



## U.S. GLOBAL HEALTH POLICY

MAPPING THE UNITED STATES GOVERNMENT  
ENGAGEMENT IN GLOBAL PUBLIC HEALTH

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## ACKNOWLEDGMENTS

This document served to provide background research used to inform the development of the Kaiser Family Foundation's report, *The U.S. Government's Global Health Policy Architecture: Structure, Programs and Funding*, April 2009, available at [www.kff.org/globalhealth/7881.cfm](http://www.kff.org/globalhealth/7881.cfm).

Several individuals contributed to the development of this background report. We would like to thank Stimson interns Brooke Crawford, Jacqueline Joliat, and Mary Kate Mohlman who made invaluable contributions to this project through their painstaking reviews of the existing literature and budget documents. Thanks to them and to Elizabeth Vanderwoude of the Stimson Center for going above and beyond the call of duty. We also extend our most sincere gratitude to the many experts in global health policy, programs, and budgets who generously found time to help us understand how and where the U.S. government addresses global health challenges.

This report was supported in part by a grant from the Bill & Melinda Gates Foundation.

## INTRODUCTION

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This report represents an effort to map the United States government's engagement in global health activities as a basis for analysis and to help decision makers understand the scope and organization of programs, policies, authorities, funding and coordinating mechanisms that comprise US support for public health abroad.

As successive US presidential administrations have elevated the prominence of the global burden of diseases such as HIV/AIDS in the foreign policy agenda, the roster of USG institutions and organizations that play some operational, coordinating, funding, or consultative role in global health programs has expanded steadily. The portfolio analysis of the US engagement in global health encompassed in the agency descriptions below represents a cross-sectional survey at a point in time, with data collection completed in February 2009. The agency and organization descriptions in the following sections were derived from published literature and interviews conducted with current and former personnel in USG agency offices on a not-for-attribution basis. The agency descriptions are not intended to list individual programs and projects associated with global health comprehensively, but outline significant roles and responsibilities, policies, and histories for each agency or organization. Many of these organizational structures are already in flux during the early months of the Obama administration, and will doubtless continue to evolve.

Budget data were compiled from multiple sources, as noted in the text, including agency Congressional budget justifications, operational reports, the Office of Management and Budget public database, and personal communications. Appropriated sums identified by the research team as global health spending are shown by account for each agency and organization for fiscal years 2004-2008. Budgets for humanitarian assistance are shown for each agency over the same period for purposes of comparison, but do not necessarily comprise global health programming and do not count toward global health budget totals.

### *Mapping the US Engagement in Global Health*

One of the challenges in mapping USG engagement in global health is the lack of a generally accepted definition of "global health activities." Global health activities tend to be defined functionally, and in some cases represent an extension of a USG program with a primarily domestic focus rather than an easily identified international mission. To complicate the issue further, international programs in areas as varied as engineering, education, environmental safety, management, nutrition, and sanitation may contribute to improved health status, but their classification as health activities varies by organization. In the absence of a coherent definition for global health activities, no convenient criteria can be used to compile or compare global health programs across the US government.<sup>i</sup> This echoes a similar quandary in defining the boundaries of the health sector at the international level, where the scope of health assistance and the number of significant public and private sector stakeholders have increased dramatically in

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<sup>i</sup> The US government not only lacks a standard definition of global health activities, but agencies variously define the countries that constitute a region, differing from each other and from the regional groupings used by United Nations agencies, including WHO.

the last decade, complicating efforts to track global health financial flows. As a result, definitions of global health tend to exist along a continuum from narrow to broad and can generally be described as follows:

1. **Narrow/Exclusive:** International programs that address a specific disease or health condition (such as maternal-child health) unambiguously meet the narrowest definition of global health activities. Many historical and contemporary documents that analyze US global health efforts rely on this definition, comprising only those programs that provide capital or technical assistance to support basic health services or disease detection, treatment, prevention and/or control.
2. **Middle Ground:** Several factors underlie a broadened definition of global health activities found with increasing frequency in the published literature, including the narratives accompanying USG budget justifications. Increasingly widely held concerns about the shortcomings of vertical or “stove-piped” disease programs have contributed to a growing emphasis on programs that strengthen health systems more generally.<sup>ii</sup> Broader definitions are thus required to capture and evaluate the range of capacity-building activities (such as workforce development, policy reform, or information management) that are not associated with a specific disease or condition. Programs that promote access to adequate and safe nutrition and water reduce the risks of exposure to food- and water-borne infectious diseases, and decrease susceptibility to a range of communicable and non-communicable diseases. The US government has very recently increased its efforts to integrate food assistance (historically associated with humanitarian relief) and safe water programs more closely with other health programs, including PEPFAR.<sup>1</sup> Finally, changes in behavior associated with urbanization and increased economic development carry their own cost; noncommunicable diseases already account for almost half of the disease burden in low- and middle-income countries, and WHO projects that they will account for an increased proportion of all deaths in coming decades.<sup>2</sup> Thus, a more comprehensive definition of global health activities encompasses communicable and non-communicable diseases; health systems strengthening; maternal and child health, water/sanitation, nutrition, environmental health, and relevant field and basic research.
3. **Broad/Inclusive:** At the most inclusive extreme, the “One World, One Health” framework considers global public health in the context of the worldwide animal-human-ecosystem interface. This framework (the topic of the most recent International Ministerial Conference on Avian and Pandemic Influenza in October 2008)<sup>3</sup> is particularly useful for defining USG global health activities that address zoonotic diseases, such as highly pathogenic avian influenza or SARS. Current USG avian influenza and pandemic preparedness efforts (such as those coordinated through the State Department-directed Avian Influenza Action Group) increasingly embrace the One World, One Health system to cover the range of human and animal health needs that intersect at the village and national level. Under this framework, activities as diverse as building animal health laboratories and monitoring markets for wildlife trade in developing nations could be characterized as global public health efforts, if their aims included preventing zoonotic outbreaks by limiting human exposure to emerging infections.

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<sup>ii</sup> The deleterious effects of vertical disease programs in resource-constrained nations may range from a simple lack of coordination, with the concomitant potential for wasting donor resources, to more damaging internal brain drain of qualified personnel from local systems to externally funded programs that serve only a fraction of the population.

For the purposes of mapping the US agency global health programs that appear in the subsequent sections, we have adhered to the middle (second) definition of global health programs, as described above. In addition, the compiled budget data collected to reflect this definition do not include funding for any international programs or activities that primarily:

- Fulfill an intelligence function for the purposes of providing strategic or tactical information to high-level decision makers (such as the assessments of potential global health risks and capabilities produced by the National Center for Medical Intelligence, formerly the Armed Forces Medical Intelligence Center);
- Address biological threat reduction through law, treaty enforcement or personnel and physical security of laboratory facilities; or
- Provide health services for USG personnel abroad (such as the planning activities of the State Department’s Offices of Medical Services or Consular Services).

The globalization of US development assistance and the broadening of programs in the past decade have created an increasingly complex network of US global health activities. Therefore, in addition to defining the scope of USG global health for mapping, several broad categories for such activities – with the major USG actors in each area – were defined as follows:

- **Disease detection and response:** As described above, such programs are among the most easily defined, and generally accepted, global health efforts. US contributions to the Measles Initiative and Global Polio Eradication Initiative,<sup>iii</sup> and programs such as PEPFAR and the President’s Malaria Initiative, are examples of disease-focused global health programs. CDC generally serves as the lead implementing agency in building partner nations’ capacities for disease surveillance and control through technical assistance, training, and laboratory support. The Department of Defense (DOD) supports disease surveillance activities in host nations through a network of overseas laboratories and programs, and helps other militaries build health system capacities to diagnose, treat, and prevent communicable diseases such as HIV/AIDS. Both DOD- and CDC-supported international research facilities strengthen local and regional disease surveillance networks by serving as reference laboratories in partnership with host governments and WHO. USAID provides technical assistance and awards funds to public and private sector partners that supply basic health services, including disease detection, treatment, prevention, and control. Peace Corps volunteers can support disease control efforts at the community level. Other HHS programs play roles in specific disease programs, such as the Health Resources and Services Administration (HRSA), tapped by PEPFAR because of its experience in implementing HIV/AIDS programs in the US
- **Health systems strengthening:** Increasingly, policy makers have expressed concerns about the impact and sustainability of programs aimed at detecting and responding to only one disease. The PEPFAR re-authorization specifically cited strengthening national health systems among the program’s purposes; USAID identifies health systems as one of its technical areas of focus.<sup>4,5</sup> These and other USG communications have stressed the need to build integrated systems capable of supporting a full range of public health, clinical, and laboratory services – as well as management and information systems

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<sup>iii</sup> Both global efforts spearheaded by WHO in partnership with CDC and with other United Nations agencies, national governments, and non-governmental organizations.

needed to govern them effectively – that meet local or national priorities, rather than only donor goals. Health systems strengthening can include issues related to:

- Workforce
- Policy reform
- Health systems management
- Financing/finance management
- Commodity supply (medical products, vaccines, and technologies)
- Health information collection/analysis/sharing
- Leadership
- Governance
- Improving service delivery

USAID leads USG efforts to strengthen other nations' health systems, especially through promotion of workforce development, systems for managing pharmaceutical supplies and commodities, and building information and financial management capacities in host nations. CDC also plays a significant role in commodity supply for internationally coordinated immunization programs, and in public health leadership development. Both Peace Corps volunteers build local human capacity through grassroots-level health training and education. DOD humanitarian and civic assistance programs can address health physical infrastructure needs, such as building or improving clinics.

- **Nutrition:** Nutritional status plays an important role in determining vulnerability to infectious and chronic diseases, as well as influencing physical and intellectual development during childhood. In the FY2008 reauthorization of the Farm Bill,<sup>6</sup> Congress stressed the importance of food security (rather than building international trade) as a goal of food aid, and set minimum funding levels for non-emergency food assistance that increase incrementally over the five-year program. The Congressionally mandated “HIV and Food Security Conceptual Framework” to coordinate PEPFAR activities with USAID’s Food for Peace (P.L. 480 Title II) program established a “programmatic continuum to address the nutrition, dietary supplementation and food security needs of HIV-infected and -affected populations.”<sup>7</sup> Thus, from FY2009 on, non-emergency food assistance to support global health missions will constitute a growing fraction of global health programs. USAID and USDA are the two main partners in implementing food assistance programs, including non-emergency food aid; CDC has evaluated nutrition and health status among vulnerable populations, particularly during complex humanitarian emergencies.
- **Safe water, sanitation, and mitigating environmental hazards:** Clean water is a prerequisite to health. Diarrheal diseases remain a top cause of child mortality in the developing world, and the technologies to achieve clean water and minimize such diseases are relatively cheap and easy to deploy. Despite this, the US investment in water programs for health remains relatively small, especially when compared to spending on disease-specific programs. USAID, the Environmental Protection Agency (EPA) and CDC – mainly sponsoring public-private development of safe water systems – play roles in safe water programs aimed at improving global health (in contrast to managing water for agricultural, industrial, or navigational use). EPA also addresses environmental hazards, such as air pollution. The Paul Simon Water for the Poor Act of 2005 directed the State Department to take the lead in developing a strategy for including safe water and sanitation as a priority for US development assistance strategies.<sup>8</sup>

- **Population and maternal/child health:** Despite political controversy associated with some aspects of family planning, USG global health programs have consistently included maternal and reproductive health and child survival programs ranging from micronutrient supplementation to immunizations to training skilled birth attendants. Although CDC supports international programs focused on sexually transmitted diseases and supplies vaccines for global polio and measles eradication initiatives, USAID is by far the lead USG agency on issues of maternal and reproductive health and child survival.
- **Research:** The US conducts and supports international research in a vast range of fields, although – outside of AIDS research – NIH offers little compiled information on the full scope of research conducted in international institutions, leaving the definition of “international research” as inconclusive as that of “global health.” NIH leads USG efforts in basic and clinical research in a range of technical areas, while CDC, and to a lesser extent, DOD, support field research to understand disease trends. (Within PEFAR, HRSA also supports “operations research” or health services research to improve service delivery.) Although the National Science Foundation does support international research, it focuses on basic research disciplines rather than medical sciences.<sup>9</sup>

For all overseas programs, the State Department coordinates the USG international presence through the planning and policy development process at home and through the chiefs of mission in the field.

## BACKGROUND

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Infectious disease outbreaks have posed an obvious threat to human health throughout recorded history. The need to prevent epidemics if possible and contain them when necessary has shaped the United States government engagement in public health – domestic *and* global – for well over a century. Although contemporary culture tends to frame globalization as a new and dramatic phenomenon, the world began shrinking in earnest in the 19<sup>th</sup> century. World-spanning empires, exuberantly international trade, and massive immigration fostered convergent networks of markets and people.<sup>10</sup> Their movements, in turn, abetted epidemics of familiar and emerging infectious diseases, such as the successive waves of cholera that deluged Europe, necessitating new domestic public health measures and creating political momentum for international public health cooperation.<sup>11</sup>

In 1892, the world's maritime powers agreed to the first “international sanitary convention” to prevent the spread of cholera, yellow fever, and plague at ports of entry without hampering trade and travel.<sup>12</sup> This treaty and the negotiations that produced it established a regulatory framework that endured, through the International Health Regulations of 1969, well into the contemporary era.<sup>13</sup> Although their narrow focus on a few diseases of historical importance made the treaties themselves increasingly irrelevant, the demonstration that states could cooperate in public health matters for mutual benefit fostered a new acceptance of international health activities and intergovernmental bodies to coordinate them, underpinning the creation of the World Health Organization (WHO) as a specialized United Nations agency in 1948.<sup>14</sup>

Within the US, a yellow fever outbreak that spread rapidly from New Orleans along the Mississippi River inspired the National Quarantine Act of 1878, the first in a series of laws that expanded the Federal role in containing disease outbreaks.<sup>15</sup> To support this role, Congress steadily expanded the responsibilities of the organization that evolved into the Public Health Service in 1912, adding quarantine, border screenings, and finally the investigation and control of all human diseases to its authorities.<sup>16</sup> The mandates and capabilities created to meet these missions mandate persist today in the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the National Institutes of Health (NIH).

These trends of increased international health cooperation and investment in an unparalleled body of research and public health expertise within US government (USG) agencies continue to shape the USG engagement in global health. From the beginning, USG global health strategies have mingled the moral imperatives of humanitarian aid, overarching diplomatic and security goals, and clearly articulated self-interest: the need to contain public health threats abroad before they affect vital US interests.

### ***US and International Development Policies, 1940's-1990's***

Although the US has cumulatively increased its commitments to sustainable development and global health in the last few decades, policymakers have continually (and sometimes contentiously) sought to redefine foreign assistance and its delivery. US foreign assistance after World War II focused on the immediate need to rebuild an economically stable Europe through the Marshall Plan and its implementing office, the Economic Cooperation Agency. By the 1950's, decision makers sought a satisfactory foreign assistance strategy that would look beyond

emergency relief, creating a rapid succession of short-lived agencies with varying degrees of autonomy from the State Department to implement a range of development and security assistance programs.<sup>17</sup> Congress emphasized a new direction for technical and economic assistance, supporting “soft loans” through the new international development banks and innovations such as the 1954 Food for Peace (Public Law 480) program, an interagency effort<sup>iv</sup> that allowed the US to provide humanitarian relief, meet nutritional needs, and support development in recipient nations while disposing of surplus agricultural commodities.<sup>18,19</sup>

President Kennedy embraced the “Decade of Development” in the 1960s, creating the Peace Corps and uniting various existing US foreign aid functions into the new US Agency for International Development (USAID, a semi-autonomous agency under the State Department) to manage bilateral assistance with an emphasis on sustainable development rather than Cold War diplomatic imperatives.<sup>20</sup> In 1973, chronic dissatisfaction with the purposes and effectiveness of foreign aid prompted Congress to re-direct USAID’s operational focus to “basic human needs” – food and nutrition, population planning, health and education, human resources development, and other specific problems – in the world’s poorest countries, emphasizing technical assistance and capacity building.<sup>21</sup> Satisfaction with USAID’s results remained uneven, and President Carter (responding to Congressional pressure) created the International Development Cooperation Agency to coordinate all of the programs included in foreign assistance legislation, including those within the Department of Treasury, USAID, the Peace Corps, and the Overseas Private Investment Corporation, but granted the agency no authority over personnel, programs, or budgets. (IDCA persisted as an office until eliminated by President Clinton).<sup>22</sup>

Highly publicized famines and other crises in Africa fanned domestic support for humanitarian relief activities into the mid-1980’s, helping maintain levels of US assistance for sub-Saharan Africa amid shifting political priorities.<sup>23,24</sup> However, structural adjustment policies imposed by multilateral development financing organizations, including the World Bank and International Monetary Fund, indirectly encouraged borrower governments to cut spending on public health and other social programs to meet economic requirements for refinancing debts or obtaining new loans.<sup>25</sup> Although life expectancies increased worldwide from the early to the mid-twentieth century, the austerity mind-set may have eroded the capacity of public health systems around the world to respond to unexpected disease outbreaks. The eruption of the HIV/AIDS epidemic in the 1980s hinted at the scope of this miscalculation. The lack of disease detection and reporting systems allowed HIV to become an entrenched problem in Africa long before the appearance of unusual opportunistic infections in the US and Europe prompted a search for the cause. Donor

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<sup>iv</sup> The Public Law 480 foreign food aid programs, first authorized in the Agricultural Trade Development and Assistance Act of 1954 (Public Law 83-480), sought to cultivate markets for US agricultural products while also addressing development, humanitarian assistance, and foreign policy objectives. After its 1961 launch, the US Agency for International Development (USAID) acquired responsibility for operating the P.L. 480 Title II emergency and non-emergency food aid programs from the US Department of Agriculture (USDA). The Food for Peace Act of 1966 and subsequent revisions shifted the primary emphasis of P.L. 480 programs from expanding international trade to meeting humanitarian and development needs. The composition of the multi-agency advisory committee established to oversee P.L. 480 programs has varied over time, and is currently embodied in a consultative relationship between USAID and USDA. [Sources: Susan Epstein, *Primer on P.L. 480 (CRS Report 84-803)*, Congressional Research Service: Washington, 1984; USDA, [Fact Sheet: Food Assistance](#), April 2009.]

states and organizations seeking to mitigate the devastating effects of HIV in severely affected developing nations encountered public health infrastructures insufficient to support even narrowly focused assistance programs.

### ***US Global Health Programs (1940's – 1980's): New Ambitions, New Confidence***

At the end of World War II, the Public Health Service and its components began to engage in international technical assistance that – while often modest in scope – established the US public health agencies as a global resource for disease detection and response. CDC's success in eradicating malaria in the US by 1949<sup>v</sup> demonstrated a competence much in demand by the newly created WHO and other international partners.<sup>26</sup> By the 1950's, CDC routinely supplied technical assistance in malaria control and other outbreak responses to partner nations, first through international organizations and then by dispatching its own teams overseas.<sup>27</sup>

US leadership in the global smallpox eradication campaign ushered in the contemporary era of US global health engagement. By 1963, CDC possessed the technical expertise and evidence to approach the eradication of smallpox in the developing world, but lacked resources and a political mandate; USAID contemporaneously wished to conduct extremely labor-intensive measles vaccination programs in Central and West Africa that required CDC's assistance to implement.<sup>28</sup> The agencies negotiated a compromise (see Box 1). In 1965, the President announced that USAID and CDC would conduct a joint campaign to protect 105 million people from smallpox *and* measles in 18 African countries, justifying the effort in terms of domestic benefits to the US (which then spent about \$20 million a year on compulsory vaccination and other measures to prevent re-introduction of smallpox).<sup>29</sup> The US commitment prompted WHO to reinvigorate its moribund smallpox eradication program, increasing the budget from \$266,000 in 1965 to \$2.4 million in 1966, with vaccines supplied by the Soviet Union.<sup>30</sup> WHO confirmed the eradication of naturally occurring smallpox in 1980. The smallpox campaign helped establish expectations and mechanisms for US health programs on the global scale, and shaped international values for public health efforts in ways that continue to influence policy development and implementation.

- The “campaign” against smallpox cemented the metaphor of war against an enemy disease that can be vanquished. The favorable cost-benefit ratio and clear metrics for success associated with campaigns against communicable diseases (especially where effective vaccines are available) encouraged decision makers to favor vertical programs to “fight” specific diseases rather than horizontal funding to strengthen health systems.
- During the Cold War, the US and Soviet Union overcame contemporary political intransigence to cooperate through WHO on a “neutral” health topic, sustaining international momentum for the difficult project. This reinforced a now widely accepted norm: governments can, and should, compromise temporarily on sovereignty issues in the context of public health campaigns.<sup>vi</sup>

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<sup>v</sup> Built on the work of its predecessor organization, the World War II-era Public Health Service office for Malaria Control in War Areas.

<sup>vi</sup> Examples include numerous cease-fires during open hostilities to allow international organizations to conduct “vaccination days.” [See: WHO: [“Health as a Bridge for Peace: Humanitarian Cease-Fires Project.”](#)]

- USAID and CDC worked together in a pattern that endures today, with CDC supplying technical expertise and working with local health personnel and USAID providing resources and in-country logistical support. However, the partnership also illuminated some of the weaknesses of this working relationship. The differences in capabilities and objectives between the two agencies inevitably required compromise, but mismatched working styles and incongruent perceptions of conditions and needs on the ground placed CDC in the position of negotiating in mid-stream – occasionally acrimoniously – for resources necessary to implement the program as designed and approved.<sup>31, 32, 33</sup>
- Although Public Health Service units, including CDC, had previously conducted international health activities abroad as an extension of their domestic public health mandates, the smallpox eradication campaign helped establish the global health-economic-security nexus as an accepted norm. Justifying the US role in smallpox control in Africa on the basis of economic self-interest (cost-effectiveness for the US once it ceased domestic smallpox prevention measures) and human security (eliminating the risks of vaccination and imported infections) rather than humanitarian relief established a common contextual framework for describing US global health programs to domestic policy makers and the public as a matter of security rather than development. Over the last decade, concerns about the health status of populations outside of the US – once primarily the province of humanitarian, development assistance, and public health professionals – have also assumed prominence in the agendas of the intelligence, security, and foreign policy communities.

**Introduction Box 1: 1966, Global Health, and the USAID-CDC Partnership.** Two events initiated in 1966 helped shape CDC's role in global health engagement, and highlighted the potential frictions in interagency planning early in the USAID-CDC partnership. In 1963-4, CDC's smallpox unit executed a successful mass smallpox vaccination pilot project on the island of Tonga, demonstrating that new "jet injectors" and heat-stable vaccines made population-level eradication feasible. The team envisioned expanding the program to 20 countries in West and Central Africa, where smallpox remained a major disease burden, but unsuccessful campaigns against yaws and malaria left WHO and the US government with little enthusiasm for another global disease eradication strategy. At the same time, USAID initiated a measles vaccination demonstration project targeting children in West and Central Africa at the request of 11 partner nations. The program's demands overwhelmed NIH, the first technical partner; USAID soon tasked CDC to provide more and more personnel to support an expanding measles campaign that CDC's experts found logistically flawed. D.A. Henderson, head of CDC's surveillance programs, and CDC Director David Sencer persuaded USAID to combine the smallpox and measles vaccination strategies at incremental cost, made possible by integrating the programs into existing local health service structures rather than creating autonomous systems. CDC launched the smallpox eradication-measles control program in 1966, stressing tailored, evidence-based practices; continual disease surveillance and research; and day-to-day oversight of local health personnel by CDC experts on the ground. CDC's successes revitalized the successful WHO global smallpox eradication campaign.

In 1966, USAID also transferred its faltering international malaria eradication program to CDC. The strategy depended upon house-to-house spraying for malaria-bearing mosquitoes through USAID-funded programs carried out by the countries themselves. Malaria control staff of wildly varying abilities in 18 different countries suddenly joined the CDC payroll (making CDC, transiently, the largest employer in Haiti), but remained under the direct supervision of US missions whose goal was to promote host-country economic development, not disease surveillance and response. USAID still controlled deployment of CDC staff to the field, and resisted any role for US personnel beyond monitoring host country efforts. (Over time, CDC officials gradually persuaded WHO authorities to shift the international community's emphasis from a strategy of eradication to more manageable goals in malaria control and preventing malaria deaths in children.)

These campaigns illustrated differences in agency norms, rooted in the cultures of the public health and foreign aid professionals that staff them, that persist today. CDC favored trained US personnel in the field directly guiding local teams toward technical milestones; USAID emphasized developing host nation capacities through building public health infrastructure, with oversight by local governmental and non-governmental organizations. [Sources: Elizabeth W. Etheridge, *Sentinel for Health: A History of the Centers for Disease Control*, University of California Press: Berkeley, 1992.; "CDC's 60th anniversary: director's perspective-David J. Sencer, M.D., M.P.H., 1966—1977." *MMWR* 2006; 55:745-9.; David Sencer, [Oral History of West Africa Smallpox Eradication Program](#) (Emory University, July 7, 2006); Donald A. Henderson, "Eradication: Lessons from the Past." *MMWR* 1999; 48(SU01):16-22.]

### ***Global Health and US HIV/AIDS Intervention Strategies (1980's-1990's)***

The first reports of HIV/AIDS in the US appeared in 1981, as cases of unusual pneumonias in young gay men began to emerge.<sup>34</sup> Cases were identified in Uganda in 1982, and by 1983, doctors working in Central Africa (and in Europe with patients from or linked to Central Africa) described patterns of opportunistic infections and aggressive cancers similar to those seen in the high-risk groups in the US.<sup>35, 36</sup> WHO convened its first meeting on AIDS (acquired immune deficiency syndrome) in November of that year, initiating global surveillance for infections with the virus that came to be known as HIV (human immunodeficiency virus).<sup>37</sup> Research into

African medical records soon found examples of previously unnoted increases in AIDS-related conditions in Zaire, Uganda, Tanzania, Rwanda, and Zambia as early as the 1970's.<sup>38</sup> The global nature of the epidemic was apparent by the time that the first International AIDS Conference convened in 1985; in the same year, the US Public Health Service began issuing recommendations on prevention of mother-to-child transmission, the FDA licensed the first screening test, and advocacy groups gathered momentum in demanding a comprehensive US response.<sup>39</sup> The Joint United Nations Programme on AIDS (UNAIDS) estimates that, by 1990, just over 5 million people were living with HIV/AIDS in Sub-Saharan Africa alone, more than half of the total number infected.<sup>40</sup> (By 2007, that number had climbed to approximately 22 million people living with HIV/AIDS in Sub-Saharan Africa of about 33 million worldwide, accounting for two-thirds of infections and 75% of AIDS deaths.<sup>41</sup>)

Through the 1980's, the US government agencies with existing global health (and human development) mandates developed individual approaches to the emerging HIV/AIDS crisis consistent with their missions and programmatic styles.

*NIH* – In 1983, the US Congress appropriated the first funds designated specifically for HIV/AIDS activities, including research at NIH.<sup>42</sup> NIH gradually developed a portfolio of extramural and intramural research programs (including partnerships with international institutions) that came under the Office of AIDS Research in 1988.

*USAID* – Under its mandate to protect child survival and health in the poorest nations, USAID established its international HIV/AIDS program in 1986, the first US spending aimed explicitly at the global epidemic. Significant early milestones include:

<i>Year</i>	<i>Program/Event</i>	<i>Purpose/Main recipient</i>
1986	\$2 million award	To support WHO's new Global Programme on AIDS, the first award of US funds for the global epidemic <sup>43</sup>
1987	USAID develops an agency-wide HIV/AIDS policy framework that authorizes an AIDS Technical Support Project	Created a mechanism for supporting HIV/AIDS prevention and control activities by US private voluntary organizations (PVOs) and CDC and for USAID mission and bureau participation. <sup>44</sup>
1987	AIDS Public Health Communication Project (AIDSCOM)	A 5-year cooperative award to develop social marketing for preventing sexually transmitted HIV [Awarded to Academy for Educational Development (PVO)] <sup>45</sup>
1987	AIDS Technical Support Project (AIDSTECH)	A 5-year cooperative award to prevent sexual and blood-borne transmission of HIV in 35 countries <sup>vii</sup> through screening, education, and promotion of safe sex practices [Awarded to Family Health International (PVO)] <sup>46</sup>
1990	Internal program review	Concluded that the breadth and overlap of AIDSCOM and AIDSTECH, in terms of both geography and subject matter, overextended existing resources and created policy confusion. <sup>47</sup>
1991	AIDS Control and Prevention Project (AIDSCAP)	5-year cooperative agreement with a budget of \$168 million that replaced predecessor efforts; focused more narrowly on reducing the rate of sexually transmitted HIV infection in vulnerable populations in 15 countries <sup>viii</sup> by strengthening their capacity to encourage condom use, decrease sexually transmitted illnesses, and promote safer sexual behaviors. [Awarded to Family Health International (PVO)] <sup>48</sup>

<sup>vii</sup> AIDSTECH operated in Africa (Burkina Faso, Cameroon, Ghana, Kenya, Tanzania, Zaire, and Zimbabwe), Southeast Asia (Philippines and Thailand), and Latin America and the Caribbean (Brazil, Dominican Republic, Haiti, Mexico, and the Eastern Caribbean).

<sup>viii</sup> Target countries were Cameroon, Ethiopia, India, Brazil, Kenya, Nigeria, Indonesia, Dominican Republic, Rwanda, Senegal, Nepal, Haiti, South Africa, Thailand, Honduras, Tanzania, Zimbabwe, and Jamaica. Implementing PVO Family Health International eventually included more than 25 additional "associate" countries for smaller, targeted projects.

Between 1986 and 1991, Congress appropriated about \$168 million for USAID's HIV/AIDS activities, including about \$88 million for the WHO Global AIDS Programme and approximately \$80 million for bilateral HIV/AIDS accounts; USAID obligated about \$68 million more for HIV/AIDS prevention (primarily to promote condom use) through existing programs.<sup>49</sup> Its bilateral programs, as described in the table above, relied upon cooperative awards to large international NGO's, which in turn awarded subcontracts to other NGO's to implement parts of the programs. By 1992, some decision makers questioned the scope and direction of USAID's international HIV/AIDS programs, including whether to integrate its HIV/AIDS policies more closely with other country-level planning and economic development strategies.<sup>50</sup>

*CDC* – During this period, CDC provided technical assistance in HIV/AIDS to USAID through an interagency agreement, as well as initiating its own programs.<sup>51</sup> In 1988, CDC established a field station in Abidjan in partnership with the Cote d'Ivoire Ministry of Health to conduct epidemiological research in HIV/AIDS and build public health infrastructure.<sup>52</sup> In the next ten years, CDC added field-based programs in Uganda, South Africa and Thailand to its ongoing partnership in Cote d'Ivoire, with financial support from USAID.<sup>53</sup> Although quite modest in scope, these projects underlined a new trend: CDC, a domestic USG agency, established its own international field offices rather than deploying personnel to an existing USAID mission. These CDC field offices were eventually absorbed into successor bilateral US HIV/AIDS programs.

### ***The Looming Threat of Infectious Diseases (1992-2000)***

The 1990's brought the end of the Cold War and its pressures to focus aid on supporting diplomatic and political goals in a bipolar global struggle, and the dawning awareness of a new era of globalization. At the outset of the Clinton presidency, the focus on the domestic health agenda and its political fallout consumed much of the incoming administration's health expertise. By 1994, the Clinton administration's commitment to reducing the deficit converged with the budget-trimming goals of the newly Republican-controlled Congress to pare away discretionary spending in many areas, including development assistance. However, by the mid-1990's the White House had launched a new series of initiatives and programs aimed at increasing US engagement in global health on the grounds that the infectious disease burden in low- and middle-income countries threatened US national security.

With the global eradication of smallpox in 1977 and the restriction of once ubiquitous scourges such as cholera, polio, and measles primarily to the developing world, US policy makers developed a sense of invulnerability about disease threats. In 1992, an Institute of Medicine committee chaired by Nobel Laureate Joshua Lederberg concluded that the resulting erosion of the US public health infrastructure and general societal complacency about infectious diseases, combined with a new global disease ecology, created a generally underappreciated and very serious domestic vulnerability.<sup>54</sup> A 1994 USG interagency working group on emerging infectious diseases, led by CDC, State, USAID, FDA, NIH, and the Department of Defense under the auspices of the National Science and Technology Council (NSTC), recommended that the US commit significant resources to strengthening disease surveillance, reporting, and response capacities globally and domestically.<sup>55</sup> WHO, under pressure from the US and other member states, created a new Division of Emerging and other Communicable Diseases in 1995 (with a two-year budget of \$23 million) to coordinate technical assistance on worldwide disease

detection and control.<sup>56</sup> In 1996, the White House released Presidential Decision Directive (PDD) NSTC-7, which established an integrated USG-wide strategy to address the threat of emerging infectious diseases and assigned USG agencies specific roles in improving surveillance, prevention, and response measures at home and abroad.<sup>57</sup>

New economic theories looked beyond the humanitarian aspects of the AIDS crisis to link poor population health, stagnant economic progress, and sociopolitical instability, suggesting that HIV/AIDS and other persistent health threats could undermine already fragile states and decimate forces responsible for maintaining regional security. An influential 1999 US National Intelligence Estimate examined the potential impact of HIV/AIDS and other emerging infections in the context of these theories on health and development and concluded that the global disease burden poses a threat to US vital interests.<sup>58</sup> The White House Office of National AIDS Policy (ONAP), created in 1993 to provide a focus for the US national response to HIV/AIDS, and the USG Interdepartmental Task Force on HIV/AIDS began looking beyond the domestic agenda to embrace a larger international role.<sup>59</sup> On July 19, 1999, the Administration announced the creation of the Leadership and Investment in Fighting an Epidemic (LIFE) Initiative, a new plan to address the global AIDS pandemic starting with a \$100 million increase in US support to prevent the further spread of HIV in Sub-Saharan Africa and India.<sup>60</sup> The plan pledged to support the goals and objectives established by the Joint United Nations Programme on AIDS (UNAIDS, the trans-UN organization that absorbed WHO's Global Programme on AIDS and other parallel UN programs in 1996), and named USAID the lead agency – in partnership with HHS and DOD – to target the most severely affected nations, focusing “where the potential for impact is greatest, and where USG agencies are already active.”<sup>61</sup> The LIFE Initiative provided the platform for launching both CDC's Global AIDS Program and the DOD HIV/AIDS Prevention Program in 2000, two programs that continue to play key roles in US global health engagement.

In January 2000, with urging from Vice President Gore, the United Nations Security Council addressed a health issue for the first time, defining the HIV/AIDS crisis in Africa as a security concern requiring an international response.<sup>62</sup> In April 2000, the Clinton White House declared global AIDS a threat to US national security, directing the National Security Council to re-examine US global HIV/AIDS efforts and calling for a doubling of the contemporary budget (then to \$254 million) for FY 2001.<sup>63</sup> In August 2000, Congress enacted the Global AIDS and Tuberculosis Relief Act of 2000 (P.L. 106-264), authorizing \$300 million for each of fiscal years 2001 and 2002 for a comprehensive, coordinated, worldwide HIV/AIDS effort under USAID.<sup>64</sup>

### ***The US Response to New Health Threats (2001-8)***

The George W. Bush administration entered the White House in 2001 internally conflicted about the role of “soft security” issues, including global health, and ambiguous about its intentions to continue the Clinton-era HIV/AIDS and disease surveillance capacity-building programs.<sup>65</sup> Some HIV/AIDS activists regarded its early commitments to multilateral efforts such as the new Global Fund to Fight AIDS, Tuberculosis and Malaria and slight increases for LIFE Initiative bilateral HIV/AIDS activities as tepid, at best.<sup>66</sup> The Bush administration's early reinstatement of the Reagan-era “Mexico City Policy,” a set of restrictions on non-governmental organizations

that receive US assistance to implement overseas family planning programs – which frequently encompass maternal and child care and HIV/AIDS screening, prevention or treatment services – proved immediately contentious.<sup>67</sup>

The 2001 anthrax assaults in the US, only a few weeks after the September 11<sup>th</sup> terrorist attacks, and the 2003 international outbreak of SARS (severe acute respiratory syndrome) vividly illustrated the limitations of disease surveillance networks and biological defenses forewarned in the 1990's. The SARS epidemic demonstrated that emerging infections can exact a psychological, political, and economic toll far beyond the immediate human costs; despite causing fewer than 800 deaths worldwide, estimates place the cost of SARS to Southeast and East Asia alone at US\$18-60 billion in direct expenditures, lost tourism and business, and slowed economic development.<sup>68</sup> The ongoing spread of an avian influenza strain with pandemic potential emphasized the vulnerability of even highly developed nations to emerging infections in an age of rapid travel and economic interdependence. Estimates suggest that an influenza pandemic could result in 200,000 to 2 million deaths in the US, depending on the virulence of the virus, with a projected economic cost of US\$71.3 to \$166.5 billion.<sup>69</sup>

These events radically reshaped the Bush administration's domestic and global public health agenda. In the wake of the anthrax assaults, the President requested and Congress authorized enormous sums (just under \$50 billion through FY 2009) for "biodefense."<sup>70</sup> Although this includes research on pathogens that are endemic diseases in the developing world as well as potential biological weapons, the majority of this funding supports domestic public health infrastructure- and capacity-building programs.<sup>ix</sup> A more comprehensive "all-hazards" policy framework that encompassed potential pandemics as well as deliberate epidemics emerged in the later years of the Bush administration, including assistance to build disease detection and response capabilities in low- and middle-income nations considered at highest risk of a catastrophic outbreak. Congress has appropriated funding specifically for pandemic influenza preparedness annually since fiscal year 2004 (including \$6.1 billion in emergency supplemental appropriations for FY2006), with a portion allocated toward building international disease detection and response capabilities through bilateral assistance to partner nations.<sup>71</sup>

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<sup>ix</sup> This framework also strengthened biosecurity regulatory policy – the "Select Agent Rules"—designed to prevent deliberate theft or misuse of pathogens in US-supported laboratories that complicated both international research collaborations to study diseases on the Select Agent List (even if they are endemic to the country where they are studied) and access of foreign national students and researchers to US labs. Combined with visa controls initiated after the 9/11 attacks, the cumulative effect could be perceived as inimical to the spirit of international research.

