



BCM



Baylor College of Medicine

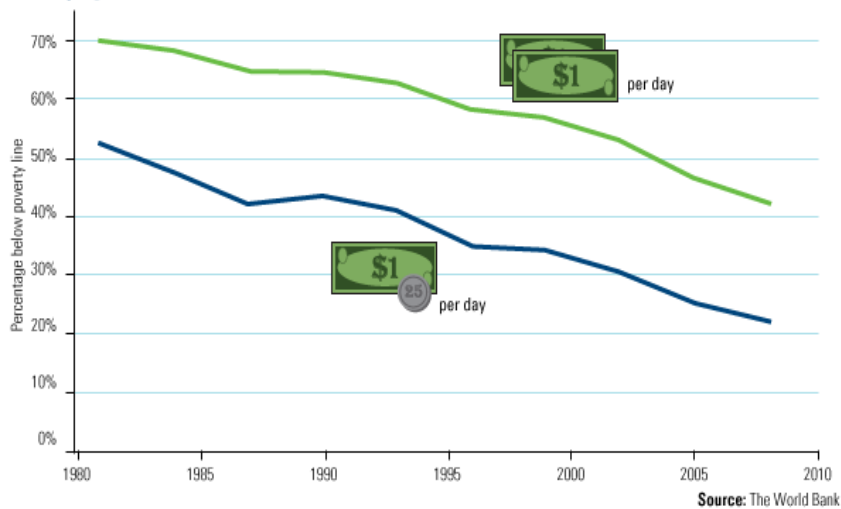


“BLUE MARBLE HEALTH”

Peter Hotez, MD PhD

“The Bottom Billion”

Developing World Never Been Richer



- 1.29 billion today live less than \$1.25 per day (22%)
- Just over 40% live on less than \$2 per day

“The Colors of Poverty”

www.ejordanphotography.com

The Neglected Tropical Diseases

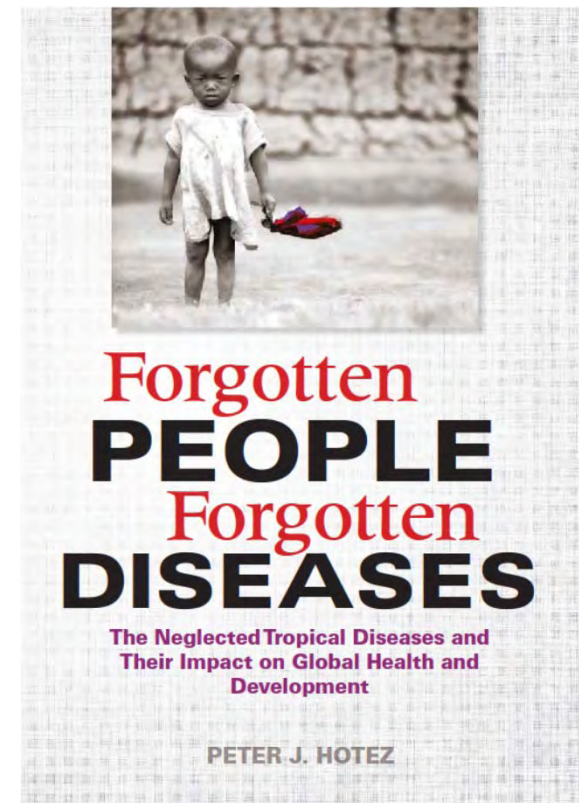
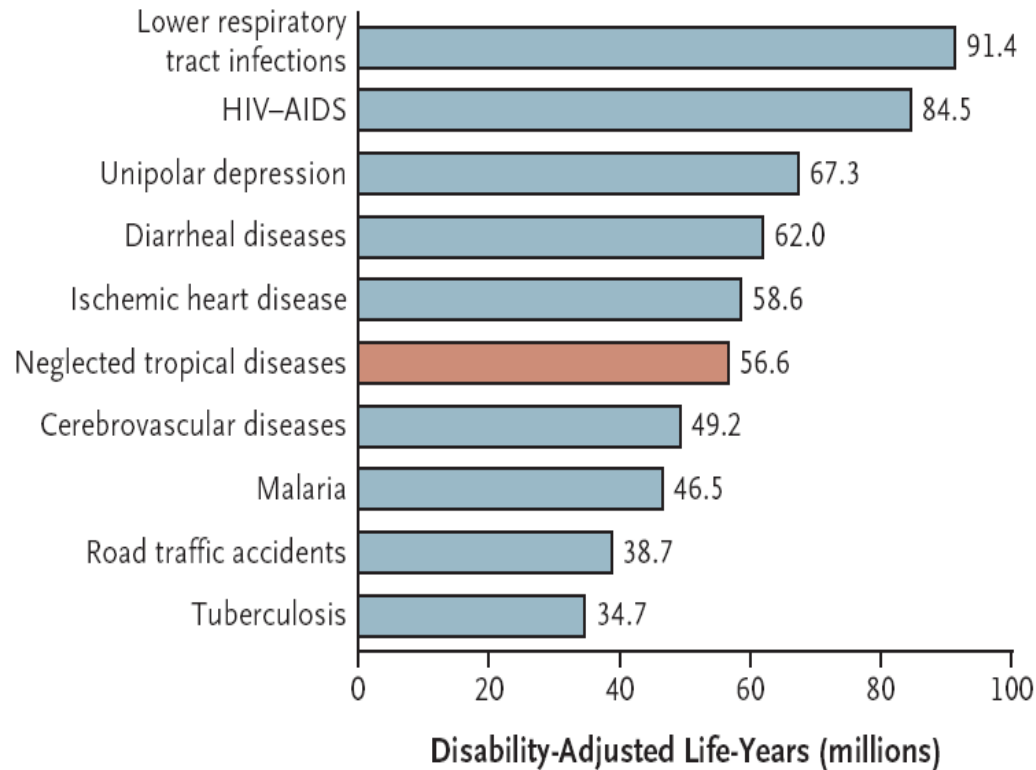
The 17 “NTDs” Most common infections of the “bottom billion”

• Ascariasis	800 million
• Hookworm	700 million
• Trichuriasis	600 million
• Schistosomiasis	400 million
• Lymphatic Filariasis	100 million
• Food-borne Trematodes	50 million
• Dengue	50 million
• Onchocerciasis	20 million
• Trachoma	20 million
• Leishmaniasis	10 million
• Chagas disease	10 million
• Buruli ulcer	< 1 million
• Leprosy	< 1 million
• African Sleeping Sickness	< 1 million
• Rabies	< 1 million



“The Biblical Diseases”

The NTDs : The World's Disablers



Hotez PJ et al. N Engl J Med 2007

NTDs & Poverty



NTDs
PROMOTE
 POVERTY



*The 17 NTDs
 Chronic & Disabling Conditions*

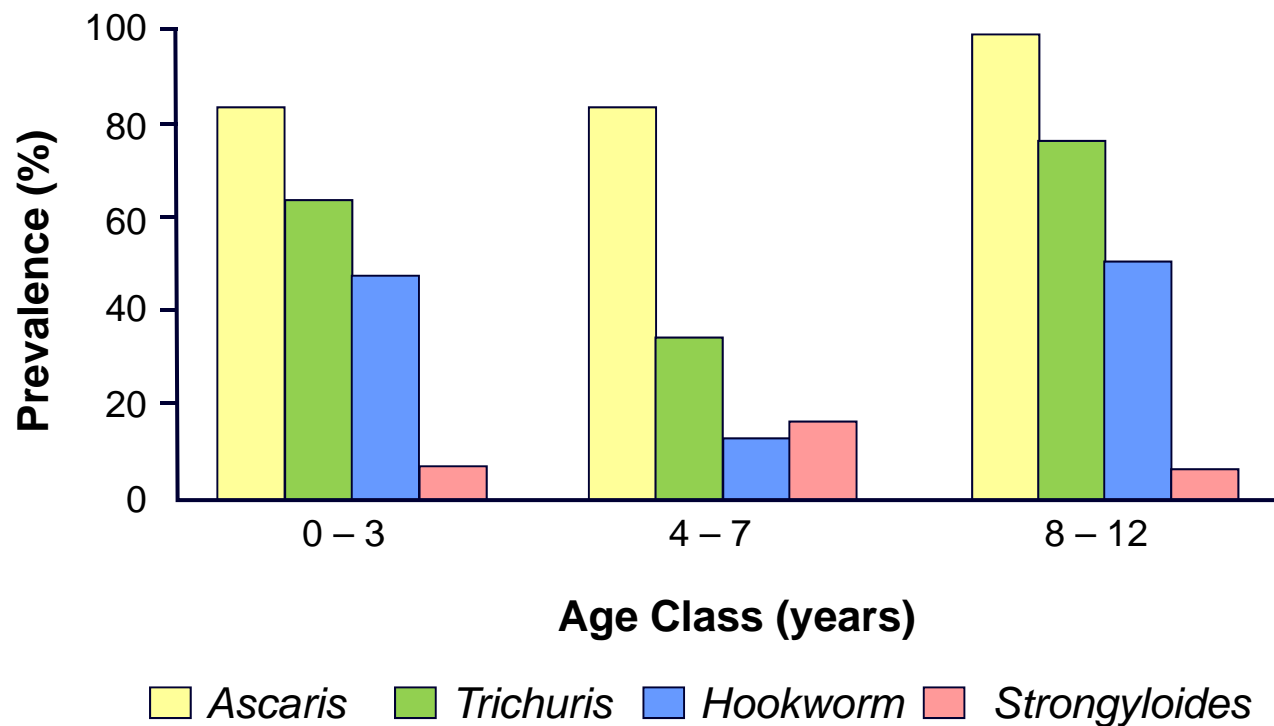
- Reduce productive capacity
- Impair intellectual & physical development in children
- Cause adverse pregnancy outcomes

Property of the Global Network 

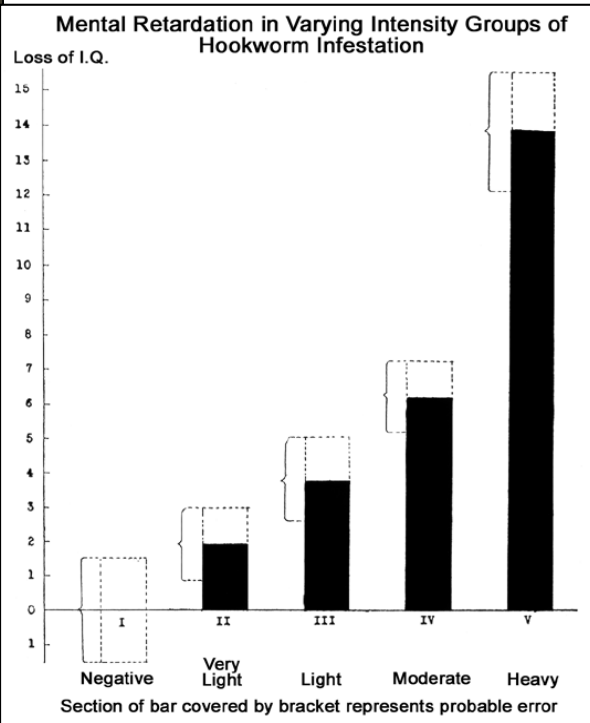
Hotez PJ, Fenwick A, Savioli L Molyneux DH. Rescuing the bottom billion through control of neglected tropical diseases. *Lancet* 2009; 373: 1570-6

