



ECONOMIC OPPORTUNITY SERIES

The Role of the Health Care Sector in Expanding Economic Opportunity

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Preface

Beth Jenkins, CSR Initiative, Kennedy School of Government, Harvard University

The past fifty years have witnessed a “revolution” in global economic growth. Yet not everyone has participated in this revolution. More than 65% of the world’s population, over four billion people, still lives on the equivalent of less than \$4 per person per day. Even worse, the world’s poor are severely constrained – and often completely lacking – in opportunity to do better for themselves.

The business community has both the capabilities and the strategic, business reasons to play a major role in creating these opportunities. The CSR Initiative’s Economic Opportunity Series, a product of our Economic Opportunity Program, explores this role across a range of industries.

“Economic opportunity enables people to manage their assets in ways that generate incomes and options.”

For the poor, livelihood choices – in employment and entrepreneurship – are constrained by a wide range of interdependent obstacles, ranging from geographic isolation to market failures to political exclusion. This suggests that when we think about eradicating poverty, we should think broadly about creating economic opportunity. Economic opportunity is not, in itself, a solution; instead it is a context in which individuals can create their own solutions. It is a combination of factors that enables the poor to manage their assets in ways that generate incomes and options.

Creating or expanding economic opportunity could rightly be considered a responsibility of governments toward their citizens. But in today’s global market environment, various risks and opportunities provide reason for business to engage.

One key reason, across industries, is for business to leverage its own comparative advantage in society. As Milton Friedman might say, “the business of business is business” – and this is exactly what gives firms the capability and credibility to expand economic opportunity. Business activity creates jobs, cultivates inter-firm linkages, enables technology transfer, builds human capital and physical infrastructure, generates tax revenues for governments, and, of course offers a variety of products and services to consumers and other businesses. Each of these contributions has multiplier effects on development.

In developing countries, companies’ multipliers often fail to reach the scale or leverage of which they might be capable – often due to market failures and governance gaps. More deliberate management attention is required to unlock their full potential.

The Economic Opportunity Series explores four key strategies companies can use to expand economic opportunity:

Creating Inclusive Business Models	Involving the poor as employees, entrepreneurs, suppliers, distributors, retailers, customers, and sources of innovation in financially viable ways
Developing Human Capital	Improving the health, education, experience, and skills of employees, business partners, and members of the community
Building Institutional Capacity	Strengthening the industry associations, market intermediaries, universities, governments, civil society organizations, and grassroots groups who must all be able to play their roles effectively within the system
Helping to Optimize the “Rules of the Game”	Shaping the regulatory and policy frameworks and business norms that help determine how well the economic opportunity system works, and the extent to which it is inclusive of the poor

There is enormous variation in the roles companies can play, depending on their industries, their particular business models and relationships, and the contexts in which they operate. The industry reports in the Economic Opportunity Series explore this variation, offering more specific and detailed examples for different industry sectors. The research suggests, in general, that inclusive business models can be the most effective and sustainable ways companies can contribute. Complementary strategies such as developing human capital, building institutional capacity, and helping to optimize the “rules of the game” can also have significant impacts. These strategies are often used in combination with inclusive business models, to enhance both their commercial viability and their development impact.

The research that has gone into this series also suggests that company efforts to expand economic opportunity can draw upon core business, philanthropic, and public donor funding, depending on the balance of business and social benefits expected, the likely timeframe for their realization, and the level of uncertainty or risk involved. Hybrid approaches are increasingly common.

So is collaboration. Complex, systemic challenges like expanding economic opportunity present frustratingly frequent bottlenecks to unilateral action, corporate or otherwise. Even the best-resourced efforts eventually run into limitations on scale somewhere. Collaboration allows parties to share knowledge and information, pool scarce or diverse assets and resources, access new sources of innovation, create economies of scale, and enhance the legitimacy of the parties’ own individual activities. In addition to assembling the necessary resources and capabilities, collaboration can generate new capabilities and change operating environments in ways that create new strategic opportunities.

The Economic Opportunity Series is part of a growing effort within the business and development communities to make the links between business activity and poverty alleviation. Experimentation and learning are happening fast. As a result, the series must be considered a work-in-progress, and readers are invited to share their experience and reflections with us. We look forward to being part of the dynamic growth and development occurring in this field.

■ Executive Summary

Multinational health care companies can play critical roles not only in improving access to medicines and quality care for citizens of developing countries, but also in expanding economic opportunities in those countries. While the health care industry broadly defined includes a wide range of businesses, for the purposes of this paper, we have focused on the pharmaceutical industry and the ways it can participate in expanding economic opportunity in developing countries.

Compared to many other industries, the pharmaceutical industry is unique in the ways it creates economic opportunity. First, because many parts of the pharmaceutical value chain require only a small number of well-educated workers, the industry is typically not well positioned to directly provide large-scale employment in developing countries. In addition, the markets that multinational pharmaceutical companies target for their products are fairly limited in developing countries, and this restricts the scale of employment in those markets. Finally, the core competencies of pharma companies lie in expanding access to medicine and health care. The majority of their efforts in the developing world focus on these issues through activities such as drug donation and patient assistance programs. While these programs may not always lead directly to expanded economic opportunity, they help lay the foundation for it by improving public health, an essential enabling condition for individual productivity and overall economic development.

Companies can consider a number of motivations and risks when determining how deeply or deliberately to engage in expanding economic opportunity. Motivations include the possibility of creating competitive advantage, increasing operational efficiencies, and enhancing philanthropic impact, while risks include reputational risk and regulatory risk related to intellectual property rights and counterfeit drugs.

Currently, pharma companies engage in a variety of economic opportunity strategies through both their business and philanthropic activities. This paper organizes the industry's initiatives into three tiers of activity based on their potential for impact.

1. Creating Inclusive Business Models: Inclusive business models are the “strategic cornerstones” for action to expand economic opportunity due to their potential for developing local businesses and creating new highly-skilled jobs. For pharma companies, inclusive business models incorporate a range of activities such as foreign direct investment, or establishing a local presence in developing countries; technology transfer or voluntary licensing agreements; and incorporating local businesses into the company's value chain through sourcing of raw materials or outsourcing services such as information technology.