**Introduction, Box 2: The Changing Global Health Landscape.** Highly visible emerging infections like SARS and HIV constitute only a fraction of newly recognized diseases; according to WHO, investigators discovered an average of one emerging infection of public health importance each year from 1973 to 2002. New demands on the global food supply and changing land use patterns have altered the human-domestic animal-wildlife interface, creating new opportunities for animal diseases to cross into human populations. So-called disease amplifiers, such as urban crowding complicated by inadequate public services, poor infection control practices, and misuse of antibiotics leading to drug resistant pathogens foster the spread of both emerging and well-characterized infectious diseases. Poor populations in low and middle-income countries are at greater risk of health problems, suffer higher maternal/child mortality, and are more vulnerable to insurmountable debts when health catastrophes arise, with profound consequences for economic stability at the individual and community level. High endemic disease burdens in these countries diminish the human resource pool available to people the armed forces, acquire technical skills necessary to build local capacity in all fields, and generally look strategically to the future rather than relying on a subsistence existence. Migrants in and from these nations represent a specific disease concern: they are mobile vectors of diseases, and are also less likely than indigenous populations to have good access to either preventive public health services or curative clinical care (especially those of irregular migration or refugee status).

Neither the emergence of lethal new diseases nor the increased vulnerability of poor and marginalized populations to health catastrophes of every sort represents a new phenomenon. What has changed in recent decades is the extreme and routine mobility of international air travelers, the interdependence of economies via financial markets and global inventory systems, and a new sensitivity to the security risks posed by weak states. As noted by Dr. Margaret Chan, Director-General of WHO, “Traditional defences at national borders are no protection against a microbe incubating in an unsuspecting traveler or an insect hiding in a cargo hold....This has made all nations vulnerable – not just to invasion of their territories by pathogens, but also to the economic and social shocks of outbreaks elsewhere.” [Sources: *Achieving Sustainable Global Capacity for Surveillance and Response to Emerging Diseases of Zoonotic Origin: Workshop Summary*, National Academies Press: Washington, DC 2008; and Dr. Margaret Chan, Opening Statement, World Health Day Debate on International Health Security (Singapore, 2 April 2007).]

In an unexpected twist, the Bush administration turned back to the legacy of HIV/AIDS prevention programs established in the late 1990’s and dramatically expanded them under the President’s Emergency Plan for AIDS Relief (PEPFAR), the largest global health campaign ever focused on a single disease. Several converging factors encouraged the Bush administration to take up global HIV/AIDS efforts: the need to burnish US global standing in the face of an increasingly unpopular military engagement strategy; greater awareness of and concern about the epidemic’s impact among the public and Congressional leaders; and growing pressure from the US evangelical community – a key constituency in the administration’s political base – to confront the humanitarian crisis precipitated by HIV/AIDS in Africa.<sup>72, 73</sup> The 2002 National Security Strategy cited the HIV/AIDS crisis in poor nations as a priority for the broadened US security agenda, although administration officials closely guarded the developing White House strategy for PEPFAR.<sup>74, 75</sup> In his January 2003 State of the Union Address, President Bush called upon a receptive Congress “to turn the tide against AIDS in the most afflicted nations of Africa and the Caribbean.”<sup>76</sup> Congress passed the United States Leadership Against HIV/AIDS,

Tuberculosis, and Malaria Act in May 2003,<sup>x</sup> authorizing \$15 billion over five years for a “comprehensive, integrated five-year, global strategy to fight HIV/AIDS” concentrated on fifteen focus countries.<sup>xi</sup> The program integrated the existing and expanded USG global HIV/AIDS programs under a new Office of the Global AIDS Coordinator (OGAC), based within the State Department but separate from State’s existing international health structures.<sup>77</sup>

The new PEPFAR program dedicated an unprecedented level of resources to treatment and care of HIV-infected individuals in addition to prevention of new infections, emphasizing the scale-up and accelerated roll-out of services. The ambitious scale of the five-year performance targets – providing anti-retroviral treatment to 2 million people, preventing 7 million new infections and providing care for 10 million patients suffering from AIDS by 2010 – required rapid implementation, made even more urgent by the lag between the launch of the plan and appropriation of the first year’s funding.<sup>78</sup> In practice, this meant that actions sometimes outstripped the development of clear guidance, policies, operational research, and management structures to support effective programs tailored to each country’s needs.<sup>79</sup> Congressionally mandated spending requirements that allocated a fixed 33% of prevention funding to abstinence and fidelity programs, and ambiguity in the interpretation of this requirement, presented challenges to country teams attempting to develop plans based on local evidence and needs.<sup>80</sup> The US emphasis on bilateral over multilateral actions sparked concerns that the investment in PEPFAR might undermine long-term US support for the Global Fund and foster competition rather than cooperation between the two efforts.<sup>81</sup> The bilateral focus and real or perceived constraints imposed by US policies (from spending mandates to limits on information-sharing to the requirement that PEPFAR funds purchase only pharmaceuticals approved by the FDA, rather than accepting the WHO approval process commonly used internationally) also thwarted effective coordination with other donors and harmonization with partner nation plans, increasing the potential for duplicative and inefficient international programming.<sup>82</sup>

Despite these challenges, PEPFAR focus countries saw dramatic increases in antiretroviral therapy coverage in the program’s first five years.<sup>83</sup> The US commitment to PEPFAR underpinned a dramatic increase in international assistance for the response to HIV/AIDS in low- and middle-income countries from 2002-2007.<sup>84</sup> In 2008, Congress authorized an increase of up to \$48 billion over five years (FY2009-2013) to continue and expand PEPFAR programs, removing some of the more contentious spending requirements.<sup>85</sup> The structure and implementation of PEPFAR are described in detail in the sections that follow.

Following upon the successes of PEPFAR, political and logistical, the Bush administration launched two global health policy and planning coordination programs that are less ambitious in scope but target diseases of significance in low- and middle-income countries. The President’s Malaria Initiative (PMI), announced in June 2005, applies some of the principles of PEPFAR – including integrating and rapidly rolling out various prevention and treatment services in 15

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<sup>x</sup> The sense of Congress expressed in the prelude of the US Leadership against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 (Public Law 108-25) explicitly described HIV/AIDS in security terms, from “personal security ...affecting the health, lifespan, and productive capacity of the individual and the social cohesion and economic well-being of the family,” to economic, sociopolitical, military, and international security.

<sup>xi</sup> The 14 originally authorized focus countries include Botswana, Côte d’Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda, and Zambia, with Vietnam added by the President several months after enactment.

focus countries – but relies primarily upon USAID as the lead agency and CDC as the technical/implementing partner.<sup>86</sup> The Neglected Tropical Diseases initiative (NTD), announced in February 2008, addresses seven debilitating parasitic diseases common in the world’s poorest nations, integrating existing prevention, treatment, and control programs that previously addressed each of the specific diseases individually under the direction of USAID.<sup>87</sup> The 2005 US National Strategy for Pandemic Influenza placed responsibility for coordinating US support for avian and pandemic influenza activities in more than 100 countries with the State Department, which created a special representative to lead an interagency Avian Influenza Action Group.<sup>88,89</sup>

Most of the new global health initiatives arose on an ad hoc basis, adding to existing bureaucratic structures rather than streamlining or replacing them. Many of the primarily domestic agencies involved in supporting global health programs through funding and technical assistance have dramatically increased their international activities in only a few years. Responsibility for planning and implementing the hugely amplified US global health mission remains spread among various agencies, with different interagency coordinating and oversight bodies for specific disease strategies. The rapidly expanding US government (USG) programs spurred ongoing inter- and intra-departmental reorganizations, with no single focal point to harmonize global health policies and actions. Unsurprisingly, the lack of an overarching USG global health strategy or single coordinating authority outside of the PEPFAR program has encouraged decentralized priority setting and funding allocation.<sup>90</sup> Experts have recommended a number of as-yet untested solutions, from task forces to global health czars, to strengthen interagency coordination and develop a coherent USG global health strategy.<sup>91,92</sup>

The sections below describe USG institutions, agencies, and organizations that play some role in US global health engagement, as well as the existing formal USG mechanisms to coordinate interagency global health efforts.

## THE DEPARTMENT OF AGRICULTURE (USDA)

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### *Mission and roles*

As the lead agency for US food and agricultural issues, USDA focuses most of its international energies on securing market opportunities for US agricultural products. Through food assistance programs, USDA also contributes to global health, delivering commodities and emergency food assistance that simultaneously strengthen the US agricultural economy.<sup>93</sup>

### *Organization and focus*

With passage of the Agricultural Trade Development Assistance Act of 1954 (renamed The Food for Peace Act in 1961, and also known simply as “P.L. 480”), the US foreign assistance framework explicitly encompassed delivery of food aid in the context of development. Food aid policies continue to evolve; P. L. 480 Title I, which originally authorized USDA to sell US commodities to developing country governments on credit or grant terms, was revised in 2008 to emphasize food security rather than market development. (USAID administers P.L. 480 Title II food assistance programs.)<sup>94</sup>

Through the Foreign Agricultural Service (FAS), USDA currently administers two funded food assistance programs:

- **The McGovern-Dole International Food for Education (FFE) Program** provides US agricultural products and associated financial and technical assistance for maternal and child nutrition projects – particularly school feeding programs – to governments and nongovernmental organizations in low-income countries. USDA-FAS gives priority to applicant countries that have low income levels and nutritional status but are politically stable and committed to universal education.<sup>95</sup> For fiscal year 2009, FAS pledged to distribute about \$100 million (72,000 tons) in agricultural commodities to FFE awardees<sup>xii</sup> as resources become available, an amount estimated to reach about 3 million children.<sup>96</sup>
- **The Food for Progress Program** allows the donation or credit sale of US commodities to developing countries committed to supporting democracy and free enterprise in agricultural markets. (All food aid under this program to date has been

### SNAPSHOT - USDA

**Primary role:** Providing food assistance (primarily commodities) to programs in low-income nations.

#### **Global programming:**

- Household food security/food aid
- Infant/young child feeding

#### **Mechanisms:**

- Funding – donation of commodities for consumption or sale to generate cash (monetization)
- Technical/advisory

**Areas of focus:** Low-income nations meeting specific policy and political criteria.

#### **Significant dates:**

**1862** – USDA created.  
**1954** – Passage of Public Law 480, renamed “Food for Peace Act” in 1961.  
**2002** - McGovern–Dole International Food for Education and Child Nutrition Program authorized.

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<sup>xii</sup> These included programs sponsored by international organizations in Bangladesh, Cambodia, Cameroon, Chad, Ethiopia, Guatemala, Kenya, Laos, Liberia, Malawi, Mozambique, Pakistan, Rwanda, Sierra Leone, and Yemen. Others listed as priority countries in program considerations for FY2009-10 include Afghanistan, Angola, Guinea, Guinea Bissau, Madagascar, Mali, Niger, Senegal, Tanzania, and Uganda.

donated.<sup>97</sup>) USDA funds about 15-20 proposals each year that affect about 1 million people, giving priority to countries in political and economic transition; statutory caps limiting freight costs to no more than \$40 million functionally limits the amount of the commodities that can be moved.<sup>98</sup>

- **The Bill Emerson Humanitarian Trust** is not a food aid program, but a food (or cash) reserve administered by USDA that can be mobilized rapidly to address humanitarian food crises in developing countries.<sup>99</sup>

Although USDA’s Agricultural and Plant Health Inspection Service (APHIS) does not address human health directly, the recent USG focus on avian influenza and the animal-human health interface has increased APHIS technical partnerships with CDC and FDA on zoonotic diseases and antibiotic resistance. USDA has expanded technical assistance and funding for building veterinary diagnostic and outbreak response capacities in low- and middle-income countries.<sup>100</sup>

**USG interactions**

USDA and USAID – the primary USG food assistance actors – constitute the core of the public-private Food Aid Consultative Group (although this has not guaranteed harmonized food aid policies).<sup>101</sup> As a member of the PEPFAR Technical Working Group on Food and Nutrition, USDA provides technical assistance and consultative support on feeding programs, including helping to define parameters for the PEPFAR-USAID HIV and Food Security Conceptual Framework.<sup>102</sup> The FFE program falls into the general universe of activities coordinated by the Interagency Committee for Highly Vulnerable Children led by USAID.<sup>103</sup> FAS currently deploys more than 100 foreign service personnel (including 60 FAS agricultural attachés) to 55 countries,<sup>104</sup> where they serve as part of the State Department’s US mission country teams.

**Legislation and authorities**

Year	Focus	Authority	Purpose(s)
1862	Nutrition	7 USC Sec. 2201	Lincoln created the Department of Agriculture
1930	Nutrition	Foreign Agricultural Service Act of 1930 (P.L. 71-304)	Created Foreign Agricultural Service (FAS)
1938	Nutrition	Executive Order	The FAS was abolished and its staff headquarters renamed the Office of Foreign Agricultural Relations (OFAR).
1954	Nutrition	<a href="#">Public Law 83-480</a> (sections 201-7): The Agricultural Trade Development Assistance Act, renamed The Food for Peace Act in 1961	USDA as executive agent: authorized concessional sales of US agricultural commodities to developing countries and private entities (Title 1) – no appropriation since FY2006.
1971	Nutrition	By Regulatory authority of the Secretary of USDA	The animal and plant regulatory functions were separated from the Agricultural Research Service to become the Animal and Plant Health Service (APHIS)
1972	Nutrition	By Regulatory authority of the Secretary of USDA	The meat and poultry inspection divisions of the Consumer and Marketing Service were added to APHS; Established Animal and Plant Health Inspection Service.
1985	Nutrition	Public Law 99-198 (Title XI): The Food for Progress Act of 1985	Authorized USDA to provide US agricultural commodities to emerging democracies and developing countries committed to promoting free enterprise in agricultural development.

2002	Nutrition	<a href="#">Public Law 107-171</a> : The Farm Security and Rural Investment Act of 2002	Reauthorized Food for Peace Act through 2007; original authorization for McGovern–Dole International Food for Education and Child Nutrition Program through USDA’s Foreign Agricultural Service.
2005	Nutrition	<a href="#">House Report 109-265</a> , accompanying <a href="#">Public Law 109-102</a> : The Foreign Operations, Export Financing, and Related Programs Appropriations Act, 2006	Tasks OGAC in conjunction with USAID to report on HIV/AIDS-nutrition links and develop an interagency strategy for addressing the nutritional requirements of persons receiving care and treatment for HIV/AIDS in context of PEPFAR programs.
2008	Nutrition	<a href="#">Public Law 110-246</a> : The Food, Conservation, and Energy Act of 2008	USDA as executive agent: Comprehensive reauthorization of all US food and farm policies, including Food for Education, Food for Progress, and Food for Peace programs; re-titled Title I from “Trade and Development Assistance” to “Economic Assistance and Food Security.”

**Budget**

The following budget information includes appropriated funds and amounts borrowed from the Commodity Credit Corporation (CCC), a line of credit available to USDA through the US Treasury. Budget numbers here do not reflect funds for Public Law 480 Title II food assistance programs, which – although funded through the agricultural appropriation and authorized through the most current version of the Farm Bill – are provided directly to and administered by USAID.

<b>USDA Budget for International Food Assistance</b>					
	<b>FY 2004</b> Actual	<b>FY 2005</b> Actual	<b>FY 2006</b> Actual	<b>FY 2007</b> Actual	<b>FY 2008</b> Actual
<b>Global Food and Nutrition Activities (\$US thousands)</b>					
<b>McGovern-Dole Food for Education Program</b>	50000	87000	99000	98000	99000
<b>P.L. 480 Title I</b>					
<b>Food for Progress Program</b>	95000	31000	44000	16000	0
<b>Total</b>	<b>145000</b>	<b>118000</b>	<b>143000</b>	<b>114000</b>	<b>99000</b>

(Appropriation: Agriculture)

Sources:

[USAID FY2009 Congressional Budget Justification](#)

FY 2004: <http://www.gpoaccess.gov/usbudget/fy06/pdf/appendix/agr.pdf>

FY 2005: <http://www.gpoaccess.gov/usbudget/fy07/pdf/appendix/agr.pdf>

FY 2006: <http://www.gpoaccess.gov/usbudget/fy08/pdf/appendix/agr.pdf>

FY 2007: <http://www.gpoaccess.gov/usbudget/fy09/pdf/appendix/agr.pdf>

FY 2008: <http://www.gpoaccess.gov/usbudget/fy10/pdf/appendix/agr.pdf>

## THE DEPARTMENT OF COMMERCE (COMMERCE)

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### *Mission and roles*

The Department of Commerce serves as the US government's lead agency on economic development. To fulfill this role, Commerce coordinates US efforts to promote international trade from a strong economic position, to make the best use of technological and scientific resources for growth, and to foster progressive domestic business policies and promote economic stability in states and communities.<sup>105</sup>

Commerce comprises analytical expertise within its component bureaus, which include the National Institute on Standards and Technology and the National Oceanic and Atmospheric Administration as well as the Economics and Statistics Administration that contains the Bureau of the Census. Commerce contributes to US global health engagement mainly through its role as a PEPFAR implementing agency.

### *Organization and focus*

In authorizing the PEPFAR program, Congress encouraged the exploration of public-private partnerships as a potentially cost-effective path to sustainable programs. Commerce fosters such partnerships mainly through outreach to the private sector, building awareness of global HIV/AIDS interventions and highlighting specific opportunities for businesses or industries to participate. Such outreach includes presentations about HIV/AIDS and potential private sector contributions in industry/trade advisory committee meetings; development of sector-specific strategies; support for private sector meetings; sharing practices with the World Bank and other multilateral organizations; and networking with companies already working on HIV/AIDS to identify possible partnerships.<sup>106</sup>

The Health Studies Branch (International Programs Center, Population Division) of the Census Bureau compiles and manages data on demographics and HIV infections in the PEPFAR focus countries, supporting mapping of country-level activities and health indicators.<sup>107</sup> This analysis offers decision makers a tool in monitoring HIV/AIDS trends and evaluating interventions.

### *USG interactions*

Commerce engages with the PEPFAR implementing agencies through the working groups convened by the Office of the Global AIDS Coordinator in the State Department, and also works with State on international business issues. The continuing Census Bureau engagement with USAID on HIV/AIDS data analysis predates PEPFAR.

### SNAPSHOT - COMMERCE

**Primary role:** fostering public-private partnerships in global HIV/AIDS interventions through PEPFAR.

**Global programming:**

- HIV/AIDS

**Mechanisms:**

Policy, technical/advisory

**Areas of focus:**

PEPFAR focus countries

**Significant dates:**

1987—Census Bureau and USAID develop platform for HIV/AIDS Surveillance Data Base.

### **Legislation**

<b>Year</b>	<b>Focus</b>	<b>Authority</b>	<b>Purpose(s)</b>
2003	Global health (HIV/AIDS)	<a href="#">Public Law 108-25:</a> United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003	Required a comprehensive, integrated 5-year strategy for a coordinated USG response to global HIV/AIDS; established Office of the Global AIDS Coordinator in the State Dept.; amended the Foreign Assistance Act of 1961 to define eligibility and formulae for USG HIV/AIDS assistance; mandated goals, benchmarks, and metrics for program evaluation; authorized up to \$15 billion from FY2004-8, primarily in 15 focus countries.
2008	Global health (HIV/AIDS)	<a href="#">Public Law 110-293:</a> The Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008	Authorized an increase of up to \$48 billion over five years (FY2009-2013) to continue PEPFAR programs; extended the geographic and programmatic scope of HIV/AIDS, malaria, and tuberculosis control and prevention strategies; proposed use of framework agreements with recipient countries; removed some spending requirements on prevention efforts; endorsed health systems strengthening; and established a Global Malaria Coordinator in USAID.

### **Budget**

Commerce receives no direct appropriation for its HIV/AIDS activities; USAID supports the Census Bureau's analytical activities.

## THE DEPARTMENT OF DEFENSE (DOD)

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### *Mission and roles*

DOD's capabilities in medical services and disease surveillance and control evolved as a necessary response to the "disease/non-battle injuries" that even now incapacitate more service members than combat injuries during conflicts.<sup>108</sup> Force health protection remains the central mission of the Military Health System. However, the military's ongoing engagement in "security, stability, transition, and reconstruction operations," interest in "soft power" as a means of averting radicalization, and concerns about emerging disease threats have fostered new enthusiasm within DOD for expanding humanitarian and health assistance programs as an aspect of security cooperation.<sup>109</sup>

The US military health system has historically treated local populations abroad during and after complex emergencies such as disasters and conflicts. Legislation passed in 1986 extended the scope of DOD's humanitarian assistance portfolio, allowing the services some flexibility to engage host nations in non-crisis projects (including providing health services, technical assistance, and training) in the context of military exercises and operations.<sup>110</sup> In addition to responding to international humanitarian crises, DOD operates military-to-military health systems capacity-building programs and conducts research into diseases of significance in low- and middle-income nations.

### *Organization and focus*

The 2006 Quadrennial Defense Review, a new policy framework for stability and security operations,<sup>111</sup> and a series of highly publicized health service failures for wounded troops returning from Iraq and Afghanistan prompted a comprehensive internal review of DOD's health systems in 2007. This culminated in newly articulated missions (including "conducting diplomacy through health"), a partial reorganization of DOD's Office of Health Affairs, renewed emphasis on transparency and accountability to stakeholders, and a fresh focus on the Military Health System – rather than the health beneficiary system TRICARE – as the face of DOD's health enterprise.<sup>112</sup>

### SNAPSHOT - DOD

**Primary role:** supporting humanitarian aid, military to military health systems capacity-building, and disease surveillance and research in support of US strategic objectives.

#### **Global programming:**

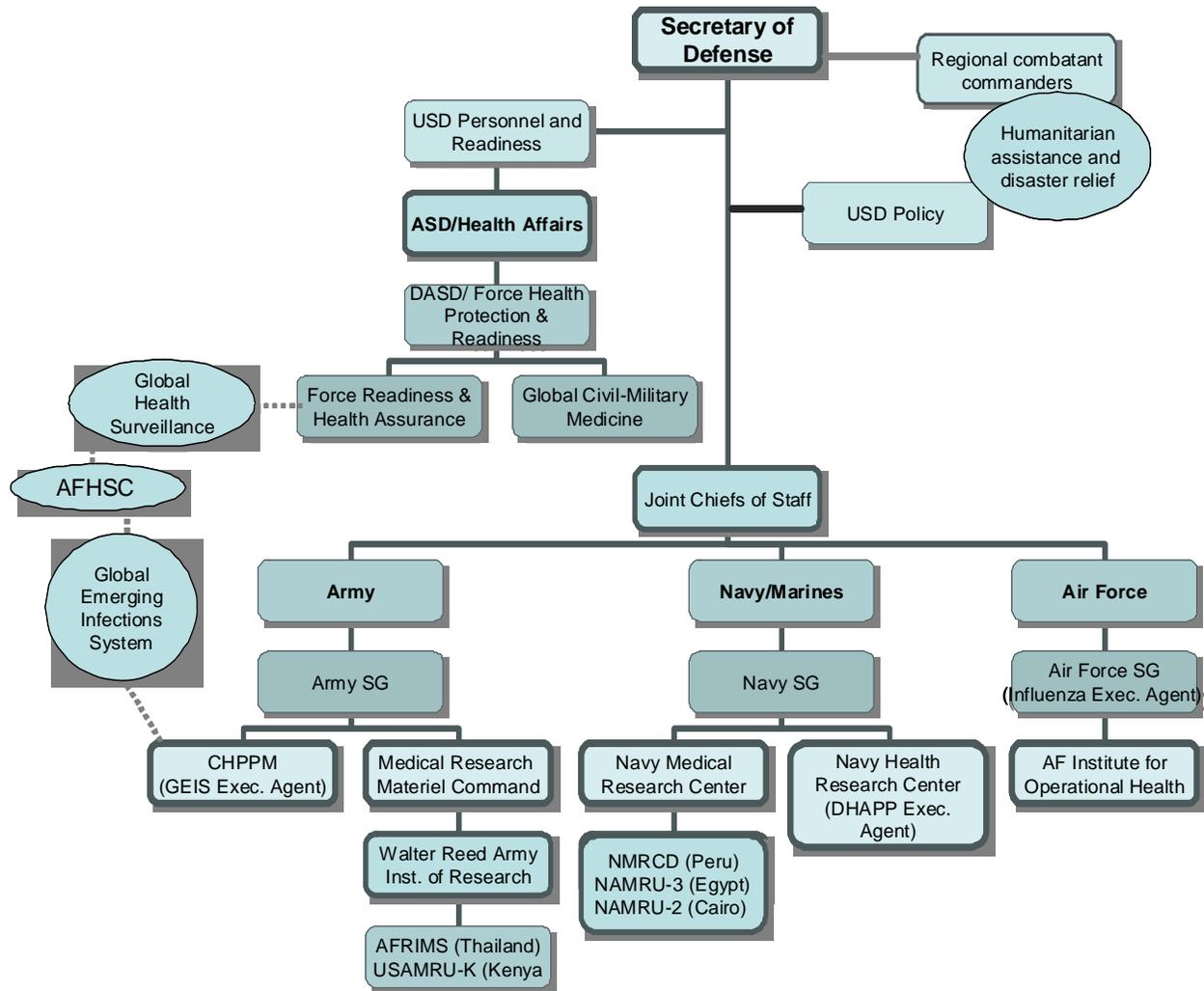
- Communicable diseases (HIV/AIDS, malaria, neglected tropical diseases, avian and human influenza, other emerging infections)
- Direct health services delivery
- Training and exchanges
- Capacity building
- Health systems strengthening
- Field and basic research

#### **Mechanisms:**

Operational, policy, funding, research and technical/advisory

**Areas of focus:** Global (emphasis on Sub-Saharan Africa, Latin America and the Caribbean, and Southeast Asia)

DOD’s considerable medical and health care capabilities<sup>xiii</sup> reside primarily within the medical departments of the Army, Navy and Air Force, each headed by its own Surgeon General. In addition to conducting research and providing health care to servicemembers and their families, each service’s medical system acts as Executive Agent for at least one specific international health issue.<sup>xiv</sup>



**DOD Figure 1: Overview of DOD offices that plan and implement global health policies.** Most of DOD’s global health capabilities reside in the armed services, which also act as executive agents for specific programs. The ASD for Health Affairs coordinates policy development and planning through various global health offices, and (through the AFHSC, or Armed Forces Health Surveillance Center) oversees disease surveillance capacity-building activities under the Global Emerging Infections Surveillance and Response System (GEIS).

<sup>xiii</sup> In FY 2007, the Medical Health System’s budget of almost \$7 billion for medical military personnel supported 89,400 military and 44,100 civilian employees (per the [2008 Military Health Systems Stakeholder Report](#)).

<sup>xiv</sup> For example, the Navy – through the Naval Health Research Center in San Diego, under the oversight of the Navy Surgeon General – serves as DOD Executive Agent for the DOD HIV/AIDS Prevention Program (DHAPP).

Internationally, operational programs may be coordinated through one of the regional combatant commands. For FY2009, the combatant commanders of the Pacific Command (PACOM, which includes all of Asia and Oceania), Southern Command (SOUTHCOM, covering Latin America and the Caribbean), and the newly-established Africa Command (AFRICOM) collectively proposed 578 non-crisis humanitarian assistance programs and activities with an estimated cost of \$63.8 million, accounting for about 80% of the total Overseas Humanitarian, Disaster Assistance and Civic Aid (OHDACA) account request.<sup>113</sup>

The Assistant Secretary of Defense for Health Affairs (ASD/HA), reporting to the Undersecretary for Personnel and Readiness, serves as the primary advisor and coordinator for DOD health policy development. The 2007 reorganization of the Office of Health Affairs consolidated responsibility for most DOD global health planning under the Deputy Assistant Secretary of Defense (DASD) for Force Health Protection & Readiness (FHP&R), creating the new divisions of Global Civil-Military Medicine and International Health,<sup>114</sup> and an office for Global Health Surveillance (under Force Readiness and Health Assurance).<sup>115</sup>

DOD's major contributions to USG global health engagement fall into three categories.<sup>xv</sup>

- *Medical security cooperation, which includes medical humanitarian aid, medical humanitarian and civic assistance projects, and the international disease surveillance and research centers.* As noted above, the regional combatant commands can initiate humanitarian assistance programs using OHDACA funds to support regional security strategies. Activities include stand-alone Medical Readiness Training Exercises (or MEDRETEs), which allow military health professionals to maintain their skills while providing basic and specialized medical care and training to underserved host nation populations. The regional commands also sponsor deployments by the hospital ships USNS Comfort and USNS Mercy. The number of humanitarian and civic assistance projects has grown steadily, from about 155 projects in 35 countries in FY1997 to about 480 in 46 countries in FY2007.<sup>116</sup>

### **Significant dates:**

**1862** - Armed Forces Institute of Pathology established.

**1893** - Walter Reed Army Institute for Research founded.

**1941** - Army founds Industrial Hygiene Laboratory (precursor to US Army Center for Health Promotion and Preventive Medicine, or USACHPPM).

**1942** - First overseas Navy Medical Research Unit (NAMRU-2) launched on Guam, in cooperation with the Rockefeller Institute.

**1946** - Navy Medical Research Unit-3 founded in Cairo, Egypt.

**1947** - Modern Department of Defense created by National Security Act of 1947.

**1958** - Army launches Armed Forces Research Institute for Medical Sciences (AFRIMS) in Bangkok, Thailand.

**1969** - Launch of US Army Medical Research Unit-Kenya (USAMRU-K) and domestic US Army Medical Research Institute of Infectious Diseases (USAMRIID).

**1986** - Humanitarian and civic assistance programs authorized as part of peacetime activities.

**1997** - Global Emerging Infections Surveillance and Response System (GEIS) established in response to Presidential Decision Directive (PDD) NSTC-7.

**2001** - DOD HIV/AIDS Prevention Program (DHAPP) established under executive agency of the Naval Health Research Center, San Diego.

**2004-5** - Massive resource mobilization for Indian Ocean tsunami and Pakistan earthquake relief efforts.

**2005** - New DOD policy framework for security and stability operations, including humanitarian aid.

<sup>xv</sup> This report deliberately omits health sector stabilization and reconstruction in conflict and post-conflict settings and medical intelligence-gathering activities undertaken primarily to advise senior policymakers.

After World War II, Army and Navy researchers initiated joint projects with their counterparts in several developing nations to study communicable diseases that affected local populations as well as deployed US forces. Seven of these matured into cooperatively operated medical research facilities; five continue to conduct basic and field research, provide training, and offer technical assistance. Army facilities include the Armed Forces Research Institute of Medical Sciences (AFRIMS)<sup>117</sup> in Bangkok and the US Army Medical Research Unit-Kenya (USAMRU-K)<sup>118</sup> in Nairobi, both offshoots of the Walter Reed Army Institute of Research. The Naval Medical Research Center supports the Naval Medical Research Center Detachment (NMRCDD)<sup>119</sup> in Lima, Peru; US Naval Medical Research Unit Three (NAMRU-3)<sup>120</sup> in Cairo, Egypt; and US Naval Medical Research Unit Two (NAMRU-2) in Jakarta, Indonesia.<sup>xvi</sup> In addition to building local research capabilities, the facilities serve as regional reference laboratories in collaboration with the WHO and local ministries of health and defense. In response to a 1996 Presidential directive addressing the threat of emerging infectious diseases, DOD established the Global Emerging Infections Surveillance and Response System (GEIS).<sup>121</sup> GEIS integrates the existing overseas research laboratories, aspects of the Military Health System, and the humanitarian assistance programs.<sup>122</sup> GEIS enhances the overseas laboratories' diagnostic capabilities by facilitating information-sharing and supporting disease surveillance and research programs, concentrating on respiratory diseases (particularly influenza), food-borne illnesses, dengue fever, malaria, antimicrobial resistance, and sexually transmitted diseases.<sup>123</sup>

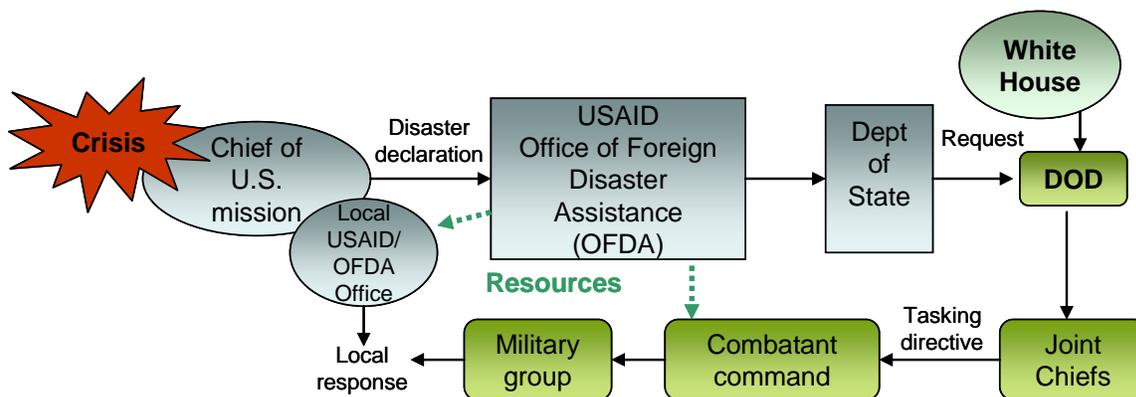
- *Military-to-military capacity building, manifested most comprehensively in the DOD HIV/AIDS Prevention Program (DHAPP).* Launched as part of the Clinton Administration's LIFE (Leadership and Investment in Fighting an Epidemic) initiative in 1999, DHAPP supports HIV/AIDS prevention, education, care, and treatment programs through international military cooperation aimed at averting the epidemic's de-stabilizing effects on regional security. Now under the aegis of PEPFAR, DHAPP implements operational,

**DOD Box 1: Humanitarian and civic development assistance through the regional commands.** Title 10 USC §401 and Title 10 USC § 2561 authorize a wide range of humanitarian assistance activities as long as they meet the security needs of the US and host nation, offer training opportunities for US forces, and do not duplicate other assistance. The regional combatant commanders have made increasing use of these authorities to build goodwill among local populations while providing complex training environments for military health professionals. For example, in FY2008, SOUTHCOM sponsored 65 MEDRETEs in 17 countries, with medical professionals from all service branches and the uniformed Public Health Service ultimately treating more than 200,000 people (including 2,063 surgeries). An interagency crew on the Navy hospital ship USNS Comfort, complemented by two non-governmental organizations, supported SOUTHCOM's humanitarian assistance efforts ashore in 12 countries, using the ship as a base for outpatient services, in what has been seen as a model for future civil-military health projects. These efforts are designed to help meet the Military Health System goal of "conducting diplomacy through health," though the cost-effectiveness of such programs has still not been measured conclusively. [Source: US Southcom, [Humanitarian Assistance \(December 18, 2008\).](#)]

<sup>xvi</sup> Although rarely referenced by the US government openly, the future of NAMRU-2 in Indonesia remains unclear after political controversy obstructed renewal of the now-expired Memorandum of Understanding between the US Navy and the Indonesian Ministry of Health. [See: Dennis Normile, "Dispute Clouds the Future of US Naval Lab in Indonesia," *Science* (2008)320:598-9.]

communications, and capacity-building programs to support host militaries and civilian communities in more than 70 countries (including 13 PEPFAR focus countries) in Sub-Saharan Africa, Asia, and Latin America and the Caribbean. Working in partnership with other PEPFAR agencies and non-governmental organizations, DHAPP addresses the specific risk factors associated with defense services and builds infrastructure and human capacity for HIV/AIDS testing, treatment, and care.<sup>124</sup>

- Supporting the USG international humanitarian response to disasters.* Although USG budget formulations do not classify disaster response as development assistance, such efforts can devote massive US resources to emergency relief, health services, and delivery of food, water, and medical supplies. The military’s logistical capacity for mobilizing supplies, equipment, and technical expertise rapidly creates demand for DOD support in the USG response to humanitarian crises, ranging from a single cargo plane to the more than 15,000 service members deployed in response to the 2004 Asian tsunami.<sup>125</sup> US military assets within the regional combatant commands can supply technical expertise, providing direct health services and safe drinking water, as well as transporting supplies and equipment for other agencies or non-governmental organizations. In the 2007 USG response to Cyclone Sidr in Bangladesh, for example, DOD airlifted more than 327 metric tons of relief commodities to affected sites within the country, including more than 54,000 liters of water, and US military medical teams worked with Bangladeshi military and civilian counterparts to provide health services in affected areas.<sup>126</sup> DOD responds to disasters upon request by the State Department through the “Executive Secretariat process,” under the guidance of USAID’s Office of Foreign Disaster Administration (OFDA), through a pathway triggered by the US ambassador or chief of mission in a disaster-affected nation.<sup>127</sup>



**DOD Figure 2: Activating military assets to support the USG humanitarian response to disasters.** This schematic demonstrates the general mechanism for integrating US military humanitarian assistance into the general US response to a major international crisis.

In response to a 2005 DOD directive that elevated the strategic importance of “stability operations” to the level of combat operations, as well as to lessons learned from the massive military aid mobilizations following the 2004 Asian tsunami and the 2005 earthquake in Pakistan, DOD began overhauling its leadership structure for humanitarian actions in 2007.<sup>128</sup>

Under the Under Secretary of Defense for Policy, new assistant and deputy assistant secretaries address coalition and multinational operations, global security affairs, and partnership strategies. In addition to the research conducted in the overseas laboratories, each of the services maintains US-based research programs that focus on infectious diseases (including HIV/AIDS and malaria), and occupational and environmental health. DOD also supports programs with global health applications through the Uniformed Services University of the Health Sciences (such as the Center for Disaster and Humanitarian Assistance Medicine<sup>129</sup>) or the regional commands (such as the Center for Excellence in Disaster Management and Humanitarian Assistance within PACOM<sup>130</sup>). Such programs in turn support DOD’s operational programs in global health through basic research, training, and technical assistance.