The Most Widespread NTDs: Ascariasis, Trichuriasis, Hookworm

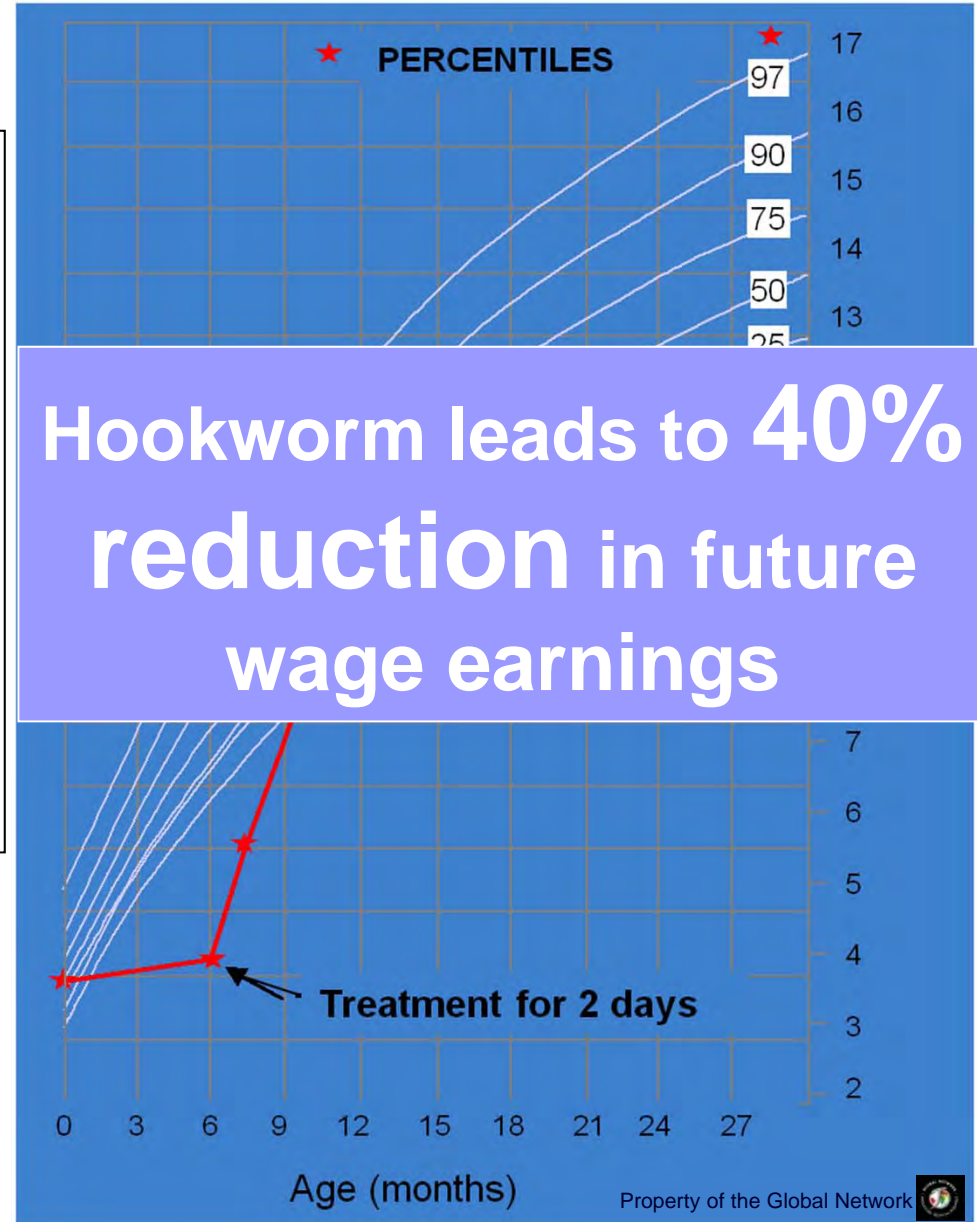
Village of Paquila, Guatemala



Hookworm and Ascariasis

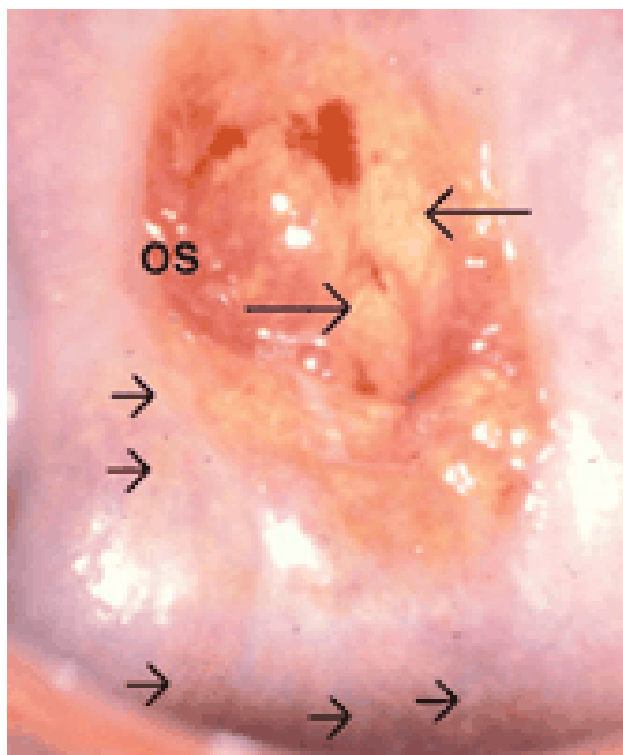


**Child growth,
Intellectual
Cognitive
development**



BCM Female Genital Schistosomiasis, Girls, & HIV/AIDS

Baylor College of Medicine



100 million girls & women

Africa's most common gynecologic condition?



Zimbabwe

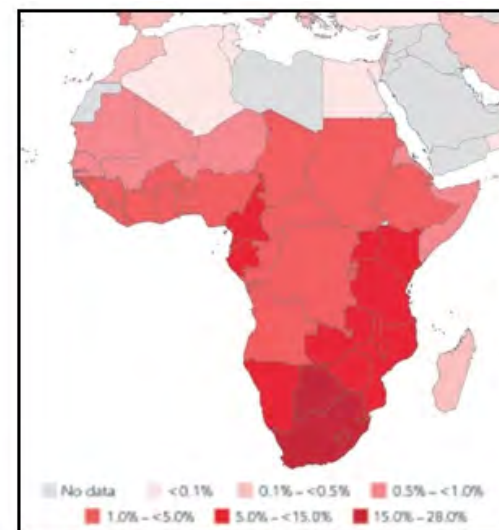
OR = 3 increase in HIV/AIDS
Kjetland et al. AIDS 2006

Tanzania

OR = 4 increase in HIV/AIDS
Downs et al. AJTMH 2011



Urogenital Schistosomiasis
King C, 2001



HIV Prevalence in Adults Aged 15-49
UNAIDS, 2010

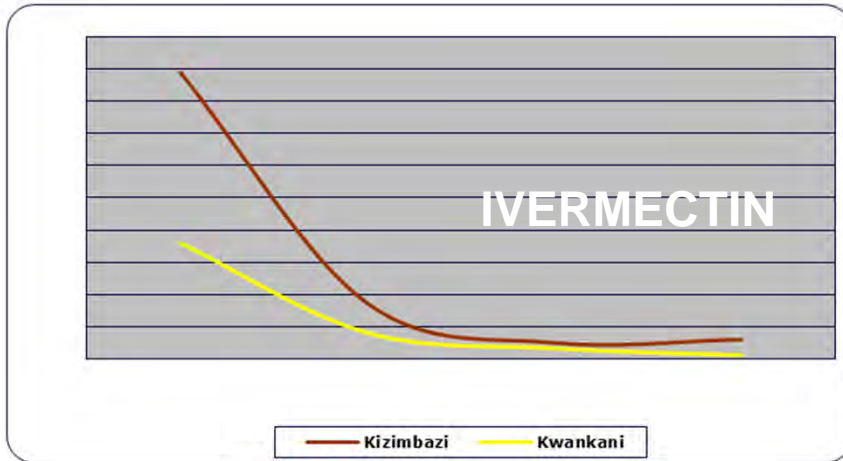
The Beginning of NTD Control



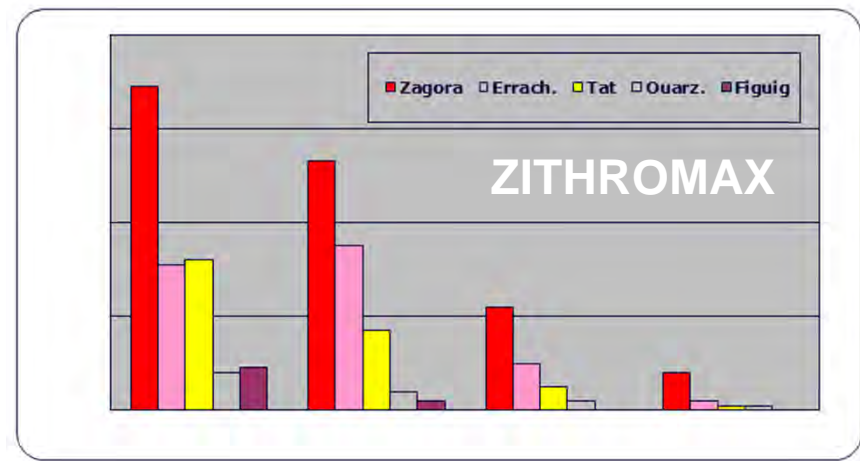
Hawking and Mao: The Pioneers of “Preventive Chemotherapy” (MDA)

Hotez PJ. Forgotten People, Forgotten Diseases ASM Press,

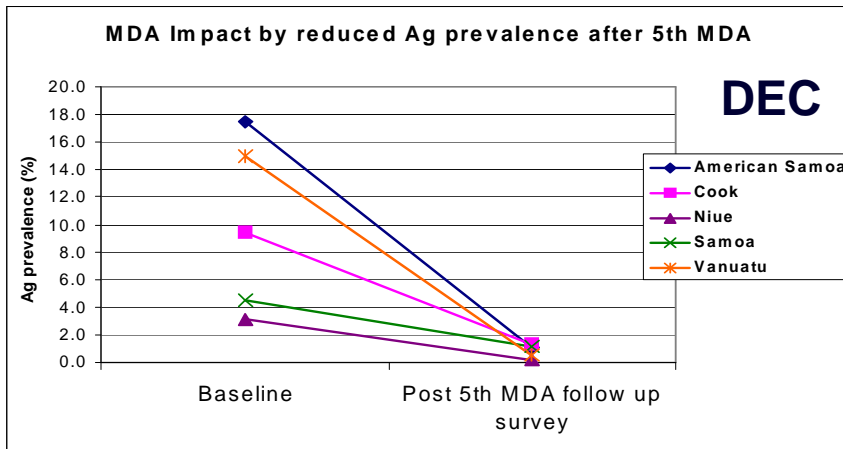
“Franchising Preventive Chemotherapy”



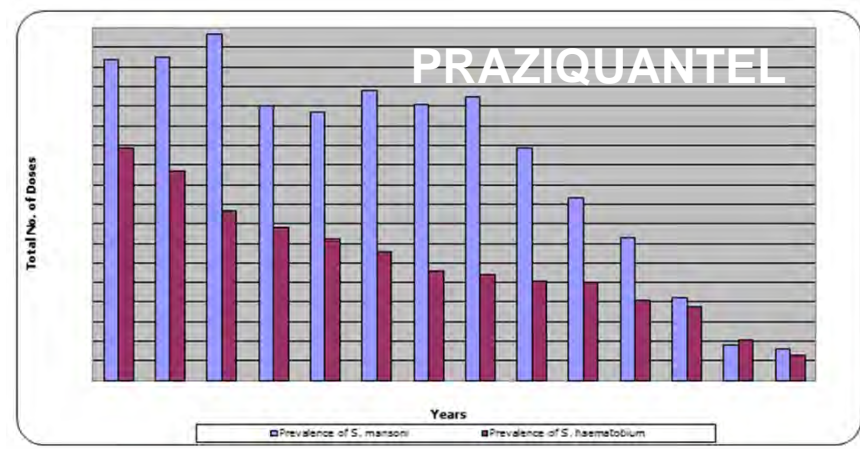
Lymphatic filariasis - Zanzibar



Trachoma - Morocco



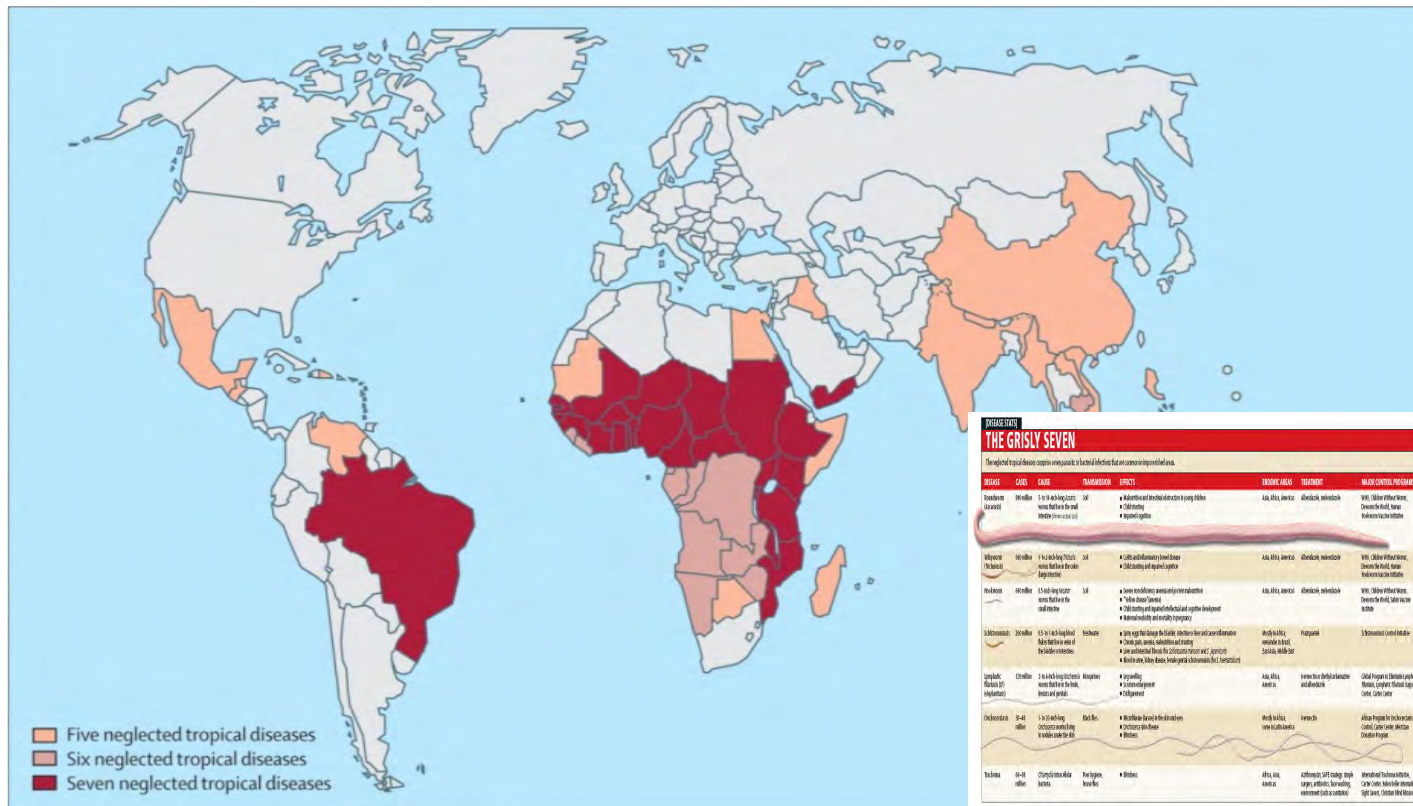
Lymphatic filariasis – South Pacific



Schistosomiasis - Egypt

The Bottom Billion Suffers from Multiple NTDs!

