a single disease the number of donors can often be overwhelming for ministries of health.

Studies show that aid tends to be unpredictable, volatile, and short term, making it challenging for recipient governments to make long-term investments or plan budgets (Lane and Glassman, 2007). Analysis of trends over the last 10 years shows that aid for health is fragmented into large numbers of small projects; more than two-thirds of all commitments were for less than \$500,000 (WHO et al., 2008). Coordinating multiple donors around the delivery of a basic health plan consumes time and resources, especially when short donor time scales (55

percent of donor projects end within one year) lead to continual renegotiation (OECD, 2006).

Countries have been so concerned about the long-term sustainability of donor funding that they have at times refused aid. In India, an immunization program promoted by GAVI was not implemented because the government believed it was not sustainable without continuous, long-term financial support (Lele et al., 2006).

The U.S. government and other donors often provide aid “off-budget” so that it is delivered and managed either through NGOs outside the recipient government’s budgeting system (Schieber et al., 2006) or through U.S. embassies, which may be directly overseen by the ambassador or consular staff (Garrett, 2009). The United States is not alone in delivering aid in this way. In fact, only about 20 percent of global health assistance goes directly to support government health systems (Dodd et al., 2007; Foster, 2005). Even in Tanzania, a country where donor coordination efforts have been under way for a long time, many donors are continuing to put only a small fraction of their funds into this pooled approach and are keeping 95 percent for projects emblazoned with their own donor imprint (Ferranti, 2008).

While delivering aid off-budget allows the U.S. government and other donors several benefits—greater oversight of how the money is spent, quality control over each program, and the ability to demonstrate a direct link between taxpayer money and results—it can create disincentives for the recipient country to accept long-term ownership and accountability for the health of its population. Emerging evidence suggests that off-budget donor financing can lead to decreased government spending on health. The World Bank estimates that a “10 percent increase in off-budget donor funding generates an 0.87 percent reduction in domestically funded government health expenditures” (Gottret and Schieber, 2006).

Another disadvantage of off-budget aid is that its recipients, such as international or domestic NGOs, rather than governments, take charge of healthcare delivery. This has left a number of countries with parallel health systems, as well as weaker control of their own health systems. Just as many would question whether a government-run health system is the best answer for the United States, the committee does not necessarily advocate that all health be delivered by governments. Nongovernmental organizations can be a positive force in strengthening in-country capacity, provided they do not duplicate efforts or take responsibility away from the government. What remains important is the provision of adequate resources and the inclusion of nongovernmental organizations in the private sector in health delivery and planning.

Support for Country-Led Health Plans

To reduce the burden on recipient countries in coordinating donor efforts around a basic health plan, donors should support countries in developing results-

focused, country-led agreements that rally all development partners around one country-led health plan, one monitoring and evaluation framework, and one review process. Country-led health plans, at a minimum, require countries to articulate a health strategy that is “consistent with the macroeconomic and fiscal policies of the country, articulates specific goals in a results-based framework, and aligns the development of health systems and cross-sectoral contributions to the health sector with the achievement of sustainable improvements in health outcomes through a balanced and multi-sector development strategy” (World Bank, 2006). This approach requires donors to engage in respectful partnership and support countries on a demand-driven basis, aligning their assistance with country-driven strategies and procedures.

Country-led plans are not new and have been used with varying degrees of effectiveness over the last two decades. In response to the burdensome, fragmented, donor-driven, and often duplicative aid model, the international community began to reform its methods of aid delivery using the Sector-Wide Approach (SWAp). Under SWAp, project funds contribute directly to a sector-specific umbrella and are tied to a defined sector policy under a government authority. A key characteristic of SWAp is that the government clearly leads and owns the program; external partners confine themselves to work in support of that program, including provision of all or a major share of funding for the sector, in keeping with the government’s unified policy and expenditure plan.

While SWAps have been successful in some countries, they have received mixed reviews (WHO et al., 2008). This is in part due to their exclusion of disease-specific programs, such as the President’s Emergency Plan for AIDS Relief (PEPFAR), and commercial and nongovernmental organizations. Excluding the work of large programs such as PEPFAR when planning donor operations can lead to much duplication and inefficiency. Mozambique provides an example of the successful integration of vertical programs, multilaterals, and NGOs into overall sector programs. Development partners are now part of Mozambique’s Health SWAp, and disburse monies through a common fund that is aligned with the country SWAp (WHO, 2009).

Given the reality that the private sector plays an increasingly important role in health delivery in many low- and middle-income countries, ignoring its role can only hinder progress. Indeed, the need to regulate the activities of the private sector has become increasingly apparent. However, many countries have little experience of regulation, and in low-income countries the priority of health ministries is to deliver basic health care rather than implement regulatory frameworks (SDC, 2008; Soderlund et al., 2003). In addition, health ministries in many countries seem to be moving away from direct line management toward commissioning services through procedures such as contracting and accreditation (Egger et al., 2007). The United States can make an important contribution to the potential benefits for private providers and countries by building capacity within ministries of health to set standards and regulate the private sector while integrating it with the public system (Kadaï et al., 2006).

Country-led plans that go beyond the public sector to coordinate with multilaterals, international NGOs, the private health delivery sector, and even disease-specific programs are emerging. In 2004, key donors reaffirmed their commitment to strengthening national AIDS responses led by the affected countries themselves. To avoid duplication and fragmentation, donors endorsed the “Three Ones” principles: one agreed HIV/AIDS Action Framework that provides the basis for coordinating the work of all partners; one National AIDS Coordinating Authority, with a broad-based multisectoral mandate; and one agreed country-level Monitoring and Evaluation System (UNAIDS, 2004).

The Paris Declaration, endorsed in March 2005, was an international agreement to “increase efforts in harmonization, alignment, and management of aid with a set of monitorable actions and indicators” (OECD, 2005). The accord was signed by more than a hundred ministers, agency heads, and other senior officials.

Another example of a commitment by donors and recipient government agencies to utilize a common work plan is the International Health Partnership (IHP+), jointly supported by WHO and the World Bank. IHP+ is now taking the Sector-Wide Approach a step further in streamlining the management of health aid with the development of “Country Compact” agreements. Like SWAps, the IHP+ continues to exclude private business, NGOs, and disease-specific programs from its plans.

Regardless of which of these country-coordinating mechanisms is used, donors should deliver aid in ways that support technically and financially sound country-led health plans to the greatest extent possible, in order to ensure that countries retain ownership and accountability for the health of their populations and to promote long-term sustainability. This does not necessarily mean that donors must pool their funding into “one country pot.” Yet delivering a greater proportion of aid that is predictable, long term, on plan, and on budget—and provided under the assumption that governments implement agreed-upon strategies in a transparent fashion—would be a tremendous step forward in supporting the long-term capacity of national health systems. It is preferable that funds be neither earmarked for specific purposes nor tied to being spent on U.S. goods or services (tied aid has been estimated to increase program costs by 15 to 30 percent) (Roodman, 2008). This would allow countries to use the funds to fill gaps that are agreed upon and to finance the most needed areas for improving health outcomes, as called for in the Paris Declaration.

The committee acknowledges the trade-off that may arise when delivering a larger portion of aid through government-owned systems. Yet while some of the short-term resources may not end up serving population health due to bottlenecks and weaknesses in existing systems, taking steps to ensure that countries own and build capacity for addressing the health needs of their populations is imperative. By making efforts to deliver aid through budget support, the U.S. government and other donors will also strengthen the demand for, and delivery of, timely and transparent budgets and expenditure records by recipient countries. This

would complement technical assistance and capacity building efforts that focus on improving transparency, procurement management, and auditing in financial systems, all of which are known to reduce corruption (Carter and Lister, 2007; Powell-Jackson and Mills, 2007). A particular focus on strengthening ministries of health and finance in recipient countries is required, since both are central to the effectiveness of aid programs.

Role of International NGOs

International NGOs should neither replace the actions of governments nor merely duplicate their efforts. NGOs have an important role in increasing access to health services and promoting public and private partnerships to improve the health of populations. Rather than directly providing services, international NGOs should make capacity building and health systems strengthening their primary goals; by acting as catalysts or facilitators, NGOs can improve the sustainable delivery of services to marginalized populations.

One of the most important roles an NGO can fill is as a collaborator between the various participants in public health, specifically communities, health institutions, bilateral and multilateral donors, academia, and other NGOs working in complementary fields. Working as a team allows the sharing of ideas and information and the expansion of coverage, while community participation is key to sustainability.

NGOs occupy a unique position in having access to policy makers, as well as the communities affected by their policies, and can therefore provide useful community feedback to improve policies. While NGOs play an important role in global and local advocacy, this role could be strengthened by working in a coalition or partnership.

Since NGOs can focus on priority populations, they can play a particularly influential role in empowering women. As the primary caregivers in families, women greatly influence the health and education of children. “Empowering women to participate in, negotiate with, influence, control, and hold accountable the institutions within their communities will build the capacity of the communities themselves” (Gayle and Sinho, 2009).

NGOs step in to fill a variety of needs in global health ranging from advocacy at the global and national levels to policy development, technical assistance, health service delivery, and emergency relief. These organizations bring unique advantages to the field of health that neither public nor private sector entities possess. The United States in particular has some of the most effective and experienced NGOs with a rich track record in reducing disability and disease. The U.S. global health enterprise should therefore continue to support NGOs—especially in providing emergency relief efforts and strengthening national health systems—and should encourage their inclusion in country-led coordination efforts,

while also supporting the overall alignment of U.S. NGOs working in the health sector.

Role of U.S. Government

To deliver health aid as recommended by the committee, the United States should coordinate its activities across the various agencies and departments at the country level to ensure coherence, while exploring other collaborative channels, for example, by leveraging the efforts of other multilateral participants on the ground. The absence of such coordination is currently fueling the administrative burden on many local governments; U.S. government agencies are sometimes found to be working in the same country on the same agenda and even contracting out to the same agency, without any coordination.

To reverse this trend, the committee commends the 2008 reauthorization of PEPFAR calling for the establishment of country compacts. These nonbinding frameworks are created with partner countries to promote a more sustainable approach, characterized by strengthened country capacity, ownership, and leadership. The 2008 PEPFAR reauthorization uses the term “Partnership Framework” to describe the five-year joint strategic framework for cooperation between the U.S. government, the partner government, and in some cases, other partners to coordinate financial commitments. In keeping with donor harmonization and alignment efforts, the reauthorized PEPFAR Partnership Frameworks are required to be fully in line with the national HIV/AIDS plan of the host country and continue to emphasize sustainable programs with increased country ownership (including decision-making authority and leadership).

This example set by the PEPFAR Partnership Framework is a sign of progress toward correcting the incoherence of U.S. aid efforts; however, the committee questions why this level of commitment to partner with countries does not encompass all U.S. government activities in health. U.S. government agencies should coordinate their global health activities with wider development programs, when relevant; these coordination efforts can be led by the local embassy or even by U.S.-based NGOs working in the country. However, a directive from the highest levels in the U.S. government will be required to harmonize aid to this degree; an agreement at the country level alone will not suffice to ensure routine cooperation and the removal of bureaucratic barriers.

Recommendations 6-2. To ensure that countries retain ownership and accountability for the health of their populations and to promote long-term sustainability, donors should support recipient countries in developing results-focused, country-led agreements that rally all development partners around one country-led health plan, one monitoring and evaluation framework, and

a unified review process. Donors should also aim to build local capacity to regulate and integrate local private sector participants in the government's health plan.

Recommendations 6-3. To reduce the burden on countries in coordinating donor efforts around a basic health plan, all funders of global health should strive to deliver a greater proportion of aid in support of technically and financially sound country-led health plans provided on the premise that the recipient government implements agreed-upon strategies in a transparent fashion.

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7

Call to Action

A PROMINENT ROLE FOR HEALTH IN U.S. FOREIGN POLICY

At this historic moment, the United States has the opportunity to advance the welfare and prosperity of people around the globe through intensified and sustained attention to better health. Especially during this time when the global economy is under pressure, attention to global health is essential. Working with partners in other countries and building on previous commitments, the United States has the opportunity to demonstrate global leadership by fulfilling its responsibility to save lives and improve the quality of life for millions around the world, and there are a variety of reasons to do so. U.S. leadership in global health reflects many motives: the national interest of protecting U.S. residents from threats to their health; the humanitarian obligation to enable healthy individuals, families, and communities everywhere to live more productive and fulfilling lives; and the broader mission of U.S. foreign policy to reduce poverty, build stronger economies, promote peace, and enhance the U.S. image in the world.

Protecting Health at Home Requires Transnational Attention

The 1997 Institute of Medicine (IOM) report *America's Vital Interest in Global Health* emphasized America's self-interest in solving global health problems (IOM, 1997). The report suggested that the United States could reap economic benefits and provide security to its citizens through increased attention to global health. The messages of that report still hold true and perhaps are even more pressing. The 2009 H1N1 (swine) influenza illustrates that Americans do have a stake in the health and healthcare systems of low- and middle-income countries.

Twelve years after the initial IOM global health report, globalization has increased the urgency and changed the way in which nations must protect and promote health, in part due to the growing number of health hazards that increasingly cross national boundaries (Dodgson et al., 2002; Lee, 2002, 2003). These threats include infectious diseases, such as avian flu, swine flu, and severe acute respiratory syndrome (SARS), as well as unhealthy imports, such as tobacco, which heighten the risk of many noncommunicable and chronic diseases (Dodgson et al., 2002; Lee, 2003; Lee et al., 2002). Common, modifiable risk factors—unhealthy diet, physical inactivity, and tobacco use—underlie the major chronic diseases and explain the vast majority of premature deaths from chronic diseases, among men and women, in all parts of the world (Donaldson and Banatvala, 2007).

No country, acting alone, can adequately protect the health of its citizens or significantly ameliorate the deep problems of poor health in low- and middle-income countries. Mitigating the spread of disease and the import of unhealthy consumer goods into already burdened, low-resource societies depends on international cooperation and assistance. Globalization also demands creative solutions to complex problems in areas such as trade and the environment that affect the determinants of health (Dodgson et al., 2002).

Leveraging solutions to address our “shared” global disease burden is essential. In low- and middle-income countries, the purchasing power of investments in health is amplified by local ingenuity, as well as lower labor costs and overhead. (Goldman Sachs estimates that research and development in India costs 12.5 percent of R&D in wealthy countries [Gardner et al., 2007].) The emerging markets increasingly function as big global “labs;” for example, countries such as China, India, and Mexico are experiencing huge variations of diseases like diabetes and obesity within their populations and provide ideal conditions for large-scale drug trials.

Investments in Global Health Reflect American Values

Despite the economic downturn, a large majority of Americans support U.S. efforts to improve health in low- and middle-income countries. This support is grounded in both an altruistic concern for the poor and an understanding that in today’s interconnected, globalized world, a health crisis in any country can impact Americans. In fact, a greater share of Americans support global health spending because it is “the right thing to do” than because it will advance U.S. national objectives (KFF, 2009; WorldPublicOpinion.org, 2009).

In today’s market crisis, the financial policies and practices of high-income nations, including the United States, are seen as the cause of painful economic spillovers in low- and middle-income countries. During economic downturns, the health of a country’s population worsens due to lowered household income and reduced access to health care (Hopkins, 2006; Pongou et al., 2006; Waters et al., 2003). The poor in low-income countries are most affected because they pay a large portion of their healthcare costs out-of-pocket, without the benefit of social

safety nets (Gottret and Schieber, 2006; Hopkins, 2006). It is therefore crucial for the reputation of the United States that the nation live up to its humanitarian responsibilities, despite current pressures on the U.S. economy, and assist low-income countries in safeguarding the health of their poorest members.

Good health is a necessary condition for economic development and global prosperity (Bloom and Canning, 2000; Feachem, 2002). Numerous studies have demonstrated that as people benefit from the positive economic aspects of globalization, good health is important in keeping them from falling back into poverty. Ill health has been shown to be one of the leading reasons that individuals and families descend into poverty in countries such as Argentina, Chile, Ecuador, Honduras, India, Kenya, Peru, Uganda, and Vietnam (Baeza and Packard, 2006; Eggleston et al., 2006; Krishna, 2007a, 2007b). Poor health not only reduces economic productivity and earning potential, it also reduces personal resources by imposing higher healthcare costs and diminishing savings (WHO, 2005; World Bank, 2007). Without investments in health, prosperity from economic growth will be tenuous, especially among the poor.

Improvements in health are thus a core investment in stable and vibrant economies around the world. One study shows that more than half of Africa's growth shortfall, relative to the high-growth countries of East Asia, can be explained by disease burden, demography, and geography, rather than by the more traditional variables of macroeconomic policy and political governance (Bloom and Sachs, 1998; WHO, 2001). The Commission on Macroeconomics and Health of the World Health Organization (WHO) estimated that 8 million lives saved from infectious diseases and nutritional deficiencies would save approximately \$186 billion per year (WHO, 2001). China, India, and the Russian Federation could each forgo between \$200 billion and \$550 billion in national income over the next 10 years as a result of heart disease, stroke, and diabetes (WHO, 2005). Investments in health can also demonstrate a U.S. commitment to avert conflict and promote a more peaceful world (Hotez, 2001). Many of the world's poorest societies either are currently engaged in a civil war or have recently been through one (Collier, 2007). Indeed, countries with the highest infant and child mortality rates are those most likely to be engaged in war (Hotez, 2001); in both 1990 and 2005, Afghanistan, Angola, and Sierra Leone—three war-torn countries—had the highest mortality rates in the world for children under 5, even during times of relative peace (UNICEF, 2008). Implementing disease control and public health activities—which help break the cycle of poor health, poverty, and conflict—is particularly challenging in these fragile states, especially under conditions of conflict (Hotez et al., 2007). However, by improving health and restoring human dignity, the United States can help avoid or reverse the social fragmentation, economic decay, and political instability that often cause, prolong, or result from devastating conflict.

The expansion of U.S. government investments in global health has the potential to change perceptions that the United States is indifferent to the plight of the global poor. Health is a highly valued, visible, and concrete investment.

Public opinion polls following U.S. aid efforts in the aftermath of the Pakistan earthquake and the South Asian tsunami showed an improvement in how America is viewed (Terror Free Tomorrow, 2005, 2006). In fact, while the recent opinion of the United States has been negative in most regions of the world, the U.S. image has remained consistently positive in Africa (Ray, 2008), the region that has received the most U.S. foreign aid for health (U.S. Department of State, 2007). Saving and improving lives worldwide will help to rebuild global trust in U.S. leadership and make possible the global cooperation required for the critical challenges of the twenty-first century, such as nuclear disarmament and climate change.

Global Health Is a Responsibility and an Opportunity to Be Seized

Given the importance of health in building stable and prosperous communities, the committee encourages the new President to make a bold public statement that global health not only is important for protecting the health of Americans, but is an essential component of U.S. foreign policy. This could be confirmed by a major speech early in his tenure to pledge support to successful U.S. investments in this arena and propose new means for pursuing global health objectives in a committed, cooperative, and nonpartisan manner. In this address, the President should declare that the dominant rationale for U.S. government investments in global health is that the United States has both the responsibility as a global citizen and the opportunity as a global leader to contribute to improved health around the world.

The U.S. government should act in the global interest, recognizing that long-term diplomatic, economic, and security benefits for the United States will follow. Priorities should be established on the basis of achieving sustained health gains most effectively, rather than on short-term strategic or tactical U.S. interests. Government efforts should focus on reducing deaths and disabilities among the most vulnerable and marginalized populations in regions with the greatest need, in countries that possess the capacity to effectively use financial and technical resources.

Equally important, health resources should not be withheld from people in countries where the United States takes an unfavorable view of the governing regime. The U.S. offer of cyclone assistance to Myanmar in February 2008 was a good example of prioritizing humanitarian needs over politics. In developing sanctions at the United Nations (UN) and elsewhere, food, medicine, and other health necessities should not be included among the areas of denied trade or assistance.

Recommendation 7-1. The President should highlight health as a pillar of U.S. foreign policy. The U.S. government should act in the global interest, recognizing that long-term diplomatic, economic, and security benefits for

the United States will follow. Priorities should be established on the basis of achieving sustained health gains most effectively, rather than on short-term strategic or tactical U.S. interests.

INCREASE COORDINATION AND COHERENCE WITHIN THE U.S. GOVERNMENT

If health is to hold a more prominent position in U.S. foreign policy, the U.S. government will have to increase coordination among the multiple agencies and departments engaged in global health promotion. Through greater coordination, the U.S. government can vastly enhance its own effectiveness, mobilize a critical mass of the nongovernmental sector, and also be an example for the global health community. The administration should take this opportunity to examine whether the existing architecture, investments, and activities of the U.S. global health enterprise are best geared to achieving sustainable and measurable global health gains.

To this end, the committee examined two aspects of the U.S. enterprise: (1) the governance structures across U.S. government agencies and departments that engage in global health, either by providing financial and technical resources to countries to expand public health infrastructure or through research focusing on health problems endemic to poor countries, and (2) the relationship of the United States to nonstate actors within and beyond U.S. borders.

Need for Coherent Strategy for U.S. Government Involvement in Global Health

More than 20 U.S. government agencies work internationally, with many of them contributing to some aspect of human development. Seven executive branch departments, four independent federal agencies, and numerous departmental agencies and operating units contribute to single- and multiagency initiatives that operate in more than 100 countries. More than 15 congressional committees have jurisdiction or oversight over global health programs (see Figure 7-1) (Kates et al., 2009).

Despite the involvement of multiple government agencies and the growth in the global health budget, to date, the committee is not aware of any efforts to broadly coordinate U.S. actions in global health across even the *major* government agencies, let alone the smaller agencies less directly involved in health. A governing body to help guide U.S. investments in global health across the U.S. government does not exist.

Not only are health programs not well coordinated within the U.S. government, but “at times their efforts appear to be at odds, competing for resources and attention on the ground” (Garrett, 2009). Agencies are often working in the same country on the same agenda and contracting out to the same organization

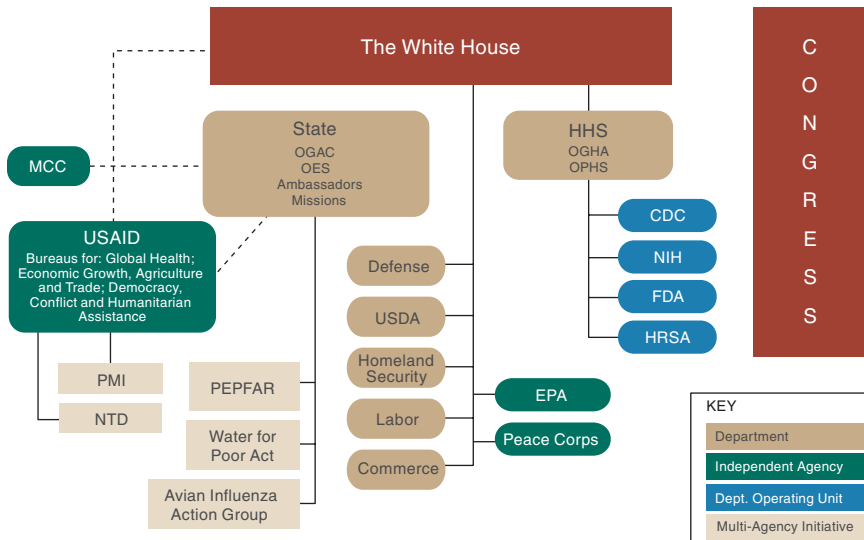


FIGURE 7-1 U.S. government global health architecture.
 SOURCE: Kates et al., 2009.

without any coordination, either among themselves or with U.S.-based private sector health actors. Such duplication is both inefficient and wasteful and should be prevented, especially in an increasingly competitive environment for limited resources.

To ensure that the U.S. government is working in a strategic fashion and having the greatest possible impact to improve health globally, the government should inventory current U.S. efforts as a baseline and should track, measure, and coordinate future investment across different federal agencies and departments both at home and on the ground within countries. This strategy should consult the increasingly important nongovernmental sector. It is within this context that the committee suggests governance reforms to the U.S. government global health enterprise.

Appoint a Senior White House Official and an Interagency Committee on Global Health

The 1997 IOM global health committee called for the establishment of an Interagency Task Force on Global Health within the U.S. government to anticipate and address global health needs and to maximize global health opportunities—for both the United States and the world—in a coordinated and strategic fashion (IOM, 1997). The 1997 committee further recommended that the U.S.

Department of Health and Human Services (HHS) coordinate global health strategy and priority setting across the federal agencies represented in the Inter-agency Task Force and act as the lead agency in establishing liaison with the private sector and international agencies. While this recommendation has yet to be implemented, the potential benefits of formalizing cooperation and coordination across government agencies and departments engaged in the important task of achieving global health can be realized. This IOM committee supports the concept of the 1997 IOM recommendation, but finds that the interagency group should be located more centrally, in the White House. Locating the effort in the White House, potentially within the National Security Council (NSC), and reporting to the President through the NSC adviser would give it convening authority among agencies and the ability to make policy recommendations directly to the President. Any other reporting line would not have the coordinating power that comes with the direct presidential chain of authority. Moreover, housing the interagency group in one of the major departments or agencies, such as the State Department, the U.S. Agency for International Development (USAID), or HHS, might imply that one group is more relevant than others, when several have an important and unique role in global health improvements; for example, while the State Department may be the development and diplomacy arm of the U.S. government, health expertise rests with HHS.

The committee recommends that the President create a White House Inter-agency Committee on Global Health to lead, plan, prioritize, and coordinate the budgeting for U.S. government global health programs and activities. The interagency committee, which would consist of heads of major U.S. departments and agencies involved in global health activities, would play the crucial role of ensuring that the U.S. government has a coherent strategy for ongoing investments in global health, including the means to achieve measurable, significant, and sustained health gains. This interagency committee would be the primary structure for bringing together the diverse and widespread global health efforts cutting across multiple government operations. While some agencies, such as HHS, the Office of Management and Budget (OMB), the State Department, and USAID, would be ongoing participants, other agencies such as the Department of Defense, the Department of Homeland Security, the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA) could participate as appropriate.