***USG interactions***

Paradoxically, DOD is among the most self-contained and the most extensively networked USG agencies. In planning for and executing disaster relief, DOD works primarily with the State Department and USAID/OFDA, as well as HHS or other agencies as requested by USAID during crises (with personal or backchannel communications frequently supplementing the more deliberate Executive Secretariat process).<sup>131</sup> DOD has made recent outreach efforts to include other agencies and non-governmental organizations (NGO) in its non-crisis humanitarian assistance efforts—as an example, SOUTHCOM and HHS formalized arrangements in late 2008 that allow members of the uniformed Commissioned Corps of the US Public Health Service to serve with military health professionals on MEDRETEs and other medical operations, and SOUTHCOM has sponsored seminars to improve coordination among the USG agencies and NGOs most likely to participate in a regional disaster response.<sup>132, 133</sup> As a PEPFAR implementing agency, DOD works under coordination of State’s Office of the Global AIDS Coordinator for policy development and coordination and with the chiefs of mission’s country teams in the field. Technical experts in DOD and CDC interact formally and informally on specific health research and disease detection and response programs. The DOD overseas laboratories and GEIS hubs in Egypt, Kenya, and Thailand are located near CDC Global Disease Detection Centers, and interact through the country teams (although the extent of collaboration in the field can be personality-dependent). At the same time, decision makers in other agencies noted that DOD “does good work,” but that the complexity of DOD’s interagency management makes assessing the shape and scope of DOD’s global health activities challenging.

***Legislation and authorities***

<b>Year</b>	<b>Focus</b>	<b>Authority</b>	<b>Purpose(s)</b>
1789			The War Department is established.
1862	Emerging Infectious Diseases	By authority of the Secretary of War	The Armed Forces Institute of Pathology (AFIP) is established as part of the Army Medical Museum to serve as a repository for disease specimens obtained from Civil War soldiers.
1893	Global Health	By authority of the Surgeon General of the Army	The Walter Reed Army Institute of Research (WRAIR) is founded.
1938	Global Health	Funding appropriated by Congress	Congress appropriates funds for the acquisition of land for the construction of a new Naval medical center (National Naval Medical Center in Bethesda, MD).

1941	Global Health	By authority of the Surgeon General of the Army	The Army Industrial Hygiene Laboratory, also known as US Army Environmental Hygiene Agency or USAEHA (the precursor to the US Army Center for Health Promotion and Preventive Medicine, or USACHPPM), is established at the beginning of World War II.
1942	Emerging Infectious Diseases	By authority of the Surgeon General of the Navy	Navy enters into cooperation with Rockefeller Institute to launch Navy Medical Research Unit-2 (NAMRU-2), which is established as a facility on Guam by 1944.
1946	Emerging Infectious Diseases	By authority of the Surgeon General of the Navy	The Egyptian government invites the US Navy to continue the work of the WWII US Typhus Commission laboratory in Cairo in collaboration with the Egyptian Ministry of Health. NAMRU-3 is established in Cairo to study locally endemic diseases.
1947		National Security Act of 1947	Established the current Department of Defense.
1949	Emerging Infectious Diseases	By Authority of the Secretary of Defense	Following US signature of the North Atlantic Treaty, forming NATO, the Navy Entomology Center of Excellence in Jacksonville, FL (NECE JAX) is incepted as Malaria and Mosquito Control Unit Number 1.
1958	Emerging Infectious Diseases	By Authority of the Surgeon General of the Army	AFRIMS is established by a group of US and Thai scientists conducting a joint study on a cholera epidemic in Thailand.
1961	Emerging Infectious Diseases	By Authority of the Surgeon General of the Army	AFRIMS' laboratory mission is expanded to include research on tropical diseases.
1969	Emerging Infectious Diseases	By Authority of the Surgeon General of the Army	The US Army Medical Research Unit – Kenya (USAMRU-K) is established as a temporary program at the invitation of the Kenyan government to study trypanosomiasis.
1969	Emerging Infectious Diseases	General Order No. 6, Office of the Surgeon General of the Army	US Army Medical Research Institute of Infectious Diseases (USAMRIID) is established.
1976	Emerging Infectious Diseases/ Influenza	By Authority of the Surgeon General of the Air Force.	The DOD Influenza Surveillance Program begins.
1986	Humanitarian assistance	Public Law 99-661 (Section 333) Humanitarian and Civic Assistance (HCA) program in the National Defense Authorization Act for Fiscal Year 1987, as amended in: Title 10 USC §401 Title 10 USC §402	Authorizes US military forces to carry out humanitarian and civic assistance activities in conjunction with other operations (such as joint exercises) if such activities support mutual US-host country interests, build US force operational readiness skills, and do not duplicate other USG assistance (401); permits the military to transport humanitarian supplies for NGOs without charge (“the Denton Amendment,” Section 402).

1992	Humanitarian assistance	Title 10 USC § 2561 Humanitarian assistance	Authorizes US military forces to carry out country-specific humanitarian assistance projects (such as construction or renovation of medical facilities) using funds designated in the Overseas Humanitarian, Disaster and Civic Aid (OHDACA) Appropriation; expands authorities to transport humanitarian cargo for international or non-governmental organizations using appropriated funds.
1994	Humanitarian assistance	<a href="#">Public Law 103-337</a> The National Defense Authorization Act (NDAA) for Fiscal Year 1995	Authorizes DOD to provide assistance in response to manmade or natural disasters outside the US (codified in Title 10 USC §404) – rarely used due to inflexibility of authority relative to President’s powers under the Foreign Assistance Act of 1961; creates the Overseas Humanitarian, Disaster and Civic Aid (OHDACA) account to cover humanitarian and civic assistance programs and establishes an initial authorization of \$86 million for FY1995.
1996	Emerging infectious diseases	<a href="#">Presidential Decision Directive (PDD) NSTC-7</a>	Establishes national policy and implementing actions to address the threat of emerging infectious diseases by improving surveillance, prevention, and response measures; names CDC and NIH lead agencies, in interagency disease surveillance and response and research coordination, respectively; expands DOD’s mission to include support of global surveillance, training, research, and response to emerging infectious disease threats.
1998	Humanitarian assistance	By authority of the Secretary of Defense	The Center for Disaster and Humanitarian Assistance Medicine (CDHAM) is established within the USUHS Department of Military and Emergency Medicine.
1999	Global Health (HIV)	Executive Order 13139	Establishes the HIV and AIDS Research and Development Program within the Department of the Army.
2000	Global health (HIV/AIDS)	BUMED Letter 5400 Ser 00/MED-26 (11/9/2000)	Tasks the Naval Health Research Center, San Diego to serve as the Executive Agent for the DOD HIV/AIDS Prevention Program (DHAPP), initially funded in FY2001 as part of the LIFE Initiative.
2001		By authority of the Secretary of Defense	The Defense Institute for Medical Operations (DIMO) is created from the merger of the USAF Institute of Global Health and the US Navy’s Defense Healthcare Management Institute.
2005	Humanitarian assistance	<a href="#">DOD Directive 3000.05</a> Military Support for Stability, Security, Transition, and Reconstruction (SSTR) Operations (28 Nov 2005)	Categorizes stability and security operations as comparable in importance to combat operations; provides guidance and assigns responsibility within DOD for specific SSTR tasks, including a policy framework for humanitarian assistance.

2006	Global health (HIV/AIDS)	<a href="#">DOD Directive 6485.02E</a> HIV/AIDS Prevention: Support to Foreign Militaries (7 Nov 2006)	Assigns responsibilities to the ASD/HA and ASD(SO/LIC) for policy development and guidance for DOD HIV/AIDS prevention support to foreign militaries consistent with Public Law 108-25 (PEPFAR); designates the Navy as the DOD Executive Agent for the technical and logistical support of the global Defense HIV/AIDS Prevention Program (DHAPP); establishes a Coordinating Board for DOD international HIV/AIDS activities with foreign militaries.
2008	Global health	<a href="#">DOD Directive 5136.01</a> Assistant Secretary of Defense for Health Affairs (ASD/HA) (June 4, 2008)	Redefines the roles and responsibilities of the ASD/HA as the principal advisor to the Secretary of Defense and the Undersecretary of Defense for Personnel and Readiness on all DOD health policies, programs, and force health protection activities, with authority to effect internal reorganizations.
2008	Global health	By authority of the Deputy Secretary of Defense	The Armed Forces Health Surveillance Center (AFHSC) is established by the Deputy Secretary of Defense to unify several strategic DoD health surveillance assets and develop additional capabilities in a single organization. Among the programs brought together are the DoD Global Emerging Infections Surveillance and Response System (GEIS) and the Defense Medical Surveillance System (DMSS).

### ***Budget***

The role of the individual armed services as “executive agents” for specific DOD programs shapes military global health budgets. For example, the operating budget for the GEIS global disease surveillance program draws upon funds appropriated to support personnel and research programs in the individual armed services that contribute to the GEIS efforts rather than a single line item in the DOD budget (with the exception of a one-time emergency supplemental appropriation), so that personnel are, for practical purposes, detailed to serve the program rather than hired through a central, permanent authority.

<b>DOD Budget by Activity – Global Health</b>					
	FY 2004 Actual	FY 2005 Actual	FY 2006 Actual	FY 2007 Actual	FY 2008 Actual
<b>Global Health Activities (\$US thousands)</b>					
<b>Air Force RDT&amp;E</b>	9115	0	0	0	0
<b>Army RDT&amp;E</b>	76698	75598	77125	76687	105866
<b>DOD DHP</b>			1586	3842	18150
<b>DOD RDT&amp;E</b>		9500	7400	8900	2500
<b>DHP (Avian Flu Supplemental)</b>	0	0	40000	40000	0
<b>Total</b>	<b>85813</b>	<b>85098</b>	<b>126111</b>	<b>129429</b>	<b>126516</b>

DOD humanitarian assistance budgets are shown below for purposes of comparison, but do not necessarily comprise global health activities and do not count toward global health budget totals. Budgets for humanitarian assistance below reflect only amounts appropriated for the Defense OHDACA (Overseas Humanitarian, Disaster, and Civic Action) account, rather than any amounts appropriated for the Combatant Commander Initiative Fund (CCIF), which may be used for a variety of humanitarian or civic assistance projects with wide discretion. Totals also do not include supplemental appropriations for USG-wide responses to foreign disasters.

<b>DOD Budget by Activity – Humanitarian Assistance</b>					
	FY 2004 Actual	FY 2005 Actual	FY 2006 Actual	FY 2007 Actual	FY 2008 Actual
<b>Humanitarian Activities (\$US thousands)</b>					
<b>Overseas Humanitarian Disaster and Civic Aid (051)</b>	<b>94000</b>	<b>176000</b>	<b>121000</b>	<b>63000</b>	<b>102000</b>

Sources:

<http://www.saffm.hq.af.mil/shared/media/document/AFD-070221-113.pdf>

<http://www.asafm.army.mil/budget/fybm/FY09/rforms/vol1.pdf>

<http://www.geis.fhp.osd.mil/GEIS/aboutGEIS/annualreports/GEIS07AR.pdf>

[http://www.defenselink.mil/comptroller/defbudget/fy2009/budget\\_justification/pdfs/09\\_Defense\\_Health\\_Program/VOL\\_2/Vol\\_2\\_Sec\\_3\\_-\\_B\\_RDT\\_and\\_E\\_Projects\\_09PB\\_DHP.pdf](http://www.defenselink.mil/comptroller/defbudget/fy2009/budget_justification/pdfs/09_Defense_Health_Program/VOL_2/Vol_2_Sec_3_-_B_RDT_and_E_Projects_09PB_DHP.pdf)

[http://www.defenselink.mil/comptroller/defbudget/fy2008/budget\\_justification/pdfs/03\\_RDT\\_and\\_E/Vol\\_3\\_OSD/B-A-3.pdf](http://www.defenselink.mil/comptroller/defbudget/fy2008/budget_justification/pdfs/03_RDT_and_E/Vol_3_OSD/B-A-3.pdf)

[http://www.defenselink.mil/comptroller/defbudget/fy2009/budget\\_justification/pdfs/09\\_Defense\\_Health\\_Program/VOL\\_2/Vol\\_2\\_Sec\\_3\\_-\\_B\\_RDT\\_and\\_E\\_Projects\\_09PB\\_DHP.pdf](http://www.defenselink.mil/comptroller/defbudget/fy2009/budget_justification/pdfs/09_Defense_Health_Program/VOL_2/Vol_2_Sec_3_-_B_RDT_and_E_Projects_09PB_DHP.pdf)

# THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

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## *Mission and roles*

HHS serves as the US government's principal agency in all areas of health, supporting activities that range from basic research to financing health care. HHS encompasses 11 operating divisions that include:

- Centers for Disease Control and Prevention (CDC),
- Food and Drug Administration (FDA),
- National Institutes of Health (NIH), and
- Health Resources and Services Administration (HRSA).

These divisions contribute significant technical expertise to PEPFAR and other USG global health efforts, and their actions are described in detail elsewhere in this report. At the agency level, HHS coordinates global health policy development across its functional programs, maintains its own liaisons and agreements in interagency processes such as PEPFAR, and represents the US internationally in bilateral and multilateral negotiations on health issues. In 2006, then-HHS Secretary Leavitt identified international health diplomacy as one of the ten "HHS Priority Activities for America's Health Care."<sup>134</sup>

## *Organization and focus*

Although HHS emerged as a distinct department only in 1980, after being part of the Department of Health, Education and Welfare (HEW), it encompasses a much older set of core Public Health Service (PHS) functions. Throughout a series of governmental reorganizations that from the mid-1800's onward continually re-shaped the structures and leadership of PHS, its primary missions – conducting disease control, prevention, and research activities and promoting public health – remained intact in PHS components such as CDC, FDA, NIH.<sup>135</sup> Since 1945, these functions have included an office for international health.<sup>136</sup> By the time that the Department of Education Organization Act of 1979 created HHS from the former HEW, the leadership of PHS and its constituent agencies resided with the Assistant Secretary for Health (see HHS Box 1).

In 1995, a departmental reorganization re-designated the eight PHS agencies as "operating divisions" that report directly to the Secretary, and moved the Office of International and Refugee Health to a newly created Office of Public Health and Science.<sup>137</sup> A December 2001 reorganization renamed this the Office of Global Health Affairs (OGHA) and assigned it functions previously in the immediate Office of the Secretary, such as:

## SNAPSHOT - HHS

**Primary role:** Lead agency for health issues, representing the US in international health negotiations and overseeing operational divisions (CDC, FDA, NIH, HRSA) that implement global health programs.

### **Global programming:**

- HIV/AIDS
- Maternal health/mortality
- Avian and Human Influenza/Pandemic Preparedness
- Bioterrorism and other EID
- Basic health services
- Functions under the operational divisions

### **Mechanisms:**

Policy, technical/advisory, regulatory, funding

### **Areas of focus:** Global

### **Significant Dates:**

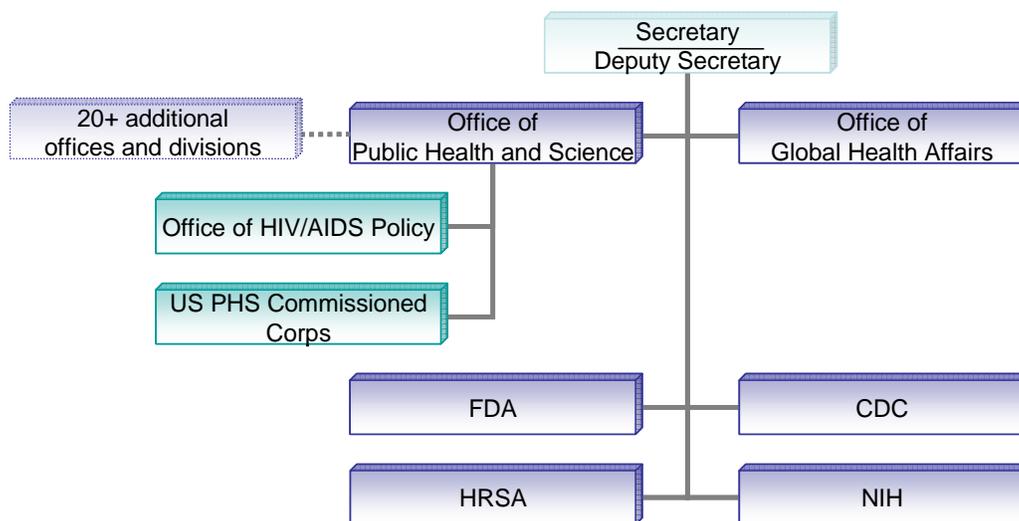
**1912** – Public Health Service renamed for expanded duties

**1960** - Authorized the Secretary enter into international cooperative agreements for biomedical and health activities

**1968** – Leadership of PHS shifts from Surgeon General to Assistant Secretary for Health

**1980** – HHS created by split of education from HEW

representing HHS to other Federal agencies, international organizations, multilateral institutions, the private sector, and other governments on international health matters; clearing all documents related to international health; reviewing and approving all HHS international travel; and promoting cooperative health programs in other nations.<sup>138</sup> In 2004, another reorganization elevated OGHA to the level of a division, placing global health at the same level as the other 26 offices and divisions that report directly to the Secretary.<sup>139</sup>



**HHS Figure 1:** This organizational chart highlights the HHS offices and divisions (all Public Health Service components) primarily responsible for planning, supporting, coordinating, or implementing global health programs. The two programs shown under the Office of Public Health and Science, the Office of HIV/AIDS policy and the Commissioned Corps, are not operational global health programs but play a role in setting policy and providing human resources, respectively. The Office of Global Health Affairs represents the US government in bilateral and multilateral engagements that involve health issues (for example, by leading the US delegation to the World Health Assembly, the decision-making body of the World Health Organization), participates in the interagency process, and coordinates global health policies across the HHS operational divisions. Four operational divisions – CDC, FDA, HRSA, and NIH – offer technical assistance, implement programs, monitor progress, set standards, and conduct research within PEPFAR and other programs, collectively providing the critical mass of expertise that supports US global health engagement.

Through its five regional offices, an office for multilateral affairs, and an international influenza unit, OGHA currently serves as the focal point for HHS global health activities. In coordination with the Office of the Global AIDS Coordinator, OGHA remains heavily engaged in issues related to the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), participating in the US interagency working groups as well as the international working groups that provide input on its policies.<sup>140</sup> OGHA also coordinates intra- and inter-agency policy in refugee health issues (a legacy of its origins) and supports specific bilateral initiatives through coordination, technical assistance and funding. Since 2004, focus areas have included maternal/child health in

Kabul, Afghanistan; research, coordinating, and health screening events under the US-Mexico Border Health Commission; and establishing the REDI (Regional Emerging Disease Intervention) Center in Singapore.<sup>141</sup> OGHA also manages the health attaché program, which deploys HHS staff to US missions to serve as part of the country team and represent the US government to host country ministries of health, regional organizations, WHO and other international organizations. Currently, health attachés are posted to (or being selected for) US missions at UNESCO Paris, Guatemala, New Delhi, Baghdad, Abuja, Pretoria, Geneva, Dar es Salaam, Hanoi, Beijing and Brasilia.<sup>142</sup> The CDC country director in Bangkok also fulfills the functions of the health attaché.<sup>xvii</sup>

### **Legislation and authorities**

Year	Focus	Authority	Purpose(s)
1944	Public health	<a href="#">The Public Health Service Act</a> (as amended)	Defined the powers and duties of the US Public Health Service (PHS) created in 1912, outlined the policy framework for Federal-state cooperation in public health, and established regulatory authorities that transferred with PHS to HEW and then HHS. The full act is captured under Title 42 of the US Code, "The Public Health and Welfare."
1953	HHS organization	Reorganization Plan No. 1 of 1953, effective April 11, 1953	Transferred the Public Health Service from the Federal Security Agency to Department of Health, Education, and Welfare (HEW).
1960	Global health	<a href="#">Public Law 86-610</a> The International Health Research Act of 1960	To advance the health sciences through cooperative international research and training; Section 307 as amended (incorporated into USC Title 42) authorized the Secretary of HHS to enter into international cooperative agreements for biomedical and health activities.
1979	HHS organization	<a href="#">Public Law 96-88</a> Department of Education Organization Act of 1979	Created the Department of Education, separating its functions from the Department of Health, Education, and Welfare; in 1980, President Carter renamed the department Health and Human Services (HHS).
1994	Public health	Public Law 103-400 United States-Mexico Border Health Commission Act	Authorizes an agreement with Mexico to establish a bi-national commission to conduct a needs assessment of health problems in the US-Mexican border and review methods for reimbursing unpaid healthcare costs incurred by border populations.

<sup>xvii</sup> The dramatic elevation of OGHA's profile as a coordinating agent across HHS operational divisions that have historically enjoyed varying degrees of autonomy caused enough friction to elicit Congressional attention on more than one occasion. Much of the tension stems from strict implementation of oversight processes with implicitly – and sometimes explicitly – political overtones. For example, some felt that the requirement that OGHA individually approve all overseas travel by HHS scientists, including participation in international scientific conferences and technical working groups as well as overseas postings, related more to “political vetting” than fiscal prudence, and might adversely affect US and international health and research activities. [See Jocelyn Kaiser, “The Man Behind the Memos.” *Science* 2004(305):1552-3 and a [May 4, 2007 letter from Rep. Henry A. Waxman, Chairman, US House Committee on Oversight and Government Reform to HHS Secretary Michael Leavitt.](#)] Less publicly visible, persistent concerns regarding the respective roles and relationships of personnel from HHS/OGHA and the HHS operating divisions such as CDC, when deployed to the same host nation, remain unresolved.

1995	HHS organization	<a href="#">60 FR 56605</a> Statement of authorities establishing the Public Health Service agencies as HHS operating divisions (under authority of Reorganization Plan No. 1 of 1953 and Reorganization Plan No. 3 of 1966, 5 USC. 301)	Designated CDC, FDA, NIH, HRSA, AHCPR, ATSDR, IHS, and SAMSHA as HHS operating divisions comprising the Public Health Service; required operating divisions to report directly to the Secretary rather than the Assistant Secretary for Health; and created the Office of Public Health and Science in the Office of the Secretary.
2001	HHS organization	<a href="#">67 FR 1359</a> Statement of authorities renaming and expanding the functions of the Office of Global Health Affairs (Statutory authority 5 USC. § 301)	Renamed the Office of Refugee and International Health the Office of Global Health Affairs (OGHA) and transferred international affairs functions to OGHA from the Office of the Secretary.
2002	Global health	<a href="#">Public Law 107-327</a> Afghanistan Freedom Support Act of 2002	Authorizes US government to develop programs to improve maternal and child health and reduce maternal and child mortality.

### ***USG interactions***

HHS – primarily through OGHA – interacts on global health issues with other USG agencies indirectly (through its operational divisions such as CDC, NIH, and FDA) and directly via representation on interagency working groups convened through the Office of the Global AIDS Coordinator (PEPFAR) and the Avian Influenza Action Group, both based at the Department of State, and the National Security Council. HHS belongs to inter-agency trade policy committees convened by the US Trade Representative (for example, when agreements include provisions related to pharmaceuticals).<sup>143</sup> HHS also serves as the US lead agency in implementing the revised International Health Regulations (IHR 2005), with the Secretary’s Operations Center responsible for reporting events to WHO, and the Assistant Secretary for Preparedness and Response (ASPR) providing expertise on domestic and international compliance issues.

### **Budget**

The HHS budget shown below reflects global health activities within the General Departmental Management, which supports OGHA's operations and projects. (Budgets for the operational divisions are shown elsewhere in this report.)

<b>HHS Budget for Global Health</b>					
	FY 2004 Actual	FY 2005 Actual	FY 2006 Actual	FY 2007 Actual	FY 2008 Actual
<b>Global Health (\$US thousands)</b>					
<b>Global Health (OGHA)</b>	<b>9000</b>	<b>9000</b>	<b>10000</b>	<b>10000</b>	<b>9610</b>

Source: [FY 2009 HHS CBJ](#)

**HHS Box 1: A Brief History of the Public Health Service (PHS):** From a 19<sup>th</sup> century network of loosely affiliated marine hospitals, PHS evolved into the nation's central organization for disease detection, control, and research – functions still preserved in PHS operating divisions such as CDC and NIH. Legislation passed in 1912 broadened the authorities of PHS beyond military medicine and border screenings to include general communicable disease investigation. A subsequent series of government reorganizations transferred PHS and its constituent agencies from the Department of Treasury to the Federal Security Agency (by Reorganization Plan No. I of 1939) and to Department of Health, Education, and Welfare (HEW) by Reorganization Plan No. 1 of 1953. In 1968, an HEW reorganization order shifted leadership of PHS from the Surgeon General – until then always a career public health professional in the uniformed PHS Commissioned Corps – to the Assistant Secretary for Health, a political appointee, in an attempt to make HEW's public health functions more responsive to policymakers. PHS remained in the renamed Department of Health and Human Services after the Department of Education Organization Act of 1979 removed the education functions to a new department. HHS still comprises eight PHS operational divisions ([Agency for Health Care and Research Policy \(AHRQ\)](#), [Agency for Toxic Substances and Disease Registry \(ATSDR\)](#), [CDC](#), [FDA](#), [HRSA](#), [Indian Health Service \(IHS\)](#), [NIH](#), and the [Substance Abuse and Mental Health Services Administration \(SAMHSA\)](#)) as well as the Commissioned Corps, whose more than 6,000 uniformed public health professionals support domestic and international USG health programs. [Sources: J. Parascandola, *Public Health Service* (1998) and *Records of the Public Health Service (PHS), 1912-1968*, National Archives.]

## HHS/CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

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### *Mission and roles*

From its roots as a domestic malaria control organization during and immediately after World War II,<sup>xviii</sup> CDC emerged by the 1950's as a national resource to serve state and local health departments in controlling the introduction and spread of infectious diseases.<sup>144</sup> CDC's successes in domestic malaria eradication and high-profile outbreak investigations secured its credibility; inspired leadership in disease surveillance and policymakers' Cold War-era concerns about potential biological warfare helped it steadily build its laboratory and epidemiologic capacity. Early in its history, CDC began to respond to increasingly frequent requests for technical assistance in areas such as malaria control from WHO and other international organizations, and dispatched its own team to investigate an overseas outbreak for the first time in 1958.<sup>145,146</sup> In 1966, CDC formally accepted key roles in two ambitious worldwide health efforts coordinated by WHO, inheriting leadership of USAID's shaky malaria eradication program and agreeing to spearhead the ultimately successful global smallpox eradication campaign in Central and West Africa.<sup>147</sup> At home and abroad, CDC's mandates began to expand beyond communicable disease surveillance, prevention, and control to include other conditions and health concerns. CDC has since engaged continuously in international health efforts as an extension of its mandate to protect US health and safety. A strategic framework adopted in 2007 explicitly includes global health promotion among CDC's overarching goals.

### *Organization and focus*

CDC's workforce of about 15,000 employees and contractors encompasses public health expertise unparalleled within any other US – or international – organization. Its global health assets include US-based diagnostic and research capabilities that address diseases of concern in low- and middle-income nations, and a growing number of CDC-staffed programs operating for sustained periods on the ground in other countries.

Reflecting this duality, CDC relies upon two internal mechanisms to coordinate global health activities: first, through central oversight of all programs – domestic and international – within a specific functional or technical area, and second, through strategic and logistical supervision by the Coordinating

### SNAPSHOT - CDC

**Primary role:** the national focus for disease control and prevention and health promotion.

#### **Global programming:**

- All communicable, non-communicable, and chronic diseases
- Vaccination against childhood diseases
- Health systems strengthening
- Training and exchanges
- Capacity-building (laboratory and disease surveillance)
- Clean water and sanitation
- Mitigating environmental hazards
- Field and basic research

#### **Mechanisms:**

Operational, policy, technical/advisory, funding (grants and cooperative agreements), basic and field research

**Areas of focus:** Global (personnel stationed in >50 countries)

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<sup>xviii</sup> See CDC Box 1: "CDC's Roots."

Office for Global Health (COGH) in programs with an overseas presence. Since 1980, CDC has primarily organized its operational programs around “national centers” that focus on specific diseases, conditions, or public health needs.<sup>148</sup> All twelve of CDC’s current national centers encompass some global health programming; the scope of effort ranges from simple consultative relationships with international organizations to multi-year, multi-million dollar major partnerships in global disease control strategies. Although global programming comprises a relatively limited fraction of a broader portfolio for most of these national centers, CDC’s generally vigorous support for international partnerships is reflected in its 26 WHO Collaborating Centers,<sup>149</sup> in which a specific CDC national center (or component division or branch) serves as a partner in an inter-institutional network that supports national, regional, or global WHO objectives.<sup>xix</sup>

Four of these national centers, overseen by the Coordinating Center for Infectious Diseases (CCID),<sup>xx</sup> support the lion’s share of CDC’s global health activities. They generally provide local, state, and international partners with technical assistance to improve disease surveillance and monitoring, build laboratory capacity, and promote successful practices and policies. These programs also conduct and support combinations of clinical, field, and laboratory research. In addition to routinely deploying experts overseas at the direct request of other nations or as part of international teams, CDC provides technical expertise to USAID and the State Department to implement global health strategies through CCID-managed programs that include:

- the Global AIDS Program (GAP),<sup>xxi</sup> which works under the aegis of PEPFAR to strengthen laboratory, epidemiology, surveillance, public health evaluation and workforce capacity in more than 60 resource-constrained countries in Africa,

### Significant dates:

- 1946** – Malaria Control in War branch re-designated Communicable Disease Center.
- 1951** – Epidemic Intelligence Service established to protect against biological warfare.
- 1958** – First deployment of CDC team in response to overseas outbreak (cholera and smallpox in Southeast Asia).
- 1966** – CDC inherits faltering malaria eradication program and spearheads successful smallpox eradication campaign in Central and West Africa, both with USAID funding.
- 1970** – Renamed Center for Disease Control.
- 1980** – Thailand Ministry of Public Health (MOPH), WHO and CDC jointly establish the first international Field Epidemiology Training Program (FETP).
- 1988** – CDC establishes a collaborative HIV/AIDS field station with Cote d’Ivoire.
- 2000** – CDC launches the Global AIDS Program (GAP), establishing programs in India and 14 African countries in the first year.
- 2001** – In collaboration with Thailand’s Ministry of Public Health, CDC establishes first International Emerging Infections Program field site.

<sup>xix</sup> Collaborating centers provide WHO with expertise and institutional capabilities necessary to fulfill its mandates in disease control and health promotion, which far exceed its resources; designation as a WHO collaborating center benefits the host institution by essentially validating its capabilities and facilitating international communications.

<sup>xx</sup> On Friday, March 23, 2007, HHS Secretary Michael O. Leavitt officially approved the creation of the Coordinating Center for Infectious Diseases (CCID) as part of a contentious CDC restructuring effort that grouped operational centers with similar missions under a new layer of shared management. Rob Stein, “Internal Dissension Grows as CDC Faces Big Threats to Public Health.” *Washington Post* (March 6, 2005; A09). [http://www.washingtonpost.com/wp-dyn/content/article/2005/03/25/AR2005032502888\\_pf.html](http://www.washingtonpost.com/wp-dyn/content/article/2005/03/25/AR2005032502888_pf.html)

<sup>xxi</sup> GAP was created in 2000 under HHS regulatory authority as part of the Leadership and Investment in Fighting an Epidemic (LIFE) Initiative, a 1999 White House proposal to increase international AIDS spending.

Asia, Central and South America, and the Caribbean, with physicians, epidemiologists, public health advisors, behavioral scientists, and laboratory scientists stationed in 29 partner countries (including the 15 PEPFAR focus countries);<sup>150</sup>

- the Global Immunization Division, which offers technical support and procures vaccines as a key partner to WHO, UNICEF, the Global Alliance for Vaccines and Immunization (GAVI), Rotary International, the American Red Cross, and the UN Foundation in the global polio eradication and measles initiatives.<sup>151</sup> The program also offers technical assistance to strengthen vaccination programs in low- and middle-income nations and supports development, evaluation and introduction of new vaccines to prevent diseases, including often under-addressed killers such as pneumonia, meningitis, and diarrhea;<sup>152</sup>
- the Malaria and Entomology Branches of the Division of Parasitic Diseases, whose experts jointly manage Presidential Malaria Initiative (PMI) activities with USAID, providing technical assistance that includes stationing a CDC Malaria Advisor in each of the 15 PMI target countries;<sup>153</sup> other experts in the same division support technical and operational decision-making by USAID in the President's Initiative on Neglected Tropical Diseases (NTD); and
- the Influenza Division, which in response to the emergence of highly pathogenic H5N1 avian influenza in poultry in parts of Asia, the Middle East, and Africa – and a new strategic focus by US policymakers on pandemic preparedness as a facet of homeland security – has assumed a greater global health role in the last five years.<sup>xxii</sup> In addition to analyzing 7,000-8,000 international influenza specimens annually through its WHO Collaborating Center on Influenza, the Influenza Division's experts work through a web of representatives (including in the Influenza Coordinating Unit in CCID and the Influenza Coordination Center at HHS) to contribute to the USG-wide avian influenza and pandemic preparedness effort loosely coordinated through the State Department's Avian Influenza Action Group. As of May 2007, CDC supported WHO National Influenza Centers in 29 countries and had expanded its international presence from short-term technical assistance to 21 influenza consultants stationed in China, Egypt, Guatemala, Kenya, Thailand, Cambodia, the Congo, Egypt, India, Indonesia, Kazakhstan, Laos, Peru, Philippines, Vietnam, and Europe.<sup>154,155</sup>

More modest CDC programs provide technical assistance and laboratory, diagnostic, and coordinating support to international partners on a range of vector- and food-borne diseases of global significance. Such efforts, including CDC's relatively limited international nutrient and safe water research and promotion programs, rely heavily on external partnerships with governmental, nongovernmental and private sector organizations for financial as well as programmatic support.<sup>156</sup>

CDC's overseas presence has grown steadily in the last decade. International assignments range from rapid outbreak responses concluded in days or weeks to two-year tours in overseas CDC programs and US missions. In 2008, CDC assigned 224 US staff to 54 countries around the world for fixed-term appointments, also employing about 1,400 local staff to support global

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<sup>xxii</sup> The baseline funding to expand CDC's global activities in influenza came in Public Law 109-13, The Emergency Supplemental Appropriations Act for Defense, the Global War on Terror, and Tsunami Relief, 2005, which appropriated \$15 million specifically to CDC to control the spread of avian influenza in consultation with USAID ([http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109\\_cong\\_bills&docid=f:h1268enr.txt.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_bills&docid=f:h1268enr.txt.pdf)).

**CDC Box 1: CDC's Roots.** The Malaria Control in War branch of the Public Health Service (PHS) was created in 1942 to prevent endemic or imported malaria outbreaks from threatening personnel in military bases and strategic industrial sites in the Southeastern US Under the authority of the Surgeon General, the office was designated the Communicable Disease Center on July 1, 1946. With the rest of PHS, CDC moved to the Department of Health, Education, and Welfare (HEW) under Reorganization Plan No. 1 of 1953. In 1970, CDC was renamed the Center for Disease Control to reflect its growing mandate in non-communicable diseases and other public health priorities (Public Law 91-464, The Communicable Disease Control Amendments of 1970). CDC assumed autonomous status within PHS by HEW reorganization order on July 1, 1973, then moved with PHS to the new Department of Health and Human Services (HHS) pursuant to the Department of Education Organization Act of 1979. The Preventive Health Amendments of 1992 (Public Law 102-531), which expanded block grant programs for preventive health services, amended the name to Centers for Disease Control and Prevention but mandated retention of the acronym CDC. [Sources: E. Etheridge, *Sentinel for Health* (1992), and Records of the Centers for Disease Control and Prevention (1921-2004), National Archives.]

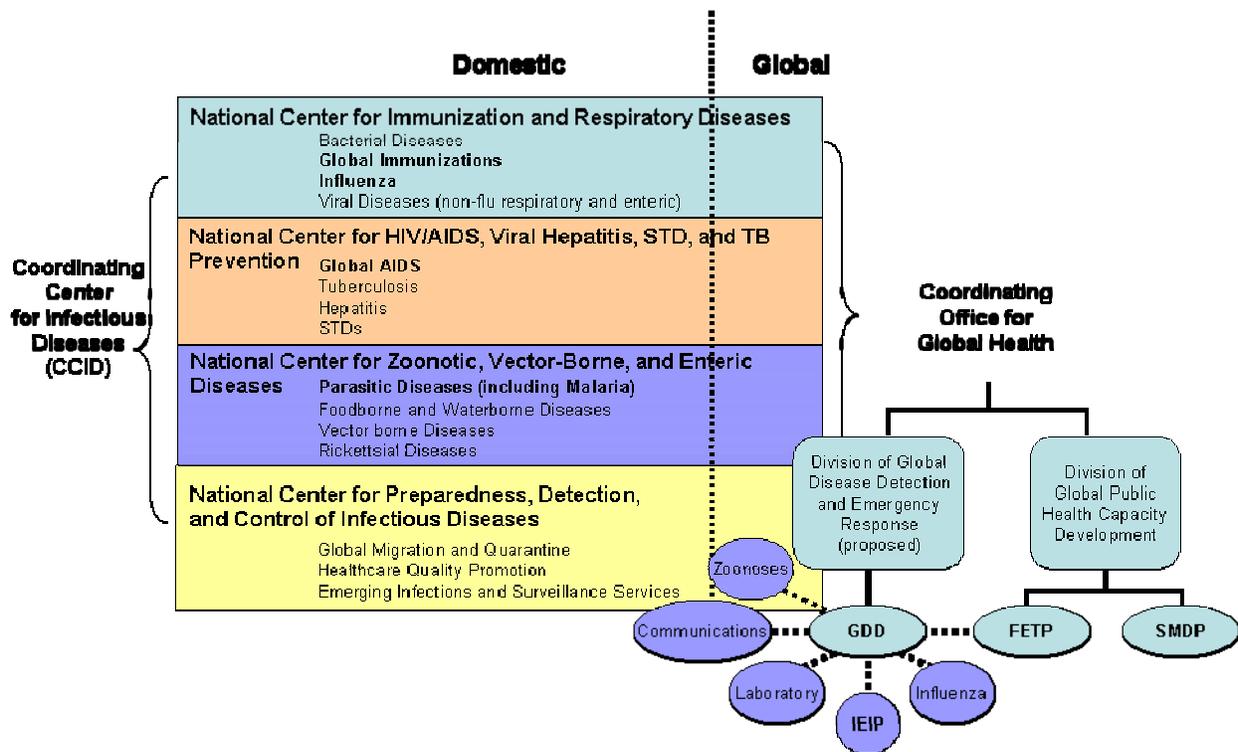
health programs.<sup>157</sup> (About one-quarter of CDC's overseas staff are personnel seconded to WHO or other international organizations.<sup>158</sup>)

The Coordinating Office for Global Health (COGH)<sup>xxiii</sup> serves as the focal point for CDC's global policies and programs, and its director as the CDC Director's primary advisor on global health strategies. A portion of COGH's role consists of management activities to support CDC's growing overseas workforce: assisting in an annual analysis of CDC's overseas workforce needs, facilitating international travel, and offering logistical support to CDC's overseas staff. However, unlike other CDC coordinating centers, COGH also manages operational programs (including several previously existing CDC functions now consolidated under its two divisions). COGH's Division of Global Public Health Capacity Development incorporates:

- the Sustainable Management Development Program (SMDP), which provides public health management training through partnerships with other CDC programs (such as GAP) and ministries of health and educational institutions; its graduates include 349 health professionals from 63 countries.<sup>159</sup>
- the Field Epidemiology Training Program (FETP, which sometimes includes a laboratory component), a program modeled after the CDC's Epidemic Intelligence Service that supports an in-country advisor to provide expertise in training and outbreak investigations – COGH currently supports 11 resident advisors in 10 countries (China, Guatemala, Kenya, India, Jordan, Kazakhstan, Pakistan, South Africa, South Sudan, and Thailand) which draw trainees from 9 additional nations;<sup>160</sup> and
- supporting roles in other global CDC programs, including the USAID-supported cross-center effort to assist partner nations in Africa (currently Uganda, Ghana, Tanzania, and Zimbabwe) in Integrated Disease Surveillance and Response – a key step in achieving compliance with the now-binding International Health Regulations (2005).<sup>161</sup>

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<sup>xxiii</sup> COGH was created as part of CDC's general 2005-7 restructuring effort under HHS regulatory authority, replacing the previous Office of Global Health. See 70 FR 58421 (October 6, 2005), <http://frwebgate4.access.gpo.gov/cgi-bin/PDFgate.cgi?WAISdocID=456407359415+1+2+0&WAIAction=retrieve>.



