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Evolution of the Global Donor Market for Male Condoms

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Abbreviations

ASTM	American Society for Testing and Materials
CDC	Centers for Disease Control and Prevention
CEN	Comité Européen de Normalisation
CSI	Custom Services International
FAA	Foreign Assistance Act
FHI 360	Family Health International 360
HIV	Human Immunodeficiency Virus
ISO	International Organization of Standardization
JSI	John Snow Inc.
LIG	London International Group
LTA	Long Term Agreement
NIH	National Institutes of Health
PATH	Program for Appropriate Technology
PIACT	Program for the Introduction and Adaptation of Contraceptive Technology
SSL	Seton Scholl Limited International
STI	Sexually Transmitted Infection
TC	Technical Committee
UNAIDS	Joint United Nations Program on HIV/AIDS
UNFPA	United Nations Population Fund
US FDA	United States Food and Drug Administration
USAID	United States Agency for International Development
WHO	World Health Organization

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Introduction

The global donor-funded market for male condoms for low- to middle-income countries (LMICs) was \$53,905,642 in 2015, with more than 1.5 billion condoms procured by five major funding sources: United States Agency for International Development (USAID), United Nations Population Fund (UNFPA), United Nations Development Program (UNDP), International Planned Parenthood Federation (IPPF), and Marie Stopes International (MSI), according to data from RH Interchange.¹ A subsequent additional funder was the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM).

As of the latest data readily available, 63 countries were recipients of these donor-funded condoms² and, as of 2014, 26 different manufacturers served this market, many (but not all) located in middle-income countries with lower production costs and prequalified by UNFPA (see Appendix 1).³ USAID, through their quality assurance contractor, FHI 360, also assesses condom manufacturers. (Currently, not all of the manufacturers pre-qualified by UNFPA have been reviewed and/or approved by FHI 360.) Historically, the market has not always been so competitive and diversified, however. This case study examines the evolution of the donor-funded male condom market from one characterized by higher costs and quality problems to one of improved functioning and market outcomes in terms of quality and supply competition, lead times, and prices. The case examines the role of USAID and UNFPA in particular, as they represent, respectively, 60% and 28% of the total market by dollar value.

This case study is intended for practitioners and participants in global health markets who seek examples of how individual markets have advanced as a result of market shortcomings being identified and addressed. This document details the global donor-funded male condom market as a learning opportunity for how an interrelated set of actors addressed key issues affecting this large-scale global public health intervention. We strive to explore the major themes of quality and supplier base expansion, and will reference others such as market data, differential packaging/pricing, and social marketing that could be explored in different venues.

Importance of the Global Male Condom Market

Despite continued efforts to develop dual- and multi-purpose prevention technologies, condoms are the only commonly used contraceptive that offers protection against sexually transmitted infections (STIs), including human immunodeficiency virus (HIV). Due in part to its dual purpose, the male condom is likely the most widely available contraceptive in both public and private sectors worldwide. Global donors and non-profit organizations have led the effort to increase

access to male condoms in low- and middle-income countries, where the greatest burden of unintended pregnancy and HIV often coincide.

Historical Characteristics of the Male Condom Market

In the 1980s, USAID procured male condoms through the US General Services Administration. In 1989, however, USAID brought procurement in-house following the recommendation of an audit by the Inspector General.⁴ The USAID Central Contraceptive Procurement (CCP) project began shortly after, in 1990, to provide a mechanism for consolidating USAID purchases of contraceptives. From the perspective of one representative of USAID, it was between 1990 and 2010 that the world of condom quality changed dramatically.

In the 1990s and early 2000s, USAID procured male condoms exclusively from US manufacturers, but this case study will subsequently describe how that has changed (see Table 1). The US manufacturers underwent various consolidation and ownership changes. London International Group (LIG) owned multiple manufacturing facilities in Alabama. LIG was purchased by Seton Scholl Healthcare in 1999, forming Seton Scholl Limited International (SSL).⁵ In late 2000, SSL sold the condom factory in Alabama formerly owned by LIG to Custom Services International (CSI), a Nevada-based condom importing, distributing, and manufacturing company.⁶ Alatech Healthcare Products was based in Alabama. During this time, source selection was guided by government sourcing policies, including the regulations outlined in Foreign Assistance Act (FAA) Section 604(a) and domestic preference outlined in the Buy American Act (see Appendix 2). Political pressure also played a role in USAID's sourcing decisions, as it continued to source male condoms exclusively from US manufacturers long after the 1993 amendment to FAA Section 604(a) that allowed USAID to procure from countries other than the United States with certain restrictions (see Appendix 3).

