



Appendices to the
Guidance on the Definition and Use of the
Global Health Programs Account
A Mandatory Reference for ADS Chapter 200

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APPENDICES

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APPENDIX I: Excerpts from Relevant Legislation and Congressional Reports

Relevant Excerpt from Foreign Assistance Act of 1961, as amended

Section 104 (b)

ASSISTANCE FOR POPULATION PLANNING.—In order to increase the opportunities and motivation for family planning and to reduce the rate of population growth, the President is authorized to furnish assistance, on such terms and conditions as he may determine, for voluntary population planning. In addition to the provision of family planning information and services, including also information and services which relate to and support natural family planning methods, and the conduct of directly relevant demographic research, population planning programs shall emphasize motivation for small families.

Section 104 (c)(2)

In carrying out the purposes of this subsection, the President shall promote, encourage, and undertake activities designed to deal directly with the special health needs of children and mothers. Such activities should utilize simple, available technologies that can significantly reduce childhood mortality, such as improved and expanded immunization programs, oral rehydration to combat diarrheal diseases, and education programs aimed at improving nutrition and sanitation and at promoting child spacing. In carrying out this paragraph, guidance shall be sought from knowledgeable health professionals from outside the Agency primarily responsible for administering this part. In addition to government-to-government programs, activities pursuant to this paragraph should include support for appropriate activities of the types described in this paragraph which are carried out by international organizations (which may include international organizations receiving funds under chapter 3 of this part) and by private and voluntary organizations, and should include encouragement to other donors to support such types of activities.

Section 104A (c)(1)

(c) **AUTHORIZATION.**—

(1) **IN GENERAL.**—Consistent with section 104(c), the President is authorized to furnish assistance, on such terms and conditions as the President may determine, for HIV/AIDS, including to prevent, treat, and monitor HIV/AIDS, and carry out related activities, in countries in sub-Saharan Africa, the Caribbean, and other countries and areas.

Section 104B (c)

(c) **AUTHORIZATION.**—To carry out this section and consistent with section 104(c), the President is authorized to furnish assistance, on such terms and conditions as the President may determine, for the prevention, treatment, control, and elimination of tuberculosis.

Section 104C (c)

(c) AUTHORIZATION.—To carry out this section and consistent with section 104(c), the President is authorized to furnish assistance, on such terms and conditions as the President may determine, for the prevention, treatment, control, and elimination of malaria.

Appropriations Act, 2008
DEPARTMENT OF STATE, FOREIGN OPERATIONS, AND RELATED PROGRAMS
APPROPRIATIONS ACT, 2008

As noted below, the FY 2008 Appropriations language defines the Global Health and Child Survival Account and delineates notwithstanding provisions.

DEPARTMENT OF STATE, FOREIGN OPERATIONS, AND RELATED PROGRAMS
APPROPRIATIONS ACT, 2012

As noted below, the FY 2012 Appropriations language defines the Global Health Programs Account and delineates notwithstanding provisions.

[Excerpt 1]

For necessary expenses to carry out the provisions of chapters 1 and 10 of part I of the Foreign Assistance Act of 1961, for global health activities, in addition to funds otherwise available for such purposes, \$2,625,000,000, to remain available until September 30, 2013, and which shall be apportioned directly to the United States Agency for International Development (USAID): Provided, That this amount shall be made available for training, equipment, and technical assistance to build the capacity of public health institutions and organizations in developing countries, and for such activities as: (1) child survival and maternal health programs; (2) immunization and oral rehydration programs; (3) other health, nutrition, water and sanitation programs which directly address the needs of mothers and children, and related education programs; (4) assistance for children displaced or orphaned by causes other than AIDS; (5) programs for the prevention, treatment, control of, and research on HIV/AIDS, tuberculosis, polio, malaria, and other infectious diseases including neglected tropical diseases, and for assistance to communities severely affected by HIV/AIDS, including children infected or affected by AIDS; and (6) family planning/reproductive health: Provided further, That funds appropriated under this paragraph may be made available for a United States contribution to the GAVI Alliance: Provided further, That none of the funds made available in this Act nor any unobligated balances from prior appropriations Acts may be made available to any organization or program which, as determined by the President of the United States, supports or participates in the management of a program of coercive abortion or involuntary sterilization: Provided further, That any determination made under the previous proviso must be made no later than 6 months after the date of enactment of this Act, and must be accompanied by the evidence and criteria utilized to make the determination: Provided further, That none of the funds made available under this Act may be used to pay for the performance of abortion as a method of family

planning or to motivate or coerce any person to practice abortions: Provided further, That nothing in this paragraph shall be construed to alter any existing statutory prohibitions against abortion under section 104 of the Foreign Assistance Act of 1961: Provided further, That none of the funds made available under this Act may be used to lobby for or against abortion: Provided further, That in order to reduce reliance on abortion in developing nations, funds shall be available only to voluntary family planning projects which offer, either directly or through referral to, or information about access to, a broad range of family planning methods and services, and that any such voluntary family planning project shall meet the following requirements: (1) service providers or referral agents in the project shall not implement or be subject to quotas, or other numerical targets, of total number of births, number of family planning acceptors, or acceptors of a particular method of family planning (this provision shall not be construed to include the use of quantitative estimates or indicators for budgeting and planning purposes); (2) the project shall not include payment of incentives, bribes, gratuities, or financial reward to: (A) an individual in exchange for becoming a family planning acceptor; or (B) program personnel for achieving a numerical target or quota of total number of births, number of family planning acceptors, or acceptors of a particular method of family planning; (3) the project shall not deny any right or benefit, including the right of access to participate in any program of general welfare or the right of access to health care, as a consequence of any individual's decision not to accept family planning services; (4) the project shall provide family planning acceptors comprehensible information on the health benefits and risks of the method chosen, including those conditions that might render the use of the method inadvisable and those adverse side effects known to be consequent to the use of the method; and (5) the project shall ensure that experimental contraceptive drugs and devices and medical procedures are provided only in the context of a scientific study in which participants are advised of potential risks and benefits; and, not less than 60 days after the date on which the USAID Administrator determines that there has been a violation of the requirements contained in paragraph (1), (2), (3), or (5) of this proviso, or a pattern or practice of violations of the requirements contained in paragraph (4) of this proviso, the Administrator shall submit to the Committees on Appropriations a report containing a description of such violation and the corrective action taken by the Agency: Provided further, That in awarding grants for natural family planning under section 104 of the Foreign Assistance Act of 1961 no applicant shall be discriminated against because of such applicant's religious or conscientious commitment to offer only natural family planning; and, additionally, all such applicants shall comply with the requirements of the previous proviso: Provided further, That for purposes of this or any other Act authorizing or appropriating funds for the Department of State, foreign operations, and related programs, the term "motivate", as it relates to family planning assistance, shall not be construed to prohibit the provision, consistent with local law, of information or counseling about all pregnancy options: Provided further, That information provided about the use of condoms as part of projects or activities that are funded from amounts appropriated by this Act shall be medically accurate and shall include the public health benefits and failure rates of such use.

In addition, for necessary expenses to carry out the provisions of the Foreign Assistance Act of 1961 for the prevention, treatment, and control of, and research on, HIV/AIDS, \$5,542,860,000, to remain available until September 30, 2016, which shall be apportioned directly to the Department of State: Provided, That funds appropriated under this paragraph may be made available, notwithstanding any other provision of law, except for the United States Leadership

Against HIV/AIDS, Tuberculosis and Malaria Act of 2003 (Public Law 108–25), as amended, for a United States contribution to the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), and shall be expended at the minimum rate necessary to make timely payment for projects and activities: Provided further, That the amount of such contribution should be \$1,050,000,000: Provided further, That up to 5 percent of the aggregate amount of funds made available to the Global Fund in fiscal year 2012 may be made available to USAID for technical assistance related to the activities of the Global Fund: Provided further, That of the funds appropriated under this paragraph, up to \$14,250,000 may be made available, in addition to amounts otherwise available for such purposes, for administrative expenses of the Office of the United States Global AIDS Coordinator.

[Excerpt 2]

GLOBAL HEALTH ACTIVITIES

SEC. 7058. (a) IN GENERAL.—Funds appropriated by titles III and IV of this Act that are made available for bilateral assistance for child survival activities or disease programs including activities relating to research on, and the prevention, treatment and control of, HIV/AIDS may be made available notwithstanding any other provision of law except for provisions under the heading “Global Health Programs” and the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 (117 Stat. 711; 22 U.S.C. 7601 et seq.), as amended: Provided, That of the funds appropriated under title III of this Act, not less than \$575,000,000 should be made available for family planning/reproductive health, including in areas where population growth threatens biodiversity or endangered species.

(b) GLOBAL HEALTH MANAGEMENT.—

(1) Not later than 180 days after enactment of this Act, the Secretary of State, in consultation with the Administrator of the United States Agency for International Development (USAID), shall submit to the Committees on Appropriations an analysis of short and long-term costs, to include potential cost savings or increases, associated with transitioning the function, role, and duties of the Office of the United States Global AIDS Coordinator into USAID: Provided, That such report shall also assess any programmatic advantages and disadvantages, including the ability to achieve results, of making such a transition. (2)(A) Not later than 45 days after enactment of this Act, the Secretary of State, in consultation with the Administrator of the United States Agency for International Development (USAID), shall submit to the Committees on Appropriations a report on the status of the Quadrennial Diplomacy and Development Review (QDDR) decision to transition the leadership of the Global Health Initiative (GHI) to USAID, to include the following— (i) the metrics developed to measure progress in meeting each benchmark enumerated in Appendix 2 of the QDDR and the method utilized to develop such metrics; and (ii) the status of, and estimated completion date for, meeting each benchmark. (B) Within 90 days of submitting the initial report required by subparagraph (A), and each 90 days thereafter until the GHI transition is completed, an update shall be provided to the Committees on Appropriations on the status of meeting each benchmark: Provided, That if as part of any such update it is determined that the QDDR target date of September 2012 will not be met, the Secretary of State, in consultation with the USAID Administrator, shall submit a detailed explanation of the delay and a revised target date for the transition

to be completed.

(c) GLOBAL FUND REFORMS.—

(1) Of funds appropriated by this Act that are available for a contribution to the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), 10 percent should be withheld from obligation until the Secretary of State determines and reports to the Committees on Appropriations that— (A) the Global Fund is maintaining and implementing a policy of transparency, including the authority of the Global Fund Office of the Inspector General (OIG) to publish OIG reports on a public Web site; (B) the Global Fund is providing sufficient resources to maintain an independent OIG that— (i) reports directly to the Board of the Global Fund; (ii) maintains a mandate to conduct thorough investigations and programmatic audits, free from undue interference; and (iii) compiles regular, publicly published audits and investigations of financial, programmatic, and reporting aspects of the Global Fund, its grantees, recipients, sub-recipients, and Local Fund Agents; and (C) the Global Fund maintains an effective whistleblower policy to protect whistleblowers from retaliation, including confidential procedures for reporting possible misconduct or irregularities. (2) The withholding required by this subsection shall not be in addition to funds that are withheld from the Global Fund in fiscal year 2012 pursuant to the application of any other provision contained in this or any other Act.

(d) PANDEMIC RESPONSE.—If the President determines and reports to the Committees on Appropriations that a pandemic virus is efficient and sustained, severe, and is spreading internationally, funds made available under titles III, IV, and VIII in this Act and prior Acts making appropriations for the Department of State, foreign operations, and related programs may be made available to combat such virus: Provided, That funds made available pursuant to the authority of this subsection shall be subject to prior consultation with, and the regular notification procedures of, the Committees on Appropriations.

[Excerpt 3]

SEC. 7057 (g) PERSONAL SERVICES CONTRACTORS.—Funds appropriated by this Act to carry out chapter 1 of part I, chapter 4 of part II, and section 667 of the Foreign Assistance Act of 1961, and title II of the Agricultural Trade Development and Assistance Act of 1954, may be used by USAID to employ up to 40 personal services contractors in the United States, notwithstanding any other provision of law, for the purpose of providing direct, interim support for new or expanded overseas programs and activities managed by the agency until permanent direct hire personnel are hired and trained: Provided, That not more than 15 of such contractors shall be assigned to any bureau or office: Provided further, That such funds appropriated to carry out title II of the Agricultural Trade Development and Assistance Act of 1954, may be made available only for personal services contractors assigned to the Office of Food for Peace.

[Excerpt 4]

PROHIBITION OF PAYMENT OF CERTAIN EXPENSES

SEC. 7020. None of the funds appropriated or otherwise made available by this Act under the headings “International Military Education and Training” or “Foreign Military Financing Program” for Informational Program activities or under the headings “Global Health Programs”, “Development Assistance”, and “Economic Support Fund” may be obligated or

expended to pay for— (1) alcoholic beverages; or (2) entertainment expenses for activities that are substantially of a recreational character, including but not limited to entrance fees at sporting events, theatrical and musical productions, and amusement parks.

Excerpts from the United States Leadership Against HIV/AIDS Tuberculosis, and Malaria Act of 2003, as amended by the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008

[Excerpt 1]

SEC. 4. PURPOSE.