Ascariasis, Trichuriasis, Hookworm, Schistosomiasis, LF, Onchocerciasis, Trachoma, Food-borne Trematodes



The Rapid Impact Package

US \$0.50
all inclusive

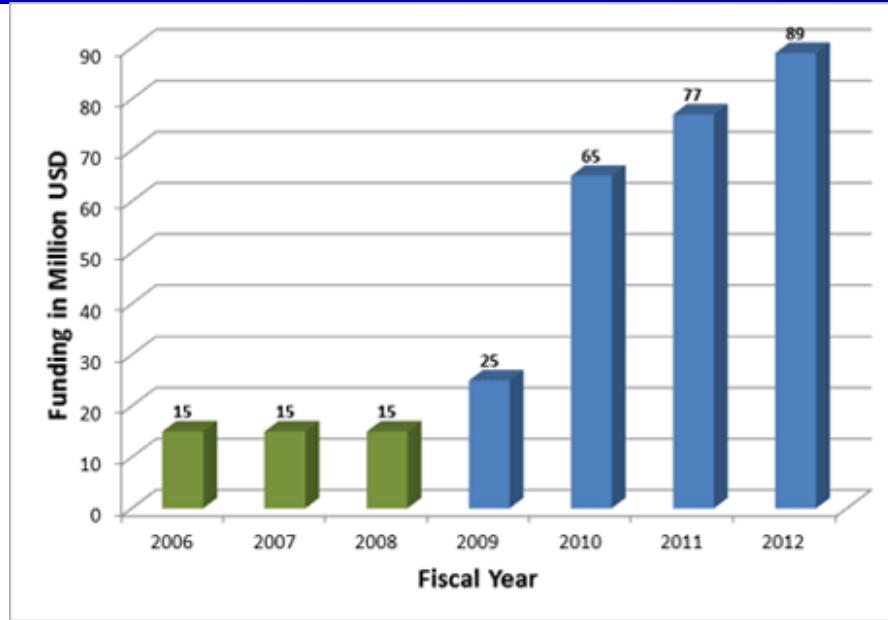
DRUGS

- + Delivery
- + Equipment
- + Health education materials
- + Training of personnel
- + Monitoring and Evaluation

US \$0.50 per person per year

NTD Scale up with the U.S. Government





Today, only 36% of the world's bottom billion who require Preventive Chemotherapy actually receive it

Total reliance of the public support from the governments of the US and UK



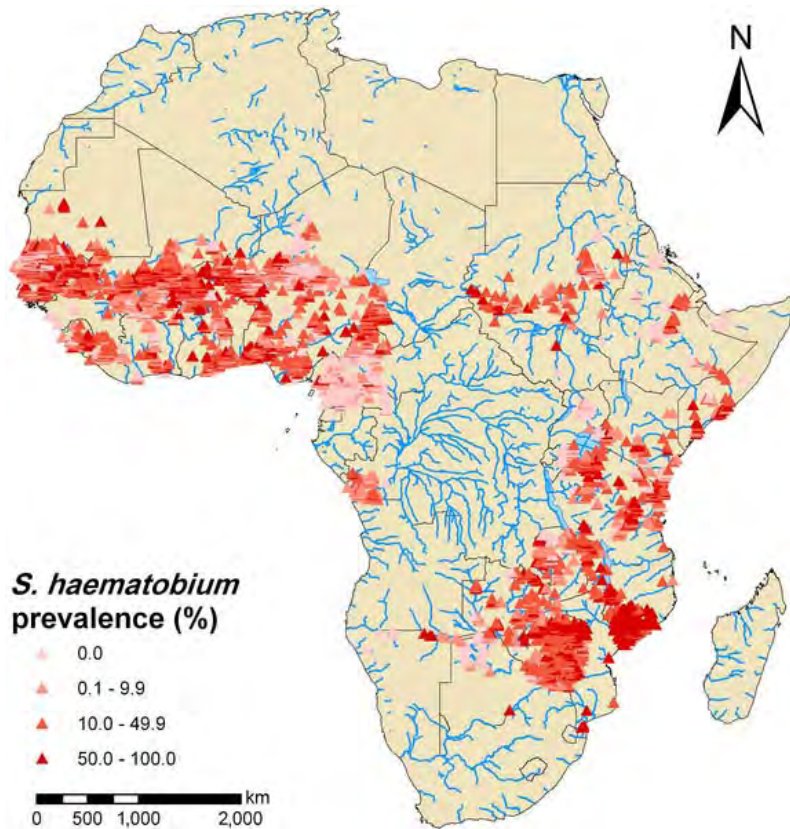
USAID
FROM THE AMERICAN PEOPLE



We're relying completely on US and UK and some private support to eliminate LF, Onchocerciasis Trachoma, Leprosy



The Technical Gaps



Global Helminth Atlas: www.thiswormyworld.org
 Swiss Tropical and Public Health Institute

PERSPECTIVE

The proposed rule reflects a strong commitment to tying the quality of care to financial rewards. ACOs must report their results on 65 quality measures, grouped into five domains — patient and caregiver experience, care coordination, patient safety, preventive health, and health of at-risk and frail/elderly populations. Although claims data can provide information on some of these measures, ACOs will have to obtain information on others from medical records or surveys — a highly expensive proposition, at least for some. CMS needs to focus on “value” in quality measurement as well as in care. The agency has made it clear that quality measurement will evolve over the life of ACO contracts, but this proposition increases the degree of risk for ACOs; it would be better for CMS to commit to stability over the duration of a contract. After all, there will be additional contracts down the road that can incorporate advances in quality measurement.

The other side of the coin, however, is a real risk that the bar is set so high that too few ACOs will apply. Noting the sub-

stantial investments ACOs to improve some have prospects for a return small and that have been too large to generate large savings in essence, in short-term value-driven care, and get needed infrastructure for improvement than getting the fee-for-service system. It may be better to spend now in order to save later and avoid the consequences of the inevitable ratcheting down of fee-for-service rates.

Clearly, much is at stake. As the country's single largest purchaser of care, Medicare has the potential to push care delivery in a new direction. Interest in ACOs is so high that many would-be ACOs probably aren't ready for prime time. CMS is right to set the bar relatively high to keep its management chal-



1. Centers for Medicare and Medicaid Services. Summary of proposed rule provisions for accountable care organizations under the Medicare shared savings program: fact sheet 2011. (http://www.cms.gov/MLNProducts/downloads/ACO_NPDM_Summary_Factsheet_ICN906224.pdf)
 2. Medicare shared savings program: accountable care organizations and Medicare program: waiver designs in connection with the Medicare shared savings program and the innovation center; proposed rule and notice. Fed Regist 2011;76:19528-654. (<http://edocket.access.gpo.gov/2011/pdf/2011-7880.pdf>)
 3. Haywood TT, Kosal KC. The ACO model — a three-year financial loss? *N Engl J Med* 2011;364(14):e27. (Available at www.nejm.org)
- Copyright © 2012 Massachusetts Medical Society.

Integrating Neglected Tropical Diseases into AIDS, Tuberculosis, and Malaria Control

Peter J. Hotez, M.D., Ph.D., Neeraj Mistry, M.D., M.P.H., Joanna Rubinstein, D.D.S., Ph.D., and Jeffrey D. Sachs, Ph.D.

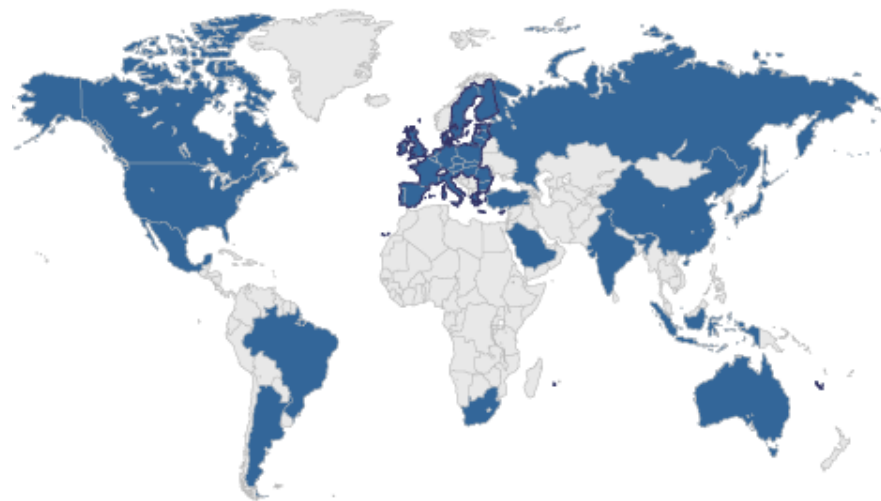
Today, approximately 1.4 billion people in the world live in extreme poverty, with incomes so low that they cannot fill their basic needs. In 2000, when eight Millennium Development Goals (MDGs) were set to guide efforts to combat various dimensions of extreme poverty, a specific call

was made in the sixth MDG “to combat HIV/AIDS, malaria, and other diseases.” In response, new financing and delivery mechanisms for disease control were introduced through the Global Fund to Fight AIDS, Tuberculosis, and Malaria, as well as the U.S. President's Malaria Initiative (PMI)

and the President's Emergency Plan for AIDS Relief (PEPFAR). To date, approximately \$20 billion has been committed to the Global Fund, \$32 billion to PEPFAR, and \$1 billion to PMI. Many billions of additional dollars are promised through 2014. This level of support for antiretroviral drugs,

Most of the NTDs Occur among the Poor in Wealthy (G20) Countries!!