The interagency committee should work with OMB to create a review mechanism for global health funding across the major contributing agencies. The interagency committee and the OMB could review agency proposals to ensure that the U.S. government is meeting its overarching policy goals, to reduce duplication of efforts, and to fill gaps.

The committee also recommends that the President designate a senior official at the White House (Executive Office of the President, potentially within the NSC) at the level of deputy assistant to the President to chair the interagency

committee. The deputy assistant to the President for global health should serve as the primary adviser at the White House on global health, attend all NSC meetings that deal in any way with global health issues, and work with the national security adviser, the director of management and budget, and the President's science adviser in carrying out his or her responsibilities.

The deputy for global health should be an individual of recognized accomplishment, with a significant background in health issues and programs, and should have the stature to play a leading role in formulating U.S. global health policy. A staff of three to five officers should support his or her work at the White House.

Finally, if the deputy for global health and the interagency committee are to be effective, individuals who directly oversee global health activities within the various government agencies should be strong and effectual leaders with significant experience and success in global health programming.

Designate Nongovernmental Advisory Committee on Global Health

As previously mentioned, the nongovernmental sector is playing an increasingly significant role in global health financing and programming. To acknowledge its role and create a formal feedback mechanism, the deputy for global health should create a small committee of nongovernmental advisers to oversee the work of the interagency committee.

The nongovernmental advisory committee would be a first step to formally involve civil society, academia, and private industry in discussions regarding global health activities and programs across the U.S. government. By engaging this sector, the U.S. government would help to resolve the deficit of its representation on intergovernmental bodies such as the UN and WHO, which are driven by the interests of their member countries. The U.S. government could further involve nonstate actors by consulting with the nongovernmental sector in forming the U.S. platform on global health policies at UN agencies, such as WHO.

Coordinate U.S. Government Response to Global Health Research

Federal agencies in the United States have played a critical role in global health research; their work has helped to transform the understanding, prevention, and treatment of diseases that disproportionately affect populations in low- and middle-income countries. The National Institutes of Health (NIH) has been a world leader in studying the basic biology of infectious diseases and developing strategies for vaccines and drug treatments. For example, work by intramural and extramural NIH-funded scientists is responsible for the sequencing of genomes of many pathogens responsible for infectious diseases prevalent in the developing world and for much of the progress that has been made against HIV and AIDS. DOD, spurred by the exposure of field personnel in tropical countries, has contributed to the development of biomedical technologies that also benefit the global

poor, such as its trailblazing work in malaria. The Centers for Disease Control and Prevention—the world’s premier public health agency—has developed successful programs and partnerships in many countries over many years, especially epidemiological research to improve the surveillance and control of diseases and conditions from avian influenza to road traffic safety. With decades of field experience and a presence in more than 70 countries, USAID is uniquely positioned to integrate health research into foreign assistance programs, help strengthen health systems, collaborate with partner agencies, and provide leadership for programs in the field (USAID, 2006).

Government agencies such as the EPA and the FDA may be poised to play a more prominent role in global health. For example, the FDA recently launched guidelines to clarify its role in the development of vaccines to protect against global infectious diseases (FDA, 2008). Given that regulatory authorities in many low- and middle-income countries lack the capacity to review new biomedical interventions, the FDA can play a major role in the registration of safe and effective interventions for diseases with direct impact on global health, through its “guidances,” expertise, and experience. This is particularly important in light of the maturing pipeline of drugs from global health product development partnerships.

The committee recognizes that the full potential for contributions of the U.S. agencies to research on global health has yet to be tapped and will require additional financial support and coordinated efforts. Given the importance of the U.S. government contribution to health research, increased coordination between and among the various U.S. government agencies involved in global health research is critical to create the desired synergies.

The Interagency Committee on Global Health can be an important forum for coordinating global health research across these agencies and others. Such coordination may avoid wasteful duplication of efforts, identify promising research opportunities that are not being effectively pursued, and create a global health enterprise in which the advantages and skills of each agency are appropriately tapped and supported. Such an interagency committee, under the leadership of the deputy for global health, can recommend a coherent plan for advancing and financing global health research, and this plan can be reflected in the President’s budget.

Address Overlap Between Health Sector and Other Fields

The interagency committee would also play the critical role of making sure health is taken into account when setting U.S. foreign policy in others areas, such as trade, environment, and security. Public health is currently underrepresented in many key areas of international economic and trade policy (Friel et al., 2008). The growing overlap between the health sector and other fields presents a number of tensions that could impede global health objectives, as well as synergies that could be utilized to improve health.

For example, increased trade liberalization, one of the driving forces behind globalization, may well improve economic prosperity generally, while the increased trade in health-related goods, services, and people offers numerous opportunities to economies around the world (Blouin et al., 2009). Yet trade can also bring challenges by spreading disease across borders, advertising unhealthy lifestyles, and potentially limiting access to medicines under restrictive trade rules.

The health sector itself also has a significant impact on the trade sector. Diseases such as SARS and avian flu can have a powerful economic impact on travel, tourism, and commerce (Drager and Sunderland, 2007; Gostin and Mok, 2008; Helble et al., 2009). The interlinkages between trade and health are complex and require debate and new rules. Because the two sectors bring entirely different philosophies, institutions, and laws, their intersection can raise larger questions. For example, In the event of tension or a conflict, which philosophy, institution, or legal system should prevail, and why (Gostin and Mok, 2008)? Support for the International Health Regulations to protect the health of Americans and communities abroad is an important step in mitigating the negative health consequences associated with increased systems of trade.

Environment and health are clearly linked, with environmental deterioration leading to insufficient potable water, indoor smoke, road traffic, urban air pollution, unintentional poisonings, and lead exposure (Smith et al., 1999). Climate variability causes disease and death through natural disasters such as droughts and tsunamis, as well as longer-term problems such as food security (Confalonieri et al., 2007). These environmental factors especially affect the most vulnerable populations, placing most of the burden on children under the age of 5 and those living in low- and middle-income countries (Smith et al., 1999). U.S. government efforts to participate in global agreements to curtail climate change have important consequences for human health.

In the past, health was thought to be of “little importance in the hierarchy of foreign policy objectives” (Fidler, 2007). However, recent pandemics such as H1N1 (swine) flu and national security threats from bioterrorism have dramatically elevated the status of health on foreign policy agendas. The international community now links health and foreign policy in relation to three key areas: (1) national security (i.e., the need to protect from external threats); (2) trade, economic prosperity, and political stability; and (3) globalization and development (Owen and Roberts, 2005). As previously discussed, global health—when done well and in the global interest—can bring long-term diplomatic, economic, and security wins to the United States.

Recommendation 7-2. Within the first year of his administration, the President should create a White House Interagency Committee on Global Health to lead, plan, prioritize, and coordinate the budgeting for major U.S. govern-

ment global health programs and activities. The President should also designate a senior official at the White House (Executive Office of the President, potentially within the National Security Council) at the level of deputy assistant to the President for global health to chair the interagency committee.

CALL FOR SUMMIT TO HIGHLIGHT U.S. COMMITMENT TO GLOBAL HEALTH

In recognition of the partnership needed to achieve the health-related Millennium Development Goals and meet the global burden of disease for the twenty-first century, the President should call together world leaders for a summit at the UN General Assembly in the fall of 2009 to announce the U.S. commitment to work with the global community to support global health and other major development initiatives, such as food and water security. The President should take this opportunity to highlight the importance of health in building stable and prosperous communities and should pledge to assist low- and middle-income countries in safeguarding the health of their poorest members.

The President should announce the U.S. commitment to the overall funding levels recommended in this report (\$15 billion spent annually by 2012) and ask heads of state of other wealthy countries to recommit to their financial promises on global health. In the interest of sovereignty and sustainability, the President should also ask low- and middle-income countries to commit publicly to providing additional resources by 2012 to finance their own health initiatives. Despite temporary setbacks to the growth of their gross domestic product, the commitment by low- and middle-income countries to leverage additional resources for health is particularly important given the emerging data on health financing showing that with external assistance, the financing pie often does not get bigger; countries merely shift expenditures out of government spending onto donors, defeating the goal of increasing overall health spending to ensure long-term sustainability.

Undertaking investments and activities in global health is not only a matter of protecting Americans' health from overseas threats or leveraging global know-how to solve our shared disease burden. Today, U.S. leadership in global health reflects the values of many Americans—generosity, compassion, optimism, and a wish to share the fruits of U.S. technological advances with others around the world who can benefit from them. Resources dedicated to improving health also play a crucial role in the broader mission of U.S. foreign policy to reduce poverty, build stronger economies, promote peace, and enhance the U.S. image in the world today. Working with partners around the world and building on previous commitments, the United States has the responsibility and chance to save and improve the lives of millions; this is an opportunity that the committee hopes the United States will seize.

Recommendation 7-3. In recognition of the partnership needed to achieve global health, the President should call together world leaders for a summit meeting at the UN General Assembly General Debate and the meeting of the G20 in September 2009 to announce a commitment to the overall funding levels recommended in this report (\$15 billion spent annually by 2012) and to emphasize the importance of the closely related issues of food and water security. In the interest of sovereignty and sustainability, the President should also ask low- and middle-income countries to commit publicly to providing additional resources by 2012 to finance their own health initiatives.

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Appendix A

Statement of Task

The IOM will convene a consensus committee to examine the case for why multiple elements of American society should invest in global health, what areas need the most attention, and how best to accomplish the ultimate objective.

The final report will highlight the committee's consensus on the most significant global health challenges, address the case for a deeper commitment to global health and associated aspects of human development by Americans, and communicate specific conclusions and recommendations that would pertain to not only the government in general and individuals of variable economic means, but also the public health and scientific research communities, the multinational commercial sector, the diplomatic and national security communities, the media, new and established foundations, a range of elements from the university community, and nongovernmental organizations to include faith-based and international service organizations (e.g., Rotary).

Prior to the release of the final report, the committee will offer to the above stakeholders an evidence-based vision for the U.S. government that highlights specific short-, medium-, and long-term goals and objectives for the better implementation of the U.S. global health enterprise. The committee will present this vision in a letter report, which will be released in December 2008 to coincide with the Presidential transition. The subsequently released report will extend the enumeration of short-, medium-, and long-term goals and objectives to other entities potentially involved with the U.S. global health enterprise.

The committee will consider a broader vision for global health to include a renewed recognition of public health and health systems issues. The broader vision of global health could include not only a range of acute and chronic diseases and the transnational economic aspects of global health, but also encompass

American interests from the perspective of diplomatic impact, humanitarian value, social justice, and global governance.

An aspect of the charge to the IOM committee would also be to identify key advances, trends, and “lessons learned” since the 1997 *America’s Vital Interest in Global Health* report. As part of the study the committee would work with an external polling organization and commission a poll that would illuminate at least current patterns in American attitudes towards global health aid and identify those aspects which resonate particularly well with the public.

A final and critical task would be to not only release a quality report, but also to disseminate it in a strategic fashion and at an important time in the national leadership cycle so as to have maximum impact. The target date for the release of the committee’s final report in pre-publication form will be April 2009.

Appendix B

Committee Biographies

Thomas R. Pickering, M.A. (Co-Chair) retired from the State Department as Under Secretary of State for Political Affairs. In a diplomatic career with service in each of the major continents, Ambassador Pickering reached the rank of Career Ambassador, the highest in the U.S. Foreign Service. He served as U.S. Ambassador to the Russian Federation, India, Israel, El Salvador; Nigeria, and Jordan. He also was the U.S. Ambassador and Representative to the United Nations in New York, where he led the U.S. effort to build a coalition in the UN Security Council during and after the first Gulf War. He has held additional positions in Tanzania, Geneva, and Washington, including as Assistant Secretary of State for the Bureau of Oceans, Environmental and Scientific Affairs and as Executive Secretary of the Department and Special Assistant to Secretaries of State William P. Rogers and Henry A. Kissinger. After retiring from the State Department in 2000, Ambassador Pickering joined The Boeing Company as Senior Vice President International Relations and member of the Executive Council, where he was responsible for the Company's relations with foreign governments and the globalization of Boeing. Ambassador Pickering holds a B.A. from Bowdoin College, an M.A.L.D. from the Fletcher School of Law and Diplomacy, and a second M.A. from the University of Melbourne in Australia, where he studied under a Fulbright Scholarship. He speaks French, Spanish, and Swahili fluently and also is proficient in Arabic, Hebrew, and Russian.

Harold Varmus, M.D. (Co-Chair) is the President of the Memorial Sloan-Kettering Cancer Center in New York City. Before his current position, Dr. Varmus served as the Director of the National Institutes of Health (NIH) as appointed by President Bill Clinton. His scientific training occurred first as a Public Health

Service officer at the NIH, where he studied bacterial gene expression with Ira Pastan, and then as a post-doctoral fellow with J. Michael Bishop at the University of California, San Francisco (UCSF). Much of his scientific work was conducted during 23 years as a faculty member at UCSF, where he, Bishop, and their co-workers demonstrated the cellular origins of the oncogene of a chicken retrovirus. For this work, Drs. Bishop and Varmus received the 1989 Nobel Prize in Physiology or Medicine. Dr. Varmus majored in English literature at Amherst College and earned a master's degree in English at Harvard University. A graduate of Columbia University's College of Physicians and Surgeons, he worked as a medical student in a hospital in India and served on the medical house staff at Columbia-Presbyterian Hospital. Dr. Varmus also serves as Chairman of the Scientific Board of the Gates Foundation Grand Challenges in Global Health and chairs the Advisory Committee for the Global Health Division; is a member of the Science Initiatives Group that oversees the Millennium Science Initiative; and is a co-founder and Chairman of the Board of the Public Library of Science.

Nancy Kassebaum Baker represented Kansas in the U.S. Senate from 1978 to 1997. She was the first woman to serve in the Senate who had not served in the House of Representatives or been appointed to fill out the term of a deceased husband. She devoted much of her attention in the Senate to education, health care, childcare, and foreign aid. She was the first woman to chair a major Senate committee, heading the Committee on Labor and Human Resources. She was also chair of the Commerce Committee's Aviation Subcommittee and the Foreign Relations Committee's African Subcommittee. She was a cosponsor with Senator Edward Kennedy of the Health Insurance Reform Act, which guaranteed portability of health care. She also worked for improvements in Medicaid and was a strong supporter of family planning programs in the United States and abroad. Since leaving public office, Kassebaum Baker has continued to be involved in health issues, serving on the National Advisory Committee on Rural Health to the secretary of health and human services. In 2005, she served on Prime Minister Blair's Commission for Africa. Senator Kassebaum Baker served on the board of trustees of the Robert Wood Johnson Foundation and the Kaiser Family Foundation and serves on the advisory board of the Partnership for a Secure America.

Paulo M. Buss, M.A., M.D., is the Director of Fundação Oswaldo in Rio de Janeiro, Brazil. He graduated from Universidade Federal de Santa Maria (1972) with a Master's Degree in Social Medicine from Universidade do Estado do Rio de Janeiro (1980). He is a specialist in Pediatrics (Sociedade Brasileira de Pediatria, 1975) and Public Health (Escola Nacional de Saúde Pública Sergio Arouca, ENSP, 1975). In 1979 he founded the Associação Brasileira de Pós-graduação em Saúde Coletiva (ABRASCO), Latin America's greatest public health scientific society, of which he was the first executive secretary from 1979 to 1983 and vice president between 2000 and 2003. Dr. Buss was president of

the Associação Latino-americana e do Caribe de Educação em Saúde Pública (ALAESp) (1998-2000) and of the Federação Internacional de Cooperação entre Centros de Pesquisa em Sistemas e Serviços de Saúde (1990-1994). At the ENSP, Dr. Buss held offices as deputy-director (1985-1989) and director for two terms (1989-1992 and 1998-2000). He was vice president of Education and Information at Fundação Oswaldo Cruz (1992-1996). He represented Brazil in the World Health Organization's Executive Council (from December 2004 to May 2007), nominated by the President of Brazil, and represents Fiocruz in the world networks of the Health Research Institutes.

Haile T. Debas, M.D., the Executive Director of UCSF Global Health Sciences, is recognized internationally for his contributions to academic medicine and is currently widely consulted on issues associated with global health. At UCSF, between 1993 and 2003, he served as Dean (Medicine) for 10 years, Vice Chancellor (Medical Affairs) for 6 years, and Chancellor for one year. A gastrointestinal surgeon by training, Dr. Debas is also the Maurice Galante Distinguished Professor of Surgery and chaired the UCSF Department of Surgery from 1986 to 2003. A native of Eritrea, he received his M.D. from McGill University and completed his surgical training at the University of British Columbia. He was a member of the faculty of Surgery at the University of British Columbia (1971-1979), UCLA (1980-1985), and the University of Washington (1985-1987). Under Dr. Debas's stewardship, the UCSF School of Medicine became a national model for medical education, an achievement for which he was recognized with the 2004 Abraham Flexner Award of the AAMC. His prescient grasp of the implications of fundamental changes in science led him to create several interdepartmental and interdisciplinary research centers that have been instrumental in reorganizing the scientific community at UCSF. He played a key role in developing UCSF's new campus at Mission Bay. He has held leadership positions with numerous membership organizations and professional associations including serving as president of the American Surgical Association and chair of the Council of Deans of the AAMC. He has been a member of the Institute of Medicine since 1990, and is the current chair of the Membership Committee. He is a fellow of the American Academy of Arts and Sciences. He currently serves on the United Nations' Commission on HIV/AIDS and Governance in Africa and on the Committee on Science, Engineering, and Public Policy of the National Academy of Sciences.

Mohamed T. El-Ashry, Ph.D., is a Senior Fellow at the United Nations Foundation. Prior to joining the foundation, Dr. El-Ashry served as Chief Executive Officer and Chairman of the Global Environment Facility (GEF). He served as the GEF Chairman between 1991 and 2002, and was appointed the first CEO and Chairman of the GEF in 1994. Dr. El-Ashry came to the GEF from the World Bank, where he was the Chief Environmental Advisor to the President and Director of the Environment Department. Prior to joining the World Bank, he served

as Senior Vice President of the World Resources Institute (WRI) and as Director of Environmental Quality with the Tennessee Valley Authority (TVA). Dr. El-Ashry received his Bachelor of Science degree with honors in 1959 from Cairo University and his doctorate degree in geology in 1966 from the University of Illinois. He has received numerous international awards and honors and is the author of three books and more than 200 papers.

Maria Freire, Ph.D., is President of The Albert and Mary Lasker Foundation. Prior to her appointment at the Lasker Foundation, Dr. Freire was the Chief Executive Officer of the Global Alliance for TB Drug Development (TB Alliance). An internationally recognized expert in technology commercialization, Dr. Freire directed the Office of Technology Transfer at the U.S. National Institutes of Health (NIH) from 1995 to 2001. Before her position at the NIH, Dr. Freire established and headed the Office of Technology Development at the University of Maryland at Baltimore and the University of Maryland, Baltimore County. Dr. Freire trained at the Universidad Peruana Cayetano Heredia in Lima. She received a Ph.D. in biophysics from the University of Virginia and completed post-graduate work in immunology and virology at the University of Virginia and the University of Tennessee, respectively. Dr. Freire has been active on a number of national and international boards and committees. She is the recipient of numerous awards, including the HHS Secretary's Award for Distinguished Service, the 1999 Arthur S. Flemming Award, and the 2002 Bayh-Dole Award.

Helene Gayle, M.D., M.P.H., is President and CEO of CARE, an international relief and development organization. She worked at the CDC for 20 years in a variety of capacities, including the Director of CDC's Washington Office and Director for the National Center for HIV, STD and TB Prevention. Dr. Gayle has served as the AIDS Coordinator and Chief of the HIV/AIDS Division for the U.S. Agency for International Development (USAID). She has also served as a health consultant to international agencies including the World Health Organization, UNICEF, the World Bank, and UNAIDS and has worked extensively in Africa, Asia, and the Americas. Prior to assuming her current position, she was the Director of the HIV, TB and Reproductive Health Program for the Bill and Melinda Gates Foundation. Dr. Gayle has published numerous articles on public health, especially related to HIV/AIDS and has received many awards for her scientific and public health contributions. She attained the rank of Rear Admiral (Assistant Surgeon General) in the U.S. Public Health Service.

Margaret Hamburg, M.D., is the Commissioner of the United States' Food and Drug Administration. She previously served as Vice President for the Biological Program, and then as a Senior Scientist, for the Nuclear Threat Initiative. Before arriving at NTI, Dr. Hamburg was Assistant Secretary for Planning and Evaluation at the U.S. Department of Health and Human Services. She was the Com-

missioner of Health for the City of New York and former Assistant Director of the Institute of Allergy & Infectious Diseases at the National Institutes of Health. Dr. Hamburg earned her doctorate from Harvard Medical School, and completed her training at the New York Hospital/Cornell University Medical Center. She is a member of the Institute of Medicine (IOM) of the National Academies of Science, the Council on Foreign Relations, and is a fellow for the American Association of the Advancement of Science. Dr. Hamburg also serves on a number of Boards, including the Rockefeller Foundation, Rockefeller University, The Trust for America's Health, Doctors of the World, the National Health Museum, and Henry Schein, Inc. Very active within the National Academies, she serves on the IOM Council, chairs the IOM Board on Global Health, is co-chair of the Forum on Microbial Threats, and is a member of the Committee on International Security and Arms Control.

J. Bryan Hehir, Th.D., M.A., is the Parker Gilbert Montgomery Professor of the Practice of Religion and Public Life. He is also the Secretary for Social Services and the President of Catholic Charities in the Archdiocese of Boston. Dr. Hehir earned an interdisciplinary doctorate degree from Harvard University in applied theology, combining the study of international relations and ethics. He served on the faculty of Georgetown University, first as a MacArthur Foundation Fellow (1984-1988) and then as the Joseph P. Kennedy Professor of Christian Ethics (1988 to 1992). In 1993, Dr. Hehir returned to Harvard Divinity School as a professor of the practice of religion and society and was appointed to Chair of the Executive committee in 1998. His research and writing focus on ethics and foreign policy and the role of religion in world politics and in American society. His writings include *The Moral Measurement of War: A Tradition of Continuity and Change*; *Military Intervention and National Sovereignty*; *Catholicism and Democracy*; and *Social Values and Public Policy: A Contribution from a Religious Tradition*.

Prabhat Jha, M.D., D.Phil., is the Canada Research Chair of Health and Development at the University of Toronto. He is also the founding director of the Centre for Global Health Research, St. Michael's Hospital; professor in the Department of Public Health Sciences, University of Toronto; research scholar at the McLaughlin Centre for Molecular Medicine; and professor extraordinaire at the Université de Lausanne, Switzerland. Prior to returning to the University of Toronto, Dr. Jha served as a senior scientist with the World Health Organization where he led the work on adult health issues in the Human Development Network. Dr. Jha is lead author of *Curbing the Epidemic: Governments and the Economics of Tobacco Control* and coeditor of *Tobacco Control in Developing Countries*. Both are among the most influential books on tobacco control. He is the principal investigator of the world's largest prospective study of health, focusing on 1 million deaths in India. He also conducts studies of HIV transmis-

sion in various countries, focusing on documenting the risk factors for the spread of HIV and interventions to prevent the spread of the HIV/AIDS epidemic. Dr. Jha has published widely on tobacco, HIV/AIDS, and health of the global poor. His awards include a Gold medal from the Poland Health Promotion Foundation (2000), the Top 40 Canadians under Age 40 Award (2004), and the Ontario Premier's Research Excellence Award (2004). He holds an M.D. from the University of Manitoba and a D. Phil. in epidemiology and public health from Oxford University, where he studied as a Rhodes Scholar.

Roderick K. King, M.D., M.P.H., is currently Senior Faculty at the Massachusetts General Hospital (MGH) Disparities Solutions Center, faculty in the Department of Social Medicine, and on staff in the Office of Diversity and Community Partnership at Harvard Medical School (HMS). In addition, Dr. King was recently selected as one of two Inaugural IOM Anniversary Fellows where he serves on the Board on Global Health. He most recently served as the Director for the Health Resources and Services Administration, Boston Regional Division and as a Commander in the US Public Health Service, U.S. Department of Health and Human Services. Prior to returning to Harvard, Dr. King was the New England Regional Director, the youngest ever appointed, for the Health Resources and Services Administration, a branch of the U.S. Department of Health and Human Services, and a Commander in the U.S. Public Health Service. Dr. King earned a B.S. degree in biomedical engineering from Johns Hopkins University and his medical degree from Cornell University Medical College with honors in research.

Jeffrey P. Koplan, M.D., M.P.H., is Vice President for Global Health and Director of the Global Health Institute of Emory University. From 1998 to 2002, Dr. Koplan served as the Director of the Centers for Disease Control and Prevention (CDC). Prior to his appointment at the CDC, Dr. Koplan was President of the Prudential Center for Health Care Research. Dr. Koplan began his public health career in the early 1970s as one of the CDC's Epidemic Intelligence Service Officers. Since then, he has worked on virtually every major public health issue, including infectious diseases such as smallpox and HIV/AIDS, environmental issues such as the Bhopal chemical disaster, and the health toll of tobacco and chronic diseases, both in the United States and around the globe. Dr. Koplan is a graduate of Yale College, the Mt. Sinai School of Medicine, and the Harvard School of Public Health. He is a Master of the American College of Physicians and was elected to membership in the IOM and serves on its Council. He has served on many advisory groups and consultancies in the United States and overseas, and has written more than 200 scientific papers.