The purpose of this Act is to strengthen and enhance United States leadership and the effectiveness of the United States response to the HIV/AIDS, tuberculosis, and malaria pandemics and other related and preventable infectious diseases as part of the overall United States health and development agenda by--

(1) establishing comprehensive, coordinated, and integrated 5-year, global strategies to combat HIV/AIDS, tuberculosis, and malaria by—

(A) building on progress and successes to date;

(B) improving harmonization of United States efforts with national strategies of partner governments and other public and private entities; and

(C) emphasizing capacity building initiatives in order to promote a transition toward greater sustainability through the support of country-driven efforts;

(2) providing increased resources for bilateral and multilateral efforts to fight HIV/AIDS, tuberculosis, and malaria as integrated components of United States development assistance;

(3) intensifying efforts to—

(A) prevent HIV infection;

(B) ensure the continued support for, and expanded access to, treatment and care programs;

(C) enhance the effectiveness of prevention, treatment, and care programs; and

(D) address the particular vulnerabilities of girls and women;

(4) encouraging the expansion of private sector efforts and expanding public-private sector partnerships to combat HIV/AIDS, tuberculosis, and malaria;

(5) reinforcing efforts to—

(A) develop safe and effective vaccines, microbicides, and other prevention and treatment technologies; and

(B) improve diagnostics capabilities for HIV/AIDS, tuberculosis, and malaria; and

(6) helping partner countries to--

(A) strengthen health systems;

(B) expand health workforce; and

(C) address infrastructural weaknesses.

[Excerpt 2]

SEC. 102. HIV/AIDS RESPONSE COORDINATOR.

(f) HIV/AIDS RESPONSE COORDINATOR.—

(1) **IN GENERAL.**—There shall be established within the Department of State in the immediate office of the Secretary of State a Coordinator of United States Government Activities to Combat HIV/AIDS Globally, who shall be appointed by the President, by and with the advice and consent of the Senate. The Coordinator shall report directly to the Secretary.

(2) AUTHORITIES AND DUTIES; DEFINITIONS.—

(A) AUTHORITIES.—The Coordinator, acting through such nongovernmental organizations (including faith-based and community-based organizations) and relevant executive branch agencies as may be necessary and appropriate to effect the purposes of this section, is authorized—

(i) to operate internationally to carry out prevention, care, treatment, support, capacity development, and other activities for combatting HIV/AIDS;

(ii) to transfer and allocate funds to relevant executive branch agencies; and

(iii) to provide grants to, and enter into contracts with, nongovernmental organizations (including faithbased and community-based organizations) to carry out the purposes of section.

(B) DUTIES.—

(i) **IN GENERAL.**—The Coordinator shall have primary responsibility for the oversight and coordination of all resources and international activities of the United States Government to combat the HIV/AIDS pandemic, including all programs, projects, and activities of the United States Government relating to the HIV/AIDS pandemic under the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 or any amendment made by that Act.

(ii) **SPECIFIC DUTIES.**—The duties of the Coordinator shall specifically include the following:

(I) Ensuring program and policy coordination among the relevant executive branch agencies and nongovernmental organizations, including auditing, monitoring, and evaluation of all such programs.

(II) Ensuring that each relevant executive branch agency undertakes programs primarily in those areas where the agency has the greatest expertise, technical capabilities, and potential for success.

(III) Avoiding duplication of effort.

(IV) Ensuring coordination of relevant executive branch agency activities in the field.

(V) Pursuing coordination with other countries and international organizations.

(VI) Resolving policy, program, and funding disputes among the relevant executive branch agencies. “(VII) Directly approving all activities of the United States (including funding) relating to combatting HIV/AIDS in each of Botswana, Cote d’Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda, Zambia, and other countries designated by the President, which other designated countries may include those

countries in which the United States is implementing HIV/AIDS programs as of the date of the enactment of the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003.

(VIII) Establishing due diligence criteria for all recipients of funds section and all activities subject to the coordination and appropriate monitoring, evaluation, and audits carried out by the Coordinator necessary to assess the measurable outcomes of such activities.

[Excerpt 3]

TITLE III—BILATERAL EFFORTS

SEC. 104A. ASSISTANCE TO COMBAT HIV/AIDS.

(c) Authorization.--

(1) In general.--Consistent with section 104(c), the President is authorized to furnish assistance, on such terms and conditions as the President may determine, for HIV/AIDS, including to prevent, treat, and monitor HIV/AIDS, and carry out related activities, in countries in sub-Saharan Africa, the Caribbean, Central Asia, Eastern Europe, Latin America, and other countries and areas, particularly with respect to refugee populations or those in postconflict settings in such countries and areas with significant or increasing HIV incidence rates.

(d) Activities Supported.--Assistance provided under subsection (c) shall, to the maximum extent practicable, be used to carry out the following activities

(1) Prevention.--Prevention of HIV/AIDS through activities including—

(A) programs and efforts that are designed or intended to impart knowledge with the exclusive purpose of helping individuals avoid behaviors that place them at risk of HIV infection, including integration of such programs into health programs and the inclusion in counseling programs of information on methods of avoiding infection of HIV, including delaying sexual debut, abstinence, fidelity and monogamy, reduction of casual sexual partnering and multiple concurrent sexual partnering, reducing sexual violence and coercion, including child marriage, widow inheritance, and polygamy, and where appropriate, use of male and female condoms;

(B) assistance to establish and implement culturally appropriate HIV/AIDS education and prevention programs that are designed with local input and focus on helping individuals avoid infection of HIV/AIDS, implemented through nongovernmental organizations, including faith-based and community-based organizations, particularly those locally based organizations that utilize both professionals and volunteers with appropriate skills, experience, and community presence;

(C) assistance for the purpose of encouraging men to be responsible in their sexual behavior, child rearing, and to respect women;

(D) assistance for the purpose of providing voluntary testing and counseling

(including the incorporation of confidentiality protections with respect to such testing and counseling) and promoting the use of provider-initiated or ‘opt-out’ voluntary testing in accordance with World Health Organization guidelines;

(E) assistance for the purpose of preventing mother-to-child transmission of the HIV infection, including medications to prevent such transmission and access to infant formula and other alternatives for infant feeding;

(F) assistance to—

- (i) achieve the goal of reaching 80 percent of pregnant women for prevention and treatment of mother-to-child transmission of HIV in countries in which the United States is implementing HIV/AIDS programs by 2013; and
- (ii) promote infant feeding options and treatment protocols that meet the most recent criteria established by the World Health Organization;

(G) medical male circumcision programs as part of national strategies to combat the transmission of HIV/AIDS;

(H) assistance to ensure a safe blood supply and sterile medical equipment;

(I) assistance to help avoid substance abuse and intravenous drug use that can lead to HIV infection; and

(J) assistance for the purpose of increasing women's access to employment opportunities, income, productive resources, and microfinance programs, where appropriate.

(K) assistance for counseling, testing, treatment, care, and support programs, including—

- (i) counseling and other services for the prevention of reinfection of individuals with HIV/AIDS;
- (ii) counseling to prevent sexual transmission of HIV, including—
 - (I) life skills development for practicing abstinence and faithfulness;
 - (II) reducing the number of sexual partners;
 - (III) delaying sexual debut; and
 - (IV) ensuring correct and consistent use of condoms;
- (iii) assistance to engage underlying vulnerabilities to HIV/AIDS, especially those of women and girls;
- (iv) assistance for appropriate HIV/AIDS education programs and training targeted to prevent the transmission of HIV among men who have sex with men;
- (v) assistance to provide male and female condoms;
- (vi) diagnosis and treatment of other sexually transmitted infections;
- (vii) strategies to address the stigma and discrimination that impede HIV/AIDS prevention efforts; and
- (viii) assistance to facilitate widespread access to microbicides for HIV prevention, if safe and effective products become available, including financial and technical support for culturally appropriate introductory programs, procurement, distribution, logistics management, program delivery, acceptability studies, provider training, demand generation, and postintroduction monitoring.”

- (2) Treatment.--The treatment and care of individuals with HIV/AIDS, including—
- (A) assistance to establish and implement programs to strengthen and broaden indigenous health care delivery systems and the capacity of such systems to deliver HIV/AIDS pharmaceuticals and otherwise provide for the treatment of individuals with HIV/AIDS, including clinical training for indigenous organizations and health care providers;
 - (B) assistance to strengthen and expand hospice and palliative care programs to assist patients debilitated by HIV/AIDS, their families, and the primary caregivers of such patients, including programs that utilize faith-based and community-based organizations;
 - (C) assistance for the purpose of the care and treatment of individuals with HIV/AIDS through the provision of pharmaceuticals, including antiretrovirals and other pharmaceuticals and therapies for the treatment of opportunistic infections, pain management, nutritional support, and other treatment modalities.;
 - (D) as part of care and treatment of HIV/AIDS, assistance (including prophylaxis and treatment) for common HIV/AIDS-related opportunistic infections for free or at a rate at which it is easily affordable to the individuals and populations being served;
 - (E) as part of care and treatment of HIV/AIDS, assistance or referral to available and adequately resourced service providers for nutritional support, including counseling and where necessary the provision of commodities, for persons meeting malnourishment criteria and their families;
- (3) Preventative intervention education and technologies.—
- (A) With particular emphasis on specific populations that represent a particularly high risk of contracting or spreading HIV/AIDS, including those exploited through the sex trade, victims of rape and sexual assault, individuals already infected with HIV/AIDS, and in cases of occupational exposure of health care workers, assistance with efforts to reduce the risk of HIV/AIDS infection including post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides.
 - (B) Bulk purchases of available test kits, condoms, and, when proven effective, microbicides that are intended to reduce the risk of HIV/AIDS transmission and for appropriate program support for the introduction and distribution of these commodities, as well as education and training on the use of the technologies.
- (4) Monitoring.--The monitoring of programs, projects, and activities carried out pursuant to paragraphs (1) through (3), including—

(A) monitoring to ensure that adequate controls are established and implemented to provide HIV/AIDS pharmaceuticals and other appropriate medicines to poor individuals with HIV/AIDS;

(B) appropriate evaluation and surveillance activities;

(C) monitoring to ensure that appropriate measures are being taken to maintain the sustainability of HIV/AIDS pharmaceuticals (especially antiretrovirals) and ensure that drug resistance is not compromising the benefits of such pharmaceuticals;

(D) monitoring to ensure appropriate law enforcement officials are working to ensure that HIV/AIDS pharmaceuticals are not diminished through illegal counterfeiting or black market sales of such pharmaceuticals.;

(E) carrying out and expanding program monitoring, impact evaluation research and analysis, and operations research and disseminating data and findings through mechanisms to be developed by the Coordinator of United States Government Activities to Combat HIV/AIDS Globally, in coordination with the Director of the Centers for Disease Control, in order to—

- (i) improve accountability, increase transparency, and ensure the delivery of evidence-based services through the collection, evaluation, and analysis of data regarding gender-responsive interventions, disaggregated by age and sex;
- (ii) identify and replicate effective models; and
- (iii) develop gender indicators to measure outcomes and the impacts of interventions; and

(F) establishing appropriate systems to—

- (i) gather epidemiological and social science data on HIV; and
- (ii) evaluate the effectiveness of prevention efforts among men who have sex with men, with due consideration to stigma and risks associated with disclosure.

(5) Pharmaceuticals.—

(A) Procurement.--The procurement of HIV/AIDS pharmaceuticals, antiviral therapies, and other appropriate medicines, including medicines to treat opportunistic infections.

(B) Mechanisms for quality control and sustainable supply.--Mechanisms to ensure that such HIV/AIDS pharmaceuticals, antiretroviral therapies, and other appropriate medicines are quality-controlled and sustainably supplied.

(C) Mechanism to ensure cost-effective drug purchasing.—Subject to subparagraph (B), mechanisms to ensure that safe and effective pharmaceuticals, including antiretrovirals and medicines to treat opportunistic infections, are

purchased at the lowest possible price at which such pharmaceuticals may be obtained in sufficient quantity on the world market, provided that such pharmaceuticals are approved, tentatively approved, or otherwise authorized for use by—

- (i) the Food and Drug Administration;
- (ii) a stringent regulatory agency acceptable to the Secretary of Health and Human Services; or
- (iii) a quality assurance mechanism acceptable to the Secretary of Health and Human Services.

(D) Distribution.--The distribution of such HIV/AIDS pharmaceuticals, antiviral therapies, and other appropriate medicines (including medicines to treat opportunistic infections) to qualified national, regional, or local organizations for the treatment of individuals with HIV/AIDS in accordance with appropriate HIV/AIDS testing and monitoring requirements and treatment protocols and for the prevention of mother-to-child transmission of the HIV infection.

(6) Related and coordinated activities.--The conduct of related activities, including—

(A) the care and support of children who are orphaned by the HIV/AIDS pandemic, including services designed to care for orphaned children in a family environment which rely on extended family members;

(B) improved infrastructure and institutional capacity to develop and manage education, prevention, and treatment programs, including training and the resources to collect and maintain accurate HIV surveillance data to target programs and measure the effectiveness of interventions; and

(C) vaccine research and development partnership programs with specific plans of action to develop a safe, effective, accessible, preventive HIV vaccine for use throughout the world.;

(D) coordinated or referred activities to—

- (i) enhance the clinical impact of HIV/AIDS care and treatment; and
- (ii) ameliorate the adverse social and economic costs often affecting AIDS-impacted families and communities through the direct provision, as necessary, or through the referral, if possible, of support services, including—
 - (I) nutritional and food support;
 - (II) safe drinking water and adequate sanitation;
 - (III) nutritional counseling;
 - (IV) income-generating activities and livelihood initiatives;
 - (V) maternal and child health care;
 - (VI) primary health care;
 - (VII) the diagnosis and treatment of other infectious or sexually transmitted diseases;
 - (VIII) substance abuse and treatment services; and

(IX) legal services;

(E) coordinated or referred activities to link programs addressing HIV/AIDS with programs addressing gender-based violence in areas of significant HIV prevalence to assist countries in the development and enforcement of women's health, children's health, and HIV/AIDS laws and policies that—

- (i) prevent and respond to violence against women and girls;
- (ii) promote the integration of screening and assessment for gender-based violence into HIV/AIDS programming;
- (iii) promote appropriate HIV/AIDS counseling, testing, and treatment into gender-based violence programs; and
- (iv) assist governments to develop partnerships with civil society organizations to create networks for psychosocial, legal, economic, or other support services;

(F) coordinated or referred activities to—

- (i) address the frequent coinfection of HIV and tuberculosis, in accordance with World Health Organization guidelines;
- (ii) promote provider-initiated or 'opt-out' HIV/AIDS counseling and testing and appropriate referral for treatment and care to individuals with tuberculosis or its symptoms, particularly in areas with significant HIV prevalence; and
- (iii) strengthen programs to ensure that individuals testing positive for HIV receive tuberculosis screening and to improve laboratory capacities, infection control, and adherence; and

(G) activities to—

- (i) improve the effectiveness of national responses to HIV/AIDS;
- (ii) strengthen overall health systems in high-prevalence countries, including support for workforce training, retention, and effective deployment, capacity building, laboratory development, equipment maintenance and repair, and public health and related public financial management systems and operations; and
- (iii) encourage fair and transparent procurement practices among partner countries; and
- (iv) promote in-country or intra-regional pediatric training for physicians and other health professionals, preferably through public-private partnerships involving colleges and universities, with the goal of increasing pediatric HIV workforce capacity.