2. Capacity-Building Initiatives: While capacity-building activities do not always lead directly and immediately to new jobs, they have the potential for significant impact in developing countries, where educational and professional training opportunities are limited and local infrastructure systems are often weak. By helping train workers and strengthen local institutions, these activities act as precursors to expanding economic opportunity.

3. Rule-Shaping Activities: Companies can help shape the “rules of the game” that affect the extent of economic opportunity available by influencing changes in public policy or regulation that lead to job creation or foster better business environments. These activities, while often longer-term in nature, can lead to large-scale economic impact in developing countries.

The examples highlighted in this paper demonstrate that companies have pursued a broad range of initiatives with various business and philanthropic goals, representing a range of potential for economic opportunity impact. There is no single right way to engage in expanding economic opportunity in developing countries; multiple opportunities to contribute exist and each company’s strategy will depend on its business objectives, competitive advantages, and corporate social responsibility or philanthropic goals.

Our research has identified three major themes for companies to consider going forward.

1. Engage in Rule-Shaping: Pharmaceutical companies’ greatest opportunity to achieve large-scale impact is through activities aimed at optimizing the “rules of the game.” Such activities, while long-term in nature, create the foundation for increased economic opportunity by establishing the conditions that attract business and generate job creation. However, while rule-shaping offers a compelling opportunity for pharmaceutical companies to achieve both social and business impact, the incentives for Western pharma companies to engage in these activities may be limited in the very near term given the current size of the market in developing countries.

2. Track and Communicate: Our research has identified a lack of emphasis on identifying, tracking, and communicating the economic impact of pharma companies’ current activities. Undertaking simple measures to track economic opportunity impact – even when programs are focused on other outcomes – can provide the industry with the opportunity to highlight its economic footprint without the need for additional large investments. Communicating about economic benefits also allows the industry to supplement its messages about the value it brings to society, beyond health care.

3. Collaborate to Maximize Impact: Finally, collaboration within and outside the industry can play a significant role in multiplying the impact of pharma companies’ economic opportunity strategies. While not all activities lend themselves equally to collaboration, many of the examples highlighted in this paper feature successful partnerships. These arrangements allow partners to focus on their respective comparative advantages to increase impact, share risks, and increase the credibility of the efforts with other important stakeholders.

As pharmaceutical companies become more involved in both business and philanthropic activities in developing countries, it will be important for each company to identify the best strategies available to it to create new economic opportunities and to leverage the benefits of activities already underway. While the primary focus of the industry is, and will most likely continue to be, on increasing access to health care, the potential for expanding economic opportunities through its activities should not be overlooked as a significant outcome.

1 ■ The Role of the Health Care Sector in Expanding Economic Opportunity

Multinational health care companies can play critical roles not only in improving access to medicines and quality care for citizens of developing countries, but also in expanding economic opportunities in those countries. While the major focus of health care companies is to provide access to health services and medicines, they also contribute to expanding economic opportunities through job creation, training and capacity-building, and shaping public policy.

The health care industry broadly defined includes a wide range of businesses: drug manufacturers, including pharmaceuticals and biotechnology; diagnostics and device manufacturers; hospitals; insurance providers; and health technology and information providers. For the purposes of this paper, we have focused on the pharmaceutical industry and the ways it can participate in expanding economic opportunity in developing countries. While other actors in the health care sector can be important contributors to economic opportunity as well, the resources that large pharmaceutical companies can harness – their multinational reach, relationships with governments, and enormous potential for financial value creation – offer unique opportunities for social impact in the developing world.

BOX 1 OTHER PLAYERS IN THE HEALTH CARE SECTOR

Other companies within the health care sector, such as insurance providers and hospital chains, offer the potential to create large-scale economic opportunities in developing countries. These companies can often employ large numbers of local citizens at different positions (health care providers, managerial staff, support staff) with varying degrees of skills and training. Their operations also contribute to creating clusters of economic activities formed around various supporting industries, such as information technology and financial services, catering, medical equipment supplies, and so on. However, our research did not identify major multinational chains in these industries that were operating in developing markets. Weak demand conditions and government provision of health care in developing countries may help explain this gap. While it may still take several years for multinational insurance or hospital chains to appear, the economic opportunity potential of these companies remains high.

It is also important to note that while this paper focuses on multinational companies in the pharmaceutical industry, local businesses in developing countries can also have powerful impacts in creating economic opportunities. Due to their very location, these local companies employ thousands of citizens of developing countries. More importantly, in recent years several developing world generics manufacturers have rapidly expanded operations to countries around the world. As a result of their global operations, these companies have been able to increase production and create new and better-paying jobs in their home countries. For example, the Indian generics manufacturer Ranbaxy operates in 49 countries and employs 2,500 people in India.¹ While not a focus of this paper, many of these companies are in fact multinational in nature and provide significant economic opportunities.

Compared to many other industries, the pharmaceutical industry is unique in the ways it creates economic opportunity. First, the core competencies of pharmaceutical companies lie in expanding access to medicine

and health care. It is not a coincidence that the vast majority of activities undertaken by pharma companies in the developing world are related to these core competencies. While drug donation or patient assistance programs may not always lead directly to economic opportunity, access to health is essential to creating the necessary conditions for economic development across all industries.² Jane Nelson, Director of the Corporate Social Responsibility Initiative at Harvard University, observes, “Unhealthy workforces and weak public health systems, especially in situations where HIV/AIDs and other diseases are widespread, often result in lower productivity, increased absenteeism and staff turnover, loss of skills, increased costs, and declining profits and investments.”³

It is extremely important, therefore, that pharma companies continue these activities, given the industry’s specific skills, resources, and expertise, and the impact on health outcomes resulting from these programs. Klaus Leisinger, President of the Novartis Foundation for Sustainable Development, comments on the role of the industry’s involvement in tackling social challenges: “It is advisable that companies become engaged in the sectors where their core competence lies and not in general social or other issues – e.g., pharma companies should choose engagements in the health sector.”⁴

Second, compared to many other industries, many parts of the pharmaceutical industry value chain in developing countries are not extremely labor intensive.⁵ The staff employed in this industry require a certain level of education and training, and often, specialized expertise for jobs that involve scientific discovery, regulatory affairs, and medical marketing. In contrast to industries such as food and beverage or hospitality, job creation by pharma companies in developing countries does not usually focus on the very poor, who are often less educated. Reeta Roy, Vice President of Abbott Fund and Divisional Vice President, Global Citizenship and Policy at Abbott Labs, comments, “Given the types of research and manufacturing jobs we have, we’d clearly go after an educated, well-informed population. Our target group is fairly small.” Stavros Nicolaou, Senior Executive at the South African pharma company Aspen Pharmacare, noted the limitations of individual pharma companies in creating large-scale impact: “The pharmaceutical industry isn’t labor intensive the way the textiles industry is, for example. We have employed more people [in the past few years], but when you have a 30% unemployment rate, ours is not a major absorption effort. The larger benefits lie elsewhere, such as ensuring supply security, improving sub-Saharan Africa’s balance of payments and bridging Africa’s escalating pharmaceutical trade imbalance, and enabling domestic players to become meaningful players in the growing infectious disease market.”