Ruth Levine, Ph.D., is Vice President for Programs and Operations and Senior Fellow at the Center for Global Development (CGD), where she leads the Cen-

ter's work on global health policy. Dr. Levine has a doctorate in economic demography from Johns Hopkins University. She is a health economist with more than 15 years of experience designing and assessing the effects of social sector programs in Latin America, Eastern Africa, the Middle East, and South Asia. Before joining the CGD, Dr. Levine designed, supervised, and evaluated loans at the World Bank and the Inter-American Development Bank. Between 1997 and 1999, she served as the advisor on the social sectors in the office of the executive vice president of the Inter-American Development Bank. She has co-authored *The Health of Women in Latin America and the Caribbean* (World Bank, 2001) and *Millions Saved: Proven Successes in Global Health* (CGD, 2004, updated as *Cases in Global Health: Millions Saved* (Jones and Bartlett, 2007)).

Afaf I. Meleis, Ph.D., R.N., F.A.A.N., is the Margaret Bond Simon Dean of Nursing at the University of Pennsylvania School of Nursing, Professor of Nursing and Sociology, and Director of the School's WHO Collaborating Center for Nursing and Midwifery Leadership. Dr. Meleis graduated Magna Cum Laude from the University of Alexandria (1961), earned an M.S. in nursing (1964), an M.A. in sociology (1966) and a Ph.D. in medical and social psychology (1968) from the University of California, Los Angeles. Prior to coming to Penn, she was a Professor on the faculty at the University of California Los Angeles and the University of California San Francisco for 34 years. She is a Fellow of the American Academy of Nursing, the Royal College of Nursing in the United Kingdom, and the College of Physicians of Philadelphia; a Trustee of the National Health Museum; and a Board Member of the Global Health Council, CARE (a global intervention group), and the Nurses Education Fund, Inc.; and a member of the Robert Wood Johnson Foundation Nurse Faculty Scholar National Advisory Committee. She is Council General of the International Council on Women's Health Issues. Dr. Meleis is the recipient of numerous honors and awards, as well as honorary doctorates and distinguished and honorary professorships around the world. Among her awards, in 1990, Egyptian President Hosni Mubarak presented her the Medal of Excellence for professional and scholarly achievements. Dr. Meleis' scholarship is focused on global health, immigrant and international health, women's health, and on the theoretical development of the nursing discipline. She is the author of more than 150 articles in social sciences, nursing, and medical journals; 40 chapters; and numerous monographs, proceedings, and books.

Nelson Sewankambo, MBChB, MMED, MSc, FRCP, is Dean of Medicine at Makerere University in Kampala, Uganda and Co-Principal Investigator (Co-PI) of the Rakai Health Sciences Program. Dr. Sewankambo was among the first scientists to publish data on AIDS in Africa and was instrumental in starting the AIDS Clinic at Mulago Hospital and he continues to be active in HIV/AIDS research. He was founding Director of the Clinical Epidemiology Unit, and a co-PI on the Canadian IDRC-funded behavioral and qualitative research on AIDS

Prevention. Dr. Sewankambo has served on numerous local and international advisory boards including the Working Party on the Ethics of Clinical Research in Developing Countries of the Nuffield Council for Bioethics, The Joint Learning Initiative, the WHO African Advisory Committee on Health and Research Development, and the Board of Directors of the International Clinical Epidemiology Network. Dr. Sewankambo is also Chairman of the Infectious Diseases Institute Board, a member of Council of the Global Forum for Health Research and a Chair of Initiative for Strengthening Health Research Capacity in Africa.

Bennett M. Shapiro, M.D., is a Partner at PureTech Ventures. He also Chairman of the Drugs for Neglected Diseases initiative-North America, and a Director of DNDi, the Mind and Life Institute, the Tricycle Foundation, and the Garrison Institute. Prior to this, he was Executive Vice President, Worldwide Licensing and External Research at Merck, where he directed all of Merck's research relationships with the academic and industrial biomedical research community. He joined Merck in September of 1990 as Executive Vice President, Worldwide Basic Research, Merck Research Laboratories. In this position he was responsible for all the basic and preclinical research activities at Merck worldwide. Earlier, he was Professor and Chairman of the Department of Biochemistry at the University of Washington. He is the author of over 120 papers on the molecular regulation of cellular behavior and the biochemical events that integrate the cascade of cellular activations at fertilization. Shapiro received his bachelor's degree in chemistry from Dickinson College and his doctor's degree in medicine from Jefferson Medical College. Following an Internship in Medicine at the University of Pennsylvania Hospital, he was a Research Associate at the NIH, then a Visiting Scientist at the Institut Pasteur in Paris, and returned to the NIH as Chief-Section on Cellular Differentiation in the Laboratory of Biochemistry, prior to joining the University of Washington. Dr. Shapiro has been a Guggenheim Fellow, a Fellow of the Japan Society for the Promotion of Science and a Visiting Professor at the University of Nice. He has served on many institutional advisory boards and scientific review panels. In addition to being a Partner at PureTech Ventures, Shapiro is Chairman of Vascular Biogenics, Ltd., and a Director of Momenta Pharmaceuticals, Protein Forest, Satori, and Elixir Pharmaceuticals.

Marc Van Ameringen, M.A., is the Executive Director of Global Alliance for Improved Nutrition (GAIN). Prior to joining GAIN, Mr. Van Ameringen was Vice President of the Canadian-based Micronutrient Initiative which focuses primarily on delivering vitamin A supplementation programs around the world. Before this assignment, he was Special Advisor to the G8 Summit, assisting the G8 in responding to the NEPAD initiative. From 1992 to 2002, Mr. Van Ameringen was a Director based in Africa for the International Development Research Centre (IDRC), responsible for a number of large donor programs across Africa. He played an important role in assisting South Africa and other

countries in Southern Africa in their reconstruction and development. Prior to moving to Africa, he held various senior positions in Canada for IDRC and other organizations. Mr. Van Ameringen has served as a board member and trustee of many different development organizations and has published a number of books on development in Africa.

Appendix C

Public Committee Meeting Agendas

COMMITTEE ON THE U.S. COMMITMENT TO GLOBAL HEALTH

COMMITTEE MEETING ONE

March 24, 2008

1:00-1:10 p.m. Welcome

Ambassador Thomas Pickering, Co-Chair

Dr. Harold E. Varmus, Co-Chair

1:10-1:40 p.m. Opening Addresses

Dr. Elias Zerhouni

Director, U.S. National Institutes of Health

Dr. Paula Dobriansky

Under Secretary of State for Democracy and Global Affairs, U.S. State Department

1:40-3:00 p.m. Open Discussion of Committee Charge with Sponsors

Dr. Roger Glass

Director, Fogarty International Center, U.S. National Institutes of Health

Ambassador Don Mahley

Acting Deputy Assistant Secretary for Threat Reduction, Export Controls, and Negotiations (ISN/TRECN), U.S. State Department

Dr. Ariel Pablos-Mendez
Managing Director, Rockefeller Foundation

Dr. Mark Feinberg
Vice President, Medical Affairs and Policy, Merck Vaccines and Infectious
Diseases, Merck & Co., Inc.

Mr. William H. Lyerly, Jr.
Director of International Affairs, Special Assistant for Global Health
Security to the Assistant Secretary for Health Affairs U.S. Department
of Homeland Security

Ms. Alison Kelly
Chief for Strategy and Innovation, Coordinating Office for Global Health,
Centers for Disease Control and Prevention

Mr. Todd Summers
Senior Program Officer for Global Health, Bill and Melinda Gates
Foundation

3:00-3:10 p.m. Break

3:10-5:00 p.m. Panel

Dr. Harvey V. Fineberg, moderator
President, Institute of Medicine

Ambassador Mark R. Dybul
Global AIDS Coordinator, U.S. Department of State

Ms. Laurie Garrett
Senior Fellow for Global Health, Council on Foreign Relations

Dr. Alfred Sommer
Professor, Dean Emeritus, Johns Hopkins Bloomberg School of Public
Health

Dr. Anthony S. Fauci
Director, National Institutes of Allergy and Infectious Diseases, U.S.
National Institutes of Health

5:00-5:15 p.m. Public comment

5:15 p.m. Adjourn

Ambassador Thomas Pickering, Co-Chair

Dr. Harold E. Varmus, Co-Chair

Public reception

COMMITTEE MEETING TWO

July 21, 2008

1:00-1:05 p.m. Welcome

Ambassador Thomas R. Pickering, Committee Co-Chair

Dr. Harold E. Varmus, Committee Co-Chair

1:05-1:25 p.m.

Dr. Tim Evans, Assistant Director-General for Information, Evidence and Research, The World Health Organization

1:25-1:45 p.m.

Dr. Daniel Low-Beer, Director for Performance Evaluation and Policy, The Global Fund for HIV/AIDS, TB, and Malaria

1:45-2:05 p.m.

Dr. Anne Mills, Professor of Health Economics and Policy, London School of Hygiene and Tropical Medicine

2:05-2:25 p.m.

Dr. Joy Phumaphi, Vice President of the Human Development Network, The World Bank

2:25-2:30 p.m. Break

2:30-2:50 p.m.

Dr. Lola Dare, Executive Secretary, ACOSHED, CEO, CHESTRAD International

2:50-3:10 p.m.

Dr. Mario Henry Rodríguez, Director General, National Institute of Public Health, Mexico

3:10-3:30 p.m.

Ms. Karen Cavanaugh, Medical Officer, Office of Health and Nutrition, USAID

3:30-3:45 p.m. Public Comment

3:45 p.m. Adjourn

Appendix D

Working Group Meeting Agendas

COMMITTEE ON THE U.S. COMMITMENT TO GLOBAL HEALTH

WORKING GROUP MEETING: HUMAN RESOURCES FOR HEALTH

June 10, 2008

1:00-1:05 p.m. Welcome and Introductions by Dr. Ruth Levine

1:05-1:45 p.m. Migration Panel

Dr. Patricia Pittman, Executive Vice President, AcademyHealth
U.S.-Based International Recruitment of Health Professionals in Low- and Middle-Income Countries

Dr. Gillian Barclay, Advisor, Human Resource Development for Health,
PAHO/WHO Office of Caribbean Program Coordination
Caribbean Health Workers Emigration

Dr. Michael Clemens, Research Fellow, Center for Global Development
Health Effects of African Health Professional Emigration

Ms. Dovelyn Rannveig Agunias, Associate Policy Analyst, Migration
Policy Institute
Learning by doing: Circular Migration Among Health Care Professionals

1:45-2:45 p.m. Panel Discussion

2:45-3:00 p.m. Break

3:00-3:40 p.m. Donor Assistance and Capacity Building Panel

Dr. Kelechi Ohiri, World Bank

The Impact of Fiscal Policy on the Health Workforce

Ms. Lois Schaefer, Senior Technical Advisor, HCD and Training, USAID

Emerging Best Practices from the USAID Capacity Project

Dr. Seble Lemma Frehywot, Assistant Research Professor of Health Policy and Global Health, The George Washington University

Using Skills Mix for Care and Treatment in Low- and Middle-Income Countries

Dr. Fitzhugh Mullan, Murdock Head Professor of Medicine and Health Policy, The George Washington University

Healers Abroad: Opportunities for U.S. Institutions to Build Human Resource Capacity

3:40-4:50 p.m. Panel Discussion

4:50-5:00 p.m. Closing remarks by IOM Committee Members

WORKING GROUP MEETING: GLOBAL HEALTH GOVERNANCE

June 26, 2008

9:00-9:05 a.m. Welcome

Dr. Peggy Hamburg, IOM Committee Member

9:05-9:25 a.m. Opening Remarks

Mr. Larry Gostin, Associate Dean and Linda D. and Timothy J. O'Neill Professor of Global Health Law, Georgetown University Law Center

9:25-11:10 a.m. PANEL 1: State-centered approaches to global health governance

Dr. Julian Schweitzer, Director, Health, Nutrition, and Population, the World Bank

Dr. David Bell, Senior Medical Officer, Office of Strategy and Innovation, Centers for Disease Control and Prevention

Dr. Ian Smith, Advisor to the Director-General, WHO

Dr. David De Ferranti, President and Director of Health Financing Task Force, Results for Development

11:10 a.m.-1:20 p.m. PANEL 2: Civil society approaches to global health governance

Dr. Seth Berkley, President and CEO, IAVI (teleconference)
Dr. Rhona MacDonald, Global Health Watch (teleconference)
Dr. Clarion Johnson, Global Medical Director, Exxon Mobile
Mr. Josh Lozman, Vote '08 Policy Manager, One Campaign

1:20-3:00 p.m. PANEL 3: Optimal architecture and institutions

Dr. Jennifer Prah Ruger, Co-Director of the Yale/World Health Organization (WHO) Collaborating Centre for Health Promotion, Policy and Research
Dr. Mark Rosenberg, Executive Director, Task Force for Child Survival and Development
Dr. Maria Ivanova, Assistant Professor of Government and Environmental Policy, The College of William and Mary; Director, Global Environmental Governance Project, Yale Center for Environmental Law and Policy
Mr. David Fidler, James L. Calamaras Professor of Law, Indiana University

3:00-4:00 p.m. PANEL 4: Topic discussion

4:00 p.m. Adjourn

Dr. Peggy Hamburg

**WORKING GROUP MEETING: GAPS AND PRIORITIES IN U.S.
CONTRIBUTIONS TO GLOBAL DISEASE CHALLENGES**

July 7, 2008

9:00-9:05 a.m. Welcome

Jeff Koplan

9:05-10:35 a.m. Infectious Disease Panel

Moderator: Sir George Alleyne, Director Emeritus PAHO
HIV/TB: Dr. Stefano Bertozzi, Mexican National Institute of Public Health
Malaria: Dr. Joel Breman, NIH Fogarty International Center
Neglected Diseases: Dr. Peter Hotez, Sabin Vaccine Institute; George Washington University
Biosecurity and Pandemic Threats: Dr. Tara O'Toole, Center for Biosecurity of the University of Pittsburgh Medical Center
Surveillance: Dr. Peter Nsubuga, Centers for Disease Control and Prevention

10:35-10:45 a.m. Break

10:45 a.m.-12:45 p.m. Adult Health and Risk Factors Panel

Moderator: Dr. Dean Jamison, UCSF School of Medicine
Noncommunicable Disease Interventions: Dr. John Dirks, University of Toronto
Noncommunicable Disease Prevention: Dr. Rachel Nugent, Center for Global Development
Tobacco: Dr. Tom Frieden, New York City Department of Health and Mental Hygiene
Mental Illness: Dr. Joanna Maselko, Temple University
Essential Surgery: Dr. Colin McCord, Columbia University
Injuries: Dr. Adnan Hyder, Johns Hopkins School of Public Health
Climate Change and Health: Dr. Kirk R. Smith, University of California, Berkeley

12:45-1:15 p.m. Lunch

1:15-2:45 p.m. Child and Women's Health Panel

Moderator: Dr. Dean Jamison, UCSF School of Medicine
Maternal, Neonatal, and Reproductive Health: Dr. Khama Rogo, World Bank
Diarrheal Disease and Acute Respiratory Infections: Dr. Jerry Keusch, Boston University School of Public Health
Vaccine Preventable Diseases: Dr. Mathu Santosham, Johns Hopkins School of Public Health
Malnutrition: Dr. Robert Black, Johns Hopkins School of Public Health
Public Health Programming: Dr. Donald Bundy, World Bank

2:45-2:55 p.m. Break

2:55-3:55 p.m. Cross-Panel Discussion

Moderator: Sir George Alleyne, Director Emeritus PAHO

3:55-4:00 p.m. Adjourn

Prahbat Jha

**WORKING GROUP MEETING: CAPACITY BUILDING,
KNOWLEDGE SHARING, AND INNOVATION IN GLOBAL HEALTH**

April 3, 2009

9:00-9:10 a.m. Introduction

Maria Freire, Committee Member and Working Group Chair

9:10-9:20 a.m. Overview

Anthony So, Duke University

9:20-11:15 a.m. PANEL 1: Advancing research capacity building

Moderator: Dr. F. Gray Handley, NIAID, National Institutes of Health
Dr. Patricia Garcia, Universidad Peruana Cayetano Heredia; National
Institutes of Health, Peru

Dr. Warner C. Greene, Gladstone Institute of Virology and Immunology;
University of California, San Francisco; Accordia Global Health
Foundation

Dr. Monique Wasunna, Centre for Clinical Research, Kenya Medical
Research Institute

Ms. Mary Lou Valdez, FDA

11:15 a.m.-12:15 p.m. Lunch

12:15-2:00 p.m. PANEL 2: Sharing information, knowledge, and materials

Moderator: Dr. Anthony So, Duke University

Dr. Ashley Stevens, Boston University

Dr. Paul Herrling, Novartis

Dr. David J. Lipman, NCBI, NLM, NIH

Dr. Simon Kennedy, Boston Consulting Group

Mr. Clark Freifeld, HealthMap.org

Panel discussion: Questions from committee and from the public

2:00-2:10 p.m. Break

2:10-3:55 p.m. PANEL 3: Exploring novel collaborative research models and
partnerships

Moderator: Dr. Margaret Anderson, Faster Cures

Dr. Alpheus Bingham, InnoCentive

Dr. Chris Elias, PATH

Dr. Elaine K. Gallin, Doris Duke Foundation

Dr. Rachel Glennerster, MIT

Panel discussion: Questions from committee and from the public

3:55-4:00 p.m. Concluding remarks

Maria Freire, Committee Member and Working Group Chair

Appendix E

COMMISSIONED PAPER

Global Health Governance Report

*Lawrence O. Gostin**

*Emily A. Mok***

I. Introduction

Global health is of primary importance to human functioning and well-being. Yet the state of global health by many measures is dire. The dual burdens of infectious and chronic diseases among the world's poorest people are enduring. Profound disparities in health and life expectancy between the rich and poor are wide and resistant to change. And all countries, rich and poor, are at risk of pronounced health hazards from the movement of people, goods, and services.

No country, acting alone, can adequately protect the health of its citizens or significantly ameliorate the deep problems of poor health in developing countries. The spread of disease, the importation of consumer goods, and the migration of health professionals cannot be adequately controlled by states in isolation, but depend on international cooperation and assistance. Globalization—the “process of increasing economic, political and social interdependence, and global integration that occurs as capital, traded goods, people, concepts, images, ideas and values diffuse across national boundaries” (Taylor 2002)—is changing the way that states must protect and promote health due to the growing number of health hazards that increasingly cross national boundaries (Dodgson et al. 2002, Lee et al. 2002, Lee 2003). Globalization similarly demands creative solutions to

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**Visiting Researcher, O’Neill Institute of National and Global Health Law, Georgetown University, and D.Phil candidate, Centre for Socio-Legal Studies, University of Oxford.

complex problems that affect the determinants of health such as in trade, human rights, and the environment (Dodgson et al. 2002).

Despite the importance of a coherent strategy for global health, the traditional system of international health governance, which primarily encompasses states and intergovernmental organizations (IGOs), has been unable to effectively govern in the new global health context (Dodgson et al. 2002). Today, the international community faces a number of hard global health governance (GHG) problems. Here, we highlight several “grand challenges,” which are vital to the improvement of world health and the reduction in glaring health disparities (Gostin 2008a):

- *Leadership*—WHO must gain the capacity and authority to establish a clear mission, achieve objectives, and influence health-promoting activities globally.
- *Harness Creativity, Energy, and Resources for Global Health*—The GHG system must create and align incentives of private/public actors and stakeholders to promote imaginative, well-funded solutions for global health improvement.
- *Collaboration and Coordination of Multiple Players*—The GHG system must create effective partnerships and coordinate currently fragmented funding, programs, and activities to create synergies and avoid destructive competition among funders and service providers or, worse, with local government and business initiatives.
- *Basic Survival Needs*—The GHG system must help build health systems and infrastructures that are scalable and sustainable to meet fundamental human needs, including sanitation, food and water, vector control, and maternal/infant health.
- *Funding and Priorities*—The GHG system must gain agreement on funding levels needed to achieve key priorities, the responsibility of rich states to devote adequate funding for international health assistance, and ensure adequate health system capacities in poor states.
- *Accountability, Transparency, Monitoring, and Enforcement*—The GHG system must create rules for accountability, transparency, monitoring progress, and norm enforcement needed to fulfill commitments and meet goals.

The conspicuous voids left by the traditional governance system in the face of global health crises have prompted the creation of various ad hoc initiatives sponsored bilaterally or by nonstate actors such as nongovernmental organizations (e.g., humanitarian organizations, industry associations, foundations, and other private associations) and businesses (e.g., pharmaceutical companies). For some initiatives, states and IGOs have joined forces with nonstate actors to form public-private partnerships (PPPs) or “hybrid” organizations in an attempt to

address global health problems such as the Global Fund for HIV/AIDS, Tuberculosis and Malaria (“the Global Fund”) and the International Finance Facility for Immunisation (IFFIm).

Despite the proliferation of actors and initiatives in the global health space, the current approach to governance is not solving the global health crisis. Numerous global health initiatives have missed or are missing their targets (e.g., WHO’s “3 by 5” initiative and the UN Millennium Development Goals) due, in part, to problems of governance. Furthermore, there is growing concern over the popularity of short-term, narrowly focused disease programs over long-term capacity building initiatives aimed at generalized health protection and promotion (Burriss and Beletsky 2005).

This commissioned Institute of Medicine paper addresses why the most important global health objectives are being hindered by global health governance today. The most vital goals include improved health and longevity among the world’s poor, maternal and infant survival, reduced health disparities, and reduced spread of health hazards across national boundaries. First, in section II, we review the “grand challenges” for global health that need to be addressed by GHG. The issues highlighted are not meant to be an exhaustive list of today’s global health challenges, but rather to assist in understanding why global health has not progressed further and determining what needs to be done.

In Section III, we survey the range of key global health actors and the decentralized environment within which they operate, and investigate the reasons behind their inability to meet contemporary global health challenges. The growing overlap between institutional mandates, sectors, and laws has transformed global health into a disorganized world of territorial actors, uneven partnerships, and tenuously balanced multisectoral approaches. This section highlights the need for a more coherent approach to address the broad governance challenges of global health as a whole.

Finally, in Section IV, we explore innovative approaches to global health governance. As the problems of global health governance continue to grow, several prominent scholars have devised creative solutions that may help to transform today’s global health situation. We briefly review their ideas and consider how they might function in practice. These proposals represent only a start to what clearly has to be a broadly conceived, imaginative approach to global health governance, where innovation is urgently needed.

II. Grand Challenges in Global Health Today

Globalization has dramatically transformed how the international community must respond to modern health hazards. As the forces of globalization (such as mass travel, trade, industrialization, and communication) bring states closer together, there is a newfound sense of urgency regarding the spread of disease due to the potential for widespread and rapid dispersion. A sudden rush to address

this issue in terms of national security has resulted in a greater focus on particular health issues, such as HIV/AIDS and biosecurity, and resulted in an influx of narrowly focused, overlapping initiatives without a coherent sense of the big picture of global health.

Today, many are wondering why health targets are not being reached and what has become of the investments made. Meanwhile, a number of other critical health issues such as chronic conditions (Daar et al. 2007) and less popular diseases of poverty (i.e., the so-called “neglected diseases”) continue to be left at the wayside despite their significant burden on society—especially in resource-poor countries (Gostin 2008a). Overall, there is a sense that underlying health needs are being “obscured” by current tendencies for popular health initiatives (Burris and Beletsky 2005).

The intractability of progress in global health can be attributed to a number of “grand challenges” (Gates Foundation 2003). These grand challenges are the enduring, hard-to-solve obstacles that persist in the political, legal, economic, and social contours of the current international landscape and prevent the achievement of global health with justice (Gostin and Taylor 2008). In this section, we highlight six of the key grand challenges in relation to global health governance. We offer more specificity regarding these challenges later in the paper. It is important to note that all of these challenges are interconnected and, in some instances, overlapping and a systemic approach is necessary to address these issues appropriately and adequately.

1. WHO Leadership

The first grand challenge relates to the lack of leadership that WHO has exhibited in its role as the premier agency for health. WHO, despite its unique directive to lead using an array of powerful mechanisms (e.g., treaties and regulations) and legitimacy, has shied away from providing the much needed leadership for the promotion of international health. At the same time, other IGOs have challenged WHO’s primacy in global health, such as the World Bank and WTO, using their resource-based or political powers (Gostin and Taylor 2008). Although this void in leadership is explained partly by structural and power dynamics at WHO, it has nonetheless resulted in flawed implementation of and weak compliance with WHO norms by states. Consequently, WHO needs to gain the capacity and authority to establish a clear mission, achieve objectives, and influence health-promoting activities globally.

2. Harness the Creativity, Energy, and Resources for Global Health

The second grand challenge is the need for the current international system of states and IGOs to harness the creativity, energy, and resources of other actors and stakeholders for global health. It is well understood that nonstate actors, such as civil society, foundations, and private enterprises, play an increasingly impor-

tant role in global health, but their role and obligations remain unclear. Businesses can offer great benefits for the health of the global community, for example, by innovations in pharmaceuticals, vaccines, and medical devices; producing and selling healthier foods and safer products; and creating healthier and safer places to work. Philanthropists can provide much needed resources for urgent and enduring health needs, as well as imaginative ideas for how to serve the health needs of poor people. And civil society has demonstrated the capacity for helping those within their communities and advocating for social change.

The GHG system needs to devise a means to create incentives, facilitate, coordinate, and channel the activities of these nonstate actors. It needs to enhance health-producing activities and discourage harmful ones. How, for example, can the GHG system increase the involvement of the nonhealth sectors (e.g., food, energy, and transportation) and encourage them to think in health-conscious ways? It has even been suggested that WHO, or another international entity, could “monitor, evaluate, and rank corporations on their degree of ‘health responsibility,’ much the way that companies are ranked on their ‘greenness’” (Bloom 2007).