(7) Comprehensive HIV/AIDS public-private partnerships.—The establishment and operation of public-private partnership entities within countries in sub-Saharan Africa, the Caribbean, and other countries affected by the HIV/AIDS pandemic that are dedicated to supporting the national strategy of such countries regarding the prevention, treatment, and monitoring of HIV/AIDS. Each such public-private partnership should-

(A) support the development, implementation, and management of comprehensive HIV/AIDS plans in support of the national HIV/AIDS strategy;

(B) operate at all times in a manner that emphasizes efficiency, accountability, and results-driven programs;

(C) engage both local and foreign development partners and donors, including businesses, government agencies, academic institutions, nongovernmental organizations, foundations, multilateral development agencies, and faith-based organizations, to assist the country in coordinating and implementing HIV/AIDS prevention, treatment, and monitoring programs in accordance with its national HIV/AIDS strategy;

(D) provide technical assistance, consultant services, financial planning, monitoring and evaluation, and research in support of the national HIV/AIDS strategy; and

(E) establish local human resource capacities for the national HIV/AIDS strategy through the transfer of medical, managerial, leadership, and technical skills.

(8) Compacts and framework agreements.—The development of compacts or framework agreements, tailored to local circumstances, with national governments or regional partnerships in countries with significant HIV/AIDS burdens to promote host government commitment to deeper integration of HIV/AIDS services into health systems, contribute to health systems overall, and enhance sustainability, including—

(A) cost sharing assurances that meet the requirements under section 110; and

(B) transition strategies to ensure sustainability of such programs and activities, including health care systems, under other international donor support, or budget support by respective foreign governments.

[Excerpt 4]

(e) LIMITATION.—No funds made available to carry out this Act, or any amendment made by this Act, may be used to promote or advocate the legalization or practice of prostitution or sex trafficking. Nothing in the preceding sentence shall be construed to preclude the provision to individuals of palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides.

(f) LIMITATION.—No funds made available to carry out this Act, or any amendment made by this Act, may be used to provide assistance to any group or organization that does not have a policy explicitly opposing prostitution and sex trafficking.

[Excerpt 5]

SEC. 302. ASSISTANCE TO COMBAT TUBERCULOSIS.

(a) Amendment of the Foreign Assistance Act of 1961.--Chapter 1 of part I of the Foreign Assistance Act of 1961 (22 U.S.C. 2151 et seq.), as amended by section 301 of this Act, is further amended by inserting after section 104A the following new section:

SEC. 104B. ASSISTANCE TO COMBAT TUBERCULOSIS.

(a) Findings.--Congress makes the following findings:

(1) Congress recognizes the growing international problem of tuberculosis and the impact its continued existence has on those countries that had previously largely controlled the disease.

(2) Congress further recognizes that the means exist to control and treat tuberculosis through expanded use of the DOTS (Directly Observed Treatment Short-course) treatment strategy, including DOTS-Plus to address multi-drug resistant tuberculosis, and adequate investment in newly created mechanisms to increase access to treatment, including the Global Tuberculosis Drug Facility established in 2001 pursuant to the Amsterdam Declaration to Stop TB and the Global Alliance for TB Drug Development.

(b) Policy.—It is a major objective of the foreign assistance program of the United States to control tuberculosis. In all countries in which the Government of the United States has established development programs, particularly in countries with the highest burden of tuberculosis and other countries with high rates of tuberculosis, the United States should support the objectives of the Global Plan to Stop TB, including through achievement of the following goals:

(1) Reduce by half the tuberculosis death and disease burden from the 1990 baseline.

(2) Sustain or exceed the detection of at least 70 percent of sputum smear-positive cases of tuberculosis and the successful treatment of at least 85 percent of the cases detected in countries with established United States Agency for International Development tuberculosis programs.

(3) In support of the Global Plan to Stop TB, the President shall establish a comprehensive, 5-year United States strategy to expand and improve United States efforts to combat tuberculosis globally, including a plan to support—

(A) the successful treatment of 4,500,000 new sputum smear tuberculosis patients under DOTS programs by 2013, primarily through direct support for needed services, commodities, health workers, and training, and additional treatment through coordinated multilateral efforts; and

(B) the diagnosis and treatment of 90,000 new multiple drug resistant tuberculosis cases by 2013, and additional treatment through coordinated multilateral efforts.

(c) Authorization.--To carry out this section and consistent with section 104(c), the President is authorized to furnish assistance, on such terms and conditions as the President may determine, for the prevention, treatment, control, and elimination of tuberculosis.

(d) Coordination.--In carrying out this section, the President shall coordinate with the World Health Organization, the Global Fund to Fight AIDS, Tuberculosis, and Malaria, and other organizations with respect to the development and implementation of a comprehensive tuberculosis control program.

(e) Priority To Stop TB Strategy.—In furnishing assistance under subsection (c), the President shall give priority to—

(1) direct services described in the Stop TB Strategy, including expansion and enhancement of Directly Observed Treatment Short-course (DOTS) coverage, rapid testing, treatment for individuals infected with both tuberculosis and HIV, and treatment for individuals with multi-drug resistant tuberculosis (MDR-TB), strengthening of health systems, use of the International Standards for Tuberculosis Care by all providers, empowering individuals with tuberculosis, and enabling and promoting research to develop new diagnostics, drugs, and vaccines, and program-based operational research relating to tuberculosis; and

(2) funding for the Global Tuberculosis Drug Facility, the Stop Tuberculosis Partnership, and the Global Alliance for TB Drug Development.”.

(f) Assistance for the World Health Organization and the Stop Tuberculosis Partnership.—In carrying out this section, the President, acting through the Administrator of the United States Agency for International Development, is authorized to provide increased resources to the World Health Organization and the Stop Tuberculosis Partnership to improve the capacity of countries with high rates of tuberculosis and other affected countries to implement the Stop TB Strategy and specific strategies related to addressing multiple drug resistant tuberculosis (MDR-TB) and extensively drug resistant tuberculosis (XDR-TB).

(g) Annual report.—The President shall submit an annual report to Congress that describes the impact of United States foreign assistance on efforts to control tuberculosis, including—

(1) the number of tuberculosis cases diagnosed and the number of cases cured in countries receiving United States bilateral foreign assistance for tuberculosis control purposes;

(2) a description of activities supported with United States tuberculosis resources in each country, including a description of how those activities specifically contribute to increasing the number of people diagnosed and treated for tuberculosis;

(3) in each country receiving bilateral United States foreign assistance for tuberculosis control purposes, the percentage provided for direct tuberculosis services in countries receiving United States bilateral foreign assistance for tuberculosis control purposes;

(4) a description of research efforts and clinical trials to develop new tools to combat tuberculosis, including diagnostics, drugs, and vaccines supported by United States bilateral assistance;

(5) the number of persons who have been diagnosed and started treatment for multidrug-resistant tuberculosis in countries receiving United States bilateral foreign assistance for tuberculosis control programs;

(6) a description of the collaboration and coordination of United States anti-tuberculosis efforts with the World Health Organization, the Global Fund, and other major public and private entities within the Stop TB Strategy;

(7) the constraints on implementation of programs posed by health workforce shortages and capacities;

(8) the number of people trained in tuberculosis control; and

(9) a breakdown of expenditures for direct patient tuberculosis services, drugs and other commodities, drug management, training in diagnosis and treatment, health systems strengthening, research, and support costs

(h) Definitions.--In this section:

(1) DOTS.--The term 'DOTS' or 'Directly Observed Treatment Short-course' means the World Health Organization-recommended strategy for treating tuberculosis, including—

- (A) low-cost and effective diagnosis, treatment, and monitoring of tuberculosis;
- (B) a reliable drug supply;
- (C) a management strategy for public health systems;
- (D) health system strengthening;
- (E) promotion of the use of the International Standards for Tuberculosis Care by all care providers;
- (F) bacteriology under an external quality assessment framework;
- (G) short-course chemotherapy; and
- (H) sound reporting and recording systems.

(2) DOTS-plus.--The term 'DOTS-Plus' means a comprehensive tuberculosis management strategy that is built upon and works as a supplement to the standard DOTS strategy, and which takes into account specific issues (such as use of second line anti-

tuberculosis drugs) that need to be addressed in areas where there is high prevalence of multi-drug resistant tuberculosis.

(3) Global alliance for tuberculosis drug development.--The term 'Global Alliance for Tuberculosis Drug Development' means the public-private partnership that brings together leaders in health, science, philanthropy, and private industry to devise new approaches to tuberculosis and to ensure that new medications are available and affordable in high tuberculosis burden countries and other affected countries.

(4) Global tuberculosis drug facility.--The term 'Global Tuberculosis Drug Facility (GDF)' means the new initiative of the Stop Tuberculosis Partnership to increase access to high-quality tuberculosis drugs to facilitate DOTS expansion.

(5) Stop TB strategy.—The term 'Stop TB Strategy' means the 6-point strategy to reduce tuberculosis developed by the World Health Organization, which is described in the Global Plan to Stop TB 2006–2015: Actions for Life, a comprehensive plan developed by the Stop TB Partnership that sets out the actions necessary to achieve the millennium development goal of cutting tuberculosis deaths and disease burden in half by 2015.

(6) Stop tuberculosis partnership.--The term 'Stop Tuberculosis Partnership' means the partnership of the World Health Organization, donors including the United States, high tuberculosis burden countries, multilateral agencies, and nongovernmental and technical agencies committed to short- and long-term measures required to control and eventually eliminate tuberculosis as a public health problem in the world.'

(b) Authorization of Appropriations.—

(1) In general.--In addition to funds available under section 104(c) of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b(c)) for such purpose or under any other provision of that Act, there are authorized to be appropriated to the President, from amounts authorized to be appropriated under section 401, a total of \$4,000,000,000 for the 5-year period beginning on October 1, 2008 to carry out section 104B of the Foreign Assistance Act of 1961, as added by subsection (a).

(2) Availability of funds.--Amounts appropriated pursuant to the authorization of appropriations under paragraph (1) are authorized to remain available until expended.

(3) Transfer of prior year funds.--Unobligated balances of funds made available for fiscal year 2001, 2002, or 2003 under section 104(c)(7) of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b(c)(7) (as in effect immediately before the date of enactment of this Act) shall be transferred to, merged with, and made available for the same purposes as funds made available for fiscal years 2009 through 2013 under paragraph (1).

[Excerpt 6]

SEC. 303. ASSISTANCE TO COMBAT MALARIA.

(a) Amendment of the Foreign Assistance Act of 1961.--Chapter 1 of part I of the Foreign

Assistance Act of 1961 (22 U.S.C. 2151 et seq.), as amended by sections 301 and 302 of this Act, is further amended by inserting after section 104B the following new section:

SEC. 104C. ASSISTANCE TO COMBAT MALARIA.

(a) Finding.--Congress finds that malaria kills more people annually than any other communicable disease except tuberculosis, that more than 90 percent of all malaria cases are in sub-Saharan Africa, and that children and women are particularly at risk. Congress recognizes that there are cost-effective tools to decrease the spread of malaria and that malaria is a curable disease if promptly diagnosed and adequately treated.

(b) Policy.--It is a major objective of the foreign assistance program of the United States to provide assistance for the prevention, control, treatment and cure of malaria.

(c) Authorization.--To carry out this section and consistent with section 104(c), the President is authorized to furnish assistance, on such terms and conditions as the President may determine, for the prevention, treatment, control, and elimination of malaria.

(d) Coordination.--In carrying out this section, the President shall coordinate with the World Health Organization, the Global Fund to Fight AIDS, Tuberculosis, and Malaria, the Department of Health and Human Services (the Centers for Disease Control and Prevention and the National Institutes of Health), and other organizations with respect to the development and implementation of a comprehensive malaria control program."

(b) Authorization of Appropriations.—

(1) In general.--In addition to funds available under section 104(c) of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b(c)) for such purpose or under any other provision of that Act, there are authorized to be appropriated to the President, from amounts authorized to be appropriated under section 401, \$5,000,000,000 during the 5-year period beginning on October 1, 2008 to carry out section 104C of the Foreign Assistance Act of 1961, as added by subsection (a), including for the development of anti-malarial pharmaceuticals by the Medicines for Malaria Venture.

(2) Availability of funds.--Amounts appropriated pursuant to paragraph (1) are authorized to remain available until expended.