In addition, the markets that multinational pharmaceuticals target for their products are also fairly limited in developing countries. While many Western firms provide drug donations and discounted prices, and local generics manufacturers have also increased access in developing country markets in recent years, branded pharmaceutical drugs still remain out of reach for the majority of developing country citizens. The small market size for their products in developing countries also influences pharma companies’ scale of employment across their value chains in those markets.

Therefore, both because of the nature of the business and the industry’s workforce needs, most pharma companies’ philanthropic and value chain activities are not explicitly focused on creating economic opportunity; rather, they focus on creating access to medicine and health care. Economic opportunity, however, is often an important by-product of these efforts. “The primary goal of our philanthropic

activities is improvement in the provision of health care for the local population and improved access to our medicines. While not the main objective of our activities, the creation of economic opportunities in the form of jobs is a positive by-product,” comments Sebastian Fries, Director of Strategic Planning for Africa, Middle East, and Latin America at Pfizer.

Given the industry’s focus on health, it is perhaps not surprising that few companies appear to track or measure their direct contributions towards expanding economic opportunity. In spite of several examples of successful philanthropic programs or value chain activities that have created economic opportunity, most companies do not communicate about the opportunities created by their efforts. Furthermore, only a handful of the large pharma companies mention economic development specifically on their websites or in their citizenship reports. Our research has identified opportunities for pharmaceutical companies to not only expand their roles in developing countries, but also to leverage the economic impact of their existing efforts in those markets. Novo Nordisk, for example, has developed an “economic footprint” model and illustrates on their website the direct and indirect impact the company has on economic activities in developing countries.⁶

Methodology

This paper’s research methodology applies the results of primary and secondary research to a strategic framework. Due to limitations on time, scope, and space, the sample size of companies interviewed for the paper is small, and the authors acknowledge that the research may omit some companies that deserve to be profiled. The primary research for the paper draws on phone interviews with 11 experts representing multinational pharmaceutical corporations, locally-based pharmaceutical companies, and an industry trade group (see Appendix A, List of Companies Interviewed). The phone interviews focused on developing an in-depth understanding of approaches to increasing economic opportunity and lessons learned through these activities. Secondary research included a review of relevant reports, studies, and articles from a range of sources on the subject of corporate responsibility and economic opportunity.

The findings of this paper are divided into three primary sections. The first section provides an overview of the value of engagement for pharma companies in expanding economic opportunity in developing countries. It also identifies the risks associated with minimal participation in these activities. The second section presents a strategic framework developed by the authors to depict the different strategies large pharmaceutical companies can employ in developing countries. The third section outlines potential roles for the industry to play in expanding economic opportunity in the future. Finally, the fourth section provides case studies profiling the strategies employed by several pharmaceutical companies.

We hope that the discussion and findings provide ideas that will lead pharmaceutical and other health care companies to make more deliberate strategic investments that will enhance economic opportunities for citizens of developing countries.

2 ■ The Value of Engagement

What incentives exist to encourage pharmaceutical companies to increase their engagement in expanding economic opportunities in developing countries? As discussed, most major pharmaceutical companies already administer extensive drug donation programs and other initiatives aimed at improving access to health care in developing countries – primarily as part of their philanthropic initiatives. Together, for example, the seven companies profiled in this paper donated products valued at over \$4 billion in the most recent year for which data are available.⁷ So what is the business case for increasing involvement in these countries?

Companies can consider a number of motivations and risks when determining how deeply and deliberately to engage in expanding economic opportunity. For pharmaceutical companies, motivations include the possibility of creating competitive advantage, increasing operational efficiencies, and increasing the impact of philanthropic activities in developing countries. Potential risks include reputational risk and regulatory risk related to intellectual property rights and counterfeit drugs.

2.1 Motivations: How Companies Benefit

2.1.1 Creating Competitive Advantage

A key incentive for companies to engage in activities that create economic opportunity is the potential to create competitive advantage. This is particularly true in key emerging markets, such as China, India, Brazil, South Africa, and Russia, where the near-term prospect of increased sales and revenue makes local investment an attractive opportunity. Companies' economic opportunity activities can assist them in entering new markets through fostering relationships with key stakeholders and demonstrating a commitment to the local community. Merck's competitiveness initiative, for example, has helped the company gain access to government leaders in Mexico and Brazil and has positioned it as a partner of choice for future collaborations with local governments, businesses, and civil society groups. Even in other developing countries, creating competitive advantage can serve as a motivation for companies to engage in economic opportunity activities. Peter Gerhardsson of Novo Nordisk comments, "There is a very strong will for us to engage in poorer countries. Our interventions help these countries, and in the long run they help our market potential in those countries as well."

2.1.2 Increasing Operational Efficiencies

Economic opportunity activities in developing countries can also help companies achieve operational efficiencies through streamlining drug production and distribution processes for products that are widely used in those markets. For example, Sanofi-Aventis recently transferred all production of a rifampicin-based drug used to treat tuberculosis from a site in Italy to a site in South Africa. This decision was motivated by several factors: first, it moved production closer to the areas where rifampicin-based drugs are used; second, it allowed Sanofi-Aventis to lower its production cost for each treatment by about 35%; and third, it bolstered the sustainability of the South African facility by strengthening the site's tuberculosis expertise and increasing manufacturing activity there.