Public-private partnerships (PPPs) have served as a primary means for engaging private industry in health initiatives in order to leverage industry strengths in research and development, product manufacturing, and product distribution. At the same time, private industry can benefit from the opportunities offered by engaging in such work. For example, PPPs offer pharmaceuticals the ability to obtain subsidies for research and assistance in clinical trials, as well as good PR for entry into drug markets (Buse and Walt 2002). This arrangement, however, could result in conflicts of interest between the pharmaceutical’s corporate strategy and PPP objectives. Overall, the GHG system needs to find a way to create and align the incentives for private/public actors and stakeholders to promote imaginative, well-funded solutions for global health improvement (Buse and Harmer 2007).

3. Collaboration and Coordination of Multiple Players

The third grand challenge is the need for collaboration and coordination among the multiple players in global health. A number of actors, beyond the traditional state-centric governance system, now occupy the field of global health. This has resulted in rampant problems of fragmentation and duplication in the sea of funding, programs, and activities that span the global health domain. Such problems have crippling effects at the national level where “[developing country] governments looking to tackle health problems . . . face a bewildering array of global agencies from which to elicit support” and, in consequence, typically results in overburdening the health ministries with “writing proposals and reports for donors whose interests, activities, and processes sometimes overlap, but often differ” (Bloom 2007, IDC 2008).

Related to fragmentation among the current proliferation of actors is the growing competition between international NGOs and local service providers

(e.g., governments, business and community based organizations) for funding and human resources (Garrett 2007a). It is feared that this encroachment of international actors upon capable actors at the local level will hinder efforts at greater country ownership¹ and control. When well-funded NGOs create AIDS clinics or other services on the ground, they are often able to offer more lucrative salaries and far better working conditions than local providers. This can drain public or private initiatives in the host country, making it even more difficult to provide sustainable services.

Rather what is needed is a system of governance that fosters effective partnerships and coordinates initiatives to create synergies and avoids destructive competition at all levels—international, national, and local (Rosenberg et al. forthcoming). Several recent efforts at coordination and harmonization among actors have been launched, such as the “Health 8” and the International Health Partnership,² but it remains to be seen whether these initiatives will achieve their goals (International Health Partnership 2007, NORAD 2007, IOC 2008).

4. *Basic Survival Needs*

The fourth grand challenge pertains to meeting fundamental human needs through the development of scalable and sustainable health systems and infrastructures. Meeting fundamental human needs lack the glamour of high-technology medicine or rescue, but their value is the significant potential for impact on health because they deal with the major causes of common disease and disabilities across the globe. These needs are essential to restoring human capability and functioning, which one of us has termed “basic survival needs” (Gostin 2008a). Basic survival needs include sanitation and sewage, pest control, clean air and water, tobacco reduction, diet and nutrition, essential medicines and vaccines, and functioning health systems for the prevention, detection, and mitigation of disease and premature death. By focusing on these needs, the international community could dramatically improve prospects for the world’s population. A number of the needs are laid out in international agreements. Three of the eight MDGs, for

¹ According to a recent U.K. International Development Committee report, developing countries’ “ownership” of their own development effort is a key aspect of aid effectiveness (IDC 2008).

² The “Health 8” refers to the group of eight major international health-related agencies (i.e., WHO, World Bank, GAVI, UNICEF, UNFPA, UNAIDS, the Global Fund to fight AIDS, Tuberculosis and Malaria, and the Bill and Melinda Gates Foundation), which meet informally to discuss ways to scale up services and improve health-related MDG outcomes (International Health Partnership 2007, NORAD 2007). The International Health Partnership (IHP) is an effort that was launched in 2007 by some donor countries “to improve the coverage and use of health services—whether through public or private channels, or through non-governmental organisations—in order to deliver improved outcomes” related to the health-related MDGs and universal access commitments (*Lancet* 2007, Ooms et al. 2008, International Health Partnership 2007). The International Health Partnership has also been a topic of discussion by the H8 and led to an interagency coordination process and common workplan known as IHP+ (for IHP and related initiatives).

example, are health-related: child mortality, maternal health, and reducing the burden of infectious diseases (UN Dep't of Int'l Econ. & Soc. Aff. 2006). The UN Economic & Social Council finds that basic survival needs are a core commitment of the right to health, including immunization, essential medicines, food, potable water, sanitation, disease prevention and treatment, primary health care, and health education (UN Comm. on Econ., Soc. & Cultural Rights, *General Comment 14* 2000).

Building enduring health systems is critical to population health. Such health systems require sound infrastructures and human resources, which would give countries the tools to safeguard their own populations. Poor countries need to gain the capacity to provide basic health services themselves. Health system capacity has the added benefit of improving world health by significantly reducing the potential for disease migration to other countries and regions. Local capacities empower health professionals to prevent, rapidly detect, treat, and contain health hazards before they spread out of control (WHO 2000). Unfortunately, as discussed in the next grand challenge, the priority placed on addressing basic survival needs and building health systems by international assistance tends to be low. The GHG system must find a way to redress this critical problem.

5. Funding and Priorities

The fifth grand challenge relates to the skewed priorities in international funding. Currently, a significant amount of funding is directed towards “specific diseases or narrowly perceived national security interests” that have been placed high on the global health agenda by a small number of wealthy donors (such as OECD countries, the Gates Foundation and the Global Fund) (Garrett 2007b, Gostin and Taylor 2008). As a result, funding tends to be diverted from the larger, systemic approaches, such as building stable local systems to meet basic survival needs (Prakongsai et al. 2008, Waddington 2004).

In priority setting, a stronger cooperative approach needs to be taken between donors and recipient countries in defining and advancing developing country health agendas (Bloom 2007). Proper resource allocation based upon attainment of basic survival needs, support for basic infrastructure and capacity building, and cost-effective interventions have the potential to make donor funding go further. And, it is important to prioritize funding in light of its potential for health impact over a substantial period of time—e.g., 10 to 15 years (Levine 2008). The Disease Control Priorities Project (DCPP) is an illustration of a current effort to assist developing countries with the improvement of their health systems. The DCPP provides technical resources to inform policy making on topics such as the cost-effectiveness of different health-improving interventions and cross-cutting issues crucial to the delivery of quality health services (Laxminarayan et al. 2006).

Funding needs to be provided at adequate and predictable levels that are scalable to needs. Such needs exist at both the international and national level, as

WHO is highly dependent on Member States for financial resources to carry out its functions and developing countries need funding to build capacity. A problem with current funding approaches is that there is no method of holding rich states accountable to provide sufficient and stable international health assistance to states that lack the capacity. For example, developed countries have not even fulfilled their pledges made in 1975 of giving 0.7 percent of gross national income (GNI) per annum on overseas development assistance (ODA). More than 30 years later, their real contribution has only recently risen to reach a high of 0.33 percent. In general, the GHG system must gain agreement on funding levels needed to achieve key priorities, the responsibility of rich states to devote adequate funding for international health assistance, and ensure adequate health system capacities in poor states. Figuring out innovative ways to ensure adequate and enduring levels of funding, and agreed-upon priorities, will be vital in ensuring that poor countries gain the capacity to deal with everyday health threats, as well as public health emergencies.

6. Accountability, Transparency, Monitoring, and Enforcement

Finally, the sixth grand challenge pertains to the need for greater transparency, accountability, monitoring, and enforcement in meeting global health goals. Accountability in global health has been problematic. WHO and other IGOs are officially accountable to their Member States, but “they often lack detailed and realistic targets for health outcomes or for the intermediate actions they take to promote health” (Bloom 2007). States themselves tend to enter into voluntary, rather than binding, commitments towards health and it is difficult to hold them accountable under such weak mechanisms. Other actors, such as civil society, foundations, and corporations, report to an array of different interest groups and cannot be held accountable for their failures or shortcomings.

At the same time, there is insufficient transparency both with respect to IGO and state decision making. Transparency, literally truthfulness and openness to view, has no fixed meaning, but most definitions include the following overlapping features: open governance, free flows of information, and civic participation. These are values that support accountability and are widely believed to be hallmarks of good governance.

Monitoring and enforcement in global health are similarly problematic. While there have been increased efforts to build “monitoring and evaluation” systems to track the progress of various health initiatives, the lack of an enforcement mechanism generally leaves things at a voluntary level for the actors involved. Reliance on voluntary practice can be unreliable and unstable unless there are adequate incentives to drive performance. All in all, the GHG system needs to adapt by creating rules for accountability, transparency, monitoring progress, and norm enforcement for the fulfillment of commitments and achievement of goals.

To conclude, these six “grand challenges” represent some of the critical features needed in a coherent system of global health governance. To ensure effective and well-functioning health systems in poor countries, and to meet basic survival needs, the international community, in partnership with host countries, must invest in health system infrastructure. It is not simply the amount of money spent that is important, but how those resources are invested and used. This requires a structured approach that sets priorities, ensures coordination, and monitors and enforces results. Accomplishing a system of coordinated and effective international aid will require political will and a system that unifies the myriad efforts of states, IGOs, NGOs, businesses, and private foundations. On top of all of this is a need for clear and strategic leadership. As the next section indicates, current global health governance efforts have not been able to accomplish these goals, and a fresh approach is badly needed.

III. The Inadequacy of the Current Approach to Global Health Governance

As highlighted by the six grand challenges, the advancement of global health requires leadership, coordinated global health actors, priorities, basic survival needs, and accountability, transparency, monitoring, and enforcement. Unfortunately, as this section will illustrate, the current approach to global health governance has not been able to meet these needs. A central, and actually inherent, problem to the current approach is the lack of leadership in global health. Leadership unifies actors. It also sets the direction for priorities and has the potential to drive basic survival needs to the fore. At the same time, it can help align incentives and engage in monitoring and enforcement.

Without clear leadership, current priorities have been skewed towards popular, disease-focused initiatives and away from basic survival needs. A proliferation of actors with “little or no formal mandate in health” has entered the global health domain and, in general, they have not worked well together. Despite the creation of novel financing mechanisms, such as the Global Fund, funding levels continue to be missed as separate mechanisms are adopted (e.g., PEPFAR). Overall, accountability is questionable and enforcement has been nonexistent.

This section points out the inadequacies in the current approach to governance. First, it identifies the reasons behind the lack of global health leadership by the World Health Organization. It goes on to consider the proliferation of players in global health, through a look at several prominent actors (i.e., the World Bank, PEPFAR, the Gates Foundation, and the Global Fund), and presents some of the key criticisms regarding each of their approaches. Finally, the section concludes with a look at four emerging areas of overlap with the health sector and what the overlap means for GHG in terms of synergies and tensions.

A. The Lack of Leadership by the World Health Organization

Leadership is vitally important to achieve vital objectives in global health. Individuals and organizations that take leadership can effectively influence the activities of multiple actors to establish a clear mission and achieve objectives. In the global health field, the United Nations established the World Health Organization (WHO) to exercise leadership. The WHO has in many ways been an admirable organization advancing world health, but it has failed to live up to expectations in its leadership role. The fault is not entirely its own, but the vacuum in leadership over the years has significantly impeded progress on the key parameters of global health.

The WHO, the UN specialized agency for health, was established in 1948 and includes 193 member states. The WHO Constitution envisioned an agency that would act as the “directing and coordinating authority on public health” (Art. 2) and endowed it with extensive normative powers to proactively promote the attainment of “the highest possible level of health.” These powers include the adoption of conventions (Art. 19), the promulgation of binding regulations (Art. 21), and the recommendations (Art. 23), and monitor national health legislation (Art. 63).

The WHO’s treaty-making powers are noteworthy. The agency can adopt binding conventions or agreements which, unlike normal treaties, affirmatively require States to “take action”—submitting the convention for ratification and notifying the Director General of the action taken and State’s reasons within 18 months (WHO Constitution, Art. 19 and 20). The WHO also possesses quasi-legislative powers to adopt regulations on a broad range of health topics—e.g., international epidemics; the safety, potency, and advertising of biologicals and pharmaceuticals; and a nomenclature for diseases, causes of death, and public health practices (WHO Constitution, Art. 21). WHO regulations, unlike most international law, are binding on Member States unless they proactively “opt out.” Once adopted by the World Health Assembly (WHA), the regulations apply to all WHO member countries, even those that voted against it, unless the government specifically notifies WHO that it rejects the regulation or accepts it with reservations.

WHO’s binding normative powers, therefore, are extraordinary. It possesses the authority to oblige States to take health treaties seriously by submitting them to a national political process and informing the international community of the result. Its regulatory powers are even more far-reaching, as States can be bound by health regulations without the requirement to affirmatively sign and ratify. States, moreover, have ongoing duties to make annual reports to the agency of actions taken on recommendations, conventions, and regulations (WHO Constitution, Art. 62).

Despite these impressive powers, modern international health law is remarkably thin—two of the three existing international health instruments predate the

agency. The WHA, at its first session in 1948, adopted World Health Regulation No. 1, Nomenclature with Respect to Diseases and Causes of Death, which formalized a long standing international process on the classification of disease (WHO 1990). By providing standardized nomenclature, the regulation facilitates the international comparison of morbidity and mortality data. The Nomenclature Rule was modest at onset, but it subsequently became merely advisory, now known as the International Classification of Diseases. The Rule is, therefore, technical, rather than normative, and recommended rather than obligatory.

World Health Regulation No. 2, the International Health Regulations (IHR), dates back to a series of international sanitary conferences held in Europe during the second half of the nineteenth century to address the transboundary effects of infectious diseases. The sanitary conferences had little to do with improving health in developing countries. Rather, they reflected the national interests of European powers to prevent the importation of devastating tropical diseases (Howard-Jones 1975). The legal and diplomatic work begun by the international sanitary conferences eventually produced the International Sanitary Regulations (ISR), which the WHA adopted in 1951 and which were renamed the IHR in 1969 (Fidler 2005). Before the IHR was fundamentally revised in 2005, they applied only to cholera, plague, and yellow fever—the same diseases originally discussed at the first International Sanitary Conference in Paris (1851) (WHO 2005).

Not unlike the original ISR, the revised IHR was motivated by the potentially drastic economic and security consequences of fast moving infectious diseases, in this case hemorrhagic fevers, SARS, avian influenza, and bioterrorism. The IHR's primary focus is on "public health emergencies of international concern," defined as "a public health risk to other States through the international spread of disease" (WHO 2005, IHR Art. 1). The IHR, therefore, historically and politically, was intended to prevent transmigration of disease, rather than to improve health in poor countries. To be sure, the revised IHR is far more expansive and bold than its predecessors, but it is unlikely to do the work that is needed in global health—namely, to dramatically improve the plight of the world's least healthy people (Fidler and Gostin 2006).

The WHO did not create a health convention until 2003, when the WHA adopted the Framework Convention on Tobacco Control (FCTC) (WHO 2003). The FCTC declares the bold objective of protecting present and future generations from "the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke" (Art. 3). It adopts multidimensional strategies, including demand reduction, supply reduction, and tort litigation (Taylor and Lariviere 2005, Taylor and Bettcher 2000). Although a laudable achievement, the FCTC is almost *sui generis* because it regulates the only lawful product that is uniformly harmful. The FCTC was politically feasible because the industry was vilified for denying scientific realities, engineering tobacco to create dependence, engaging in deceptive advertising, and targeting youth, women, and minorities (Brandt 2007, Mehl et al. 2005).

The adoption of normative mechanisms under the WHO has been highly skewed towards recommendations over treaties and regulations. Consequently, the agency has strongly favored technical advice over creating norms and gaining conformance of the international community. Recommendations can take various forms, but two primary types include resolutions and codes of conduct. Resolutions are recommendations of the WHA that help “draw international attention to important issues faster than multilateral treaty approaches” and allow Member States great flexibility with its implementation. Codes of conduct are recommendations that often “call upon governments to pass national legislation and urge industry to adhere voluntarily to [its] provisions.” Both approaches are considered to be “persuasive with no binding legal power” or, in other words, soft law (Lakin 1997).

A problem with these approaches, however, is the difficulty of influencing Member States to act in ways that promote national and global health and holding them accountable. The explanations for this inability to lead are economic, legal, and political. The agency does not have the economic power to effectively create incentives and achieve tasks. Its funding is usually inadequate to fulfill its broad mission. This is true in absolute terms, as it is reliant on external funding from States, foundations, or other donors such as the GAVI alliance. Additionally, the funding it does receive is often specifically targeted. As a result, the WHO often must follow the priorities of funders rather than exercising its own judgment about needs and priorities.

The WHO also does not have the legal power due to its inadequate monitoring and enforcement of reporting and other state requirements. According to Article 62 of WHO’s constitution, “[e]ach Member shall report annually on the action taken with respect to recommendations made to it by the Organization and with respect to conventions, agreements and regulations.” The constitution also states, under Article 63, that countries should report “important laws, regulations, official reports and statistics pertaining to health which have been published in the State concerned.” Taylor (1992), for example, observes that the WHO reporting procedure has not been “strictly applied.” As a result, Member States either “routinely [fail] to report required information to WHO” or present “self-serving” information (Fidler 1998, Taylor 1992).

The politics of WHO are also formidable. Not only do Member States and external funders direct funding, but also the agency feels the need to gain broad agreement of Member States to support its mission, priorities, and goals. This may take the form of formal approval of the WHA. Or, it may be that particularly powerful states can influence, or even block, activities that the agency would otherwise wish to pursue.³

³There has not always been consensus between member states and the WHO Secretariat on the normative mechanisms selected at the WHO. The International Code of Marketing of Breast-milk substitutes (Burci and Vignes 2004, Resolution WHA 34.22 (1981)) was one such case. This code

Finally, the economic, legal, and political realities of WHO make it hard to function in the modern environment. It is clear that states play only a limited role in harming, or helping, global health efforts. In the modern environment, WHO needs to lead not only with respect to what states may, or may not, do, but also a wide variety of stakeholders. The WHO must harness the creativity, energy, and resources of multiple actors, such as foundations, NGOs, businesses, public-private partnerships, and civil society more broadly. The WHO Constitution never envisaged this kind of all-embracing role, but effectively leadership requires the organization to effectively engage, influence, and coordinate the activities of a wide range of important actors in global health.

Much criticism has been directed at WHO for its reluctance to apply stronger international health governance mechanisms, despite the bold mission and sweeping powers granted in its Constitution (Fidler 1998, Taylor 1992, 2004, Lakin 1997). Scholars observe that the organization “appears to envision its legislative role as neither active nor even reactive, but merely observational” (Taylor 1992). This has resulted in beliefs that WHO’s weak policy controls are “slavishly in thrall to its Member States,” whereby “appropriate respect for national sovereignty” has been “overtaken by [WHO’s] blind obeisance to narrow national wishes” (Fidler 1998). These critics argue that the meaning of “sovereign state” has changed in the context of today’s global health environment, and WHO must “reorient its attitude towards Member State[s]” (Fidler 1998). Such an effort would require WHO to revamp its current reputation for observational data collection and technical medical standardization to one of “dynamic” international governance, as originally intended by its Constitution (Lakin 1997, Taylor 1992, Burci and Vignes 2004).

While scholars have attributed WHO’s reluctance to apply its legal powers to the organization’s “traditional conservatism,” WHO’s organizational behavior has actually been changing since the term of Director-General Gro Brundtland (which ran between 1998-2003) (Taylor 2004). Examples, such as the WHO’s changing attitude towards its engagement with other institutions (e.g., WTO), approach to health issues (e.g., human rights), and use of legal powers (e.g., the 2005 IHR revision), indicate a significant move from being a strictly technical organization. Yet, given the frequent turnover in WHO leadership that has occurred since 2003 (with the sudden death of Lee Jong-wook, the interim direction by Anders

arose from concerns over the processed food industry’s controversial marketing practices for breast-milk substitutes. These concerns led to a 1979 joint meeting on infant and young child feeding by WHO and UNICEF, and the subsequent draft code that was submitted to the WHO Executive Board for consideration in 1981. A key topic of discussion at this meeting was whether to adopt the code as a regulation or a recommendation. Interestingly, the WHO Legal Counsel at the time argued that breast-milk substitutions should be considered “nutritional medicine” which meant that this topic could be regulated under Article 21. The Executive Board, however, ultimately decided upon the application of a recommendation in order to “avoid rejection of a binding code by a number of developed countries trying to safeguard their commercial interests” (Burci and Vignes 2004).

Nordstrom, and the relatively recent installment of Margaret Chan), it remains unclear whether Brundtland's legacy of organizational change will be carried on to achieve a "genuine adaptation or evolution of WHO's conservative culture" (Taylor 2004).

Furthermore, WHO's ability to change is constricted by its limited budgetary resources and a growing need to compete with other international agencies for the financial support of Member States and the private sector. The ongoing practice by Member States of primarily funding outside the WHO General Budget, which receives only 28 percent of non-earmarked funds while 72 percent goes into specified programs,⁴ has transformed WHO into a very "donor-driven" organization and restricted its ability to direct and coordinate the agenda (WHO 2007c, Burci and Vignes 2004). (For further details on the WHO budget, please refer to the Appendix at the end of this paper.) A consequence is that WHO's operations have become increasingly fragmented, compartmentalized programs so that donors can claim credit and assert control. It is believed that this has also led to the associated problem of "unhealthy competition among departments within the WHO" (People's Health Movement et al. 2008). In the end, WHO's financial struggle significantly hinders its ability to promote institutional leadership against the pressures of state sovereignty and to advance the application of its legal powers (Taylor 2004).

In summary, global health is such a complex and important goal that it demands effectively leadership. A good leader has the tools, and political will, to establish, in collaboration with others, a clear mission and priorities, govern diverse activities, monitor progress, and ensure the achievement of major goals. Due to a variety of economic, legal, political, and functional reasons, the WHO has not been able to exercise the leadership needed in the modern global health context.

B. The Proliferation of Actors in Global Health

Without effective global health leadership, the response to vital challenges has been ad hoc and highly fragmented. A proliferation of actors has appeared on the global health scene armed with differing agendas and a selective set of initiatives. In the response to HIV/AIDS and other high profile health crises, an upsurge in actors, funds and initiatives has occurred, but with little coordination.

The proliferation of actors, of course, can be beneficial, as it brings potentially great wealth and creativity into the global health arena. Global health, like global climate change, used to attract little attention from states, foundations,

⁴ A recent study by Stuckler et al. revealed that WHO's general budget "was much more closely aligned with the actual global burden of disease than were the extra-budgetary funds." WHO's general budget (2006-2007) allocates 61 percent to infectious diseases, 38 percent to noncommunicable diseases and about 1 percent to injuries. On the other hand, WHO's extra-budgetary funds (for 2006-2007) allocate 91 percent to infectious diseases, 8 percent to noncommunicable diseases, and about 1 percent to injuries (Stuckler et al. 2008).

NGOs, and businesses, but that is changing rapidly. The goal, of course, is not to have these actors disengage, but rather to fully engage them in ways that are well coordinated and highly effective. It is an enormous missed opportunity when all of these stakeholders enter the global health arena in scattered, sometimes conflicting, ways. What is most important is to harness the energy, resources, and creativity of all these actors to work together to significantly improve global health.

To examine the challenges that the growth in actors presents for governance, this section considers the involvement of the four most powerful players in global health today. They are the World Bank, PEPFAR, the Global Fund, and the Gates Foundation. These organizations also represent the different categories of actors (i.e., IGOs, bilaterals, nonstate actors, and PPPs) that have come to dominate the global health field. Through their resource-based power, these actors have been able to exercise considerable influence on the direction of global health policy. However, because these institutions all answer to different stakeholders, the approach taken by each has not been consistent and is tied to institutional survival instincts. This raises serious concerns about the accountability and appropriateness of these actors in global health, and how the GHG system must deal with the issue.

Intergovernmental Organizations Influencing Health: The World Bank

Many non-health-focused IGOs, such as UNICEF and UNDP, have crossed into the realm of global health (Dodgson et al. 2002). Yet, none have traversed the global health boundary quite as far as the World Bank. Since the 1990s, the World Bank has become known for its large financial investments in health initiatives in developing countries. Upon recognizing the connection between public health and its mission of “reducing poverty and improving living standards” in developing countries (Abbasi 1999), the World Bank moved beyond its core financier operations and launched the implementation of “a whole array of health initiatives . . . bringing new money and fresh ideas to tackle disease” (Yamey 2002).

The combination of the World Bank’s financial power and aggressive health initiatives led many observers to believe that the World Bank would displace the WHO as the “premier global health agency” (Yamey 2002). During the 1990s, such prospects were possible for the World Bank because WHO had become stagnant in its international role. Reports of “cronyism, a lack of direction and cohesion, a reluctance to shift its focus away from prevention of infectious diseases, and a reluctance to tarnish its image with governments” were crippling problems that plagued WHO under the leadership of then Director-General Hiroshi Nakajima (Abbasi 1999). As a result, WHO was sidelined to the supporting role of providing “medical expertise and technical support” while the World Bank worked on health initiatives with the ministries of health, finance, and planning in developing countries (Abassi 1999).

In spite of the World Bank's efforts to spearhead more responsive health initiatives in developing countries over the past two decades, its institutional competence was challenged when it failed to reach promised goals and was accused of reporting false outcomes (Attaran et al. 2006). One major criticism of the World Bank has been its lack of technical expertise necessary to implement health programs (Abassi 1999). Critics have argued that the World Bank holds "no compelling advantage" in working with the health ministries and urged the institution to "revert strictly to its core competence as a financier—a bank—and deposit the pledged commitments . . . into a dedicated fund for the exclusive use of other, more technically competent and transparent agencies" (Attaran et al. 2006).