(3) Transfer of prior year funds.--Unobligated balances of funds made available for fiscal year 2001, 2002, or 2003 under section 104(c) of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b(c)) (as in effect immediately before the date of enactment of this Act) and made available for the control of malaria shall be transferred to, merged with, and made available for the same purposes as funds made available for fiscal years 2009 through 2013 under paragraph (1).

(c) Conforming Amendment.--Section 104(c) of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b(c)), as amended by section 301 of this Act, is further amended by adding after paragraph (3) the following:

(4) Relationship to other laws.--Assistance made available under this subsection and sections 104A, 104B, and 104C, and assistance made available under chapter 4 of part II to carry out the purposes of this subsection and the provisions cited in this paragraph, may be made available notwithstanding any other provision of law that restricts assistance to foreign countries, except for the provisions of this subsection, the provisions of law cited in this paragraph, subsection (f), section 634A of this Act, and provisions of law that limit assistance to organizations that support or participate in a program of coercive abortion or involuntary sterilization included under the Child Survival and Health Programs Fund heading in the Consolidated Appropriations Resolution, 2003 (Public Law 108-7)."

(c) Statement of policy.—Providing assistance for the prevention, control, treatment, and the ultimate eradication of malaria is—

(1) a major objective of the foreign assistance program of the United States; an

(2) 1 component of a comprehensive United States global health strategy to reduce disease burdens and strengthen communities around the world.

(d) Development of a Comprehensive 5-Year Strategy.—The President shall establish a comprehensive, 5-year strategy to combat global malaria that—

(1) strengthens the capacity of the United States to be an effective leader of international efforts to reduce malaria burden;

(2) maintains sufficient flexibility and remains responsive to the ever-changing nature of the global malaria challenge;

(3) includes specific objectives and multisectoral approaches and strategies to reduce the prevalence, mortality, incidence, and spread of malaria;

(4) describes how this strategy would contribute to the United States' overall global health and development goals;

(5) clearly explains how outlined activities will interact with other United States Government global health activities, including the 5-year global AIDS strategy required under this Act;

(6) expands public-private partnerships and leverage of resources;

(7) coordinates among relevant Federal agencies to maximize human and financial resources and to reduce duplication among these agencies, foreign governments, and international organizations;

(8) coordinates with other international entities, including the Global Fund;

(9) maximizes United States capabilities in the areas of technical assistance and training and research, including vaccine research; and

(10) establishes priorities and selection criteria for the distribution of resources based on factors such as—

- (A) the size and demographics of the population with malaria;
- (B) the needs of that population;
- (C) the country's existing infrastructure; and
- (D) the ability to closely coordinate United States Government efforts with national malaria control plans of partner countries.”

[Excerpt 7]

SEC. 304. MALARIA RESPONSE COORDINATOR.

(a) In General.--There is established within the United States Agency for International Development a Coordinator of United States Government Activities to Combat Malaria Globally (referred to in this section as the `Malaria Coordinator'), who shall be appointed by the President.

(b) Authorities.--The Malaria Coordinator, acting through nongovernmental organizations (including faith-based and community-based organizations), partner country finance, health, and other relevant ministries, and relevant executive branch agencies as may be necessary and appropriate to carry out this section, is authorized to—

(1) operate internationally to carry out prevention, care, treatment, support, capacity development, and other activities to reduce the prevalence, mortality, and incidence of malaria;

(2) provide grants to, and enter into contracts and cooperative agreements with, nongovernmental organizations (including faith-based organizations) to carry out this section; and

(3) transfer and allocate executive branch agency funds that have been appropriated for the purposes described in paragraphs (1) and (2).

(c) Duties.--

(1) In general.--The Malaria Coordinator has primary responsibility for the oversight and coordination of all resources and international activities of the United States Government relating to efforts to combat malaria.

(2) Specific duties.--The Malaria Coordinator shall--

(A) facilitate program and policy coordination of antimalarial efforts among relevant executive branch agencies and nongovernmental organizations by auditing, monitoring, and evaluating such programs;

(B) ensure that each relevant executive branch agency undertakes antimalarial programs primarily in those areas in which the agency has the greatest expertise, technical capability, and potential for success;

(C) coordinate relevant executive branch agency activities in the field of malaria prevention and treatment;

(D) coordinate planning, implementation, and evaluation with the Global AIDS Coordinator in countries in which both programs have a significant presence;

(E) coordinate with national governments, international agencies, civil society, and the private sector; and

(F) establish due diligence criteria for all recipients of funds appropriated by the Federal Government for malaria assistance.

[Excerpt 8]

TITLE IV--AUTHORIZATION OF APPROPRIATIONS

SEC. 401. AUTHORIZATION OF APPROPRIATIONS.

(a) In General.--There are authorized to be appropriated to the President to carry out this Act and the amendments made by this Act \$48,000,000,000 for the 5-year period beginning on October 1, 2008.

(b) Availability.--Amounts appropriated pursuant to the authorization of appropriations in subsection (a) are authorized to remain available until expended.

(b) Sense of Congress.—It is the sense of the Congress that the appropriations authorized under section 401(a) of the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, as amended by subsection (a), should be allocated among fiscal years 2009 through 2013 in a manner that allows for the appropriations to be gradually increased in a manner that is consistent with program requirements, absorptive capacity, and priorities set forth in such Act, as amended by this Act.

(c) Availability of Authorizations.--Authorizations of appropriations under subsection (a) shall remain available until the appropriations are made.

SEC. 402. SENSE OF CONGRESS.

(a) Increase in HIV/AIDS Antiretroviral Treatment.--It is a sense of the Congress that an urgent priority of United States assistance programs to fight HIV/AIDS should be the rapid increase in distribution of antiretroviral treatment so that—

(1) by the end of fiscal year 2004, at least 500,000 individuals with HIV/AIDS are receiving antiretroviral treatment through United States assistance programs;

(2) by the end of fiscal year 2005, at least 1,000,000 such individuals are receiving such treatment; and

(3) by the end of fiscal year 2006, at least 2,000,000 such individuals are receiving such treatment.

(b) Effective Distribution of HIV/AIDS Funds.--It is the sense of Congress that, of the amounts appropriated pursuant to the authorization of appropriations under section 401 for HIV/AIDS assistance, 10 percent should be used for orphans and vulnerable children.

SEC. 403. ALLOCATION OF FUNDS.

(a) Therapeutic Medical Care.--For fiscal years 2006 through 2008, not less than 55 percent of the amounts appropriated pursuant to the authorization of appropriations under section 401 for HIV/AIDS assistance for each such fiscal year shall be expended for therapeutic medical care of individuals infected with HIV, of which such amount at least 75 percent should be expended for the purchase and distribution of antiretroviral pharmaceuticals and at least 25 percent should be expended for related care. For fiscal years 2006 through 2008, not less than 33 percent of the amounts appropriated pursuant to the authorization of appropriations under section 401 for HIV/AIDS prevention consistent with section 104A(d) of the Foreign Assistance Act of 1961 (as added by section 301 of this Act) for each such fiscal year shall be expended for abstinence-until-marriage programs.

(a) Balanced funding requirement.—

(1) In general.—The Global AIDS Coordinator shall—

(A) provide balanced funding for prevention activities for sexual transmission of HIV/AIDS; and

(B) ensure that activities promoting abstinence, delay of sexual debut, monogamy, fidelity, and partner reduction are implemented and funded in a meaningful and equitable way in the strategy for each host country based on objective epidemiological evidence as to the source of infections and in consultation with the government of each host country involved in HIV/AIDS prevention activities.

(2) Prevention strategy.—

(A) Establishment.—In carrying out paragraph (1), the Global AIDS Coordinator shall establish an HIV sexual transmission prevention strategy governing the expenditure of funds authorized under this Act to prevent the sexual transmission of HIV in any host country with a generalized epidemic.

(B) Report.—In each host country described in subparagraph (A), if the strategy established under subparagraph (A) provides less than 50 percent of the funds described in subparagraph (A) for activities promoting abstinence, delay of sexual debut, monogamy, fidelity, and partner reduction, the Global AIDS Coordinator shall, not later than 30 days after the issuance of this strategy, report to the appropriate congressional committees on the justification for this decision.

(3) Exclusion.—Programs and activities that implement or purchase new prevention technologies or modalities, such as medical male circumcision, public education about risks to acquire HIV infection from blood exposures, promoting universal precautions, investigating suspected nosocomial infections, pre-exposure pharmaceutical prophylaxis to prevent transmission of HIV, or microbicides and programs and activities that provide counseling and testing for HIV or prevent mother-to-child prevention of HIV, shall not be included in determining compliance with paragraph (2).

(4) Report.—Not later than 1 year after the date of the enactment of the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, and annually thereafter as part of the annual report required under section 104A(e) of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b–2(e)), the President shall—

(A) submit a report on the implementation of paragraph (2) for the most recently concluded fiscal year to the appropriate congressional committees; and

(B) make the report described in subparagraph (A) available to the public.

(b) Orphans and Vulnerable Children.—For fiscal years 2009 through 2013, not less than 10 percent of the amounts appropriated pursuant to the authorization of appropriations under section 401 for HIV/AIDS assistance for each such fiscal year shall be expended for assistance for orphans and other children affected by, or vulnerable to HIV/AIDS, of which such amount at least 50 percent shall be provided through non-profit, nongovernmental organizations, including faith-based organizations, that implement programs on the community level.

(c) Funding allocation.—For each of the fiscal years 2009 through 2013, more than half of the amounts appropriated for bilateral global HIV/AIDS assistance pursuant to section 401 shall be expended for—

(1) antiretroviral treatment for HIV/AIDS;

(2) clinical monitoring of HIV-seropositive people not in need of antiretroviral treatment;

(3) care for associated opportunistic infections;

(4) nutrition and food support for people living with HIV/AIDS; and

(5) other essential HIV/AIDS-related medical care for people living with HIV/AIDS.

(d) Treatment, prevention, and care goals.—For each of the fiscal years 2009 through 2013—

(1) the treatment goal under section 402(a)(3) shall be increased above 2,000,000 by at least the percentage increase in the amount appropriated for bilateral global HIV/AIDS assistance for such fiscal year compared with fiscal year 2008

(2) any increase in the treatment goal under section 402(a)(3) above the percentage increase in the amount appropriated for bilateral global HIV/AIDS assistance for such fiscal year compared with fiscal year 2008 shall be based on long-term requirements, epidemiological evidence, the share of treatment needs being met by partner governments and other sources of treatment funding, and other appropriate factors;

(3) the treatment goal under section 402(a)(3) shall be increased above the number calculated under paragraph (1) by the same percentage that the average United States

Government cost per patient of providing treatment in countries receiving bilateral HIV/AIDS assistance has decreased compared with fiscal year 2008; and

(4) the prevention and care goals established in clauses (i) and (iv) of section 104A(b)(1)(A) of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b–2(b)(1)(A)) shall be increased consistent with epidemiological evidence and available resources.

APPENDIX II: Executive Message on President's Malaria Initiative, December 23, 2005

USAID/General Notice

ADMINISTRATOR

GH/AA

12/23/2005

EXECUTIVE MESSAGE

SUBJECT: President's Malaria Initiative

USAID is the lead agency for the President's \$1.2 billion, five-year initiative to control malaria in Africa. The goal of the initiative is to reduce malaria-related deaths by 50 percent in 15 countries by achieving 85 percent coverage of proven preventive and curative interventions. Activities are already underway with spraying and other high-impact interventions in the three, first-year target countries of Angola, Uganda, and Tanzania. This initiative will be focused, results-based, and will exhibit a high level of financial and programmatic accountability. A minimum of 50 percent of this funding will be devoted to the purchase and distribution of life-saving commodities.

While the President's Malaria Initiative (PMI) ramps up over the next five years to cover 175 million people, expectations of both the White House and Congress are that all malaria prevention and treatment programs will function in the same results-based and accountable fashion as the PMI. To this end, I have approved ten actions that institute fundamental changes to the structure and conduct of USAID's malaria programs. These changes take effect immediately, or as otherwise indicated, and include:

1. Pursuant to the President's instructions and subsequent interagency implementation agreements, there is established a position of Malaria Coordinator, reporting to the USAID Administrator, with direct authority over both the PMI and USAID non-PMI malaria programs and policy. The authorities, roles, and responsibilities of the Malaria Coordinator include:

- * All malaria policies, planning, and budgeting;
- * Direct supervision over, and hiring authority for, all USAID/Washington malaria staff;
- * All malaria budget allocations to bureaus and countries, as well as malaria staffing levels in bureaus and countries;
- * Approval of all malaria-related acquisition and assistance plans, with the authority to approve or disapprove any proposed malaria-related acquisition and assistance action or

obligations within countries and by USAID/W bureaus, subject to governing laws and procurement regulations;

* Approval of all malaria-related Monitoring and Evaluation (M&E) requirements and reporting requirements, with the authority to approve or disapprove any specific malaria-related M&E and reporting plans;

* Approval of all direct hire and non-direct hire travel to countries for malaria programs, regardless of the funding source;

* All malaria-related communication and outreach strategies and activities, in cooperation with LPA;

* Lead representation at all international malaria prevention and treatment fora and meetings, including those sponsored by Roll Back Malaria, the World Bank, the World Health Organization, and UNICEF;

* Consult and work closely with bureaus and missions on policy, programming, and budget matters affecting the implementation of the program. The Africa Bureau will be the main implementing entity for the PMI and a majority of non-PMI programs.

* The Coordinator may delegate any authorities, roles, and responsibilities to senior staff, to the fullest extent permitted by law and USAID policy.

