Testimony of USAID Senior Deputy Administrator, Bureau for Global Health, Irene Koek before the House Foreign Affairs Committee; Sub-Committee On Africa, Global Health, Global Human Rights, and International Organizations

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Introduction

Thank you, Chairman Smith, Ranking Member Bass, Members of the Subcommittee. I appreciate this opportunity to discuss the U.S. Agency for International Development's (USAID's) work to ensure critical, life-saving medicines and health supplies reach intended recipients in a secure, timely, and cost-efficient manner.

Around the world, health workers, whether community or facility-based, are the first line for public health, as they provide testing and treatment for malaria, distribute treatments for other childhood diseases, and fill prescriptions for anti-retroviral medicines (ARVs) for people who are living with HIV. The health successes of the networks of these health workers depend on the effectiveness of the supply chains that procure and distribute diagnostic materials, medicines, and key health commodities. A well-functioning supply-chain is vital to the success of any public health program.

On behalf of the other members of the United States Government (USG) global health interagency partnership, USAID manages the procurement and delivery of medicines and critical commodities for the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), and the President's Malaria Initiative (PMI), as well as for USAID's programs in voluntary family planning, maternal and child health, and other health areas.

Our supply-chain activities also provide technical assistance to build capacity and expertise in partner countries to deliver, routinely and licitly, life-saving products purchased with revenues raised locally or from other donors, while also improving trust in local health institutions and services. This technical assistance is an important contributor to Administrator Green and Ambassador Birx's shared vision of moving countries along the path to self-reliance. I am here today to discuss with you the work we do in supply-chain management and the procurement of medicines and commodities; provide an update on the performance of our current contractor in this area; share our experience and lessons learned to date; and describe the path forward.

Background

For decades, USAID has been a world leader in providing critical, life-saving medicines and commodities for public health programs. The generosity of the American people has helped many millions of men, women, and children around the world avoid and recover from illness, and saved millions of lives.

The success of the U.S. Government's global health programs has depended on our investments to ensure the consistent availability of high-quality products for HIV/AIDS, malaria, voluntary family planning and reproductive health, maternal and child health, and other health programs in the countries where we work. Today, we remain as committed as ever to that mission.

USAID's internal supply-chain staff work together with clinical and scientific experts from USAID, the Office of the U.S. Global AIDS Coordinator (S /GAC) at the U.S. Department of State, and the Centers for Disease Control and Prevention (CDC) of the U.S. Department of Health and Human Services (HHS) in Washington, Atlanta, and the field to ensure that the right medicines get to the right people at the right time. The clinical staff follow the latest science and international guidelines, and work with national Ministries of Health and implementing partners to select the best medicines to treat malaria, HIV, and other health ailments. They ensure that Ministries have the proper evidence-based protocols in place, and are able to train clinical staff, to use the medicines appropriately. Our supply chain staff and the clinical teams at USAID, S/GAC and HHS/CDC work together with the U.S. Government field teams and national Ministries to develop the forecasts for each product we procure, and turn them into supply plans approved by an interagency team and then given to our contractor for negotiation, purchase and delivery. This close integration ensures that science, real-world demand, and the best clinical practice drive our procurements.

In recent decades, the scale and complexity of our investments have grown dramatically to support PEPFAR and PMI, while we continue to serve other public health programs.

For example, when President George W. Bush launched PEPFAR in 2003, the number of HIV-positive people in sub-Saharan Africa who were on ARV treatment was, at most, measured in the tens of thousands. Today through PEPFAR, the U.S. Government supports more than 13.3 million patients on ARV therapy (ART), delivered through more than 80,000 different facilities. PEPFAR has played a critical role in moving HIV /AIDS from a fatal disease to a manageable, chronic condition.

PMI has had similar growth. When President Bush started it in 2006, it began in just three countries. PMI now implements 27 programs, which span 24 countries in sub-Saharan Africa and three programs in the Greater Mekong Subregion of Southeast Asia. In partnership with national governments and malaria stakeholders, PMI's investments in the prevention, treatment, and control of malaria are benefiting over half a billion (570 million) people in Africa from the Sahel, to the Horn, to Southern Africa. Significant investments in the procurement and delivery of medicines and commodities have been a core component of PMI's strategy since the very beginning.

