

# **Progress in Combating Neglected Tropical Diseases (NTDs): U.S. and Global Efforts from FY2006 to FY2013**

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## Summary

The term "neglected tropical diseases" (NTDs) was coined by the World Health Organization (WHO) in 2003 to describe a set of diseases that are ancient, worsen poverty, and typically impair health and productivity while carrying low death rates. Some NTDs are easily treatable; others are not. While the use of the term "NTDs" has helped to raise awareness about these long-standing health challenges, its use risks simplifying a complicated health challenge. Health interventions to address the array of NTDs vary, but a common factor to an enduring solution to these illnesses is economic development. Industrialized countries, including the United States, have controlled these diseases in their territories by combining drug treatment with the construction and use of improved sanitation, modernization of agricultural practices, and utilization of improved water systems. Neglected tropical diseases are diseases that primarily plague the poorest people in developing countries. Changes in the environment and population flows, however, make industrialized countries, including the United States, increasingly vulnerable to some NTDs, particularly dengue haemorrhagic fever, for which there is no cure.

Congressional interest in NTDs has been growing. Appropriations for NTD programs have steadily increased from \$15 million in FY2006 to \$89 million in FY2012. The Administration requested \$67 million to support NTD programs in FY2013. In addition to raising spending for NTDs, Congress has taken other actions to demonstrate support for tackling NTDs. In October 2009, for example, the House Malaria Caucus expanded its purview to include NTDs. The Senate Malaria Caucus did the same in September 2012.

The international community has made substantial progress in combating select NTDs, though some have been tackled more effectively than others. Guinea worm disease, for example, is on the cusp of eradication. More generally, expanding access to mass drug administration is contributing to decreases in prevalence of several NTDs, particularly across Latin America. Despite these advances, WHO cautions that these diseases cannot be banished without improving global access to clean water and sanitation, strengthening local health capacity (veterinary as well as human), and intensifying case detection and management. Making improvements in these areas will require long-term investments that are complex and may entail facing thorny issues such as addressing corruption, transferring ownership of health programs from donors to recipient countries, and evaluating the impact of political and economic policies on health programs (e.g., international lending requirements).

The United States has played an important role in combating NTDs, and President Barack Obama has prioritized tackling NTDs. Recommendations for congressional action may largely reflect broader arguments about congressional engagement in improving global health. Analysts who support congressional directives that set programmatic targets, outline the types of activities to be implemented in U.S. global health programs, and mandate reporting requirements would probably argue for the 113<sup>th</sup> Congress to take similar steps. Observers who maintain that these steps make U.S. global health programs less effective by minimizing the capacity of implementing agencies to adapt global health programs to local conditions would likely argue for limiting congressional support for combating NTDs to appropriating sufficient resources. This report discusses the prevalence of NTDs, U.S. and global actions to address them, and options the 113<sup>th</sup> Congress might consider. For additional background on NTDs, including photographs and discussions about transmission of NTDs, descriptions of activities to combat NTDs by other agencies, and additional policy issues, see CRS Report R41607, *Neglected Tropical Diseases: Background, Responses, and Issues for Congress*, by Tiaji Salaam-Blyther.

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## Introduction

Over the past decade, global health has become a priority in U.S. foreign policy, and U.S. appropriations for global health-related efforts have more than tripled. Neglected tropical diseases (NTDs) have become an important part of these efforts.<sup>1</sup> Congressional appropriations for NTDs have grown from \$15 million in FY2006 to \$89 million in FY2012. The Administration requested \$67 million to support NTD programs in FY2013. Heightened congressional interest in combating NTDs has been reflected not only in higher appropriation levels but also in the development of caucuses on these issues. In October 2009, the House Malaria Caucus expanded its purview to include NTDs, and in September 2012, the Senate Malaria Caucus did the same.

Tropical diseases encompass all diseases that occur solely, or principally, in the tropics.<sup>2</sup> Of these, the World Health Organization (WHO) describes 17 as "neglected tropical diseases," as until recently, resources for curing, controlling, and researching improved treatments for these were limited. The 17 NTDs are found mostly among the poorest people in 149 countries and territories (**Figure 1**), primarily where access to clean water, sanitation, and health services is limited. Some NTDs are transmitted by people; others are spread by vectors like snails, flies, or mosquitoes; and several others proliferate in contaminated sources (like infested soil or water). Among the 17 NTDs, 7 account for roughly 90% of the global NTD burden (**Table 1**). These are the three soil-transmitted helminthiases [intestinal worms (STH)], schistosomiasis (snail fever), lymphatic filariasis (elephantiasis), trachoma, and onchocerciasis (river blindness). Intestinal worms or STH account for more than 80% of the seven most common NTDs (**Figure 2**).



#### Figure I. Global NTD Burden Map

**Source:** Adapted by CRS from Uniting to Combat NTDs, http://www.unitingtocombatntds.org/downloads/ press/ntd\_event\_burden\_map\_updated.pdf, accessed on October 25, 2012.

<sup>&</sup>lt;sup>1</sup> For additional background information on NTDs, see CRS Report R41607, *Neglected Tropical Diseases: Background, Responses, and Issues for Congress*, by Tiaji Salaam-Blyther.

<sup>&</sup>lt;sup>2</sup> WHO webpage on tropical diseases at http://www.who.int/topics/tropical\_diseases/en/.