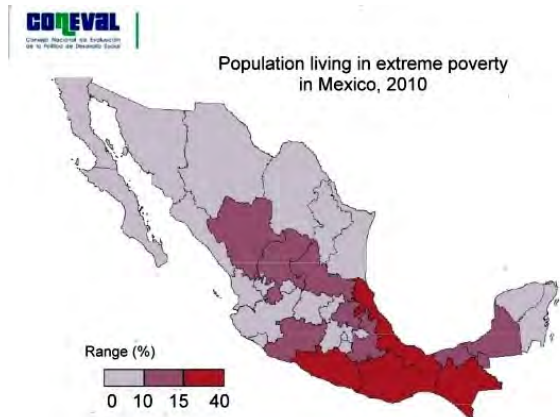
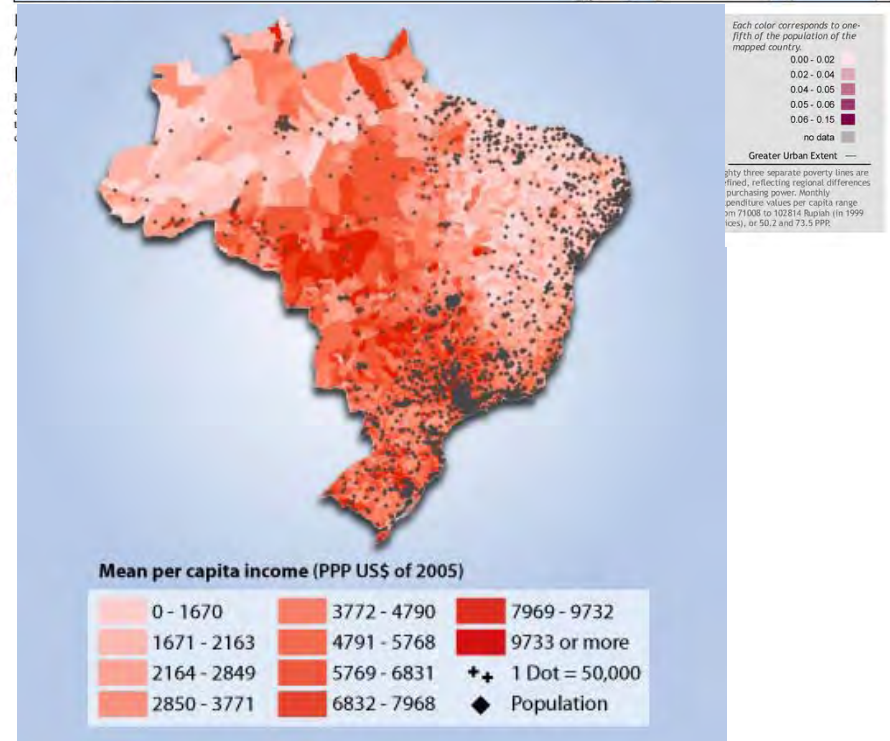
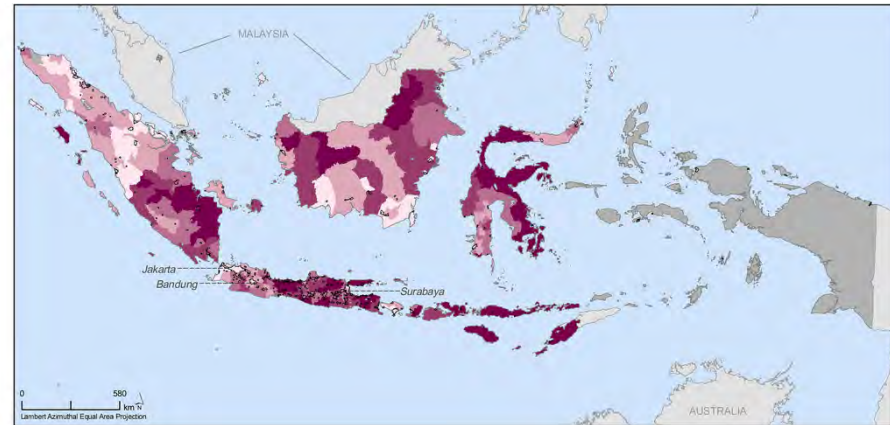
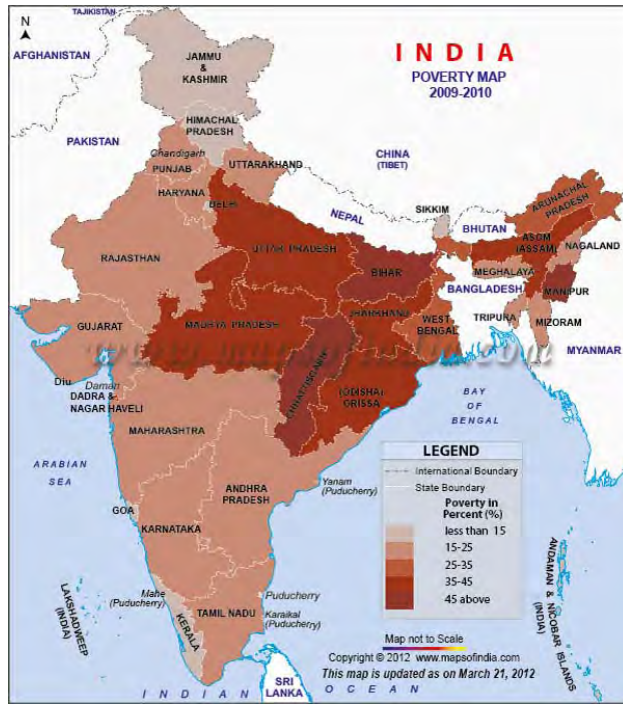
- NTDs in the G20 (+ Nigeria)
 - 77% Leprosy
 - 71% Food-borne trematodiasis
 - 67% Leishmaniasis
 - 61% Chagas disease
 - 60% Lymphatic filariasis
 - 43% Hookworm
 - 17% Schistosomiasis



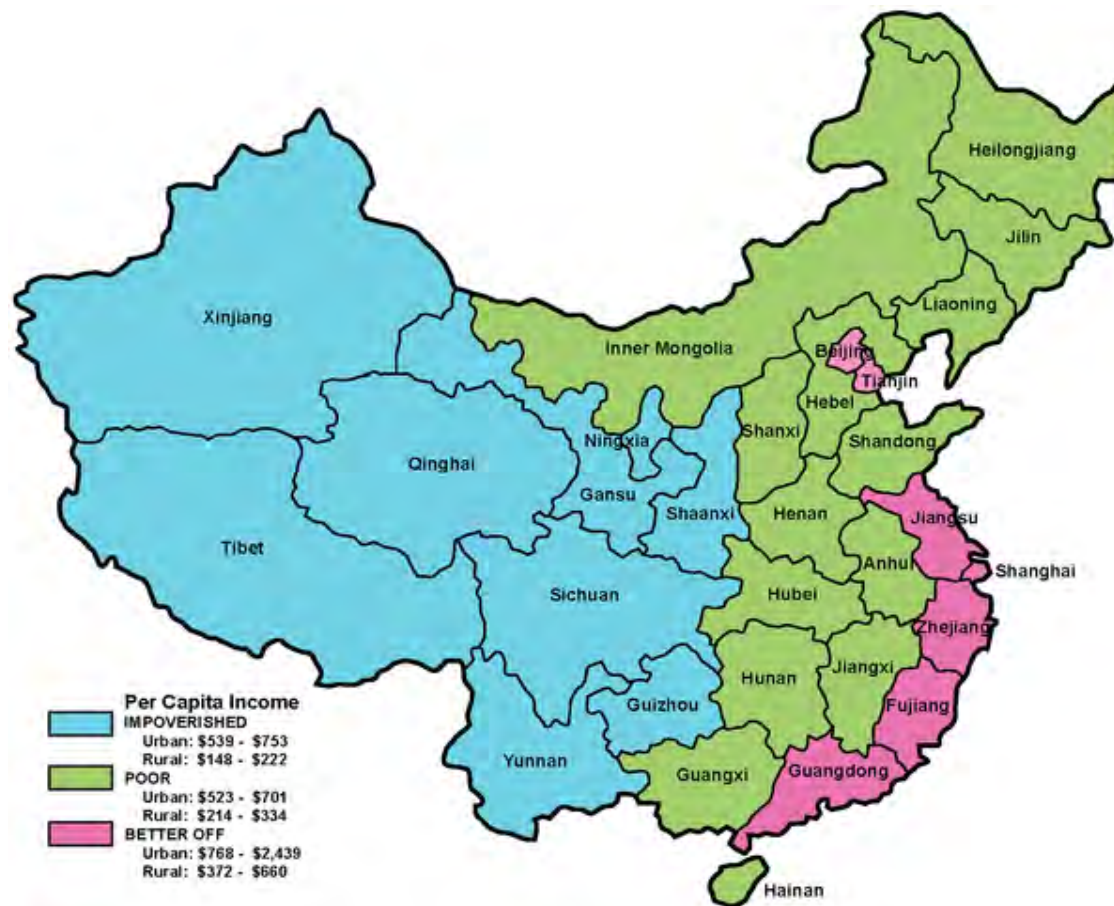
58% of the “bottom billion”
in G20 countries

G20 countries provide 75%
of the global economy

Most of the NTDs Occur among the Poor in Wealthy (G20) Countries!!



Poverty in China



Widespread
Hookworm
and other NTDs
In SW China

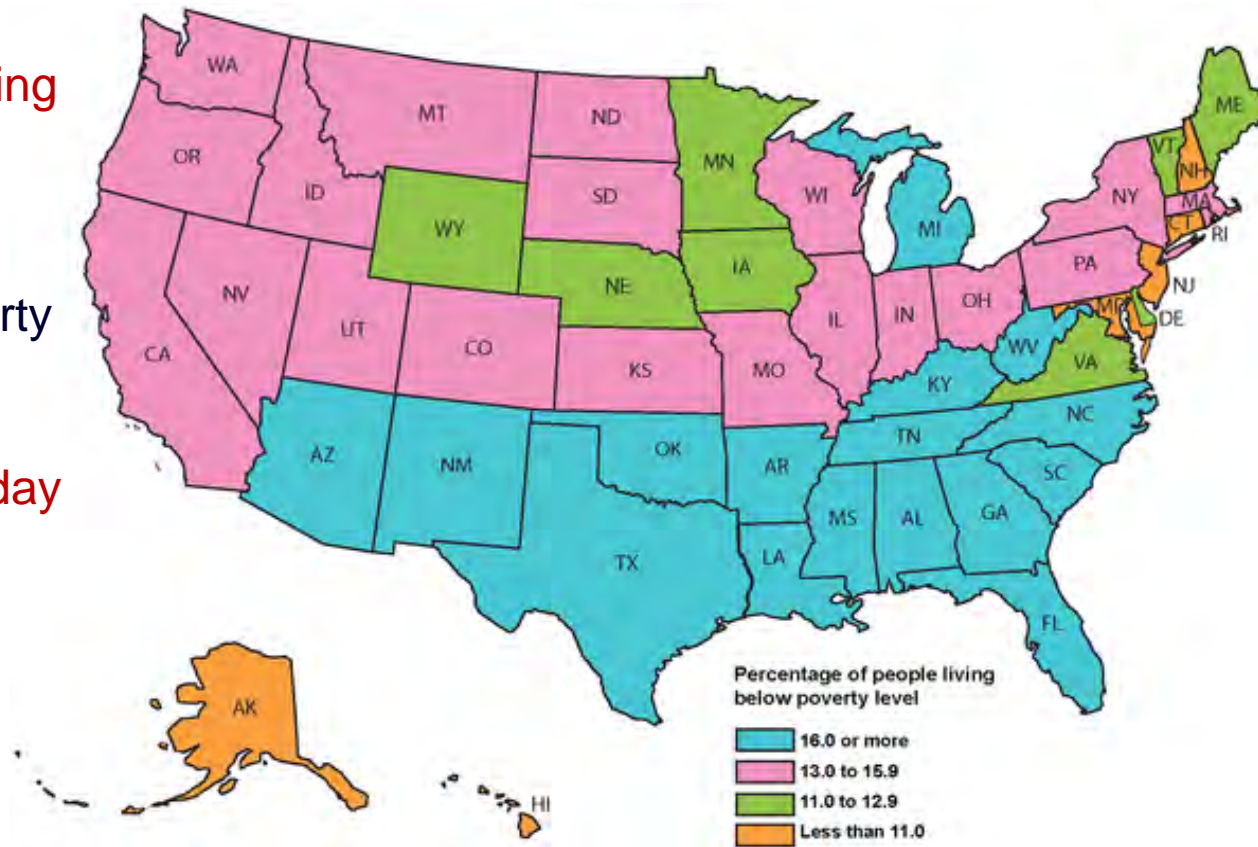
Hotez PJ (2012) Engaging a Rising China through Neglected Tropical Diseases. *PLoS Negl Trop Dis* 6(11): e1599.
doi:10.1371/journal.pntd.0001599
<http://www.plosntd.org/article/info:doi/10.1371/journal.pntd.0001599>

Poverty in the United States

46 million
Americans living
poverty

20 million in
extreme poverty

4-5 million on
less <\$2 per day



Hotez PJ (2012) Engaging a Rising China through Neglected Tropical Diseases. PLoS Negl Trop Dis 6(11): e1599.

doi:10.1371/journal.pntd.0001599

<http://www.plosntd.org/article/info:doi/10.1371/journal.pntd.0001599>

“Blue Marble Health”

- No longer developed vs. developing
- Unexpected NTD Disease Burden from the G20 Nations
- G20 share a level of economic wealth that make it possible to treat all of the bottom billion people who need MDA
- Eliminate Lymphatic Filariasis, Onchocerciasis, Trachoma, Leprosy, and Food-borne trematodes