Companies can also increase operational efficiencies through local sourcing practices that have a significant positive impact on local economies. Sourcing of raw materials from developing countries, while not a widespread practice, also offers an opportunity for increased operational efficiency. Novartis, for example, developed a partnership with the Kenya-based company East African Botanicals (EAB) in order to expand production of an active ingredient in its antimalarial drug Coartem[®]. Coartem[®] is the only fixed-dose Artemisinin-based Combination Therapy (ACT) pre-qualified by the WHO for procurement by United Nations agencies, and has been adopted as the first-line defense against malaria in dozens of countries in Africa. These conditions created significantly increased demand for the product between 2003 and 2005. Developing a partnership with EAB enabled Novartis to meet the demand for its drug while also permitting EAB to provide supply contracts to several thousand local farmers in Kenya and Tanzania.

Finally, companies can outsource different parts of their value chain to smaller firms based in developing countries. Such arrangements enable multinational companies to keep their production costs down while providing growth opportunities for locally-based companies and expanding economic opportunities for citizens in developing countries. Pfizer, for example, has contracted with the Malaysian drug company, Pharmaniaga Manufacturing Berhad, since 1991 to lower costs associated with manufacturing tablets.

2.1.3 Increasing Philanthropic Impact

In many developing countries where pharma companies engage in philanthropic activities, economic opportunity engagements can help improve companies' ability to achieve their philanthropic goals. Activities that lead to increased economic opportunity, such as collaborating with local organizations, can improve the efficiency and effectiveness of philanthropic activities by expanding capacity, reducing transaction costs and time requirements, catering to local needs, and involving local citizens in developing health solutions.

For example, Lilly provided technology transfer for its capreomycin (Capastat[®]) and cycloserine (Seromycin[®]) drugs to Aspen Pharmacare, the South African company, when it was discovered that those drugs are effective in treating Multi-Drug Resistant Tuberculosis (MDR-TB). Though Lilly made investments to expand supply of the drugs, it could not meet the growing demand alone. Providing technology transfer to Aspen Pharmacare enabled Lilly to meet increased demand for its products in an efficient and cost-effective manner that also expanded economic opportunities for South Africans. "Now that we've transferred the technology to [Aspen Pharmacare], and have enhanced their capabilities through training, they now have additional opportunities to produce other products that will be in compliance with Good Manufacturing Practices," says Gail Cassell, Vice President for Scientific Affairs and Distinguished Research Scholar for Infectious Diseases at Lilly. While the primary motivation for the partnership was the reduction of TB instances, the partnership resulted in both new jobs and an effective program that advances Lilly's philanthropic goals in the region.

2.2 Risks: What Companies Stand to Lose

2.2.1 Reputational and Relationship Risk

One of the most significant drivers of companies' engagement in developing countries is the reputational risk they face if they do not fulfill the social obligations placed on them by multiple stakeholders. Companies have experimented with several approaches to managing the tension that exists between the fundamental business

model of the pharmaceutical industry – in which companies rely on profits from patented products to fund significant investment in new research and development – and the needs presented by millions of people across the globe who suffer from treatable diseases but lack the ability to pay for needed medicines. Almost all major pharmaceutical companies, for example, administer extensive drug donation programs in Latin America, Africa, and Asia. Nonetheless, pharmaceutical companies continue to face tremendous pressure from various stakeholders, including consumers, advocacy organizations, and even shareholders, to do more to increase access to medicines and basic health care services. By taking a proactive approach to increasing economic opportunity in developing countries, pharmaceutical companies do not just minimize their reputational risk; they can actually help improve their public image by demonstrating their commitment to improving the lives of poor people in those countries. While pricing and intellectual property rights remain contentious issues, generating good will in these countries can help the industry protect its basic business model by showcasing the positive social impact it creates. Finally, partnership activities that expand economic opportunities allow pharmaceutical companies to develop and strengthen relationships with key external stakeholders – a major priority for the industry.

2.2.2 Regulatory Risk

Companies that do not engage in policy discussions related to intellectual property laws, laws governing the production and distribution of counterfeit drugs, and other laws related to drug regulations risk becoming constrained by the establishment of hostile business environments in developing countries. In 2006, for example, the WHO estimated that there were several countries in Africa, Asia, and Latin America where more than 30% of the medicines on sale could be counterfeit, in comparison to a rate of less than 1% in industrialized countries with robust and effective regulatory systems and market control.⁸ Increased involvement by pharmaceutical companies in shaping the “rules of the game” related to drug regulation and penalties for counterfeiting helps address a serious public health concern. In addition, stronger anti-counterfeit rules and their enforcement may induce further investment by the pharmaceutical industry in developing countries. While “rule shaping” activities are an indirect and long-term strategy for creating economic opportunity, Western pharmaceutical companies are well positioned to engage effectively in these activities.⁹ By leveraging their government influence, pharma companies can contribute to the establishment of better business environments that will drive both local economic expansion and foreign investment.

3 ■ Economic Opportunity Strategies

3.1 Three Tiers of Activity to Increase Economic Opportunity

Our research has shown that large pharmaceutical companies engage in a variety of economic opportunity strategies in developing countries. However, as stressed above and highlighted in the case studies, these strategies are not typically employed with the explicit goal of creating economic opportunity. Rather, the strategies are often incorporated into corporate initiatives aimed at a host of business and philanthropic goals, including increased operational efficiency, increased market share, improved strategic positioning, improved business environment, and expanded access to health care for citizens of developing countries. Many of these initiatives often contribute to increased economic opportunity, even though that is not their primary objective.

The strategies employed by multinational pharmaceutical companies can be organized into three tiers based on how directly they contribute to increased economic opportunity for citizens in developing countries. The first tier, which contributes most directly to increased economic opportunity, is Creating Inclusive Business Models. Activities in this tier tie business activity to increased economic opportunity through the creation of new or higher-skilled jobs and the expansion of local businesses. The second tier of activity is Capacity-Building aimed at individuals and institutions. Capacity-building activities are a less direct form of economic opportunity expansion because they usually do not lead immediately to job creation; however, they are important in the context of developing countries, where educational and professional training opportunities are often limited, and institutions often weak. The third tier of activity, Rule-Shaping, is the most indirect form of economic opportunity expansion because its impact is long term and does not directly affect individual workers. However, these activities help to create large-scale impact by helping to optimize the legal and regulatory environments in which businesses in developing countries operate.