**CDC Figure 1:** Organization of CDC’s primary global disease detection and response programs. This figure represents the relationships among the national centers, which encompass CDC’s epidemiological, laboratory, and research capabilities in specific subjects, and the two coordinating centers (CCID and COGH) which oversee their overall and global activities, as well as the role of the Global Disease Detection (GDD) program in convening existing international expertise in public health, surveillance, training, and laboratory methods abroad.

In 2004, Congress appropriated funding to support a CDC global disease detection system.<sup>162</sup> The Global Disease Detection and Emergency Response Branch (GDD) under COGH currently operates six overseas centers (functioning robustly in Thailand and Kenya, and at various stages of maturity in Guatemala, China, Egypt, and Kazakhstan).<sup>163</sup> Each GDD Center constitutes a partnership between CDC, the host country, and neighboring nations to build capacity for routine disease detection and response interventions, and to function as part of WHO’s Global Outbreak Alert and Response Network (GOARN) during health crises. The mature GDD Centers employ about six full-time CDC personnel and 50-100 local staff through cooperative agreements with host ministries of health.<sup>164</sup> GDD Centers also house the overseas staff of three established overseas CDC programs now functionally coordinated through GDD where they are co-located:

- FETP Program resident advisors in China, Guatemala, Kenya, Kazakhstan, and Thailand;

- the International Emerging Infections Program (IEIP) sites,<sup>xxiv</sup> which combine epidemiologic and laboratory expertise through partnerships collaboratively administered by COGH and ministries of health, conducting emerging infectious disease surveillance and research, providing diagnostic and epidemiologic resources when outbreaks occur, training local scientists, serving as platforms for regional disease control activities, and disseminating public health tools;<sup>165</sup> and
- Influenza Division personnel (influenza coordinators) in all six GDD Centers.<sup>xxv</sup>

Although assigned a strong intra-agency coordinating role during the CDC reorganization completed in 2007,<sup>166</sup> COGH has no direct budgetary or other mechanism to enforce cooperation by the operational centers under its jurisdiction at CDC's Atlanta headquarters or in the field. Country directors who report to COGH play a role in selecting the country leads of GAP, FETP, IEIP, and other programs and coordinating their activities in partner nations with the greatest CDC presence (currently Thailand, Kenya, Guatemala, and a part-time director in China), in an attempt to present a united logistical and policy front to host governments. However, CDC subject matter experts in the field ultimately report to the leadership of their centers, divisions, or branches at CDC's headquarters, rather than to GDD. Plans to increase the number of country directors have not been supported with additional resources. Clear definitions of COGH's coordinating and management roles have also been complicated by the simultaneous evolution of parallel functions within the HHS Office of Global Health Affairs, which have occasionally conflicted or created redundancies with COGH activities.

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<sup>xxiv</sup> For the most part, IEIP offices are housed within GDD Centers, with the exception of a presence in Bangladesh resulting from long-term research collaborations with the International Centre for Diarrheal Disease Research, Bangladesh (ICDDR-B), and a recently established presence in Kazakhstan.

<sup>xxv</sup> CDC influenza coordinators have also been posted internationally to WHO regional and country offices, to Global AIDS Program offices in affected countries with no GDD center, and to US missions.



### Legislation and authorities

Year	Focus	Authority	Purpose(s)
1944	Public health	<a href="#">The Public Health Service Act</a> (as amended)	Defined the powers and duties of the US Public Health Service (PHS), outlined the policy framework for Federal-state cooperation in public health, and established regulatory authorities that transferred with PHS to HEW and then HHS. The full act is captured under Title 42 of the US Code, "The Public Health and Welfare."
1946	Public health	Communicable Disease Center established under authority of Surgeon General, Public Health Service	Under the authority of the Surgeon General, the Malaria Control in War branch of the Public Health Service was designated the Communicable Disease Center. CDC moved to the Department of Health, Education, and Welfare (HEW) under Reorganization Plan No. 1 of 1953.
1960	Global health	<a href="#">Public Law 86-610</a> The International Health Research Act of 1960	To advance the health sciences through cooperative international research and training; as amended (42 USC §242I) authorized the Secretary of HHS to enter into international cooperative agreements for biomedical and health activities.
1970	Public health	Public Law 91-464: The Communicable Disease Control Amendments of 1970	Renamed CDC the "Center for Disease Control." CDC assumed autonomous status within PHS by HEW reorganization order on July 1, 1973, then moved with PHS to the new Department of Health and Human Services (HHS) pursuant to the <a href="#">Department of Education Organization Act of 1979 (P.L. 96-88)</a> . The Preventive Health Amendments of 1992 (P.L. 102-531) expanded block grant programs for preventive health services and amended the name to Centers for Disease Control and Prevention but mandated retention of the acronym CDC.
1961	Foreign assistance/U SAID	<a href="#">Public Law 87-195</a> The Foreign Assistance Act of 1961 (as amended)	Created a policy framework for foreign assistance to developing nations and mandated the creation of an agency to promote long-term assistance for economic and social development; section 104 specifies the US strategy for foreign assistance related to populations and health, including the HIV/AIDS, tuberculosis, and malaria provisions of PEPFAR.
1996	Emerging infectious diseases	<a href="#">Presidential Decision Directive (PDD) NSTC-7</a>	Established integrated strategy for addressing the threat of emerging infectious diseases by improving surveillance, prevention, and response measures; named CDC lead agency in disease surveillance and response.
2000	Global health (HIV/AIDS)	<a href="#">Public Law 106-113</a> Consolidated Appropriations Act of 2000, as described in <a href="#">House Report 106-419</a>	Congress first appropriates funding specifically for CDC's international AIDS activities (\$35 million), used to support the newly launched CDC Global AIDS Program.

2003	Global health (HIV/AIDS)	<a href="#">Public Law 108-25:</a> United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003	Required a comprehensive, integrated 5-year strategy for a coordinated USG response to global HIV/AIDS; established Office of the Global AIDS Coordinator in State; amended the Foreign Assistance Act of 1961 to define eligibility for HIV/AIDS assistance; mandated goals, benchmarks, and metrics for program evaluation; authorized up to \$15 billion from FY2004-8, primarily in 15 focus countries.
2005	Global health	<a href="#">70 FR 58421</a> Statement of authorities establishing the Coordinating Office for Global Health at the Centers for Disease Control and Prevention (Statutory authority 5 USC. § 301)	Established the Coordinating Office for Global Health (replacing the previous Office of Global Health) to provide intra-agency leadership in global health as part of an agency-wide reorganization under regulatory authority of the Secretary of HHS. Congress first appropriated funds for the COGH Global Disease Detection program in <a href="#">The Consolidated Appropriations Act, 2004 (P.L.108-199)</a> , referenced in <a href="#">House Report 108-188</a> and <a href="#">Senate Report 108-081</a> .
2005	Influenza	<a href="#">The Department of Defense, Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act, 2006</a>	Appropriated supplemental funds for FY2006 to address hurricanes in the Gulf of Mexico and pandemic influenza, including support for CDC's international influenza activities.
2008	Global health (HIV/AIDS)	<a href="#">Public Law 110-293:</a> The Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008	Authorized an increase of up to \$48 billion over five years (FY2009-2013) to continue PEPFAR programs; extended the geographic and programmatic scope of HIV/AIDS, malaria, and tuberculosis control and prevention strategies; proposed use of framework agreements with recipient countries; removed some spending requirements on prevention efforts; endorsed health systems strengthening; and established a Global Malaria Coordinator in USAID.

### USG interactions

Due to its complement of public health and laboratory expertise, CDC is an implementing and/or technical assistance partner on almost every major USG global health initiative. The table below illustrates how a handful of major interagency USG global health frameworks create interactions between CDC and other USG partners.

Focus Area	Global HIV/AIDS	Malaria	Avian and Potentially Pandemic Influenza
<b>CDC's Role</b>	PEPFAR implementing agency [Main agent: GAP]	President's Malaria Initiative technical-implementing partner [Main agent: DPD/NCVZED]	International influenza detection and response under National Strategy for Pandemic Influenza [Main agent: Influenza Division]
<b>USG Partners</b>	<p><b>Leadership:</b> State (Office of the Global AIDS Coordinator)</p> <p><b>Other implementing agencies:</b> USAID (Office of HIV/AIDS) Defense (DOD HIV/AIDS Prevention Program) Commerce Labor Peace Corps Health and Human Services (Office of Global Health Affairs, HRSA, NIH, FDA) National Security Council</p>	<p><b>Leadership:</b> USAID (Global Malaria Coordinator)</p> <p><b>Steering group:</b> USAID State Defense National Security Council Office of Management and Budget</p>	<p><b>Leadership:</b> State (Avian Influenza Action Group)</p> <p><b>Technical partners:</b> USAID Defense (Naval Medical Research Units, Air Force, DOD-GEIS) USDA HHS (OGHA and Influenza Coordination Center) Homeland Security Council National Security Council</p>

Ties between USAID and CDC to support mutual global health objectives date to CDC's earliest forays into significant international health leadership in 1966. From the beginning, USAID has primarily supplied funds (with some programmatic strings attached)<sup>xxvi</sup> and tasked CDC to supply technical assistance in the form of personnel who either implement programs in the field in collaboration with local counterparts or serve in advisory roles – to USAID and other USG agencies as well as to international partner organizations. USAID supports CDC's activities in the control and prevention of many diseases of global significance, such as tuberculosis and malaria, for which CDC's appropriated funds (about \$2 million and \$9 million, respectively, in FY2008) are not equal to disease impact or the mandates of specific USG programs such as the President's Malaria Initiative. This frequently leaves CDC to negotiate with USAID for funds appropriated for foreign operations, complicating budget- and priority-setting for programs where CDC acts as the technical/implementing partner.

<sup>xxvi</sup> For example, CDC gained USAID support to lead the WHO's smallpox eradication effort in Central and West Africa by agreeing to combine smallpox efforts with a measles-control program requested by USAID.

### **Budget**

The budget below represents sums appropriated for CDC's global health activities, and includes neither funds transferred from the State Department's global health account for PEPFAR activities, USAID's child survival and health account for other partnerships, nor emergency supplemental appropriations for avian influenza and pandemic preparedness.

<b>CDC Global Health Budget by Activity</b>					
	FY 2004 Actual	FY 2005 Actual	FY 2006 Actual	FY 2007 Actual	FY 2008 Actual
<b>Global Health Activities (\$US thousands)</b>					
Global AIDS Program	266864	123830	122560	120985	118863
Global HIV/AIDS Research	9000	14000			
Global Immunization Program	137903	144386	144282	142338	139851
Global Disease Detection	11609	21426	32443	32004	31445
Global Malaria Program	9186	9108	8975	8851	8696
Other Global Health	2403	3403	71364	3319	3516
<b>Total</b>	<b>436965</b>	<b>316153</b>	<b>379624</b>	<b>307497</b>	<b>302371</b>

Source: [CDC FY 2010 CJ](#)

## HHS/THE FOOD AND DRUG ADMINISTRATION (FDA)

### *Mission and roles*

FDA, an operating division of HHS, leads Federal efforts to ensure access to safe and effective drugs, biological products, medical and radiation-emitting devices, cosmetics, and a safe and nutritious food supply in the US. FDA facilitates public communication to share accurate information on the health implications of foods and medicines and warn people of potential safety problems, and promotes innovations to make medicines and foods safe and affordable.<sup>167</sup>

Most of FDA's international activities relate directly back to its primary mission: protecting US public health and safety through the review, licensure and inspection of imported pharmaceutical, biological, medical, and food products – before they enter the US market, if possible. FDA also conducts outreach to its regulatory counterparts in other nations to seek harmonization of guidelines, mutual recognition of standards, and to offer training in US regulatory requirements and methods.<sup>168</sup> In this vein, FDA plays a role in approving generic pharmaceutical products eligible for use in USG-funded HIV/AIDS programs. FDA has also expanded its overseas presence in nations that are major exporters of food and drugs to the US to help partner nations build capacity for Good Manufacturing Practices and strong quality assurance systems.

### *Organization and focus*

FDA regulates the safety of biologics (such as blood products and vaccines) through the Center for Biologics Evaluation and Research, pharmaceuticals intended for the US market through the Center for Drug Evaluation and Research (CDER), and foods through the Center for Food Safety and Nutrition. These centers, in addition to other regulatory offices within FDA, all conduct international activities from inspections to prioritizing requests for visits and training by representatives from foreign regulatory agencies and international regulatory organizations.

The Office of International Programs serves as the focal point for FDA's international activities, coordinating interactions with international counterparts, setting priorities for international activities, and coordinating international policies.<sup>169</sup> In addition, due to the scope of its activities, CDER maintains its own International Activities Coordinating Committee to coordinate its programs for inspection, training, outreach, monitoring, and scientific collaborations.<sup>170</sup>

### SNAPSHOT - FDA

**Primary role:** screening pharmaceutical and biological products for safety and efficacy.

**Global programming:**

- Capacity building
- Training/exchanges

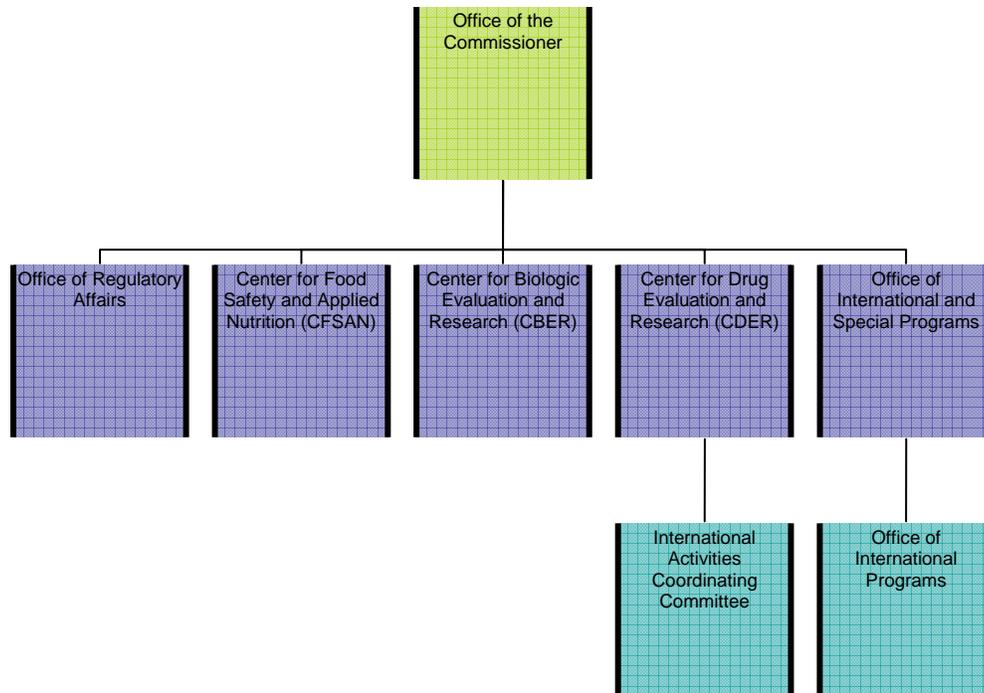
**Mechanisms:**

Regulatory, policy technical/advisory

**Areas of focus:** Products from all countries.

**Significant dates:**

**2004** – FDA announces plan for expedited review of antiretroviral drugs from worldwide sponsors  
**2006** – PEPFAR guidance for industry released  
**2008** – FDA assigns staff to missions in China, creating permanent overseas presence



**FDA Figure 1:** Organization of FDA offices involved in international health activities, including evaluating potential PEPFAR products and building local capacity to maintain good manufacturing processes and quality assurance programs.

The 2003 legislation that authorized PEPFAR specified that any pharmaceuticals purchased for distribution, including antiretroviral therapies, would be “quality-controlled.”<sup>171</sup> At the initiation of PEPFAR, the State Department’s Office of the Global AIDS Coordinator determined that this standard would be met by using medications approved by FDA.<sup>172,173</sup> However, no precedent existed to guide FDA in approving generic equivalents of patented anti-retroviral treatments manufactured outside the US for use beyond US borders. This effectively prevented PEPFAR funds from purchasing lower-cost generic pharmaceuticals favored by other donors and national HIV/AIDS programs (which largely relied on the WHO Prequalification of Medicines Project to assess drug quality), maintaining consistency in US intellectual property law, but decreasing cost efficiency and creating barriers to harmonization between PEPFAR and parallel programs.<sup>174</sup>

In May 2004, HHS Secretary Tommy Thompson announced that FDA would develop guidance for reviewing the safety and efficacy of new HIV/AIDS combination therapies produced abroad for potential use in PEPFAR programs, and FDA soon outlined a CDER special initiative to review applications for antiretroviral medications from international manufacturers on an expedited basis in order to establish their acceptability for purchase with PEPFAR funds.<sup>175,176</sup> Through this system, FDA extended its domestic regulatory authority to internationally manufactured, generic antiretroviral therapies specifically for the purpose of allowing them to be purchased with USG funds for use overseas. This process can confer a special “tentative” designation to validate pharmaceuticals produced under compulsory licenses that could not be marketed within the US due to patent protections.<sup>177</sup>

In 2008, FDA announced that it would expand its permanent international presence, assigning staff to US missions in three Chinese cities (Beijing, Guangzhou and Shanghai), with plans to create offices in India, Europe, Latin America and the Middle East.<sup>178</sup> This increasing overseas activity reflects the new regulatory demands on FDA in a globalized economy, with an increasing number of pharmaceutical precursors as well as finished products manufactured internationally for import into the US market. Assisting international sponsors with good manufacturing practices can be expected to build capacity for quality control/quality assurance that will also benefit consumers in the local markets.

### ***Legislation and authorities***

Year	Focus	Authority	Purpose(s)
1906	Food and drug safety	The Federal Food and Drugs Act	Conferred upon FDA precursor organization (the Bureau of Chemistry) the right to regulate food additives and pharmaceuticals.
1938	Food and drug safety	The Food Drug and Cosmetic Act (as amended)	Expanded FDA's authority to include cosmetics and natural food safety – basis of current law in USC. Title 21.
1944	Public health	<a href="#">The Public Health Service Act</a> (as amended)	Defined the powers and duties of the US Public Health Service (PHS), outlined the policy framework for Federal-state cooperation in public health, and established regulatory authorities that transferred with PHS to HEW and then HHS. The full act is captured under Title 42 of the US Code, "The Public Health and Welfare." Section 307 authorized the Secretary of HHS to enter into international cooperative agreements for biomedical and health activities.
1997	Food and drug safety	<a href="#">Public Law 105-115</a> The Food and Drug Administration Modernization Act of 2007	Charged FDA with overhauling procedures and regulatory processes for medical devices, foods, and pharmaceuticals, including "fast track" reviews for essential drugs.
2000	Global health (HIV/AIDS)	<a href="#">Executive Order 13155 (May 10, 2000)</a> Access to HIV/AIDS Pharmaceuticals and Medical Technologies; 65 FR 30521 (May 12, 2000)	Prohibits USG retaliatory action (pursuant to the Trade Act of 1974) with respect to any law or policy in beneficiary sub-Saharan African countries that promotes access to HIV/AIDS pharmaceuticals or medical technologies and that provides adequate and effective intellectual property protection consistent with the TRIPS Agreement.
2003	Global health (HIV/AIDS)	<a href="#">Public Law 108-25:</a> The United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003	Required a comprehensive, integrated 5-year strategy for a coordinated USG response to global HIV/AIDS; established Office of the Global AIDS Coordinator in the State Dept.; amended the Foreign Assistance Act of 1961 to define eligibility and formulae for USG HIV/AIDS assistance; mandated goals, benchmarks, and metrics for program evaluation; authorized up to \$15 billion from FY2004-8, primarily in 15 focus countries.

2006	Global health (HIV/AIDS)	<a href="#">Guidance for Industry</a> : Fixed-Dose Combinations, Co-Packaged Products, and Single-Entity Versions of Previously Approved Antiretrovirals for the Treatment of HIV FDA/CDER (by regulatory authority)	Guidance for international sponsors to clarify the regulatory requirements to evaluate applications for FDA approval of generic antiretroviral therapies on an expedited basis to establish eligibility for purchase with PEPFAR funds.
2008	Global health (HIV/AIDS)	<a href="#">Public Law 110-293</a> : The Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008	Authorized an increase of up to \$48 billion over five years (FY2009-2013) to continue PEPFAR programs; extended the geographic and programmatic scope of HIV/AIDS, malaria, and tuberculosis control and prevention strategies; proposed use of framework agreements with recipient countries; removed some spending requirements on prevention efforts; endorsed health systems strengthening; and established a Global Malaria Coordinator in USAID.

***USG interactions***

FDA serves as a PEPFAR implementing agency, but has no formal assignment to any specific standing committee through the Office of the Global AIDS Coordinator. FDA coordinates with other HHS agencies through an intra-agency communications process, and works closely with CDC and USDA on antimicrobial resistance and food and pharmaceutical safety issues to identify potential threats to public well-being.

***Budget***

FDA has no budget appropriation specifically for its PEPFAR activities; budgets for overseas staffing reflect a primarily domestic regulatory mission, and are not included here.

## HHS/ HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA)

### *Mission and roles*

HRSA, an operating division of HHS, leads Federal efforts to improve access to healthcare services for underserved and medically vulnerable people within the US. Since its creation in 1982 from two precursor offices, HRSA has funded programs to provide community-based healthcare, train health professionals, and strengthen health systems in rural areas. HRSA provides leadership, funding and program support in every US state and territory to facilitate health care services targeting the uninsured, people living with HIV/AIDS, and maternal and child health.<sup>179</sup>

Since 1991, HRSA has administered the domestic Ryan White HIV/AIDS Program, providing primary health care, support services and anti-retroviral treatments to more than 500,000 HIV/AIDS infected people and their families each year who have no other source of coverage.<sup>180</sup> In 2003, HRSA leveraged this technical and policy experience in providing comprehensive HIV/AIDS care to underserved communities to implement an international HIV/AIDS portfolio under the aegis of the newly launched PEPFAR program.

### *Organization and focus*

HRSA manages its PEPFAR activities through the Global HIV/AIDS Program, within the HIV/AIDS Bureau. The Global HIV/AIDS Program focuses on two general goals: strengthening clinical and administrative systems to build networks capable of delivering high quality, comprehensive HIV/AIDS care; and supporting training, research, and education activities to develop human and organizational capacity necessary to sustain HIV/AIDS services.<sup>181</sup>

HRSA manages grants and cooperative agreements with academic institutions and non-governmental organizations to implement care and treatment, capacity building, and monitoring and evaluation programs. The HRSA Global HIV/AIDS program provides technical assistance to government and non-governmental agencies in developing care and treatment strategies, and has funded consortia of private and faith-based organizations to deliver antiretroviral therapies (ART) in PEPFAR focus countries.<sup>182</sup>

### SNAPSHOT – HHS/HRSA

**Primary role:** Building human and organizational capacity to deliver high quality, comprehensive HIV/AIDS care in PEPFAR countries.

#### **Global programming:**

- HIV/AIDS
- Health systems strengthening
- Capacity building
- Training and exchanges
- Direct health services delivery
- Health systems research

#### **Mechanisms:**

Funding, policy, technical/advisory

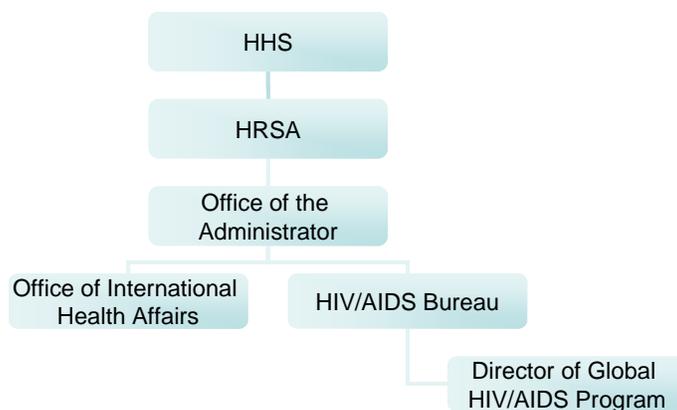
**Areas of focus:** PEPFAR countries

#### **Significant dates:**

**1982** - Health Resources Administration and Health Services Administration consolidated to create HRSA.

**1990** – Ryan White HIV/AIDS program authorized in HRSA.

HRSA training activities have emphasized nursing workforce development through “twinning” programs,<sup>xxvii</sup> clinical mentoring partnerships, and the I-TECH initiative to develop training curricula and materials, launched in collaboration with CDC and modeled on the US-based AIDS Education and Training Centers supported by the Ryan White HIV/AIDS Program.<sup>183</sup> HRSA also supports research to evaluate and share models for quality improvement, and disseminates clinical care data management software developed for the Ryan White program to PEPFAR countries to help practitioners improve service by capturing patient data accurately.



**HHS/HRSA Figure 1: Organization of HRSA’s global health activities.** HRSA administers its PEPFAR activities through the Global HIV/AIDS Program, an office of the HIV/AIDS Bureau.

**Legislation and authorities**

Year	Focus	Authority	Purpose(s)
1944	Public health	<a href="#">The Public Health Service Act</a> Title III (as amended)	Defined the powers and duties of the US Public Health Service (PHS) created in 1912, outlined the policy framework for Federal-state cooperation in public health, and established regulatory authorities that transferred with PHS to HEW and then HHS. The full act is captured under Title 42 of the US Code, "The Public Health and Welfare."
1953	HHS organization	Reorganization Plan No. 1 of 1953, effective April 11, 1953	Transferred the Public Health Service from the Federal Security Agency to Department of Health, Education, and Welfare (HEW).
1979	HHS organization	<a href="#">Public Law 96-88</a> Department of Education Organization Act of 1979	Created the Department of Education, separating its functions from the Department of Health, Education, and Welfare; in 1980, President Carter renamed the department Health and Human Services (HHS).
1982	HHS organization	HHS reorganization order (August 20, 1982)	Consolidated the Health Resources Administration and the Health Services

<sup>xxvii</sup> This refers to the development practice of longer-term partnerships between two organizations, often a donor and recipient. This practice was made popular by Scandinavian development agencies offering 7 years’ worth of funding to field NGOs.

			Administration.
1990	Public health (HIV/AIDS)	<a href="#">Public Law 101-381</a> The Ryan White Comprehensive AIDS Resources Emergency Act of 1990 (reauthorized as amended in 2000 and 2006).	Created a Federal program, administered by HRSA, to provide quality healthcare and services to individuals and families affected by HIV/AIDS who have inadequate insurance coverage and no other source of care. The act was most recently re-authorized in 2006 ( <a href="#">Public Law 109-415</a> ), with a new emphasis on spending for urban areas with the highest prevalence rates, services for racial/ethnic minorities, and direct health care.
1995	HHS organization	<a href="#">60 FR 56605</a> Statement of authorities establishing the Public Health Service agencies as HHS operating divisions (under authority of Reorganization Plan No. 1 of 1953 and Reorganization Plan No. 3 of 1966, 5 USC. 301)	Designated CDC, FDA, NIH, HRSA, AHCPR, ATSDR, IHS, and SAMSHA as HHS operating divisions comprising the Public Health Service; required operating divisions to report directly to the Secretary rather than the Assistant Secretary for Health; and created the Office of Public Health and Science in the Office of the Secretary.
2003	Global health (HIV/AIDS)	<a href="#">Public Law 108-25:</a> United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003	Required a comprehensive, integrated 5-year strategy for a coordinated USG response to global HIV/AIDS; established Office of the Global AIDS Coordinator in the State Dept.; amended the Foreign Assistance Act of 1961 to define eligibility and formulae for USG HIV/AIDS assistance; mandated goals, benchmarks, and metrics for program evaluation; authorized up to \$15 billion from FY2004-8, primarily in 15 focus countries.
2008	Global health (HIV/AIDS)	<a href="#">Public Law 110-293:</a> The Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008	Authorized an increase of up to \$48 billion over five years (FY2009-2013) to continue PEPFAR programs; extended the geographic and programmatic scope of HIV/AIDS, malaria, and tuberculosis control and prevention strategies; proposed use of framework agreements with recipient countries; removed some spending requirements on prevention efforts; endorsed health systems strengthening; and established a Global Malaria Coordinator in USAID.

### ***USG interactions***

HRSA interacts with the other Public Health Service operating divisions (including CDC and FDA) directly, as well as through intra-agency coordination within HHS. HRSA and CDC have collaborated directly to launch HIV/AIDS training and research programs. As a PEPFAR implementing agency, HRSA participates in technical working groups under the coordination of the Office of the Global AIDS Coordinator within the State Department.

### ***Budget***

HRSA receives no budget appropriated specifically for global health activities, but administers or oversees PEPFAR programs supported through the State Department's Global HIV/AIDS Initiative.

## HHS/THE NATIONAL INSTITUTES OF HEALTH (NIH)

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### *Mission and roles*

The National Institutes of Health (NIH), an operating division of HHS, provides both funding and leadership in biomedical and behavioral research. NIH supports robust intramural and extramural research portfolios aimed at identifying the causes, diagnoses, prevention, and cures for a wide range of human diseases and disorders, many of which disproportionately affect low- and middle-income nations.

Each year, NIH hosts more than 2,000 visiting scientists from other nations seeking experience and training opportunities, and many NIH institutes and centers sponsor some international research.<sup>184</sup> A PEPFAR implementing agency, NIH supports basic, clinical, and behavioral research on HIV infection and its consequences, as well as an international research and training portfolio.<sup>xxviii</sup>

### *Organization and focus*

The National Institutes of Health (NIH) consists of 27 institutes and centers (ICs), each focused on a cluster of related diseases or health issues. The Office of the Director (OD) sets policies to guide the agency, and manages coordination between ICs. Although many of these ICs encompass some international programs, most NIH funding supports work conducted by US-based researchers, who may collaborate with overseas counterparts. Research coordinated through two NIH offices can be classified less ambiguously as global health spending: the international portfolio coordinated by the Office of AIDS Research (OAR), within the Office of the Director, and the programs conducted by the John E. Fogarty International Center for Advanced Study of Health Sciences (FIC).

Rather than dedicate a distinct institute to HIV/AIDS research, NIH elected to harness the cross-disciplinary biomedical and behavioral science expertise throughout its ICs to address the many issues associated with understanding how best to improve HIV prevention and treatment measures. OAR coordinates the scientific, budgetary, legislative, and policy elements of all AIDS research conducted and supported by the NIH, which is conducted or supported by nearly every NIH Institute and

### SNAPSHOT - NIH

**Primary role:** supporting and conducting biomedical and behavioral sciences research to better understand HIV/AIDS and other diseases and disorders, with a long-term goal of increasing mechanisms for diagnosis, prevention, and treatment.

#### **Global programming:**

- Basic research
- Capacity building

#### **Mechanisms:**

Operational (research), technical/advisory, policy, funding

**Areas of focus:** Global (>90 countries)

#### **Significant dates:**

**1930** – Hygienic Laboratory renamed the National Institute of Health.

**1955** – NIAID created from former National Microbiological Institute.

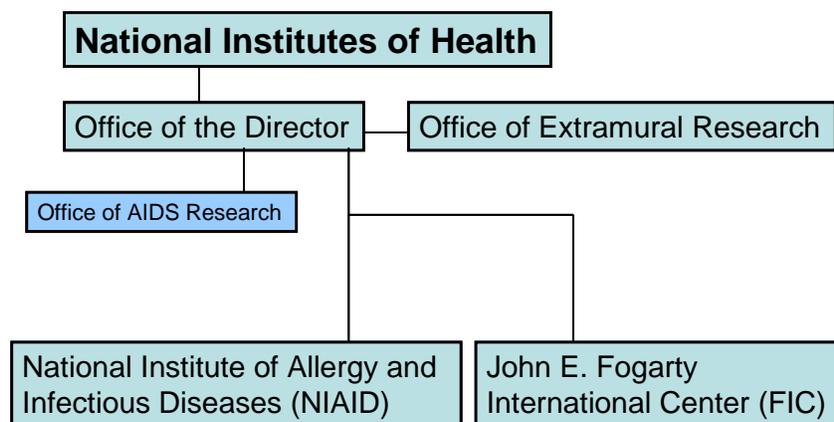
**1968** – Fogarty Center created by executive order.

**1988** – Office of AIDS Research created.

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<sup>xxviii</sup> Although NIH is categorized as a PEPFAR implementing agency, the NIH Office of AIDS Research sets its spending levels based on its research priorities, without budget guidance from the Office of the Global AIDS Coordinator. [Source: Tiaji Salaam-Blyther, *Trends in US Global AIDS Spending: FY2000-FY2008* (CRS report number RL33771), July 16, 2008].

Center.<sup>185</sup> OAR drafts an annual trans-NIH strategic plan for international AIDS research activities that guides development of the NIH AIDS research budget (as well as a Presidential “bypass budget,” based solely on scientific priorities), as mandated by the NIH Revitalization Act of 1993.<sup>186</sup> The Director of OAR is supported by an advisory council, technical working groups that help set research priorities in focus areas, and Scientific Coordinating Committees that evaluate whether individual extramural projects continue to support OAR’s strategic plan. For fiscal years 2007-9, OAR budgeted just over \$360 million per year to support AIDS research conducted in international settings, with a focus on prevention (through basic, translational, and clinical research on microbicides and vaccines development, and behavioral and social sciences associated with HIV transmission and acquisition) and research to understand and prevent HIV-associated co-morbidities, co-mortalities, and co-infections.<sup>187</sup>



**NIH Figure 1:** Organization of institutes, centers, and offices responsible for coordinating, conducting, and funding the majority of NIH international research. The Office of AIDS Research coordinates the trans-NIH AIDS research portfolio, which is not limited to any single center.

Much of the research to support OAR’s portfolio is conducted through the National Institute for Allergy and Infectious Diseases (NIAID), which supports basic and applied research to better understand, treat, and prevent infectious, immunologic, and allergic diseases. Within NIAID, the Division of Microbiology and Infectious Diseases (DMID) carries out basic research on microorganisms and infectious diseases to further understand their pathology and to develop therapeutics and prophylaxes. The Vaccine Research Center (VRC) facilitates the development of effective vaccines for human diseases, including finding a vaccine to prevent HIV/AIDS. The Division of Acquired Immunodeficiency Syndrome (DAIDS) works to bring an end to the HIV/AIDS epidemic by increasing basic knowledge of the pathogenesis and transmission of HIV. DAIDS also supports research and development of therapies for HIV infections, complications, and co-infections, and development of vaccines and other prevention strategies. Tying these divisions together is the Division of Clinical Research, which provides multi-disciplinary trans-NIAID services for facilitating clinical research and managing special projects as directed by NIAID leadership.<sup>188</sup> In FY2007, NIAID spent approximately \$378 million to support international research in more than 90 countries, including long-term study sites supported by NIAID staff assigned to China, India, Mali, South Africa, Nigeria, and Uganda.<sup>189</sup>

The Fogarty Center focuses on building international collaborations in research and training. By facilitating partnerships between US scientists and the international community, Fogarty works to find innovative research solutions while training the next generation of scientists at home and internationally. Fogarty funds about 400 research and training projects involving over 100 US universities; the US scientists, in turn, collaborate with colleagues in over 100 foreign countries, most of them in the developing world.<sup>190</sup> Fogarty also builds capacity for implementing PEPFAR and other HIV/AIDS research programs through the International Clinical, Operational, Health Services Training Awards for AIDS and TB, which strengthen the skills of scientists in low- and middle-income countries to conduct research around promising HIV and/or TB interventions at the population and health care system levels.<sup>191</sup>

### *Legislation and authorities*

Year	Focus	Authority	Purpose(s)
1944	Public health	<a href="#">The Public Health Service Act</a> (as amended)	Defined the powers and duties of the US Public Health Service (PHS), outlined the policy framework for Federal-state cooperation in public health, and established regulatory authorities that transferred with PHS to HEW and then HHS. The full act is captured under Title 42 of the US Code, "The Public Health and Welfare." Section 307 authorized the Secretary of HHS to enter into international cooperative agreements for biomedical and health activities.
1950	Public Health	Public Law 81-692: The Omnibus Medical Research Act	Established the National Institute of Allergy and Infectious Diseases, which replaced the National Microbiology Institute that had been established in 1948.
1960	Global health	<a href="#">Public Law 86-610</a> The International Health Research Act of 1960	To advance the health sciences through cooperative international research and training; as amended (USC Title 42) authorized the Secretary of HHS to enter into international cooperative agreements for biomedical and health activities.
1968	Global health	Executive Order July 1, 1968	President Lyndon Johnson issued an Executive Order establishing the John E. Fogarty International Center for Advanced Study in the Health Sciences at the National Institutes of Health.
1983	Public Health	<a href="#">Public Law 98-63</a> : Supplemental appropriations for FY1983	Provided the first funds specifically designated for AIDS activities. \$9.375 million was earmarked for the NIH. By 1986, this amount had risen to \$247.7 million, and by 1987, funding levels had reached \$448 million.
1986	Global health	<a href="#">Public Law 99-158</a> Health Research Extension Act of 1985	Defined the roles and responsibilities of the director of NIH and the specific research institutes; created, by law, the John E. Fogarty International Center for Advanced Study in the Health Sciences (as amended in 42 USC. §287b).