2. I have designated the Assistant Administrator for Global Health, Kent R. Hill, as the Acting Malaria Coordinator, until such time as a Malaria Coordinator is appointed. In this capacity, he will exercise all roles, responsibilities, and authorities of the Coordinator.

3. Beginning in FY 06, at least 40 percent of USAID non-directed malaria sub-account is designated for a centrally-managed commodity fund, for the sole, express purpose of providing to country programs life-saving commodities: environmentally-sound insecticide-treated nets, and insecticides and equipment for spraying; artemisinin-combination therapies and diagnostics; drugs for intermittent preventive treatment of pregnant women; and drugs for severe malaria. In FY 07, the intention is for this fund to achieve at least 50 percent of non-directed malaria sub-account funds. The Malaria Coordinator or Acting Malaria Coordinator, in consultation with the appropriate bureaus, shall establish the operating procedures for the use of the commodity fund. The commodities will be procured by the GH Bureau or missions, whichever is most appropriate.

4. Proven principles of development will guide all malaria programs implemented or funded by USAID. Such principles include, but are not limited to: an emphasis on country or local ownership of the problem and the solution; a clear ability to build

capacity in the affected countries, including strengthening of local institutions, transfer of technologies and skills, and adoption of appropriate policies; sustainability of programs to ensure continuation through funding or political changes in out-years; and, allocation of resources and personnel selectively and in such a way as to maximize the impact of all programs.

5. For FY 06, 25 percent of all non-PMI malaria funds (\$15 million) are designated to support exclusively indoor residual spraying activities in malaria-affected countries, as directed by the Malaria Coordinator or Acting Malaria Coordinator.

6. Beginning in FY 06, all non-PMI country and regional malaria allocations must be approved by the Acting Malaria Coordinator and, thereafter, by the Malaria Coordinator.

7. Beginning in FY 06, no country malaria program or regionally-managed country program will be funded at less than \$1.5 million of malaria funds. In FY 07, the minimum funding for country programs will rise to \$2.5 million, or any such other level as is determined by the Malaria Coordinator. When the consequences of this requirement are not in the best interest of the malaria program, the Coordinator may make exceptions on a case-by-case basis.

8. All regional funding for USAID malaria programs is capped and shall not exceed the level of FY 05 funding.

9. All operating units will report according to the new malaria data management system, transmitted to the field by PPC and GH in November, 2005. The posting on the PMI website will include all procurement documents under the PMI (e.g., contracts, grants), after "redaction" by the contractor/grantee. GH and its support contractor are responsible for managing this process.

10. No Agency malaria funds are allowed to fund non-malaria activities, including cross-cutting programs or initiatives, "taxes" to cover non-malaria costs or common costs, or any other mechanism, regardless of past practice, without the express consent of the Malaria Coordinator or Acting Malaria Coordinator.

Once these changes have been instituted, USAID will be properly positioned to achieve the goals of the President's initiative. Thank you for your cooperation.

Andrew S. Natsios

Point of Contact: Michael Miller, GH/DAA, (202) 712-1325 and Gloria Steele, DAA/GH, (202) 712-4120.

APPENDIX III: Executive Message on Avian Influenza, September 26, 2005

ADMINISTRATOR

USAID/General Notice
ES
09/26/2005

E X E C U T I V E M E S S A G E

**SUBJECT: Priority Message from the Administrator: USAID's
Response to Avian Influenza**

The following is a high priority message from the Administrator regarding the need for a rapid and coordinated Agency response to the H5N1 avian influenza (AI) virus. The threat posed by avian influenza is critical and urgent; crafting an effective response is the top priority for all missions and posts worldwide.

To date, avian influenza has been responsible for 113 human infections with 58 deaths, and the death and destruction of over 140 million domestic poultry in Vietnam, Cambodia, Indonesia and Thailand. The present threat mainly stems from animal-to-human transmission and has been mostly confined to Southeast Asia and southern China. But trends are worrisome.

First, there is growing concern that this strain of the Influenza A virus could evolve and spread efficiently from human-to-human, placing millions of lives at risk. Experts estimate that the death toll from such a mutation could range from four million to over 180 million people, depending upon the effectiveness of containment and response. This virus has the ability to jump the species barrier. The most deadly flu epidemics in history have started with similar leaps, notably the Spanish Flu epidemic of 1918, which killed an estimated 20 to 50 million people.

Second, the geographic reach of avian influenza is rapidly increasing (see attachment). In the last two months, infected migratory birds have been located in Eurasia, moving the threat westward. Isolated outbreaks have been reported in places as far away as Russia, Mongolia and Kazakhstan. As of yet, no infected birds have been found in the Western Hemisphere.

Finally, it is also worth noting that economic ramifications of avian influenza have already been significant. At current levels of transmission, the economic cost associated with avian influenza and containment efforts is estimated to have already exceeded \$10 billion; in 2004, it cost the Vietnamese economy alone an estimated \$200 million. Moreover, a worldwide influenza pandemic would have a major effect on the global economy, including travel, trade, tourism, consumption and eventually, investment and financial markets.

I am communicating this information not to cause undue alarm, but to stress the importance of an early and effective response from all missions. If we take this threat seriously and pursue

necessary actions now, we can mitigate a potential outbreak and potentially save millions of lives.

Already in Washington, D.C., significant steps are being taken. Last week, at the High-Level Plenary Meeting of the United Nations General Assembly, the President announced a new, U.S.-led International Partnership on Avian and Pandemic Influenza (IPAPI). The partnership will require countries to immediately share information about human infections and provide samples to the World Health Organization to ensure a rapid response to reported outbreaks.

This complements the President's May 11, 2005 signing of an emergency appropriations bill containing \$25 million to prevent and control the spread of avian influenza in Asia, of which \$10 million was allocated to USAID. Our \$10 million program targets five countries in Southeast Asia where avian influenza is now endemic in animal populations and the risk of further outbreaks is highest. It intends to increase laboratory capacities, train and support rapid responders, and enhance nationwide disease surveillance and pandemic planning in partnership with the U.S. Department of Agriculture, the U.N. Food and Agriculture Organization and the World Health Organization. We will also work with our partners to conduct public education campaigns that will increase awareness of how to prevent the spread of avian influenza, change high-risk animal husbandry and market practices, and encourage timely reporting. Finally, the Global Development Alliance will lead efforts to involve private businesses and companies and increase the availability of technical assistance, commodities, and financial support for avian influenza containment and preparedness.

In USAID/Washington, we have put in place an Avian Flu task force to develop and coordinate response planning and regional activities in affected countries of Southeast Asia. Further, we are closely monitoring new outbreaks and are planning to engage in each country on the basis of their relative risk. In coordination with other U.S. Government agencies, we are pursuing a three-step approach:

- Strengthen Pandemic Planning & Preparedness. Prepare for future outbreaks by supporting enhanced pandemic planning, improve cross-Ministerial and donor coordination, and stockpile essential commodities for response and containment of animal and human outbreaks.
- Minimize the Risk of Avian Influenza Transmission. Limit animal infections by improving farming practices that minimize contact between wild and domestic birds. Cull diseased or exposed animals to limit further spread, support animal vaccination, and strengthen surveillance and response capacities.
- Ensure Rapid and Effective Treatment and Management of Infections. Prevent human infection by promptly responding to suspected outbreaks and using protective gear when working with

infected animals and humans. Increase the capacities of local and national governments to promptly identify, confirm and isolate possible animal and human cases. Provide safe treatment and care to those infected, and conduct public awareness campaigns.

It is vital that our missions take the threat of avian influenza seriously. In a separate message, I will specifically task all Mission Directors to undertake the following actions, included here for your information:

- By September 30, identify a principal point of contact for the mission that will coordinate activities related to avian and pandemic influenza.

- By October 31, prepare and submit to your regional bureau a rapid assessment survey outlining the host country's preparedness to respond to avian and pandemic influenza. This survey will be sent to all missions later this week and will include the following:

Assess the readiness of the country. Does a pandemic plan exist? Is there an enabling political environment that is appropriately sensitized to the avian influenza threat? Are there adequate plans for supplies of commodities for managing human outbreaks? If there is a high risk of animal infection in the country (see attached map), is there an adequate capacity for early surveillance and diagnosis, and for rapid containment of animal outbreaks?

Assess the effectiveness of the plan. If a plan exists, does it make sense? Can it be practically implemented in a rapid manner? Does the plan incorporate and clearly articulate the roles and of relevant ministries, and provide a mechanism for effective coordination? Does it identify key spokespeople and articulate strategies for rapidly and coherently disseminating information to the public?

Assess the role and engagement of the donor community. What steps are other donors playing? Where are the gaps in avian influenza readiness? What role is USAID best-suited to play in the country? Is there a role for donors in the national pandemic plan and are donors prepared to fulfill that role? Is there a mechanism for donor coordination and information-sharing?

The key to an early and rapid response is political commitment and transparency. It is critical that we raise the profile of avian influenza to host governments. I am asking missions to be creative and work within existing resource constraints. Additionally, I have instructed our regional bureaus to work with missions and identify specific levels of support and activity that would be appropriate.

Dennis Carroll in the Bureau of Global Health is coordinating the Agency's avian influenza response and can provide additional information. For further information on the USAID response please refer to:

http://www.usaid.gov/our_work/global_health/home/News/news_items/avian_influenza.html.

For regular updates on new developments and USAID actions refer to:

http://www.usaid.gov/our_work/global_health/home/News/news_items/actions.html

Andrew S. Natsios

POINT OF CONTACT: Dennis Carroll, GH/HIDN, (202) 712-50

Andrew S. Natsios

Point of Contact: Any questions concerning this Notice may be directed to Dennis Carroll, GH/HIDN, (202) 712-5009 and/or Robbin Boyer, PPC/SPP/SRC, (202) 712-4489.

APPENDIX V: USAID Family Planning Requirements, Statutory and Policy

Provision	Applies To	Statutory Text from Foreign Assistance Act and/or Appropriations Act for FY 2012
Helms (1973) ⁽¹⁾	All assistance ⁽²⁾ All entities ⁽⁴⁾ All instruments ⁽⁵⁾	None of the funds made available under this Act may be used to pay for the performance of abortion as a method of family planning or to motivate or coerce any person to practice abortions. ⁽⁶⁾⁽⁷⁾
Leahy (1994) ⁽¹⁾	All assistance ⁽²⁾ All entities ⁽⁴⁾ All instruments ⁽⁵⁾	For purposes of this or any other Act authorizing or appropriating funds for the Department of State, foreign operations, and related programs, the term “motivate”, as it relates to family planning assistance, shall not be construed to prohibit the provision, consistent with local law, of information or counseling about all pregnancy options. ⁽⁷⁾⁽⁸⁾
Biden (1981) ⁽¹⁾	All assistance ⁽²⁾ All entities ⁽⁴⁾ All instruments ⁽⁵⁾	None of the funds made available to carry out part I of the Foreign Assistance Act of 1961, as amended, may be used to pay for any biomedical research which relates in whole or in part, to methods of, or the performance of, abortions or involuntary sterilization as a means of family planning. ⁽⁶⁾⁽⁷⁾
Siljander (1981) ⁽¹⁾	All assistance ⁽²⁾ All entities ⁽⁴⁾ All instruments ⁽⁵⁾	None of the funds made available under this Act may be used to lobby for or against abortion. ⁽⁷⁾
Kemp-Kasten (1985) ⁽¹⁾	All assistance ⁽²⁾ All entities ⁽⁴⁾ All instruments ⁽⁵⁾	None of the funds made available in this Act nor any unobligated balances from prior appropriations Acts may be made available to any organization or program which, as determined by the President of the United States, supports or participates in the management of a program of coercive abortion or involuntary sterilization. Any determination made under the previous proviso must be made no later than 6 months after the date of enactment of this Act, and must be accompanied by the evidence and criteria utilized to make the determination. ⁽⁷⁾
DeConcini (1985) ⁽¹⁾	FP assistance ⁽³⁾ All entities ⁽⁴⁾ All instruments ⁽⁵⁾	In order to reduce reliance on abortion in developing nations, funds shall be available only to voluntary family planning projects which offer, either directly or through referral to, or information about access to, a broad range of family planning methods and services. ⁽⁷⁾
Livingston- Obey (1986) ⁽¹⁾	FP assistance ⁽³⁾ All entities ⁽⁴⁾ All instruments ⁽⁵⁾	In awarding grants for natural family planning under section 104 of the Foreign Assistance Act of 1961 no applicant shall be discriminated against because of such applicant’s religious or conscientious commitment to offer only natural family planning; and, additionally, all such applicants shall comply with the requirements of the [DeConcini Amendment]. ⁽⁷⁾
Tiaht (1998) ⁽¹⁾	FP assistance ⁽³⁾ All entities ⁽⁴⁾ All instruments ⁽⁵⁾	Any such voluntary family planning project shall meet the following requirements: (1) service providers or referral agents in the project shall not implement or be subject to quotas, or other numerical targets, of total number of births, number of family planning acceptors, or acceptors of a particular method of family planning (this provision shall not be construed to include the use of quantitative estimates or indicators for budgeting and planning purposes); (2) the project shall not include payment of incentives, bribes, gratuities, or financial reward to: (A) an individual in exchange for becoming a family planning acceptor; or (B) program personnel for achieving a numerical target or quota of total number of births, number of family planning acceptors, or acceptors of a particular method of family planning; (3) the project shall not deny any right or benefit, including the right of access to participate in any program of general welfare or the right of access to health care, as a consequence of any individual’s decision not to accept family planning services; (4) the project shall provide family planning acceptors comprehensible information on the health benefits and risks of the method chosen, including those conditions that might render the use of the method inadvisable and

		those adverse side effects known to be consequent to the use of the method; and (5) the project shall ensure that experimental contraceptive drugs and devices and medical procedures are provided only in the context of a scientific study in which participants are advised of potential risks and benefits; and, not less than 60 days after the date on which the USAID Administrator determines that there has been a violation of the requirements contained in paragraph (1), (2), (3), or (5) of this proviso, or a pattern or practice of violations of the requirements contained in paragraph (4) of this proviso, the Administrator shall submit to the Committees on Appropriations a report containing a description of such violation and the corrective action taken by the Agency. ⁽⁷⁾
Additional Provisions (1977) ⁽¹⁾ (1986) ⁽¹⁾	All assistance ⁽²⁾ All entities ⁽⁴⁾ All instruments ⁽⁵⁾	None of the funds made available to carry out part I of the Foreign Assistance Act of 1961, as amended, may be used to pay for the performance of involuntary sterilization as a method of family planning or to coerce or provide any financial incentive to any person to undergo sterilizations. ⁽⁶⁾⁽⁷⁾ None of the funds made available to carry out part I of the Foreign Assistance Act of 1961, as amended, may be obligated or expended for any country or organization if the President certifies that the use of these funds by any such country or organization would violate [the Helms Amendment, the Biden Amendment, or the provision above listed as the first “Additional Provision”]. ⁽⁷⁾

