

Analysis of the U.S. Global AIDS Program and the PEPFAR Supply Chain Management System (SCMS)

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BACKGROUND

On September 27, 2005, USAID announced a contract to a consortium of 15 companies and institutions for a Supply Chain Management System (SCMS). The consortium is charged with management, procurement, quality assurance, and delivery of all medicines and medical commodities for HIV/AIDS treatment and care programs receiving PEPFAR and US government funding in developing countries.ⁱ The contract sets aside \$77 million in operating expenses and technical assistance over the first three years according to the USAID statement announcing the award. The contract provides a guaranteed minimum amount as \$2.5 million and a ceiling of \$7 billion. Previous USAID statements estimated that \$4 billion would be spent for the purchase of pharmaceuticals needed to meet PEPFAR's stated goal of providing antiretroviral (ARV) therapy for 2 million people by 2008.

CONCERNS

A U.S.-centralized system based with a one-size-fit-all approach is not a sustainable solution: The primary concern with a centralized U.S.-run system is that it is not a sustainable or efficient solution to persistent problems in supply chain management at the local level in all overseas HIV/AIDS programs receiving U.S. funding. (In addition to the 15 PEPFAR focus countries, the U.S. Global AIDS Initiative funds HIV/AIDS programming in an additional 80-plus countries, and, in two years, all countries receiving funding from the Global Fund to Fight AIDS, TB, and Malaria will also be eligible to utilize the SCMS.) While the SCMS may be described as a "one-stop shop" by OGAC and USAID, each country has a different matrix of indigenous supply chain capacity drawing on public, private, and NGO distribution networks. Although the U.S. SCMS contract proposes that the consortium should try to rely upon and strengthen existing supply chain systems, the major focus of the contract is developing a global supply chain that in many instances will bypass and/or duplicate local systems. To achieve efficiency, let alone sustainability, it would be far better to focus on strengthening existing systems, both public and private, rather than create a monolithic, short-term, silo-system that will prove once again that one-size doesn't fit all.

A parallel SCMS process could undermine domestic efforts to build sustainable capacity: The SCMS could further erode efforts at the local and national level to build sustainable capacity. Although USAID and OGAC stress capacity building in the announcement of the grant, the SCMS Statement of Work (SOW) does not specifically call for local groups—including existing drug supply organizations (DSOs), government agencies, and other bodies—to be included in the planning and implementation of SCMS at the national level. Likewise, although the SOW was revised multiple times, one persistent and troubling aspect was the over-reliance on large international institutions and organizations to create a new system rather than collaboration with local entities and agencies. These local groups—including many non-profit DSOs that have been supplying ARVs—need capacity building rather than a U.S.-centralized system buying drugs on their behalf.ⁱⁱ Instead of promoting national ownership and initiative in improving current procurement systems and instead of prioritizing capacity building for domestic drug supply organizations and public sector procurement bodies, the SCMS risks undermining national efforts and initiative with its pre-packaged, made-in-America solution.

Already there are problems where facilities receiving multiple streams of funding (e.g PEPFAR, GFATM, and/or private funding) have difficulty in managing complex reporting requirements and different OGAC procurement rules, which strain already constrained resources. Rather than creating uniformity at the facility level to ease the workload and confusion, or at the national level to build national capacity, SCMS seeks uniformity and harmonization at the PEPFAR-system level.

The SCMS promotes privatization instead of public sector capacity: The majority of the partnership members are private for-profit U.S. corporations, which while in keeping with a U.S. agenda towards greater privatization of social and health services, runs counter to many local civil society movements which have long time been advocating for public sector responsibility and greater cohesion, where possible, with the private not for profit groups, including those ecumenical groups that now provide so many services in the PEPFAR focus countries.