Table 1: Male condom shipments procured by USAID by manufacturer, 1995-2013

Year	LIG	CSI	Alatech	Ansell/Su retex	UNIDUS	Qingdao	KAREX	SURETEX	THAI NIPPON	Innolates
1995	✓									
1996	✓									
1998	✓									
1999	✓	✓								
2000	✓	✓								
2001		✓	✓							
2002		✓	✓							

2003		✓	✓							
2004		✓	✓							
2005		✓	✓	✓	✓					
2006			✓	✓	✓					
2007			✓		✓	✓				
2008			✓		✓	✓				
2009			✓		✓	✓	✓			
2010			✓		✓	✓	✓			
2011					✓	✓	✓			
2012					✓	✓	✓	✓	✓	
2013					✓	✓	✓	✓	✓	✓

Source data: RHInterchange

Shortcomings of Early Procurement

Prior to the development of the WHO/UNFPA specification and prequalification scheme in 2001, strategic purchasing of male condoms was not a leading priority of two of the largest global procurers, USAID and UNFPA. However, during the 1990s USAID had begun working with the FDA to improve condom quality, and there were long term purchasing agreements in place as well. But there were limitations and commonly, orders/requests from country programs were received by the procurement department of each organization, and purchase orders were placed with known manufacturers with minimal consideration for factors other than price. Procurement was conducted primarily on an ad-hoc, transaction-oriented basis. As one insider put it, “There were very few procurement staff and all they did was place orders: It was a purely administrative function. The staff would receive a request from a country office and place a purchase order. They would not look into quality, rejections, or so forth.”⁷ During this time, attention to male condom product quality commenced and would become a game-changer.

Quality Awareness and Evidence

The 1980s witnessed a growing awareness and interest in the quality and associated effectiveness of male condoms as a method of contraception. In addition, the increasing urgency of the HIV epidemic in subsequent years shifted the focus of condom use away from solely contraception and toward the added purpose of preventing the transmission of HIV and other STIs.⁸ The gravity of this new purpose for condoms, and the associated increase in demand, fueled the already growing priority on condom quality.

Multiple research groups and organizations were instrumental in providing the evidence needed to instigate positive change to the regulation, manufacture, and distribution of condoms. As early as 1980, the Program for the Introduction and Adaptation of Contraceptive Technology (PIACT) began conducting studies on the relationship between condom strength and failure during use, and the effect that time and packaging have on condom failure.⁹⁻¹¹ With support and funding from the US Food and Drug Administration (US FDA), PIACTⁱ led a study between 1988 and 1995 to investigate the effects of various environmental and storage conditions on the mechanical properties of condoms, with the goal of predicting and extending their shelf life.¹²

Published in 1992, the PIACT study called for a reduction in condom breakage if condoms were to be used as an effective method to prevent unintended pregnancy and transmission of STIs. Family Health International (FHI) and The Population Council also collaborated to expose the disconnect between existing laboratory tests and standards and actual failure rates during condom use.¹³ In 1998, FHI published a monograph summarizing available information on multiple aspects of male condoms, citing rates of condom breakage and slippage between 0 and 12% worldwide, and between 0% and 5% in the United States.¹⁴ In the same year, Consumers International lobbied the International Organization of Standardization (ISO) for stronger regulations on the quality of condoms, stating a specific concern regarding the quality of condoms sold in developing countries.¹⁵

Two years later, in 2000, multiple federal agencies of the United States held a workshopⁱⁱ to review and understand the scientific evidence on the effectiveness of the use of male latex condoms to prevent STI transmission. The panel of experts responsible for the development of the summary report found that, in general, existing published literature was inadequate to determine whether condoms were effective at preventing infection, as most studies failed to use a prospective design. However, published data on the effectiveness of male condoms in preventing HIV transmission were the strongest. Following a meta-analysis of available data, the panel concluded that consistent (“always”) use of male condoms significantly reduced the risk of HIV infection in both men and women.¹⁶

Development of Quality Standards by ISO, CEN, ASTM and WHO/UNFPA

In parallel to considering the multiple efforts by entities such as PATH, FHI, Consumers International and US agencies to measure and then advocate for improved condom quality; it is similarly instructive to introduce the contributing quality standards entities and their role in this market evolution. These entities derive from the broader industrial sphere as well as the global health consortium of WHO, UNFPA UNAIDS, and FHI 360 along with others.

ⁱ By this time, PIACT had become the Program for Appropriate Technology (PATH).