- (1) Indicates the date the amendment or policy was first enacted. Unless otherwise stated, the amendment or policy remains in effect.
- (2) Applies to all funds appropriated for any purpose under the FY 12 Foreign Operations Appropriations Act.
- (3) Applies only to family planning assistance (from any account) appropriated under the FY 12 Foreign Operations Appropriations Act.
- (4) Applies to all entities (e.g., U.S. non-governmental organizations (NGOs), foreign non-governmental organizations (FNGOs), public international organizations (PIOs), and foreign governments).
- (5) Applies to all instruments (e.g., grants, cooperative agreements, contracts, and SOAGs (or other similar bilateral agreements)).
- (6) Text from Section 104(f) of the Foreign Assistance Act of 1961, as amended
- (7) Text from FY 2012 Foreign Operations Appropriations Act, Title III, “Bilateral Economic Assistance—Global Health Programs” and/or Title VI, Section 7018.
- (8) The term “motivate” refers to language in the Helms Amendment.

USAID FAMILY PLANNING REQUIREMENTS – POLICY

Provision	Applies To	USAID Policies
USAID Policy on Voluntarism and Informed Choice	FP assistance ⁽³⁾ All entities ⁽⁴⁾ All instruments ⁽⁵⁾	USAID places highest priority on ensuring that its family planning (FP) and reproductive health activities adhere to the principles of voluntarism and informed choice. The Agency considers an individual’s decision to use a specific FP method or to use any FP method at all voluntary if based upon the exercise of free choice and not obtained by any special inducements or any element of force, fraud, deceit, duress, or other forms of coercion or misrepresentation. USAID defines informed choice to include effective access to information on FP choices and to the counseling, services, and supplies needed to help individuals choose to obtain or decline services and the option to see, obtain, or follow up on a referral or simply to consider the matter further.
PD-3 (1977) ⁽¹⁾	FP assistance ⁽³⁾ All entities ⁽⁴⁾ All instruments ⁽⁵⁾	In 1982, USAID issued a policy paper on population assistance, which clearly states its commitment to voluntarism in the provision of family planning (FP) services. Annex PD-3 of the Population Policy of 1982 includes specific requirements for USAID-supported programs that include voluntary sterilization. These requirements cover informed consent, ready access to other methods, and guidelines on incentive payments. PD-3 requires that informed consent be obtained in writing from every VS acceptor. Informed consent is defined as voluntary, knowing consent after being advised of the surgical procedures, the attendant discomforts and risks, the expected benefits, the availability of alternative FP options, the purpose and irreversibility of the operation, and the option to withdraw consent prior to the operation. Voluntary consent is defined as consent based upon free choice and not obtained by any element of force, fraud, deceit, duress, or other forms of coercion or misrepresentation. PD-3 further requires that potential VS acceptors have ready access to a range of FP methods whenever VS services are offered. PD-3 prohibits the payment of incentives to potential VS acceptors, providers,

		<p>and referral agents, but permits compensation of reasonable expenses in order to make VS as equally available as other contraceptive methods.</p> <p>More detailed information on PD-3 can be found at: http://www.usaid.gov/our_work/global_health/pop/populat.pdf.</p>
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- (1) Indicates the date the amendment or policy was first enacted. Unless otherwise stated, the amendment or policy remains in effect.
- (2) Applies to all funds appropriated for any purpose under the FY 12 Foreign Operations Appropriations Act.
- (3) Applies only to family planning assistance (from any account) appropriated under the FY 12 Foreign Operations Appropriations Act.
- (4) Applies to all entities (e.g., U.S. non-governmental organizations (NGOs), foreign non-governmental organizations (FNGOs), public international organizations (PIOs), and foreign governments).
- (5) Applies to all instruments (e.g., grants, cooperative agreements, contracts, and SOAGs (or other similar bilateral agreements)).
- (6) Text from Section 104(f) of the Foreign Assistance Act of 1961, as amended.
- (7) Text from FY 2012 Foreign Operations Appropriations Act, Title III, “Bilateral Economic Assistance—Global Health Programs” and/or Title VI, Section 7018.
- (8) The term “motivate” refers to language in the Helms Amendment.

APPENDIX VI: Sample Template for Documenting Technical Consultations

[date]

INFORMATION MEMORANDUM FOR THE FILE

TO: The File

FROM: [NAME OF MISSION DIRECTOR], Mission Director, USAID/[MISSION NAME]

SUBJECT: Approval to use Global Health and Child Survival (GH/CS) funds for [SUMMARIZE PRIMARY USE OF FUNDS]

This memo should indicate that a proposal for the use of funds was discussed with all parties listed for clearance, and a consensus was reached.

The memo should also include a detailed description of the activity, how it directly contributes to the relevant Agency Objective(s) (or element), and the expected results. It should outline the pros and cons of moving ahead with the proposed activity, and the relevant external considerations (including political, diplomatic, and programmatic considerations). The memo should also include the amount of funds being requested.

CLEARANCE PAGE FOR INFORMATION MEMORANDUM on approval to use GH/CS funds for [PURPOSE]

[Clearance required from AA of the relevant Regional Bureau]

[Clearance required from GH]

[Clearance required from F/IIP]

[Clearance required from LPA]

[Clearance required from GC/Washington or the Regional Legal Advisor]

[Clearance required from COO]

[Bureau]:[Drafter]:[Typist's Initials]:[Desk Phone #]:[Date]: {Document Location and Name}

Sample Template for Split Decision Action Memo

[date]

ACTION MEMORANDUM FOR THE ADMINISTRATOR

FROM: [Assistant Administrator of the relevant Regional Bureau]

SUBJECT: Approval to use Global Health and Child Survival (GH/CS) funds for
[SUMMARIZE PRIMARY USE OF FUNDS]

Bureau A recommends you approve [a specific action]. Bureau B opposes.

Approve_____ Disapprove_____

Alternatively, Bureau B recommends you approve [alternate action]. Bureau A opposes.

Approve_____ Disapprove_____

Background

This memo should indicate that a proposal for the use of funds was discussed with all parties listed for clearance, and a consensus could not be reached.

The memo should also include a detailed description of the activity, how it directly contributes to the relevant Agency Objective(s) (or element), and the expected results. It should outline the pros and cons of moving ahead with the proposed activity, and the relevant external considerations (including political, diplomatic, and programmatic considerations). The memo should also include the amount of funds being requested.

CLEARANCE PAGE FOR INFORMATION MEMORANDUM on approval to use GH/CS funds for [PURPOSE]

[Clearance required from GH]

[Clearance required from F/IIP]

[Clearance required from LPA]

[Clearance required from GC/Washington or the Regional Legal Advisor]

[Clearance required from COO]

[Bureau]:[Drafter]:[Typist's Initials]:[Desk Phone #]:[Date]: {Document Location and Name}

APPENDIX VII: President's Malaria Initiative and Office of Population and Reproductive Health Guidance on the Procurement of Key, Life-saving Commodities

March 30, 2012

Dear USAID Health Officers,

USAID Forward's Implementation and Procurement Reform (IPR) is an important opportunity to strengthen partner country capacity and to improve aid effectiveness and sustainability by increasing use of reliable partner country systems and institutions.

The Global Health Bureau enthusiastically supports IPR and is playing a lead role in institutionalizing this important reform. In many countries where we work, a significant portion of our health and development investment supports life-saving health commodities. In the overwhelming majority of these countries, health commodities are purchased through central mechanisms and then are transferred to governments and local organizations for distribution and use. In addition, we have made significant investments to strengthen health commodity delivery systems.

As countries continue to advance in their economic development and improve health indicators, we anticipate that partner countries will want to explore with the donor community plans for building more self-sufficiency in their health commodity supply chains, including their ability to procure quality health commodities at an appropriate price. At USAID, we fully support dialog and action that help countries move toward self-sufficiency in a manner that:

- Supports a country's public health and development objectives;
- Complements and reinforces the approach taken by the broader donor community;
- Aligns with our global investments and policy stance with respect to key multilateral partners such as the Global Fund and GAVI; and
- Achieves and sustains our commitment to GHI targets.

With support from USAID/Washington, the procurement of health commodities through local systems can be explored, where its design and implementation will support these objectives, mitigate programmatic and fiduciary risk, and is in accordance with applicable USG and USAID requirements.

The attached President's Malaria Initiative and Office of Population and Reproductive Health Guidance on the procurement of key, life-saving commodities lays out specific criteria for local procurement of malaria and family planning/reproductive health (FP/RH) commodities. In addition to the Public Financial Management Risk Assessment, which

assesses fiduciary risks, USAID Missions considering government-to-government agreements or agreements with local non-governmental, including private sector, organizations to procure malaria or FP/RH commodities are required to conduct an additional programmatic risk assessment and develop an associated risk mitigation strategy.

Given the upcoming malaria operational plan development visits, we want to share this guidance without delay. However, USAID is continuing discussions with State/OGAC on the implications of this guidance for our PEPFAR programs and will advise the field on the outcomes of these discussions. In the meantime, I strongly encourage Missions interested in local health commodity procurement to contact the Subject Matter Experts listed below.

In closing, I want to reiterate that GH fully supports the IPR agenda to strengthen in-country capacity by empowering governments, civil society, and the local private sector to impact long term development challenges and improve sustainability. I anticipate that the attached guidance will support Missions to successfully assess additional programmatic risks associated with commodity procurement and craft project designs and agreements with country partners to address risks, build capacity, and support long-term sustainability.

Sincerely,

Subject Matter Experts:

- For PMI (malaria): Sonali Korde (skorde@usaid.gov; 202-712-1609)
- For PEPFAR (HIV/AIDS): John Crowley (jcrowley@usaid.gov; 202-712-0588)
- For Family Planning: Mark Rilling (mrilling@usaid.gov; 202-712-0876)



March 30, 2012

Subject: President's Malaria Initiative (PMI) and Office of Population and Reproductive Health (PRH) guidance on the procurement of key, life-saving commodities (medicines, diagnostics, long-lasting insecticide-treated nets, insecticides for indoor residual spray programs, contraceptives and associated supplies, condoms).

Summary of Guidance

USAID Missions considering Government-to-Government (G2G) agreements or agreements with local non-governmental, including private sector, organizations to procure malaria or family planning/reproductive health (FP/RH) commodities are required to conduct a programmatic risk assessment that addresses, at a minimum, the criteria detailed below. This programmatic risk assessment is in addition to the requirements set forth in ADS 220 for G2G agreements (including the requirements related to the Public Financial Management Risk Assessment Framework (PFMRAF), which addresses fiduciary risk) and requirements set forth in ADS 302 and 303 as they apply to awards to local organizations. In the absence of a programmatic risk assessment and specific approval by the U.S. Malaria Coordinator or Director of the Office of Population and Reproductive Health, commodities procured using USAID funds appropriated for malaria or FP/RH should be procured using pre-approved Bureau for Global Health central mechanisms. (The list of mechanisms for malaria will be updated annually in the PMI Annual Guidance and is attached for 2012. The mechanism for FP/RH is PRH's Central Contraceptive Procurement).

Discussion

a. President's Malaria Initiative

Malaria prevention and control is a major U.S. foreign assistance objective and is a core component of the comprehensive U.S. Government's (USG) Global Health Initiative (GHI), announced in May 2009 by President Barack Obama to reduce the burden of disease and strengthen communities around the world. The 2008 Tom Lantos and Henry J. Hyde Global Leadership against HIV/AIDS, Tuberculosis, and Malaria Act (Lantos/Hyde Act) authorizes up to \$5 billion in USG funding for malaria prevention and control for the period FY2009–2013.

The USG Lantos Hyde-Malaria Strategy for 2009–2014 proposes an expanded approach to USG-

supported malaria control efforts directed at halving the burden of malaria (morbidity and mortality) in 70 percent of at-risk populations in sub-Saharan Africa (approximately 450 million people), thereby removing malaria as a major public health problem and promoting economic growth and development throughout the region. This will be accomplished through the sustained scale up of key malaria prevention and case management interventions, each of which is dependent on the provision of lifesaving commodities:

- Universal coverage of long-lasting insecticide treated nets (LLINs);
- Intermittent preventive treatment of malaria for pregnant women (IPTp) involving the use of sulfadoxine-pyrimethamine (SP);
- Indoor residual spraying (IRS) involving the use of insecticides, sprayers, and personal protective equipment;
- Effective diagnosis and treatment of malaria involving the use of rapid diagnostic tests (RDTs), microscopes and lab supplies, artemisinin-based combination therapy (ACTs), and severe malaria treatments.