3.1.1 Tier One: Creating Inclusive Business Models

As outlined in the introduction, inclusive business models are the “strategic cornerstones” for action to expand economic opportunity. For pharmaceutical companies, inclusive business models incorporate a range of activities, such as:

- Foreign direct investment (FDI), or establishing a presence in developing countries to employ people at their own facilities;
- Technology transfer or voluntary licensing agreements that allow local generic drug manufacturers to produce drugs they otherwise would not be able to; and
- Incorporating local businesses into the company’s value chain through sourcing raw materials or outsourcing other services, such as information technology.

These business activities directly contribute to the creation of new, often higher-skilled and better-paying jobs, and enable local businesses to expand their operations and strengthen their financial positions. Roche

Pharmaceuticals, for example, recently granted a license to Universal Corporation Limited in Kenya to produce the generic equivalent of saquinavir, an Antiretroviral Therapy (ARV). The agreement highlighted Roche's role in expanding access to ARV treatments and also contributed to expanding economic opportunity in Kenya, where Universal's new \$10-million plant employs 280 people.

While inclusive business models offer the most direct opportunity to create economic opportunity, the nature of the pharmaceutical industry value chain limits the impact a single company can achieve utilizing this approach. Due to the complex procedure of drug manufacturing, the process requires high-skilled employees in relatively small numbers. The need for higher skilled employees prevents direct recruitment aimed at the very poor, who are often less educated. The Roche example above underscores this limitation of the pharmaceutical industry in the creation of large-scale employment opportunities. "We're not best suited to creating a lot of local manufacturing jobs. We're not a labor intensive industry," says Jon Pender, Director of Government Affairs at GlaxoSmithKline. While direct investment in setting up facilities may not often involve extensive collaboration, the other activities in this tier often involve collaborating with in-country partners.

3.1.2 Tier Two: Human and Institutional Capacity-Building

The second tier of activities that expand economic opportunity in developing countries focuses on building local institutional and human capacity. While all major pharma companies engage in training or capacity-building activities in developing countries, we have highlighted here a small subset of those programs. For example, although not detailed in this paper, many drug donation programs incorporate training.

Human capacity-building programs may not always lead directly and immediately to new jobs, but they have the potential for significant impact in developing countries, where educational and professional training opportunities are limited and local infrastructure systems are often weak. By providing the necessary training for acquiring better jobs or the institutional capacity to create new ones, these activities are often precursors to expanding economic opportunities.¹⁰ While the majority of capacity-building activities highlighted in this paper are carried out as part of the philanthropic activities of pharma companies, training activities are also carried out through companies' business practices. For example, pharma companies' clinical trial efforts in developing countries contribute to capacity-building and increased economic opportunity. Training and capacity-building activities also involve high levels of collaboration, usually with non-profit partners in the recipient developing countries.

Most multinational pharmaceutical companies are actively engaged in human capacity-building initiatives targeting physicians, nurses, community health workers, and other vocational health care workers. Pfizer, Abbott, GSK, and Novo Nordisk, for example, all fund several training programs to increase the number of highly skilled and knowledgeable health care workers in countries across Africa and Asia. Abbott's HIV/AIDS program in Tanzania, for example, has trained over 10,000 professional and community-based health care workers in HIV care and treatment, counseling and testing, equipment operation, and hospital management since its launch in 2001. GSK's Thai Nursing program is another example that has graduated 500 nurses in five years and has provided critical training in primary care, prevention, and disease management to women who may otherwise have ended up in prostitution. Training programs help already-employed professionals access better-paying jobs and can also position unskilled workers for new jobs they may not have previously qualified for. Thus, while these activities may be less direct, human capacity-building programs achieve impact

on a larger scale than individual business operations by creating a cadre of trained health-care workers who move on to employment across the entire health sector of a country.

Pharmaceutical companies are also engaged in helping to build local institutional capacity through providing a variety of resources, including technical assistance, strategic planning advice, financial support, mentoring, and networking assistance. These activities help contribute to the development of robust health care infrastructure systems, which can then employ more local staff and increase access to health care services for citizens. Strong infrastructure systems also help facilitate companies' ability to access new markets and increase distribution of products and services in existing markets. For example, the work of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) to increase developing country capacity for drug registration and regulation will likely result in job creation and higher pay for regulatory workers, and will expedite the review and approval processes for new drugs in those markets. Such activities impact both individual job creation and the business constraints for pharmaceutical companies.

3.1.3 Tier Three: Helping to Optimize the “Rules of the Game”

The final category of activities in creating economic opportunity includes influencing changes in public policy or regulation that lead to job creation or foster better business environments. By shaping the “rules of the game,” these activities can lead to large-scale economic impact over time. Due to the long-term and often complex nature of affecting public policy, these activities require strong partnerships with local champions and other companies. For example, Merck's Competitiveness Initiative for Latin America works with local non-profit and business partners to promote competitiveness in Latin America, with an emphasis on projects that support the development of the life sciences sector. Over the long term, the initiative will contribute to enhanced economic opportunity by helping develop business cases, policies, and incentives that will drive the development of new life sciences clusters in the region.

Shaping the “rules of the game” is the most indirect way through which to increase economic opportunity; however, the potential for pharma companies to have economic opportunity impact is probably greatest in this area. Significant opportunities for business impact also exist. For example, through working with governments and regulatory agencies to address the problem of counterfeit drugs – a key business constraint for the pharmaceutical industry – companies can help create a healthier business environment with strong property rights and rule of law. The better business environment offered in these countries may encourage more companies to establish local offices or forge partnerships with local firms. For example, GSK's decision to partner with Aspen Pharmacare was driven in part by the existence of a relatively robust drug regulation infrastructure in South Africa, as well as by Aspen's reputation for respecting international intellectual property laws. Our research also indicates that rule-shaping is an area where few pharmaceutical companies are actively engaged, providing an opportunity for high impact and differentiation.