ⁱⁱ The National Institutes of Health (NIH) was responsible for organizing the workshop. The three other federal agencies who participated in organizing the review were the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the United States Agency for International Development (USAID).¹⁹

In 1980, the high uniformity of male condoms produced by manufacturers in the United States and the United Kingdom was attributed to self-regulation of the condom industry, advances in manufacturing processes, and early government regulations.¹⁷ The only standards available were general standards for rubber materials developed by a few organizations.¹⁸ By 1998, however, three organizations that developed international standards for all types of products -- the ISO, the European Committee for Standardization (Comité Européen de Normalisation) (CEN), and the American Society for Testing and Materials (ASTM) -- had developed standards for manufacturing male latex condoms.²⁰

ISO is the largest global developer of voluntary international standards and is an independent, non-governmental membership organization.²¹ The ISO Technical Committee 157, which was created in 1974 and first met in 1975, was originally responsible for the development of standards for “mechanical contraceptives,” now referred to as “non-systemic contraceptives and STI barrier prophylactics.”²² The published standard for male latex condoms is ISO 4074 which addresses the standards for product safety and performance, test methods to verify compliance, minimum quality requirements and package labeling standards for male condoms made from natural rubber latex.^{23,24} The first edition of ISO 4074 was published in 2002, although sections of the standard had been published as early as 1980.²⁵ The ISO 9000 series addresses good manufacturing practices and quality assurance.²⁶ Many countries have adopted the ISO standards, and in some countries, compliance with ISO 4074 is mandatory.²⁷

The CEN is an association of National Standardization Bodies of 33 European countries, and is one of the three European Standardization Organizations which have been recognized by the European Union and the European Free Trade Association as responsible for developing and defining voluntary standards.²⁸ Male condoms are within the purview of the CEN Technical Committee (TC) 205 on Non-Active Medical Devices. The scope of the TC 205 is to identify, adopt or adapt ISO or other standards, or to prepare CEN standards when no ISO or other standard exists. As such, CEN publishes ISO 4074 standards.²⁹

ASTM, an organization established in 1898 to create consensus on industrial materials standards, is now an international standards developing organization with members from over 140 countries. Although ASTM standards have been historically developed for use in the United States, half of ASTM standards are now distributed outside of the U.S.³⁰ The ASTM subcommittee D11.40 develops standards on consumer rubber products, included in which is ASTM D3492 Standard Specification on Rubber Contraceptives (Male Condoms).³¹ ASTM D3492 was first published in 1997.

Additional standards for male condom manufacturing and procurement were developed by a consortium of global donors and procurers. The World Health Organization (WHO)/United

Nations Population Fund (UNFPA) *Specification and Guidelines for Condom Procurement* was first published in 1989, while revised versions have been supported by additional organizations and published intermittently.³²⁻³⁵ The WHO/UNFPA Specification for male condoms is based on ISO 4074 and other international standards, but includes additional requirements around performance, design and packaging.³⁶ These guidelines are developed through a review of available evidence by a consortium of individuals representing a wide variety of stakeholders, including the ISO, manufacturers, regulatory agencies, research institutes, nongovernmental organizations, and international agencies, among others.³⁷ The document itself is funded and published jointly by the WHO Department of Reproductive Health and Research, the Joint United Nations Program on HIV/AIDS (UNAIDS), UNFPA, and FHI.

Market Interventions

The increased value and priority placed on product quality in male condom procurement contributed to a shift away from ad-hoc transactions toward a more strategic approach in this donor-funded market. Coincident to the quality emphasis, there was also a focus on increasing efficiency, improving customer service and mitigating risk. These factors, combined with increasing pressure to improve condom quality, the development of international standards, and the growth in global condom demand, contributed to the advancing of procurement within each organization's strategy. Both entities adopted a more holistic and strategic approach to procurement, which encouraged better condom quality and likely enabled a larger supplier base.

USAID | DELIVER PROJECT Procurement

As noted in the introduction, USAID is a predominant funder/procurer in the global male condom market, constituting about 60% by market value. In this section, we will describe USAID's approach to procurement for health and family planning programs, in order to detail the role of quality and supplier selection.