Historically, PMI has been allocating 40-50% of country budgets to lifesaving commodities and scale-up of interventions. This allocation and focus on commodities is expected to continue over the next few years with the aim of driving down malaria burden towards the vision of achieving Near Zero Deaths from malaria. PMI's focus on scale-up of evidence-based interventions has demonstrated results. In the last six years, substantial reductions in mortality among children less than five years of age have been recorded together with improvements in coverage with malaria interventions. Of the eleven PMI focus countries (Angola, Ethiopia, Ghana, Kenya, Madagascar, Malawi, Rwanda, Senegal, Tanzania, Uganda, and Zambia), where baseline and follow up health surveys with data on childhood mortality have been conducted, all-cause mortality rates among children less than five years of age have dropped by 16 (Malawi) to 50 percent (Rwanda). This progress in malaria control represents the cumulative effect of malaria funding and control efforts by PMI, targeted funding from the USG prior to PMI, national governments, the Global Fund, World Bank, and other donors.

b. Family Planning and Reproductive Health

Reducing unintended pregnancy is also a major U.S. foreign assistance objective and a core component of the Global Health Initiative. The USG's objective for FP/RH is to reduce unintended pregnancy by expanding access to high-quality, voluntary family planning services and information and reproductive health care on a sustainable basis. This enhances the ability of couples to decide the number, timing, and spacing of births, and makes substantial contributions to reducing abortion, to reducing maternal and child mortality and morbidity, and to mitigating adverse effects of population dynamics on natural resources, economic growth and state stability. Under GHI, the following FP/RH targets were established:

- Prevent 54 million unintended pregnancies over the course of the GHI.
- Increase modern contraceptive prevalence by up to two percentage points annually on average across assisted countries.
- Reduce first births to women under age 18 by 15 percent.
- To meet these goals, Mission country programs strive towards improvements in:
 - Modern contraceptive prevalence rate overall and in the lowest two wealth quintiles.
 - Proportion of demand for family planning satisfied with modern FP methods.
 - Proportion of births spaced at least three years apart.
 - Proportion of women aged 20-24 who had their first birth before age 18.
 - Proportion of births that are parity five or higher.

The selection and prioritization of programming approaches and areas of focus differ across countries. In most Sub-Saharan African and South Asian countries, unmet need remains high and actual family size continues to exceed desired family size. FP/RH programs are designed to increase awareness of, access to, and voluntary use of family planning. The principal challenges include increasing contraceptive availability, decreasing stockouts, reducing unmet need particularly of poor and rural families, and increasing contraceptive choice across a range of modern contraceptive methods. In Latin America and East Asia, a number of countries are approaching graduation from USG FP/RH assistance. In these countries, the principal challenges are to address sub-national disparities and inequities in access to FP/RH services as well as to solidify program sustainability. In Eastern European countries, the total fertility rate is often at or below replacement and abortion is widely used as a method of fertility control. The USG programs in this region are designed to increase awareness and use of contraception as a substitute for abortion.

Program maturity as measured by the modern contraceptive prevalence rate is used as a guide to the selection and prioritization of programming approaches. It is also an important guide in considering G2G agreements or agreements with local organizations for the procurement of contraceptives and condoms. Annex 3 provides guidance for these considerations based on low, medium and high modern contraceptive prevalence—and suggests priority areas of programmatic emphasis in each category.

c. PMI, PRH, and USAID Forward

PMI and PRH fully support the USAID Forward and Implementation and Procurement Reform (IPR) agendas to strengthen in-country capacity by empowering governments, civil society, and the local private sector to impact long-term development challenges and improve sustainability. PMI and PRH encourage country teams to continue to further expand and build upon existing funding agreements for G2G and local organizations provided that the use of the funds is consistent with the objectives of PMI and/or PRH and in line with applicable requirements for G2G agreements (e.g., the PMFRAF) and for agreements with local organizations. For PMI,

these proposed agreements must be reviewed as part of the interagency PMI malaria operational plan review and approval process.

d. PMI and PRH Commodity Procurement and IPR: Specific Risks and Challenges

PMI and PRH support the establishment of high-performing, accountable, country-owned procurement and supply chain systems to ensure a secure, long-term supply of high-quality malaria and FP/RH commodities. Requirements applicable to G2G (e.g., PFMRAF) and those applicable to working with local organizations (e.g., responsibility determination) are intended to address certain political and financial risks associated with these agreements. Additional programmatic risks and policy issues pertaining to the local procurement of malaria and FP/RH commodities through G2G or local partner organizations must be addressed before the Agency moves forward with a proposed project in this area. The additional considerations for malaria and FP/RH commodities are listed below.

- 1. Any interruption in the supply of malaria and/or FP/RH commodities will have immediate consequences with respect to malaria morbidity and mortality, and/or unplanned pregnancy.** For example, an interruption of ACT supply in Kenya was associated with an immediate increase in under-five mortality.¹ In Rwanda, the National Malaria Control Program documented a significant upsurge in the number of malaria cases, after a three-year sustained period of declining cases, following a 12-month delay in the procurement of Global Fund-financed LLINs.

In Bangladesh, an increase in contraceptive stock outs nationwide, caused in large part by delays in procurement, was associated with a decline in modern contraceptive prevalence and an increase in unintended pregnancies, many of which ended in abortion. Data from countries in Eastern Europe and Central Asia, where use of modern contraception was long delayed, shows that beginning in the 1990s increases in the use of modern family planning methods have been strongly correlated with declines in abortion rates. Further, contraceptive use has a profound impact on maternal mortality. Declines in total fertility from 1990 to 2005, due primarily to increasing use of contraception, resulted in 1.2 million fewer maternal deaths. These health impacts are not possible without reliable access to quality, affordable contraceptives.

- 2. Malaria pharmaceuticals have well-documented quality assurance issues and all USAID-procured malaria pharmaceuticals must adhere to stringent quality assurance requirements referenced in ADS 312 as well as specific malaria technical testing protocols and product selection criteria.** Since malaria is not endemic in the

¹ A Reversal in Reductions of Child Mortality in Western Kenya, 2003-2009; Hamel, et.al. American Journal of Tropical Medicine and Hygiene. Am J Trop Med Hyg **2011** vol. 85 no. 4 **597-605**

United States or Western Europe, there have been limited incentives for pharmaceutical companies to develop and then submit dossiers for medicines indicated in the treatment of malaria for approval through the U.S. Food Drug Administration or other stringent regulatory authorities. In addition, as documented in peer-reviewed literature, malaria medicines are also prone to being widely counterfeited and or adulterated to a substandard level, likely contributing to increased mortality and selecting for drug resistance.²

There have been, and are on-going, serious cases of theft and loss involving both USAID- and Global Fund-financed malaria commodities, particularly ACTs, in several African countries. These thefts have mostly occurred after ownership and legal chain of custody of donated commodities has been transferred to recipient host country control. Malaria commodities may be at greater risk for theft and diversion due to the common practice of treating all fevers in endemic areas with antimalarials and to the inherent, high value for malaria ACTs in informal markets in Africa. Due to several open USAID and Global Fund Inspector General investigations in several countries, PMI would need to apply additional safeguards to address this issue.³

- 3. Insecticides for indoor residual spraying and long-lasting insecticidal nets are also restricted commodities and subject to strict environmental regulations, specified in Regulation 22 CFR 216 and operationalized in USAID’s Vector Control Programmatic Environmental Assessment,** which dictates that country-level environmental assessments and mitigation plans are required for any country implementing IRS, with any insecticide. Such mitigation plans require assurance that insecticides have been managed from procurement to disposal. LLINs do not require country-level assessments but are required to adhere to procurement regulations on insecticides that are safe for human use.
- 4. PMI notes the recommendations from the High Level Independent Review Panel on Fiduciary Controls for the Global Fund to Fight AIDS, TB and Malaria on pooled procurement of commodities.** The report and its recommendations were fully endorsed by the U.S. Government. The High Level Panel Report on Fiduciary Controls and Oversight Mechanisms of the Global Fund to Fight AIDS, Tuberculosis and Malaria⁴ states that the procurement and management of pharmaceuticals and medical products

² Poor Quality Vital Antimalarials in Africa-an urgent neglected health priority; Newton et al. Malaria Journal 2011, 10:352 <http://www.malariajournal.com/content/10/1/352>

³ For G2G agreements, see Section 7031 of the FY2012 State, Foreign Operations and Related Programs Appropriations Act, which states that “no level of acceptable fraud is assumed.”

⁴ <http://www.theglobalfund.org/en/highlevelpanel/>

poses larger risks to the Global Fund's finances, operations, and reputation than any other activity. The report goes on to recommend that Global Fund grants centralize pooling of procurement of health commodities as the default mode.

e. Programmatic Risk Assessment Criteria for Considering Procurement of Malaria and FP/RH Commodities through G2G Mechanisms or Local Institutions

PMI and PRH recognize that certain countries may wish to explore local procurement for select malaria and/or FP/RH commodities in support of IPR objectives. Specific approval by the U.S. Malaria Coordinator or Director of the Office of Population and Reproductive Health (Bureau for Global Health) will be required for any procurement of malaria or FP/RH commodities, respectively, through G2G agreements or agreements with local non-governmental or other private sector organizations.

Due to the considerations listed above, a programmatic risk assessment that addresses the minimum criteria described below will be required prior to the U.S. Malaria Coordinator's or PRH Director's approval. The findings of the programmatic risk assessment will factor significantly in their decision making. In the absence of this programmatic risk assessment and specific approval by the U.S. Malaria Coordinator or PRH Director, commodities procured using USAID funds appropriated for malaria or FP/RH shall be procured using pre-approved Bureau for Global Health central mechanisms. (The list of mechanisms for procurement of malaria commodities will be updated annually in the PMI Annual Guidance and is attached for 2012. The mechanism for FP/RH commodities is PRH's Central Contraceptive Procurement, CCP.)

This programmatic risk assessment is in addition to other applicable requirements for G2G agreements and agreements with local organizations. For G2G activities, a Mission must comply with the requirements of ADS 220 including the requirement for a favorable PFMRAF for the specific entity proposed to receive malaria or FP/RH funds. As part of that process, the recipient country must demonstrate that risk mitigation measures are in place or in progress for any significant weaknesses found. There should be detail on how funding flows through the host government system and clarity on which entity receives and is ultimately accountable for the funding. Highly conservative financial risk mitigation measures should be in place to manage funding for malaria and FP/RH commodities. Depending on the country, funding flows for health commodities may move through the Ministry of Finance, Ministry of Health, or a parastatal entity (e.g., central medical store or medical supplies department). In addition, G2G activities must comply with the statutory requirement set forth in Section 7031 of the FY2012 State, Foreign Operations and Related Programs Appropriations Act (See Annex 2). Agreements with local organizations must comply with requirements applicable to assistance and acquisition agreements, including the requirement to obtain a responsibility determination.

Missions must prepare a programmatic risk assessment report that addresses the factors set forth below, for approval by the U.S. Malaria Coordinator or Director of PRH, as applicable:

- 1. Agreement on Quality Assurance Requirements and Standards for Procurement of Pharmaceuticals:** There should be an agreement between the host government entity (for G2G) or the local organization, as applicable, and the relevant USAID operating unit to adhere to quality-control requirements equivalent to those set forth in ADS 312 in addition to adherence to PMI's and/or PRH's specific regulatory authority approval requirements and testing protocols.
- 2. Agreement on Environmental Management and Mitigation Measures for Insecticides and Related Commodities and Medical Waste:** USAID must comply with the environmental regulations set forth in 22 CFR 216. Addressing those regulations should include agreement between the host country government, for G2G, or local organization, as applicable, and the USAID operating unit that they will adhere to environmental regulations equivalent to those in Regulation 22 CFR 216. Missions should work with their Regional Legal Advisor and environmental officers to address this issue.
- 3. Sufficient Evidence to Demonstrate Minimum Risk to Program Outcomes (Mortality/Transmission)—Do No Harm:** There should be evidence from the programmatic risk assessment to demonstrate the recipient government's or local institution's capacity to successfully manage commodity funding and minimize any risk on program outcomes. The recipient or local organization should have a demonstrated successful track record in managing the procurement and distribution of health commodities to ensure uninterrupted supply that meets clients' needs.

For malaria, there should be a demonstrated successful track record specifically in managing all Global Fund-financed malaria commodities. This would also include a demonstrated track record of ensuring arrival of LLIN and IRS commodities in time to meet LLIN campaign and seasonal IRS spray schedules and ensuring uninterrupted supply of malaria ACTs and RDTs at all levels in the distribution system.

For FP/RH, there should be a demonstrated successful track record of allocating country-managed budgets for contraceptives and condoms, using third party or local institutions for procurement and ensuring full supply of a range of contraceptives and condoms at all levels in the distribution system. In addition, USAID funds must ensure an acceptable mix of modern contraceptive methods and not be used to support programs where one method predominates.

For both malaria and FP/RH, the assessment should use agreed-upon **quantitative** benchmarks of stock outs at each level in the supply system, e.g., 10 percent at the peripheral

(health facility) levels.