Seven Most Common NTDs (90% of all NTDs)	Other NTDs	
Lymphatic Filariasis (Elephantiasis)	Buruli Ulcer	
Onchocerciasis (River Blindness)	Chagas Disease	
Schistosomiasis (Snail Fever)	Cysticercosis/Taeniasis	
Soil-Transmitted Helminthiases (STH)	Dengue	
• Hookworm	Dracunculiasis (Guinea worm disease)	
Whipworm	Echinococcosis	
Roundworm	Foodborne Trematode Infections	
Trachoma	Human African Trypanosomiasis (Sleeping Sickness)	
	Leishmaniasis	
	Leprosy	
	Rabies	
	Yaws	

 Table 1.17 Neglected Tropical Diseases

**Source:** Created by CRS from WHO website on NTDs, http://www.who.int/neglected\_diseases/diseases/en/, accessed on November 7, 2012.

Drugs used in global NTD programs to treat the seven most common NTDs are donated or sold by pharmaceutical companies at subsidized prices ranging between \$0.02 and \$2.23 per dose. These drugs are taken once or twice annually.<sup>3</sup> Although costs vary by location, treating these diseases has become increasingly inexpensive relative to other diseases that commonly afflict the poor in developing countries (Table 2). The cost of treating some NTDs has dropped in part because medicines to treat several of the most common NTDs are interchangeable and can be used to treat more than one disease. In addition, treatments for the most common NTDs can be dispensed to a broad population irrespective of individual disease status. This process, known as mass drug administration (MDA), has become an important tool in global efforts to control and eliminate NTDs.





**Source:** Created by CRS from Peter Hotez, Forgotten People, Forgotten Diseases (Washington, DC: ASM Press, 2008).

<sup>&</sup>lt;sup>3</sup> WHO, Accelerating Work to Overcome the Global Impact of Neglected Tropical Diseases: A Roadmap for Implementation, 2012, p. 16.

(U.S. dollars)			
Disease	Low Estimate	High Estimate	
HIV/AIDS	100.00	335.00	
Tuberculosis	100.00	500.00	
Malaria	0.50	1.40	
NTDs	0.02	2.23	

#### Table 2. Annual Per Patient Cost of Treating Key Infectious Diseases Globally

**Sources:** HIV/AIDS data was compiled from UNAIDS, World AIDS Day Report, 2012, p. 17 and Department of State, The President's Emergency Plan for AIDS Relief Eighth Annual Report to Congress, 2012, p. 3. Tuberculosis data was taken from WHO, Global Tuberculosis Report, 2012, p. 52. Malaria data was taken from WHO, World Malaria Report, 2011, p. x,. NTD data was taken from WHO, Accelerating Work to Overcome the Global Impact of Neglected Tropical Diseases: A Roadmap for Implementation, 2012, p. 16.

## **Global Progress in Combating NTDs**

Tremendous progress has been made in tackling NTDs since 2003, when the term "neglected tropical diseases" was coined at the first WHO meeting on a set of diseases that worsened poverty and for which solutions had not been prioritized. Until then, the international community had emphasized some of these diseases, but interventions for others languished. Two diseases for which long-term international focus has led to considerable reductions in incidence are dracunculiasis (Guinea worm disease), which has been nearly eradicated, and sleeping sickness, whose cases have dropped by some 75%. Since 1986, the number of new Guinea worm disease cases has fallen by 99% (**Figure 3**). By the end of 2011, the disease was endemic in only four countries: Chad, Ethiopia, Mali, and South Sudan. Nearly 97% of the 1,058 cases identified in 2011 occurred in South Sudan, where instability remains a key threat to eradication.



Figure 3. Global Guinea Worm Disease Cases: 1989-2010

**Source:** Adapted by CRS from WHO, Accelerating Work to Overcome the Global Impact of Neglected Tropical Diseases: A Roadmap for Implementation, 2012, p. 10.

Important advances have been seen as well in decreasing new cases of Human African Trypanosomiasis (sleeping sickness). After seeing increases in annual cases over a decade, reports of new sleeping sickness cases began to drop precipitously in 1999. From 1998 through 2010, reported cases fell by roughly 75% (**Figure 4**).



Figure 4. Global Sleeping Sickness Cases: 1990-2010

**Source:** Adapted by CRS from WHO, Working to Overcome the Global Impact of Neglected Tropical Diseases: Update 2011, 2011, p. 7.

Progress in tackling NTDs is rooted in several factors:

- large, open-ended donations by pharmaceutical companies;
- increased funding from donors;
- intensified attention by the international community;
- integrated disease treatment regimens; and
- enhanced cooperation among recipient countries, pharmaceutical companies, non-governmental organizations (NGOs), and donors.

Countries develop national NTD plans and receive financial support from donors to implement them. The WHO and donors, such as the U.S. Agency for International Development (USAID), review drug donation applications and support country-level planning, training, and monitoring and evaluation. Drug companies provide treatments used for national NTD plans, either for free or at highly discounted rates. NGOs and faith-based organizations partner with recipient countries to implement the NTD plans. Academic groups, public-private partnerships, and pharmaceutical companies research and develop innovative treatments and control mechanisms.

### **Global Actions in 2012**

In 2007, WHO released the *Global Plan to Combat Neglected Tropical Diseases*, which outlined several goals and targets for global control, elimination, and eradication of NTDs by 2015.<sup>4</sup> Three key goals included in the plan were to

- eliminate or eradicate selected NTDs;
- reduce the burden of NTDs that can be treated with MDA<sup>5</sup> by:
  - ensuring that at least 65% of populations at risk of lymphatic filariasis (elphantiasis) have access to treatment;
  - ensuring that at least 75% of school-aged children at risk of STH and schistosomiasis have access to treatment;
- advance novel approaches to treating and controlling NTDs, particularly for those that are costly and difficult to treat.