We work with national systems in resource-constrained environments. We face – and work to address – challenges in infrastructure and limited storage; weaknesses in management within Ministries of Health and Provincial or District health offices; the threat of corruption, theft and diversion; unreliable electricity; poor road networks that require various modes of transportation (trucks, 4x4s, motorcycles, bicycles, canoes, camels and human conveyors); human-resource challenges; and, particularly, significant barriers to reach rural, hard-to-reach communities so products are available, affordable, and accessible.

Global Health Supply-Chain - Procurement and Supply-Management

From 2005 to 2017, USAID managed our procurement and supply-chain operations under two, large, single-award Indefinite-Quantity Contracts (ICQs), DELIVER and Supply-Chain Management Systems (SCMS).

The design process for our current supply-chain architecture commenced in 2012, and sought to incorporate lessons learned from the predecessor projects, improve management efficiencies both internal to USAID and through the contract mechanisms, and continue to find cost savings in the purchase of medicines and commodities. The design team undertook a process to solicit input from a variety of sources, including across the Agency, in Washington and the field, and from interagency organizations and initiatives including S/GAC, HHS/CDC, and PMI. For example, the design team launched a 38-question survey, which generated responses from 77 USAID and HHS/CDC field staff in 29 countries. USAID also commissioned an independent expert review of our supply-chain programs compared to those of other peer institutions -- Gavi, The Vaccine Alliance; the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM); the U.S. Departments of Defense and Veterans Affairs -- and commercial supply-chains --Hewlett-Packard, Limited Brands, Pitney Bowes Canada, and Ryder Integrated Logistics, to build on existing strengths while applying state-of-the-art and commercial-sector best practices.

One of the key findings from this process was that U.S. Government country teams experienced a heavy management burden in the field to prevent or minimize duplication of two U.S. systems (multiple warehouses, two offices in one country, etc.) at the field level. The independent expert review also suggested alternative ways to organize our global supply-chain to achieve increased efficiencies. As a result of these findings, USAID made the decision to consolidate procurement and supply-chain functions across health programs through one large award, rather than two.

We recognized that a contract of this size and scope would require a consortium robust enough to implement it successfully. It would require internal systems at USAID, and for close coordination and communication between subcontractors, functional teams at the prime contractor, and U.S. Government staff in the field.

We also knew that the transition to a new contract, regardless of who would hold it, carried risks. We took best-practice measures before making the award to mitigate the risk of interruptions in supply, such as increasing inventories beyond what is normally held and ensuring sufficient overlap between the prior contracts and the new contract—all to ensure patients' access to commodities would continue smoothly.

USAID awarded our current contract for procuring and delivering medicines and commodities and providing supply-chain technical assistance to countries in 2015: It is called the Global Health Supply-Chain - Procurement and Supply-Management Project (GHSC-PSM). GHSC-PSM began operations in January 2016 after lengthy delays during the award process because of an unsuccessful protest by one bidder to the Government Accountability Office and a lawsuit before the Federal Court of Claims, which found in favor of USAID. As a result of the built-in overlap with the predecessor contracts, GHSC-PSM' placed its first orders for medicines and commodities in August 2016.

The GHSC-PSM contract, awarded to Chemonics, has a total ceiling of \$9.5 billion over a performance period of up to eight years, primarily intended to support the procurement of medicines and commodities for HIV/AIDS, malaria, and voluntary family planning. Initial task orders under the contract end in November 2020.

The award of the GHSC-PSM contract followed a stringent, full and open competitive process, in accordance with the Federal Acquisition Regulations. The technical review panel, comprised of staff from USAID, S/GAC and HHS/CDC, had over 200 years of combined experience and expertise in supply-chain management, supply-chain analytics and optimization, freight and logistics, management of information technology (IT) and software-development, humanitarian supply-chains and food aid, U.S. Government contracting, HIV, malaria, tuberculosis, and voluntary family planning.

In the GHSC-PSM solicitation, USAID required offerors to provide information about their capability and value in procuring medicines and health commodities, which included instructions to "describe recent and relevant experience in order to demonstrate capability and capacity in operating a procurement program that secures best value." This also included the offeror's IT capacity and past performance relevant to the requirements of the contract.