1988	Public Health/ Global Health (HIV/AIDS)	<a href="#">Public Law 100-607:</a> The Health Omnibus Programs Extension of 1988	Laid the foundation for the Federal policy on AIDS, from research to education to anonymous testing. Under this Act, AIDS related grants were expedited, a clinical research review committee was established in the NIAID, and awards for international clinical research were authorized. At this time, the Office of AIDS Research was established within the NIH's Office of the Director.
1993	Public Health/ Global Health (HIV/AIDS)	<a href="#">Public Law 103-43:</a> The NIH Revitalization Act of 1993	Codified the establishment of the Office of AIDS Research in the OD and gave it greater authorities such as distributing all money designated for HIV/AIDS to the ICs.
1993	Public Health/ Global Health (TB)	<a href="#">Public Law 103-183:</a> The Preventive Health Amendments of 1993	Required the Director of NIAID to conduct or support research and training for the cause, early detection, prevention, and treatment of tuberculosis.
1994	Public Health/ Global Health (HIV/AIDS)	Public Law 103-333: The Department of Labor, HHS, and Education Appropriations Act of 1995	Consolidated appropriations for HIV/AIDS research to the Office of AIDS Research.
1996	Emerging infectious diseases	<a href="#">Presidential Decision Directive (PDD) NSTC-7</a>	Established national policy and implementing actions to address the threat of emerging infectious diseases by improving surveillance, prevention, and response measures; named CDC and NIH lead agencies, respectively, in interagency disease surveillance and response and research coordination; expanded DOD mission to include support of global surveillance, training research, and response to emerging infectious disease threats.
2003	Global health (HIV/AIDS)	<a href="#">Public Law 108-25:</a> United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003	Required a comprehensive, integrated 5-year strategy for a coordinated USG response to global HIV/AIDS; established Office of the Global AIDS Coordinator in the State Dept.; amended the Foreign Assistance Act of 1961 to define eligibility and formulae for USG HIV/AIDS assistance; mandated goals, benchmarks, and metrics for program evaluation; authorized up to \$15 billion from FY2004-8, primarily in 15 focus countries.
2008	Global health (HIV/AIDS)	<a href="#">Public Law 110-293:</a> The Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008	Authorized an increase of up to \$48 billion over five years (FY2009-2013) to continue PEPFAR programs; extended the geographic and programmatic scope of HIV/AIDS, malaria, and tuberculosis control and prevention strategies; proposed use of framework agreements with recipient countries; removed some spending requirements on prevention efforts; endorsed health systems strengthening; and established a Global Malaria Coordinator in USAID.

### ***USG interactions***

As a PEPFAR implementing agency, NIH interacts with the other agencies under the coordination of the Office of the Global AIDS Coordinator, State Department, through the Scientific Steering Committee and technical working groups as needed. NIH also coordinates with other HHS offices and operating divisions through intra-agency coordination.

### ***Budget***

The budget below represents sums appropriated for NIH research activities reported by center or disease category, with the exception of the funds designated to pass through NIH for transfer to the Global Fund to Fight AIDS, Tuberculosis and Malaria.

<b>NIH Budget for International HIV/AIDS and other Research</b>					
	FY 2004 Actual	FY 2005 Actual	FY 2006 Actual	FY 2007 Actual	FY 2008 Actual
<b>Global health activities (\$US thousands)</b>					
International HIV/AIDS	317000	370000	373000	362000	363628
Fogarty International Center	66344	66632	66378	66378	66912
Malaria	89000	104000	98000	104000	106000
Global Fund to Fight AIDS, Tuberculosis and Malaria	149000	99000	99000	99000	294759
<b>Total</b>	<b>621344</b>	<b>639632</b>	<b>636378</b>	<b>631378</b>	<b>831299</b>

Sources: [FIC Congressional Justifications FY2007-9](#); [PEPFAR Sources of Funding FY2005-7](#).

## THE DEPARTMENT OF HOMELAND SECURITY (DHS)

### *Mission and roles*

The Homeland Security Act of 2002 created a new Federal agency, combining law enforcement, border and coastline security, immigration, critical infrastructure protection, transportation, emergency management, and research functions previously dispersed among many agencies into one combined organization with a shared mission: preventing terrorist attacks within the US<sup>192</sup> Later, the new Department of Homeland Security (DHS) expanded this mission to include mitigation of and preparedness for natural disasters and health crises.

### *Organization and focus*

DHS comprises more than 25 offices and directorates that report directly to the DHS Secretary. Although the Office of Intelligence and Analysis plays a role in collecting international information on health trends and threats, and the Directorate for Science and Technology supports research and development in technologies to reduce such threats, the Office of Health Affairs serves as the Secretary's primary agent on all health and medical matters.<sup>193</sup>

Within the Office of Health Affairs (OHA), the International Affairs and Global Health Security (IAGHS) office plays an advisory and coordinating role. The division collects and shares lessons learned and best practices from international sources, and provides technical expertise and support to other OHA offices (which include Weapons of Mass Destruction and Biodefense, Medical Readiness, and Component Services and Workforce Health Protection) and DHS leadership.<sup>194</sup> OHA/IAGHS facilitates communications among international and domestic partners during crises, and serves as a liaison to USG agencies that implement global health programs, directly and through the Avian Influenza Action Group.

### SNAPSHOT - DHS

**Primary role:** Lead agency on all matters of domestic security, integrating Federal, state, and local capabilities to detect and respond to all categories of threats

#### **Global programming:**

- Avian and Human Influenza/Pandemic Preparedness
- Bioterrorism and other EID

#### **Mechanisms:**

Technical/advisory, coordination

#### **Areas of focus:** US

#### **Significant dates:**

**2002** – DHS created.  
**2007** - Office of the Chief Medical Officer replaced by expanded Office of Health Affairs.

### *Legislation and authorities*

Year	Focus	Authority	Purpose(s)
2002	DHS Organization	<a href="#">Public Law 107-296</a> Homeland Security Act of 2002	Created Department of Homeland Security, established organization and mission.
2005	Influenza	<a href="#">National Strategy for Pandemic Influenza</a>	Delineated roles and responsibilities of Federal government in strengthening preparedness for pandemic influenza.
2006	Influenza	<a href="#">Public Law 109-417</a> Pandemic and All-Hazards Preparedness Act	Establishes roles and responsibilities of HHS in domestic pandemic preparedness and lays out several areas for international leadership and capacity-building in avian-human influenza.

***USG interactions***

DHS interacts with the other Federal agencies working on avian influenza and pandemic preparedness bilaterally and through the Avian Influenza Action Group at the State Department, which also includes HHS, USDA, DOD, USAID, and the Homeland Security Council.

***Budget***

<b>Department of Homeland Security – International Health Budget</b>					
	FY 2004 Actual	FY 2005 Actual	FY 2006 Actual	FY 2007 Actual	FY 2008 Actual
<b>International Health Activities (in \$US thousands)</b>					
<b>OHA/OIA</b>					<b>250</b>

Source: [http://www.dhs.gov/xlibrary/assets/budget\\_fy2009.pdf](http://www.dhs.gov/xlibrary/assets/budget_fy2009.pdf)

## DEPARTMENT OF LABOR (DOL)

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### *Mission and roles*

DOL serves as the lead US government agency on workforce issues, developing a framework for workplace safety and non-discrimination policies, wage and benefit issues, and tracking employment trends.<sup>195</sup> Internationally, DOL focuses on preventing child labor and exploitation. DOL also acts as an implementing agency within PEPFAR, providing international technical assistance on HIV/AIDS education policies in the workplace to public and private sector partners.

### *Organization and focus*

DOL primarily conducts its international activities through the International Labor Affairs Bureau (ILAB), led by the Deputy Under-Secretary for International Labor Affairs. Offices within ILAB conduct research, provide technical assistance, and fund programs to prevent child labor and sexual exploitation, and represent the US government on these and international workplace safety issues in bilateral negotiations and multilateral partnerships.<sup>196</sup>

The ILAB's Office of Child Labor, Forced Labor & Human Trafficking has funded technical cooperation projects addressed at prevention child labor and exploitation in more than 75 developing nations in Africa, Asia, the Middle East, Latin America and the Caribbean, and through 35 global or multi-region projects.<sup>197</sup> Funds support non-governmental organizations and other international partners that carry out education programs designed to prevent the employment of children in both formal and informal industries, particularly the most hazardous. About 11 of these education projects are specifically aimed at addressing the needs of HIV/AIDS-affected orphans or vulnerable children forced to work or into prostitution (in Botswana, Ethiopia, Kenya, Lesotho, Rwanda, South Africa, Swaziland, and Uganda).

Under the aegis of PEPFAR, ILAB provides technical assistance to support HIV/AIDS workplace education programs with private and public sector partners in PEPFAR countries, such as “train the trainer” programs designed to provide local leaders with the facts and vocabulary to teach their colleagues about HIV/AIDS and to reduce workplace stigma against HIV-infected people. ILAB works most frequently in partnership with the HIV/AIDS office of the International Labor Organization, as well as with UNICEF and nongovernmental and faith-based organizations.

### SNAPSHOT - DOL

**Primary role:** promoting safe workplaces and preventing child labor and exploitation globally, including through HIV/AIDS workplace education programs.

#### **Global programming:**

- HIV/AIDS
- Training (education)
- Child health

#### **Mechanisms:**

Technical/advisory, funding, regulatory, policy

#### **Areas of focus:**

Africa, South and Southeast Asia, the Middle East, Latin America and the Caribbean (including PEPFAR focus countries)

#### **Significant dates:**

2001 – Global HIV/AIDS Workplace Education program authorized.

### Legislation and authorities

Year	Authority	Purpose(s)
1947	By authority of the Secretary of Labor	The Bureau of International Labor Affairs was created as a means to formally institutionalize the international directives of the Department of Labor.
2001	<a href="#">Public Law 106-554</a> Department of Labor Appropriations Act, 2001	Authorized ILAB to award funds under and administer DOL's Global HIV/AIDS Workplace Education program.
2003	<a href="#">Public Law 108-25</a> : United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act	Sec. 102 (a) B Grants the office of the Global AIDS coordinator the task of overseeing all HIV/AIDS related activity in PEPFAR focus countries. OGAC has the authority to create policy to task agencies of the US government in a coordinated manner. The Department of Labor is one of those agencies.
2008	<a href="#">Public Law 110-293</a> : The Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act	Authorized up to \$48 billion from FY2009-2013 to continue PEPFAR programs, extending the geographic and programmatic scope of HIV/AIDS, malaria, and tuberculosis control and prevention strategies.

### USG interactions

DOL works with the Office of the US Trade Representative through the interagency Trade Policy Review Group to evaluate partner countries' commitments to fair labor standards. DOL is an implementing partner in PEPFAR, working under the coordination of the Office of the Global AIDS Coordinator (OGAC) in the State Department.

### Budget

The sums below include only funds appropriated specifically for international HIV/AIDS programs, and do not include funds transferred to DOL by OGAC to continue ongoing programs, or budgets for programs aimed generally at preventing child exploitation. Appropriated funds dropped steadily from an average of about \$10 million per year from FY2001-FY2004 (when conference language earmarked the full amount for transfer to the International Labor Organization) to slightly less than \$2 million (again earmarked for transfer) in FY2005. The administration requested no funds from FY2006 on, although OGAC did allocate a total of \$5 million to ILAB from FY2005-7.<sup>198</sup>

<b>DOL Budget for HIV/AIDS Programs</b>					
	<b>FY 2004 Actual</b>	<b>FY 2005 Actual</b>	<b>FY 2006 Actual</b>	<b>FY 2007 Actual</b>	<b>FY 2008 Actual</b>
(in \$US thousands)					
<b>Bureau of International Labor Affairs (ILAB)</b>	<b>10000</b>	<b>2000</b>	<b>0</b>	<b>0</b>	<b>0</b>

Source: <http://www.pepfar.gov/about/77649.htm>

## THE DEPARTMENT OF STATE (DOS)

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### *Mission and roles*

One of the original agencies of the US government, the State Department leads the executive branch in all matters related to foreign policy by:

- Representing the US government overseas through US embassies, consulates, and diplomatic missions;
- Negotiating agreements and treaties;
- Promoting mutual understanding between the people of the US and the people of other nations;
- Coordinating and supporting the international activities of other US agencies; and
- Leading interagency coordination and managing resources for foreign relations.<sup>199</sup>

In the last decade, State has drawn upon all of these missions in a dramatically expanded global health role as the lead agency in the President's Emergency Plan for AIDS Relief (PEPFAR) and coordinator of the Avian Influenza Action Group. State also facilitates agreements between host governments and the USG agencies – including HHS, CDC, and FDA – that have steadily broadened their global health programs, and supports the short- and long-term overseas postings of the experts who implement them.

### *Organization and focus*

State organizes its programs through the geographic bureaus, which work closely with the US missions overseas and the foreign embassies within their regional jurisdictions; the functional bureaus, which focus on clusters of issues, such as the Bureau of Oceans and International Environmental and Scientific Affairs (OES); and the offices within or attached to the Office of the Secretary. Although officers in the geographic bureaus may have interests in health issues specific to their regions, the vast majority of global health policy development and coordination activities within State lie in programs under the Office of the Secretary, the Under Secretary for Democracy and Global Affairs, and (tangentially) the Under Secretary for Arms Control and International Security.

### SNAPSHOT - STATE

**Primary role:** Lead agency on all matters of foreign policy, including coordinating and supporting international health activities of other US agencies, and coordinator of the President's Emergency Plan for AIDS Relief.

### **Global programming:**

- HIV/AIDS
- Avian and Human Influenza/Pandemic Preparedness
- Bioterrorism and other EID
- Maternal/child health
- Health systems strengthening

### **Mechanisms:**

Policy, technical/advisory, operational, funding, coordination

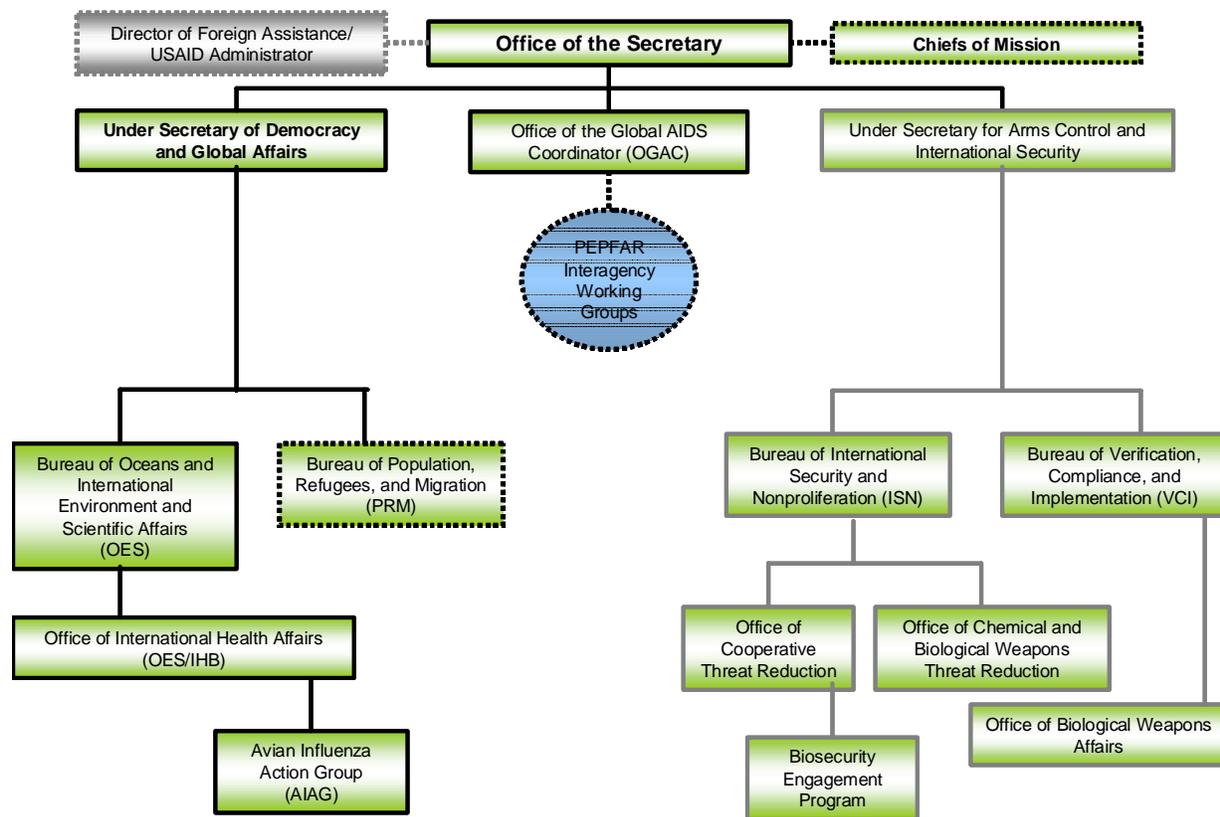
### **Areas of focus:** Global

### **Significant dates:**

**1973** - Bureau of Oceans and Environmental and Scientific Affairs established as focal point for science and technology issues.

**2003** - Office of Global AIDS Coordinator created.

**2006** - Special Representative for Avian Influenza and Pandemic Preparedness created.



**State Figure 1: Organization of State Department offices with global health missions.** The Office of the Global AIDS Coordinator (OGAC), in the Office of the Secretary, coordinates interagency activities under PEPFAR (the President’s Emergency Plan for AIDS Relief) and transfers the Global HIV/AIDS Initiative funds appropriated through the Foreign Operations appropriation to PEPFAR implementing agencies. The Avian Influenza Action Group, currently supervised by a Special Representative on Avian Influenza and Pandemic Preparedness, serves as a coordinating point for USG-wide global influenza programs. All other major health issues fall under the Office of International Health Affairs. The Bureau of Population, Refugees, and Migration coordinates with HHS on some refugee health issues. Several offices that focus primarily on biological threat reduction have begun to include aspects of laboratory capacity building and disease surveillance in their issue portfolios, although their missions remain focused on security risks rather than improving health status in developing nations.

- *Office of the Global AIDS Coordinator (OGAC)* – The United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 (Public Law 108-25) authorized up to \$15 billion over 5 years for a plan to coordinate existing US global HIV/AIDS activities and then build upon them dramatically. The same law mandated the establishment of a Global AIDS Coordinator to develop and implement a five-year strategy to provide HIV/AIDS prevention, treatment, and care services in 15 focus countries.<sup>xxix</sup> Since its launch, OGAC has developed mechanisms for planning and reporting, coordination, monitoring and evaluating outcomes, and sharing information among US-based and in country agencies.

<sup>xxix</sup> Only 14 focus countries in Sub-Saharan Africa and the Caribbean were named in legislation; Vietnam was added several months later by the President, and included formally at the reauthorization of PEPFAR in 2008.

OGAC directly approves all USG HIV/AIDS activities in the 15 PEPFAR focus countries, tracks spending, and transfers funds from the Global HIV/AIDS Initiative (GHAI) account to the implementing agencies.<sup>200</sup> OGAC also coordinates and oversees bilateral HIV/AIDS programs in non-PEPFAR focus countries. The Coordinator reports directly to the Secretary of State and manages an interagency PEPFAR decision-making structure that includes the Policy Group, Deputy Principals Group, Technical Working Groups, Country Core Teams, Scientific Steering Committee, and OGAC operating units.<sup>201</sup> OGAC, working in consultation with the HHS Office of Global Health Affairs, represents the US to international partners such as the Global Fund to Fight AIDS, Tuberculosis and Malaria.

- *Avian Influenza Action Group (AIAG)* – Prompted by concerns that ongoing outbreaks of highly pathogenic avian influenza in birds and sporadic bird-to-human disease transmissions in endemic countries could spark a pandemic, the Homeland Security Council released a National Strategy for Pandemic Influenza in 2005. The strategy assigned State the lead role in coordinating USG international pandemic preparedness efforts, leading to the creation in 2006 of the AIAG, headed by the Special Representative for Avian and Pandemic Influenza. AIAG coordinates USG international influenza efforts, which include substantial laboratory and disease surveillance and response capacity-building efforts in developing nations by CDC, DOD, and USAID. In addition to overseeing USG influenza programs abroad, AIAG aims to engage political leadership in avian-influenza affected nations through bilateral interactions and multilateral fora; to strengthen transparency and international cooperation; to strengthen coordination between health, agriculture, and foreign ministries; and to help coordinate concerned countries.<sup>202</sup>

AIAG drew very heavily upon OGAC as a model. Like OGAC, AIAG was designed and implemented as a “virtual” organization, with a very small core staff that depends heavily on personnel detailed from implementing agencies, task forces and technical working groups. Both AIAG and OGAC also address their coordination roles through weekly meetings of Deputy Principals from participating agencies.<sup>203</sup> However, unlike OGAC, AIAG does not control programmatic funds for the implementing agencies. In 2006, the newly created Special Representative reported directly to the Under Secretary for Democracy and Global Affairs; a February 2009 State Department reorganization moved the AIAG office into the Office of International Health and Biodefense (see next section).

- *Office of International Health and Biodefense (OES/IHB – also known as International Health Affairs)* – IHB’s small staff works through diplomacy and coordination to promote effective strategies for global health in a variety of areas, including health in post-conflict situations, environmental health, infectious disease detection and response, and health security. The office works with other USG agencies to represent the US position on health matters in international fora and assists US diplomatic posts in their health-related activities with foreign governments. Partners include other departments in State, USAID, HHS, USDA, DOD, DHS, the National Security Council and the Homeland Security Council, and intelligence agencies. IHB also works with international organizations such as UN agencies, the private sector, non-governmental organizations, and foreign governments to protect US security and global economic growth by promoting global health.

- *Other offices* – The Bureau of Population, Refugees and Migration (PRM) develops policy in some areas related to global health – including international population policies and migration of healthcare workers from low- and middle-income countries to developed economies; PRM represents the US on these issues to relevant international organizations, but does not fund programs.<sup>204</sup> State compiles and publishes information on USG international clean water programs as mandated by the Paul Simon Water for the Poor Act of 2005, and works in partnership with USAID and other stakeholders to develop strategies to incorporate safe water and sanitation programs into US development assistance efforts, but does not fund operational water programs.

The US missions and embassies abroad, and their chiefs of mission, play a significant role in coordinating USG global health programs in the field as well as supporting their operations and interactions with host country governments. In any given host country, all of the agencies working on HIV/AIDS programs under PEPFAR belong to one team, whose designated leader meets routinely with the ambassador or chief of mission and relevant embassy staff.<sup>205</sup>

### ***Legislation and authorities***

<b>Year</b>	<b>Focus</b>	<b>Authority</b>	<b>Purpose(s)</b>
1973	Foreign operations	Public Law 93-126 Department of State Appropriations Authorization Act of 1973	Established the Bureau of Oceans and Environmental and Scientific Affairs within State as State's focal point for international science and technology activities.
2003	Global health (HIV/AIDS)	<a href="#">Public Law 108-25</a> : United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003	Required a comprehensive, integrated 5-year strategy for a coordinated USG response to global HIV/AIDS; established Office of the Global AIDS Coordinator in the State Dept.; amended the Foreign Assistance Act of 1961 to define eligibility and formulae for USG HIV/AIDS assistance; mandated goals, benchmarks, and metrics for program evaluation; authorized up to \$15 billion from FY2004-8, primarily in 15 focus countries.
2005	Global health (influenza)	President's National Strategy for Pandemic Influenza	Assigned the lead role for the USG international efforts in dealing with avian and pandemic influenza to the Department of State.
2005	Water/ Sanitation	<a href="#">Public Law 109-121</a> Paul Simon Water for the Poor Act	Amended the 1961 Foreign Assistance Act to include safe water and sanitation as a priority for US development assistance strategy; required State (in consultation with USAID and other stakeholders) to develop a strategy to provide affordable and equitable access to safe water and sanitation in developing countries and to identify high-priority focus countries.

2008	Global health (HIV/AIDS)	<a href="#">Public Law 110-293:</a> The Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008	Authorized an increase of up to \$48 billion over five years (FY2009-2013) to continue PEPFAR programs; extended the geographic and programmatic scope of HIV/AIDS, malaria, and tuberculosis control and prevention strategies; proposed use of framework agreements with recipient countries; removed some spending requirements on prevention efforts; endorsed health systems strengthening; and established a Global Malaria Coordinator in USAID.
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### *USG interactions*

Because OGAC (PEPFAR) and the AIAG (international influenza activities) each coordinate a relatively broad interagency collaboration, State engages with a wide number of global health actors. PEPFAR implementing agencies include HHS (CDC, FDA, HRSA, and NIH), USAID, DOD, Labor, the Peace Corps, and Commerce; the Policy Group of Agency Principals also includes the National Security Council and the White House. The AIAG includes HHS, USDA, DHS, DOD, USAID, and the Homeland Security Council. Intra-agency coordination appears relatively weak within State, exacerbated by the fact that all three of the main global health offices (OGAC, AIAG, and IHB) report to authorities at different levels of the departmental hierarchy; OGAC and AIAG – at least through the structure developed during the George W. Bush administration – even report ultimately to different security organizations.

### *Budget*

<b>State Department Budget for Global Health</b>					
	FY 2004 Actual	FY 2005 Actual	FY 2006 Actual	FY 2007 Actual	FY 2008 Actual
<b>Global health activities (\$US thousands)</b>					
Global HIV/AIDS Initiative (151)	488000	1374000	1777000	2869000	4116455*
Global Fund to Fight AIDS, Tuberculosis and Malaria (151)	0	0	198000	378000	545545
Foreign Military Finance (152)	2000	2000	2000	2000	992
Contributions to International Organizations (153)	223000	243000	238956	253452	258070
<b>Totals</b>	<b>713000</b>	<b>1619000</b>	<b>2215956</b>	<b>3502452</b>	<b>4921062</b>

\*Newly consolidated “Global Health and Child Survival Account” combined GHAI with USAID Child Survival and Health Account.

State Department humanitarian assistance budgets are shown below for purposes of comparison, but do not necessarily comprise global health activities and do not count toward global health budget totals.

<b>State Department Budget for Humanitarian Assistance</b>					
	FY 2004 Actual	FY 2005 Actual	FY 2006 Actual	FY 2007 Actual	FY 2008 Actual
<b>Humanitarian Activities (\$US thousands)</b>					
Migration and Refugee Assistance (151)	782000	884000	859000	964000	1053000
Emergency Refugee and Migration Assistance (151)	30000	30000	30000	110000	45000
<b>Total</b>	<b>812000</b>	<b>914000</b>	<b>889000</b>	<b>1074000</b>	<b>1098000</b>

Sources: [PEPFAR: Table 1: Sources of Funding FY 2005 – FY 2007](#); [State Department Congressional Budget Justification \(FY2009\)](#); OMB Public Database; <http://www.state.gov/documents/organization/123415.pdf>

**State Box 1: Biosecurity and global health at State.** Several offices under the Under Secretary for Arms Control and International Security now include laboratory capacity building or disease surveillance issues in their portfolios, based primarily on the inclusion of such capabilities in the Biological and Toxin Weapons Convention (BWC) work program as a tool to detect outbreaks stemming from covert bioweapons programs. These offices mainly represent US biological security strategies in bilateral or multilateral negotiations, and have no coordinating or oversight roles in global health. However, State Department personnel from some of these offices have conducted training programs for health professionals in developing nations, and redirected cooperative threat reduction funds to strengthen diagnostic capabilities as well as security at national laboratories in Asia and Africa. In FY 2008, the HHS Office of Global Health Affairs announced that it would receive a small (\$8 million) transfer of funds to manage State’s Biotechnology Engagement Program, including “more than 20 high-priority public health projects” in Russia. The missions of the arms control offices remain based in biological risk management rather than improving health status in low-income nations, and their budgets are not included in this report. Nonetheless, they have become more closely if ambiguously integrated into the broader USG global health framework through securitization of public health and shifting biodefense priorities.

# ENVIRONMENTAL PROTECTION AGENCY (EPA)

## *Mission and roles*

Growing concerns about the impact of environmental pollution on human and animal health helped prompt creation of EPA in 1970. EPA consolidated within a single agency various Federal research, monitoring, and regulatory activities regarding the environment as part of its mission to protect human health and to safeguard the natural resources upon which life depends. EPA's international programs focus primarily upon addressing environmental hazards (such as airborne contaminants) that represent inherently transnational threats.

## *Organization and focus*

EPA's Office of International Affairs helps facilitate a relatively limited number of bilateral and multilateral partnerships aimed at three strategic priority areas:

- Reducing transboundary pollution;
- Advancing US interests by assisting in negotiation of trade agreements that include sustainable development; and
- Promoting good environmental governance.

Although ultimately aimed at limiting environmental introduction of contaminants that might affect health within the US, EPA partnerships build capacity for research, policy, and standards development in developing nations that also have a local impact on health. For example, EPA programs promoting local capacity for field research, policy development and implementation, and air quality monitoring in Ghana, Tanzania, South Africa, and Kenya addressed the growing public health risks associated with worsening urban air quality, especially for children.<sup>206</sup> EPA also supports a small number of water quality projects in India, and acts as a technical advisory to multilateral partners such as the United Nations Environmental Program.

## SNAPSHOT - EPA

**Primary role:** the national focus for environmental science, research, education and assessment.

**Global programming:** Mitigating environmental hazards

**Mechanisms:** Policy, technical/advisory, field research

**Areas of focus:** Sub-Saharan Africa, Asia/Pacific (primarily India and China), and Central America.



**EPA Figure 1: Organization chart for EPA's Office of International Affairs.**

**USG interactions**

EPA partners with USAID and the State Department to implement its international air and water quality programs with global health implications, and works with the United States Trade Representative (USTR) to develop, negotiate, and implement environment-related provisions in all new free trade agreements. EPA also contributes to research on the effects of global climate change (including health) through the interagency US Climate Change Science Program.

**Legislation and authorities**

Year	Focus	Authority	Purpose(s)
1970	Environment	<a href="#">Reorganization Plan No. 3 of 1970</a> Special Message from the President to the Congress About Reorganization Plans to Establish the Environmental Protection Agency and the National Oceanic and Atmospheric Administration	Created the EPA by executive authority from functions previously delegated to other agencies.
1990	Environment	<a href="#">Public Law No: 101-549</a> The Clean Air Act (as amended); incorporated into 42 USC. § 7671-7671q	Authorized the president to enter into international agreements to foster cooperative research and to develop standards and regulations to improve air quality; authorized assistance to developing nations to support participation in air pollution reduction global protocols.
1990	Environment	Public Law 101-606 US Global Change Research Act of 1990	To require the establishment of a Global Change Research Program aimed at understanding and responding to global change, including the cumulative effects of human activities and natural processes on human and environmental health.

**Budget**

EPA does not have an account specifically for international health projects, but funds international activities in clean air and safe water through its Environmental Programs and Management budget.

<b>EPA Budget for International Activities</b>					
	FY 2004 Actual	FY 2005 Actual	FY 2006 Actual	FY 2007 Actual	FY 2008 Actual
<b>International Activities (\$US thousands)</b>					
<b>International Environmental Programs</b>	20036	25279	23466	20710	19222

Source: EPA Budget FY2009 <http://www.epa.gov/budget/2009/2009bib.pdf> , EPA Budget in Brief FY2010: <http://www.epa.gov/ocfo/budget/2010/2010bib.pdf>

## US AGENCY FOR INTERNATIONAL DEVELOPMENT (USAID)

### *Mission and roles*

Shortly after the end of World War II, the US launched the Marshall Plan to combat “hunger, poverty, desperation and chaos” by rebuilding the infrastructure and economies of war-ravaged Europe.<sup>207</sup> This initiated a new era for US foreign assistance. Throughout the 1950’s, policymakers sought long-term strategies for foreign aid that would go beyond humanitarian relief but satisfy constituencies with vastly different expectations for what such aid might accomplish, authorizing a new food assistance program, the Public Law 480 or “Food for Peace Act” in 1954, as well as series of short-lived agencies that tested various mechanisms for integrating technical assistance, military and economic support independently and under the aegis of the State Department (see USAID Box 1).<sup>208,209</sup>

By 1960, aid to developing nations had become a politically contentious topic, prompting the incoming Kennedy Administration to propose a new US foreign assistance program.<sup>210</sup> With the Foreign Assistance Act of 1961, Congress articulated a development cooperation policy that emphasized alleviation of poverty, promotion of sustainable and equitable growth, fostering of civil and economic rights, promotion of good governance, and integration of developing nations into the international economy, all part of a foreign policy based on “encouragement and sustained support of the people of developing countries in their efforts to acquire the knowledge and resources essential to development and to build the economic, political, and social institutions which will improve the quality of their lives.”<sup>211</sup> The Foreign Assistance Act also separated military and non-military aid, and mandated the creation of a new agency (under the policy guidance of the State Department) to oversee existing and new foreign assistance programs. On November 3, 1961, President Kennedy established the US Agency for International Development (USAID) to fulfill this role.<sup>212</sup>

### SNAPSHOT - USAID

**Primary role:** Supports the US foreign assistance agenda by supporting projects to build infrastructure, promote health and economic security, and achieve human security in developing nations.

#### **Global programming:**

- HIV/AIDS
- Malaria and tuberculosis
- Health systems strengthening
- Maternal and child health
- Capacity-building
- Clean water and sanitation
- Mitigating environmental hazards
- Other infectious diseases

#### **Mechanisms:**

Operational, funding, policy, technical/advisory

**Areas of focus:** Sub-Saharan Africa, Asia; Latin America and the Caribbean; Europe and Eurasia; the Middle East.

#### **Significant dates:**

**1961:** Authorized/created.

**1973:** Congress directs USAID to focus on basic needs, including health, in poorest countries.

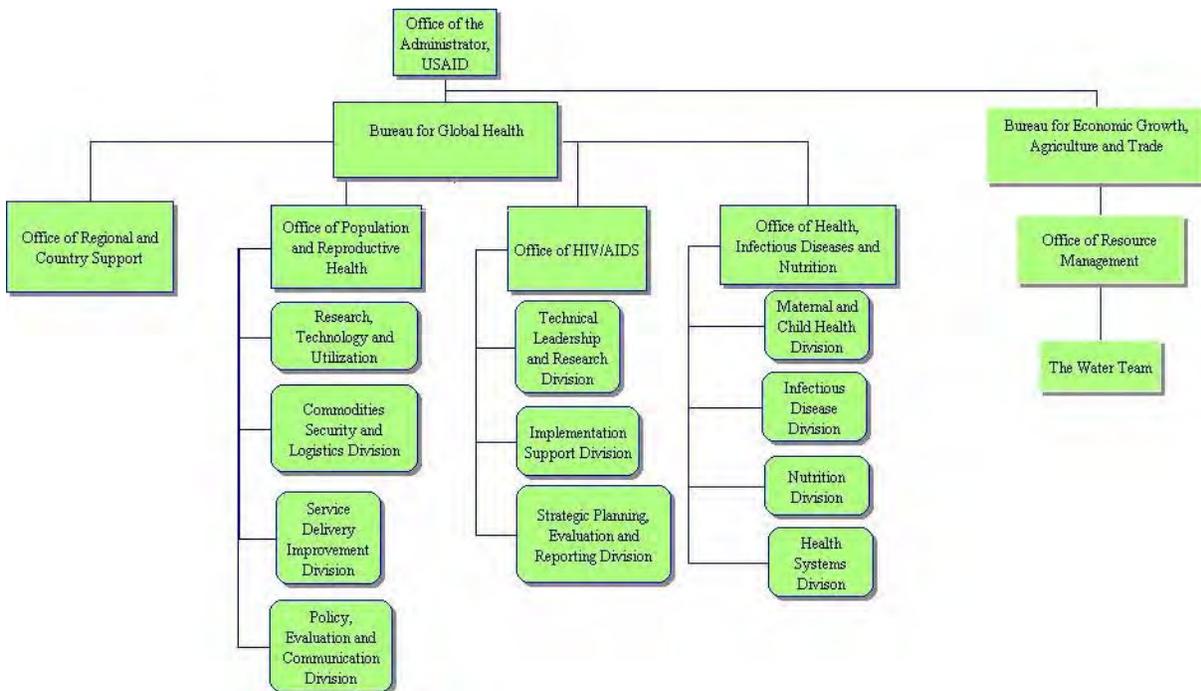
**1986:** International HIV/AIDS program launched.

**2001:** Bureau for Global Health created.

**Organization and focus**

USAID works under the aegis of the Secretary of State as a semi-autonomous Federal agency, directed by an Administrator who (per a State Department reorganization announced in 2006) also serves as the State Department Director of Foreign Assistance.<sup>213, xxx</sup> USAID leads USG efforts to support long-term, sustainable development in low- and middle-income countries. USAID supports economic, health, and capacity- and infrastructure-building programs through technical assistance to host nations and through awards and cooperative grants that support governments, local and international non-governmental organizations, and private sector actors in implementing assistance programs. USAID also serves as the lead USG agency in coordinating the international humanitarian response to disasters and humanitarian crises.

USAID is organized by functional and geographic areas. USAID maintains five regional bureaus that cover Sub-Saharan Africa, Asia, Latin America and the Caribbean, Europe and Eurasia, and the Middle East, as well as three functional bureaus in economic growth, agriculture and trade; global health; and democracy, conflict prevention and humanitarian assistance.



**USAID Figure 1: Organization of the offices that implement global health programs.** This chart shows the offices within the Bureau of Global Health and the Bureau for Economic Growth, Agriculture, and Trade that implement the majority of global health assistance programs, including bilateral and PEPFAR HIV/AIDS programs and safe water initiatives.