A parallel SCMS process could undermine smaller, but effective supply chain entities: According to WHO and others experts, the lessons learned to date is that "not-for-profit private central medical stores have proven sustainability without external subsidy" in many countries and "can also be natural partners for pooled procurement initiatives." While the SOW points to strengthening of local capacity as an extra function of the SCMS, the work of an intermediary consortium is not needed when and where local capacity already exists and is proven to be working well. This extra level of administration benefits the consortium members and their high-level partners rather than local entities, which, if supported, could certainly play a major role at the country level in supply and distribution. Also, some DSOs that currently supply many PEPFAR funded facilities, such as mission hospitals, claim they will be unable to compete with the SCMS (including on the vendor side in terms of priority order and prices). An important opportunity to build up these local DSO (and functioning public sector bodies) to buy drugs and manage their own supply system will have been lost.

Until it was revised to allow voluntary participation, the SOW stated use of the SCMS by PEPFAR-funded facilities was mandatory. However, it is unclear whether the vast majority of facilities providing treatment and care and receiving funds from PEPFAR will have true autonomy to self-select SMCS services or chose to use existing drug supply organizations (DSOs) and systems. It seems much more likely that those decisions will be made at the control level-whether by USAID/CDC/embassies/or coordinating agencies or by primary partners.

The SCMS will be costly and inefficient because of high overhead costs: The new system is ambitious in size and spending, but compared with existing systems it is also wasteful because it adds extra layers of costs due to high overhead (layers of management, administration, and expensive U.S.-based consultants). Many of the consortium partners have in-house expertise and others have access to a network of technical experts. However, the costs of posting a large number of U.S.-based managers and experts in developing countries costs is quite high, especially when compared to the cost of local experts. Moreover, the lack of local knowledge will add to the expense of expatriate consultants, who will incur informational transaction costs in acclimating themselves to local conditions.

The SCMS is precluded from sourcing non-U.S. and non-U.S.-approved medicines adding to cost and creating chaos where local treatment guidelines mandate alternative medicines: SCMS must adhere to current U.S. procurement policies regarding Source, Origin and Nationality Requirements for non-ARV medicines (which shuts out non-U.S. local or regular suppliers of simple drugs like antibiotics), and regarding ARVs (which restricts procurement to drugs that have received at least tentative marketing approval by the US FDA).

Because the U.S. has set up a time-consuming approval process for generic antiretrovirals, no therapeutically appropriate three-in-one fixed dose combination medicines have received tentative approval from the FDA so as to be eligible for procurement by PEPFAR. These fixed-dose combination medicines are crucial in treating AIDS because they simplify treatment protocols, simplify product

procurement and distribution, ease patients' pill burden, promote treatment adherence, and reduce medicines splitting. In contrast to the U.S., the WHO Prequalification Project has already approved fixed-dose combinations from multiple suppliers using Good Manufacturing Practice quality and bio-equivalence standards that are virtually identical to those used in the U.S. These lower-cost, pre-qualified generics of assured quality are already being used to treat hundreds of thousands of people with AIDS worldwide.

Moreover, many PEPFAR contractees have not been given the green light to procure, or in some cases even notification of the existence of, FDA-approved generic antiretrovirals. Even though these generics are much more affordable than their brand-name equivalents, a multi-year SCMS tender, solicited from uninformed PEPFAR contractees, could effectively preclude access to lower-cost generic drugs thereby wasting scarce treatment resources.

Finally, the FDA approval system precludes procurement of some of the newest and most effective medicines because fast-track approval is not possible where data exclusivity rules prevent comparison of generic bio-equivalence data with the originator's FDA marketing approval data. Under current rules, originators are entitled to five-years of data exclusivity for new chemical entities, meaning that some very important second-generation AIDS medicines will have single-source suppliers only.

CONCLUSION: Sustainability is threatened

PEPFAR has the potential to make a difference. But to guarantee sustainable programmes and to break the yoke of dependence and build national dignity, support should ensure full participation and capacity building of the local partners and the existing health infrastructures. While PEPFAR rightly focuses on getting treatment to the patients as soon as possible, its vertical one-donor approach may collapse the very system it needs to strengthen.ⁱⁱⁱ
- Ecumenical Pharmaceutical Network (EPN) Newsletter

A key question is how much SCMS money will go to building local expertise through in-country recruitment and staffing for key roles throughout the supply chain management. SCMS could become another negative case study for public health students in decades to come. Like other similar international procurement systems including malaria and smallpox delivery systems that replaced local agencies and groups and then dissipated, SCMS could leave nothing in its place.^{iv}