Figure 5. Global Access to Drugs for Seven Most Common NTDs: 2005-2009

**Source:** Adapted by CRS from WHO, Accelerating Work to Overcome the Global Impact of Neglected Tropical Diseases: A Roadmap for Implementation, 2012, p. 6.

In 2012, WHO released a report that highlighted progress in reaching the 2015 goals and set new ones for 2020.<sup>6</sup> Key goals include

- ensuring supply of drugs and other interventions to help:
  - eradicate Guinea worm disease.
  - eliminate elephantiasis, leprosy, sleeping sickness, and blinding trachoma by 2020.

<sup>&</sup>lt;sup>4</sup> WHO, Global Plan to Combat Neglected Tropical Diseases 2008-2015, 2007.

<sup>&</sup>lt;sup>5</sup> Mass drug administration refers to preemptively treating all people in an affected area without testing to establish individual diagnoses.

<sup>&</sup>lt;sup>6</sup> Ibid, Accelerating Work to Overcome the Global Impact of Neglected Tropical Diseases: A Roadmap for Implementation, 2012.

- **control** snail fever, soil-transmitted helminthiases (STH), Chagas disease, visceral leishmaniasis, and river blindness by 2020;<sup>7</sup>
- advancing R&D to identify next-generation treatments and interventions; and
- providing technical support, tools, and resources for monitoring and evaluation.

The report noted progress in treating onchocerciasis (river blindness), but little improvement in expanding access to medicines for schistosomiasis (snail fever) and soil-transmitted helminthiases due to inadequate drug supply (**Figure 5**). Insufficient progress in tackling STH is important, as these diseases account for roughly 80% of the seven most common NTDs (**Figure 2**).

#### The London Declaration on Neglected Tropical Diseases

Following the release of the 2012 WHO report, 13 pharmaceutical companies, the Bill & Melinda Gates Foundation (Gates Foundation), the World Bank, several NGOs, and officials representing the United States, Britain, and the United Arab Emirates (UAE) convened in London, England, to reaffirm their commitment to combatting NTDs. Participants signed the *London Declaration on Neglected Tropical Diseases*, which highlighted the role each signatory would play in reaching the 2020 goals outlined in the WHO report.

Implementing partners agreed to donate a range of treatments, funds, intellectual property rights, and research and development (R&D) resources. Appendix A lists the funding commitments and activities donors pledged to support.<sup>8</sup> These pledges included

- \$785 million (includes pre-existing commitments) to strengthen drug distribution and program implementation;
- 1.4 billion drug treatments annually;
- access to drug compound libraries to identify new treatments;
- increased financial support for NTD programs (some of which amended previous commitments to ongoing efforts), such as:
  - a five-year, \$363 million pledge by the Gates Foundation,
  - a five-year, £245 million (roughly \$393 million) pledge by Britain, and
  - a joint \$40 million donation to the Carter Center by UAE, Gates Foundation, and the Children's Investment Fund Foundation;
- commitments by the governments of Bangladesh, Brazil, Mozambique, and Tanzania to devote political and financial resources to combat endemic NTDs.

Pledges by pharmaceutical companies to support research and development (R&D) on new treatments, vaccines, and testing supplies is vital considering the emergence of evidence that hookworm, one of the STHs (that comprise 80% of all NTDs), may be developing resistance to

<sup>&</sup>lt;sup>7</sup> *Eradicate* means to end all transmission of a disease worldwide by exterminating the agent. *Eliminate* means to reduce transmission of a disease to a predetermined low level (not necessarily zero) with the aim of interrupting the transmission cycle. When elimination is achieved, MDA is no longer necessary and case detection is used to identify individual cases. *Control* refers to operations or programs aimed at reducing incidence or prevalence of a disease.

<sup>&</sup>lt;sup>8</sup> http://www.unitingtocombatntds.org/downloads/press/ntd\_event\_table\_of\_commitments.pdf.

existing medication.<sup>9</sup> Concerns about drug resistance aside, R&D commitments are also important as signatories of the London Declaration indicate existing tools are not sufficient to meet the WHO 2020 goals (**Figure 6**).





**Source:** Adapted by CRS from Uniting to Combat NTDs, http://www.unitingtocombatntds.org/downloads/ press/ntd event 2020 goals graphic.pdf, accessed on October 25, 2012.

**Notes:** "Possible progress with existing tools" predicts advancement of elimination and control efforts without development of new tools. "Possible progress with new tools" predicts advancements that could be made if new tools were developed, such as more effective treatments and vaccines.

\* Guinea worm disease is targeted for eradication.

**Acronyms:** Lymphatic Filariasis (LF), Human African Trypanosomiasis (HAT), Soil-Transmitted Helminthiases (STH).

## **U.S. Efforts to Tackle NTDs**

U.S.-based institutions have long supported efforts to control NTDs. These institutions include the federal government, pharmaceutical companies, philanthropic organizations, and NGOs. Key U.S. government players include the U.S. Agency for International Development (USAID), U.S. Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), and Department of Defense (DOD).<sup>10</sup> NGOs include groups like the Carter Center and RTI International; philanthropic organizations include the Gates Foundation and the Sabin Vaccine

<sup>&</sup>lt;sup>9</sup> Hotez, Peter "Mass Drug Administration and Integrated Control for the World's High-Prevalence Neglected Tropical Diseases," *Clinical Pharmacology & Therapeutics*, vol. 85, no. 6 (June 2009), pp. 659-664.

<sup>&</sup>lt;sup>10</sup> For more information on related efforts by these agencies, see CRS Report R41607, *Neglected Tropical Diseases: Background, Responses, and Issues for Congress*, by Tiaji Salaam-Blyther.