<sup>xxx</sup> USAID’s precise status in relationship to the State Department remains curiously ambiguous. Although State enjoys statutory authority over the USAID budgeting process, the extent to which this is exercised has varied among administrations. In 2006, the State Department created a “dual-hatted” position for the USAID Administrator/State Department Director of Foreign Assistance (deputy secretary level) as part of the “F process” of foreign aid reform, also integrating the USAID and State budgeting processes. [Source: Noam Unger, “[Foreign Assistance Reform: Then, Now and Around the Bend](#),” InterAction Monday Developments (July 2007).]

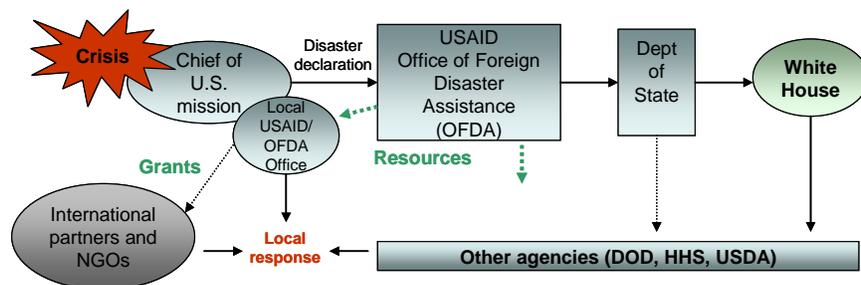
The majority of USAID's global health programs are coordinated through the Bureau for Global Health (BGH). Headed by the Assistant Administrator for Global Health, the bureau is home to the Office of HIV/AIDS, the Office of Population and Reproductive Health, the Office of Maternal Health, Infectious Diseases and Nutrition, and the Office of Regional and Country Support. BGH funds programs implemented by partner organizations through a variety of mechanisms (grants, cooperative agreements, collaborative agreements, contracts, and indefinite quantity contracts) and provides technical expertise to national governments and non-governmental organizations. BGH executes overall program evaluation and performance measurements, and assists USAID's human resources with planning, recruitment, development and assignment of headquarters and field staff in the population, health and nutrition sector.

In addition to supporting PEPFAR activities as a primary implementing agency, USAID also manages bilateral HIV/AIDS programs, with programs in 50 countries (including the PEPFAR focus countries). USAID had implemented HIV/AIDS programs bilaterally even prior to the launch of the President's LIFE (Leadership and Investment to Fight an Epidemic) Initiative in 1999. Under PEPFAR, USAID provides training, technical assistance, and commodities (such as pharmaceuticals) to public and private sector partners through its Foreign Service officers, trained physicians, epidemiologists, and public health advisors. USAID supports multi-sectoral responses to HIV/AIDS that go beyond the health sector, supporting programs in areas such as agriculture, education, democracy, and trade that reduce the social and economic impacts on HIV-affected nations, communities, families, and individuals. USAID also supports the New Partners Initiative (NPI) to build the capacity of organizations at the community level, while also building local ownership of HIV/AIDS responses for the long term.

USAID also supports international partnerships and organizations (such as the International AIDS Vaccine Initiative and UNAIDS), supports the US delegation to the Global Fund to Fight AIDS, Tuberculosis and Malaria, and works with Global Fund local coordinating committees to integrate Global Fund and USG programs. Finally, USAID supports targeted research, development, and dissemination of new technologies and supports packaging and distribution of anti-retroviral drugs through the Supply Chain Management System.

The Water Team – under the Bureau for Economic Growth, Agriculture and Trade – implements projects geared at improving access to potable water and improving water and sanitation systems, including during humanitarian crises. USAID also administers the largest US non-emergency food assistance program, the Public Law 480 Title II or “Food for Peace Program” through the Office of Food for Peace in the USAID Bureau for Democracy, Conflict & Humanitarian Assistance. Language in the House conference report accompanying the Foreign Assistance Appropriation Act of 2006 tasked the Office of Global AIDS Coordination to work with USAID to develop an interagency strategy for addressing the nutritional requirements of persons receiving care and treatment for HIV/AIDS in context of PEPFAR programs.<sup>214</sup> In FY2008, USAID began implementing the resulting HIV and Food Security Conceptual Framework, developed by with technical input from USDA and other agencies to better integrate PEPFAR and the Food for Peace nutrition and feeding programs.<sup>215</sup>

The Office of Foreign Disaster Administration (OFDA), also in the Bureau for Democracy, Conflict & Humanitarian Assistance, was established in 1964 to coordinate the interagency humanitarian response to international disasters, through a pathway triggered initially by the US ambassador or chief of mission in a disaster-affected nation.<sup>216</sup> OFDA can mobilize funds, materials, or personnel to natural or man-made disasters, and can request up to \$50,000 for local use within 24 hours. The president is authorized to borrow up to \$50 million in funds (usually from other planned regional programs, which may or may not be refunded through an emergency supplemental appropriation) for relief. Funding for humanitarian responses varies from year to year, based on the unpredictable nature of disasters, but has generally increased steadily over the last two decades to about \$3 billion or more annually from FY 1999-2006.<sup>217</sup> USAID can also use its Public Law 480 food assistance authorities to provide emergency food relief during disasters, and can call upon USDA to mobilize additional resources.



**USAID Figure 2: Activating the USG humanitarian response to disasters.** This schematic demonstrates the general mechanism, referred to as the “Executive Secretariat process,” by which the USAID Office of Foreign Disaster Administration works through the State Department to request interagency assistance for overseas disaster responses.

The regional bureaus oversee the bilateral and regional field missions, which consist of 3-15 full-time US direct hires (who support one to four strategic objectives, depending upon the size of the office) as well as locally hired foreign service nationals who assist in logistical support and program implementation.<sup>218</sup> In the past decade, USAID has embarked upon a gradual transformation from an agency primarily focused on accomplishing its goals through direct technical assistance in the field to heavily relying on funding public and private sector partners through contracts, grants, and cooperative awards. (In 2004, USAID claimed just over 260 direct-hire, contract, and foreign service national staff with health expertise.<sup>219</sup>) Many commissions and studies have suggested that USAID has insufficient staffing to fulfill its mandates effectively, creating a gap in capabilities and overstressing current resources. In 1990, nearly 3,500 USAID personnel administered a total of approximately \$5 billion annually; by 2008, USAID employed only 2,200 direct-hire personnel to administer more than \$8 billion annually in development and other assistance (excluding cash grants), following cumulative staff reductions of nearly 40% during the past two decades.<sup>220</sup>

**USAID Box 1: Creating USAID – false starts and new strategies.** At the conclusion of the Marshall plan in June 1951, Congress began seeking a strategy for replacing the Economic Cooperation Agency (1948-51) with a new office that would unite military and economic programs with technical assistance. The Mutual Security Act of 1951 (the first of a series of such acts) created the Mutual Security Agency (1951-53) “to provide military, economic, and technical assistance to friendly nations in the interest of international peace and security.” The President’s Reorganization Plan No. 7 of 1953 abolished this agency and replaced it with the Foreign Operations Administration, an independent government agency outside the Department of State, to consolidate economic and technical assistance. One year later, the Mutual Security Act of 1954 revised and consolidated all previous foreign assistance legislation, creating the International Cooperation Agency (ICA) under the authority of the State Department to administer aid for economic, political and social development purposes. Revisions to the Mutual Security Act in 1957 created the Development Loan Fund (DLF) to finance projects other than technical assistance for the ICA. This led to an organizationally and politically untenable plurality of uncoordinated assistance programs. A series of studies commissioned by Congressional committees and the State Department in 1959 and 1960 released contradictory proposals (recommending, respectively, consolidation of the existing agencies into an independent agency, creating a new function within State, and creating a new cabinet-level agency to administer foreign aid). The Foreign Assistance Act and the Act for International Development of 1961 gave President Kennedy the statutory authority to reorganize existing US foreign assistance programs into the newly created USAID. USAID became a statutory agency only with the Foreign Affairs Reform and Restructuring Act of 2005. [Sources: Carol Lancaster, *Foreign Aid: Diplomacy, Development, Domestic Politics*, University of Chicago Press: Chicago, 2006; [About USAID: USAID History](#);; Noam Unger, “[Foreign Assistance Reform: Then, Now and Around the Bend](#),” InterAction Monday Developments (July 2007).]

### ***USG interactions***

USAID plays a prominent role in three major global health initiatives: PMI, the President’s NTD Initiative and PEPFAR. Within PMI, USAID works in partnership with CDC, providing funding for the distribution of insecticide-treated bed nets as well as indoor spraying against mosquitoes. USAID also works in partnership with CDC under the NTD Initiative to accomplish the goal of delivering integrated treatment against seven neglected tropical diseases to 300 million people over five years. Under the direction of the Office of the Global AIDS coordinator, USAID administers PEPFAR funds to community initiatives aimed at providing care, treatment and prevention of HIV/AIDS. (Although the Administrator of USAID holds a dual-titled position equivalent to a deputy secretary within the State Department, he or she serves only in an advisory role to the Office of the Global AIDS Coordinator.)

USAID leads the Interagency Committee for Highly Vulnerable Children, which integrates USG efforts that affect orphans and vulnerable children, including those affected by HIV/AIDS.<sup>221</sup> USDA and USAID – the primary USG food assistance actors – constitute the core of the public-private Food Aid Consultative Group (although this has not guaranteed harmonized food aid policies).<sup>222</sup>

The USAID administrator also holds a seat on the board of the Millennium Challenge Corporation, the US corporation focused on providing consultation and funding to developing countries with comprehensive plans to meet the millennium development goals. To facilitate coordination, USAID has established the Millennium Challenge Coordination division. This

division is tasked with developing operational policies and practices that harmonize the operations of USAID and the MCC.

Finally, based in part on lessons learned in the response to the 2004 Asian tsunami and post-conflict assistance in Afghanistan and Iraq, USAID established the Office of Military Affairs (OMA) in 2005 to create liaisons between DOD and USAID teams in planning and in the field in an attempt to better integrate civil-military joint responses.<sup>223</sup>

### ***Legislation and authorities***

<b>Year</b>	<b>Authority</b>	<b>Authority</b>	<b>Purpose(s)</b>
1954	Nutrition	<a href="#">Public Law 83-480</a> (sections 201-7): The Agricultural Trade Development Assistance Act, renamed The Food for Peace Act in 1961	Authorized concessional sales of US agricultural commodities to developing countries and private entities by USDA (Title 1); direct donation of US agricultural commodities for emergency relief and development (Title II) and government-to-government grants of agricultural commodities tied to policy reform (Title 3), both assigned to USAID in 1961 (also known as Public Law 480).
1961	Foreign assistance/ USAID	<a href="#">Public Law 87-195</a> The Foreign Assistance Act of 1961	Created a policy framework for foreign assistance to developing nations and mandated the creation of an agency to promote long-term assistance for economic and social development; section 493 gives the president flexibility in implementing the humanitarian response to international crises.
1965	Foreign assistance/ USAID	Reorganization (by statutory authority), USAID Administrator	Establishment of USAID's family planning program.
1969	Foreign assistance/ USAID	Reorganization (by statutory authority), USAID Administrator	Office of Population is established.
1973	Foreign assistance/ USAID	<a href="#">Public Law 93-189</a> The New Directions Legislation of 1973 (in the Foreign Assistance Act of 1973)	New Directions amended the Foreign Assistance Act of 1961, directing USAID to focus its operational programs on five categories of assistance for meeting the basic needs of the poorest countries: <ul style="list-style-type: none"> <li>• food and nutrition</li> <li>• population planning</li> <li>• health, education, and human resources development</li> <li>• selected development problems</li> <li>• selected countries and organizations.</li> </ul>
1979	Foreign assistance/ USAID	The International Development Cooperation Act of 1979 (22 USC. 3501 et seq)	Includes population as a focus for international development.
1979	Foreign assistance/ USAID	<a href="#">Executive Order No.12163 of September 29, 1979</a>	Entitled "Administration of Foreign Assistance and Related Functions;" establishes the International Development Coordination Agency to execute non-military foreign assistance.
1979	Foreign assistance/ USAID	Reorganization Plan No.2 of 1979 (44 FR 41165)	Delegates "Population and Development" under the purview of the IDCA.
1985	Foreign assistance/ USAID	By Authority of the Administrator, USAID	USAID begins funding programs providing technical assistance in environmental health (water and sanitation).

1999	Foreign assistance/ USAID	<a href="#">Public Law 105-118</a> The Foreign Affairs Reform and Restructuring Act of 1998	Abolished the International Development Coordination Agency and established the US Agency for International Development as an executive agency effective April 1 <sup>st</sup> 1999.
2001	Foreign assistance/ USAID	By authority of the Administrator, USAID	Establishment of the Bureau for Global Health. All previous health programs are folded into this functional bureau.
2005	Water/ Sanitation	<a href="#">Public Law 109-121</a> Paul Simon Water for the Poor Act	Amended the 1961 Foreign Assistance Act to include safe water and sanitation as a priority for US development assistance strategy; required State (in consultation with USAID and other stakeholders) to develop a strategy to provide affordable and equitable access to safe water and sanitation in developing countries and to identify high-priority focus countries.
2006	Foreign assistance/ USAID	Department of State Delegation of Authority No. 293	The Secretary delegated to the USAID Administrator authority for USAID programs.
2002	Nutrition	<a href="#">Public Law 107-171</a> : The Farm Security and Rural Investment Act of 2002	Reauthorized Food for Peace Act through 2007; original authorization for McGovern–Dole International Food for Education and Child Nutrition Program through USDA’s Foreign Agricultural Service.
2005	Nutrition	<a href="#">House Report 109-265</a> , accompanying <a href="#">Public Law 109-102</a> : The Foreign Operations, Export Financing, and Related Programs Appropriations Act, 2006	Tasks OGAC in conjunction with USAID to report on HIV/AIDS-nutrition links and develop an interagency strategy for addressing the nutritional requirements of persons receiving care and treatment for HIV/AIDS in context of PEPFAR programs.
2008	Nutrition	<a href="#">Public Law 110-246</a> : The Food, Conservation, and Energy Act of 2008	USDA as executive agent: Comprehensive reauthorization of all US food and farm policies, including Food for Education, Food for Progress, and Food for Peace programs; re-titled Title I from “Trade and Development Assistance” to “Economic Assistance and Food Security.”

**Budget**

<b>USAID Budget by Activity – Global Health</b>					
	FY 2004 Actual	FY 2005 Actual	FY 2006 Actual	FY 2007 Actual	FY 2008 Actual
<b>Global Health (including HIV/AIDS), Safe Water, and Nutrition Programs (\$US thousands)</b>					
Global Fund to Fight AIDS, Tuberculosis and Malaria	398000	248000	248000	248000	0
Child Survival and Health	1425000	1562400	1435902	1642508	1799396
DA			8789	8589	9600
DA (Water)		81547	35398	42973	109693
AEEB/FSA	87600	87400	70603	53023	54865
AEEB/FSA/ACI (Water)		33756	5659	3157	6030
ESF	128800	120400	136729	122972	246839
ESF (Water)		54410	321758	61623	118809
IO&P (UNICEF)	119292	124000	125730	125730	127955
P.L. 480 Title II Food for Peace Program (non-emergency)	10000	10000	172781	148449	120309
<b>Total</b>	<b>2168692</b>	<b>2321913</b>	<b>2561349</b>	<b>2457024</b>	<b>2593496</b>

USAID humanitarian assistance budgets are shown below for purposes of comparison, but do not necessarily comprise global health activities and do not count toward global health budget totals.

<b>USAID Budget by Activity – Humanitarian Assistance</b>					
	FY 2004 Actual	FY 2005 Actual	FY 2006 Actual	FY 2007 Actual	FY 2008 Actual
<b>Humanitarian Activities (\$US thousands)</b>					
P.L. 480 Title II (humanitarian relief)	1166000	1417000	1316219	1546551	1439691
International Disaster Assistance	544000	674000	579000	526000	429000
<b>Total</b>	<b>1710000</b>	<b>2091000</b>	<b>1895219</b>	<b>2072551</b>	<b>1868691</b>

Sources:

<http://www.state.gov/documents/organization/100326.pdf>  
<http://www.usaid.gov/policy/budget/cbj2009/101417.pdf>  
<http://www.state.gov/documents/organization/67716.pdf>  
<http://www.state.gov/documents/organization/101429.pdf>  
<http://www.state.gov/documents/organization/123415.pdf>  
<http://www.state.gov/documents/organization/122513.pdf>

## OTHER ORGANIZATIONS: THE MILLENNIUM CHALLENGE CORPORATION (MCC)

### *Missions and roles*

The Millennium Challenge Corporation (MCC) was created in January 2004 to improve upon perceived shortcomings in USG provision of foreign assistance. Focused on reducing global poverty through targeted and tailored development projects, including some that address health, MCC provides funds through competitive, multi-year “compacts” with countries that meet specific political and development criteria.<sup>xxx1</sup>

### *Organization and focus*

MCC is a USG corporation, governed by a Board of Directors chaired by the Secretary of State, with the Secretary of Treasury as Vice-Chair. The board is rounded out by the US Trade Representative, the Administrator of USAID, the CEO of MCC and four Senate-confirmed public members.<sup>224</sup> MCC follows a public and transparent methodology aimed at targeting countries that will provide the most return on investment, as well as encouraging recipient participation in planning development projects. The selection process includes five major steps:

1. *Identification of Candidate Countries* – Each fiscal year, MCC submits a Report to Congress with a list of candidate countries based on per capita income (low and low-middle).
2. *Publication of MCC’s Selection Criteria and Methodology* – MCC also submits a Report to Congress each fiscal year describing the policy criteria and the methodology they will use to identify eligible countries. Indicators include public health expenditures and immunization rates, as well as political and trade policies.
3. *Publication of the MCC Scorecard* – Following a public comment period on the selection criteria and methodology, MCC publishes country performance “scorecards” on its website for all candidate countries and countries that would be candidates but for legal prohibitions.
4. *Selection of Compact-Eligible and Threshold-Eligible Countries* – From the pool of candidate countries, the MCC Board selects and invites new compact-eligible countries to begin developing proposals for MCC consideration.
5. *Determining Compact Content* – MCC reviews proposals’ feasibility, potential to reduce poverty and stimulate economic growth, and standards for economic rates of return on the individual projects.<sup>225</sup>

<sup>xxx1</sup> Developing countries are assessed against 17 indicators measuring factors from transparency and rule of law to a supportive business environment. The two health-specific indicators are immunization rate and public investment in health care (<http://www.mcc.gov/selection/indicators/index.php>).

### SNAPSHOT - MCC

**Primary role:** distribute development assistance funding through five-year “compacts” with countries meeting specific political and income criteria.

#### **Global programming:**

- Health systems strengthening
- Clean water and sanitation
- Capacity-building

#### **Mechanisms:**

Funding

**Areas of focus:** Global (currently funding health-related projects in *El Salvador, Georgia, Lesotho, Mongolia, Mozambique, Tanzania*)

#### **Significant dates:**

**2004** – MCC launched.

This begins an iterative dialogue which can result in multiple proposals from the country before the MCC Compact Development team assigned to that country "green-lights" the compact to be submitted to the Board for final approval. The following countries are currently engaged in compacts with the MCC: Armenia, Benin, Burkina Faso, Cape Verde, El Salvador, Georgia, Ghana, Honduras, Lesotho, Madagascar, Mali, Mongolia, Morocco, Mozambique, Namibia, Nicaragua, Tanzania, and Vanuatu. The MCC also supports threshold programs aimed at countries identified with one or two weak indicators but showing high potential returns on projects. Threshold monies (ranging from as low as 6 million to as high as 55 million) are intended to ramp up these countries towards full compact eligibility.<sup>xxxii</sup>

The table below depicts a list of the health-related projects (including clean water and sanitation) included in the currently budgeted MCC country compacts.<sup>xxxiii</sup>

Country	Description	FY 2007	FY 2008
<b>El Salvador</b>	Water resources policy and administrative management	33,913,997	-33,913,997
	Basic drinking water supply and basic sanitation	0	23,670,000
<b>Georgia</b>	Water supply and sanitation - large systems	0	43,485,000
<b>Lesotho</b>	Health policy and administrative management	2,588,000	10,352,000
	Medical education/training	0	7,414,000
	Medical services	0	5,741,000
	Basic health infrastructure	1,348,000	79,955,000
	Health personnel development	500,000	14,500,000
	Water resources policy and administrative management	459,000	34,371,000
	Water resources protection	324,000	4,644,000
	Water supply and sanitation - large systems	4,130,416	120,099,168
<b>Mongolia</b>	Health policy and administrative management	0	10,430,119
	Medical education/training	0	6,597,000
<b>Mozambique</b>	Water supply and sanitation - large systems	0	173,579,307
	Basic drinking water supply and basic sanitation	0	8,990,044
	Education and training in water supply and sanitation	0	21,016,042
<b>Tanzania</b>	Water supply and sanitation - large systems	0	66,335,000
<b>Total (US\$)</b>		<b>43,263,413</b>	<b>597,264,683</b>

Compact countries are expected to demonstrate improvement along indicators to maintain funding. To date, Nicaragua is the only country to have its disbursements and projects suspended (for "voting irregularities" in municipal elections in November 2008, deemed by MCC to reflect a lack of comment to good governance).

For reasons that include concerns about MCC's slow pace in disbursing funds to compact countries, Congress has routinely appropriated amounts for MCC activities far below budget requests.<sup>226</sup> The table below depicts funds appropriated to the Millennium Challenge Account

<sup>xxxii</sup> At the time of publication, Albania, Burkina Faso, Guyana, Indonesia, Jordan, Kenya, Kyrgyz Republic, Liberia, Malawi, Moldova, Niger, Paraguay, Peru, Philippines, Rwanda, São Tomé and Príncipe, Tanzania, Timor-Leste, Uganda, Ukraine, Yemen, and Zambia had participated in the threshold program at some point since 2004.

<sup>xxxiii</sup> Of the threshold countries, Indonesia maintains the largest health focus. Of the \$55 million total allocation, \$20 million is devoted to improving childhood immunization rates (<http://www.mcc.gov/documents/qsr-indonesia.pdf>). Peru also has an immunization component in its threshold program (<http://www.mcc.gov/documents/qsr-peru.pdf>).

(MCA) by the Senate and House Foreign Operations subcommittees annually, since 2004, as compared to the annual President's request:

Fiscal Year	President's Request	Congressional Appropriation
2004	1.3 Billion	1.0 Billion
2005	2.5 Billion	1.5 Billion
2006	3.0 Billion	1.75 Billion
2007	3.0 Billion	1.75 Billion
2008	3.0 Billion	1.54 Billion
2009	2.2 Billion	875 Million

Source: [http://www.cgdev.org/section/initiatives/active/mcmonitor/about\\_mca#MF](http://www.cgdev.org/section/initiatives/active/mcmonitor/about_mca#MF)

### *Legislation and authorities*

Year	Focus	Authority	Purpose(s)
2004	Development Assistance	<a href="#">Title V, Public Law 108-199</a> The Millennium Challenge Act of 2003 (in the Consolidated Appropriations Act, 2004)	Establishes the MCC as USG corporation responsible to administering funds from the Millennium Challenge Account; outlines by-laws for operations and structure

### *USG interactions*

MCC's relationships with other USG bodies were structurally built into its Board of Directors, where the Secretary of State serves as chairperson of the board and the Administrator of USAID maintains a permanent seat. The Department of State, particularly through US missions overseas, monitors compact country indicators and responses, and USAID maintains a Millennium Challenge Coordination Division that acts as an institutional bridge between USAID and MCC as well as other Federal agencies. The division is largely oriented around developing operational policies and practices that harmonize the operations of USAID and MCC, especially as they relate to the candidate countries not yet available for MCC assistance. Other US offices, including OPIC and USTDA, have piggybacked grants to complement compact and threshold agreements with the MCC.

### *Budget*

MCC enters into agreements for five-year budget commitments, with funds disbursed annually; the sums below represent total commitments in US\$ by fiscal year, rather than compact year, for health-specific projects.

<b>MCC Budget for Global Health Activities</b>					
	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008
<b>Health and Water Projects in Compacts (\$US thousands)</b>					
Water and sanitation			0	38827	462276
Health			0	4436	134989
<b>Total</b>			<b>0</b>	<b>43263</b>	<b>597265</b>

## OTHER ORGANIZATIONS: OFFICE OF THE US TRADE REPRESENTATIVE (USTR)

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### *Mission and goals:*

The US Trade Representative, a Cabinet member, serves as the president’s principal trade advisor, negotiator, and spokesperson on trade issues. The Office of the United States Trade Representative (USTR) negotiates directly with foreign governments to create trade agreements, resolve disputes, and participate in global trade policy organizations. USTR is also responsible for promoting US interests and protecting the intellectual property rights of US citizens through bilateral, regional and multilateral trade fora, including the United Nations Conference on Trade and Development and the World Trade Organization (WTO).<sup>227</sup>

### *Organization and focus:*

USTR (located within the Executive Office of the President) coordinates USG trade policy through an interagency structure. To ensure that trade agreements benefit and promote US interests, USTR is tasked with convening and managing interagency working groups and committees. The Trade Policy Staff Committee (TPSC) and the Trade Policy Review Group (TPRG), administered and chaired by USTR and composed of 19 Federal agencies and offices, examine proposed trade agreements on a subject by subject basis, voting either to support the agreement or recommend renegotiation or cessation.

USTR also implements Section 301 of the Trade Act of 1974,<sup>228</sup> which requires the US to impose trade sanctions against foreign countries found to violate US rights or benefits, including intellectual property rights of US citizens (such as patent protections).<sup>xxxiv</sup>

### *USG interactions:*

Through the TPSC and TPRG, USTR convenes representatives of the Departments of Defense, Health and Human Services (FDA), State (Trade Policy and Programs Division), Labor (the Bureau of International Affairs), Agriculture (the Foreign Agriculture Service), Homeland

### SNAPSHOT - USTR

**Primary role:** promoting, negotiating, and shaping US interests in global free trade.

**Global programming:** Negotiating trade agreements and protecting intellectual property rights of US citizens (with implications for drug production and technology transfer in developing nations).

**Mechanisms:** Policy, planning

**Areas of focus:** Global

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<sup>xxxiv</sup> In November 2001, all WTO member states – including the US – agreed to the [Ministerial Declaration on Trade-Related Aspects of Intellectual Property Rights \(TRIPS\) and Public Health](#). This declaration recognized that intellectual property protections can prevent the developing nations most affected by HIV/AIDS and other diseases from promoting access to essential drugs, and reaffirmed that the WTO TRIPS agreement offers member states the right to grant compulsory licenses (allowing local manufacture of patented drugs) when confronted with public health crises. Although USTR helped mediate this agreement and has repeatedly committed to enforcing no stricter intellectual property standards than TRIPS in support of global health efforts, the office has also pushed for controversial “TRIPS-Plus” measures in bilateral trade agreements to limit such compulsory licensing. [See Toni Johnson, “[Generic Drugs: The Other Drug War](#),” Council on Foreign Relations backgrounder (7 January 2009).]

Security, Commerce, Energy, Interior, Justice, Transportation, the Environmental Protection Agency (Office of International Affairs), and USAID. The Trade Representative also serves as a board member of the Overseas Private Investment Corporation (OPIC), a non-voting member of the Export-Import Bank, and a member of the National Advisory Council on International Monetary and Financial Policies.

### ***Legislation and Authorities***

<b>Year</b>	<b>Focus</b>	<b>Authority</b>	<b>Purpose(s)</b>
1962	Trade	The Trade Expansion Act of 1962 (Implemented by Executive Order 11106)	Required the President to appoint a Special Representative for Trade Negotiations and established an interagency trade organization to make recommendations to the President on policy issues arising from trade agreements.
1974	Trade	Public Law 93-618 The Trade Act, 1974	Codified STR as part of the Executive Office of the President; made STR responsible for trade agreements programs under the Tariff Act of 1930, the Trade Expansion Act of 1962, and the Trade Act of 1974; made STR directly accountable to both the President and the Congress (Sec. 141); and, as amended, authorized the President to take action against foreign countries that inadequately protect the intellectual property rights of US citizens (Sec. 301, 19 USC. § 2411).
1974	Trade	Executive Order 11846	Elevated the STR to cabinet level.
1979	Trade	Reorganization Plan No.3 and Executive Order 12188	Renamed STR as the Office of the United States Trade Representative (USTR), centralized USG policy-making and negotiating functions for international trade, and greatly expanded USTR.

### ***Budget***

USTR has no budget related directly to global health activities.

## OTHER ORGANIZATIONS: THE PEACE CORPS

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### *Organization and focus*

Founded in 1961 by President Kennedy, the Peace Corps is devoted to three core goals:

1. To help the people of interested countries in meeting their need for trained men and women.
2. To help promote a better understanding of Americans on the part of the peoples served.
3. To help promote a better understanding of other peoples on the part of Americans.

To accomplish these goals, the Peace Corps sends US citizens to act as volunteers in communities across the globe. Peace Corps volunteers operate as teachers, technical experts and administrators of both US and local initiatives focused on improving the lives of developing citizens while promoting a positive global image of US activities.

Over the last five years, Peace Corps has played an increasing role in PEPFAR (the President's Emergency Plan for AIDS Relief). Now operating in 10 of the 15 PEPFAR focus countries, approximately 20% of all Peace Corps volunteers are engaged in public health activities and HIV.<sup>229</sup> Programmatically, HIV policy is defined, administered and coordinated by the Office of AIDS relief at Peace Corps headquarters.<sup>230</sup> It also ensures the agency's compliance with PEPFAR commitments. According to the 2009 congressional budget justification, 195 volunteers are funded by PEPFAR monies. Examples of activities that volunteers do to support health and HIV/AIDS work include:

- teaching—formally and informally—about HIV/AIDS prevention and care;
- expanding peer education to urge youth and others to reduce risky behaviors;
- promoting healthy lifestyles, especially for youth;
- supporting youth and orphan activities and care;
- providing nutrition and hygiene education classes in communities;
- promoting education about infectious disease prevention;
- assisting in maternal and child health clinics;
- strengthening NGO health-delivery systems;
- constructing and managing water systems; and
- supporting community sanitation efforts.

As of 2008, the Peace Corps had 2,857 volunteers abroad working on HIV related work,<sup>231</sup> 58% of whom operate in Africa. Zambia has the most volunteers of any host country (160 volunteers or approximately 6% of the entire volunteer corps).

### SNAPSHOT – PEACE CORPS

**Primary role:** provide volunteers to communities in developing nations globally, including in support of PEPFAR.

#### **Global programming:**

- HIV/AIDS
- Maternal/child health
- Basic health services

#### **Mechanisms:**

Operational

#### **Areas of focus:**

Global

#### **Significant dates:**

**1961** – Peace Corps created under guidance of State as part of President Kennedy's "Decade of Development."

**1979** – Peace Corp established as autonomous agency.

### *Legislation and authorities*

Year	Focus	Authority	Purpose(s)
1961	Development Assistance/ Diplomacy	<a href="#">Public Law 87-293</a> : The Peace Corps Act	Establishes the right of the President to appoint a director of the Peace Corps (Sec.4 a); Establishes the Secretary of State as the direct supervisor of the Director of Peace Corps (Sec. 4. c. 3); Empowers the Director of the Peace Corps to execute the powers of the President as described in this act (Sec 4. b)
1971	Development Assistance/ Diplomacy	Executive Order 11603	In July 1971, President Richard Nixon, an opponent of the program, brought the Peace Corps under the umbrella agency ACTION.
1979	Development Assistance/ Diplomacy	Executive Order 12137	President Carter establishes the Peace Corps as an autonomous entity.
2008	Global Health (HIV)	<a href="#">Public Law 110-293</a> : The Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008.	Sec. 102 inserts Peace Corps as a member of the interagency working group.

### *USG interactions*

Peace Corps is listed as “heavily involved”<sup>232</sup> in PEPFAR, under coordination of the Office of the AIDS Coordinator in the Department of State. Peace Corps operations overseas are coordinated through the US Embassy or mission in each host country. Within the interagency process, Peace Corps volunteers and staff offer expertise in grassroots interventions, from direct health services delivery (such as caring for people infected with HIV) to educating students and the community about HIV/AIDS.

### **Budget**

The Peace Corps budget does not include a specific allocation for health activities. The following budget represents an estimate calculated by multiplying the total budget for direct volunteer activities by the percentage of Peace Corps volunteers conducting HIV/AIDS and global health work (20%) cited in the FY2008 Peace Corps Congressional Budget Justification.<sup>xxxv</sup>

<b>Peace Corps Budget – Global Health (Estimated)</b>					
	FY 2004 Actual	FY 2005 Actual	FY 2006 Actual	FY 2007 Actual	FY 2008 Actual
<b>Total for 20% of Direct Volunteer Activities (\$US thousands)</b>					
<b>Total</b>	48835	48831	52736	50688	55494

Source: [http://www.peacecorps.gov/multimedia/pdf/policies/peacecorps\\_cbj\\_2009.pdf](http://www.peacecorps.gov/multimedia/pdf/policies/peacecorps_cbj_2009.pdf)

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<sup>xxxv</sup> Peace Corps makes payments (ICASS) to the Department of State for administrative support. Some financial management support is also included here, although the Peace Corps has directly provided most financial management support to its overseas posts since the end of FY1998.

## OTHER ORGANIZATIONS: INSTITUTE OF MEDICINE (IOM)

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### *Mission and goals:*

As a nonprofit organization created outside of the framework of government, IOM provides policy makers, professionals, and the public with evidence-based analysis and guidance to improve health worldwide.

### *Organization and focus:*

IOM was founded through a Congressional charter in 1970 as a component of the National Academies of Science. Like the other organizations of the National Academies, IOM does not receive direct Federal appropriations, but does frequently conduct studies at the request of, and with support from, executive branch agencies. IOM generally conducts studies by selecting a committee of unpaid experts with expertise relevant to the study topic. The committee considers evidence from the available literature and outside experts, and generally produces a consensus report (subject to peer review through an internal process).<sup>233</sup> IOM is generally considered a neutral authority on health policy topics, and its reports are used internationally as well as to inform policy-making in the US

IOM studies focus on specific health topics and USG global health programs, such as the committee to study implementation of the President's Emergency Plan for AIDS Relief (PEPFAR), and the Board on Global Health's study of the US commitment to global health.

### *Budget:*

The majority of IOM studies are requested and sponsored by Federal agencies, often as mandated by legislation, although the private sector, foundations, and state and local governments can also initiate and/or support IOM-initiated studies.<sup>234</sup>

### SNAPSHOT - IOM

**Primary role:** convene experts to offer unbiased, evidence-based advice on complex health policy questions.

#### **Global programming:**

- Research

#### **Mechanisms:**

Research, policy

#### **Areas of focus:**

Global (primarily focused on USG issues).

## OTHER ORGANIZATIONS: CONGRESSIONAL COMMITTEES

### *Missions and goals:*

Several committees in the US House of Representatives and the US Senate play roles in authorizing the activities of, and appropriating the funds for, the USG agencies engaged in global health activities. Members of Congress introduced more than 30 bills addressing at least one aspect of global health in both the 109<sup>th</sup> and 110<sup>th</sup> Congress; particularly key legislation in this period included reauthorization of the President’s Emergency Plan for AIDS Relief.<sup>235</sup>

### *Organization and focus:*

Although many Congressional committees indirectly affect global health programs through oversight of agency function and workforce issues (such as the House Committee on Oversight and Government Reform or the Senate Committee on Government Affairs), the tables below include those committees that directly oversee or fund the operational programs that comprise USG global health engagement.

### SNAPSHOT – CONGRESSIONAL COMMITTEES

**Primary role:** create the legal framework that authorizes and funds USG global programs.

**Global programming:**

- Legislation

**Mechanisms:**

Policy

**Areas of focus:** Global

Significant Relevant Appropriations Subcommittees		
House	Senate	Global Health Focus/Jurisdiction
<a href="#">Labor, HHS, Education</a>	<a href="#">Labor, Health and Human Services, Education, and Related Agencies</a>	Funding for all HHS programs, including CDC, NIH, FDA, and HRSA
<a href="#">Agriculture</a>	<a href="#">Agriculture, Rural Development, Food and Drug Administration, and Related Agencies</a>	Funding for food assistance programs, including P.L. 480/Food for Peace and McGovern-Dole Food for Education, and avian influenza programs
<a href="#">State, Foreign Operations</a>	<a href="#">State, Foreign Operations, and Related Programs</a>	Funding for foreign assistance and administration of international programs through USAID and the State Department
<a href="#">Defense</a>	<a href="#">Defense</a>	Funding for military health programs, including humanitarian aid, HIV/AIDS assistance, and overseas laboratories

<b>Significant Relevant Authorizing Committees</b>		
<b>House</b>	<b>Senate</b>	<b>Global Health Focus/Jurisdiction</b>
<a href="#"><u>Energy and Commerce Subcommittee on Health</u></a>	<a href="#"><u>Health, Education, Labor, and Pensions</u></a>	All HHS programs, including CDC, NIH, and HRSA, all legislation related to global health
<a href="#"><u>Foreign Affairs</u></a>	<a href="#"><u>Foreign Relations</u></a>	All foreign assistance, including global health activities administered through the State Department and USAID (including PEPFAR)
<a href="#"><u>Agriculture</u></a>	<a href="#"><u>Agriculture, Nutrition, and Forestry</u></a>	Food assistance programs and animal health programs
<a href="#"><u>Armed Services</u></a>	<a href="#"><u>Armed Services</u></a>	All programs within the Department of Defense, including humanitarian assistance, military-military HIV/AIDS assistance, and overseas disease surveillance and research

The Congressional Global Health Caucus, founded in 2005, provides a bipartisan forum for briefings and discussions of global health issues under six co-chairs in the House of Representatives.<sup>236</sup>

## OTHER ORGANIZATIONS: THE EXECUTIVE OFFICE OF THE PRESIDENT (EOP)

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### *Missions and goals:*

Since the founding of the United States, presidents have tested a variety of formal and informal mechanisms to secure advice and assistance in overseeing the increasingly complex functions of the U.S. government. Precursor organizations to the contemporary White House advisory and administrative structures ranged from small enclaves of trusted friends to enormous councils consisting of most or all of the Cabinet plus other Federal agency and private sector leaders. In 1939, with Congressional approval, President Roosevelt consolidated six offices and advisory groups into the Executive Office of the President (EOP).<sup>237</sup>

In the intervening seven decades, presidents and Congress have created and dissolved dozens of EOP institutions through executive orders, appropriations acts, and statutes.<sup>238</sup> By 2009, the Obama administration recognized 16 EOP entities, including the White House Office (itself composed of many additional support functions that range from pragmatic scheduling and office management leadership to advisory commissions).<sup>239</sup> Only a single office, the Office of National AIDS Policy, explicitly addresses health issues. However, other EOP institutions play varying significant roles in informing global health policy through analyses, coordination, and funding.