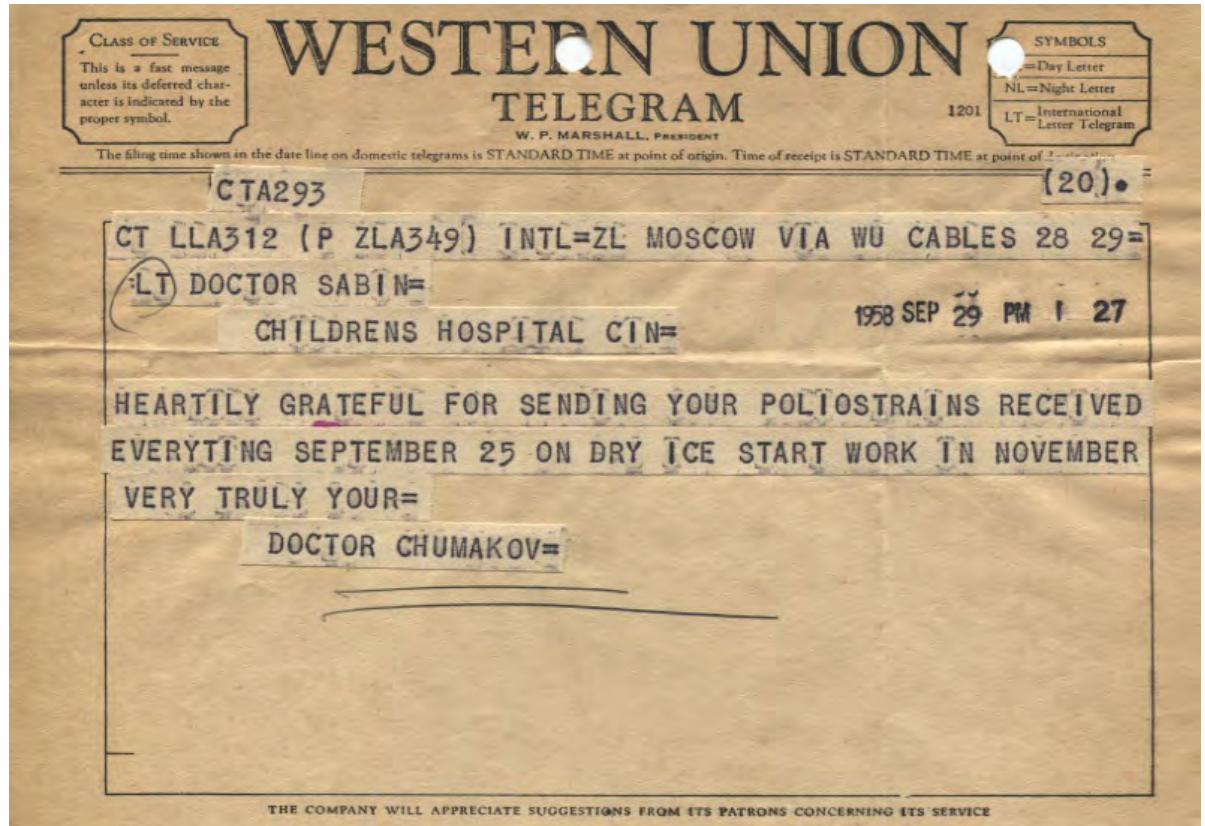
Blue Marble photographed by Eugene Cernan, Ron Evans, and Jack Schmidt
Apollo 17, December 7, 1972

Science Diplomacy

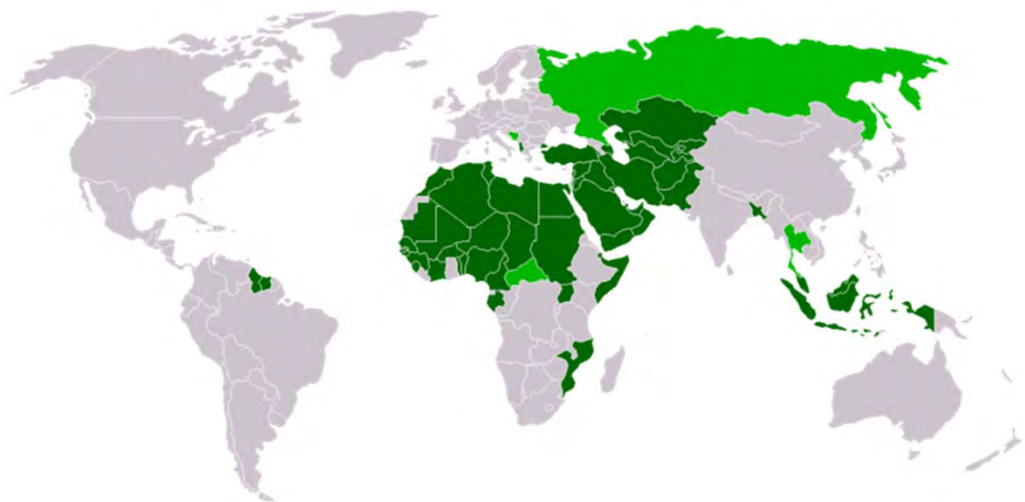
- Extraordinary opportunity for science diplomacy
- For most of the remaining NTDs we need new control tools
 - Drugs
 - Diagnostic
 - Vaccines
- Incredible scientific horsepower among the G20: India, China, Saudi Arabia, South Africa, Indonesia, in addition to the U.S. and Europe



Origins of Vaccine Diplomacy

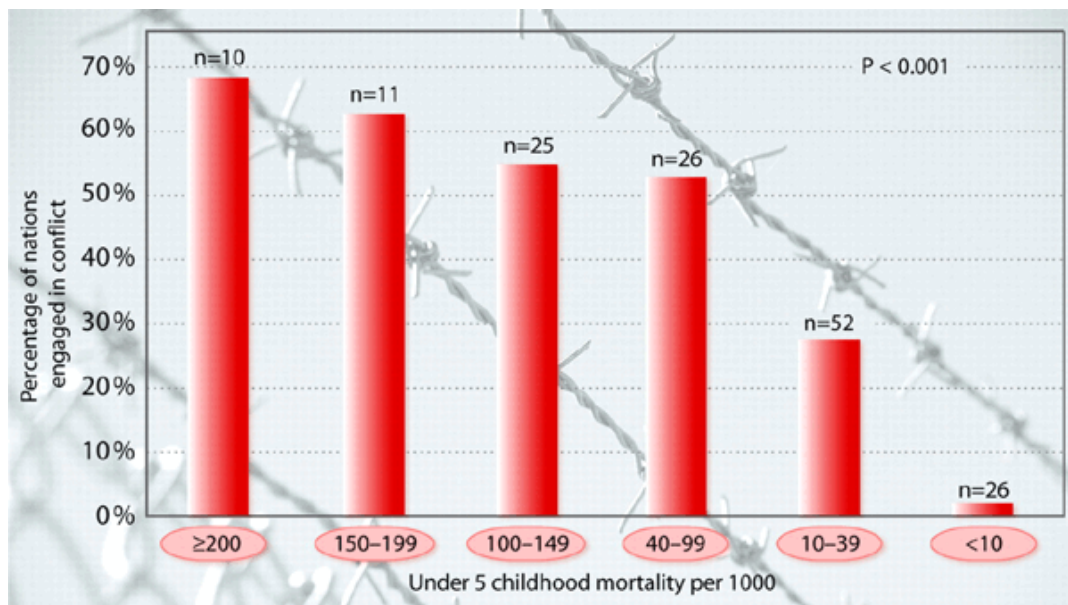


Modern Day Vaccine Diplomacy



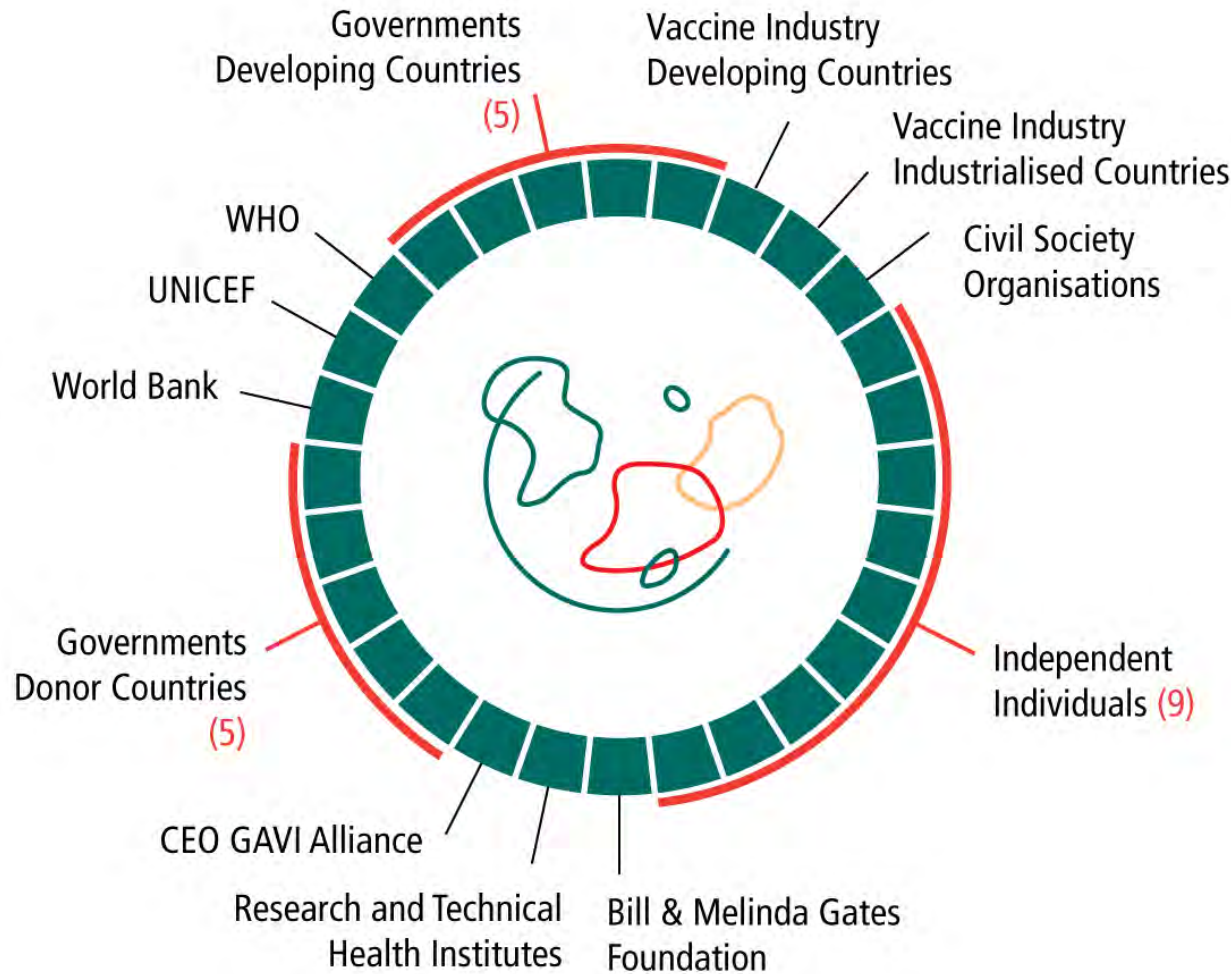
Organization of the Islamic Conference

Approximately one-third of NTDs in OIC countries
Pakistan, Iran, Indonesia, Gulf Oil States



“Conflict And Contagion”