The programmatic risk assessment should include **a rapid appraisal of capacity in supply chain functions such as, but not limited to, quantification, selection, inventory, distribution, quality assurance and environmental risk management.**

- 4. Sufficient Evidence to Address Issues of Fraud.** There should be a determination that no outstanding facts or credible allegations would negatively impact a responsibility determination of the host government or local organization. Where such information exists, the host government or local organization must adequately respond to such information and satisfy USAID that corrective actions have been taken and/or that a valid mitigation plan is in place to address the risk. For example, a responsibility determination would be adversely impacted in the case that there are known ongoing USAID Inspector General or Global Fund Office of Inspector General investigations triggered by allegations related to the entity or funding stream in question. In addition, there should be no adverse USAID Inspector General or Global Fund Office of Inspector General audit or investigations report with outstanding recommendations or findings for the country in question that would affect the responsibility of the host government or local entity. An internal control assessment of the supply chain may also be required to meet this condition. There should be written agreement between the recipient country and/or local organization and USAID on audit rights.
- 5. Sufficient Evidence to Ensure that FP/RH Statutory and Policy Requirements Are Met:** USAID's family planning activities are subject to a number of statutory and policy requirements, many of which reflect the principles of voluntarism and informed choice that have guided USAID's family planning activities for decades. These principles are articulated in program guidelines and a number of legislative and policy requirements that govern the use of U.S. family planning assistance. USAID takes these family planning requirements very seriously and USAID/Washington works with Missions and partners to ensure [compliance](#) with the family planning requirements in their programs as part of routine monitoring of program implementation. Programs or activities where the commodities will be distributed must be in compliance with these requirements. Missions should work with their Regional Legal Advisors to understand the applicability of these requirements to the proposed project.
- 6. Agreement on Systems to Ensure Adequate Transparency, Accountability and Communication:** There should be agreement with the recipient government and/or local entity on regular communication, reporting and monitoring and evaluation requirements needed to ensure that USAID funds are used for their intended purpose and programmatic gain. This will entail independent inspections and testing of goods procured, spot inventory

checks, environmental assessments, health facility and warehouse visits/surveys, and other internal control assessments.

- 7. Commodity pricing, cost sharing, and competition:** The programmatic risk assessment should examine the extent to which the host country government or local organization achieves cost efficiencies through transparent tendering processes in the procurement of health commodities. This includes adhering to competitive bidding processes and price ceilings for delivered prices based on international (e.g., Global Fund’s Price and Quality Reporting mechanism) or USAID documented price benchmarks. For FP/RH, this should include attention to product selection, ensuring rational decisions based on programmatic utility (e.g., hormones selected as well as their dosage, regimen and presentation), drawing on accepted essential medicines lists and standard treatment guidelines using WHO as a reference.

f. Additional Design Considerations

In addition to the programmatic risk assessment, there are important technical considerations related to malaria and FP/RH procurement and supply chain that should be incorporated into the Project Appraisal Documents and final agreements with the recipient government or local entity. PMI, PRH, and GH Bureau Supply Chain technical experts can provide assistance in this area. The following list, while not exhaustive, includes additional design elements that should be considered:

- **Phasing and scalability of the project. Commodities and increased dollar values should be phased over time based on demonstrated success against benchmarks;**
- **Agreement on standardized performance-based metrics and indicators (Performance Monitoring Plan);**
- **Identification of accompanying technical assistance, as needed.**
- There should be an agreed-upon level of cost sharing with the recipient government. See Annex 3 for guidance on cost-sharing for FP/RH commodities.

Other design considerations will likely emerge from the risk assessment and risk mitigation strategy. For example, certain risk mitigation measures may be built into the project design and their completion serve as benchmarks for continuation or expansion of the project.

g. Additional Legal Requirements

Missions must also ensure compliance with the Agency’s source and nationality rules set forth in ADS 310, unless waivers are available. In addition, for the procurement of pharmaceuticals, Missions must ensure compliance with **Section 606(c) of the Foreign Assistance Act of 1961**,

as amended (FAA), which provides that USAID cannot finance a pharmaceutical that is manufactured outside the United States, if the pharmaceutical is covered by a valid U.S. patent, unless the U.S. patent owner expressly authorizes the manufacture of the pharmaceutical. Without such an express authorization, the pharmaceutical must be purchased from the U.S. patent holder. Missions should work with their Regional Legal Advisors to ensure compliance with these requirements.

Annex 1:

FY2012 and FY2013 PMI Non-IRS Central Commodities Mechanisms

Missions that have not completed the aforementioned programmatic risk assessment for G2G or local entity procurement must use the centrally managed DELIVER Malaria Task Order 7 Project (the follow-on to the previous Malaria Task Order 3 Project) for all non-IRS PMI commodities. The only allowable exception from this policy is for those countries where UNICEF has historically supported the procurement of malaria commodities (primarily LLINS). If Missions wish to take advantage of the UNICEF mechanisms, please contact Jennifer Murphy at jmurphy@usaid.gov for information on the requirements of Quality Assurance and Quality Control (QA/QC) protocols.

FY 2012 and FY2013: IRS Mechanisms

Missions that have not completed the aforementioned programmatic risk assessment for G2G or local entity procurement must use one of the following mechanisms to procure IRS-related commodities: the centrally managed IRS IQC 2 Task Order 4, a bilateral task order under the IRS IQC 2, or directly via the USAID Mission. The only allowable exception from this policy is for those countries that already have a MOP-approved bilateral award or follow on. If Missions would like to procure insecticides directly, please contact Elissa Jensen at eljensen@usaid.gov to go over requirements on QA/QC protocols, technical requirements including waiver requirements for procurement of restricted commodities, and competition.

Annex 2:

<http://www.gpo.gov/fdsys/pkg/BILLS-112hr2055enr/pdf/BILLS-112hr2055enr.pdf>

FINANCIAL MANAGEMENT AND BUDGET TRANSPARENCY SEC. 7031. (a) LIMITATION ON DIRECT GOVERNMENT-TO-GOVERNMENT ASSISTANCE

- (1) Funds appropriated by this Act may be made available for direct Government-to-Government assistance only if—
- (A) each implementing agency or ministry to receive assistance has been assessed and is considered to have the systems required to manage such assistance and any identified vulnerabilities or weaknesses of such agency or ministry have been addressed; and
 - (i) the recipient agency or ministry employs and utilizes staff with the necessary technical, financial, and management capabilities;
 - (ii) the recipient agency or ministry has adopted competitive procurement policies and systems;

- (iii) effective monitoring and evaluation systems are in place to ensure that such assistance is used for its intended purposes; and
 - (iv) no level of acceptable fraud is assumed.
- (B) the Government of the United States and the government of the recipient country have agreed, in writing—
- (i) on clear and achievable objectives for the use of such assistance; and
 - (ii) that such assistance should be made on a costreimbursable basis.
- (2) In addition to the requirements in subsection (a), no funds may be made available for such assistance without prior consultation with, and notification to, the Committees on Appropriations: *Provided*, That such notification shall contain an explanation of how the proposed activity meets the requirements of paragraph (1): *Provided further*, That the requirements of this paragraph shall only apply to direct Governmentto-Government assistance in excess of \$10,000,000 and all funds available for cash transfer, budget support, and cash payments to individuals.
- (3) The USAID Administrator or the Secretary of State, as appropriate, shall suspend any such assistance if the Administrator or the Secretary has credible information of material misuse of such assistance, unless the Administrator or the Secretary determines and reports to the Committees on Appropriations that it is in the national interest of the United States to continue such assistance.
- (4) Not later than 90 days after the enactment of this Act and 6 months thereafter, the USAID Administrator shall submit to the Committees on Appropriations a report that—
- (A) details all assistance described in subsection (a) provided during the previous 6-month period by country, funding amount, source of funds, and type of such assistance; and
 - (B) the type of procurement instrument or mechanism utilized and whether the assistance was provided on a cost-reimbursable basis.
- (5) The USAID Administrator shall submit to the Committees on Appropriations, concurrent with the fiscal year 2013 congressional budget justification materials, amounts planned for assistance described in subsection (a) by country, proposed funding amount, source of funds, and type of assistance.
- (b) NATIONAL BUDGET AND CONTRACT TRANSPARENCY.—
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- (1) LIMITATION ON FUNDING.—None of the funds appropriated

under titles III and IV of this Act may be made available to the central government of any country that does not meet minimum standards of fiscal transparency: *Provided*, That the Secretary of State shall develop “minimum standards of fiscal transparency” to be updated and strengthened, as appropriate, to reflect best practices: *Provided further*, That the Secretary shall make an annual determination of “progress” or “no progress” for countries that do not meet minimum standards of fiscal transparency and make those determinations publicly available in an annual “Fiscal Transparency Report”.

(2) MINIMUM STANDARDS OF FISCAL TRANSPARENCY.—For purposes of paragraph (1), “minimum standards of fiscal transparency” shall include standards for the public disclosure of budget documentation, including receipts and expenditures by ministry, and government contracts and licenses for natural resource extraction, to include bidding and concession allocation practices.

(3) WAIVER.—The Secretary of State may waive the limitation on funding in paragraph (1) on a country-by-country basis if the Secretary reports to the Committees on Appropriations that the waiver is important to the national interest of the United States: *Provided*, That such waiver shall identify any steps taken by the government of the country to publicly disclose its national budget and contracts which are additional to those which were undertaken in previous fiscal years, include specific recommendations of short- and long-term steps such government can take to improve budget transparency, and identify benchmarks for measuring progress.

(4) ASSISTANCE.—Of the funds appropriated under title III of this Act, not less than \$5,000,000 should be made available for programs and activities to assist the central governments of countries named in the list required by paragraph (1) to improve budget transparency or to support civil society organizations in such countries that promote budget transparency: *Provided*, That such sums shall be in addition to funds otherwise made available for such purposes.

(c) ANTI-KLEPTOCRACY.—

(1) Officials of foreign governments and their immediate family members who the Secretary of State has credible information have been involved in significant corruption, including corruption related to the extraction of natural resources, shall be ineligible for entry into the United States.

(2) Individuals shall not be ineligible if entry into the United States would further important United States law enforcement objectives or is necessary to permit the United States to fulfill its obligations under the United Nations Headquarters

Agreement: *Provided*, That nothing in this provision shall be construed to derogate from United States Government obligations under applicable international agreements.

(3) The Secretary may waive the application of paragraph (1) if the Secretary determines that the waiver would serve a compelling national interest or that the circumstances which caused the individual to be ineligible have changed sufficiently.

(4) Not later than 90 days after enactment of this Act and 180 days thereafter, the Secretary of State shall submit a report, in classified form if necessary, to the Committees H. R. 2055—427

on Appropriations describing the information regarding corruption concerning each of the individuals found ineligible pursuant to paragraph (1), a list of any waivers provided under subsection (3), and the justification for each waiver.

Annex 3: GUIDANCE ON COST-SHARE FOR FP/RH COMMODITIES BY COUNTRY CLASSIFICATION

Low Prevalence (<10% MCPR) countries characterized by:

- High fertility rates
- Low contraceptive access and use
- Demand may be low or unsatisfied demand may be high
- Highest unmet need tends to be in higher wealth quintiles

Program focus:

- Train health personnel
- Provide information and counseling, including healthy birth spacing
- Expand contraceptive supplies and distribution
- Improve access and quality to reach underserved
- Create supportive policy environment

G2G or local non-governmental cost-share for commodity procurement:

- 1:1 cost-share match between host country organization and USAID Mission

Medium Prevalence (10-50% MCPR)

- Declining fertility rates
- High unsatisfied demand and rapidly increasing prevalence
- Expanding, but limited method mix

Program focus:

- Expand method choice, including long-term methods
- Fund rapid expansion of services
- Expand supplies and services through private sector
- Address operational policy barriers
- Address gender norms and equity issues

G2G or local non-governmental cost-share for commodity procurement:

- 10-30% MCPR has a 60:40 cost-share between host country organization and USAID Mission
- 30-40% MCPR has a 70:30 cost-share between host country organization and USAID Mission
- 40-50% MCPR has a 80:20 cost-share between host country organization and USAID Mission

High Prevalence (50+% MCPR)

- Low fertility
- High contraceptive prevalence

Program focus:

- Quality
- Availability of long-term methods
- Expanding private sector participation
- Sustainability, contraceptive security, and financing
- Attention to underserved populations, including adolescents

- Address equity in access to services
- Graduation

G2G or local non-governmental cost-share for commodity procurement:

- Graduation plan developed to move to full funding by host country organization without cost share by USAID Mission

CLEARANCE PAGE FOR PMI Guidance on the Procurement of Key, Life-saving Commodities (medicines, diagnostics, long lasting insecticide treated nets, and insecticides for indoor residual spray programs

GH/AA, AMendez	_____	Date_____
GH/AA, TZiemer	_____	Date_____
GH/AA, WWarren	_____	Date_____
GH/AA, BNahlen	<u>Clear</u> _____	Date <u>email 3/14/12</u>
GH/PRH, SRadloff	<u>Cleared E. Starbird</u> _____	Date <u>email 3/30/12</u>
GH/HIDN, JWallace	<u>Clear</u> _____	Date <u>email 3/13/12</u>
LPA, Barbara Bennett	<u>Clear</u> _____	Date <u>email 3/19/12</u>
CFO, Tom Briggs	<u>Clear</u> _____	Date <u>email 3/19/12</u>
GC/G, GGirod/DWeed	<u>Clear</u> _____	Date <u>email 3/13/12</u>
GC/G, MMcLaughlin	<u>Clear</u> _____	Date <u>email 3/30/12</u>
GH/HIDN, EFox	<u>Clear</u> _____	Date <u>email 3/15/12</u>
GH/HIDN, EJensen	<u>Clear</u> _____	Date <u>email 3/13/12</u>

HIDN Contact: S. Korde 2-1609

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