Institute; and private companies include Merck, Johnson & Johnson and Pfizer. While each of these plays an important role in combating NTDs, this section focuses exclusively on the USAID-managed NTD Program.<sup>11</sup>

In 2006, the Bush Administration launched the Neglected Tropical Disease Control Program, the first U.S. effort to address a group of NTDs. The program was created in response to language in the FY2006 Foreign Operations Appropriations Act, which made available up to \$15 million "to support an integrated response to the control of neglected diseases including intestinal parasites [STH], schistosomiasis, lymphatic filariasis, onchocerciasis, trachoma and leprosy."<sup>12</sup> The language signaled congressional support for calls to integrate and expand access to drugs for the seven most common NTDs. Until that time, most countries and their implementing partners focused on tackling a single NTD. The NTD Program sought to document the feasibility of integrating treatment for several NTDs and advance application of this strategy. At the outset, the NTD program aimed to support the provision of 160 million NTD treatments to 40 million people in 15 countries. In 2008, President George W. Bush reaffirmed his commitment to the program and proposed spending \$350 million over six years (from FY2008 through FY2013) on expanding the program to 30 countries.<sup>13</sup>

During his first term, President Barack Obama named the NTD Program a priority. While announcing the Global Health Initiative (GHI) in May 2009,<sup>14</sup> President Obama indicated the NTD Program would be a key part of the initiative and would be increasingly integrated into other global health efforts. The 2009-2014 Lantos-Hyde United States Government Malaria Strategy exemplifies this priority by outlining how the Administration plans to integrate malaria and NTD activities with other U.S. global health efforts.<sup>15</sup>

Through GHI, the Obama Administration seeks to

- administer 1 billion NTD treatments,
- halve the prevalence of the seven most common NTDs by 2013,
- eliminate leprosy in all endemic countries by 2016,
- eliminate onchocerciasis in Latin America by 2016, and
- eliminate lymphatic filariasis globally by 2017.

Through the first half of FY2012, the NTD Program had supported the provision of 584.6 million treatments (**Figure 7**) to 257.9 million people across 20 countries. A map of the countries is in **Appendix B**.

<sup>&</sup>lt;sup>11</sup> See respective websites of each organization for additional information on their NTD Programs.

<sup>&</sup>lt;sup>12</sup> Section 593, P.L. 109-102, FY2006 Foreign Operations Appropriations.

<sup>&</sup>lt;sup>13</sup> See White House, "President Bush Announces New Global Initiative To Combat Neglected Tropical Diseases," press release, February 20, 2008.

<sup>&</sup>lt;sup>14</sup> For more information on GHI, see CRS Report R41851, U.S. Global Health Assistance: Background and Issues for the 112<sup>th</sup> Congress, by Tiaji Salaam-Blyther.

<sup>&</sup>lt;sup>15</sup> USAID et al., Lantos-Hyde United States Government Malaria Strategy, 2009-2014, April 2010.



Figure 7. NTD Treatments Administered in USAID Programs: FY2007-FY2012

**Source:** Adapted by CRS from NTD Program website at http://www.neglecteddiseases.gov/about/index.html, accessed on November 28, 2012.

### FY2013 Funding

USAID has spent more than \$300 million on the NTD Program since it began in FY2006 through FY2012 (Figure 8). The FY2013 budget request includes \$67 million for the program. The 112<sup>th</sup> Congress did not complete legislation for FY2013 Foreign Operations Appropriations, through which the program is funded. The House Appropriations Committee included positive language about the program but did not specify an amount for the NTD effort in its committee report. The Senate Appropriations Committee recommended \$125 million for the program in its committee report.

## **Issues for Congress**

FY2006-FY2012 (current U.S. \$ millions)

Figure 8. USAID Spending on the NTD Program:



**Source:** Adapted by CRS from USAID website, http://www.neglecteddiseaess.gov/funding/index.html, accessed on October 25, 2012.

Notes: \*FY2013 amount is a budgetary request.

The international community has made substantial progress in combating select neglected tropical diseases. Some NTDs have been tackled more effectively than others. Guinea worm disease, for example, is on the cusp of eradication and with expanding mass drug administration campaigns, the prevalence of several NTDs is declining, particularly in Latin America. Despite these advancements, WHO cautions in the 2020 Roadmap that these diseases cannot be banished without improving global access to clean water and sanitation, strengthening local health capacity (veterinary as well as human), and intensifying case detection and management.

The United States has played an important role in combating NTDs and will likely be a central player in global efforts to advance the 2020 NTD goals. Recommendations for congressional action may largely reflect broader arguments about the appropriate role for Congress in improving global health. Analysts who applaud congressional directives that set programmatic targets, outline the types of activities to be implemented in U.S. global health programs, and mandate reporting requirements would probably argue for the 113<sup>th</sup> Congress to take similar steps in meeting the 2020 NTD goals. Observers who maintain that these steps make U.S. global health programs less effective by minimizing the capacity of implementing agencies to adapt global health programs to local conditions would likely argue for limiting congressional support for combating NTDs to appropriating sufficient resources.

The section below discusses a range of issues U.S. and international organizations may face as they attempt to reach the WHO 2020 goals, as well as those set by the Administration (see "U.S. Efforts to Tackle NTDs"). Some of the discussion includes an analysis of steps the 113<sup>th</sup> Congress might consider.

### Accessing Clean Water and Sanitation

Transmission of most NTDs is facilitated by insufficient access to clean water and sanitation.<sup>16</sup> An estimated 2 billion people are carrying soil-transmitted helminths, for example, which are spread primarily through openly defecating on the ground. Eggs of these intestinal worms, which account for roughly 80% of the seven most common NTDs (which together account for about 90% of all NTD cases), can persist in the environment for many years.