Based on the extensive evaluation of the proposals received, USAID awarded the GHSC-PSM contract in April 2015 to a 12-member consortium led by Chemonics International, which includes world leaders in supply-chain such as IBM and Kuehne and Nagel. Chemonics proposed not only to ensure an uninterrupted supply of medicines and commodities for U.S.

Government programs in global health, but also to introduce a number of innovations and best practices that would advance our global supply-chain and strengthen our supply-chain assistance.

The GHSC-PSM contract is part of USAID's broader Global Health Supply-Chain Program that includes a suite of other contracts, grants, and cooperative agreements intended to support the U.S. Government's overall supply-chain operations and in-country technical assistance for strengthening national delivery systems. As such, we competed other, complementary awards from 2014 to 2016, including for projects to offer supply-chain technical assistance, improve the quality-assurance of drugs and supplies, improve business intelligence and analytics, and support supply-chain innovation, as well as a small-business set-aside to procure rapid diagnostic tests for HIV.

Performance Problems with GHSC-PSM

To-date, GHSC-PSM has established offices in 32 countries, and delivered or processed commodity orders to 60 countries valued at more than \$1.1 billion. Nevertheless, it is well-known that GHSC-PSM faced management challenges in the initial months of implementing the procurement and delivery component of its contract with USAID. GHSC-PSM was initially unable to buy and deliver drugs and commodities as quickly as needed, and has not yet met its contractual targets for on-time delivery (OTD¹) and on-time-in-full (OTIF²) delivery, as it reached only 31 percent for overall OTIF in Fiscal Year (FY) 2017, including a low of seven percent in the second quarter. USAID staff identified key problems with the consortium's operations, such as long lead times in processing orders, delays in the delivery of medicines and health commodities, reliance on manual systems, a lack of accountability, and team organization issues, all of which contributed to poor on-time performance.

USAID noted these issues as early as August 2016, and raised them repeatedly with project staff, orally and in writing over several months. We then escalated them to Chemonics leadership in April 2017 when the project's performance did not improve. Throughout this time, USAID staff, in Washington and the field, worked to minimize the impact of the late deliveries, including by assisting in the redistribution of commodities between facilities to prevent stock-outs. We should not have had to do so.

Numerator: Number of line items with an ADD during the reporting period that were delivered to the recipient on time **Denominator:** Total number of line items with an ADD during the reporting period

Numerator: Number of line items delivered to the recipient on time and in full during the reporting period

Denominator: Total number of line items delivered to the recipient during the reporting period

¹ On-time delivery (OTD) Definition: Percentage of line items delivered within the minimum delivery window (within -14/+7 calendar days of the agreed delivery date (ADD))

² On-time in full (OTIF) Definition: Percentage of line items delivered within the minimum delivery window (within -14/+7 calendar days of the agreed delivery date (ADD)) and in the agreed-upon quantity

In response to USAID's demands for improvement, Chemonics developed and implemented an action plan to address the consortium's deficiencies. The actions included in the plan included shifting to full use of GHSC-PSM's management-information system (MIS), restructuring GHSC-PSM's global supply-chain operations, and transitioning to a new regional distribution center network. These changes have led to an improvement in Chemonics' OTD rate of (73 percent for the quarter ending in March 2018) and OTIF rate (67 percent for the same quarter).

While these improvements signal a positive trend, the consortium has more work to do to meet its contractual targets of 80 percent for both OTD and OTIF. Supplies and drugs to prevent and treat malaria remain of particular concern. OTD and OTIF for several malaria products lag behind the overall average; in response to our request, Chemonics has submitted an action plan to address these issues.