The Decade of Vaccines and the GAVI Alliance



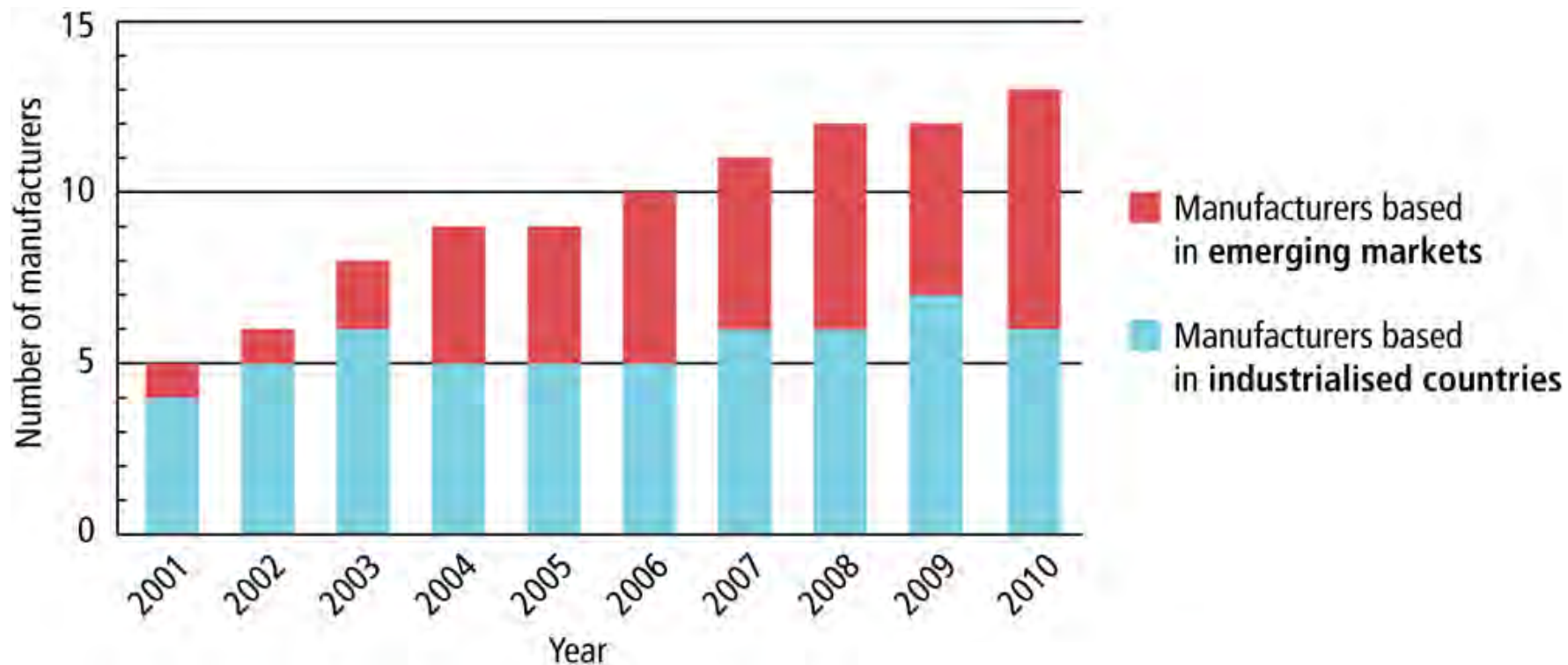
Accelerate uptake of new vaccines

Shape & increase predictability of vaccine markets



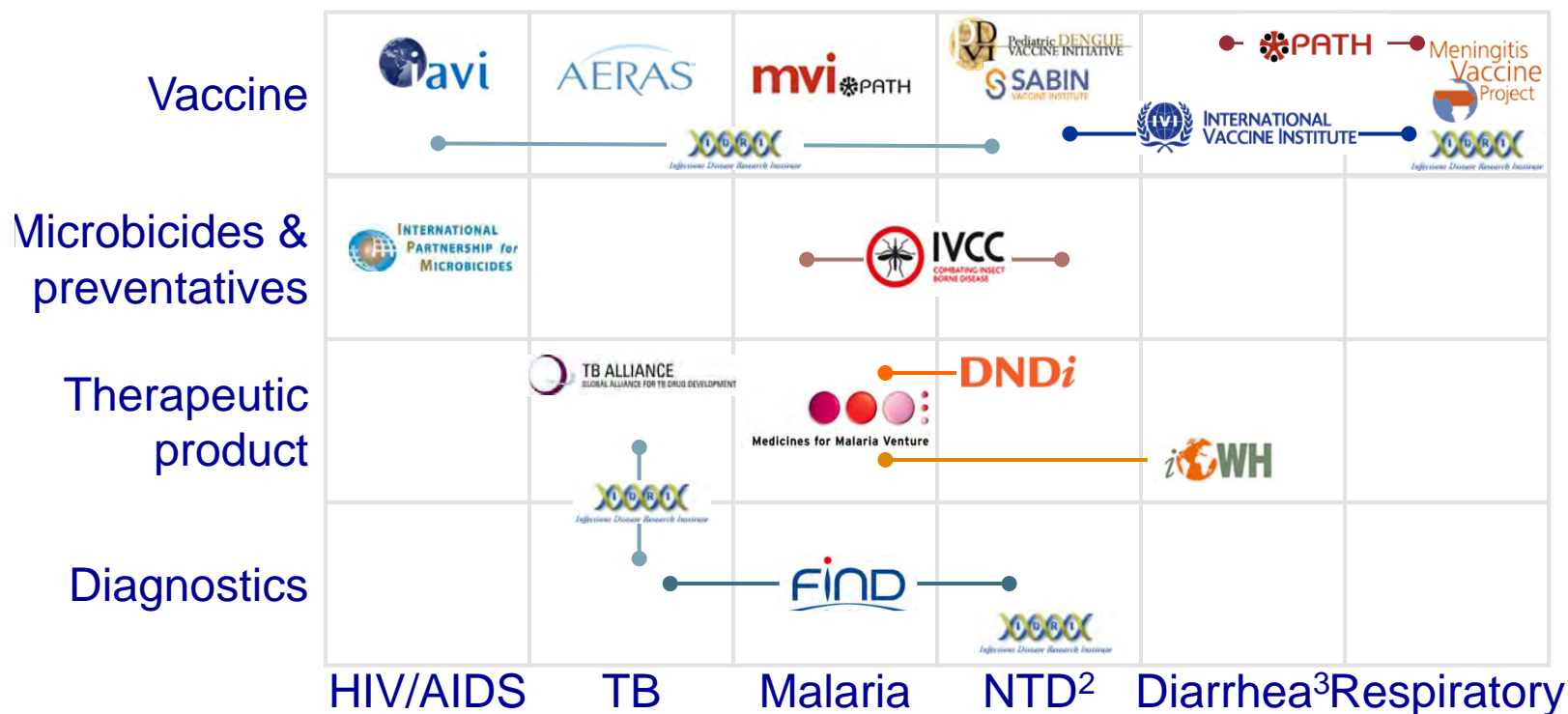
www.gavialliance.org

Increasing Number of GAVI Vaccine Suppliers based in Emerging Markets



Source: UNICEF Supply Division, 2011

PDPs Work across Different Diseases and Modalities



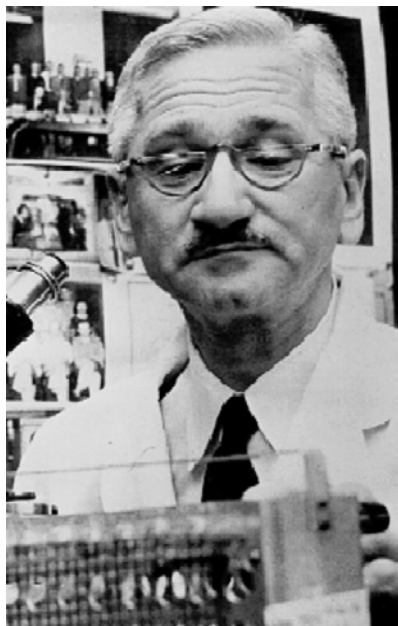
Aeras: Aeras Global TB Vaccine Foundation
DNDi: Drugs for Neglected Diseases Initiative
FIND: Foundation for Innovative New Diagnostics
GATB: Global Alliance for TB Drug Development
Sabin/HHVI: Human Hookworm Vaccine Initiative
IAVI: International AIDS Vaccine Initiative
IDRI: Infectious Disease Research Institute
IOWH: Institute for One World Health

IPM: International Partnership for Microbicides
IVCC: Innovative Vector Control Consortium
IVI: International Vaccine Institute
MMV: Medicine for Malaria Venture
MVI: Malaria Vaccine Initiative (PATH)
MVP: Meningitis Vaccine Program (PATH)
PDVI: Pediatric Dengue Vaccine Initiative
PATH VAC: PATH's Vaccine Development Program

1. PVS includes Rota Vaccine Program (RVP), Pneumo Vaccine Project (PVP), Enteric Vaccine Initiative (EVI), Influenza Vaccine Development Program (IVDP)
 2. Includes HAT, visceral leishmaniasis, chagas, hookworm, and dengue 3. Includes cholera, typhoid, and rotavirus
 Sources: Combating Diseases Associated with Poverty, FSG, Nov 2004, Health partnership Review, Global Forum for Health Research, May 2008

“A scientist who is also a human being cannot rest while knowledge which might reduce suffering rests on the shelf.”

–Dr. Albert B. Sabin



FIGHTING CRITICAL DISEASES

By Peter Hotez

A Handful Of 'Antipoverty' Vaccines Exist For Neglected Diseases, But The World's Poorest Billion People Need More

DOI: 10.1093/heap/haa028
HEALTH AFFAIRS 30,
NO. 4 (2011): 1080-1087
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The American People's Health
Foundation, Inc.

Peter Hotez (peter.hotez@sabin.org) is president of the Sabin Vaccine Institute, in Washington, D.C., and Houston, Texas.

ABSTRACT So-called neglected tropical diseases are the most common infections of the world's poor. Almost all of the "bottom billion"—the 1.4 billion people who live below the poverty level defined by the World Bank—suffer from one or more neglected diseases including hookworm infection, sleeping sickness, or Chagas disease. These diseases are actually a cause of poverty because of their adverse effects on child growth and development and worker productivity. Vaccines to combat such diseases have come to be known as "antipoverty vaccines." Unfortunately, the recent surge in the development and delivery of vaccines to combat the major childhood killers—such as pneumococcal pneumonia and measles—has bypassed neglected diseases. Nevertheless, some vaccines for these neglected diseases are now entering the clinical pipeline. In this article I describe how some antipoverty vaccine development is proceeding and offer recommendations for stimulating further development such as through pooled funding for innovation, developing-country manufacturers, and public-private partnerships for product development.

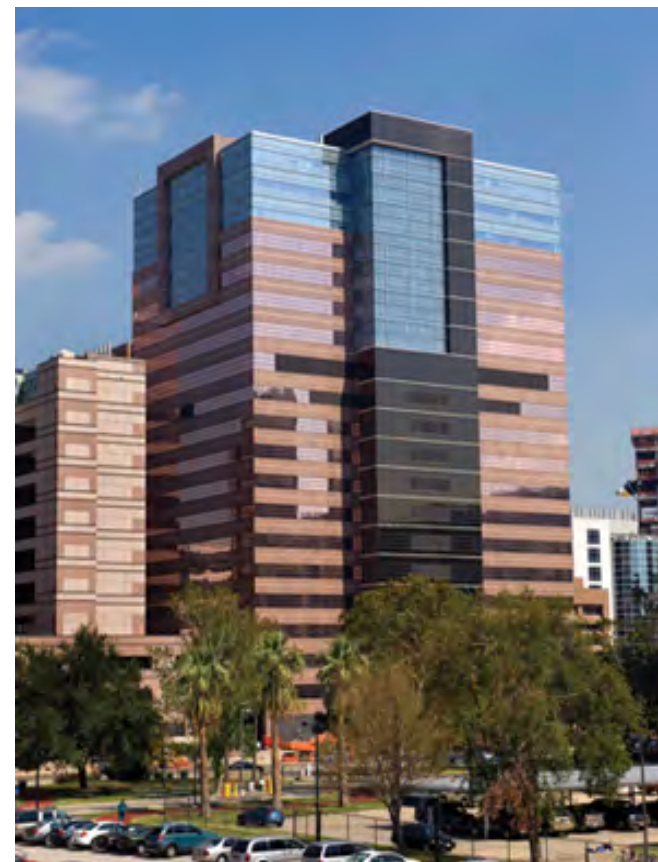
A full year has passed since the launch of the "Decade of Vaccines," which was articulated when the Bill & Melinda Gates Foundation made a ten-year commitment to ensuring the development and delivery of new vaccines for the poorest people living in the world's low- and middle-income countries. Since then, enormous progress has been made in increasing global access to vaccines that combat the great childhood killer diseases such as pneumococcal pneumonia, rotavirus, Haemophilus influenzae type b, and measles.

That progress was made possible through enhanced cooperation between the GAVI Alliance, the multinational pharmaceutical companies, and organizations supported by the Bill & Melinda Gates Foundation such as the Program for Appropriate Technology in Health, known as PATH. New financial incentives including a \$1.5 billion advance market commitment have

also contributed to the progress.¹ Laggard far behind these global efforts against the major killer childhood diseases, are parallel activities to produce and deliver a new generation of vaccines for so-called neglected diseases (these are sometimes known as neglected tropical diseases).² These neglected diseases are the most common infections of the world's poor, and almost all of the "bottom billion"—the 1.4 billion people who live below the poverty level defined by the World Bank—suffer from one or more of the neglected diseases.^{3,4} The World Health Organization now identifies seventeen conditions as "neglected tropical diseases."⁵ The most common neglected diseases are caused by parasitic worms, including hookworm infection, ascariasis (intestinal roundworm), trichuriasis (whipworm), schistosomiasis (bilharzia), lymphatic filariasis (elephantiasis), and onchocerciasis (river blindness); by parasitic protozoa, including Chagas

Sabin Portfolio of Vaccines

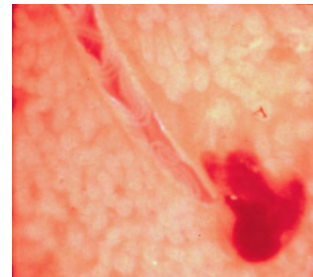
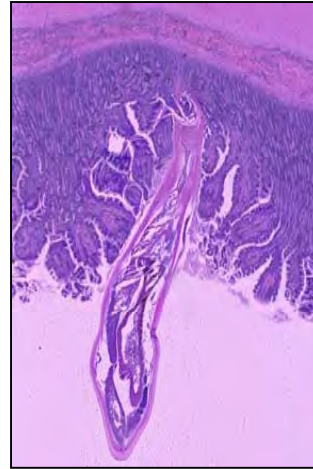
- Human Hookworm Vaccine
 - Bivalent recom protein vaccine
 - Na-GST-1 + Na-APR-1
 - Alhydrogel formulation \pm synthetic lipid A
 - IND filing FDA – Phase 1 testing Brazil (FIOCRUZ Biomanguinhos)
- Human Schistosomiasis Vaccine
 - Monovalent recombinant protein vaccine
 - Sm-TSP-2
 - Alhydrogel formulation \pm synthetic lipid A
 - cGMP pilot manufacture Brazil (Instituto Butantan)
- Chagas disease and Leishmaniasis Vaccines
 - Bivalent recombinant protein vaccines
 - Alhydrogel formulation + synthetic lipid A
 - cGMP pilot manufacture Mexico (Birmex)
- SARS vaccines