In 2006, the USAID | DELIVER Project (DELIVER) was awarded as an indefinite quantity contract to John Snow Inc. (JSI), which then assumed responsibility over USAID funded-tenders, negotiations, awards, issuing purchase orders and managing contracts for multiple products related to health and family planning programs in developing countries.³⁸ In collaboration with USAID and FHI 360, DELIVER soon developed new policies and practices to make procurement more strategic and to improve contraceptive supply security. USAID first tasked DELIVER with negotiating and awarding contracts for male condoms in 2008. At this time, FHI 360 was

contracted by USAID to oversee quality assurance activities for male condoms which extended to the procurement by DELIVER.³⁹

Global Forecasting and Supplier Volumes

DELIVER's procurement process begins with a global forecast. USAID and DELIVER look at a global forecast for a period of years to determine the maximum amount of male condoms that DELIVER will procure. DELIVER updates the forecasted demand semi-annually to determine future funding requirements and review demand trends. DELIVER provides an aggregate annual forecast to each supplier so they have a sense of USAID and DELIVER's total condom demand for the coming year. On a monthly basis DELIVER reviews pending and expected orders against projected demand and allocates production orders across suppliers. DELIVER communicates with suppliers about their orders for the coming three to six months and then stays in close touch with them – almost monthly – to advise them of shifts in the planned orders based on updated demand data. DELIVER does not disclose order quantities to competing suppliers, but suppliers know that orders are rotated to ensure continuing manufacturer participation, and high customer service levels, and that order volumes are also dependent on performance.⁴⁰

DELIVER's Bidding Process

DELIVER procures commodities under the direction of USAID's Commodity Security and Logistics Division, and procurement is governed by the same rules and regulations as USAID (see Appendix 2).⁴¹ Tenders have typically been issued at the beginning of every contract with USAID, and contracts have been made for a similar duration of time with the manufacturers. Currently, the procurement process begins with USAID issuing a procurement request to DELIVER specifying requested product(s), quality assurance requirements, approximate maximum quantity (based on long-term forecasts) and any other requirements for the product(s). The aforementioned set of international standards and requirements for condom quality have been leveraged by USAID in the development of its internal specifications and its strategy to help manufacturers attain a higher level of quality and improve product availability.

The quality specifications included in the request to procure are determined by detailed technical review of existing specifications by FHI 360ⁱⁱⁱ and a discussion of USAID's programmatic requirements. Following this review, FHI 360 makes a recommendation to USAID on the specifications to be used for the procurement. These specifications are then included in the request to DELIVER. In this way, the specifications and the performance requirements of the manufacturers are determined very early on in the procurement process.

After DELIVER publishes a tender and receives bids, a technical review panel comprised of USAID, JSI and FHI 360 convenes to review the technical proposal to determine which bids meet

ⁱⁱⁱ FHI combined with the Academy of Educational Development to form FHI 360 in 2011.⁴²

the technical requirements outlined in the tender. If a bid meets all technical requirements, DELIVER conducts the business proposal evaluation, at which time pricing is then considered. In DELIVER's 2010 tender for male condoms following the launch of Task Order 5^{iv}, multiple manufacturers met the technical requirements. The opportunity to contract with several suppliers was recognized upon review of the long-term forecast, as well as the production capabilities, prices, and condom portfolios of the bidding manufacturers. A large supplier base also provides the advantages of a stronger supply chain and better risk management. (The condom portfolios are specifically relevant because USAID procures multiple types of male condoms.) Following an evaluation of all of these elements, DELIVER submitted a proposal to USAID to select and manage a condom supplier base of five manufacturers, and this proposal was subsequently approved.

Product Specifications, Pricing and Packaging

DELIVER procures two main types of male condoms from manufacturers: catalogue products and specialty condoms.^v All but one condom manufacturer supplying USAID produces both catalogue products and specialty condoms, providing flexibility in the allocation of orders across suppliers and increasing the likelihood that condoms will be available when a customer needs them. In this allocation process, DELIVER considers quality issues, production lead times, country registrations, and manufacturer performance. Suppliers are provided with quarterly feedback on their performance.

In terms of packaging, all USAID-supplied condoms are supplied in bulk, in cartons of 3,000 with inner boxes of 100. For USAID-procured condoms, the average price is \$0.03 per condom, including commodity value, freight insurance and handling fees. Different foils (primary packaging on the individual condom), colors and scents are available. For those 'specialty' condoms, the price per condom is slightly higher. Social marketing programs in country often repack the condoms into smaller, over-branded packages.