As you have heard USAID Administrator Green say, the poor contract performance we observed is not acceptable, and the Agency has taken aggressive measures to hold the contractor accountable. I can assure you the Bureau for Global Health, and the Agency as a whole, is providing a high level of oversight and scrutiny over the GHSC-PSM contract. For example, the contract is the only individual award to appear on USAID's corporate Risk Registry, and the USAID Risk-Management Council devoted a special session to it in the Fall of 2017. USAID also submitted a negative Contractor Performance Assessment Report for GHSC-PSM for the 2016-2017 year of performance, with a marginal rating, the second-lowest possible. These reports are accessible to procurement officers across the Federal Government, and are used to assess bidders' past performance during the procurement of new awards. In addition, USAID imposed a moratorium on all salary increases for staff who work on the project. The Bureau for Global Health holds weekly management meetings with Chemonics; provides weekly in-person and/or written updates to the USAID Front Office and Ambassador Birx; demands detailed quarterly reporting from the consortium, which we share with Congress and other stakeholders; commissions other reports on specific project activities; and closely monitors key performance indicators.

USAID in Washington has also worked closely with our counterparts in our missions abroad to train them to raise problems early and to oversee the performance of the contract where it matters most, in the field. We have been monitoring inventory levels in countries, and reviewing shipments, product by product, country by country, to identify the risk of stock-outs and mitigate that risk through several strategies, including coordinating with other donors to cover gaps, prioritizing shipments across countries, redistributing available stock in country, and where appropriate substituting similar products.

GHSC-PSM's Performance Improvements Since Late 2017

As a result of USAID's oversight and management actions, we have seen significant improvement in GHSC-PSM's overall, OTD and OTIF performance. Based on GHSC-PSM's quarterly report for January through March 2018:

- Chemonics increased overall OTD from 31 percent in the fourth quarter of FY 2017 to 72 percent in the first quarter of FY 2018, and maintained it at 73 percent in the most recent quarter ending in March 2018. OTD reached 82 percent for deliveries in the month of December 2017, exceeding our target of 80 percent.
- OTIF delivery also improved from 32 percent at the end of September 2017 to 67 percent for the quarter that ended in March 2018, and it is beginning to converge with OTD.
- The consortium reduced the backlog of undelivered orders by 69 percent in the quarter that ended in December 2017, and diminished it by an additional 14 percent in the most recent quarter; the backlog is now under five percent of total shipments, an industry standard.
- The volume of medicines and commodities the consortium delivered increased by 37
 percent from September to December 2017, a level maintained in the second quarter of
 FY 2018.

While we find the consortium's overall performance improvements encouraging, they are not universal, and do not yet meet the targets specified in the contract. Malaria-specific OTD lags seriously behind overall OTD in the most recent quarter. We continue to hold GHSC-PSM accountable, and will not be satisfied until GHSC-PSM routinely meets all of its performance targets across all health elements. This includes sustaining both and OTD and OTIF delivery rate of 80 percent, quarter over quarter, which means 80 percent of deliveries arrive in the period between 14 days before and seven days after the agreed delivery date.

GHSC-PSM Is Not the End of the Story: What Happens to Drugs and Commodities Purchased by the U.S. Government When They Arrive in Country, from the Central Level to Facilities

GHSC-PSM's performance problems covered the first part of the supply- chain---from processing orders with manufacturers through delivery to a country. Yet the end-to-end supply-chain extends from manufacturing all the way to an individual rural health clinic, or even a household doorway, where patients receive their medicines and commodities. USAID is equally concerned with the second part of the supply-chain---how these commodities move from a national warehouse to patients.

GHSC-PSM has direct custody over the products the consortium procures up to the point of delivery, which is typically a central location or warehouse in the destination country. At that point, the custody of these products, and the responsibility for their in-country distribution, varies

based on the country context. A key factor in determining the level of responsibility is a country's ability to manage and account for products reliably, whether through public- or private-sector channels. For example, in certain countries, or for specialized commodities such as insecticide-treated bed nets, a USAID contractor might have custody and management responsibility for the product to the point of delivery at the facility level.

USAID provides strong monitoring of the country supply-chains we support. We continually monitor stock levels to identify and prevent shortages, help resolve resource gaps, and limit and investigate theft or diversion. In Nigeria, for example, U.S. Government monitoring included visits to over 1,000 facilities and warehouses last year. We work closely with the GFATM, including its Inspector General, to track the forecasting and movement of drugs and supplies in the countries in which we both fund grant programs. This monitoring, along with supply-chain assessments, provides for greater accountability, and provides data on the availability of stock to ensure patients have access to needed treatments for HIV, tuberculosis, and malaria.