3.2 Reinforcing Activities

While direct engagement of pharmaceutical companies in developing countries through local employment, local procurement, and local sales is the most direct way of expanding economic opportunity, two critical conditions must first be in place to facilitate this form of engagement. First, prospective employees must possess the level of knowledge and skills required for success in the newly-created positions. For the health care

industry in particular, human capacity-building is therefore an important complementary strategy to the strategic cornerstone of creating inclusive business models. Second, the laws, regulations, and tax incentives in place in developing countries must create an enabling environment that is supportive of inclusive business models. Complementary rule-shaping activities that optimize the “rules of the game” are crucial in this regard. Together, the three tiers of activity reinforce one another and form a more comprehensive approach to expanding economic opportunity in developing countries.

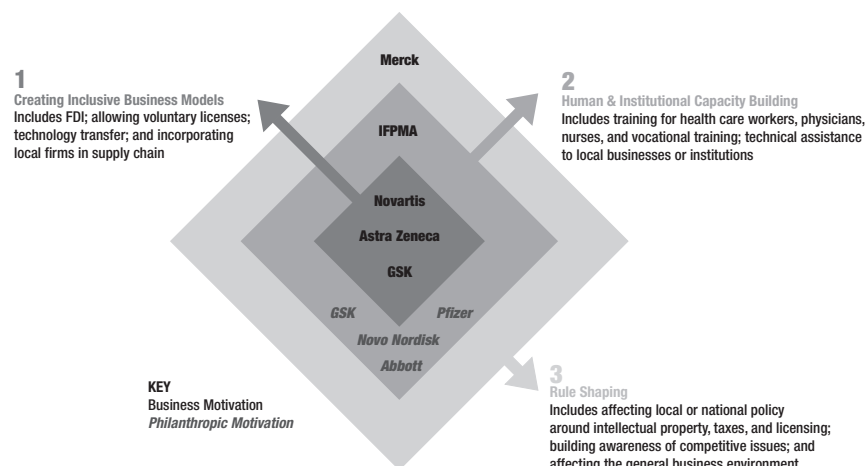
3.3 Mapping Economic Opportunity Strategies

The framework pictured in Figure 1 provides a visual depiction of the three tiers of pharmaceutical industry activity that lead to economic opportunity in developing countries. As discussed, the first tier represents the most direct way for companies to expand economic opportunity, while activities in the second and third tiers contribute more indirectly to expanded opportunity.

The size of each tier of activity within the framework is representative of the potential impact of that activity. Although inclusive business models contribute directly to the creation of new jobs and expanded economic opportunity, they typically have limited impact due to the nature of employment needs within the pharmaceutical industry. The inclusive business model tier is therefore the smallest of the three. Capacity-building initiatives, which comprise the middle tier, offer more indirect opportunities to expand economic opportunity, but often reach more people than individual business operations. Finally, rule-shaping activities that target the overall environments in which businesses operate, while most indirect, comprise the largest tier, representing pharma companies’ greatest opportunity for impact.

In addition to illustrating the different types of activity, their relationships to one another, and the relative scale of their impacts, the framework also distinguishes between activities that are motivated by companies’ business interests and those that are motivated by their philanthropic goals. Finally, the framework maps individual activities undertaken by the companies profiled in this report across these three tiers.

FIGURE 1 THE THREE TIERS OF ACTIVITIES THAT EXPAND ECONOMIC OPPORTUNITY



Note: The positioning of individual companies within the framework reflects the authors’ interpretations of the highlighted programs. Companies may be engaged in additional activities in other tiers beyond what is depicted in the framework.

A company's motivation to engage in economic opportunity is shaped by the nature of the challenge being addressed, the market potential of the target country, and the presence of internal support or champions within the company. Motivation also influences where the initiative is housed within the company. When activities are critical to the operations of pharmaceutical companies in developing countries, they are often best handled by the business units. Novartis' decision to partner with EAB in Kenya to ensure adequate supplies of a key ingredient in Coartem® is one such example. AstraZeneca represents a second example, with more than 300 local citizens employed in its two research and development facilities in Bangalore, India. Many of the training activities currently operating in developing countries, on the other hand, are undertaken by the companies' philanthropic or corporate contributions units. Occasionally, initiatives are located or managed within one unit of a company but heavily utilize the resources available in other units to ensure successful implementation. For example, Lilly's technology transfer initiative is part of its philanthropic MDR-TB partnership, but takes advantage of the skills and expertise of Lilly employees in the business units.

As expected, most of the inclusive business models we researched fall within companies' business units (the technology transfer initiative at Lilly is an exception). Each of these initiatives has a direct, but limited impact on economic opportunities in developing countries. Of the second tier of activities, the human capacity-building programs we researched are all run through companies' philanthropic units, likely due to the fact that they are part of larger initiatives designed to bolster local public health systems.¹¹ Because most of the training programs last from three to six months, they are able to target several hundred citizens over the course of a few years. Additionally, because all of the programs in this tier are also highly collaborative, relying on the engagement of local non-governmental organizations to help design and implement effective programs, the initiatives allow sponsoring companies to build relationships with local stakeholders.

IFPMA's institutional capacity-building initiative aims to strengthen government regulatory capacity through training regulatory and clinical trial workers. The initiative is run through the Partnership Taskforce, comprised of business representatives from several IFPMA member companies. The initiative has only just begun, so impact assessments are not available. However, if successful, the effort to expand in-country capacity for clinical trials and expand quality assurance and drug regulation programs is likely to result in the creation of jobs across the continent of Africa.

Finally, in rule-shaping, Merck's Competitiveness Initiative relies on the collaboration of industry and government partners to spark innovation and drive the development of business clusters in Latin America. It is housed within Merck's business unit rather than its philanthropic unit, reflecting the strategic relevance of the initiative to Merck's future business interests in the region. While this is a long-term project, its ultimate impact on the business environment and economic opportunities available in Latin America could be significant.

Our research highlights companies that have pursued economic opportunity initiatives with various business and philanthropic goals, representing a range of potential for impact. There is no single right way to engage in expanding economic opportunity in developing countries; multiple opportunities to contribute exist and each company's strategy will depend on its business objectives, competitive advantages, and corporate social responsibility or philanthropic goals. Our research indicates, however, that pharma companies' greatest opportunity to achieve large-scale impact is through activities aimed at optimizing the "rules of the game." Such activities, while long-term in nature, establish the foundation for increased economic opportunity by creating the conditions that attract business and generate job creation.

4 ■ Future Opportunities

Our research has identified three major themes for pharmaceutical companies to bear in mind as they engage in future activities in developing countries.