Experts at the CDC assert that water and sanitation improvement should be a central component of any effective and sustainable approach to controlling NTDs.<sup>17</sup> One estimate indicates that improved sanitation and water safety can reduce the prevalence rates of schistosomiasis by 75% and blinding trachoma by 25%.<sup>18</sup> Water and sanitation improvement are particularly important when addressing pathogens that cannot be eliminated by drugs alone, such as STH and schistosomiasis.

Several experts urge greater investments in water and sanitation and see attainment of global water and sanitation goals as an important step towards eliminating NTDs.<sup>19</sup> Through the Millennium Development Goals (MDGs), the international community sought to halve the share of people without access to clean water and basic sanitation by 2015.<sup>20</sup> WHO estimated that

<sup>&</sup>lt;sup>16</sup> For more information on U.S. and international efforts to improve access to clean water and sanitation, see CRS Report R42717, *Global Access to Clean Drinking Water and Sanitation: U.S. and International Programs*, by Tiaji Salaam-Blyther.

<sup>&</sup>lt;sup>17</sup> See CDC, *WASH Away Neglected Tropical Diseases*, Activity Summary, June 2010, http://www.cdc.gov/ healthywater/pdf/global/programs/wash-away-ntd-summary.pdf and CDC, *WASH Away Neglected Tropical Diseases*, Program in Brief, June 2010.

<sup>&</sup>lt;sup>18</sup> Philip Musgrove and Peter Hotez, "Turning Neglected Tropical Diseases Into Forgotten Maladies," *Health Affairs*, vol. 28, no. 6 (November/December 2009), p. 1698.

<sup>&</sup>lt;sup>19</sup> Burton Singer, "Viewpoint by Burton Singer: Bring Back Primary Prevention for Relieving the Burden of NTDs," *PLoS Medicine*, vol. 7, no. 5 (May 2010), p. e1000255; and TR Burkot et al., "The Argument for Integrating Vector Control with Multiple Drug Administration Campaigns to Ensure Elimination of Lymphatic Filariasis," *Filaria Journal*, vol. 5, no. 10 (August 2006).

<sup>&</sup>lt;sup>20</sup> The United Nations (U.N.) General Assembly adopted a declaration in 2000, which among other things, committed member states to advance health development around the world. See, *United Nations Millennium Declaration*, (continued...)

between 2005 and 2015, it would cost \$72 billion annually to implement and maintain enough water and sanitation schemes to meet global water and sanitation targets, of which \$54 billion would need to be spent on maintaining the systems.<sup>21</sup> In 2010, members of the Organization for Economic Cooperation and Development (OECD) committed \$7.8 billion towards improving global access to clean drinking water and sanitation.<sup>22</sup> U.S. and global investments in sanitation would need to increase significantly to meet this funding gap.

The 113<sup>th</sup> Congress has at its disposal an important tool for ensuring U.S. water and sanitation resources are used to reinforce the NTD Program. The Senator Paul Simon Water for the Poor Act (P.L. 109-121), which amends the Foreign Assistance Act of 1961, requires the Secretary of State to develop a strategy for expanding global access to clean water and sanitation. The act specifies that the strategy should include

specific and measurable goals, benchmarks, and timetables to achieve the objective described in [the strategy];

methods to coordinate and integrate United States water and sanitation assistance programs with other United States development assistance programs to achieve the objective described [in the strategy].<sup>23</sup>

As of the publication of this report, the Administration had not yet released a water strategy, though one is reportedly imminent.<sup>24</sup> The 113<sup>th</sup> Congress could request testimony from Administration officials on the progress in developing a strategy and integrating other development assistance programs, including global health programs like the NTD Program per legislation.

### Integrating the U.S. NTD Program

Investments in water and sanitation are considered important, as mass drug administration campaigns cannot be used in isolation to eliminate NTDs. The process of combating diseases by combining responses by practitioners across sectors, particularly those related to health, agriculture, water, construction, and waste disposal, is known as integrated vector management. Indeed, the United States was unable to control hookworm (an STH) within its own borders until

<sup>(...</sup>continued)

September 18, 2000, http://www.un.org/millennium/declaration/ares552e.pdf. Shortly thereafter, delegates developed the *Millennium Development Goals* (MDGs) to guide attainment of the priorities outlined in the Millennium Declaration. The eight MDGs are: (MDG1) eradicate poverty and hunger, (MDG2) achieve universal primary education, (MDG3) promote gender equality and empower women, (MDG4) reduce child mortality by two-thirds, (MDG5) reduce maternal mortality by two-thirds, (MDG6) combat HIV/AIDS, malaria, and other diseases, (MDG7) ensure environmental sustainability, and (MDG8) develop a global partnership for development. MDG7 includes the water and sanitation targets.

<sup>&</sup>lt;sup>21</sup> Guy Hutton and Jamie Bartram, *Regional and Global Costs of Attaining the Water Supply and Sanitation Target of the Millennium Development Goals*, WHO, 2008, p. iv, http://www.who.int/water\_sanitation\_health/ economic mdg global costing.pdf.

<sup>&</sup>lt;sup>22</sup> OECD, *Aid Activity Database*, http://stats.oecd.org/Index.aspx, accessed on July 31, 2012. For more information on U.S. spending on improving global access to water and sanitation, see CRS Report R42717, *Global Access to Clean Drinking Water and Sanitation: U.S. and International Programs*, by Tiaji Salaam-Blyther.

<sup>&</sup>lt;sup>23</sup> Sec. 6, P.L. 109-121.