USAID's technical assistance in this area has achieved results, as countries are moving along the journey to self-reliant supply chains. In the 1980s, when USAID first began strengthening country's supply-chains, the national systems we supported were parallel, managed a limited number of products, and operated out of colonial-era warehouses with inventory tracked through musty paper ledgers. The supply-chain managers had no ability to know what supplies were at each health facility, how much to resupply, or if there was a stock-out somewhere in the system. Through our financial and technical support, countries' national supply-chains have become more sophisticated. They are managing thousands of health commodities through networks of warehouses that use commercial facility-management systems and electronic managementinformation systems that provide inventory visibility throughout the supply chain, and, in some cases, outsource warehousing and distribution to the private sector. This allows them to serve more health facilities, and most important, more patients. For example, in 2003 Nigeria had fewer than 10,000 patients on ART; today, approximately one million HIV-positive Nigerians are on treatment. In South Africa, our assistance to the national supply chain, including by harnessing the capability of the private sector and improving the visibility of stock throughout the system, has improved product-availability at health facilities from 40 percent several years ago to over 86 percent now. In Zambia, a more-resource- constrained country, our technical assistance has led to a resilient national system that has maintained product-availability above 90 percent, even as the volume of commodities it manages has more than doubled.

What We Have Learned and How We Are Applying It

Some core lessons we have learned so far from our experience with the GHSC-PSM contract include the following:

- While unifying our global supply-chain across health programs might have gained some
 efficiency, it also increased our vulnerability, and reinforces the need for strong riskmitigation measures in project-design, procurement, and management.
- Strong project leadership and management is necessary to integrate consortia successfully and quickly into a functional supply-chain program; we need to strengthen how we assess this during the procurement process.
- Operating a large and complex supply-chain requires a robust and adaptable
 management-information system that is functional <u>before</u> the placement of the first
 order; we need better ways to assess information systems during the procurement
 process.
- The measures we put in place to mitigate risks during the transition were critical in minimizing the impact of GHSC-PSM's poor performance on the people we serve; however, we can strengthen some aspects, such as increasing the amount of overlap between old and new contracts.
- Within the current structure of the Bureau for Global Health, supply-chain is integrated
 into each of the health offices, which ensures the critical link between clinical/scientific
 and supply-chain staff, but means we lack a single, overarching structure that links the
 different elements; this limited our ability to communicate with a single voice, and
 fragmented our initial response.

We have started to apply the above-mentioned lessons learned to the design of USAID's next-generation supply-chain program. Building on USAID's broader procurement-reform efforts, initiated by Administrator Green, we are identifying ways to be innovative in our design, procurement, and management of resulting award(s). We are reaching out to industry to learn how they procure, monitor, and measure the performance of their supply-chain providers. We will actively engage interagency partners and the field throughout the process. We are confident we can design a program that will apply industry best practices, be more efficient, minimize risk, and incentivize a high level of performance from the beginning. We are also exploring options to change the structure within the Bureau of Global Health to improve our coordination and oversight.

Conclusion

At USAID, we take our obligation to ensure good stewardship of taxpayer resources very seriously. We set a high standard for accountability. As Administrator Green has said, "Our foreign assistance funds are precious: they come from hard-working families all across this great country. We owe it to them to use these as efficiently and effectively as possible."

We identified performance issues with the GHSC-PSM contract early, and held Chemonics accountable, which has led to improvements in performance. We have worked diligently to mitigate the impact the poor performance had on those whom we serve.

We will not relax our oversight in ensuring that no patient is at risk. We are holding Chemonics and its partners accountable for continued improvements to reach and sustain their contractual goals of at least 80 percent OTD and OTIF.

We are assertively and purposefully applying what we have learned to ensure we do better in the design of our next supply-chain contract or contracts. We are engaging with the field, the leadership of the U.S. Government interagency, and industry experts to guarantee that our next program is innovative and limits risk, and, most important, that people receive the critical health products that prevent and treat life-threatening disease.

Thank you for the opportunity to speak before you today, and I look forward to answering your questions.