### *Organization and focus:*

The White House Chief of Staff oversees the EOP, coordinating the interactions of its various offices and their directors. Each President enjoys significant flexibility in EOP structure and staff composition within its operating budget, aside from a few statutory and Senate-confirmable positions.<sup>240</sup> Since 1998, the EOP has included at least one technical advisor on international health issues relatively continuously, although the status, focus, and institutional anchor for the position have varied with the political environment and events.

Many EOP institutions affect global health policies, programs, and activities indirectly; those described below figure most prominently in USG global health decision-making. (The EOP Office of the US Trade Representative is described in detail elsewhere in this report.)

### SNAPSHOT – EXECUTIVE OFFICE OF THE PRESIDENT

**Primary role:** to support and advise the US president on all matters of policy, politics, diplomacy and administration and coordination of USG agencies and functions.

#### **Global programming:**

- All communicable, non-communicable and chronic diseases

#### **Mechanisms:**

Policy

**Areas of focus:** Global

#### **Significant dates:**

**1939** – EOP created to provide the president with an entity comprising adequate advisory and administrative support

**1947** – National Security Council established, transferred to the EOP two years later.

**1970** – Office of Management and Budget created from precursor organization.

**1976** – Office of Science and Technology Policy created by statute.

**1993** – President announces the creation of a new Office of National AIDS Policy.

**1998** – Position of special advisor for international health affairs created on National Security Council staff (eliminated in 2001).

*The National Security Council (NSC)* – The National Security Act of 1947 established the NSC to advise the President on integration of all policies (domestic, foreign, and military) related to national security. By statute, the NSC consists of the President, the Vice President, the Secretary of State, and the Secretary of Defense, advised by the Director of National Intelligence and the chairman of the Joint Chiefs of Staff; each President may invite other officials to attend NSC meetings permanently or as appropriate by subject.<sup>241</sup> The Assistant to the President for National Security Affairs, a member of the White House Office staff often referred to as the National Security Advisor, oversees the NSC staff and coordinates the working groups and other high-level and technical committees designed to inform its recommendations.<sup>242</sup> The national security advisor balances organizational and advisory duties; although successive administrations have valued these functions very differently, the complexity of interagency coordination in foreign policy – and the advisor’s role – have grown steadily.<sup>243</sup>

In 1998, the national security advisor created an NSC staff office of international health affairs and a Senior Advisor for International Health with a broad portfolio on emerging diseases and health systems in weak or failed states.<sup>244</sup> The subsequent Bush administration eliminated these institutions immediately upon taking office in 2001,<sup>245</sup> although it later created a policy coordination committee for public health and medical preparedness and a Senior Director for Biodefense to the Homeland Security Council (HSC).<sup>xxxvi</sup> The Obama administration re-established global health as an NSC focus in the context of development, appointing Gayle Smith as Special Assistant to the President and NSC Senior Director for global development, stabilization and humanitarian assistance. It is anticipated that the administration will include additional global health security coordinating and advisory capabilities on the NSC staff, although the precise structure has not been announced.<sup>246</sup>

*Office of Management and Budget (OMB)* – OMB, a Cabinet-level agency with a Senate-confirmable Director, advises the President on USG policy, regulatory, operations, and funding issues, including preparation and administration of the Federal budget.<sup>247</sup> OMB coordinates policy, regulations, and budgets for all USG agencies and programs through staff divisions whose organization mirrors the program areas and functional responsibilities that they oversee, as well as four statutory offices that focus on Federal procurement policy, financial management, regulatory affairs, and information initiatives.<sup>248</sup> Although OMB has not directly developed or implemented global health policy in the past, its staff evaluates program objectives and performance, approves regulations, and recommends funding levels to the President for all USG agencies and organizations. In early 2009, the Obama administration created a new special

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<sup>xxxvi</sup> The Bush administration created the Homeland Security Council (HSC) as a White House office advisory council in October 2001 to serve a parallel function to the NSC – interagency policy coordination and advice – for all areas related to domestic security following the 9/11 terrorist attacks. These included an office of public health and medical preparedness and a Director of Biodefense to serve as a chief advisor on integrating US biodefense, biosecurity, and pandemic preparedness policies, which encompassed the international plans and programs coordinated through the State Department’s Avian Influenza Action Group. The Bush White House appointed Dr. Kenneth Bernard, previously the first special advisor on international health issues to the NSC under President Clinton, to the HSC as the first Special Assistant to the President for Biodefense. In two of its first actions, the Obama administration appointed the Secretary of Homeland Security to the NSC and directed a review of White House structures for homeland security policy coordination and advice, initiating the process of dissolving the HSC. [Sources: [Homeland Security Presidential Directive-1](#) (October 29, 2001); [Presidential Policy Directive-1](#) (February 13, 2009); [Presidential Study Directive-1](#) (February 23, 2009).]

advisor for health policy within OMB, identifying a senior official as a focal point for coordinating USG-wide budgets and policies on global and domestic health issues (with Ezekiel "Zeke" Emanuel as the inaugural appointment).

*Office of National AIDS Policy (ONAP)* – Originally created as the White House focal point for domestic HIV/AIDS policies in 1993, ONAP's involvement in international HIV/AIDS issues expanded as the Clinton administration focused more intently on the global AIDS burden as a matter of national security, culminating in the LIFE (Leadership and Investment in Fighting an Epidemic) Initiative.<sup>249,250</sup> After initial suggestions that ONAP would be disbanded by the incoming George W. Bush administration, the Bush White House elected to maintain the office as part of the EOP.<sup>251</sup> In February 2009, the Obama administration confirmed its intentions of maintaining the office with the appointment of a new ONAP Director, although with the creation of OGAC and development of the PEPFAR framework, the focus of this office has reverted primarily to domestic HIV/AIDS priorities and strategies.<sup>252,253</sup>

*Office of Science and Technology Policy (OSTP)* – In 1976, Congress mandated the creation of OSTP, with a director subject to Senate approval, to advise the President and coordinate national science and technology policies.<sup>254</sup> Although OSTP focuses on research coordination and leadership, evidence-based decision-making, and science, technology, engineering and mathematics resources rather than public health, OSTP's portfolio includes science and technology (S&T) matters related to biodefense and avian and human influenza.<sup>255</sup> The Director of OSTP also oversees and can convene meetings of the National Science and Technology Council (NSTC), a Cabinet-level advisory council comprising the leaders of every Federal agency with any significant science, technology, and engineering capabilities (including the National Institutes of Health).<sup>256</sup> A 1996 report on emerging and re-emerging infectious diseases by an NSTC subcommittee heavily influenced the Clinton administration's subsequent decision to develop a USG policy framework for addressing the global infectious disease burden.<sup>257,258</sup>

Through the statutory appointment of the Director of National Intelligence (DNI) as an advisor to the NSC principals and the DNI's role in advising the President directly, the U.S intelligence community also informs USG global health policies. A 1999 National Intelligence Estimate on the security implications of the global infectious disease burden continues to influence perceptions of global health issues as a matter of national security.<sup>259</sup>

#### ***USG interactions:***

The flexibility of the authority of the White House over EOP functions means that different administrations utilize various formal and informal channels of communication among White House and USG agency decision-makers. The NSC formally represents the interests of its principals, including the White House, as an agency principal within the policy integration process managed by the Office of the Global AIDS Coordinator (OGAC). However, depending on the strength of personal relationships among USG organizations and the immediate policy/political environment, White House officials have interacted more or less directly with OGAC. Similarly, the strength of the relationships between the agencies primarily charged with implementing global health programs (such as the operating divisions of HHS) and the NSC have depended, at least in part, on personal relationships and the staffing of NSC, as well as the general receptiveness of contemporary White House officials to science, technology, and health

advice. However, through the Federal policy oversight, regulatory, management, and budgeting processes, EOP offices – particularly OMB – intersect with every USG agency.

### ***Legislation and Authorities***

Year	Focus	Authority	Purpose(s)
1939	White House	<a href="#">Executive Order 8248</a> (September 8, 1939), subsequently codified in The Reorganization Act of 1939, as amended	Created Executive Office of the President, granting the White House flexible powers to reorganize its units, and established the initial six EOP entities.
1947	White House	<a href="#">National Security Act of 1947</a> (as amended)	Established the National Security Council, defining its statutory functional mandates and members. Reorganization Plan 4 of 1949 moved the NSC to the Executive Office of the President.
1970	White House	Reorganization Plan 2 of 1970	Established the Office of Management and Budget in the Executive Office of the President as a successor to the Bureau of the Budget.
1976	White House	The Presidential Science and Technology Advisory Organization Act of 1976 <a href="#">Public Law 94-282</a>	Specified the functions and structure of a new Office of Science and Technology Policy in the Executive Office of the President to advise the President and coordinate USG science and technology policies.
1993	White House	<a href="#">Executive Order 12881</a> (November 23, 1993)	Established the National Science and Technology Council to coordinate the interagency science and technology policy making process.

# INTERAGENCY COORDINATION: HIV/AIDS

## THE PRESIDENT’S EMERGENCY PLAN FOR AIDS RELIEF (PEPFAR)

### *History*

In his 2003 State of the Union address, President George W. Bush called upon Congress to support a new initiative to fight HIV/AIDS in Africa and the Caribbean.<sup>260</sup> In May 2003, Congress passed the President’s Emergency Plan for AIDS Relief (PEPFAR), authorizing up to \$15 billion over five years to support HIV/AIDS prevention, care and treatment programs in 15 focus countries (Botswana, Côte d’Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda, and Zambia, with Vietnam added subsequently).<sup>261</sup>

This program dramatically expanded existing international HIV/AIDS prevention, treatment and control efforts supported by USAID and CDC. In order to develop and implement a “comprehensive, integrated, five-year strategy to combat HIV/AIDS” internationally, the legislation also created an Office of the Global AIDS Coordinator (OGAC) in the Department of State, an ambassador-level position reporting directly to the Secretary.<sup>262</sup>

The PEPFAR strategy emphasized a rapid scale-up and roll-out of interventions in a limited number of focus countries, as well as bilateral efforts in other countries, and support to the Global Fund to Fight AIDS, Tuberculosis and Malaria. The original PEPFAR plan set specific targets: provide ARV treatment to 2 million people, prevent 7 million new infections and provide care for 10 million patients suffering from AIDS by 2010 (the “2-7-10 goals,”<sup>xxxvii</sup> which OGAC announced had been met by September 2008).<sup>263</sup>

The legislation outlined a specific funding scheme:

- 55 percent of funding for treatment of people with HIV;
- 20 percent of funding for HIV prevention activities, of which 33 percent must be spent on abstinence until marriage programs;
- 15 percent of funding on palliative care of people with HIV/AIDS; and

<sup>xxxvii</sup> The PEPFAR “2-7-10” goals resonated with the contemporary WHO “3 by 5” program, which aimed to distribute antiretroviral treatment to 3 million people in 50 developing countries by the end of 2005 but fell short of that goal. Monitoring and evaluation of PEPFAR results can be contentious, due to the overlap of PEPFAR, other donor, and host country initiatives that all seek credit for successes with their stakeholders.

### SNAPSHOT – PEPFAR

**Launched:** 2003

**Leadership:** Office of the Global AIDS Coordinator, State Department

#### **Implementing agencies:**

- USAID (Office of HIV/AIDS)
- Defense (DOD HIV/AIDS Prevention Program)
- Commerce
- Labor (International Labor Affairs Bureau)
- Peace Corps
- Health and Human Services
  - CDC (Global AIDS Program)
  - HRSA (HIV/AIDS Bureau)
  - NIH (Office of AIDS Research)
  - FDA (Office of International Programs)
  - Office of Global Health Affairs

#### **Coordination mechanisms:**

- Budget oversight
- Policy development
- Implementation management
- Evidence assessment
- Field support
- Technical input

#### **Disease focus:**

Global HIV/AIDS, malaria, and tuberculosis

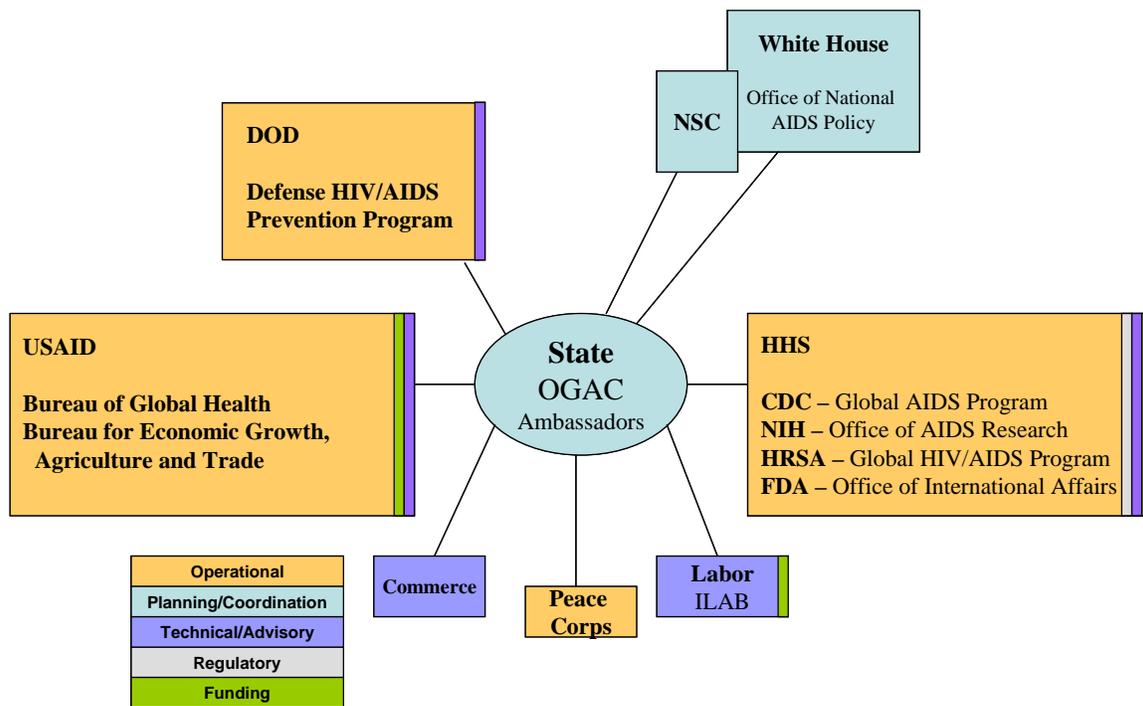
#### **Programmatic focus:**

Prevention, treatment, care, and capacity building

- 10 percent of funding for support of orphans and vulnerable children.

In 2008, Congress reauthorized the program through the "Tom Lantos and Henry J. Hyde United States Global Leadership against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008." The legislation authorized up to \$39 billion for HIV/AIDS, \$4 billion for tuberculosis, and \$5 billion for malaria programs from FY 2009-13; formally extended the geographic scope of PEPFAR beyond Sub-Saharan Africa and the Caribbean; proposed use of framework agreements with recipient countries; endorsed health systems strengthening; and established a Global Malaria Coordinator in USAID. The reauthorization also eliminated most of the funding restrictions that earmarked amounts for specific activities in the original framework, some of the more politically and socially contentious aspects of the original plan.

**Organization and focus**



**PEPFAR Figure 1. PEPFAR integrates the HIV/AIDS activities of implementing agencies through the Office of the Global AIDS Coordinator (OGAC) in the State Department.** Agencies may contribute through a range of mechanisms, from playing a technical/advisory role to international partners to implementing operational programs on the ground through training and other capacity-building efforts.

OGAC provides policy and strategic direction for PEPFAR, and manages and coordinates funding and policy development for all USG-supported HIV/AIDS programs. OGAC performs three distinct roles in the implementation of PEPFAR:

1. Direct oversight and responsibility for programs in the 15 focus countries and for achieving the prevention-treatment-care targets. The office guides and approves all funding decisions and disbursements and monitors program performance. The Coordinator also fulfills mandated reporting requirements, and conducts outreach to the public, Congress, and other stakeholders.
2. Funding and direct oversight of bilateral HIV/AIDS programs in other, non-focus PEPFAR countries through missions or regional offices, although the management of these programs remains largely with USAID and CDC, the implementing agencies.
3. Management and disbursement of the USG contribution to the Global Fund to Fight AIDS, Tuberculosis and Malaria.

The OGAC office within State comprises only a small permanent staff, with technical expertise supplied by USG personnel detailed from other agencies. The major implementing agencies divide the tasks according to their primary missions and capabilities:

*USAID:* The development agency primarily focuses on community-level, operational PEPFAR plans. Agency contractors and subcontractors support prevention programs, including condom promotion. USAID contractors also provide the majority of basic health services, including HIV testing in clinical and non-clinical settings and support for community and faith-based organizations that provide home-based care for people infected with HIV/AIDS. A significant portion of USAID work includes scale-up of interventions to prevent mother-to-child transmission (PMTCT) and systems to support anti-retroviral drug delivery.

*CDC:* With core competencies in epidemiology and laboratory sciences, CDC supports PEPFAR clinical interventions and infrastructure improvements. In most countries, this includes support to host country governments to improve injection and blood safety as well as building laboratory diagnostic capacities. In countries where CDC is the primary US presence, CDC may take the lead in strengthening public health infrastructure and clinical capacities, training healthcare workers to provide anti-retroviral therapy regimens and reducing mother-to-child transmission. CDC is primarily responsible for working with the host-country governments and multilateral donors to improve disease surveillance.

*DOD:* The Defense HIV/AIDS Prevention Program works in several PEPFAR focus countries to improve HIV/AIDS prevention, testing and treatment by building screening and treatment capacity, primarily through military-to-military assistance.

*Labor:* Labor's International Labor Affairs Bureau supports and provides technical assistance to workplace HIV/AIDS prevention and education programs in a number of focus countries. The agency supports the International HIV/AIDS Workplace Education Program that works with business leaders, government officials and labor leaders to increase awareness about HIV and AIDS and minimize discrimination against workers infected with the disease.

*Peace Corps:* The Peace Corps provides additional volunteers, through PEPFAR resources, in focus countries to work with health centers and communities on HIV/AIDS prevention and care.

*US Embassies:* The chiefs of mission coordinate the activities of the PEPFAR agencies on the ground through country teams. In some focus countries, US embassies support HIV/AIDS programming by providing small grants to community-based organizations or individuals based on proposals.

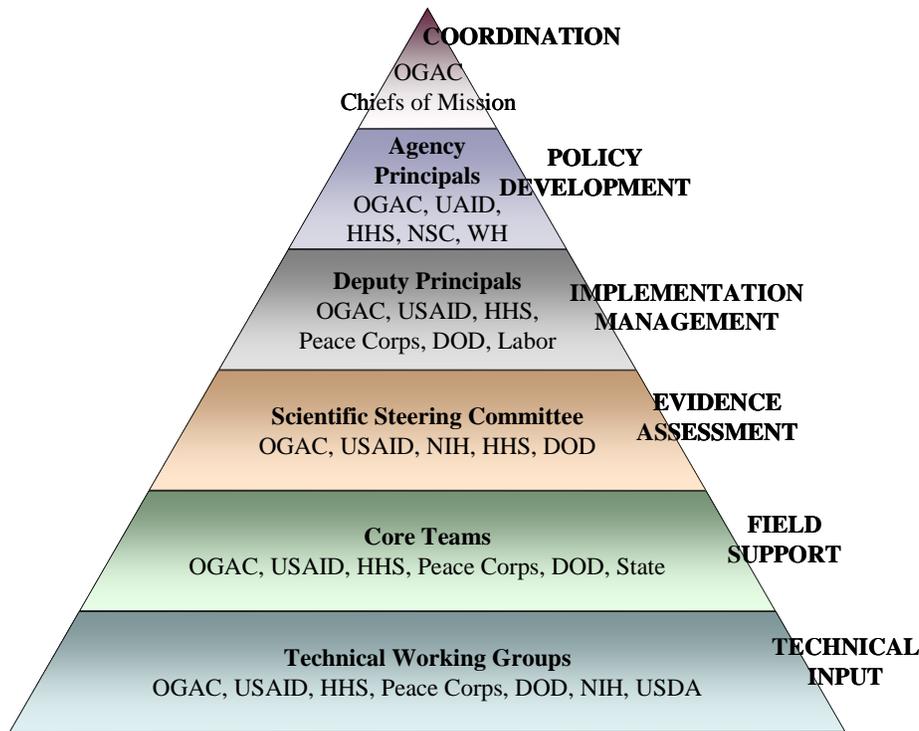
*FDA:* FDA provides quality assurance of generic anti-retroviral drugs eligible for use in PEPFAR-supported programs through testing and validation of international pharmaceutical manufacturers' products and practices, including via expedited review of medications still under patent protection in the US for purchase and use by PEPFAR programs abroad.

*NIH:* NIH plans its own HIV/AIDS research portfolio and executes its budget through the Labor-HHS appropriation, rather than through transfers from OGAC's global health account. The National Institute for Allergy and Infectious Diseases (NIAID) and its divisions, including the Division of Acquired Immunodeficiency Syndrome (DAIDS), accounted for an estimated US \$1.271 billion HIV/AIDS research portfolio in FY2008.<sup>264</sup> NIAID supports intramural and extramural research to increase knowledge of the pathogenesis and transmission of HIV, facilitate development of new therapies for HIV/AIDS, and promote vaccine development and other prevention strategies, including through basic and clinical research collaborations in developing nations.

*HRSA:* HRSA's Global HIV/AIDS Program facilitates rapid roll-out of ARV and health services delivery, training and technical assistance, nursing leadership development, and promotion of the continuum of palliative care. HRSA supports education and training in more than 25 countries through awards to academic and non-governmental organizations that implement programs locally. HRSA also assists with quality improvement models, as well as supplying patient, provider, and population-level software to PEPFAR countries to improve the quality of care.

OGAC manages this complex interagency coordination task through a series of interagency working groups, committees, and task forces at various operational levels.

In the field, the day-to-day implementation and management of programs is conducted by staff from the relevant USG technical/implementing agencies (primarily USAID and CDC). In any PEPFAR focus country, the agency personnel working on HIV/AIDS programs belong to a single team, whose designated leader meets routinely with the ambassador or chief of mission.<sup>265</sup> Ambassadors serve as country administrators of PEPFAR programs. All USG in-country implementing partners collaboratively develop a program strategy at the beginning of the fiscal year in the "Country Operational Plan."



**PEPFAR Figure 2. The Office of the Global AIDS Coordinator at the State Department utilizes a system of coordinating and advisory groups to manage policy development, monitor progress, implement programs, and support field activities.** This represents the network of advisory and management structures used by OGAC to coordinate policy and planning among PEPFAR agencies, address operations and implementation challenges, secure appropriate support to and information from the field, and obtain scientific and technical input for decision-making and program evaluation. [Modeled after original presentation by Moloney-Kitts (2005) in *PEPFAR Implementation: Progress and Promise*, National Academies Press: Washington, DC, 2007, p. 72.]

Before each fiscal year, the USG agencies meet with partner and host country governments to plan and budget activities. All PEPFAR-supported programs are implemented through partner organizations who receive awards from the USG implementing agencies to perform specific project activities. Often these awardees will sub-contract funding to smaller, community-based organizations to execute project activities. At the initiation of PEPFAR, OGAC identified three mechanisms designed to disburse funding to focus country programs as rapidly as possible while accommodating partners' varying capabilities for resource management:

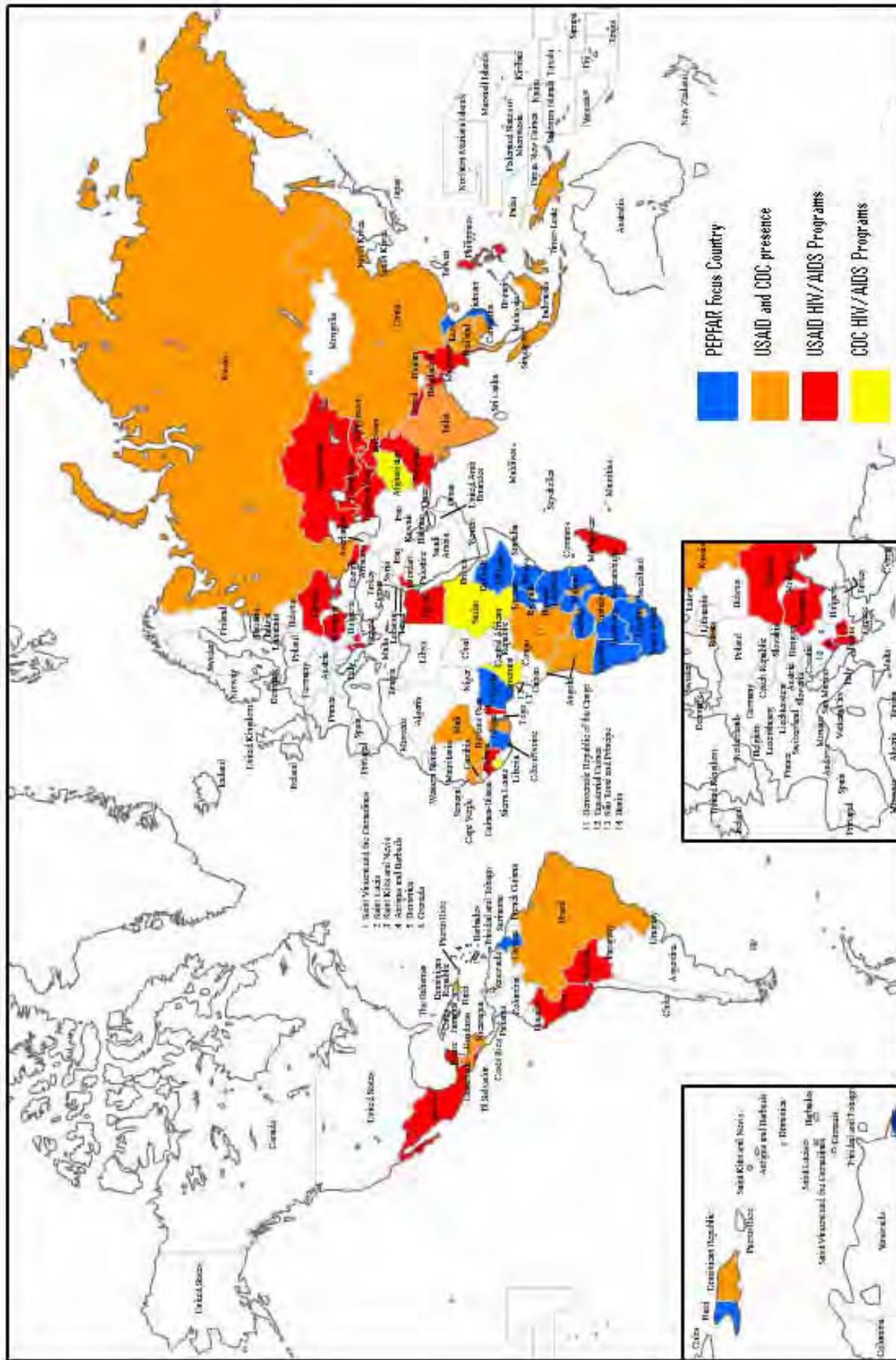
- a) **Country Managed, Country Funded Programs:** funded and managed by the USG team in the focus country. Initially, these programs involved direct agreements between the USG and host country governments. Over the life of PEPFAR, however, they have increasingly included locally designed or procurement contracts for NGOs.
- b) **Centrally Managed, Country Funded Programs:** The contracts are often pre-PEPFAR agreements between the USG agencies and international NGOs or new projects designed centrally to meet the perceived needs of the focus country. The central agencies provide minimal funding to these projects for management and all programmatic funding comes

from in-country offices. In these cases, the focus country team retains control over the budget and activities conducted by the partners without additional management burden.

- c) **Centrally Managed, Centrally Funded Programs:** These programs were originally designed by OGAC to initiate rapid scale-up of prevention, care and treatment projects regardless of recipient nation capacity. Since these partners are centrally funded, their work does not count against the budgets of focus countries, although they are expected to report to both the in-country and central offices.<sup>266</sup>

In FY2008, PEPFAR supported HIV/AIDS programs in 65 additional countries (beyond the 15 focus nations) in Africa, Asia, Latin America and the Caribbean, and the Middle East. In some cases, non-focus countries may receive a relatively large amount of support in absolute sums; for example, PEPFAR approved almost \$30 million in funding for India in FY 2008 – more than for the small focus country of Guyana, but less than other PEPFAR focus countries.<sup>267</sup>

**PEPFAR Figure 3 (following page). PEPFAR supports bilateral HIV/AIDS programs in nations beyond the 15 focus nations.** The map below shows the nations that received PEPFAR assistance in FY2008, including: focus nations (in blue), the countries in which CDC implements bilateral HIV/AIDS assistance programs (in yellow), the countries in which USAID implements bilateral HIV/AIDS assistance programs (in red), and non-focus countries in which both CDC and USAID support bilateral HIV/AIDS programs. Fourteen of the 15 focus countries (in Sub-Saharan Africa and the Caribbean) were designated in the original 2003 legislation; the president added Vietnam in mid-2004 under authority conferred for the selection of one additional nation, as codified at PEPFAR's reauthorization in 2008. Some non-focus nations, such as Cambodia, have received funding under PEPFAR every year since its inception. [Sources: [Fiscal Year 2008: PEPFAR Operational Plan](#), June 2008; About PEPFAR: [PEPFAR Countries](#).]



**Legislation and authorities**

<b>Year</b>	<b>Focus</b>	<b>Authority</b>	<b>Purpose(s)</b>
2003	Global health (HIV/AIDS)	<a href="#">Public Law 108-25:</a> United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003	Required a comprehensive, integrated 5-year strategy for a coordinated USG response to global HIV/AIDS; established Office of the Global AIDS Coordinator in the State Dept.; amended the Foreign Assistance Act of 1961 to define eligibility and formulae for USG HIV/AIDS assistance; mandated goals, benchmarks, and metrics for program evaluation; authorized up to \$15 billion from FY2004-8, primarily in 15 focus countries.
2008	Global health (HIV/AIDS)	<a href="#">Public Law 110-293:</a> The Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008	Authorized an increase of up to \$48 billion over five years (FY2009-2013) to continue PEPFAR programs; extended the geographic and programmatic scope of HIV/AIDS, malaria, and tuberculosis control and prevention strategies; proposed use of framework agreements with recipient countries; removed some spending requirements on prevention efforts; endorsed health systems strengthening; and established a Global Malaria Coordinator in USAID.

## INTERAGENCY COORDINATION: MALARIA PRESIDENT’S MALARIA INITIATIVE (PMI)

### *History*

Malaria remains one of the leading causes of death in tropical or semi-tropical developing nations, causing up to 1 million deaths each year (primarily in Sub-Saharan Africa). Despite the partial withdrawal of donor support that followed the failed global malaria eradication campaign of the 1960’s, USG agencies – primarily USAID and CDC – continued to develop bilateral assistance programs to prevent or control malaria in the most vulnerable populations. These included promoting child survival and health through low-tech and reliable interventions such as insecticide-treated bed nets, indoor residual spraying, and treatment of children and pregnant women.

Following on the successes of the PEPFAR program, in June 2005 President Bush announced that the US government would initiate a five-year, \$1.2 billion dollar strategy to halve malaria-related deaths in 15 focus countries. Like PEPFAR, PMI emphasizes rapid scaling-up and rolling out of interventions in a fixed number of focus countries through mechanisms that include public-private partnerships.

### *Organization and focus*

PMI constitutes an interagency partnership to integrate ongoing prevention, care, and treatment programs and coordinate expanded efforts with two main contributors: USAID, which is the Federal lead agency for the initiative and supplies financial support to partner organizations, and CDC, which serves as the technical/ implementing partner.

The program is overseen by USAID’s PMI Coordinator with input from an Interagency Steering Group that includes USAID, CDC, State, Defense, the National Security Council, and the Office of Management and Budget.<sup>268</sup> The PEPFAR reauthorizing legislation passed in 2008 required that a Global Malaria Coordinator be created in USAID, and authorized a specific funding level for malaria activities.<sup>269</sup>

Together, PMI and the Interagency Steering Group selected the 15 target countries based on the malaria disease burden; consistency of national malaria control policies with WHO-accepted standards; capacity to implement policies; willingness to partner with the US, and national

### SNAPSHOT – PMI

**Launched:** 2005

**Leadership:** PMI  
Coordinator/Global Malaria  
Coordinator in USAID

**Implementing agencies:**

- USAID
- CDC
- Advisory steering group: State, Defense, National Security Council, Office of Management and Budget

**Coordination mechanisms:**

- Policy development
- Evidence assessment
- Technical input
- Budget transfers

**Disease focus:**  
Malaria

**Programmatic focus:**  
Scaling up proven  
interventions in each target  
country to interrupt malaria  
transmission and reduce  
related deaths by 50 percent.

involvement of other international donors and partners in malaria control.<sup>270</sup> PMI plans to introduce its programs in the fifteen focus countries over three years, building up to a consistent annual budget of approximately \$300 million.<sup>271</sup>

Year	Focus Countries	Budget
FY2006	Angola, Tanzania, Uganda	\$30 million
FY2007	Add Malawi, Mozambique, Rwanda, Senegal	\$135 million
FY2008	Add Benin, Ethiopia (Oromia region), Ghana, Kenya, Liberia, Madagascar, Mali, and Zambia	\$300 million

The program coordinates closely with partners from national malaria control programs and international non-governmental and multilateral organizations (including UNICEF, WHO, and the Global Fund to Fight AIDS, Tuberculosis and Malaria), to support delivery of interventions in the field.

### *Legislation and authorities*

Year	Focus	Authority	Purpose(s)
2003	Global health (HIV/AIDS)	<a href="#">Public Law 108-25:</a> United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003	Required a comprehensive, integrated 5-year strategy for a coordinated USG response to global HIV/AIDS; established Office of the Global AIDS Coordinator in the State Dept.; amended the Foreign Assistance Act of 1961 to define eligibility and formulae for USG HIV/AIDS assistance; mandated goals, benchmarks, and metrics for program evaluation; authorized up to \$15 billion from FY2004-8, primarily in 15 focus countries.
2008	Global health (HIV/AIDS)	<a href="#">Public Law 110-293:</a> The Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008	Authorized an increase of up to \$48 billion over five years (FY2009-2013) to continue PEPFAR programs; extended the geographic and programmatic scope of HIV/AIDS, malaria, and tuberculosis control and prevention strategies; proposed use of framework agreements with recipient countries; removed some spending requirements on prevention efforts; endorsed health systems strengthening; and established a Global Malaria Coordinator in USAID.

## INTERAGENCY COORDINATION: NEGLECTED TROPICAL DISEASES PRESIDENT’S NEGLECTED TROPICAL DISEASE INITIATIVE (NTD)

### *Mission and roles*

Approximately one billion people, clustered in the poorest developing nations, suffer from one or more neglected tropical diseases. Seven of these diseases<sup>xxxviii</sup> can be controlled and even eliminated through targeted mass drug administration using a combination of six highly effective anti-helminthic medicines. Each medicine has an excellent safety record that has accrued from the use of millions of doses. Most of these diseases either blind, deform, or debilitate their victims. Collaterally, they can reduce school enrollment, diminished childhood growth and cognitive development, and impair economic productivity in adults.<sup>272</sup>

On February 20<sup>th</sup> 2008, President Bush announced a 5-year, \$350 million initiative to control seven neglected tropical diseases by integrating mass drug administration. Leveraging existing programs already within USAID, the initiative begins in FY 2009.<sup>273</sup>

### *Organization and focus*

The President’s Neglected Tropical Disease (NTD) Initiative consists of a plan to integrate NTD-focused treatment programs currently administered by USAID, while taking advantage of logistical “piggy-backing” opportunities offered by PEPFAR and the President’s Malaria Initiative. Building on past success at increasing the number of patients receiving treatment, the NTD initiative plans to expand activities into 30 focus countries by 2013, with a five-year cumulative budget of \$350 million dollars. NTD aims to deliver 300 million cumulative treatments over the lifespan of the initiative.

Since 2006, the Bureau for Global Health at USAID has implemented a \$15 million annual earmark for a mass drug administration program targeted at treating seven NTDs. USAID awarded program management to the firm RTI through a competitive grant process. The pilot project began in five countries: Burkina Faso, Ghana, Niger, Mali and Uganda and subsequently added Haiti, Sierra Leone, and Southern Sudan in early 2008 and later Nepal and Bangladesh. The initiative has pledged to increase focus countries to 30 by 2013, but the final country list has yet to be decided. The NTD working group, which consists of officials from the pharmaceutical

### SNAPSHOT – NTD

**Launched:** 2008

**Leadership:** USAID

**Implementing agencies:**

- USAID
- CDC

**Coordination mechanisms:**

- Policy development
- Evidence assessment
- Technical input
- Budget transfers

**Disease focus:**

Seven parasitic diseases common to the world’s poorest regions

**Programmatic focus:**

Integrating treatment programs that address the seven target diseases to increase efficiency of drug and service delivery

<sup>xxxviii</sup> The NTD initiative addresses seven diseases caused by parasitic infections: lymphatic filariasis (elephantiasis); schistosomiasis (snail fever); trachoma (eye infection); onchocerciasis (river blindness); and three soil-transmitted helminthes (hookworm, roundworm, and whipworm).