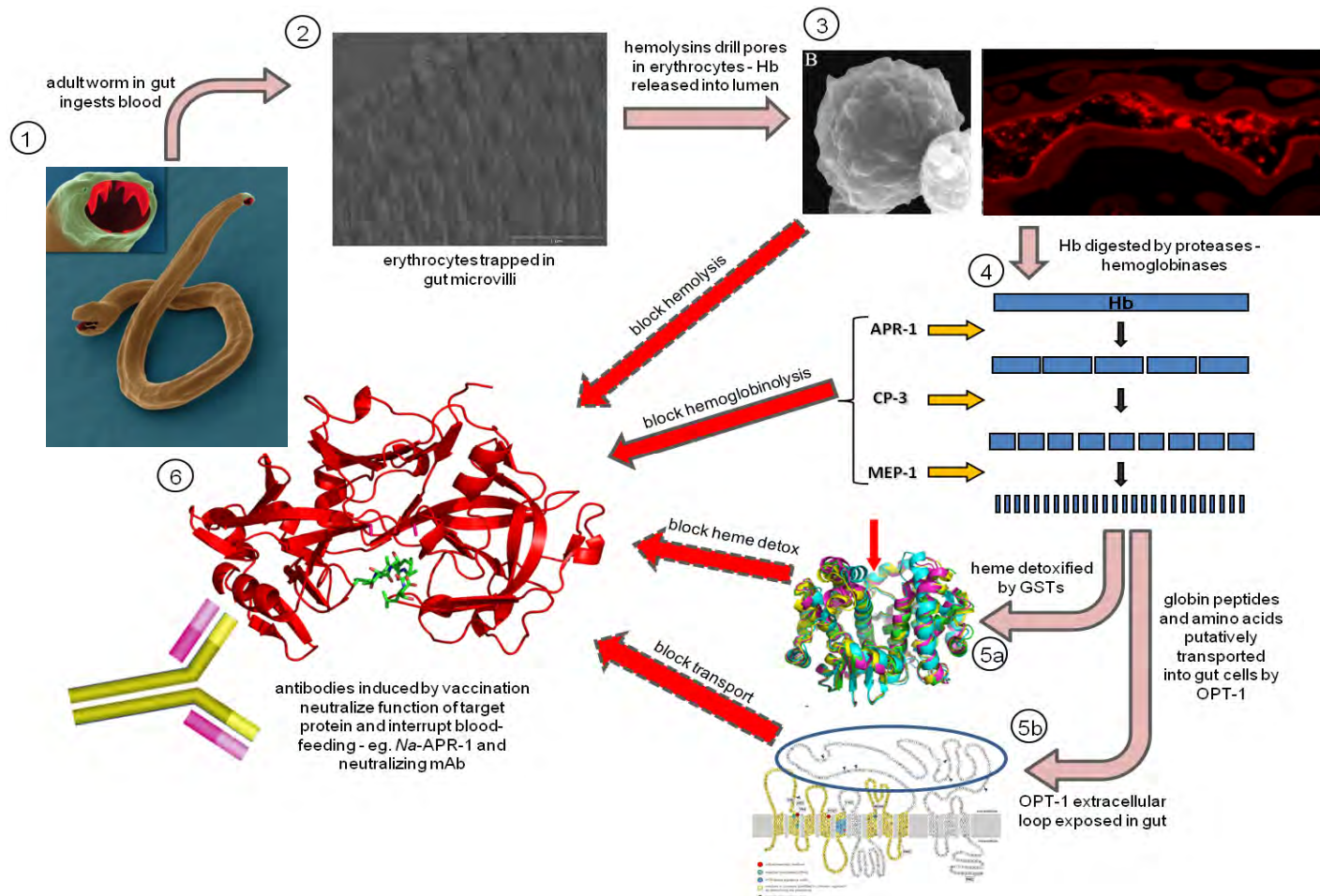
Product Development Methodology



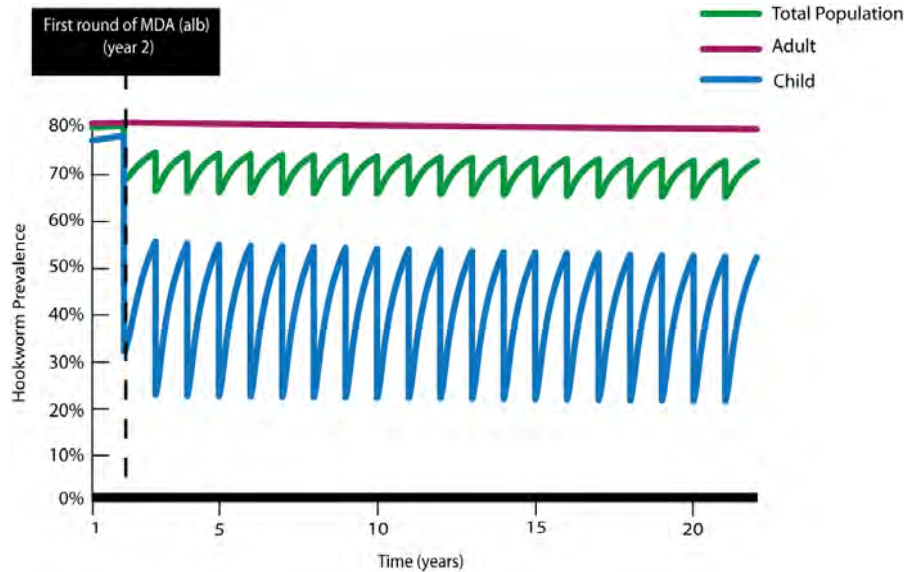
- **Human Hookworm Vaccine**
- **Reduction of 80% of moderate/heavy hookworm infections**
- **Worm burden reduction**
- **Egg reduction**
- **Reduced intestinal blood loss**
- **Reduction in anemia and malnutrition**



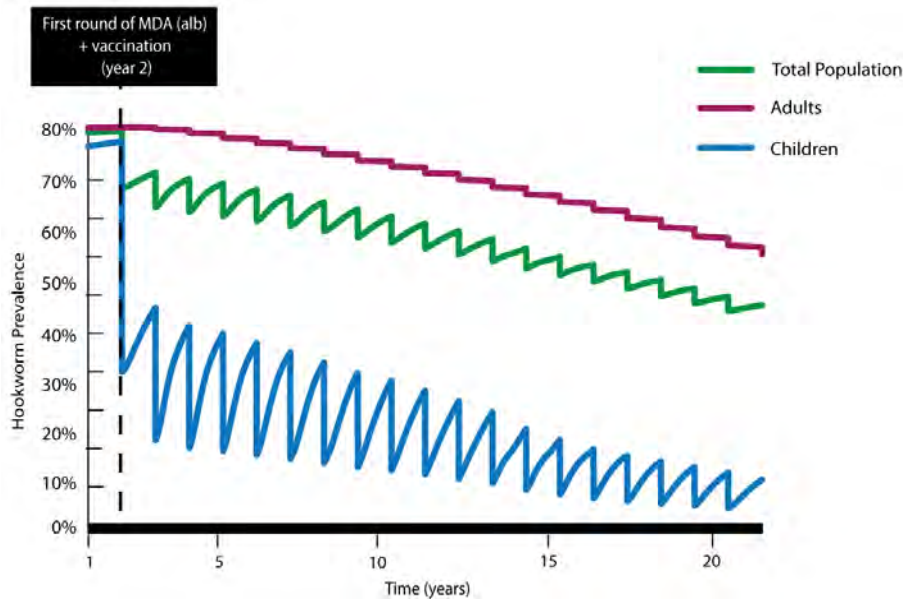
Anti-Enzyme Antibodies: Targeting Hookworm Blood Loss



Vaccines Can Improve Preventive Chemotherapy



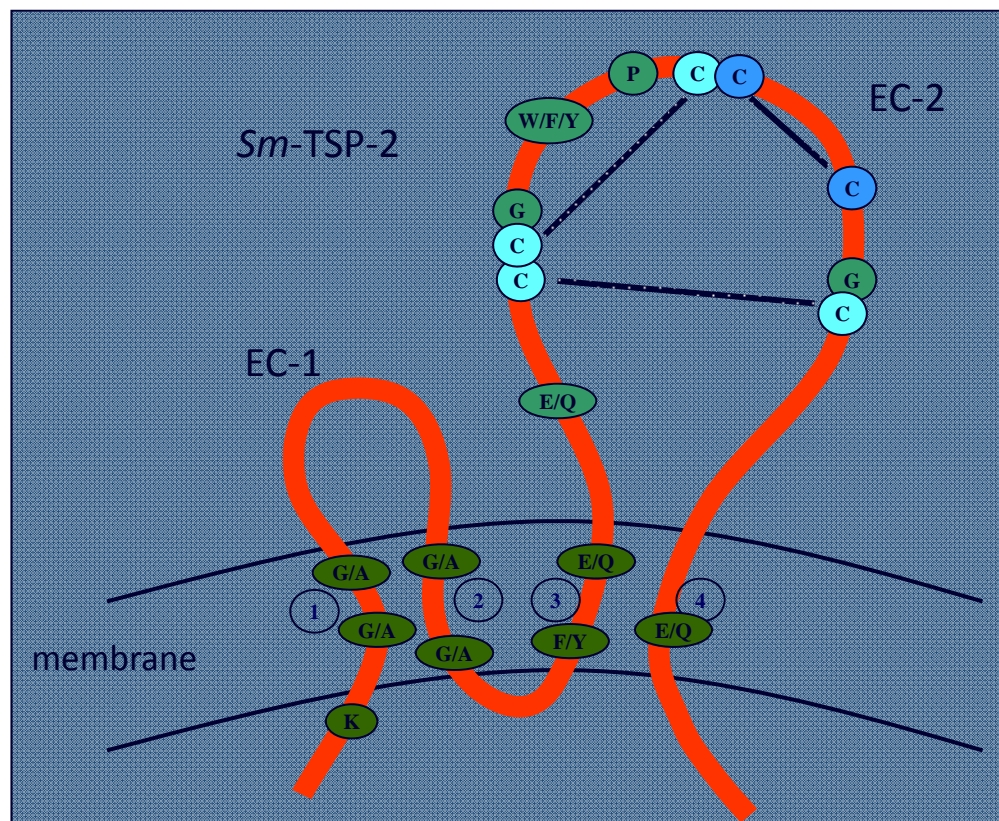
Albendazole
MDA
Alone



Albendazole MDA
+ Vaccinations

B Lee & K. Bacon Univ Pitt

- Buruli Ulcer
- Chagas Disease
- Afr. Trypanosomiasis
- Leishmaniasis
- Leprosy
- Leptospirosis
- Lymphatic Filariasis
- Schistosomiasis**
- Trachoma



The Schistosome Tetraspanin

Hotez PJ, Ferris M. The antipoverty vaccines. *Vaccine* 2006

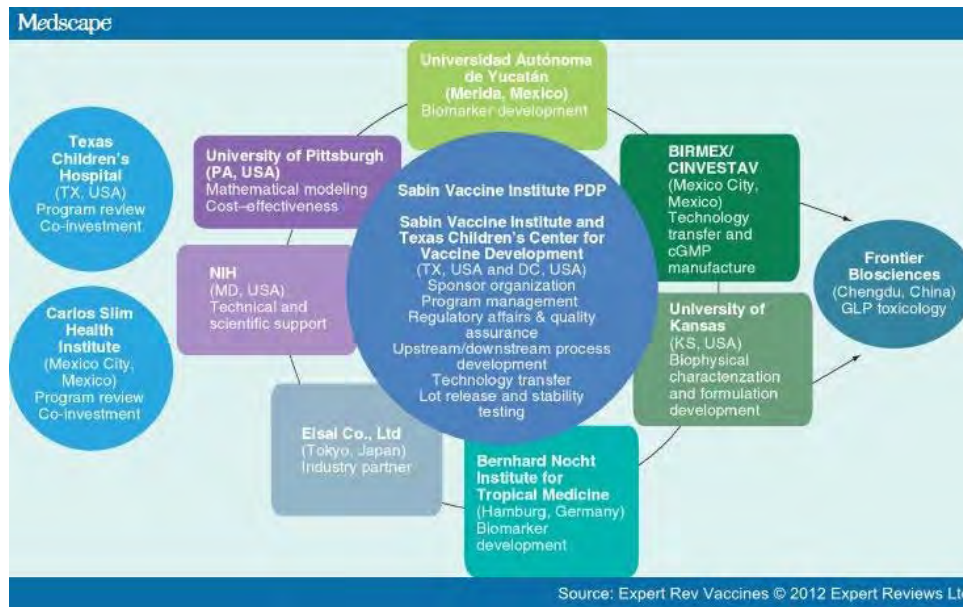
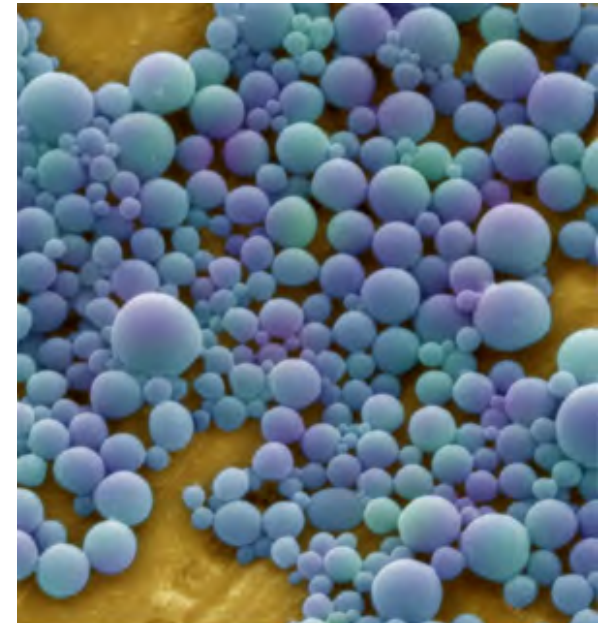
Sabin-Brazil Technology Transfer