UNFPA

Following the WHO/UNFPA prequalification program for male condoms developed in 2001, pressure came for procurement agents to develop a full service solution for male condom procurement along with prioritizing condom quality. That is, procurement should extend beyond placing orders based on price, and look at the broader spectrum of the supply chain, delivery, just-in-time, and good quality. While this case study describes USAID's procurement process in

^{iv} In 2010, the contract for DELIVER was extended for another term, launching the USAID | DELIVER PROJECT, Task Order 5 for the Procurement and Distribution of Essential Public Health Supplies. TO5 was developed to support USAID procurement and delivery of various essential health supplies, including condoms and contraceptives.⁴³

^v For catalogue products, orders are centralized by DELIVER and a central stock is held in an in-country warehouse. Specialty condoms are branded and mainly used by social marketing organizations (SMO). Orders for specialty condoms are placed with the manufacturers, and the products are sent directly from the manufacturer to the recipient.

greater detail, UNFPA is to be highlighted as a critical influence in the evolution of the global male condom market. In this same time period, UNFPA received from country donors for prequalification and quality assurance tasks, which led to a host of improvements, including support for expanding the number of manufacturers.⁴⁴

Expansion of the Supply Base

Between 2001 and 2005, UNFPA significantly increased the number of manufacturers from which it purchased male condoms. The expansion of the UNFPA male condom supplier base was driven by the objective of fostering a more competitive marketplace (including both large and small manufacturers) and was facilitated, at least in part, by the development of the WHO/UNFPA prequalification scheme; once factories became prequalified, UNFPA could be confident in their ability to reliably supply quality-assured male condoms. By 2007, UNFPA sourced from at least 10 different male condom manufacturers (Table 2).

Table 2: Male condom shipments procured by UNFPA by manufacturer 2002-2007

Manufacturer	2002	2003	2004	2005	2006	2007
Apoteket AB			✓	✓		
Condomi		✓	✓		✓	
Dongkuk Techno Rubber Industries SDN BHD			✓	✓	✓	✓
Dongkuk Trading Co. Ltd.		✓				
Drokasa Peru S.A.			✓			
GCCP				✓	✓	✓
Hankook Latex Gongup Co., Ltd.		✓		✓		
Hindustan Latex Limited		✓				
HLL Lifecare Limited			✓	✓	✓	✓
Indus Medicare Limited			✓	✓	✓	✓
Industria Nacional de Artefatos de Latex						✓
Karex Industries SDN. BHD.			✓			
Qingdao Double Butterfly Group Co. Ltd.					✓	✓
Qingdao Jiuhe Industrial Co., Ltd.	✓		✓	✓	✓	
SSL International Plc		✓	✓	✓	✓	
Suretex Limited			✓	✓		✓
TTK Protective Devices Ltd.						✓
Unidus Corporation / Seohung		✓	✓	✓	✓	✓
United Med-Health International Corp			✓	✓	✓	✓
Number of manufacturers	1	6	12	11	10	10

Source data: RHInterchange

Like UNFPA, USAID increased the number of manufacturers from which it purchased. In 2005, USAID purchased condoms from Ansell/Suretex, (Thailand), and Unidus Corporation, (Korea), in addition to US-based Alatech Healthcare Products (Table 1). The decision to source male condoms from international manufacturers was likely influenced by a combination of factors,

including quality concerns and delivery problems with the US manufacturer(s), potential supply capacity issues, and differences in the prices offered by international manufacturers versus US-based manufacturers.^{45–47} The development of the WHO/UNFPA PQ scheme four years earlier likely also influenced USAID’s decision to source from international manufacturers. Since 2011, all condom suppliers for USAID have been in middle-income countries (MICs) in Southeast Asia.

Long Term Agreements (LTAs) with Manufacturers

Under the new procurement model, UNFPA began to engage in long term agreements (LTAs) with manufacturers and utilized competitive bidding in the tender process. Specifically, UNFPA defines and evaluates multidimensional criteria for tender evaluation and selection, including technical components, delivery and packaging aspects, quality, and the price offered by each manufacturer. This holistic approach enables UNFPA to select the most economical manufacturer(s) based on an evaluation of all parameters, including quality, and the anticipated needs of recipient countries.

Like UNFPA, DELIVER likewise engages in LTAs with each awarded manufacturer. USAID began using LTAs in 2007. Its current LTAs are valid until September 2016. All generic condoms, as well as all specialty condoms, are purchased under these LTAs. The LTAs specify a maximum quantity that has been approved by the U.S. Government, within which DELIVER can place release orders for specific quantities as needed. Ordering is informed by a collaborative and rolling supply planning exercise carried out by DELIVER in collaboration with USAID, which is driven by known orders from USAID missions, inventory levels, and an effort to share (or “round robin”) orders among the multiple manufacturers.