1. Engage in Rule-Shaping: While inclusive business models offer the most direct method of creating economic opportunities through the creation of jobs, companies' greatest opportunity to achieve large-scale impact is through activities aimed at optimizing the "rules of the game." Such activities, while long-term in nature, create the foundation for increased economic opportunity by establishing the conditions that attract business and create jobs. A single pharma company's expansion, even on a relatively large scale, typically results only in a few hundred new jobs. On the other hand, changing the business environment in a developing country to encourage organic growth of local businesses or to attract multiple foreign firms can result in thousands of new jobs. In spite of the potential for impact, our research identifies a potential gap in participation in this third tier of activities – not many pharmaceutical companies are playing active roles in creating economic opportunity through rule-shaping. Both because of the potential for impact, and because of the opportunity to take a leadership role in a relatively less crowded space, rule-shaping offers a compelling opportunity for pharmaceutical companies to achieve both social and business impact. At the same time, given currently small market sizes, the incentives for Western pharma companies to engage in rule-shaping in many developing countries may be limited in the very near term.

One promising opportunity is offered by the recently founded Medicines Transparency Alliance (MeTA), a partnership among the UK Department for International Development (DFID), the World Health Organization, and several pharmaceutical companies and non-profit organizations that aims to increase transparency in the regulation, procurement, distribution, and sales of drugs in developing countries. Currently in its pilot stage, the Alliance hopes its activities will address several challenges in developing countries, including the prevalence of counterfeit drugs, lack of access to affordable treatment for poor people, and lack of quality distribution systems for medicine delivery.

2. Track and Communicate: Our research also identified a lack of emphasis on identifying, tracking, and communicating the economic impacts of efforts that pharma companies are already engaged in. As the examples in this paper show, a variety of different types of activities that the industry engages in for the primary purpose of expanding access to health care – such as training, licensing, and technology transfer – often create economic opportunities in developing countries at the same time. Yet, very few of these programs are designed to identify, track, or communicate about economic impacts. While rigorous longitudinal economic impact studies can be costly and time-consuming, various other methods such as small focus groups or informal interviews with beneficiary organizations can provide pharma companies with tangible evidence of economic opportunities created through their programs. Focusing on these very powerful positive outcomes and undertaking simple measures to track impact provide the industry with the opportunity to highlight its economic footprint without the need for large additional investments. Communicating about the economic

benefits of their operations also allows the industry to supplement their messages about the value they bring to society, beyond health care.

3. Collaborate to Maximize Impact: Finally, collaboration within and outside the industry can play a significant role in multiplying the economic opportunity impacts of pharma companies' activities. While not all activities lend themselves equally to collaboration (e.g., foreign direct investment), many of the examples highlighted in this paper feature successful partnerships. In creating economic opportunities, pharmaceutical companies can collaborate with other industries (e.g., GSK partnering with Accenture to provide training), academic institutions (e.g., Lilly with Purdue University for technology transfers), or even with their competitors (e.g., the International Federation of Pharmaceutical Manufacturers and Associations developing clinical trial and regulatory capacity or the Medicines Transparency Alliance tackling counterfeiting and distribution system challenges). Collaborations allow partners to focus on their comparative advantages to increase impact, share risks, and increase the credibility of the efforts with other important stakeholders.

The activities highlighted in this paper offer powerful examples of pharmaceutical companies' contributions to creating economic opportunity in developing countries. However, weak infrastructure in many of these countries – including insufficient supplies of electricity and clean water, and unreliable transportation and distribution systems – often limits the potential impact of these activities. These services, which foster economic growth and a healthy society in developing countries, are also critical to companies' ability to establish and grow their markets. However, because the need in each of these areas is so great, effective solutions require a greater variety and scale of resources than any one pharmaceutical company can offer. Collaboration among different industries, as well as with governments and civil society groups, may be a particularly effective tool for addressing some of these larger, systemic challenges.

As pharmaceutical companies become more involved in both business and philanthropic activities in developing countries, it will be important for each company to identify the best strategies to create new economic opportunities and to leverage the benefits of activities already underway. While the primary focus of the industry is, and will most likely continue to be, on increasing access to health care, the potential for expanding economic opportunities through its activities should not be overlooked as a significant outcome.

5 ■ Case Studies

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5.1 CREATING INCLUSIVE BUSINESS MODELS: NOVARTIS

Background

Inclusive business models are the most direct strategy through which companies create economic opportunity in developing countries. By forging strategic relationships with local suppliers and distributors or establishing their own local presences, multinational health care companies can create possibilities for local wealth and job creation.

An example of a successful inclusive business model is offered by Novartis' partnership with East African Botanicals (EAB), a wholly-owned subsidiary of the private Kenyan company Advanced Bio-Extracts. East African Botanicals is primarily engaged in the production of artemisinin, a natural extract of the *Artemisia annua* plant that is used to produce an active ingredient in Novartis' anti-malarial, Coartem®.

Coartem® is part of a class of anti-malarial drugs called artemisinin-based combination therapies (ACTs) that are recommended by the World Health Organization (WHO) for use in countries experiencing resistance to conventional anti-malarial monotherapies. Currently, Coartem® is the only fixed-dose ACT pre-qualified by the WHO for procurement by United Nations agencies. It is sold to the WHO at cost for public sector use in developing countries.¹²

Novartis' partnership with Eastern African Botanicals increased its access to artemisinin supplies and allowed it to meet the soaring demand for Coartem® that followed the announcement of the treatment's WHO pre-qualification status. The partnership also resulted in the creation of thousands of better-paying jobs for local farmers and manufacturing plant workers employed by EAB.

Motivation

Novartis' decision to partner with EAB was driven by the firm's need to ensure an adequate supply of high-quality artemisinin in order to meet Coartem® production targets under its WHO agreement. Historically, most *Artemisia annua* was sourced from remote mountain regions in China and other parts of Asia, where the plant grows wild. When demand for Coartem® increased dramatically in 2004,¹³ the yield from natural crops was insufficient to meet Novartis' supply needs. The company subsequently began exploring opportunities to establish partnerships with additional artemisinin suppliers. EAB was a natural partner because its sole business objective is to produce and distribute artemisinin. Moreover, because EAB is located in Kenya, Novartis was able to spread the risk of crop damage due to climatic events between East Africa and South East Asia. Finally, by working directly with an emerging company in East Africa, Novartis further demonstrated its commitment to economic improvement and health advancement on the African continent. All of these factors combined to make EAB an especially attractive business partner for Novartis and a key component of the company's long-term Coartem® distribution strategy.