<sup>&</sup>lt;sup>24</sup> Personal communication with Chris Holmes, Water Coordinator, USAID, October 19, 2012.

the early 1900s, when an integrated vector management (IVM) approach was applied.<sup>25</sup> WHO maintains that an effective NTD response would use an intersectoral approach that is based on five areas:

- 1. mass drug administration;
- 2. intensified case-management;
- 3. vector control;
- 4. safe water, sanitation, and hygiene; and
- 5. veterinary public health (by also controlling the NTDs that are zoonotic).<sup>26</sup>

It is unclear whether the U.S. NTD Program adheres to this multi-faceted approach. Documents by the Administration maintain the NTD Program is part of a complete package of services the United States provides to improve the health of women and children across sectors.<sup>27</sup> The Administration intends, for example, to expand the provision of drugs that treat STH in children within USAID-supported education programs.<sup>28</sup> Similarly, the Obama Administration underscores the intersection between water and sanitation and categorizes it as a "cross-cutting area" under global health. Nonetheless, in reports to Congress on progress towards advancing global health (through congressional budget justifications, for example) the Administration provides little information about how water and sanitation programs advance global health efforts or how they are integrated within global health projects.

The structure of the FY2013 Foreign Operations budgetary request suggests some separation between these activities. Requests for water programs are made across a variety of accounts, primarily Development Assistance (DA) and Economic Support Fund (ESF). In FY2013, for example, the Administration requested only 12% of water and sanitation funds through the Global Health Programs account and 76% through the DA and ESF accounts. These two accounts support a wide range of governance and economic development activities, which do not typically focus on health objectives.

Despite the limitations of mass drug administration, the U.S. NTD Program focuses almost exclusively on MDA. Administration officials recognize the importance of a comprehensive NTD Program, but maintain that "the directive from Congress was to focus on mass drug administration. [G]iven the limited resources, [MDA] is the most efficient and cost-effective way to control [and] eliminate these diseases."<sup>29</sup> The 113<sup>th</sup> Congress might debate the merits of applying an intersectoral approach to the NTD Program. Broadening the U.S. approach may not necessarily entail raising spending, but could involve improving the integration of U.S. health and development programs. The 113<sup>th</sup> Congress could, for example, request information on how key

<sup>&</sup>lt;sup>25</sup> In the early 1900s, the Rockefeller Foundation and its implementing partners combined wide-scale sanitation projects with drug administration and public education to eliminate hookworm infections, which plagued much of the southeastern United States at the time. For more on this approach, see E.A. Alderman et al., *The Rockefeller Sanitary Commission for the Eradication of Hookworm Disease* (Washington, DC: Offices of the Commission, 1915). This book is available on-line at http://www.archive.org/details/cu31924005710839.

<sup>&</sup>lt;sup>26</sup> Zoonotic diseases are transmissible under natural conditions from vertebrate animals to humans.

 <sup>&</sup>lt;sup>27</sup> Department of State, *Implementation of the Global Health Initiative: Consultation Document*, February 2010, p. 20.
 <sup>28</sup> Ibid, p. 15.

<sup>&</sup>lt;sup>29</sup> Emily Wainwright, USAID, Senior Operations Advisor, Neglected Tropical Diseases Program, December 27, 2012.

leaders at USAID (e.g., the Deputy of the Global Health Initiative and the Water Coordinator) coordinate their programs.

### **Strengthening Health Systems**

Despite the consistent decline in NTD cases since the turn of the century, weak health systems and conflict in some developing countries continue to hamper efforts to eliminate many NTDs. In the case of human African trypanosomiasis (sleeping sickness), for example, the international community had practically interrupted transmission of the disease in the 1960s.<sup>30</sup> Following the marked drop in cases, the recipient countries failed to maintain sufficient funding levels for ensuring adequate treatment measures and disease surveillance. At the same time, conflict in key areas (Angola, Sudan, and Uganda) hampered efforts to control the disease as infected individuals fleeing conflict entered areas under which health workers initially arrested the spread of sleeping sickness.<sup>31</sup> Additionally, during fighting, health workers were barred from monitoring some areas. By the 1980s, the disease had reemerged, and by the 1990s, cases were growing dramatically (**Figure 4**).

Resurgence occurred for several reasons, one of the greatest being weak capacity to maintain disease surveillance. Weak veterinary and public health systems limit the ability of several affected countries to enhance NTD programs or maintain them after international support wanes. Many critics of "vertical" or "disease-specific" programs see the poor conditions of health systems in several developing countries as an outcome of the burgeoning investments in vertical disease programs. One argument is that disease-specific efforts divert investments from the very public health systems that are needed to support vertical programs. Supporters of disease-specific initiatives argue, on the other hand, that such activities facilitate dramatic, measurable progress. Advocates of this approach point to dramatic reductions in recent years of deaths associated with HIV/AIDS and malaria. The merits of vertical disease programs have been long debated in the global health community and evidence supports both sides of the debate.

President Obama attempted to reconcile both viewpoints when he launched the Global Health Initiative in 2009. While announcing GHI, the President called for the development of a strategy that integrates health programs (where appropriate); supports primary health systems; and coordinates health activities across U.S. agencies. The initiative did not call for an end to socalled vertical programs. Indeed, the Administration has maintained support for key vertical programs like the President's Emergency Plan for AIDS Relief (PEPFAR), the President's Malaria Initiative (PMI), and the NTD Program.