In recent years, the World Bank has been "trying to find its footing on shifting ground in global health" (Levine and Buse 2006). The increase in global actors providing health assistance focusing on specific diseases (i.e., HIV/AIDS, malaria and tuberculosis), along with the criticism it received, prompted the World Bank to reevaluate its health sector strategy with an updated approach in 2007 (World Bank 2007b). With a steady decline in commitments to health sector operations between 2001-2006 from U.S. \$10B to U.S. \$7B, the World Bank has been working to focus and enhance its capacity towards its comparative advantages and the less popular global health issues such as health system strengthening at the country level (Levine and Buse 2006, World Bank 2007b). Furthermore, its 2007 health sector strategy reinforces the recent attempts by UN agencies at a collaborative division of labor with global partners. The strategy calls upon the World Bank to leave functions such as the technical aspects of disease control (e.g., the determination of treatment options for diseases), human resource training in health, and internal organization of service providers (e.g., the operation of medical services) to other organizations—such as WHO, UNICEF, and UNFPA (World Bank 2007b, Ruger 2007).

The World Bank has also become increasingly engaged in collaborative efforts with other global health actors. Earlier this year, at the XVIIth International Conference on AIDS in Mexico City, a new collaboration between the World Bank and WHO to provide technical guidance for better global health investments was announced. The collaboration was instigated in response to the ongoing debate over disease-specific initiatives versus health systems approaches and will "examine and combine the strengths of different approaches around the world in order to get better results from investments and improve health outcomes for all" (World Bank 2008).

Bilateral Programs: The President's Emergency Plan for AIDS Relief (PEPFAR)

Bilateral programs serve as a means through which donors can exercise direct control over how its funds are allocated and applied. PEPFAR, the single

largest funder of HIV/AIDS programs in the world, is a prime example of the bilateral phenomenon (Gostin 2008c, Oomman et al. 2008). Launched in 2003 under President Bush, PEPFAR began as a \$15 billion commitment over five years towards HIV/AIDS prevention and treatment assistance in 120 countries as well as the funding of HIV/AIDS research and the Global Fund. Most of PEPFAR's funds, however, are geared towards 15 focus countries which are predominantly located in Africa. PEPFAR's five-year goals, also known as the "2-7-10 goals," entail the treatment of 2 million people, the prevention of 7 million new infections, and the care of 10 million people (including orphans and vulnerable children). According to the U.S. government, PEPFAR is on track to meet these goals this year (United States President's Emergency Plan for AIDS Relief 2008). As PEPFAR nears the end of its five-year term, total spending is expected to exceed its original commitment by \$3.8 billion (for a grand total of \$18.8 billion). President Bush has also recently signed into law a reauthorization of PEPFAR for up to \$48 billion over the next five years.

Despite PEPFAR's progress, significant criticism has been directed at its approach to funding HIV/AIDS programs that are indicative of clashes between the U.S. agenda and recipient country priorities. One criticism was directed at PEPFAR's initial refusal to purchase generic versions of HIV treatments, despite WHO prequalification of those medicines (Nelson 2004). It was suspected that PEPFAR rejected the option of purchasing generics due to domestic pharmaceutical interests (McNeil 2007).

Another criticism of PEPFAR targeted its restrictive program requirements and funding preferences. Restrictive directives for the PEPFAR program include the requirement of spending a third of its prevention and education funds on abstinence-promotion, the prohibition of funding for syringes or needles for intravenous drug users, and the requirement of recipient countries to denounce prostitution (Garrett 2005, McNeil 2007). These limiting factors have prompted calls for a move away from "ideologically driven policies" towards areas of proven medical success (McNeil 2007). Also, some individuals in developing countries feel that money should be put under greater local control rather than being channeled through U.S. faith-based NGOs in order to cut costs (Stolberg 2008). PEPFAR appears to be taking steps towards addressing this concern under its reauthorization plan through the adoption of a "partnership compact" model. According to PEPFAR, this approach would increase partnerships with countries by building up country resources for HIV/AIDS and health systems among other activities (U.S. Office of the Press Secretary 2007).

Finally, PEPFAR has been criticized for not making greater contributions to the Global Fund. Instead, PEPFAR has chosen to limit its contributions to numbers that fall under its designated amount of 33 percent and direct more towards bilateral efforts. The Global Fund, as described later, has been struggling with a lack of adequate funds in recent years and many have argued that the United States should at least meet its designated contribution level. The U.S. government

has responded that the 33 percent is “a maximum limit, not an annual obligation” (United States President’s Emergency Plan for AIDS Relief 2006).

Nonstate/Private Actors: Bill and Melinda Gates Foundation

Nonstate actors, such as corporations, foundations, and civil society, play an increasingly important role in global health. Through the use of different forms of influence and power, nonstate actors can affect the direction of global health. The Gates Foundation, which has been labeled the “new ‘800 pound gorilla’ in global health,” is a key nonstate actor with significant influence on global health (Yamey 2002). With approximately \$8 billion spent towards global health projects since 2000, and an even larger amount expected with the commitment from Warren Buffett, the Gates Foundation has firmly placed itself on the global health governance map by mobilizing resources for innovative financing mechanisms and product development (Side effects of doing good 2008). The Gates apparently avoided putting money into the UN system, preferring to channel their funds “into smaller, independently governed initiatives that focus on ‘quick fix,’ high profile health problems” (Yamey 2002). This is illustrated by the Foundation’s heavy investment in the development of vaccines as well as drugs and diagnostic tests (Okie 2006). The foundation is also a major supporter of GAVI and the Global Fund.

Some are concerned by the Gates Foundation’s narrow focus on technical interventions and high-profile research rather than the broader context of public health systems (Birn 2006, Piller and Smith 2007). Critics claim that “the foundation’s grant making may not always reflect the priorities of recipients in developing countries, and its choices may influence the decisions of other agencies” (Okie 2006). It has also been reported that its initiatives are pulling away resources from basic care at the local levels (Piller and Smith 2007). The foundation has made attempts at broadening its focus through initiatives related to clean water and sanitation as well as some health system-related issues (Okie 2006), but more needs to be done. Finally, if major philanthropies are going to be part of the GHG system, it will be important to find ways to influence their activities and hold them accountable. At present, there are very few mechanisms for holding large foundations accountable to any international standard, and there are no universal rules for transparency in decision making.

Global Public-Private Partnerships: The Global Fund to Fight AIDS, TB, and Malaria

A number of global public-private partnerships (GPPPs) have appeared in the past decade, and it is estimated that about 75 to 100 GPPPs exist (WHO 2007b). While the current GPPPs cover a range of health issues, most are focused on communicable diseases—whereby about 60 percent of GPPPs target HIV/AIDS,

TB, and malaria (Caines 2005). The most prominent GPPP that exists today is the Global Fund, which was established in 2002 as a new type of financing mechanism for the prevention and treatment of HIV/AIDS, TB, and malaria. As the leading funder of malaria and TB programs and the second largest funder of HIV/AIDS programs, the Global Fund is a unique joint endeavor between governments, civil society, and the private sector that has established itself as one of the most prominent GPPPs today (Bartsch 2007, Bernstein and Sessions 2008). The model of the Global Fund is also unique in the sense that it possesses no in-country or technical assistance expertise because it strictly operates as a financing mechanism without involvement in implementation activities (Bernstein and Sessions 2008). This creates an interesting dynamic between the Global Fund and the broader network of other global health actors that provide technical assistance to developing countries, as discussed later.

The Global Fund's new prominent role has created several tensions for the governance of global health. Firstly, as a GPPP, the Global Fund is expected to engage all of its partners. Yet, there have been concerns over the lack of engagement of CSOs and private industry in the Global Fund. For example, it has been noted that Southern governments have been reluctant to grant CSOs greater involvement at the global and national levels due to a fear of "losing influence and policy options" if authority is shared with CSOs (Bartsch 2007). Also, as a PPP, the Global Fund should attempt to leverage the benefits offered by its different partners—including private industry. The Global Fund's requirement of financial donations and its obstinate refusal to allow the pharmaceutical industry's proposal of gifts in kind (e.g., medicines), or other collaborative mechanisms, has been an area of debate (Bartsch 2007).

Secondly, the Global Fund's lack of harmonization with other global health initiatives has been a significant concern. The Global Fund's support of narrow vertical (i.e., disease-focused) initiatives varies from other global health efforts that support broad, horizontal (i.e., health systems) development. It is feared that the Global Fund's approach, on top of existing health initiatives, would "contribute to a further fragmentation of health policies at the national level" (Bartsch 2007). Interestingly, the Global Fund has taken note of how basic health systems factors, such as infrastructure and capacity building, are critical to the achievement of its objectives. This led to a later decision to accept proposals for "health systems strengthening," but only "where it is directly related to AIDS, tuberculosis or malaria" and not health systems strengthening more broadly (Global Fund b).

Thirdly, the Global Fund's Country Coordinating Mechanism (CCM) has introduced a number of problems at the national and global level in terms of its lack of coordination with extant systems of governance. Under Global Fund procedures, CCMs function in the capacity of developing and submitting grant proposals as well as overseeing implementation (Global Fund a). The establishment of CCMs, however, has been "in addition" to extant national coordinating

institutions (e.g., National AIDS Council and UN Theme Groups) (Bartsch 2007). This has resulted in problems of duplication and confusion for developing countries as well as greater political competition for power and influence between the different coordinating authorities (Bartsch 2007). The CCMs have also been a source of conflict at the global level between the Global Fund and other actors. Because the Global Fund endorses a “bottom-up” approach to health initiatives, it does not have an in-country presence nor does it house technical expertise to assist CCMs with their proposals. CCMs, as a result, rely on technical assistance from bilateral and multilateral organizations. This dependency adds to the workload of other organizations, such as WHO and UNAIDS, which support the CCMs without compensation. This issue was later resolved through a revision in grant proposals to allow for technical assistance compensation.

Finally, the sustainability of the Global Fund approach has been an issue of contention. The Global Fund faces an increasing shortage of funds due to the challenges of donor fatigue, difficult economic times, and competition with other organizations for funding (Bartsch 2007). For example, the Global Fund has been “side-stepped” by the United States (a key donor of the Global Fund) through the creation of PEPFAR. With the increasing shortage of funds from donors, some wonder whether the Global Fund’s approach to supporting disease programs can continue as it would have to “mobilize enough resources to run treatment programs [for] as long as they are needed” (Bartsch 2007).

As illustrated by this set of key organizations, the current proliferation of actors in the global health domain highlights a number of problems with the current approach to governance. First, all of these actors are encroaching upon the authority of WHO. This highlights concerns about the accountability of these actors, as they all report to different stakeholders and do not necessarily hold representative “health” interests. Second, there is misalignment between country priorities and actor agendas. Most of these actors take a disease-focused approach, rather than allocating resources to the broader issues of basic survival needs and healthcare systems. Third, some of these actors are competing among each other. For example, there is tension between the PEPFAR and the Global Fund in terms of funding. There is also tension between the World Bank and the Global Fund in terms of country-level coordination. This highlights the need for greater collaboration and coordination among the various actors. Fourth, many of these actors are not harnessing the energy, creativity and resources offered by nonstate actors. The Global Fund has tried to avoid a conflict of interest by refusing name brand treatments from pharmaceuticals, but this could be a lost opportunity to harness the resources of all actors to help those in need. Also, PEPFAR’s lack of engagement with local service providers (e.g., businesses and NGOs) is a lost opportunity to foster greater country ownership. Fifth, there is no independent policing entity for these actors. While there is an emerging practice of establishing monitoring and evaluation systems for many of these actors, these actors generally participate on a voluntary basis and there is no way to enforce the achievement of goals.

C. Global Health's Overlap and Potential Tensions and Synergies with Other Sectors

The growing overlap between the health sector and other fields presents a number of tensions and synergies that need to be addressed by GHG. The tensions posed by overlapping sectors have the potential to impede global health objectives and need to be addressed by GHG appropriately. On the other hand, the potential synergies that result from overlapping sectors need to be utilized to serve the betterment of global health. In this section, we review the overlap between health and the sectors of trade, environment, and foreign policy. We consider how the sectors overlap and whether there are opportunities for governance synergy, in terms of common goals between sectors, that can be leveraged or whether there are tensions, such as conflicting sectoral objectives, that must be managed.

Health and Trade

Increased trade liberalization, one of the driving forces behind globalization, brings a number of new opportunities and challenges to the health sector. Trade liberalization may well improve economic prosperity generally and therefore improve health outcomes. Increased trade in health-related goods, services, and people (i.e., patients and professionals) offer numerous opportunities to economies around the world (Blouin et al. 2006). For example, the trade system offers the opportunity to lower prices for health-related goods with the reduction of trade tariffs or alter health systems with the transfer of health services.

On the other hand, trade brings the challenges of spreading disease across borders with traded goods, advertising unhealthy lifestyles, and potentially limiting access to medicines under restrictive trade rules. Although free-trade advocates believe that trade liberalization will lift up the prospects of the poor as well as the rich, there is still legitimate concern and controversy that free trade benefits mostly the global rich, leaving the poor in no better, and perhaps worse, shape economically. The global rich, of course, can benefit from trade liberalization and particularly international protection of intellectual property through TRIPS (see below). However, poorer countries—which lack the scientists, entrepreneurs, and industrial capacity—may not benefit as much from the world trade system.

The health sector itself also has a significant impact on the trade sector. The economic impacts on travel, tourism, and commerce of SARS, BSE, and avian influenza illustrate the powerful effects of disease on markets (Drager and Sunderland 2007, Helble et al. forthcoming).

All in all, the interlinkages between the trade and health sectors are complex and opportunities to address these ties are possible on both sides. The two sectors also bring entirely different philosophies, institutions, and laws. The intersection of these two spheres leads to deeply important questions, such as when a tension or conflict arises which philosophy, institution, or legal system should prevail, and why?

Currently, the governance of these interlinkages depends on the existing system of international rules⁵ and institutions for trade and health. The World Trade Organization (WTO), the multilateral organization for trade, has produced a number of international trade rules that are relevant to health; these rules include: General Agreement on Tariffs and Trade (GATT), the General Agreement on Trade in Services (GATS), the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), The Agreements on Technical Barriers to Trade (TBT), and the Application of Sanitary and Phytosanitary Measures (SPS). Together, these agreements form a rule-based system within which WTO members must operate. Some agreements, such as TRIPS and GATS, provide certain rule “flexibilities” or exceptions that can be exercised in recognition of public health needs (for example, please see Art. XIV GATS and the Doha Declaration on Public Health and TRIPS). Other agreements, such as SPS, allow countries to restrict trade for the purposes of protecting public health (e.g., set food safety and animal and plant standards) while preventing “arbitrary or unjustifiable discrimination” through such practices (WTO 1998). A discussion of how each of these rules impact health is beyond the scope of this report, but a number of scholars have conducted detailed analyses on this subject (WHO/WTO 2002, Bettcher et al. 2000, Labonte and Sanger 2006a, 2006b, Bloche and Jungman 2003).

From the health side, WHO has also recently produced two international health agreements with a potential impact on trade. One such agreement, the revision to the IHR (2005), addresses the issue of unduly restrictive trade and travel measures in public health responses to international disease outbreaks by calling upon the WHO and Member States to “to avoid unnecessary interference with international traffic and trade” (Abdullah 2007). Another agreement, the Framework Convention on Tobacco Control (FCTC), states in its preamble that there is a priority to the right to protect public health and it is believed that this could mean a priority over the trade matters relating to tobacco.

At the international level, there is no formal arrangement between the WTO and WHO on matters of health and trade; however, the institutions will participate in each other’s meetings (such as WTO Ministerial meeting and World Health Assembly) in an “observer” capacity. In this capacity, the WHO and WTO are allowed to attend pertinent discussions and provide expert advice at the meetings. While there is no formal arrangement, the two organizations have increasingly engaged in an array of ad hoc collaborative projects—such as joint research, training, policy consultations, and country missions (Helble et al. forthcoming). Much of this appears to be driven by the health sector as the WHO was directed by its Member States, under a 2006 WHA resolution on International Trade and Health, to collaborate with other organizations on trade and health policy matters

⁵ While international trade agreements feature prominently in the overlap between the trade and health sectors, there is also an emerging body of regional and bilateral free trade agreements (FTAs) with critical health implications (Labonte and Sanger 2006b, Helble et al. forthcoming).

(WHO 2006). Most recently, WHO hosted a set of Intergovernmental Working Group (IGWG) meetings on Public Health, Innovation and Intellectual Property to develop a global strategy and plan of action addressing the problem of research and development and funding for diseases that disproportionately affect developing countries. The global strategy and plan of action passed as a resolution (WHA 61.21) at this year's World Health Assembly (WHO 2008a). Yet there continue to be deep concerns that the major voice belongs to WTO rather than WHO for many reasons, including the perceived economic importance of trade, the binding norms of the world trade system, and the WTO institutions that wield far greater power (and rule enforcement) than is available in the health sector. As more countries join the WTO and trade liberalization grows, the governance of the health and trade sectors will only become more critical.

Health and the Environment

There are undoubtedly fundamental synergies between the environment and health, and between global climate change and global health in particular. Climate change is a significant and emerging threat to the public's health, and especially the most vulnerable populations (Heinzerling 2008). The report of the Intergovernmental Panel on Climate Change (2007) demonstrates that climate variability and change cause death and disease through natural disasters, such as heat waves, floods and droughts, which cause deaths through catastrophic events (e.g. extreme weather events such as cyclones or tsunamis), and longer term problems of food security (malnutrition) and clean drinking water (diarrheal diseases). Climate change also exacerbates common vector-borne diseases such as malaria and dengue.

The intersection of health and the environment is well understood in public health and goes well beyond climate change (WHO 2007a). Human health is directly affected by environmental deterioration, which includes insufficient potable water, indoor smoke, road traffic, urban air pollution, unintentional poisonings, and lead exposure (Smith et al. 1999, Health and Environment Linkages Initiative a). For example, unsafe drinking water, along with poor hygiene and sanitation, is one of the foremost global health and environmental concerns resulting in 1.7 million deaths per year (Health and Environment Linkages Initiative a). Such environmental risks, as a major factor in the spread of both infectious and chronic diseases, are responsible for 25-33 percent of the global disease burden (Smith et al. 1999). Additionally, these environmental factors have a disproportionate impact on different groups, placing most of the burden on children under the age of five and those living in low- and middle-income countries (Smith et al. 1999).

Another issue that intersects the fields of environment and public health is the Millennium Development Goals (MDGs). This set of objectives addresses issues of global concern, including poverty, health, and the environment, thus

facilitating an interdisciplinary approach. MDG 7 prioritizes environmental sustainability (Health and Environment Linkages Initiative a). However, addressing the environmental aspects of this goal also work to tackle several others, including eradicating extreme poverty and hunger, reducing child mortality, promoting gender equality, empowering women, and improving maternal health (Health and Environment Linkages Initiative a). Consequently, the MDGs lend themselves to promoting environmental sustainability as a means of addressing a broad range of other global issues, especially health.

The main institutions governing the health and environmental sectors are WHO and the United Nations Environment Programme (UNEP), respectively. WHO has recognized the importance of environmental influences on human health, as it focused World Health Day 2008 on protecting public health from the detrimental effects of climate change (WHO 2008b). UNEP, the United Nations' designated entity for addressing environmental issues (United Nations Environment Programme b), was established after the 1972 UN Conference on the Human Environment. UNEP's mission is "to provide leadership and encourage partnership in caring for the environment by inspiring, informing, and enabling nations and peoples to improve their quality of life without compromising that of future generations" (United Nations Environment Programme b). To address the interlinkages of health and the environmental, these two organizations have collaborated on several joint initiatives. For example, WHO and UNEP established the Health and Environment Linkages Initiative (HELI) to promote and facilitate environmental initiatives directed at protecting human health in developing countries (Health and Environment Linkages Initiative b).

In addition to informal institutional arrangements, there are numerous overlapping international norms and treaties that govern the interaction between the environmental and health sectors. One of the most important agreements affecting international environment and health, the Vienna Convention for the Protection of the Ozone Layer, established a framework for international cooperation in reducing damage to the ozone layer and eventually resulted in the establishment of the Montreal Protocol, which has effectively mitigated ozone damage. In addition, the United Nations Framework Convention on Climate Change, which has been signed by 192 countries, promotes intergovernmental efforts to combat the effects of climate change (United Nations Environment Programme a). Furthermore, countries signing the Kyoto Protocol to the UN Framework Convention on Climate Change agreed to lower their greenhouse gas emissions, further recognizing the detrimental effects of these pollutants and their effect on climate change. The international community, moreover, is actively engaged in the process of creating an international legal regime for the future.

International governance arrangements have not been fully effective in effectuating fundamental environmental reform, but it is nonetheless clear it has had a major role. And it is equally clear that there is broad and growing consensus about the importance of a communal response among states. The same cannot be

said about global health where there is still deep suspicion in some circles about the value of international law and governance.

Health and Foreign Policy

The status of health in foreign policy has dramatically changed in recent years. In the past, health was seen to be of “little importance in the hierarchy of foreign policy objectives” (Fidler 2007a). Recent pandemics and health security threats such as HIV/AIDS, SARS, bird flu, and national security efforts geared towards bioterrorism preparedness have vastly increased the level of attention nations pay to health in their foreign policy decisions. Today, the status of health on foreign policy agendas has been dramatically elevated and the international community is prone to link health and foreign policy in relation to three key areas: (1) national security (i.e., the need to protect from external threats); (2) trade, economic prosperity, and political stability; and (3) globalization and development (Owen and Roberts 2005).

National Security: Direct National Interests

The opportunities and challenges of a foreign policy based on international health are complex and important. Certainly, international health assistance can be seen as critical to a country’s national interests, including its security. Governments have no choice but to pay close attention to health hazards beyond their borders. DNA fingerprinting has provided conclusive evidence of the migration of pathogens from less to more developed countries (McNabb et al. 2002). More than thirty infectious diseases have emerged over the last two to three decades, ranging from hemorrhagic fevers, Legionnaires disease, and Hanta virus to West Nile virus and monkeypox. Vastly increased international trade in fruits, vegetables, meats, and eggs has resulted in major outbreaks of foodborne infections. Wealthy countries, moreover, are less able to ameliorate these harms because many resurgent diseases have developed resistance to front-line medications.

Trade, Economic Prosperity, and Political Stability: Enlightened Self-Interest

Beyond narrow self-interest, there may be broader, “enlightened” interests in international health assistance (Fox and Kassalow 2001). Epidemic disease dampens tourism, trade, and commerce, as the 2003 SARS outbreaks demonstrated. Animal diseases such as foot and mouth disease, bovine spongiform encephalopathy, and avian influenza similarly had severe economic repercussions, such as mass cullings of animals and trade bans. Massive economic disruption would ensue from a pandemic of human influenza, with a projected loss of 3-6 percent in global GDP (Congressional Budget Office 2005).

Countries with extremely poor health become unreliable trading partners

without the capacity to develop and export products and natural resources, pay for essential vaccines and medicines, and repay debt. Countries with unhealthy populations require increased financial aid and humanitarian assistance. In short, a foreign policy that seeks to ameliorate health threats in poor countries can benefit the public and private sectors in developed as well as developing countries.

Extremely poor health in other parts of the world can also affect the security of the United States and its allies. Research shows a correlation between health and the effective functioning of government and civil society. In a 1998 report, the CIA noted that high infant mortality was a leading predictor of State failure, (Esty et al. 2008) and in 2000, the State Department suggested that AIDS was a national security threat (BBC News Online 2000). States with exceptionally unhealthy populations are often in crisis, fragmented, and governed poorly. In its most extreme form, poor health can contribute to political instability, civil unrest, mass migrations, and human rights abuses. In these States, there is greater opportunity to harbor terrorists or recruit disaffected people to join armed struggles. Politically unstable States require heightened diplomacy, create political entanglements, and sometimes provoke military responses.

Globalization and Development: Health Diplomacy

Many highly developed countries have begun to consider the role of international development assistance for health as part of their foreign policy. Development assistance has political significance, as the electorate believes that helping others in a crisis is an important part of a country's responsibility and leadership in the world. This can be seen in health emergencies such as the Asian tsunami, the China earthquake, or the Burma cyclone, where governments and citizens see the urgent need to help.

Beyond emergency relief, international development assistance for health can have broader strategic importance. "Global health diplomacy" is a concept under which a country uses development assistance as a way of promoting its values and image in the world and demonstrating its commitments to the common good. WHO describes it more broadly as the "multi-level and multi-actor negotiation processes that shape and manage the global policy environment for health" (Kickbusch et al. 2007, Drager and Fidler 2007). In the United States, for example, the new President should consider how "health diplomacy" could improve America's tarnished image in the world. Using America's vast resources and expertise to noticeably improve the lives of poor people around the world, could have a profound positive effect on the way that others see the United States and its use of power. On November 9, 2008, for example, the Fogarty International Center and the O'Neill Institute for National and Global Health Law jointly hosted a global meeting on "health diplomacy" in celebration of the Center's fiftieth anniversary.

Foreign Policy Also Has the Potential to Undermine Global Health

Although foreign policy imperatives have undoubtedly raised the profile of global health, they also have the potential to undermine effective strategies, particularly if narrowly conceived. One common problem is that foreign policy can skew priorities and practices. When a country views particular health issues to be of high priority, it is more likely to give unwarranted attention, resources, and technical assistance to that narrow area. In the scale of balance of the receiving country, disproportionate attention to a high-visibility health issue might skew its priorities and efforts at developing a general health system. One possible example is the priority that developed countries such as the United States have placed on HIV/AIDS, and in effect, its foreign policy priority in this regard is channeled through PEPFAR. While this initiative has clearly assisted developing countries to better cope with the disease, it has caused a drain of personnel and resources from other sectors of their health systems, which equally require immediate priority, to focus on HIV/AIDS. This situation is akin to what David Fidler calls the “tragedy of under-exploitation” whereby critical health issues (e.g., chronic diseases and women’s health) “receive insufficient attention and suffer from fragmentation of public health and health-care systems” due to the proliferation of uncoordinated initiatives (Fidler 2007a).