Collaborative Supply Planning

USAID and DELIVER created a multi-faceted ecosystem with their partners and vendors that encourages open communication and incentivizes good performance. The ecosystem consists of both quantitative metrics and qualitative reviews, and is guided by a supplier management taskforce. Consisting of representatives from USAID, FHI 360 and JSI, the taskforce works to harmonize their approach to vendors and speak with a unified voice about the strategic and long-term interests and concerns of each entity. The taskforce has helped USAID, DELIVER and FHI 360 communicate more effectively with manufacturers, and has also helped USAID and the manufacturers better understand one another’s expectations.

The supply planning process carried out by DELIVER involves close collaboration and open communication with suppliers. In addition to monitoring inventory levels and pending orders, the process is informed by a long-term demand forecast as well as annual forecasts which help determine how to best allocate orders among suppliers. DELIVER regularly meets with suppliers to discuss product needs, production availability, pending orders, and expectations for orders

over the coming year (derived from forecasts).⁴⁸ These expectations are updated regularly as prospective orders turn into actual orders. In this way, each supplier has an understanding of USAID's overall demand for male condoms, and is informed of significant changes in this demand (i.e. anticipated orders). This collaborative supply planning is thought to have created greater flexibility and efficiency in the supply chain for USAID. In 2011, the adoption of collaborative supply planning was specifically credited for reducing lead times for emergency requests for condoms.⁴⁹ According to one Chinese manufacturer of male condoms supplying the donor-funded market, the demand forecasts shared by global purchasers have helped in production planning and enabled more timely order fulfillment, contributing to better supply security.

Performance Metrics

Volumes allocated to each supplier are largely dependent upon performance, which is evaluated and incentivized through a number of mechanisms. Quarterly score cards are sent to each vendor to highlight specific performance metrics related to quality and on-time delivery. DELIVER also conducts routine strategic reviews with the vendors to discuss past performance, future expectations, and the respective goals of both the vendor and DELIVER to align expectations for the future.

In addition to performance evaluations and quality assurance processes, USAID has also been willing to provide technical assistance to its vendors when they encounter issues (e.g. difficulty in developing registrations, quality control issues, etc.). Some of this support is provided through FHI 360. A representative from DELIVER stated that this ecosystem helped to improve the overall ability of vendors to consistently and more efficiently supply the global market with quality-assured male condoms.

Individual countries participate in quality assessment as well. A small number of countries require post-shipment testing before they will accept condoms. Most countries will accept the donated condoms without post-shipment testing. Regarding prequalification, DELIVER selects suppliers based on an open competition. Suppliers must meet quality criteria. Over the years, those quality criteria (and the international condom standards) have become increasingly strict. Through its quality assurance project, USAID also invests in oversight and assistance to condom suppliers to maintain their quality standards. Although USAID identifies some lot failures every year, the failures are relative few compared to the total purchased.

Market Data: Reproductive Health Interchange (RHI)

Contraceptive procurement and shipment data collection and availability also supported the evolution of the male condom market. RHI is the first and only online source of harmonized data about contraceptive orders and shipments.

RHI was initiated by RHSC in 2004 and according to the website, now provides access to harmonized data on contraceptive orders and shipments for over 140 countries. The RHI began as a web-based contraceptive procurement mechanism (RHeXchange) that would be shared and managed by USAID, UNFPA and IPPF. The original impetus was to provide a global procurement facility to countries as well as other interested global parties. This turned out to not be feasible and the scope of the activity was simplified to providing global visibility of contraceptive shipments to countries and other interested parties.

RHI data currently reflects over 80% of contraceptive supplies provided by donors over the last several years. UNFPA now hosts and maintains the data site. The data comes from the central procurement offices of major contraceptive donors and other organizations that procure contraceptives.

Potential and Realized Benefits

The male condom market's evolution into a competitive and diversified market resulted from a focus on product quality, supported by other advancements such as market data. This quality focus, prompted first by quality studies and then the WHO/UNFPA specification and prequalification scheme in 2001, led to the development of a strategic approach to procurement by international agencies, encompassing a broader, more holistic view than just one based on price.

Pursuant to the quality imperative, good procurement practices of global forecasting, LTAs, and collaborative supply planning also ensued, leading to a strong and transparent market in which procurement agents communicate regularly with multiple suppliers to keep them abreast of anticipated demand changes and to keep them advised of their performance via objective supplier scorecards.

Benefits to Manufacturers

Manufacturers were incentivized not just by possible orders from USAID and UNFPA, but also by the potential for increased order volumes based upon good performance. Furthermore, WHO prequalification standards became recognized and sought after by individual countries. For example, a representative from UNFPA observed governments asking for prequalification as a pre-requisite before even engaging in a contract with a manufacturer. As a result, manufacturers have written to the UNFPA requesting a certificate of their prequalification, which they can then provide to the requesting governments.