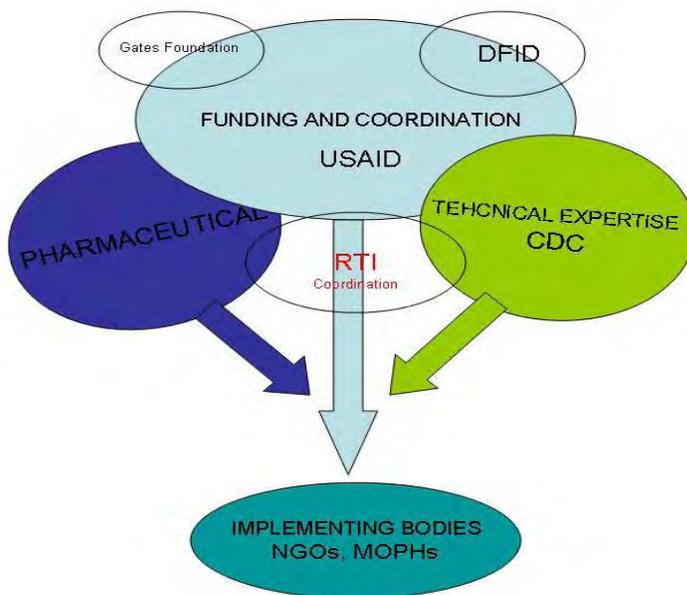
industry, USAID, CDC and philanthropic organizations like the Bill and Melinda Gates Foundation, has established a set of criteria to decide which countries, and by extension which contractors, will receive funding.<sup>274</sup>

**USG interactions**

USAID functions as the primary funding organization and coordinator. It awards competitive grants to organizations at the country level and serves as point of contact for other USG partners. CDC serves as key technical assistance partner and Peace Corps plays a role in grass roots implementation of the initiative.

USAID, CDC and WHO form the core global stakeholders group charged with setting technical and operational guidance as well as facilitating the participation of ministries of health, pharmaceutical partners, NGO partners and the NTD scientific community. The first meeting was held on October 20-21, 2008, in Washington DC. It was announced that most drugs needed to treat the seven NTDs have been donated in some measure by pharmaceutical companies, including GlaxoSmithKline, Johnson & Johnson, Merck & Co., Inc., and Pfizer Inc. These donations are valued at hundreds of millions of dollars each year, and may reduce the estimated cost for other program components to between 40 cents and slightly more than one dollar per person, per year, in Sub-Saharan Africa.

The strength of the plan is its capacity to leverage existing infrastructure and plans while drawing on comparative advantages in both the public and private sector. Current working plans incorporate complementarities with the current PEPFAR initiative, micronutrient and feeding projects alongside maternal and child health programs.<sup>275</sup>



**Legislation and authorities**

<b>Year</b>	<b>Focus</b>	<b>Authority</b>	<b>Purpose(s)</b>
2006	Neglected	FY2006 appropriations bill P. L. 109-	To fund Mass Drug Administration to five
	Tropical Disease	102, the Foreign Operations, Export Financing, and Related Programs Appropriations Act FY2006, section 593.	focus countries by USAID's Office of Infectious diseases.
2008	Neglected	Presidential Announcement	President Bush calls for \$350 million dollars
	Tropical Disease		to apportioned over 5 years; starting in FY 2009. This new initiative scales up existing activities within USAID.

**Budget (estimated)**

The NTD project has no specific appropriation of its own, but draws from funding appropriated through existing USAID accounts.

<b>Year</b>	<b>2009</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>	<b>Total</b>
<b>Funding</b>	\$25M	\$70M	\$80M	\$85M	\$90M	\$350M

## INTERAGENCY COORDINATION: AVIAN/HUMAN INFLUENZA AVIAN INFLUENZA ACTION GROUP (AIAG)

### *History*

In 1997, farmers and officials began to report outbreaks of a new and virulent avian influenza strain in poultry on farms and in markets in Hong Kong. Testing identified a novel highly pathogenic avian influenza virus, called H5N1. By December 1997, the government of Hong Kong commenced the aggressive (and at least temporarily successful) step of depopulating all poultry farms and markets, but not before the disease had spread to 18 people, killing six.<sup>276</sup>

Outbreaks of highly pathogenic H5N1 avian influenza appeared sporadically throughout East and Southeast Asia starting again in 2003. Occasional human cases of H5N1 influenza punctuated the periodic H5N1 poultry outbreaks in China, Indonesia, Thailand, and Vietnam.<sup>277</sup> Outbreaks in wild and domestic birds would be detected first in Central Asia, then Eastern Europe, and Western Europe by the fall of 2005.<sup>278</sup> In some countries, humans acted as sentinels for the avian virus, with human deaths preceding detection (or at least announcement) of cases in birds. As of April 8, 2009, WHO reported that 417 human cases had been identified since the beginning of the epidemic, with 257 deaths.<sup>279</sup>

The human impact of the epidemic in absolute terms remains overshadowed by concerns that H5N1 influenza might undergo genetic changes that would allow easy transmission between humans, triggering a pandemic like the 1918 “Spanish flu” outbreak. The 1918 pandemic infected an estimated one-third of the world’s population in a matter of months; recent estimates suggest that 50-100 million people died globally, affecting developing nations most harshly.<sup>280</sup>

The US National Strategy for Pandemic Influenza, published by the Homeland Security Council in 2005, called for efforts to build “host nation laboratory capacity and diagnostic reagents in affected regions and domestically, to provide rapid confirmation of cases in animals or humans,” and to contain outbreaks before they reach the US<sup>281</sup> In May 2006, the State Department announced creation of a new Avian Influenza Action Group to coordinate international USG avian influenza and pandemic preparedness activities.<sup>282</sup>

### SNAPSHOT – AIAG

**Launched:** 2006

**Leadership:** Senior Coordinator for AIAG, State Department

#### **Implementing agencies:**

- USAID (Avian and Pandemic Influenza Response Unit)
- Health and Human Services
  - CDC (Influenza Division, COGH, Influenza Coordination Unit)
  - NIH (National Institute of Allergy and Infectious Diseases)
  - Office of Global Health Affairs
  - Influenza Coordinating
- USDA (APHIS)
- Defense (GEIS, regional commands)

#### **Coordination mechanisms:**

- Policy development
- Evidence assessment
- Technical input

#### **Disease focus:**

Avian influenza and pandemic preparedness

#### **Programmatic focus:**

Increasing capacity and political will of international partners to detect and contain potentially pandemic influenza outbreaks before transnational spread occurs, or to mitigate the impacts of a pandemic if necessary.

### *Organization and focus*

At the launch of AIAG, the State Department established an office headed by a senior coordinator/Special Representative for Avian and Pandemic Influenza, reporting directly to the Under Secretary for Democracy and Global Affairs. Under the Bush administration, this group reported to the Homeland Security Council. Building on the OGAC model, during the Bush administration AIAG convened a weekly meeting of deputy principals to help implement programs and discuss management strategies, and a monthly meeting at the assistant secretary level. Similarly, the AIAG has an extremely small core staff and operating budget, relying on technical experts detailed from other Federal agencies. Unlike the OGAC, the AIAG has no control over budgets – its main coordination mechanism is to facilitate communications and foster development of shared strategies in key countries.

In February 2009, an internal reorganization moved AIAG into the Office of International Health and Biodefense (IHB), within the Bureau of Oceans and International Environmental and Scientific Affairs, effectively reducing its status in the State Department hierarchy. The Obama administration had not released any public comment on this change, the nearly simultaneous appointment of a new Special Representative, or whether the re-organization will substantially affect interagency coordination of USG international avian and human influenza programs at the time of this report's publication. Each implementing agency has played a specific role, coordinated through the National Strategy and the AIAG:

*USAID* – USAID primarily addresses community level risk and preparedness, supporting programs in countries affected by (or at high risk for) AI outbreaks through its field missions and regional platforms, including awards to local and international NGOs. Activities include public outreach and education and supporting community-based surveillance for poultry outbreaks. USAID has also built a stockpile of non-pharmaceutical commodities for use in international surveillance, outbreak investigation, and emergency outbreak response and containment.<sup>283</sup>

*DOD* – In addition to the influenza surveillance activities supported by DOD's five field laboratories and GEIS, the regional combatant commands – particularly PACOM, the Pacific Command – have facilitated international civil-military planning conferences and supported military-to-military capacity building.

*USDA* – USDA works through bilateral training programs as well as through multilateral organizations (such as the OIE, the French acronym of the World Organization for Animal Health) to build veterinary disease surveillance and response capabilities.

*CDC* – In addition to analyzing 7,000-8,000 international influenza specimens annually through its WHO Collaborating Center on Influenza, the Influenza Division supported WHO National Influenza Centers in 29 countries and had stationed more than 20 influenza consultants in partner nations as of May 2007. Representatives of the Influenza Division, the Influenza Coordinating Unit in CCID (and its counterpart in HHS), and the Global Disease Detection System all intersect with the AIAG through a network of detailed personnel and consultative working groups.

HHS – The Office of Global Health Affairs represents HHS-wide international health policy coordination and planning, in consultation with the Assistant Secretary for Preparedness and Response (ASPR) on pandemic preparedness issues.

### *Legislation and authorities*

Year	Focus	Authority	Purpose(s)
2005	Influenza	Public Law 109-13 The Emergency Supplemental Appropriations Act for Defense, the Global War on Terror, and Tsunami Relief	Provided \$25 million to USAID for programs to control the global spread of avian flu, and stipulated that \$15 million of it be transferred to CDC.
2005	Influenza	<a href="#"><i>National Strategy for Pandemic Influenza</i></a>	Delineated roles and responsibilities of Federal government in strengthening preparedness for pandemic influenza.
2006	Influenza	<a href="#"><i>Public Law 109-417</i></a> Pandemic and All-Hazards Preparedness Act	Establishes roles and responsibilities of HHS in domestic pandemic preparedness and lays out several areas for international leadership and capacity-building in avian-human influenza.
2006	Influenza	<a href="#"><i>Public Law 109-234</i></a> Emergency Supplemental Appropriations Act for Defense, the Global War on Terror, and Hurricane Recovery, 2006	Provided \$30 million for global disease control to USAID.

Much of the funding for USG international avian and human influenza preparedness and capacity building activities has to date derived from emergency supplemental appropriations in FY2005 and FY 2006 (with two-year or no-year flexibility to allocate the funds), totaling \$55 million for USAID programs, with \$15 million marked for transfer to CDC for global influenza activities.

Following the most recent USG pledge of \$320 million in international assistance at the Sixth International Ministerial Conference on Avian and Pandemic Influenza in October 2008, AIAG placed the cumulative USG commitment to international avian influenza control and pandemic preparedness at \$949 million, including the following health programs:

- \$51 million – bilateral cooperative agreements with National Influenza Centers and other laboratories in 39 countries;
- \$128 million – regional programs, including CDC’s Global Disease Detection sites; and
- \$102 million – international organizations, including \$42 million to WHO headquarters and regional offices for capacity building and \$10 million to build human vaccine production capacity in developing nations.

The remainder was designated for non-pharmaceutical supplies (such as USAID’s caches of protective equipment), unspecified technical and humanitarian assistance, animal surveillance, and global communications and outreach.<sup>284</sup>

## BUDGETS FOR US GOVERNMENT GLOBAL HEALTH PROGRAMS

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In the past two decades, the implication that disease burdens might further undermine already fragile states, concerns about domestic vulnerability to emerging infections, and growing awareness of the impact of HIV/AIDS and other diseases in the developing world prompted a renewed focus on the intersection of health, security, and society. US policymakers created dozens of global health initiatives, and appropriated previously unprecedented sums to fund them.

Between FY2004 and FY 2008, the annual USG global health budget more than doubled. The collection of US government programs aimed at promoting global health, especially in low- and middle-income countries where health status is often poor and the ability of national health systems to provide essential services weak, grew concomitantly in complexity and size. This rapid expansion of the US global public health policy portfolio also resulted in a proliferation of new programs laid over a patchwork of old ones, with responsibility, technical expertise, and funding fragmented among numerous agencies.

### *Budgets for global health programs*

Using the definitions described in the introduction to this report, the table below represents an overview of all USG budgets for global health programs by agency and account, including emergency supplemental appropriations (which funded international programs in avian influenza and pandemic preparedness during FY2005-6) as noted.

Account	Agency	SF	Budget line	2004	2005	2006	2007	2008
RDT&E	Air Force	051		9115	0	0	0	0
RDT&E	Army	051		76698	75598	77125	76687	105866
DHP	DoD	051	Avian flu supplemental			40000	40000	0
DHP	DoD	051				1586	3842	18150
RDT&E	DoD	051			9500	7400	8900	2500
MCC	MCC	151	Water				38827	496190
MCC	MCC	151	Health				4436	134189
Peace Corps	Peace Corps	151	Direct Volunteer Operations	48835	48831	52736	50688	55494
GHCS (GHAI)	State	151		488000	1374000	1777000	2869000	4116455
GHCS (GFATM)	State	151		0	0	198000	378000	545545
FMF	State	152		2000	2000	2000	2000	992
CIO	State	153		223000	243000	238956	253452	258070
GFATM	USAID	151		398000	248000	248000	248000	0
GHCS (CSH)	USAID	151		1425000	1562400	1435902	1642508	1799396
DA	USAID	151				8789	8589	9600
DA	USAID	151	Water		81547	35398	42973	109693
AEEB/FSA	USAID	151		87600	87400	70603	53023	54865
AEEB/FSA/ACI	USAID	151	Water		33756	5659	3157	6030
ESF	USAID	152		128800	120400	136729	122972	246839
ESF	USAID	152	Water		54410	321758	61623	118809
IO&P	USAID	151	UNICEF	119292	124000	125730	125730	127955
"	USAID	151	UNFPA					
P.L. 480 Title II	USAID	151	Non-emergency	10000	10000	172781	148449	120309
EPM	EPA	304	International	20036	25279	23466	20710	19222
McGovern-Dole Food for Education	USDA	151		50000	87000	99000	98000	99000
P.L. 480 Title I	USDA	351		95000	31000	44000	16000	0
S&E	APHIS	352	International	99567	72133	66802	61619	39369
OHA	DHS	453	OHA/OIA					250
S&E	DOL	505	HIV/AIDS Int'l	10000	2000	0	0	0
GDM	HHS	551	Global Health	9000	9000	10000	10000	9610
DCR&T	CDC	552	Global HIV/AIDS	266864	123830	122560	120985	118863
"	CDC	552	Global HIV/AIDS Research	9000	14000	0	0	0
"	CDC	552	Global Health -- Immunizations	137903	144386	144282	142338	139851
"	CDC	552	Global Health -- Disease Detection	11609	21426	32443	32004	31445
"	CDC	552	Global Health -- Malaria	9186	9108	8975	8851	8696
"	CDC	552	Global Health -- Other	2403	3403	71364	3319	3516

NIH	NIH	552	HIV/AIDS Int'l	317000	370000	373000	362000	363628
GFATM	NIH	552		149000	99000	99000	99000	294759
NIH	NIH	552	Malaria	89000	104000	98000	104000	106000
NIH	NIH/FIC	552		66344	66632	66378	66378	66912
SUBTOTAL HEALTH				4358252	5257040	6215422	7328060	9628068

### ***Humanitarian assistance and emergency relief***

USG humanitarian assistance efforts comprise a range of activities; no specific USG-wide definition distinguishes humanitarian assistance efforts from more routine development programs aside from context. DOD, in particular, often executes programs classed as humanitarian activities that promote health capacity-building or provide basic health services to underserved populations in low- and middle-income countries within the context of training or security objectives, but not necessarily in response to complex emergencies. Because humanitarian assistance efforts often – but not always – encompass efforts to protect public health, we analyzed USG funding for humanitarian assistance and emergency relief but did not include these budgets in the summary of global health spending above.

Humanitarian assistance and emergency relief following international disasters is one of the oldest – and least controversial, despite its frequently high and unpredictable cost – forms of international assistance. The USG agencies that routinely administer funds and programs for humanitarian assistance include:

- DOD, through its Overseas Humanitarian, Disaster and Civic Aid Appropriation (OHDACA) to support locally driven civic and humanitarian projects in the field as well as international disaster response;
- USAID, through financial support triggered by the Office of Foreign Disaster Assistance in response to an international disaster or through the use of emergency food assistance under the Public Law 480 Title II program; and
- State, through two different programs aimed at supporting migrants and refugees.

During the response to an international crisis that mobilizes a request for financial and other support through the local US mission, USG agencies rely on a defined system for coordinating responses, with State acting as the lead agency and the USAID Office of Foreign Disaster Assistance coordinating the various stakeholders. However, in the day-to-day conduct of “low-level” humanitarian assistance projects – such as DOD-sponsored medical exercises that provide direct health services in rural areas – coordination frequently relies on informal consultations and personal relationships at the country or regional level. Efforts to integrate programs more fully, such as the Conceptual Framework to combine country-level PEPFAR and food assistance activities, often confront coordination problems caused by completely separate delivery systems.

The following is an overview of USG appropriations for humanitarian assistance and disaster relief by agency.<sup>285</sup> USG humanitarian assistance budgets are shown below for purposes of comparison, but do not necessarily comprise global health activities and do not count toward global health budget totals.

<b>USG Humanitarian Assistance Budgets</b>					
	<b>FY 2004 Actual</b>	<b>FY 2005 Actual</b>	<b>FY 2006 Actual</b>	<b>FY 2007 Actual</b>	<b>FY 2008 Actual</b>
Total (\$US thousands)					
OHDACA (DOD)	94000	176000	121000	63000	102000
Migration and Refugee Assistance (State)	782000	884000	859000	964000	1053000
Emergency Refugee Migration Assistance (State)	30000	30000	30000	110000	45000
International Disaster Assistance (USAID)	544000	674000	579000	526000	429000
P.L. 480 Title II food aid-emergency (USAID)	1166000	1417000	1316219	1546551	1439691
<b>Total (\$US thousands)</b>	<b>2616000</b>	<b>3181000</b>	<b>2905219</b>	<b>3209551</b>	<b>3068691</b>

## CONCLUSIONS

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The commitment of billions of dollars and vast government resources to detect, treat, prevent, and study specific diseases abroad does not guarantee that the US will realize its investment in global health. US global health programs, while more ambitious in scope than any time in history, face many challenges. Based on this comprehensive review of official agency documents, the literature, and interviews, several key challenges have been identified as follows:

*Distribution of technical expertise, budgetary oversight, and policy authority among different agencies within programs* – Responsibility for planning and implementing the hugely amplified US global health mission remains spread among various agencies, with different interagency coordinating and oversight bodies for specific disease strategies. In many of the global health programs and projects executed through interagency agreements, the implementing partner houses extensive technical expertise that is not integrated efficiently into the planning or policy development phases. In other words, the experts that have to accomplish the task may have little or no “bottom-up” influence on the development of the policy framework that guides them, or the budget that supports the work.

*Intra- and interagency coordination mechanisms* – USG global health programs offer abundant examples of programs assigned strong mandates for program coordination, but given weak or no authority over budgets, personnel, and policy approval to assure compliance by component programs. Frequently, coordination often depends on the personal relationships of the principals involved; negotiations between divisions or agencies that share responsibility for programs may be productive, acrimonious, or even absent depending on the personalities. Certainly, personality conflicts are not unique to global health programming, but in many cases, the ability of such issues to affect programming stems directly from the weak oversight or coordinating mechanisms built into the system. Even where personality conflicts present no barriers, the lack of systematic interagency and intra-agency coordinating mechanisms, especially when field offices are involved, can create unintentional program redundancies and conflicts.

The Global AIDS Coordinator enjoys many advantages not conferred upon other formal or information interagency coordinating arrangements. First and foremost is the ability to control and coordinate budgets and priority-setting. The hierarchy itself is unambiguous, at least at the OGAC level, and oversight from security, advisory, and analytical positions in the Executive Office of the President are built into the organizational model through the high-level committees and working groups.<sup>xxxix</sup> The State Department itself is relatively “neutral ground” in terms of global health programming due to its historical lack of engagement in operational health programs – State is not competing against other health agencies for research dollars or authority over other health issues. OGAC serves in a coordinating role and does not have to compete for resources and authority against counterparts with overlapping operational missions. This still

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<sup>xxxix</sup> Nonetheless, some ambiguities remain. Personal relationships between the OGAC and White House staff affect how closely routine communications adhere to the formal reporting mechanisms, with senior staff sometimes bypassing the Secretary of State or the National Security Council in favor of direct communication with individuals in the Executive Office of the President.

does not entirely remove logistical challenges, such as discrepancies between planning and contracting cycles and requirements inherent in the management culture of different participating agencies that can result in resource redundancies or gaps.<sup>286</sup>

*Understanding impact* – At the agency and program level, measuring project impact remains difficult. For example, although the PEPFAR monitoring criteria have broadened from the original highly focused target evaluations – e.g., drug courses distributed, extrapolated to lives saved – finding a framework that incorporates more sensitive measurements of health outcomes, social changes, and capacity created is extremely challenging for technical as well as political reasons, both in the context of HIV and for the larger US global health portfolio. Often, assistance outstrips the capacity of local systems to collect accurate and sufficient data on health outcomes. While some outcomes, such as reduction in the incidence of malaria, can be evaluated objectively given adequate disease surveillance, diagnostic capacity, and accurate historical data, measuring broader indicators (such as prevention of HIV transmission or improvements in total life expectancy at birth) over the long term requires extrapolation from often-incomplete data and a time period that may span more than one funding cycle. The evidence base for selecting sensitive and appropriate health indicators to measure the impact of international interventions continues to evolve. The US agencies involved in providing direct technical assistance for overseas disease surveillance capacity-building only recently began to evaluate their impacts systematically, aside from tracking numbers of graduates from epidemiology and laboratory training programs.<sup>287</sup> Because monitoring and evaluation systems preferred by the individual programs and agencies have historically arisen on an ad hoc basis and not from an evidence-based USG-wide standard, available data is often not comparable among agencies. OGAC faces additional challenges in claiming credit for US efforts in countries where multiple donors may be supporting parallel or overlapping HIV/AIDS prevention and care efforts, while satisfying demands to demonstrate “bang for the buck” to policymakers.<sup>288</sup>

*Blurring of operational, funding, and policy roles* – The past decade has seen profound mission overlap between foreign policy and health interventions, with policymakers increasingly recognizing health as foreign policy and vice versa. One outcome of the precipitous expansion of USG global health programs, and the pressure to scale up existing programs very rapidly through PEPFAR and the USG avian-human influenza effort, has been the gradual expansion and overlap of organizational roles. This includes, but exceeds the “mission creep” between civil and military roles in providing humanitarian assistance. The lines between agency missions, established by tradition as well as organizational competence, have blurred in the field and at home. For example, the responsibilities of various agencies historically fell relatively cleanly among the following categories:

- International health care and services delivery – USAID,
- Disease surveillance and laboratory capacity-building – HHS/CDC,
- International biological threat reduction (nonproliferation) – State.

Now, as a direct result of integration through PEPFAR and interagency competition for previously unimaginable resources, the following can be observed:

- International health care and services delivery – HHS (through HRSA, and to some degree CDC) now delivers or at least facilitates delivery of health services in PEPFAR focus countries.
- Disease surveillance and laboratory capacity-building – USAID has claimed a greater share of resources and authority to build capacity for disease surveillance and response as part of avian-human influenza preparedness.
- International biological threat reduction (nonproliferation) – in at least one of the years covered by this study, the HHS-Office of Global Health Affairs implemented biological threat reduction programs funded by the State Department’s Bureau of International Security and Nonproliferation (ISN), and conversely, the Biosecurity Engagement Program (part of the ISN/Office of Cooperative Threat Reduction with a mandate to increase pathogen security) directly conducted training sessions in biosafety and biosecurity and funded programs to build research and diagnostic capacity in public health laboratories.
- The State Department, which previously had no tangible role in global health operations, now oversees the massive PEPFAR programs in Washington and in the field.

In many ways, this mission creep becomes self-reinforcing, as coordinating or oversight bodies that lack the technical expertise to distinguish among these missions accept the newly expanded roles as given and allocate resources accordingly. In some cases, agencies that have benefited from Congressional largesse through appropriations earmarked for these expanded missions lack the infrastructure and expertise to use the funds effectively; at best, they serve as budget “pass-through’s” for other agencies, and at worst, resources may be wasted in creating parallel, redundant capacities in the field.

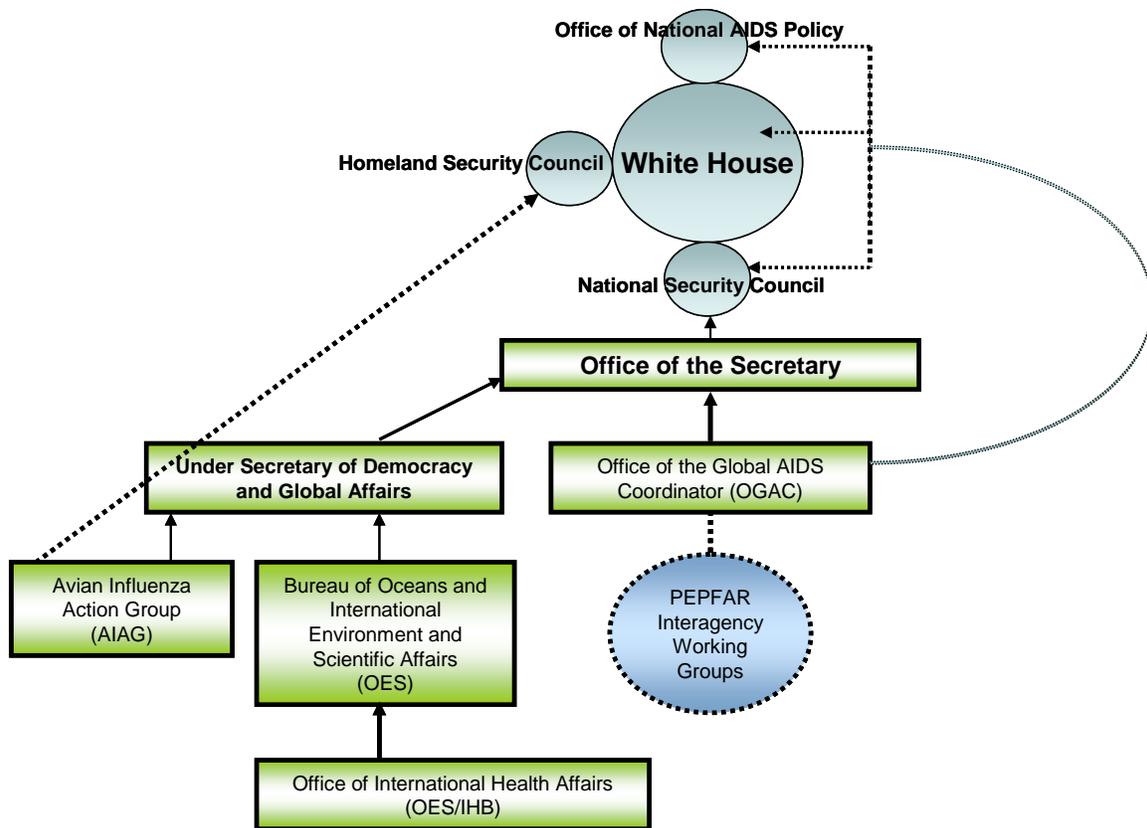
*Vertical programming:* The US government has almost always confronted emerging health concerns, such as potential bioterrorism or pandemic influenza, as threats distinct from each other as well as from established challenges such as HIV/AIDS, malaria, and tuberculosis, creating disease-centered programs “stove-piped” in both operation and leadership. This reinforces perceptions that programs aimed at securitized threats such as potentially pandemic influenza compete against (rather than establish synergies with) “pro-poor” strategies such as maternal/child health improvement that may strengthen health systems across the board, leading to desirable health outcomes and better host-nation buy-in. Part of this challenge arises from the relative ease of identifying specific outcomes and milestones in disease-focused programs, a critical issue when agencies and programs must demonstrate success to appropriators and other decision makers, especially given concerns about decreases in global health assistance funding in the face of an ongoing financial crisis.

Recently, incremental strides have been made in this area through operational coordination between PEPFAR and PMI programs, and among CDC field operations, but many opportunities for cooperation among US global health programs go unrealized. Efforts to facilitate interagency coordination more broadly around global health, rather than a specific disease or health challenge, have met with varying degrees of success. The Clinton-era NSTC-7 presidential

decision directive built on an interagency planning process to delineate USG-wide responsibilities in disease detection and response very broadly; however, the target remained emerging infections rather than all health issues.<sup>289</sup> In 2006, the State Department's Office of Strategic and Performance Planning initiated Project Horizon, a scenario-based exercise to drive USG-wide interagency planning on global issues.<sup>290</sup> CDC hosted the first Project Horizon Interagency Strategic Planning Group meeting devoted to Global Health Engagement in November 2007, with 11 government agencies represented.<sup>291</sup> This high-level interagency planning exercise adapted a military planning model to project USG-wide capabilities that might be needed to meet future threats, with a very clear focus on national security objectives (including for the health scenarios). However, this strategy still focuses on identifying capabilities that agencies can bring to bear on emerging global threats, rather than coordination of programs and resolving interagency conflicts; the utility and acceptability of the preliminary efforts remain unclear, as do the mechanism's future prospects.

*Strategic focus:* Classically, development assistance incorporates a top-down system, in which donors establish specific conditionalities for continued aid as well as metrics to determine program or project success. Recent US selection of target nations for health assistance funding appears to indicate a willingness of recipient nations to accept conditionalities related to US domestic politics (such as restrictions on reproductive health and harm reduction strategies) over a focus on countries and populations that would derive the greatest marginal benefit from US health assistance. The US interest in diminishing the disease burden is particularly manifest in sub-Saharan Africa, South Asia, and Southeast Asia, regions where endemic disease burdens pose serious threats to economic growth, fragile governments, and US supply chains, and that are most hospitable to disease emergence thanks to a combination of “mega-urbanization” and animal-human interfaces. When these health security interests are inconsistent with or subordinate to other US interests (such as trade or short-term security interests), the mechanisms for reconciling such conflicting priorities are weak.

*Lack of shared reporting mechanisms* – Presumably, overlapping authorities and conflicting missions might be remedied through intra- or interagency reporting to a single point of authority who – even if not endowed with authority to change the programs – might at least alert agency officials to overlapping programs, critical gaps, or opportunities for synergy. However, even global health offices and programs within the same department frequently report through entirely distinct chains of command, united only at the highest policy levels. For example, in the Bush administration, the three offices in the State Department with responsibility for global health programming reported notionally through the following pathways:



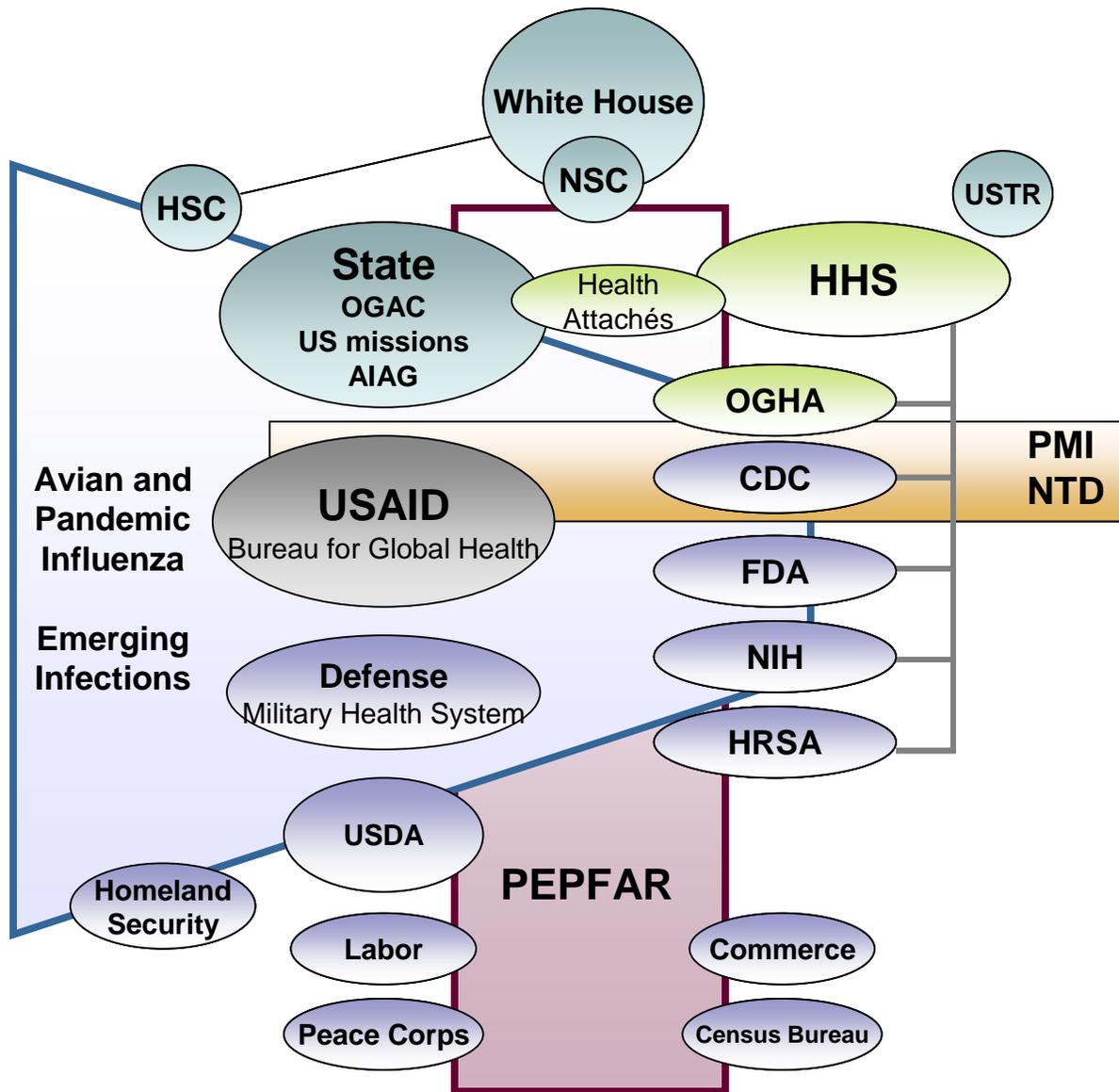
The diminishment or disbanding of the Homeland Security Council under the Obama administration (and the reorganization of the Avian Influenza Action Group as a subordinate office of the OES/Office of International Health Affairs) will address this particular convoluted, at least in part. However, the lack of a shared reporting mechanism for these agencies below the level of the Secretary of State and the White House resulted not from a cohesive operating and management strategy, but from a process of ad hoc organizational development that is far from anomalous as global health programs expand.

All of these phenomena are symptoms of a larger problem: the lack of an organizing mechanism for the USG global health enterprise. Two options for de-conflicting competing agency priorities, resolving conflicts, and increasing the effectiveness of strategic planning have been argued in recent years:

- As recommended by a high-level panel on the US commitment to global health, the president should create an office or focal point within the Executive Office of the President to coordinate all USG global health engagement policy, planning, and budget processes,<sup>292</sup> or
- Stakeholders should collectively develop a strategic framework for all USG global health engagement that clearly defines US national priorities in global health (encompassing development/humanitarian assistance and national security priorities), technical and policy goals, and agency roles based on organizational competencies.<sup>293</sup>

Arguments for a “health czar” or similar leadership point to the (at least partial) success of OGAC in integrating diverse health programs, and the need for strong leadership that cuts across the larger USG global health universe but has no vested institutional interest in a particular outcome.<sup>294</sup> Supporters of an overarching strategy contend that the implementing agencies have the appropriate technical expertise and perspective to determine the most effective policies if convened through an effective interagency coordinating body, and that a strategic framework that guides interagency priority-setting – rather than an individual arbiter susceptible to political vagaries – would provide sufficient guidance.<sup>295</sup> In that case, the central advisory role could be filled through an existing mechanism. For example, in the past, the National Security Council (NSC) has included a special advisor for health issues, a position eliminated during the Bush administration, then resurrected within the Homeland Security Council to focus on biosecurity and pandemic preparedness. Restoring this function within the NSC might provide sufficient coordination among NSC principals and high-level policymakers in the implementing agencies for setting priorities and resolving conflicts through existing interagency mechanisms, rather than through a strong coordinating authority.<sup>296</sup>

On the other hand, the concept of a strategic framework for all US global health engagement – regardless of whether the eventual coordinating principle embraced central leadership, the current status quo, or a “whole of government” approach to global health policy development – meets with very little opposition in the global health community. The elements of such a strategy, and a definition of the universe of stakeholders who might help shape it, are topics currently under study by a number of policy analysis organizations. At the most basic level, such a framework would presumably build a base vocabulary for interagency dialogue on the US engagement in global health, including a definition of the universe of global health activities.



**Conclusion Figure 1:** This schematic depicts the major formal intersections of the Federal agencies and offices – and, in some cases, their significant components – that comprised the US global health engagement in January 2009. The three named presidential initiatives [the President’s Emergency Plan for AIDS Relief (PEPFAR), the President’s Malaria Initiative (PMI) and the still-fledgling initiative for Neglected Tropical Diseases (NTD)] and the Avian Influenza Action Group represent the most well-developed interagency policy coordination mechanisms for global health programs, and draw in the greatest number of stakeholders.

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- <sup>1</sup> USAID Bureau for Democracy, Conflict & Humanitarian Assistance, Office of Food for Peace, *HIV and Food Security Conceptual Framework* (September 2007). <http://www.pepfar.gov/documents/organization/93288.pdf>
- <sup>2</sup> WHO, *The global burden of disease: 2004 update*. Geneva: WHO, 2008. [http://www.who.int/healthinfo/global\\_burden\\_disease/GBD\\_report\\_2004update\\_full.pdf](http://www.who.int/healthinfo/global_burden_disease/GBD_report_2004update_full.pdf).
- <sup>3</sup> *Contributing to One World, One Health* (10 October 2008), a consultation document produced for the UN System for Influenza Coordination, [http://un-influenza.org/files/OWOH\\_14Oct08.pdf](http://un-influenza.org/files/OWOH_14Oct08.pdf) (accessed January 2009).
- <sup>4</sup> The Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008 (Public Law 110-293). [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110\\_cong\\_public\\_laws&docid=f:publ293.110.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ293.110.pdf).
- <sup>5</sup> USAID: “Overview: USAID Support in Health Systems.” [http://www.usaid.gov/our\\_work/global\\_health/hs/](http://www.usaid.gov/our_work/global_health/hs/).
- <sup>6</sup> The Food, Conservation, and Energy Act of 2008 (Public Law 110-246). [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110\\_cong\\_public\\_laws&docid=f:publ246.110.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ246.110.pdf)
- <sup>7</sup> USAID, *HIV and Food Security Conceptual Framework* (September 2007).
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