Another problem with foreign policy-driven assistance is the tendency to favor particular countries and actors as the recipients of health aid. For example, PEPFAR narrowly targets 15 countries (predominantly in Africa) as the main recipients of its funding but this leaves out a number of other heavily disease-burdened countries in other parts of the world. The general perception that health aid is best utilized in stable states has prevented donor countries from investing in the healthcare of fragile states, which account for one-sixth of the global population and which are most in need donor intervention to prevent and ameliorate humanitarian crises (WHO 2007b). Wanting quick and direct results for their efforts, the foreign policies of governments which impose sanctions on unpopular governments by failing to assist with development aid has a ripple effect on health and international security and affect the lives of millions who otherwise do not have say in the governance of their state.

Also, some developed countries tend to channel funds through international (and sometimes local) NGOs instead of dealing directly with the official governments of recipient countries (Garrett 2008). As a result, this practice has left a number of countries with weaker control of their health systems. International health assistance is often earmarked for specific purposes, with only about 20 percent going to support the local government’s health system (WHO 2007b, Foster 2005). Furthermore, aid tends to be targeted at a vertical intervention programs and this causes a misalignment with the health priorities identified by developing country governments. Another problem with the preference for NGO control is

that most NGOs do not possess the capacity to scale up interventions or ensure their long-term sustainability (Garrett 2008).

The Critical Overlaps Between Health and Other Sectors

This section reviewed the critical overlaps between health and other sectors, such as trade, environment, and foreign policy. As indicated, the GHG system must come to terms with important intersectoral synergies and tensions. The overlap between the trade and health sector highlighted some of the current tensions that exist between the two sectors in terms of fundamentally differing philosophies, institutions, and laws. As there are no formal arrangements at the international level between the health and trade sectors, attempts to address trade-related health issues typically occur on an ad hoc basis. WHO's recent passage of the global strategy and plan of action related to intellectual property has been viewed by some as a move by developing countries to better position WHO in governing trade-related health issues (Kohlmorgen 2007). This illustrates the potential role that GHG could play in dealing with intersectoral tensions.

In terms of the overlap between the environment and health, there are a number of opportunities for greater synergy between the two sectors. Essentially, a cleaner and safer environment is good for health. The potential GHG synergies in terms of developing similar priorities, harnessing creative solutions and incentives, and drawing together actors from both fields offer incredible opportunity to solve the global health and environment challenges collectively. And there are also lessons that global health could learn from governance initiatives on climate change, which are explored further in the following section.

The overlap between health and foreign policy is another important area that holds the potential for both tensions and synergies. Developed countries might provide assistance to developing countries for reasons of self-interest or broader "enlightened" interest, or they might see international development assistance for health as part of their humanitarian obligations. We caution, however, that a foreign policy that is too narrowly conceived can actually be detrimental to those they intended to assist. An area of potential synergy offered by the intersection of health and foreign policy is the concept of global health diplomacy which a country could strategically use to both promote itself and demonstrate global commitment.

In the end, GHG must find a way to deal with the complex array of actors, sectors, laws, and interests at play. Currently, the global environment is highly decentralized and dealing with these various forces coherently can be difficult. In the next section, we turn to a few innovative approaches that could help GHG overcome the "grand challenges" in governance and deal effectively with the emerging intersectoral forces that global health faces.

IV. Innovative Approaches to Global Health Governance

Oran Young (1997) once asked, “What is to be done to close the dramatic gap between the demand for governance and the capacity to supply governance in international society?” In the context of global health, there are three potential options: (1) accept the currently fragmented, incoherent system that some have termed anarchy, (2) reform the WHO through restructuring, and (3) establish decentralized regimes (i.e., sets of roles, rules, and relationships) focused on specific issues. Decentralized regimes have been increasingly applied in global health, with the multitude of independent health initiatives that exist (e.g., the Global Fund or the health-related Millennium Development Goals), but the results of this approach still significantly lag expectations. The new “International Health Partnership and related initiatives” (IHP+)⁶ is a commendable effort towards coordination and accountability as well as greater country ownership; however, does it go far enough? At this stage, there is not enough evidence to judge the success of IHP+ but the focused nature of its initiatives raises concerns about how it would coordinate with other non-IHP+ health initiatives (e.g., currently existing disease-specific initiatives) and nonpartner actors (e.g., United States), as well as adequately address developing world concerns. Hence, the decentralization of health actors and their initiatives will persist in global health but, perhaps, at a slightly more condensed level on certain health issues. The search for alternative, innovative approaches to global health governance, in terms of structures and mechanisms, has produced several creative proposals that are considered in this section.

The proposals outlined in this section are illustrative only, intended to show some of the more interesting current proposals for global health reform. But one thing is clear. There is an urgent need for imagination and bold ideas in global health. It is well understood in the field of climate change that the entire international community has a shared responsibility to propose and implement innovative reforms in global governance. The same could be said about global health. If the international community does not embrace bold governance reforms, it should expect little improvement in the health of the world’s poorest populations. Even with all the new money and attention devoted to global health, without coherent policy and leadership, the chances of dramatic improvement are vastly reduced.

Accept Anarchy: Reconceptualizing Global Health Governance as “Source Code”

To make better sense of the global health environment today, David Fidler (2007b) proposes an alternative approach to GHG in terms of “source code” rather than architecture. He explains that this source code contains “the norma-

⁶ See also footnote 2.

tive policy reasons for why global health is important to protect and promote.” Furthermore, the source code can be applied by the entire range of global health actors, such as states, IGOs, and nonstate entities, who can produce “software programs” for certain global health problems. Such global health software programs include laws (e.g., IHR 2005 and FCTC) and hybrid organizations/mechanisms (e.g., Global Fund).

By using the metaphor to software source code, Fidler characterizes the current governance environment as being in a state of “open-source anarchy.” This captures the fact that the political environment of global health has moved beyond the traditional conceptualization of anarchy, which is monopolized by states, to a new form of anarchy that is “open” to the engagement of nonstate actors. Fidler believes that this new conceptualization provides a useful way “to make sense of the proliferation of players, problems, and processes” in global health diplomacy because “it jars the basic functions of diplomacy out of traditional State-centric patterns” (Fidler, 2008). He acknowledges that the state of open-source anarchy with its various actors is “messy and produces some negative externalities,” but it could help move global health governance further than architecturally based attempts (such as the “Health for All” initiative). Fidler concludes that open-source anarchy “may suit global health’s quest for governance better than attempts to tame the freedom of action States and non-State actors embrace in such anarchy.”

Fidler, however, does recognize a common problem for both the “source code” and architectural approaches to global health governance. It is the lack of adequate public health infrastructures in states. In the context of open-source anarchy, Fidler calls this a “hardware problem” because governance source code cannot produce the sought benefits without the proper hardware with which it must operate. Similarly, in the context of architecture, structured governance approaches will not work without the local and national foundational capabilities to interface with the global level. The lack of necessary infrastructure remains a major unaddressed hurdle to the advance of global health, and Fidler concedes that even the approach of open-source anarchy “proves difficult as a context in which to build sustainable capacity for public health within and between sovereign states.”

WHO Reform: Proposal for a WHA Committee C and Tripartite Governance Structure

Over the years, many have decried WHO’s lack of leadership in global health and clamored for its reform (Godlee 1997, Yamey 2002, Ruger and Yach 2005). They justify this by pointing to the WHO’s constitutional mandate to act as a “directing and coordinating authority” on matters of health, as discussed earlier in the paper. WHO also holds the functions of “engaging in partnerships where

joint action is needed,” “setting norms and standards and to promote and monitor their implementation,” and “providing technical support, catalyzing change, and developing sustainable institutional capacity” (Drager and Sunderland 2007). Furthermore, as leader, WHO could “provide the basis for generating public awareness, mobilizing resources, using resources rationally through coordinated action, setting priorities, and bestowing or withdrawing legitimacy from groups and causes” (Dodgson et al. 2002). The current absence of a clear authority in global health has made these aspirations difficult, if not impossible.

Two recent proposals suggest ways that the WHO could assume a greater leadership role in global health. The first is a proposal by Gaudenz Silberschmidt, Don Matheson, and Ilona Kickbusch (2008), which calls for the addition of a committee to the World Health Assembly that would help promote coordination and increase transparency and accountability in the activities of major global health stakeholders. These stakeholders include international agencies, philanthropic organizations, multinational health initiatives, and civil society groups. The proposed WHA committee, titled “Committee C,” is envisaged to (1) debate major health initiatives by other key players in the global-health arena, (2) allow these other organizations to present their plans and achievements to the WHA, and (3) address coordination and common concerns of different partners in global health. Under the current WHA structure, resolutions and decisions are handled by two committees—Committee A (on program matters) and Committee B (on budgetary and managerial issues). The proposed Committee C would be able to submit stakeholder commitments as annexes to relevant resolutions produced by the other committees. Critics argue, however, that the “ambiguity” of the Committee C structure may lead to an undue power shift from developing countries to the donors and institutions of developed countries (Batniji 2008). Silberschmidt and Kickbusch (2008) respond that the structure actually does not “reduc[e] the influence of the poorest member states but, on the contrary, [enables] them to engage formally in strategy discussions with major actors, from which they are currently excluded.”

The second proposal applies the concept of “tripartite governance” to introduce a partnership model in which WHO would play a normative steering role and the WHA would assume the central role of holding all actors accountable (as described by Silberschmidt et al. 2008). Under tripartite governance, three roles exist: (1) a normative steering role, (2) an oversight role, and (3) a service provision role (Kempa et al. 2005). The WHO would hold the normative role, while the oversight role would be designated to a new body consisting of representatives from across the range of global health stakeholders. The service provision role would be held by partnerships and agencies with functional, demand-driven tasks. This governance structure seeks to create an arrangement where the three components for “good governance” would be honed and strengthened through a clearly defined division of global health responsibilities (Kickbusch 2006).

Uniting and Coordinating Decentralized Regimes: A Framework Convention on Global Health

With the many disparate efforts that are occurring in global health today, there has been interest in uniting them under a common legal framework. Decentralized regimes, which can be understood as “roles, rules, and relationships created to deal with issue specific problems,” exist in a variety of different forms—both formal and informal (Young 1997). The variety of current efforts occurring in global health today can be conceptualized as an array of mini-regimes. Unfortunately, the big picture of global health lacks coherence and direction with the existence of the many mini-regimes that tend to cluster around popular issues and overlap.

To address this problem, one of us (Gostin 2008a) has proposed an innovative international agreement called a Framework Convention on Global Health (FCGH). The framework convention-protocol approach refers to a process of incremental regime development. In the initial stage, States would negotiate and agree to the framework instrument, which would establish broad principles for global health governance: goals, obligations, institutional structures, empirical monitoring, funding mechanisms, and enforcement. In subsequent stages, specific protocols would be developed to achieve the objectives in the original framework (WHO 2003). These protocols, organized by key components of the global health strategy,⁷ would create more detailed legal norms, structures, and processes. The framework convention approach has considerable flexibility, allowing parties to decide the level of specificity that is politically feasible now, saving more complex or contentious issues to be built in later protocols.

This approach promotes a “bottom-up strategy” that strives to achieve several objectives, which include (1) building capacity for enduring and effective health systems, (2) setting priorities so that international assistance is directed at meeting basic survival needs, (3) setting minimal funding levels for international development assistance for health, (4) engaging stakeholders—including state and nonstate actors—so that they can bring to bear their resources and expertise, (5) coordinating activities among the proliferation of actors for harmonization, and (6) evaluating and monitoring progress so that goals are met and promises are kept.

The proposed FCGH would represent an historical shift in global health, with a broadly imagined, global governance regime. It is envisioned that the initial framework would establish the key modalities, with a strategy for subsequent protocols on each of the most important governance parameters. The broad principles for the FCGH would include mission objectives; engagement and coordination; state, party, and other stakeholder obligations; institutional structures; empirical

⁷The Framework Convention on Tobacco Control (FCTC), for example, anticipates that issues such as advertisement, illicit trade, and treatment will be addressed individually in separate protocols (WHO 2003).

monitoring; enforcement mechanisms; ongoing scientific analysis; and guidance for subsequent law-making process.

The organization “Incentives for Global Health” (2008) has proposed a Health Impact Fund that is illustrative of the kind of protocol that could be achieved under a Framework Convention on Global Health. The Fund aims to stimulate research and development for life-saving pharmaceuticals. It offers pharmaceutical innovators a supplementary reward based on the health impact of their products, if they agree to sell those products at designated low prices. As the fund mainly depends on long-term financing by governments, the FCGH could serve as a mechanism to bind states to their commitments.

The FCGH possesses a number of strengths that could overcome the intractable “grand challenges” mentioned earlier in this paper. Specifically, the FCGH can help facilitate global consensus, facilitate a shared humanitarian instinct, build factual and scientific consensus, transcend shifts in political will, and engage multiple actors and stakeholders. Yet, the FCGH also has some weaknesses. It will not be a panacea, and there are multiple social, political, and economic barriers to the creation of such a framework convention. The framework convention-protocol approach cannot easily circumvent some current aspects of global health governance: the domination of the most economically and politically powerful countries; the deep resistance to creating obligations to expend, or transfer, wealth; the lack of confidence in international legal regimes and trust in international organizations; and the vocal concerns about the integrity and competency of governments in many of the poorest countries. It also does not ensure consensus on contentious issues. Furthermore, the framework convention’s extended, incremental process could encounter a loss in momentum or the derailment of subsequent protocols due to its long timeframe. But given the dismal nature of extant global health governance, an FCGH may be a risk worth taking.

These three proposals represent some of the fresh ideas on how the international community can address current problems in global health governance. David Fidler proposes a reconceptualization of GHG, away from current architecturally based thinking, and identifies the need to come to terms with global health’s natural state of “open-source anarchy.” Meanwhile, proponents of WHO reform continue to recognize the necessity of WHO in global health and seek ways to make it a more effective leader in the global health domain. This has produced two structure-based proposals. The first proposal calls for the formation of a “Committee C” within the WHA, which would help account for the important role and contributions of nonstate actors in global health, and the second proposal attempts to reinforce WHO’s leadership role within a tripartite governance structure. Finally, Lawrence Gostin proposes a way to prioritize, unite and coordinate activities to address global health needs under an overarching FCGH to create a shared vision and *modus operandi* for the future of global

health. Overall, there are a variety of innovative ways to address the inadequacy of the current approach to GHG and a bold change needs to be adopted soon.

V. Health in a New Political Era

Today, we stand before a number of critical challenges in global health. This paper highlighted how the historical lack of leadership by WHO, despite its immense powers, has significantly impeded the international governance of health and opened the door to a proliferation of actors in the global health domain. Now, an array of nonhealth IGOs, bilaterals, nonstate entities, and GPPPs dominate the field. While these actors have introduced a number of creative ideas and a vast sum of new resources to tackle global health's most difficult problems, they have also brought a new set of problems to global health in the form of misaligned priorities, heavily skewed funding, service duplication and competition, and unsustainability. Meanwhile, global health must contend with a variety of emerging external forces such as trade, environment, and foreign policy. The overlaps between the health sector and these other fields hold the potential for tensions and synergies that need to be managed.

At the same time, fundamental health needs continue to be neglected and health systems remain weak. Nonstate actors, especially at the local level, are not being sufficiently harnessed through partnership. Transparency and accountability needs to be greater, and the monitoring and enforcement of commitments should be introduced. GHG needs to resolve the current imbalances and bring a greater sense of coherence to the "big picture" of global health. In addition, WHO must find a way to assert itself in this new global health environment. An innovative approach to GHG is sorely needed, and we reviewed a few creative, initial proposals on this subject. All in all, a dramatic change to the current GHG system is critical and the international community must be prepared to confront each of the grand challenges with clarity of purpose.

As this paper sought to elucidate, many of the seemingly intractable problems in global health could be addressed through improved global health governance. Leadership; harnessing creativity, energy, and resources; collaboration and coordination; meeting basic survival needs and health systems capabilities; prioritizing funding; and accountability, transparency, monitoring, and enforcement are some of the key grand challenges that the GHG system must address. And, yet, what is the role of the United States in terms of overcoming the current grand challenges? With the recent election of Barack Obama as President, attention has turned towards the implementation of campaign promises and there are several notable global health policies (Gostin 2008b). For example, these policies include (Bristol 2008a, 2008b):

- Increasing the capacity of health systems to deliver HIV/AIDS treatment.

- Launching a “Health Infrastructure 2020 Plan.”⁸
- Changes in PEPFAR, including an additional \$1 billion over five years towards the HIV/AIDS epidemic in Southeast Asia, India, and Eastern Europe.
- Greater U.S. funding and support toward multilateral programs (including the Global Fund to Fight AIDS, Tuberculosis and Malaria and the UN Millennium Development Goals).
- Reforms in U.S. foreign assistance, including the doubling of yearly foreign assistance to \$50 billion by 2012 and 100 percent debt cancellation for the world’s heavily indebted poor countries.

It is hopeful that these policies indicate a change from the prevailing unilateral approach taken by the United States and, perhaps, will bring our country into greater alignment with other donor countries possessing effective aid programs (Bristol 2008a, The One Campaign 2008). Though the current economic climate raises some concerns about the immediate feasibility of these ambitious policies, the opportunity for the incoming administration to change the U.S. approach towards global health should not be neglected in the near term.

The Obama administration should still strive to shift the United States away from an approach of “exceptionalism” and demonstrate its “willingness to engage positively with the rest of the world” on global health (Rechel and McGee forthcoming). As a starting point, for example, there needs to be a change in U.S. foreign assistance from ideological approaches that have undermined or obstructed international health efforts (e.g., HIV prevention programs⁹) toward policies that “favor realism and reliability” (Levine 2008). The Obama administration could also show its global commitment to health through several other measures, which include the adoption of a new U.S. position on climate change (e.g., ratify the Kyoto Protocol), the reversal of health care worker “brain drain” from developing countries (e.g., build a supply of skilled workers domestically and limit international recruitment), and the promotion of fair trade for developing countries (e.g., remove obstacles for poor countries in accessing essential medicines and vaccines and developing domestic health and safety protections) (Rechel and McGee forthcoming, Gostin 2008b).

While these near-term changes would signal greater U.S. support for global health, the six “grand challenges” discussed earlier in this paper require a broader and deeper level of commitment to a dramatic change in governance for the long

⁸ The “Health Infrastructure 2020 Plan” has been described as “a global effort to work with developing countries to invest in the full range of infrastructure needed to improve and protect both American and global health” (Bristol 2008a).

⁹ Key examples of detrimental policies under the Bush administration include the “block[age] of funds for needle or syringe exchange programmes . . . in countries with injection-driven epidemics” and an “obsession with abstinence-only approaches . . . [in countries] where the epidemic is driven by sexual contact” (Rechel and McGee forthcoming).

term. In the past, the United States has been resistant to global health governance, refusing to ratify vital treaties or work cooperatively. It could make a genuine difference by agreeing to fair terms of cooperation through international agreements and partnerships. Effective global health governance could dramatically improve life prospects for millions of people and diminish our collective vulnerabilities. Ultimately, this is an ideal for the Obama administration to pursue for the U.S. commitment to global health.

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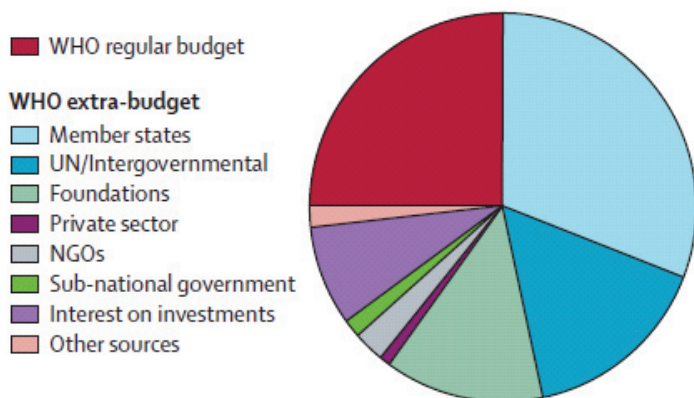


FIGURE E-1 WHO budget sources, 2006-2007.
SOURCE: Diagram from Stuckler et al., 2008.

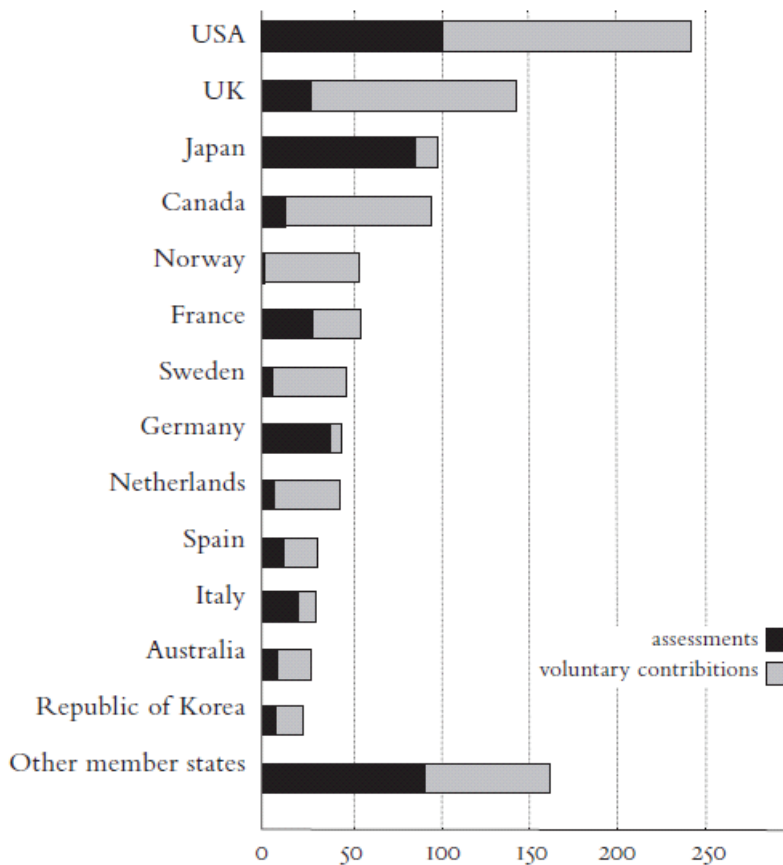


FIGURE E-2 Assessed and voluntary contributions to the WHO in 2006.
SOURCE: Diagram from People’s Health Movement et al., 2008.

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Appendix F

COMMISSIONED PAPER

Sharing Knowledge for Global Health

*Anthony D. So, MD, MPA, and Evan Stewart, BA**

The U.S. Commitment to Global Health identifies technological innovation and diffusion as the main drivers for improving health for all people by reducing avoidable disease, disabilities, and deaths. The sharing of knowledge is central to that vision, but involves far more than making a journal article open access, posting a database publicly to the web, or licensing a technology. These are all important building blocks to transferring technology effectively.

Sharing, as opposed to transferring, implies a two-way street. This is not to say that such exchanges are not asymmetric. Such exchanges slope along the steep gradients of disparities that separate industrialized and developing countries. Though only one-fifth of the world's population, the developed world is home to over two-thirds of the world's researchers, commands three-quarters of the gross expenditure on R&D, and originates over ninety percent of the patents granted by the patent offices in Europe, the United States, and Japan. The United States alone generates nearly twice the number of scientific publications (32.7% of the world total) than the whole of the developing world (17.3%).¹

These asymmetries, of course, run in the other direction when examining

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where the global burden of disease falls. Increasingly, biomedicine is turning to the growing pools of talent in the developing world. The conduct of clinical trials is burgeoning in the developing world—no doubt lured, in part, by reports that a top-notch academic center in India charges a tenth per case report of what a second-tier medical center in the United States would in mounting a clinical trial.² Pharmaceutical firms in the developing world may face different opportunity costs than large multinational corporations, and this may lead to gap-filling R&D investments, such as in more cost-effective processes for producing drugs. Shin Poong, a Korean firm that significantly lowered the costs of producing praziquantel, a drug to treat schistosomiasis, is a case in point.³ Some of these asymmetries are eroding away. From 2000 to 2006, the average annual growth rate in the number of patent filings originating from countries such as China and India outstripped that of all reported countries in Europe and North America.⁴

But the vibrancy of the scientific enterprise is only captured, in part, by traditional measures of innovation. Scientists trained, publications, patent filings, and revenues from health technologies highlight the disparities, but not the potential of research collaboration. Combination drugs effective for treating malaria may be produced by Northern pharmaceutical companies, but a core component is artemisinin, a Chinese traditional medicine. Without the collaboration of research centers in countries where SARS was endemic, the race to contain the threatening pandemic would have been crippled. Without the wild virus samples of avian flu from developing countries, steps to preparing a vaccine stockpile would slow. The interdependency of global health is clear from such examples. But these examples also underscore the importance of sharing knowledge for global health and of shaping effectively the enabling environment for doing so.

What should be the focus of the U.S. commitment to global health—leveling the slope or ensuring the flow of knowledge on that two-way street? Perhaps solutions need to address both. In a globalizing world, both knowledge and the human resources capable of applying that knowledge flow readily across borders. If the process of sharing knowledge only lures away the most talented to U.S. research laboratories, would it only exacerbate the brain drain from developing countries? If those from developing countries train here in the United States, will they return to settings where they can apply those skills? If the governance of product development partnerships represents the voices of donors but not those they purport to serve in developing countries, will the fruits of their work be effectively disseminated? As a recent study observed, U.S.-based companies increasingly have sponsored clinical trials in developing countries, but of the current Phase III clinical trials in these settings, not one in their sample focused on a disease endemic largely in developing nations.⁵ Is it really ethical or sustainable to mount clinical trials in developing countries that yield new treatments, but to fail to make these therapies affordable or more targeted to the public health needs of the populations in which they were tested?