The development and adoption of quality standards by large purchasers ultimately created an attractive business case for manufacturers to produce and consistently provide good quality

condoms. Manufacturing quality-assured condoms became an advantage in this competitive global market.

The donor-funded market, including USAID and UNFPA, constitutes a significant portion of the global demand for male condoms. As these entities developed and were the first to adopt quality assurance standards as a prerequisite for procurement, male condom manufacturers had (and continue to have) an incentive to ensure quality in order to supply this market. Increasingly, governments and other purchasers are also adopting prequalification as a prerequisite to engaging in agreements with male condom manufacturers. As described by a representative from UNFPA, factories with good quality systems in place survived the evolution of the male condom market, while many factories without these systems went out of business.

Furthermore, the development of standards for condom manufacturing, distribution and procurement facilitated the implementation of quality control measures, such as sampling and lot testing. The financial risk of quality failures (detected by these control measures) provides yet another incentive for manufacturers to ensure condom quality. Simply stated, product recalls are expensive; it is in manufacturers' best interest to ensure the delivery of good quality products to avoid costly rejections and recalls.

Global purchasers also helped raise the bar for manufacturer performance by utilizing established standards, defining expectations early on in the procurement process, and communicating frequently and sharing information with manufacturers. Competition may have served to further incentivize good manufacturer performance, which began to be monitored under the more strategic approach to procurement. In addition to ensuring quality, good performance became a competitive advantage for manufacturers.

Summary

The evolution of the global market for male condoms was instigated and propelled forward by the actions of multiple researchers, organizations, manufacturers and donors. The actors and factors behind this evolution are many, and extend far beyond those mentioned here. However, the key factors described in this report appear to have interacted to facilitate this cascade of change. The urgency of the HIV epidemic and historical sub-optimal condom quality created pressure to act. This growing pressure and the subsequent development of standards provided the foundation upon which large global procurers could redesign their own procurement into a more strategic process which requires quality-assurance and incentivizes good manufacturer performance. The sustainability of this change was ensured through the development of the business case for manufacturers to consistently produce and supply quality-assured condoms.

Although this report specifically highlights the perspective and actions of two large procurers in the donor-funded market, the changes in male condom quality and purchasing have extended beyond the public sector. A growing number of private sector companies, including a large global wholesaler and a prominent supermarket chain, are now looking to WHO prequalification as a prerequisite to purchasing condoms. Following existing standards is an easier and less expensive way for the procurement departments of large global companies to supply quality-assured condoms – eliminating the need to perform their own assessments of manufacturing facilities and reducing the risk of supplying condoms of sub-optimal quality.

Looking forward, individual countries are transitioning to responsibility for their own procurement and different funding sources for male condoms, such as the Global Financing Facility. UNFPA has provided support to countries in understanding good procurement practices. Country-level support, commitment, and use of good procurement practices will be important to maintain the quality and procurement standards advances which have been achieved.

Appendices

Appendix 1: WHO/UNFPA Prequalified Male Condom Manufacturers & Locations

Manufacturer	Country
Beiersdorf Medical Latex (DUA)	Malaysia
CPR Productions Und Vetriebs GmbH	Germany
CPL Honduras (Member of CPR GmbH Germany)	Honduras
Cupid Limited	India
Dongkuk Techno Rubber Industries Sdn. Bhd.	Malaysia
Dongkuk Vietnam Col. Ltd.	Vietnam
Guangzhou Double One Latex Products	China
Guilin Zizhu Latex Col. Ltd.	China
HLL Life Care Limited - Kakkanad	India
HLL Life Care Limited - Peroorkada	India
Indus Medicare Ltd.	India
Innolatex Limited	Malaysia
Innolatex Limited	Thailand
Karex Industries Sdn. Bhd.	Malaysia
Medevice 3S Joint Venture Co. Ltd.	Vietnam
MHL Healthcare Ltd. (Formerly Mercator Healthcare)	India
Qingdao Double Butterfly Group Co. Ltd.	China
Suretex Limited	Thailand
Suretex Prophylactics Ltd.	India
Suzhou Colour Way Enterprise Development Co. Ltd.	China
Thai Nippon Rubber Industry Co. Ltd.	Thailand

Tianjin Human Care Latex Corporation	China
TTK Protective Devices Limited - Puducherry	India
TTK Protective Devices Limited - Virudhunagar	India
Unidus Ltd. China	China
Unidus Corporation	Korea

Source data: UNFPA Prequalified Male Condom Manufacturing Sites. November 2015.