The SCMS will further fracture rather than improve integration needed to better strengthen health systems at the national level. Whereas the SCMS is limited to drugs for the treatment of HIV/AIDS and related diseases, greater coordination and support for local systems could help to address procurement and supply chain capacity for the entire spectrum of medical supplies needed for public and private health care. According to USAID's frequently asked questions on the SCMS contract: "There is an 'expectation' that the SCMS will phase out and devolve to local partners and beneficiaries."^v However, local groups will be poorly equipped to take over since SCMS exacerbates the specialization of ARV procurement and distribution, rather than growing transferable experience for projecting need and supplying reliable quantities of high quality medicines. Also, without experience, training, and opportunity to procure ARVs (including projections), ARVs and HIV/AIDS therapy will become less integrated into public health systems and general health care.

RECOMMENDATIONS

- The **Office of the Global AIDS Coordinator** should outline clear and specific requirements for local participation in the planning and development of SCMS and convene a meeting of procurement agents and local drug supply organizations to develop guidelines and rules for engagement between the Partnership and local bodies.
- The **U.S. Congress** should engage a third party for a review process, including monitoring and reporting on the SCMS impact on local capacity and the Partnership's performance in assisting local systems, especially the existing local agencies that already meet a threshold for capacity. Congress should as well appropriate funds directly to existing procurement systems...in anticipation of the turnover for local control at the end of the program.
- The **SCMS Partnership members** should work with civil society groups and existing drug supply organizations to develop a code of principles and practices in order to ensure the greatest level of participation in the planning and implementation process. Members should also be transparent in their procurement arrangements and agreements and regularly disclose the cost of administration and overhead.

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ⁱ The Partnership for Supply Chain Management includes: Affordable Medicines for Africa - Johannesburg, South Africa; AMFA Foundation - St. Charles, Ill.; Booz Allen Hamilton - McLean, Va.; Crown Agents Consultancy, Inc. - Washington, DC; Fuel Logistics Group (Pty) Ltd. - Sandton, South Africa; International Dispensary Association - Amsterdam, Netherlands; JSI Research and Training Institute, Inc. - Boston, Mass.; Management Sciences for Health, Inc. - Boston, Mass.; The Manoff Group, Inc. - Washington, DC; MAP International - Brunswick, Ga.; The North-West University - Potchefstroom, South Africa; Northrop Grumman Information Technology - McLean, Va.; Program for Appropriate Technology in Health - Seattle, Wash.; UPS Supply Chain Solutions- Atlanta, Ga.; Voxiva, Inc. - Washington, DC

ⁱⁱ Existing nation not for profit drug supply organizations that currently have capacity which could be strengthened through funding and assistance: MEDS, Kenya; Joint Medical Stores, Uganda; Christian Health Association of Zambia (CHAZ), Chan pharmaceuticals in Nigeria; Drug supply department of Eglise du Christ du Congo, DRC; Catholic Drug Centre, Ghana; ASSOMESCA in Central African Republic; Pharmaceutical unit of Cameroon Baptist Convention, Cameroon. Others that could benefit from technical assistance, support: BUFMAR in Rwanda, MEMS in Tanzania, Pharmaceutical department of Malawi (CHAM).

ⁱⁱⁱ "Is PEPFAR a Knight in Shining Armour or a Trojan Horse?" Ecumenical Pharmaceutical Network (EPN) Newsletter, 2004. Also upon request, a letter from EPN to USAID regarding SCMS, 2004.

^{iv} "Addressing the HIV/AIDS Pandemic: A U.S. Global AIDS Strategy for the Long Term," Council on Foreign Relations and Milbank Memorial Fund, 2004, page 11.

^v From the USAID Request for Applications: "The SCMS contractor shall develop credible plans to phase out and devolve activities and management to local partners and beneficiaries. These plans will include a timeline for the achievement of organizational or human capacity sustainability and track progress towards that end. Contractor performance will be evaluated, in part, on the progress towards the accomplishment of the phase-out plan and how capacity will be transferred to host country groups over the full five-year award period."