Sharing knowledge in the context of the U.S. commitment to global health often emphasizes the North-South axis of collaboration. From the vantage point

of the United States, the potential for collaboration and capacity building to improve global health is greatest along this axis. Of course, there are lessons from years of North-North collaborations across countries that might cross-apply. Not to overlook other axes though, South-South collaborations deserve particular note. The INDEPTH Network consists of 34 demographic surveillance sites in 18 countries, all in the developing world.⁶ Facilitating cross-site studies of longitudinal health and social studies in resource-limited settings, the network draws support from a range of Northern donors, including private foundations such as Gates, Rockefeller, the Wellcome Trust, and Hewlett; bilateral aid agencies such as CIDA, DFID, and Sida; and government research agencies such as IDRC and the U.S. National Institutes of Health (NIH). With its Secretariat based in Accra, Ghana, the network's governance remains largely in the hands of researchers from developing countries. Partnerships though are welcomed with Northern institutions, from product development partnerships such as the Malaria Vaccine Initiative to universities such as the London School of Hygiene and Tropical Medicine and the Swiss Tropical Institute.

The rise of modern medicine has introduced another important dimension of knowledge sharing—the bidirectional exchange between industry and publicly funded institutions such as universities and government laboratories. Disproportionate to the level of corporate funding, the norms governing this exchange have reshaped the way universities share their inventions. Some have suggested that the commercialization of university research has corrupted the mission of higher education.^{7,8} Many of these concerns trace to the nature of the agreements struck between universities and corporations. These contracts affect the publishing of research, the sharing of data and research tools, and the licensing of patented inventions. Corporations bring complementary expertise, an ability to scale up products for delivery, and additional research resources. While such collaborations may bring value to university research efforts, the conditions under which they operate deserve greater scrutiny and transparency. Society has relied on the academy to contribute to knowledge in the public domain, to maintain the independence of inquiry with safeguards against conflict of interest, and to engage in “blue-sky” research and high-risk experimentation.

The market has failed to deliver diagnostics, drugs, and vaccines that meet the disproportionate burden of disease afflicting those in developing countries. Public-private partnerships have emerged over the past decade to fill this gap. Using public sector monies, product development partnerships have embarked on drug discovery programs for neglected diseases. Half of these partnerships involved multinational corporations that conducted these projects on a “no profit-no loss” basis. Of note though, the other half of these projects were conducted by small firms doing so on a commercial basis.⁹ The opportunity costs for these smaller firms may be different. There can be an important North-South dimension to these collaborations as well. A recent survey found that over half of private sector firms in health biotechnology in developing countries had ongoing collaborations with partners in developed countries.¹⁰

STEPS TO SHARING KNOWLEDGE FOR GLOBAL HEALTH

Sharing knowledge for global health involves generating knowledge relevant to the context of low- and middle-income countries, effectively transferring such knowledge and technologies to these settings, and ensuring that its intended beneficiaries can apply it on a sustained basis. Each of these steps presents its own set of challenges, but also affords new opportunities.

Knowledge must either be relevant or adapted to the context of low- and middle-income countries. Some of this knowledge will be relevant because the health problems are shared ones between North and South. Often thought to be diseases of affluence, noncommunicable diseases, in fact, comprise a growing share and already account for nearly half of the burden of disease in developing countries.¹¹ Put in perspective, cardiovascular diseases, cancers, and diabetes comprise 16% of the burden of disease in low- and middle-income countries. By comparison, malaria is responsible for 4% of the disability-adjusted life years lost in these countries.¹²

As the 10/90 gap suggests though, the investment in global health R&D does not prioritize efforts focused on the burden of disease that disproportionately afflicts those in low- and middle-income countries. With the paying market being relatively small, some treatments rely on the spillovers from dual markets. The availability of eflornithine, the “resurrection drug” for treating sleeping sickness, has at times depended on its dual use as a treatment for the removal of facial hair in women. For those engaged in biodefense research, substantive review usually focuses on the dual use of such technologies for biodefense against emerging infections as well as for potentially nefarious purposes.¹³ Some of this research, including the platform technologies applied, might be evaluated for a third use—humanitarian applications to neglected diseases in developing countries. Not relying on the serendipity of finding incidental applications for neglected diseases, government and philanthropic funders have also invested in product development partnerships.

Sharing knowledge requires an enabling environment. The investment required to transfer information is a measure of the “stickiness” of that information.¹⁴ Stickiness is a function of the attributes of the information itself as well as that of the information seekers and providers. Intellectual property rights might make such knowledge costly to acquire while information technology has changed the speed and marginal cost of disseminating knowledge. Sometimes the skills are local to where that knowledge is being used. For example, laboratory apprenticeships may afford the firsthand experience necessary for performing certain procedures.

Several factors affect the sharing of knowledge: (1) the nature of the knowledge to be shared; (2) the norms for scientific exchange; and (3) its role in the innovation process. Today’s science has many ways of codifying knowledge, from study methods described in journal articles to patents disclosed. Tacit knowledge,

on the other hand, is not well codified. A technology new to developing country firms—such as conjugation technology for vaccine production—may not easily transfer without technical assistance. Norms over the ownership of knowledge also influence the sharing of knowledge. These norms are rooted in statutes and regulations such as the Bayh-Dole Act, prevailing practices among research institutions, and guidance provided by funding agencies as well as competition among scientists.

The sharing of knowledge matters most if innovation and scientific progress are cumulative. By cumulative innovation, one might envision several types of arrangements of research inputs and outputs (see Figure F-1).¹⁵ A single innovation might spawn multiple, second-generation innovations. For example, a receptor target might lead to several promising new drugs. Alternatively a second-generation output might require the input of multiple first-generation inputs. Some of these inputs may eventually be incorporated into the second-generation product, but other needed inputs—research tools—will not be. Finally, the process of innovation may be a quality ladder, where successively better products build on the model of the previous one. Process innovations of drugs can lower the marginal cost of production, extend its shelf life outside the cold chain, or improve its bioavailability. Each pattern of cumulative innovation responds differently to the ways in which knowledge is shared or inventions are licensed. For example, a product patent on a drug effectively may block others who might otherwise pursue process innovations in the manufacture of that drug.

Those who benefit from this sharing of knowledge must have the absorptive capacity to apply and sustain its use. The transfer of technology depends on the absorptive capacity of the setting where it would be used. Technology has both hardware and software aspects. Hardware is the tool as embodied as a physical object while software is the information base for the tool.¹⁶ The capital costs for purchasing hardware may be out of reach, but so might be the maintenance costs. Variable costs such as reagents for diagnostic tests can be prohibitively expensive. The software side consists not just of the knowledge to use the tool, but also may require the human resource expertise to apply it.

ACCESS TO THE BUILDING BLOCKS FOR RESEARCH

From bench to bedside, the value chain of R&D consists of inputs and outputs at every stage, each dependent on the sharing of knowledge. Three stages in this value chain warrant closer scrutiny because decisions at these points significantly shape what knowledge is shared within the scientific community. These building blocks for research include access to scientific publications, the norms for data and material sharing, and patenting and licensing practices. Characterizing the obstacles and opportunities at each stage can help point the way to solution paths that lower the barriers to sharing knowledge and improve the scientific community's ability to respond to the challenges of global health.

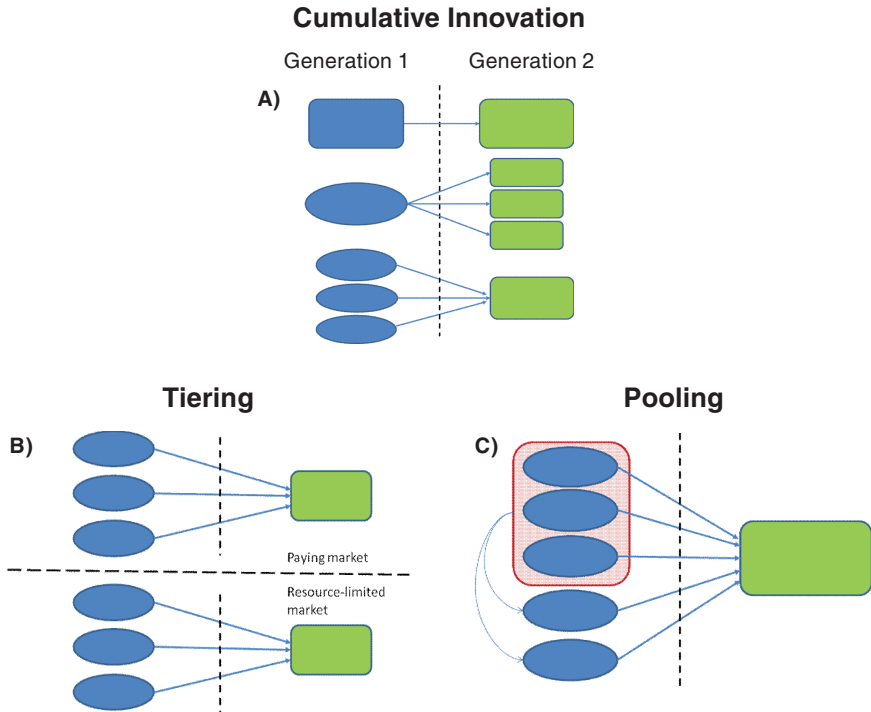


FIGURE F-1 A) Innovation may occur in several ways. One input may lead to a higher quality output, with each generation of innovation bringing a successively better product. Alternatively, a single input may spawn several outputs, as one target receptor may lead to several new drugs. Finally, several inputs may be required to produce one output; these inputs may be innovations themselves or simply research tools (adapted from Scotchmer, 2004).¹⁵ B) Tiering may segment the marketplace between a paying market and a resource-limited one that may receive a discounted price or other preferential access. C) Inputs may also be pooled, thereby reducing transaction costs to innovation and more readily enabling socially useful bundles. Such pooling—particularly when strategically done by the public and/or philanthropic sectors—may be structured to influence positively the norms and the licensing by which other inputs are also made available for innovation. Such an arrangement characterizes a *technology trust*.

Access to Scientific Publications

The challenges to sharing knowledge through scientific publication come both from the supply and the demand side. On the supply side, studies suggest that industry funding may not only occasionally introduce potential bias into the conduct of research, but also possible delays in its publication. Of those responding to a survey of life science faculties at universities receiving the most NIH

funding, nearly a third of the investigators that benefited from corporate research-related gifts indicated that their industry sponsor wanted pre-publication review of journal articles resulting from the gift.¹⁷ A majority of the contracts struck between these scientists and life science companies also mandated a six-month period of confidentiality to give time for patenting of resulting inventions.¹⁸ By contrast, the NIH has provided guidance that such delays should not exceed a 30- to 60-day window.

On the demand side, subscription prices to journals may place access to some research out of reach. This problem not only faces some institutions in the developing world, but also among patients in the developed world. For many patients, especially those with rare diseases, the high cost of accessing individual journal articles can pose an obstacle to learning about one's condition or treatment options. As a result, patient advocacy groups have recently joined the call on the U.S. government to embrace open access policies.^{19,20}

To ensure greater access to scientific publications, several strategies have been deployed. One has involved tiered pricing, and the other, the pooling of published research in open-access journals or repositories. Particularly in developing countries, mailing hard copies of journals would be prohibitively costly. With the advent of the Internet, however, much of this access can now be provided electronically.

Launched in January 2002, the WHO-led Health InterNetwork Access to Research Initiative (HINARI) seeks to provide tiered access to more than 6,200 major journals in biomedicine and related social sciences. In collaboration with participating publishers, HINARI divides low- and middle-income countries into two groups: countries with a GNI per capita from US\$1250-3500/year whose institutions can receive access for \$1000/year and those below that cutpoint whose institutions receive free access via an online research portal.²¹ The publishing company Elsevier, whose journals are made available through HINARI, claimed in 2006 that the initiative contributed to raising the rates of publication by researchers in the 105 HINARI-eligible countries. In their analysis, researchers in HINARI countries increased their rates of publication by 63% while those in non-HINARI nations saw only a 38% increase.²² However, some problems have surfaced in gaining online access to these journals. In order to be eligible for HINARI access, researchers in developing nations must have an institutional affiliation, prohibiting nonaffiliated scientists, doctors, and government officials from accessing HINARI articles.²³ Even for those with the correct institutional affiliation, investigators from a Peruvian university noted in 2007 that many of the highest impact journals were not available there.²⁴ Those journals that were accessible via HINARI were often either open-access journals or those which already provided free access to low-income countries.

Across disciplines ranging from electrical engineering to mathematics, the free, online access of journal articles corresponded to higher mean citation rates.²⁵ Several studies suggest that open access articles have a higher citation rate than

closed-access articles.^{26,27} This held true even when comparing open-access articles compared to non-open-access articles in the same journal.²⁸ Importantly, the impact of open-access publication on citations in journal publications was twice as strong in the developing world.²⁹

Open access can take several forms. By retaining copyright or nonexclusive license, authors can self-archive their work, oftentimes on their own websites or in a university repository. This is also known as the “green” road. In early 2008, Harvard University adopted its own open-access mandate through which members of the Faculty of Arts and Sciences will submit electronic copies of all completed articles to an institutional repository that will eventually be accessible worldwide via the Internet.³⁰ Faculty members may opt out of the system if they choose, but it is expected that most will grant a nonexclusive license to the university to make use of their work. The approach of an institutional open-access repository has also spread: Harvard Law School and Harvard’s Kennedy School of Government recently adopted their own open-access initiatives as have the Stanford University School of Education, Boston University, and the Massachusetts Institute of Technology.^{31,32,33,34}

Breaking with the approach to supporting journal access through subscriptions, open-access journals have offered an alternative model to scientific publishing, also known as the “gold” road. Open-access journals raise revenues from a variety of sources—endowments, institutional subsidies, membership dues, fundraising, advertising, or upfront submission or publication fees—or just depend on voluntarism. Of note, most open-access journals do not charge any publication fees.³⁵ Open-access journals make published articles more broadly available online without subscriber fees. In so doing, open-access journals enable wider distribution of the research published in these outlets, and at the same time, the copyright licensing of these works allow greater potential of “remix.” For example, if a developing country research institution sought to pull together a compendium of key articles on schistosomiasis and to share such a resource with sister institutions, the transaction costs of assembling an open-access collection of journal articles are far lower than doing so with non-open-access articles, where reprint rights would have to be negotiated with each journal holding the copyright.

Open-access publishing has benefited from Creative Commons licensing. Such licensing enables artists, writers, and researchers to lift voluntarily some or all of the copyright restrictions upon their work. The family of Creative Commons licenses allows for different permutations of the conditions under which the work might be distributed, displayed, performed, or become the basis of a derivative work. These conditions may require attribution, limit subsequent use to noncommercial purposes, not allow derivative works, or allow sharing under condition that derivative works carry the same licensing.

In the biomedical sciences, much research is funded by governments, and given this support, the public understandably expects access to the findings

from such research. The NIH estimates that 80,000 publications grew out of NIH-supported research in 2003.³⁶ Initially making a nonbinding request of its researchers, NIH asked that all publications resulting, in whole or in part, from its funding to be deposited in PubMed Central, a publicly accessible archive of scientific publications, within 12 months after the study's publication.³⁷ However, the yield from voluntary compliance with this policy was very low: fewer than 5% of NIH-funded researchers submitted their articles.³⁸ The failure of this policy prompted U.S. congressional action that mandated it as a requirement of NIH funding beginning in April 2008.³⁹ The NIH Public Access Policy requires investigators to submit final, peer-reviewed journal manuscripts arising from NIH funding to PubMed Central upon acceptance for publication. Such papers must be available to the public through PubMed Central no later than 12 months after publication. Taking a green path, this approach mandates deposit of government funded research in an online archive broadly available to the public. By allowing grantees to use NIH funding for publication fees though, the NIH also supports, in part, the gold road.

Several prominent medical research funders have made open access a condition of grant support. The European Research Council (ERC), a funding body set up by the European Union (EU) to promote research in the region, has also put forward an open-access policy requiring its grantees to post all publications to a research repository within six months of publication.⁴⁰ This marked the first EU-wide open-access policy and ERC has stated that it has interest in shortening the six-month window period in the future.^{41,42} The Wellcome Trust requires submission of scientific publications resulting from its grants into U.K. PubMed Central within six months of the publication date and even provides funding for the upfront fees associated with publishing in such outlets.^{43,44} Grantees of the Howard Hughes Medical Institute also face a similar requirement to deposit publications in PubMed within six months of the publication date.⁴⁵ By contrast, NIH's Public Access Policy remains at 12 months, twice the embargo period accepted by other leading funding agencies.

Access to Research Data and Materials

The sharing of research data and materials enables the scientific community to confirm study findings and also to build upon the work of others. Access to these building blocks of research, however, may also be encumbered for reasons similar to those encountered over scientific publications. The difference is that access to data and materials enriches immensely the pursuit of new hypotheses that derive or go substantially beyond its original research use.

Competing public policy concerns set some limits on the sharing of research data and materials. For example, some data may risk the personal privacy of human subjects, and the disclosure of other data may compromise the confidentiality of privileged proprietary information. Unlike the electronic distribution of

journal articles or data, the marginal cost of disseminating research materials may not be negligible, and these transaction costs also may pose barriers to sharing. Dual use of technologies have the potential both to advance scientific knowledge and to pose threats to public health or the environment, and such research activities as well as resulting data and materials require governmental oversight.⁴⁶ However, denying data access not only imposes additional costs and barriers to research along these lines, but also can place patients at risk of redundant or unnecessary clinical trials.

Slow responses to material transfer requests resulted in project delays of greater than a month among one out of six biomedical researchers surveyed in universities, government or nonprofit institutions.⁴⁷ Noncompliance with these material transfer requests resulted in 1 out of 14 scientists giving up a line of research on at least one of their projects each year. While noncompliance with these requests were not reported to relate to the patent status of the requested material, key reasons given for noncompliance included the costs and effort involved in providing the sample and protecting the ability to publish. Negotiating MTAs with industry often came with conditions, such as reach-through claims, royalties, and publication restrictions. This was particularly common for requests for drugs.

The role of government in facilitating access to data and research materials is bounded, in part, by statute and regulations. For example, the U.S. Copyright Act of 1976 prevents the federal government from claiming copyright protection of its publications, and OMB Circular A-130 mandates that government-produced data should be made available at the marginal cost of disseminating it. OMB Circular A-76 prohibits the government from entering into direct competition with the private sector in providing information products and services. Tensions exist between treating scientific data as a public good as opposed to a private one, and there are important implications for the research commons.⁴⁸

As with publications, open access may also multiply the impact of research data. For example, in a 2007 study of 85 cancer microarray clinical trial publications, the public sharing of available data contributed to a 69% increase in citations.⁴⁹ While half the trials in the study made their data publicly available, they comprised 85% of the total citations.

As suggested by findings in the genetics research community, there are the familiar reasons for denying access to data and research materials. When making requests for information, data, or materials related to published research, nearly half of geneticists reported that at least one of their requests had been declined over the previous three years.⁵⁰ Consequently, investigators said they could not confirm research that had been published. Among the reasons most frequently given for denying such requests, geneticists cited the high costs of producing materials or information, the need to protect their own or their colleagues' ability to publish, and the commercial value of the data or material.

In the setting of emerging infectious diseases, the need for rapid and freer

exchange of information and materials has become most clearly evident. The WHO's Global Influenza Surveillance Network played a key role in linking the world's leading laboratories and experts with real-time information during the SARS outbreak in 2003.⁵¹ In the race to identify the coronavirus as the cause of SARS, 11 laboratories recruited by the WHO regularly and voluntarily shared samples of the unknown virus and held conference calls to discuss their results.⁵² Without this level of collaboration and sharing, the transmission of SARS might not have been halted within four months. For other diseases that might not unfold as infectious disease outbreaks, would not freer exchange norms also help speed the race to a cure?

Funding agencies again have played an important role in setting norms for sharing data and materials. Providing guidance to its grantees in 2003, the NIH requires applicants for grants greater than \$500,000 to provide a plan for "timely release and sharing of final research data from NIH-supported studies for use by other researchers."⁵³ The ERC requires that "primary data" such as nucleotide or protein sequences or epidemiological data must be submitted to a database within six months.⁵⁴

Led by the Wellcome Trust and the NIH, leading sequence centers involved in the Human Genome Project pledged to deposit completed gene sequences of every 1,000 base pairs within 24 hours of completion into a publicly available database, GenBank. Called the "Bermuda Rules," these rules were created to prevent the patenting of DNA sequences through defensive publishing.⁵⁵ Providing further incentive to follow the Bermuda Rules, the NIH subsequently suggested that the patenting of work emerging from the publicly funded Human Genome Project would negatively impact the likelihood of receiving future grants.⁵⁶ Data sharing has also been supported by other initiatives since the adoption of the Bermuda Rules—by the Merck Gene Index,⁵⁷ the International Nucleotide Sequence Database Collaboration,⁵⁸ and the Worldwide Protein Data Bank among others.⁵⁹

Traditionally, the sharing of data and materials involves both informal and formal norms. Informally researchers sometimes bypass negotiation over material transfer agreements (MTAs), but such practices may place the institution at some risks that would otherwise be lessened by use of MTAs. Informal transfers of materials among investigators circumvent institutional management of the intellectual property and give advantage to some researchers better connected than others.⁶⁰ Increasingly though, informal sharing has given way to formal agreements on data or material sharing that cover concerns such as attribution, protection of patient confidentiality, the right to publish resulting research findings, and intellectual property rights (IPRs).

Various groups have sought to lower the costs of such transactions. The first strategy involves harmonizing the formal agreement form used among institutions. The Uniform Biological Material Transfer Agreement (UBMTA) offers a standard approach for transferring materials for noncommercial, research pur-

poses, and the simple letter agreement (SLA), for transferring nonproprietary biological materials among public and nonprofit research institutions.⁶¹ However, challenges remain, particularly in striking such MTA agreements between academia and commercial entities. Science Commons has more recently elaborated an MTA with modular contract options for transfers between academia and industry.⁶²

A second strategy is to lower the transaction costs at the level of the organization or even a research consortium involving multiple institutions. Research consortia may also build in preferential arrangements for sharing research materials among participating institutions. Of note, the original NIH guidance suggests adoption of the UBMTA at the organizational level, and nearly 350 institutions have signed the Master Agreement pledging to accept this standard form without modification when their scientists send materials to other nonprofit or public institutions.⁶³ In guidance to its grantees, the NIH suggested using the SLA as a means to transfer unpatented materials arising out of its funded research. It also asked that funded investigators use terms no more restrictive than those of the SLA when transferring materials to other NIH grant recipients.⁶⁴ This approach carries the promise of creating a limited public domain among these institutions. However, many of these signatories have, in practice, substituted their own agreement forms in place of the UBMTA.⁶⁵ In so doing, their practices create a collective action problem, where an individual university would have little motivation to forego what it might gain from a more restrictive and perhaps more remunerative MTA approach.

A third strategy is to create institutions specifically dedicated to the sharing of these data or materials. This is not a new strategy. The American Tissue Culture Collection, a nonprofit bioresource center, has provided a depository for biological materials since 1949 and now contains over 20,000 specimens. Lowering the transaction costs of securing reagents for research on HIV and other retroviruses, the NIH's AIDS Research & Reference Reagent Program has grown to over 8,560 reagents since 1988, distributed over 11,000 reagents last year, and has participating scientists in 65 countries.⁶⁶

As seen through the efforts of the Broad Institute, the sharing of data can come under the aegis of various sponsors. Among them, the Broad Institute and the pharmaceutical company Novartis have collaborated to share freely genetic data about diabetes online as part of the Diabetes Genetic Initiative.⁶⁷ In addition to this public-private partnership, Broad has partnered with a disease-based foundation in order to create the Multiple Myeloma Genomics Portal, which publishes the sequence of the myeloma genome,⁶⁸ and with several other research teams to create the Tuberculosis Database Project.⁶⁹ The Multiple Myeloma Genomics Portal prohibits patenting of any DNA sequences discovered, and all data must be posted to a public site upon completion of the analysis. The TB Database Project allows for both the options of posting data for public access and as private data pending publication or the resolution of intellectual property claims.

While much of the R&D capability to bring a vaccine to market exists in the developed world, avian flu cases have occurred primarily in the developing world. Thus, in order to research the virus, researchers in the industrialized world are dependent upon developing nations to supply them with wild virus samples. The need for reciprocal benefits for these developing countries to share has recently become very evident. Patenting of avian flu wild virus samples sent to developed world laboratories and the potentially high costs of any resulting vaccines created from those samples have created friction in the Global Influenza Surveillance Network. The refusal of Indonesia to share virus samples to WHO Collaborating Centers without assurances of benefit sharing demonstrates the importance of a bidirectional flow of benefits in the sharing of data and materials.⁷⁰

Obtaining data on flu virus sequences from its network of laboratories, WHO can only release the data with permission from the country of origin. WHO had provided much of the data to 17 labs in a password-protected database out of Los Alamos National Laboratory. Responding to complaints from some scientists about these barriers to broader data access, the Global Initiative on Sharing Avian Influenza Data (GISAID) was launched in 2006.⁷¹ The Initiative “is open to all scientists, provided they agree to share their own data, credit the use of others’ data, analyze findings jointly, and publish results collaboratively.”⁷² Curating the data, GISAID pledges to deposit these sequences, following analysis and validation, to one or more publicly available databases with a delay no longer than six months.⁷³ The sharing of information poses potential complications that need to be worked out, from intellectual property rights to verification by specialized reference labs.⁷⁴ Some voiced concerns that sharing data immediately jeopardized their ability to publish first on these findings after considerable investment of time and resources. Others question whether publishing the paper should receive priority over the benefits of earlier data release for public health.