The sustainability of U.S. global health investments was a central focus in the 112<sup>th</sup> Congress and will likely be an issue of importance for the next Congress. Should the 113<sup>th</sup> Congress maintain interest in this area, it may consider sustaining existing reporting requirements on implementation of the GHI, particularly those elements that are aimed at strengthening health systems. Key programs (e.g., Global Disease Detection program) supported by the Centers for Disease Control

<sup>&</sup>lt;sup>30</sup> Pere Simarro et al., "The Human African Trypanosomiasis Control and Surveillance Programme of the World Health Organization 2000-2009: The Way Forward," *PLOS Neglected Tropical Diseases*, vol. 5, no. 2 (February 2011), p. e1007.

<sup>&</sup>lt;sup>31</sup> WHO, *Control and Surveillance of African Trypanosomiasis*, WHO Technical Report Series, Number 881, 1998, p. 43, http://whqlibdoc.who.int/trs/WHO\_TRS\_881.pdf.

and Prevention (CDC) that bolster surveillance capacity, for example, could be instrumental in advancing the NTD Program.<sup>32</sup>

### **Sustaining Advancements**

NTD treatments are considered relatively inexpensive to administer (**Table 2**). The treatment costs are low primarily because pharmaceutical companies donate these drugs for little or no cost. Medicines that are not offered for free are typically sold at subsidized prices ranging between \$0.02 and \$1.02 per course.<sup>33</sup> When signing the London Declaration, several pharmaceutical companies pledged to maintain or increase donations of NTD treatments through 2020 (**Appendix A**). While these steps have enabled the USAID NTD program—and presumably other global NTD programs—to run at low costs, they also mean that these efforts are heavily reliant upon pharmaceutical companies.

According to one USAID official, "without the drug donations, there really wouldn't be a U.S. Government program."<sup>34</sup> As a result of drug donations, for example, USAID was reportedly able to disseminate NTD treatments valued at over \$1 billion for \$89 million from FY2006 through FY2011. Furthermore, the agency predicts that within two years, USAID will not have to purchase any more drugs due to pharmaceutical donations.

The extent to which global health programs, in general, and NTD programs, in particular, rely on donor support has been both a boon and a burden to health systems in developing countries. Donor emphasis on key health issues, particularly infectious diseases, has enabled recipient countries to concentrate investments in other areas, particularly primary health care. Foreign investments in tackling infectious diseases have contributed not only to reductions in related fatalities but also in improvements in other health indicators, such as child survival and maternal health. At the same time, many developing countries have become reliant upon donors to fund many major health initiatives. In some cases, ministries of finance have reduced national health budgets when foreign health aid has risen.<sup>35</sup> The reasons for cutting ministry of health budgets can include insufficient capacity to spend substantially larger budgets for a variety of reasons including low staff levels; loan requirements (e.g., requirements by international financing institutions to reduce national spending); or redirected spending on other sectors like education, agriculture, or infrastructure.

Global health experts are now grappling with sustaining and advancing improvements seen over the past several years. Given the substantial contributions made by the U.S. government in this area, resources available for addressing global health challenges may undergo scrutiny as the 113<sup>th</sup> Congress faces public pressure to resolve growing domestic debt. Congress has exercised increased involvement in shaping global health programs through funding distribution guidelines, spending directives and limitations, and priority-area recommendations. Some argue that

<sup>&</sup>lt;sup>32</sup> For more information on CDC's global health programs, including GDD, see CRS Report R40239, *Centers for Disease Control and Prevention Global Health Programs: FY2001-FY2012 Request*, by Tiaji Salaam-Blyther.

<sup>&</sup>lt;sup>33</sup> WHO, Integrated Control of the Neglected Tropical Diseases: A Neglected Opportunity Ripe for Action, May 2008, p. 3.

<sup>&</sup>lt;sup>34</sup> Information in this paragraph was compiled from correspondence with Emily Wainwright, USAID, Senior Operations Advisor, Neglected Tropical Diseases Program, December 27, 2012.

<sup>&</sup>lt;sup>35</sup> Chunling Lu et al., "Public Financing of Health in Developing Countries: A Cross-National Systematic Analysis," *The Lancet*, vol. 375 (April 17, 2010), pp. 1375-1387.

congressional spending directives have limited the ability of country teams to tailor programs to in-country needs. Others argue that congressional mandates and recommendations serve to protect critical areas in need of support and encourage the Administration to address health issues that it may not otherwise prioritize. The extent of continual congressional involvement will likely face rigorous debate in the 113<sup>th</sup> Congress.

## **Appendix A. London Declaration: Table of Donor Commitments**

NTD Disease	Activity	Financial Commitment	Contributor
	Outline disease-specific goals and strategies for control and elimination		World Health Organization (WHO)
	Research and develop new programs and country-specific approaches for combating Guinea worm disease, lymphatic filariasis, river blindness, schistosomiasis, blinding trachoma, visceral leishmaniasis	£195 million 2011-2015	U.K. Department for International Development (DFID)
	Maintain support in over 20 countries; expand support to include Mozambique, Senegal, Cambodia	Build on U.S. \$301 million investment since 2006	U.S. Agency for International Development (USAID)
	Overcome barriers to success and address critical gaps to achieve the control and elimination of targeted NTDs by 2020	\$363 million over five years	Bill and Melinda Gates Foundation
	Expand work in NTD control and program enhancement	\$5 million to selected sites in the Americas and Africa	Mundo Sano
	Country level: build stronger community health systems and integrate NTD elimination and control. Regional level: oversee finances for trust fund to fight river blindness in Africa and partner with other entities to expand trust fund to eliminate or control preventable NTDs in Africa	Extend financial and technical support	World Bank
Multiple NTDs	Apply WHO recommendations for implementing coordinated NTD plan		Brazil
	Implement fully integrated, multi-sectoral NTD plan; reach full geographic coverage of all endemic areas for lymphatic filariasis, STH, and schistosomiasis; map and reach full geographic coverage of trachoma by 2018; build capacity for surveillance and action to sustain gains from mass drug administration program		Mozambique
	Implement integrated plan to control and eliminate NTDs		Tanzania
	Implement integrated plan to control and eliminate NTDs		Bangladesh
	Consider use of Ivermectin for other NTDs		Merck
	Provide third parties, including Drugs for Neglected Diseases <i>initiative</i> (DND <i>i</i> ), access to selected substances out of compound libraries to find new NTD treatments		Bayer
	Provide third parties, including DNDi, access to selected proprietary compound libraries to develop new medicines for certain NTDs		Bristol-Myers Squibb
	Donate Azithromycin to a study on the potential for the drug to reduce mortality in young children		Pfizer