- Chagasic cardiomyopathy develops in 20-30% of seroconverted patients
- 10% of pregnancies in Latin America?
- 300,000 seropositive pregnant women
- 40,000 in North America alone
- Maternal-to-child transmission
- 5-10%



Nanoparticle for Chagas Disease Vaccine



Vaccine Diplomacy in the Middle East & Pakistan

- Highest concentration of NTDs in the World's Hotspots
 - 1/3 of NTDs in OIC countries ("the Islamic countries")
 - Up to 25% of NTDs in nuclear countries including Iran, Pakistan
 - 65 million people in poverty in the Middle East
 - Urgency for vaccines against leishmaniasis, dengue, Rift Valley fever, brucellosis,



Eliminating the World's 17 NTDs

- Urgent needs to scale up MDA
- Parallel development of a new generation of NTD control tools
- Drugs
- Diagnostics
- Insecticides
- Vaccines

Vaccine 29S(2011) D104-D110

Contents lists available at ScienceDirect

Vaccine

Journal homepage: www.elsevier.com/locate/vaccine

Enlarging the "Audacious Goal": Elimination of the world's high prevalence neglected tropical diseases

Peter Hotez*

Sabin Vaccine Institute and Department of Pediatrics and Molecular Virology and Microbiology, and National School of Tropical Medicine, Baylor College of Medicine, Houston, TX, United States

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Trichuriasis
Schistosomiasis
Lymphatic filariasis (LF)
Blinding trachoma
Onchocerciasis
Kinetoplastid infections
Leprosy
Elicase
Elimination
Disease eradication

ABSTRACT

The high prevalence neglected tropical diseases (NTDs) exhibit a global disease burden that exceeds malaria, tuberculosis, and other better known global health conditions; they also represent a potent force in trapping the world's poorest people in poverty. Through extremely low cost national programs of disease mapping and mass drug administration (MDA) for the seven most common NTDs, integrated NTD control and elimination efforts are now in place in more than 14 countries through the support of the United States Agency for International Development (USAID), the British Department for International Development (DFID), and the Global Network for NTDs and its partners. The World Health Organization (WHO) estimates that in 2008 some 670 million people in 75 countries received NTD treatments through these and other sponsored programs. With continued successes the next decade could witness the global elimination of blinding trachoma, human Africa trypanosomiasis (HAT), lymphatic filariasis (LF), onchocerciasis, trachoma, and leprosy as public health problems, in addition to the eradication of dracunculiasis. For other high prevalence NTDs, including hookworm infection, schistosomiasis, Chagas disease and leishmaniasis, new drugs and vaccines may still be required. Increasingly it is recognized that the high prevalence NTDs exhibit extensive geographic overlap and polyparasitism is commonly found throughout the world's low income countries. Therefore, global elimination will also require integrated packages of drugs together with vaccine-linked chemotherapy. Ultimately, the global elimination of the high prevalence NTDs will require continued large-scale support from the U.S. Government and selected European governments, however, the emerging market economies, such as Brazil, China, India, Mexico, and Nigeria, and wealthy countries in the Middle East will also have to substantially contribute.

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1. Introduction

In October 2007 the Bill & Melinda Gates Foundation called for a new global commitment to embrace "an audacious goal" for building a roadmap to eradicate malaria [1]. Achieving global malaria eradication will require a comprehensive set of strategies that includes the expanded use of insecticide-treated bednets and the enhanced global procurement of artemisinin combination therapies in order to provide universal access to these technologies [1]. A parallel and large-scale program of research designed to develop and test a new generation of drugs, vaccines, and insecticides will also be required [1]. Given the history of previous attempts during the 1960s to eradicate malaria that failed because of resistance to anti-malarial drugs and pesticides [2], together with subsequent losses in donor funding [1], meeting the Gates Foundation eradication challenge could be daunting. Indeed success on this front will depend on continued commitments from the U.S. President's Malaria Initiative, the Global Fund to Fight AIDS, Tuberculosis, and Malaria, and other international donors to support widespread access to available control tools together with continued successes in product development [2].

Equally challenging and an idea not yet explicitly put forward is the prospect of eliminating all seven of the world's highest prevalence neglected tropical diseases (NTDs), i.e., ascariasis, hookworm infection, trichuriasis, schistosomiasis, lymphatic filariasis (LF), blinding trachoma, and onchocerciasis, in addition to the major kinetoplastid infections and leprosy (Table 1) [3–6]. Together and according to some estimates the high prevalence NTDs exhibit a global disease burden that exceeds malaria, tuberculosis, and other better known global health conditions; they also represent a potent force in trapping the world's poorest people in poverty [3,4]. Through extremely low cost national programs of disease mapping and mass drug administration (MDA) for the seven most common NTDs, integrated NTD control and elimination efforts are now in

* Corresponding author at: Baylor College of Medicine, Departments of Pediatrics and Molecular Virology & Microbiology, One Baylor Plaza, Houston, TX, 77030, United States. Tel.: +1 202 994 3532; fax: +1 202 994 2913.
E-mail addresses: hotez@bcm.edu, peter.hotez@bcm.edu

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Where's
Brazil,
China,
Indonesia,
Mexico,
Saudi
Arabia,
South
Africa?

Country	2011 GDP ¹	2011 GDP Rank	Percentage of Global GDP	Support for NTD R&D ²	Percentage of Global Public R&D	Rank in % of Global Public Neglected Disease R&D Support
United States	\$15.0 trillion	1	21%	\$1.35 billion	69.2%	1
China	\$7.2 trillion	2	10%	<\$10 million	<0.5%	Not ranked
Japan	\$5.9 trillion	3	9%	<\$10 million	<0.5%	Not ranked
Germany	\$3.6 trillion	4	5%	\$32 million	1.6%	5
France	\$2.8 trillion	5	4%	\$60 million	3.1%	3
United Kingdom	\$2.4 trillion	6	3%	\$133 million	8.2%	2
Brazil	\$2.4 trillion	7	3%	\$11 million	0.6%	10
Italy	\$2.2 trillion	8	3%	<\$10 million	<0.5%	Not ranked
India	\$1.9 trillion	9	3%	\$34 million	1.7%	4
Canada	\$1.7 trillion	10	2%	\$10 million	0.5%	9
Russia	\$1.8 trillion	11	2%	<\$10 million	<0.5%	Not ranked
Spain	\$1.5 trillion	12	2%	\$11 million	0.6%	8
Australia	\$1.5 trillion	13	2%	\$31 million	\$1.6	6
Mexico	\$1.1 trillion	14	1%	<\$10 million	<0.5%	Not ranked
South Korea	\$1.1 trillion	15	1%	<\$10 million	<0.5%	Not ranked
Netherlands	\$0.8 trillion	16	1%	\$24 million	1.2%	7
Indonesia	\$0.8 trillion	17	1%	<\$10 million	<0.5%	Not ranked



- Diplomatic pressure on the G20 nations to control NTDs and invest in NTD R&D
- Redirecting U.S. global health ODA to NTDs and R&D
- The Global Health Observatory
- Regionalization of national regulatory authorities
- Reform of IP

Discussion Paper

Strengthening Mechanisms to Prioritize, Coordinate, Finance, and Execute R&D to Meet Health Needs in Developing Countries

Peter Hotez, Rachel Cohen, Carol Mimura, Tadataka Yamada, Stephen Hoffman*

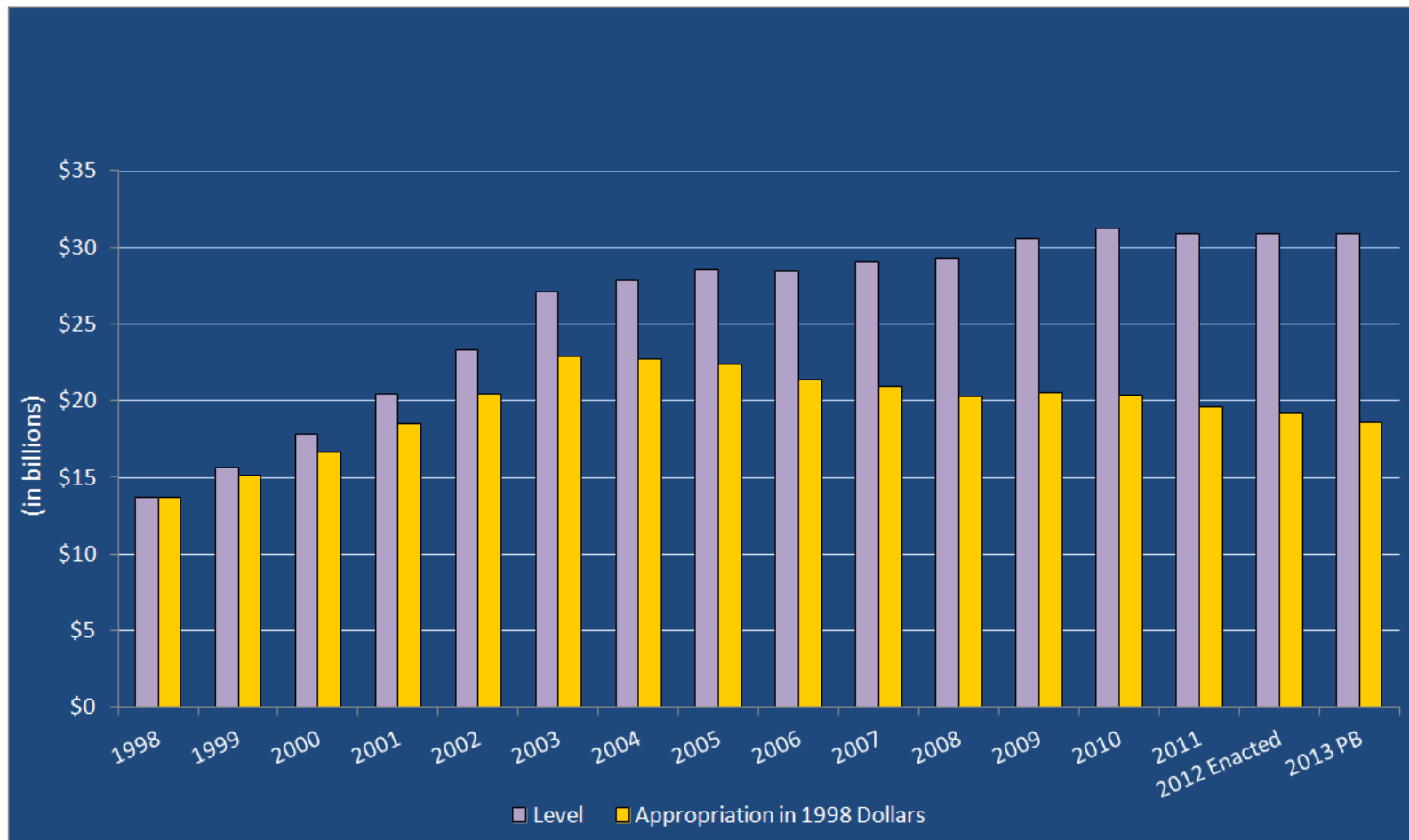
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**Participants in activities of a working group of the IOM Global Health Interest Group*

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NIH Appropriation vs. Appropriation in 1998 Dollars



A Plea for Science Advocacy

- 72% of Americans cannot name a living scientist
 - 15% Stephen Hawking
 - 01% James Watson
 - 01% Bill Nye the Science Guy
- 59% of Americans cannot name an institution where medical research is conducted
 - 10% Mayo Clinic
 - 09% NIH
 - 06% Johns Hopkins
- Only 9% of Americans identified the NIH as the major funder for biomedical research in America: 15% named FDA



Thank You!

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