As seen with MTAs, there is value in aggregating efforts and thereby lowering transaction costs to sharing the building blocks of research. Pooling research data and materials has other benefits. A registry of clinical trials allows patients and providers to find treatments undergoing testing or uncover negative findings that might otherwise remain unpublished or hidden. A pool of compound libraries might diversify the spectrum of available druggable compounds, allow researchers to pursue novel compounds from parts of the genome considered “undruggable,” and bring useful data and annotation information to a larger group of researchers, some pursuing neglected diseases otherwise without the benefit of such resources.

While there are significant challenges both to creating such repositories and to sharing the knowledge from them, there are promising developments. Different but complementary approaches to broadening compound library access have emerged, both in the rare disease and neglected disease spaces.

The European Rare Diseases Therapeutic Initiative (ERDITI) facilitates access to compounds, developed by pharmaceutical firms, for academic teams. Enlisting

the participation of 4 major companies in their efforts (Aventis, GlaxoSmithKline, Roche, and Servier) and 10 European research institutions, ERDITI screens requests from academic researchers interested in evaluating the therapeutic potential of compounds in preclinical studies for treating rare diseases.⁷⁵ Of note, academic teams broker agreements with companies on a case-by-case basis and in confidentiality. The ERDITI arrangement though precludes high-throughput screening or assembling a common pool of “non-used compounds” drawn from the various companies contributing to these efforts.

Tackling a range of neglected diseases, the Special Programme for Research and Training in Tropical Diseases (TDR) has launched a web portal, TDR Targets, to bring together data and annotation in an open-access database on tropical disease pathogens. Users can undertake searches ranging from genomic or protein structural data to information on target druggability on neglected diseases from leprosy and filariasis to Chagas disease and leishmaniasis. In the first 16 months since the database’s launch, the site has logged more than 10,000 visits, with more than 30% coming from developing countries or regions where these neglected diseases are endemic.⁷⁶ This web-based initiative complements efforts to bring together the partnerships and multidisciplinary networks needed for drug discovery for neglected diseases.⁷⁷ Now the vision for TDR is considerably more ambitious: a virtual drug discovery network with negotiated access and screening of proprietary compound libraries on a contractual and confidential basis, sponsored scientists to work in pharmaceutical companies on these neglected disease projects, and a clearinghouse to help coordinate these efforts.⁷⁸

While pharmaceutical and biotechnology firms focus on the “druggable genome,” the work of the NIH Molecular Libraries Initiative will illuminate the majority of the human genome thought to be “undruggable” in hopes of coming up with biologically useful substances and novel drug leads.⁷⁹ To support this line of work, the NIH has established the Molecular Libraries Screening Centers Network (MLSCN) comprised of 10 centers, each with particular expertise and technology. The Network as a whole conducts 20 assays on more than 100,000 compounds each year. Each Center must deposit its screening results in PubChem, an NIH-supported, publicly accessible database with more than 8 million compounds. Sharing such knowledge is not without its challenges. Patenting of probes developed under this initiative would be discouraged as they may be the source of multiple chemical analogs that offer improved properties. As one of the lead investigators in MLSCN acknowledged, publication and attribution, the tension between the data release policy and timely submissions of assay results to MLSCN, and the critical path to optimizing and synthesizing biologically useful products remain challenges.⁸⁰ As models like this emerge, resolving these issues will also require investment.

Findings of publication bias and the nondisclosure of unfavorable clinical trial results have stoked efforts to ensure the sharing of this information. Looking at efficacy trials for approved New Drug Applications for new molecular entities, a recent

study concluded that many of these trials remain unpublished even five years after FDA approval. More disconcerting, there were differences between the trial information reviewed by FDA and that found in publications of these trial results. Nearly half of the unfavorable findings found in trials submitted for FDA approval did not make it into the published papers of these clinical trials.⁸¹ When post-marketing studies found increased suicide among children using Paxil⁸² and of increased incidence of heart failure from the use of Vioxx,^{83,84} companies delayed the release of clinical trial data that reflected the risks associated with their products.

Responding to this need, the NIH has developed a clinical trial registry and results data bank for both federal and privately supported clinical trials conducted around the world. In the wake of the public outcry over the non-disclosure of clinical trial results in the Vioxx case, the International Committee of Medical Journal Editors (ICMJE) announced that their journals collectively would “require, as a condition for consideration for publication, registration in a public trials registry.”⁸⁵ Demonstrating the power of such norm-setting changes, ClinicalTrials.gov registered a 73% increase in the number of trials and a 195% increase in the number of data providers that registered trials over the 4.5 months before the ICMJE’s September 2005 deadline, with an enormous spike of new registrations in the two weeks leading up to and around the final deadline.⁸⁶ The FDA Amendments of 2007 strengthened these reporting requirements by requiring clinical trial results completed before product approval to be submitted to ClinicalTrials.gov not later than 30 days after the drug or device has received FDA approval.⁸⁷ Building upon the momentum of these efforts, WHO has sought to provide a forum for developing best practices for clinical trial registration, and a number of countries now maintain prospective trial registries.⁸⁸

Access to Patented Inventions

The patenting of inventions and their licensing influence significantly the sharing of knowledge. Patenting this knowledge enhances the potential commercial value to this work, and this can help mobilize needed private sector resources for further research and development. In a survey of those involved in biomedical R&D, licensing was routine, worthwhile projects were almost never stopped because of patents on research tools, but infringement of research tool patents was frequent.⁸⁹ In fact, the study found that one out of three respondents from industry and all nine of the government lab or university respondents admitted to using patented research tools occasionally without a license. In a larger survey of biomedical researchers in universities, nonprofit institutions and government, only 8% of respondents believed that they had conducted research involving patented inventions over the past two years, but even fewer regularly checked for patents on inputs to their research.⁹⁰ None of the respondents reported abandoning research as a consequence of third-party patents, and though delays or workarounds were reported, they were infrequent.

In several research areas, however, problems over patenting have surfaced. Particularly in the field of genomics, several studies suggest that concerns over patenting may hinder research. One survey found that the license granted on the patent needed for clinical testing of hemochromatosis prompted 30% of laboratories to discontinue or not develop genetic tests for this disease.⁹¹ A broader survey of genetic laboratory directors found that over half had decided not to develop one or more genetic tests as a consequence of the underlying patent or license held on it.⁹² Controversy over the patenting of genetic tests continues to brew. On behalf of key professional research societies, genetics researchers and patents, the American Civil Liberties Union and the Public Patent Foundation recently filed suit against Myriad Genetics over their patents on breast cancer genes. The legal complaint argues that Myriad has used the patents in a way that restricts access to the diagnostic tests for breast cancer.

The research enterprise yields both tools and products. Both may serve as inputs to follow-on research, and both may receive protection under the intellectual property rights system as inventions. Patents reward the inventor with time-limited market exclusivity, but licensing might be handled exclusively or nonexclusively. The approach to licensing shapes the conditions of access and the sharing of knowledge. The passage of the U.S. Bayh-Dole Act in 1980 encouraged nonprofit institutions to patent inventions emerging from government-funded research. Companies also may expect ownership of patentable inventions arising from sponsored research at the university.⁹³

The U.S. Copyright Act of 1976 and the NIH Public Access policy lower barriers to the sharing of knowledge through scientific publications, and OMB Circular A-130, similarly kept the price of government databases to the marginal cost of dissemination. By contrast, the Bayh-Dole Act accelerated patenting, licensing and associated revenues at universities. These practices have stirred concerns over patenting and exclusive licensing over upstream research tools. At times unnecessary for adoption by industry, these practices contribute to patent thickets that complicate bargaining and broader use. Nearly 30 years after the Act's passage, U.S. universities, hospitals and research institutions only derive 5% of total academic research dollars from licensing revenues.⁹⁴ The reality seems to overstate the benefits of Bayh-Dole on commercialization of federally funded inventions and have prompted questions over the emulation of this statute in developing countries.⁹⁵

Funders have sought to mitigate the concerns over unnecessary patenting and exclusive licensing of inventions. In 1999, NIH released "Principles and Guidelines for Sharing of Biomedical Research Resources," in which grantees were advised not to license exclusively "a broad, enabling invention that will be useful to many scientists (or multiple companies in developing multiple products), rather than a project or product-specific resource."⁹⁶ Various foundations

have also issued guidance that encourages greater sharing of inventions resulting from their research.

Some have built such conditions into their grant agreements. In funding point-of-care diagnostics for monitoring AIDS, the Doris Duke Charitable Foundation assessed how existing intellectual property affected the ability of their grantees to make good on the charitable objective of ensuring the technology's availability at an affordable cost in developing countries. Their grant agreements went further and retained a nonexclusive, royalty-free license to any patents filed in developing countries. This would allow the Foundation to sublicense rights to make and distribute the product if the grantee failed to deliver on the charitable objective.⁹⁷ The NIH itself has used "White Knight Clauses" (named after the company with which these clauses were first used) in its licensing to ensure the provision of products at cost in the developing world.⁹⁸ To make possible the low-cost production of conjugate meningitis vaccine A targeted to strains in developing countries, the U.S. Food and Drug Administration transferred conjugation technology to the Serum Institute in India and SynCo Bio Partners.⁹⁹

As with scientific publications, data and material transfers, tiering and pooling also can apply to patents and their licensing. The simplest approach to tiering is the use of two tiers. By setting limits of geography or use, licenses may offer lower royalty-free rates or reduced pricing for the invention's application in the developing world. For example, the Institute for OneWorld Health has secured exclusive license from the University of Washington and Yale University to develop azole compounds that might help treat Chagas disease in the developing world.¹⁰⁰ Similarly, the University of British Columbia licensed an oral formulation of Amphotericin B to iCo Therapeutics for treating blood-borne fungal infections in the developed world on condition that the company provides subsidized pricing of the drug to treat leishmaniasis in the developing world.¹⁰¹ Such licenses often promise little revenue return from the developing world, but by reserving rights for application in the industrialized world, revenues from paying markets remain possible.

Pooling patents can help lower the transaction costs associated with assembling the tools needed to conduct research on a health technology. The Wellcome Trust recognized the need for ready access to single-nucleotide polymorphisms (SNPs) as tools to map the human genome. With its support, a consortium of corporate, academic and funding partners came together to ensure the overall intellectual property (IP) objective "to maximize the number of SNPs that (1) enter the public domain at the earliest possible date, and, (2) to be free of third-party encumbrances such that the map can be used by all without financial or other IP obligations."¹⁰² Begun in 1999, the Consortium significantly exceeded its initial goals. Instead of releasing 300,000 SNPs by 2001, the SNPs Consortium successfully placed 1.4 million SNPs into the public domain.

REENGINEERING THE VALUE CHAIN

The value chain of R&D represents the inputs and outputs at each stage from discovery to delivery of a health technology. The sharing of knowledge constitutes a key input all throughout this value chain. The process of investigation and invention is often a cumulative one. Scientific exchange speeds its evolutionary progress, opens new directions for research, and enables interdisciplinary and cross-institutional collaborations.

Across the value chain, however, the ownership of knowledge adds friction to the process of sharing. With industry collaborations and sponsorship, proprietary control does sometime limit the dissemination of the knowledge produced. In a survey of biomedical researchers in nonprofit institutions and government laboratories, over a quarter of MTAs carried reach-through claims, and a quarter also placed restrictions on publication. For MTAs involving drug requests, 70% carried such a restriction.¹⁰³ Scientific competition also contributes to this situation as has the increasingly common practice of patenting and exclusively licensing inventions from universities. While commercial entities have an IP strategy to harness proprietary technologies to bring inventions to market, the public sector has not given as much thought as to how it might apply IPRs to protect the public good of scientific R&D.

At each link in the chain, various approaches to sharing knowledge have been discussed. Whether scientific publications, data or material transfer, or the licensing of patented inventions are the critical input to innovation, the scientific community has gravitated to solution paths that share some common elements. To be sure, there are contextual differences at each link in the chain. The dissemination of scientific publications can approach zero marginal cost, but data and material transfer involve costs to prepare or transfer, and patented inventions have at least opportunity costs. Understanding how these different solution paths contribute to scientific innovation might inform how to leverage best the U.S. commitment to global health.

At least three solution paths emerge from examining the interventions in the value chain—tiering, pooling, and open-source collaboration. The prime means by which each of these approaches ensures the sharing of knowledge is in its collective management of the ownership of knowledge. Certifying that ownership, patents give incentive to the R&D process by providing time-limited market exclusivity and enabling a tradable commodity in the market. Of course, the disadvantage of intellectual property ownership in a market comes as deadweight loss from monopoly pricing. Deadweight loss results when people are excluded from use of a good even when their willingness to pay exceeds the marginal cost of providing it. Through price discrimination, one can mitigate some of the inefficiency that comes from monopoly pricing, and tiering takes steps in this direction by making resources more available to lower-income groups. Pooling assembles research inputs in ways that lower the transaction costs of conducting studies or

reveal socially useful bundles of research tools or technologies. Pooling may help build the research commons. These solution paths are not mutually exclusive, and in fact, hybrid approaches might have significant promise. For example, pooling for neglected diseases combines aspects of both approaches. Tiering and pooling address how we organize the inputs of research. Open source focuses more on the means of knowledge production. In open-source collaborations, the locus of control shifts from the owner of knowledge to its users.

By tiering, the market is segmented between those receiving preferential treatment and those not receiving such treatment. Such preferential treatment typically means lower access costs. Tiering can occur at different points in the value chain—when pricing the final product, licensing the underlying intellectual property, or making other research inputs available. Tiering sometimes distinguishes the private market from the public sector in a developing country. If the difference in tiered prices is steep, preventing arbitrage between the public sector and the private market may be more difficult or costly to implement. Sometimes those implementation costs fall on those in developing countries where the resources and infrastructure are already stretched to their limits.

Some practices of tiering remain challenging to resolve. Selecting what countries belong to which tier is a key consideration. With the support of Gates Foundation funding, the University of California, Berkeley, provided royalty-free licenses for the microbial synthesis of artemisinin to Amyris Biotechnologies and the Institute for One World Health.¹⁰⁴ The University limited the field of use to the nonprofit production of artemisinin for treating malaria in the developing world. The University's royalty-free license covers the developing world and does so in return for a commitment from its partners to produce the drug at no profit for the developing world. By contrast, under HINARI, middle-income countries such as China, India, Indonesia, or Thailand do not even qualify either for Band 1 (Free Access) or Band 2 (Low-Cost Access) despite having a GNI per capita that falls within HINARI's bands.¹⁰⁵ Still tiering may provide more equitable pricing scaled to the resources available in developing countries.

One of the more inspired business models also takes advantage of dual markets. A nonprofit firm, Global Vaccines, Inc., proposes to undertake vaccine development with public financing for developing country markets first. The University of North Carolina has provided a royalty-free license to technology for this purpose. When the technology reaches the proof-of-concept stage, it would hopefully have promise for commercial sublicense in industrialized countries. At that point, the commercial sublicense would return revenues for both the company and for the university. This potential model places priority on diseases in developing countries with the support of government or philanthropic funding, transfers the technology from South to North, and seeks to generate revenues from the commercialization of such technology in industrialized countries.¹⁰⁶

Tiering can, however, also be divisive, particularly in regions like Latin America where the countries have sought price concessions for antiretrovirals.

In the region, countries range from large middle-income country markets like Brazil to smaller, least developed country markets like Haiti. Tiered pricing available to Haiti may not be so for Brazil. Under the Accelerating Access Initiative, five pharmaceutical manufacturers offered lower prices for HIV medicines by brokering agreements on a drug-by-drug, country-by-country basis. With only five countries in Latin America and the Caribbean initially participating in this Initiative, the countries of the Caribbean started a subregional negotiation with Accelerating Access Initiative partners. Central American countries soon followed suit *en bloc*, and then ten other Latin American countries started collective negotiations.¹⁰⁷ Each subregional negotiation improved upon the country-by-country negotiations with the Accelerating Access Initiative. The important lesson from this experience is the monopsony power of collective negotiation—or pooling—for tiered pricing.

Apart from organizing demand, pooling can facilitate access to the supply side by constructing a research commons. Such a step can lower the transaction costs of assembling these research inputs. Pools can come together by various means. Upstream in the R&D pipeline, pooling can build upon a more robust public domain of research tools and other inputs. The entanglements of IPRs might be fewer over the building blocks of knowledge. Downstream in the R&D pipeline, commercializable inventions will play a more important role in the pool, so the mix of incentives to contribute and disincentives to leave the pool may be more complicated to structure than in upstream pools.

By applying the Creative Commons Attribution License, open access publications create pools of journal articles that permit “unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.” Open-access repositories for data and journal articles posted online at universities similarly pool research resources for broad, public availability. Norm-setting approaches like the adoption of the UBMTA have the same potential, but when universities substitute their own more restrictive MTAs in lieu of following the UBMTA, the fragility of such pooling arrangements becomes clear.

While private sector pools provide access to patents comprising MPEG-2, DVD and other standards in the electronics industry, the creation of pools in biomedicine has been slower in coming. There certainly have been fledgling efforts to create a SARS patent pool,¹⁰⁸ to develop UNITAID’s proposed patent pool for HIV/AIDS drug products,¹⁰⁹ and to seed a technology trust for neglected diseases.¹¹⁰ Recently though, GlaxoSmithKline stirred renewed interest in this approach with its announced commitment to donate more than 800 patents to a pool open to researchers working on developing treatments for neglected diseases.¹¹¹ Going beyond patent pools, the “technology trust” model explores the potential for pooling across the value chain, from open-access databases to pooling of patented inventions. Using various arrangements for collectively managing intellectual property, it emphasizes the normative role that public sector pooling and its strategic use of IPRs can play in encouraging greater scientific exchange and innovation.¹¹²

Significant start-up costs exist for creating a pool. Organizers have to consider how to define what patents are essential to a pool or not; set valuation and remuneration, if any, for patented inventions or copyrighted materials in the pool; establish incentives for joining the pool and disincentives for leaving it; and seek antitrust guidance to ensure the pool is pro-competitive. In agricultural biotechnology, the Rockefeller and McKnight Foundations along with 10 universities created Public Sector Intellectual Property Resources in Agriculture (PIPRA) in 2003. Its stated goals were to “overcome the fragmentation of public-sector IP rights and re-establish the necessary FTO [freedom to operate] in agricultural biotechnology for the public good, while at the same time improving private-sector interactions by more efficiently identifying collective commercial licensing opportunities.”¹¹³ Acting more as a clearinghouse than a pool, its public database comprised of patented inventions from member institutions makes it easier to identify socially useful bundles of intellectual property for commercialization.

Public sector and philanthropic funders seldom foot these transaction costs for pooling in biomedical R&D. NIH grantees cannot charge legal fees for patenting or licensing as a direct cost to their project. However, it can be built into the indirect facilities and administrative costs of a grant. This certainly limits the means by which nonprofit research institutions might be willing to use IP strategically to protect the public domain. After all, patenting involves both legal, filing and maintenance fees, and protecting IP for the public domain does not promise a financial return on this investment. Nonetheless, the willingness of some funders and even some universities to support upfront fees for publication in open-access journals is a promising step in this direction, perhaps one that might be emulated when patenting to protect public access is at stake.^{114,115}

Not paying these transaction costs for pooling, however, can be problematic, particularly for emerging infectious diseases. In these cases, the spread of the epidemic may outpace the prosecution of patents at the Patent Office. As a result, developers of diagnostics and treatments for the disease receive little certainty from the patent system as the epidemic unfolds. The U.S. Centers for Disease Control and Prevention and the British Columbia Cancer Agency argued that the rationale for rushing to the Patent Office during the SARS outbreak was to maintain the freedom to operate for potential innovators in this space.¹¹⁶ This example reveals the perceived need by public agencies to patent in order to protect researcher access and the public’s interest in areas of critical public health concern. With patents still issuing years after the initial SARS epidemic has been contained, pooling may help resolve the uncertainty faced by pharmaceutical firms working on emerging infectious diseases during the outbreak.

Effectively used, tiering and pooling efforts can contribute to greater openness in the sharing of knowledge. Open-source science focuses more on the way in which the resulting collaboration is organized. Taking a page from the free software movement, the philosophy is embodied in the General Public License that allows a copyright owner to license a user to use his or her work, examine the underlying source code, modify it, and redistribute modified or unmodified

versions of the work. The license provides this right without paying a fee in return to the owner, but stipulates that the same conditions must be passed along to any subsequent user of that work.

This open-source approach turns the traditional model of innovation on its head. Open-source production empowers end users in the innovation of a technology, and in so doing, emphasizes transparency as well as peer review and feedback.¹¹⁷ Attribution of contributions in such communities is more difficult to trace than the authorship of scientific publications. With the successful experiences of open source in software, would such an approach apply in biomedicine? Perhaps bioinformatics might be, by analogy, a good starting point. The advent of the Internet has certainly changed the costs of open-source production. Distributed computing projects such as Folding@Home involve nonscientists and scientists alike in contributing desktop computing power to solving computationally intensive problems like protein folding. Moving from distributing computing projects to peer-based production among scientists may be more challenging.

Still some have applied similar open-source principles to biomedical science. Initially the Haplotype Map (HapMap) Project required users of its database to agree to a license, whereby investigators committed “not to use the data in any way that will restrict the access of others, and will only share the data obtained with others who have accepted the same license.”¹¹⁸ While such a license reaches virally through to subsequent users of the data, it may pose problems for those seeking to commercialize inventions in a marketplace where secure IP holdings can spell the difference between access to venture capital or not. Some have proposed the possible application of open source to finding cures for tropical diseases, where there is not a large paying market.¹¹⁹ The adoption of such an approach among wet lab scientists has been slower in coming.

However, the Open Source Drug Discovery (OSDD) project, launched by India’s Council of Scientific and Industrial Research in 2008, is a promising model to watch. The online platform allows a community of scientists to share and collaborate on projects, from gene sequencing to new drug development, on *Mycobacterium tuberculosis*. Backed by US\$38 million in commitments from the Indian government, this open-source website has already engaged 700 participants from 130 cities across 56 active projects.¹²⁰ OSDD differs from previous open-source drug discovery projects in that it has the support of a leading research institution in a major developing country, promises to adopt 30 colleges throughout India where students will have the opportunity to contribute research to this initiative, and importantly, has substantial financial resources to leverage research collaborations. Public financing may be the key to applying open-source production in biomedicine, both paying for what cannot be volunteered and supporting the open exchange important for collaboration.

By reengineering the value chain of R&D, alternative models for innovation may emerge and potentially better meet the needs of global public health. The approaches of tiering, pooling, and open source point to potential ways in which

the sharing of knowledge might be improved. While some of these efforts will emerge spontaneously from the scientific community, others will require targeted and strategic public and philanthropic investment. Unlike the private sector, the public and philanthropic sector does relatively little to manage collectively or strategically its IPRs to seek fair returns from its investment.

Yet arguably if publicly funded research were not freely available, the taxpayers would have paid for the results several times over—grants for the academic research, salaries for those academics giving their time for peer review, and subscriptions for such journals.¹²¹ For drugs, diagnostics, and vaccines, taxpayers pay for much of the basic science and some of the clinical research, the academic training of research scientists, and of course, for the final product. Some have argued for the federal government to pay for clinical trials, so that the results would be treated as a public good.¹²²

This calculus of “pay now or pay more later” might guide where the public ought to direct its investments to maximize the returns to the health care system. For example, in the value chain of scientific journal publication, paying the publication fees for open-access journals is one way of supporting a business model that encourages the sharing of knowledge. Going further, the U.S. government could develop a system of supporting open-access journals that publish peer-reviewed, publicly funded research. For those open-access journals that charge publication fees, it could build support into the direct or indirect cost structure of grants. For those open-access journals that do not charge fees, it could provide direct or indirect subsidies. Either way, it could support journals that provide open access rather than impose subscription fees on patients, providers, and universities. This support could factor in transition costs, the citation impact factor of the journal in that field, the rejection rate, and the number of publicly funded research articles published by the journal.

For clinical trials, greater public funding could also reap significant benefits. If structured appropriately, such support might result in improved data transparency and access, the sharing of clinical trial information on shelved products, the removal of financial conflict of interest in the conduct of clinical trials, priority placed on trials addressing major public health concerns, and transparency of R&D costs that might allow policy makers to assess reasonable pricing of the resulting products. The recently approved NIH funding for comparative effectiveness trials is a useful first step in this direction.¹²³

Reengineering the value chain might also involve investing in alternative business models, one that might lower the cost of R&D for neglected diseases. The Gates Foundation grant to the Institute for One World Health, the University of California, Berkeley, and Amyris Biotechnologies to produce artemisinin at no profit for the developing world is one such example. Another example comes from the work of Global Vaccines, Inc., a nonprofit firm that seeks to develop affordable products for developing country markets with the support of public funding and then to disseminate this technology through commercial sublicenses

for markets in industrialized countries. With Wellcome Trust and UK government funding, investigators from Imperial College and the London School of Pharmacy reengineered not only the existing version of hepatitis C treatment, pegylated interferon, but also the approach to help ensure its scale-up as a product affordable to the many afflicted with this disease in the developing world.^{124,125} Through a university spin-off, they licensed the drug to Shantha Biotechnics, bypassing the more customary route of licensing it to a multinational pharmaceutical firm. Facing different clinical trial costs, Shantha Biotechnics will try to produce a more affordable treatment than the one currently available.

Sharing knowledge from bench to bedside is critical to bringing about innovation the world—and particularly its poor—need from the biomedical sector. Overcoming the disparities between industrialized and developing countries sometimes seems like a Sisyphean challenge, but strategic steps taken by the public and philanthropic sector can help create an environment that enables both North and South to work together towards improved innovation and greater access to health technologies.

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