Appendix 2: USAID Governance

The United States Agency for International Development (USAID) was created by the Foreign Assistance Act (FAA) of 1961 to administer non-military U.S. foreign assistance programs.⁵⁰ Funding for USAID is made available by the U.S. Congress and derives largely from taxes paid by U.S. citizens. USAID procurement is primarily governed and/or guided by the FAA, the Federal Acquisition Regulation (FAR), the Code of Federal Regulations (CFR), and the Automated Directives System (ADS).

Considered to be USAID's statutory procurement authority, Section 604(a) of the FAA placed limitations on the procurement of goods outside of the United States, stating that funds made available under the FAA could be used for procurement outside of the United States only if the President determines that such procurement will not result in adverse effects upon the U.S. economy or the industrial mobilization base.⁵¹ USAID implemented this directive by adapting its source, origin and nationality (S/O/N) requirements that had been developed under USAID's Commodity Import Program (CIP) to all program funded procurements under the FAA.⁵² In 1993, Congress amended FAA Section 604(a) to allow for USAID to procure from the U.S., the recipient country, or developing countries (but not advancing developing countries) (see Appendix 2). However, USAID did not update its procurement regulations to align with the amended FAA until 2012.

The FAR is the uniform set of policies and procedures for purchasing by all agencies of the U.S. government, while the CFR contains the general and permanent rules and regulations published in the Federal Register by the agencies and departments of the federal government of the United States.⁵³ CFR title 22 part 228 pertains to the rules for procurement of commodities and services financed by USAID.

The Buy American Act^{vi}, implemented by CFR title 48 part 25, Subpart 25.1, was enacted in 1933 to provide a domestic preference in procurement by the federal government.⁵⁴ The five primary exemptions of the Act include: procurements to which application would be inconsistent with the public interest, procurements to which application would be unreasonable in cost, procurements of products for use outside of the U.S., procurements of products not produced in the U.S. in sufficient and reasonably available quantities, and procurements under \$2,500.⁵⁵ "Unreasonable in cost" is defined by a differential of 6% for most federal contracts and 12% if the contract involves a small business or labor surplus area.⁵⁶ All agencies of the United States are required to annually report to Congress a summary of all procurements, including purchases from foreign sources, the dollar value of non-domestic products procured, and a list of the waivers of the Buy American act.⁵⁷

Finally, the ADS of USAID contains the organization, functions, policies and procedures which guide USAID's programs and operations.⁵⁸ ADS Series 300 on Acquisition and Assistance includes policies and guidance around Commodity Import Programs (CIP) and Source, Original and Nationality (S/O/N).

^{vi} 41 U.S.C. 10a–10d.

Appendix 3: FAA Section 604(a)

FAA 1961 Section 604(a)

“Procurement.—(a) Funds made available under this Act may be used for procurement outside the United States only if the President determines that such procurement will not result in adverse effects upon the economy of the United States or the industrial mobilization base, with special reference to any areas of labor surplus or to the net position of the United States in its balance of payments with the rest of the world, which outweigh the economic or other advantages to the United States of less costly procurement outside the United States, and only if the price of any commodity procured in bulk is lower than the market price prevailing in the United States at the time of procurement, adjusted for differences in the cost of transportation to destination, quality, and terms of payment.”⁵⁹

FAA 1961 Section 604(a), as amended in 1993

“Procurement.—(a)(1) LIMITATIONS ON PROCUREMENT OUTSIDE THE UNITED STATES.—Funds made available for assistance under this Act may be used by the President for procurement— (A) only in the United States, the recipient country, or developing countries; or (B) in any other country but only if— (i) the provision of such assistance requires commodities or services of a type that are not produced in and available for purchase in any country specified in subparagraph (A); or (ii) the President determines, on a case-by-case basis, that procurement in such other country is necessary— (I) to meet unforeseen circumstances, such as emergency situations, where it is important to permit procurement in a country not specified in subparagraph (A); or (II) to promote efficiency in the use of United States foreign assistance resources, including to avoid impairment of foreign assistance objectives. (2) For purposes of this subsection, the term “developing countries” shall not include advanced developing countries. (b) No funds made available under this Act shall be used for the purchase in bulk of any commodities at prices higher than the market price prevailing in the United States at the time of purchase, adjusted for differences in the cost of transportation to destination, quality, and terms of payment.”⁶⁰

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