NTD Disease	Activity	Financial Commitment	Contributor
Blinding Trachoma	Elimination of trachoma in China	\$6.9 million	Pfizer
	Continued donation of Azithromycin for blinding trachoma until at least 2020		Lions Clubs International Foundation
	Double existing annual donation of Nifurtimox to 1 million tablets through 2020		Bayer
Chagas Disease	Provide DNDi targeted access to proprietary compound libraries to develop new medicines		Abbot, AstraZeneca, Eisai, GlaxoSmithKline, MSD, Novartis, Pfizer, and Sanofi
Guinea worm disease	Fill global funding gap	Gates Foundation (\$23.3 million); DFID (£20million); United Arab Emirates (\$10 million); Children's Investment Fund Foundation (\$6.7 million)	DFID, Gates Foundation, United Arab Emirates, Children's Investment Fund Foundation
Leprosy	Extend existing donation of rifampicin, clofazimine, and dapsone through 2020 in quantities requested by WHO		Novartis
	Organize multi-stakeholder initiative to intensify leprosy control efforts		Novartis
Lymphatic	Provide 120 million DEC tablets to WHO for its Global Lymphatic Filariasis Elimination program; ensure a sufficient supply of DEC from 2012 through 2020		Gates Foundation, Eisai, and Sanofi
Filariasis	Donate 2.2 billion tablets of DEC from 2014-2020		Eisai
	Maintain annual donation of 600 million tablets of Albendazole indefinitely		GlaxoSmithKline
Lymphatic Filariasis and River Blindness (Onchocerciasis)	Repurpose Flubendazole to kill adult worms associated with lymphatic filariasis and river blindness; conduct drug reformulation studies; provide expertise for pre-clinical development and provide technical and supply assistance. If pre-clinical development is successful, Johnson & Johnson will co-fund clinical development; obtain regulatory approval; provide technical support		Abbot, DNDi, Johnson & Johnson, Pfizer
	Provide DNDi with access to proprietary compound libraries to develop new medicines that kill adult worms associated with lymphatic filariasis and river blindness		AstraZeneca, Johnson & Johnson, Novartis, Sanofi
	Increase annual donation of Praziquantel from 25 million to 250 million tablets/year indefinitely		Merck KGaA
	Develop child-friendly formulation of Praziquantel		
River Blindness	Maintain unlimited donation of Ivermectin indefinitely		MSD

NTD Disease	Activity	Financial Commitment	Contributor
Schistosomiasis	Provide financial support for a WHO school-based schistomiasis program		Merck KGaA
	Extend existing donations of related treatments through 2020		Sanofi
	Extend existing donations of related treatments through 2020		Bayer
Sleeping Sickness (Human African Trypanosomiasis)	Provide DNDi with access to proprietary compound libraries to develop new medicines		Abbot, AstraZeneca, Eisai, GlaxoSmithKline, MSD, Novartis, Pfizer and Sanofi
	Partner with DNDi to develop a new oral drug candidate for sleeping sickness		Sanofi
	Logistical support to ensure drugs reach patients at point of care free of charge		
Soil-Transmitted	Extend donation of 400 million Albendazole tablets/year through 2020		GlaxoSmithKline
Helminthiases	Extend donation of 200 million Mebendazole tablets/year to 2020		Johnson & Johnson
Visceral Leishmaniasis	Provide DNDi with access to proprietary compound libraries to develop new medicines		Abbot, AstraZeneca, Eisai, Novartis, Pfizer, Sanofi, GlaxoSmithKline, and MSD
	Partner with DNDi to transform drug currently in trials for Chagas Disease as a new treatment for leishmaniasis		Eisai
	Donate AmBisome for 50,000 patients in South Asia and East Africa from 2012-2017; continue program to offer VL at cost; investigate and invest in technologies and process to reduce cost of Ambisone in resource-limited countries		Gilead
	Develop new training tools for leishmaniasis care for health care providers and patients		Sanofi

**Source:** Adapted by CRS from Uniting to Combat Neglected Tropical Diseases, *Table of Commitments*, January 30, 2012, http://www.unitingtocombatntds.org/ downloads/press/ntd\_event\_table\_of\_commitments.pdf.

## Appendix B. Map of USAID NTD Program



Figure B-1. NTD Program Countries

**Source:** USAID website on NTDs, http://www.neglecteddiseases.gov/countries/index.html, accessed on October 25, 2012.

**Notes:** The 20 NTD Program countries are Bangladesh, Burkina Faso, Cambodia, Cameroon, Democratic Republic of Congo, Ghana, Guinea, Haiti, Indonesia, Mali, Mozambique, Nepal, Niger, Philippines, Senegal, Sierra Leone, Tanzania, Togo, Uganda, and Vietnam. The countries in which USAID operates can change. In 2011, for example, USAID stopped operations in South Sudan as a result of new investments by another donor focused on NTD control activities in the country.

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