Activities

Novartis' partnership with EAB began in January, 2005, when EAB signed a five-year supply agreement requiring it to vastly expand production of artemisinin. EAB's business model relies on the cultivation of *Artemisia annua* plants through both company-controlled irrigated crops and smallholder farms. Local farms and individual farmers under contract with EAB are provided with planting material and comprehensive training in Good Agricultural Practice (GAP) guidelines for *Artemisia annua* cultivation to ensure high-quality returns.¹⁴ In 2006, EAB employed about 7,500 local farmers¹⁵ and increased production of *Artemisia annua* from 200 hectares to more than 1,000 hectares.¹⁶

Cultivation of the *Artemisia annua* plants is the first step in the process of producing artemisinin. After the plant leaves are harvested, they are processed in EAB facilities in Kenya and Uganda to extract artemisinin, which is then shipped to Novartis and used to produce artemether, one of the active ingredients in Coartem®. 2007 marked the first year of product delivery to Novartis; all 17 batches of the first shipment of artemisinin were approved.¹⁷

Impact

The partnership between Novartis and EAB has created significant business and social impact for all parties involved. On the business side, the partnership was the key driver behind EAB's rapid growth. "Novartis has proven to be our most important partner as we move to large-scale production of artemisinin in East Africa. By placing firm orders for extracted artemisinin, providing financial support for infrastructure improvements, and delivering technical support and know-how, Novartis has made a major contribution to creating a sustainable market for this key natural ingredient," said Patrick Henfrey, Chief Executive Officer of Advanced Bio-Extracts.¹⁸

The supply contract marked a major milestone for EAB, which until that time had struggled to find farmers interested in growing *Artemisia annua*, or investors who would provide capital to sustain and grow the business. The agreement with Novartis helped the company overcome both challenges. Philip McLellan, Managing Director at EAB, explained that the promise of large-scale artemisinin purchases from a major pharmaceutical company reduced the risk to farmers in switching crops.¹⁹

The company was also able to attract new investors after Novartis offered financial support and technical assistance to help bring its operations to scale.²⁰ The infusion of new capital enabled EAB to construct a multi-million dollar processing plant in Kenya and purchase and expand a similar factory in Uganda, acquiring the necessary building materials from local manufacturers.²¹ These improvements to EAB's infrastructure have helped position the company for long-term success in the artemisinin sales market.

For Novartis, the partnership enabled the company "to meet our own production goals for Coartem[®] and bring this life-saving medicine to millions more patients suffering from malaria," says Sivlio Gabriel, Executive Vice President, Malaria Initiatives for Novartis. During 2006, Novartis supplied more than 62 million Coartem[®] treatment courses to more than 30 countries across Africa. The company estimates that it has now reached capacity to distribute about 100 million treatment courses each year, with appropriate notification.²²

For thousands of residents of East Africa, EAB offers highly paid farming and manufacturing employment opportunities that had previously been unavailable. Due to the high demand for *Artemisia annua*, the crop is expected to deliver higher financial returns than coffee, and four times the return of corn.²³ In 2006, 850 smallholder farmers in Northern Tanzania saw their incomes rise a total of \$320,000 (\$376 per farmer on average) after selling their *Artemisia annua* crops to EAB.²⁴ As more pharmaceutical companies begin manufacturing greater quantities of ACTs, the increased demand for *Artemisia annua* will likely mean more job creation in the region in addition to higher pay.

Finally, the increase in the number of Coartem[®] treatments made available through partnerships like the one between Novartis and EAB has meant that more poor people in developing countries have access to the life-saving medicines they need. The 62 million Coartem[®] treatments distributed by Novartis in 2006 helped save an estimated 200,000 lives.²⁵

5.2 CREATING INCLUSIVE BUSINESS MODELS: **ASTRAZENECA'S EXPANSION IN INDIA**

Background

Inclusive business models are the first tier of activities and the most direct method that health care companies can employ to create economic opportunity in a developing country. Inclusive business models, which stem from value chain linkages, are at the core of a firm's activities. Examples include foreign direct investment (FDI), international partnerships, technology transfers, outsourcing, voluntary licensing and the incorporation of local firms into the supply chain. Inclusive business models have the potential to increase local sales, procurement, and employment in a developing country.

AstraZeneca has utilized this model by embarking on a significant expansion of its operations into India, most recently culminating in the establishment of a Process Research and Development (PR&D) laboratory in Bangalore. AstraZeneca's inauguration of the PR&D laboratory in March, 2007, complemented its existing R&D center and manufacturing and marketing offices in India. The new PR&D laboratory, only the fourth built by the company, is AstraZeneca's first such facility outside of Europe.

Motivations

AstraZeneca's expansion into India is motivated by strategic business opportunity. Approximately 30% of tuberculosis (TB) cases in the world occur in India and the new PR&D facility, in conjunction with the existing R&D center, is focused on finding a cure for TB. Moreover, according to Dr. Tanjore Balganes, head of research at the Bangalore AstraZeneca unit, currently available TB drugs, while effective against the disease, possess many side effects, have prolonged treatment periods, and are highly toxic. By leveraging India's strength in process chemistry, AstraZeneca expects to develop a new drug to combat TB by 2012.²⁶

In addition to the core strategic business motivation, AstraZeneca has been motivated by its corporate social responsibility efforts to combat TB in other high-incidence areas in Central Asia, namely Kyrgyzstan and Turkmenistan. Partnering with the Red Cross in 2002, AstraZeneca's Bangalore division funded community-based programs. These programs built local capabilities in prevention and control of the disease, and improved education awareness about TB and the advantages of early diagnosis. As a result of the progress from these programs – increased number of diagnosed patients, higher treatment completion rates, and a greater sense of general awareness – AstraZeneca's R&D center received the 2005 Corporate Community Partner Award at the Pharmaceutical Achievement Awards Conference.²⁷

Activity Description

The new PR&D facility cost \$15 million to build. It can accommodate up to 80 process scientists, supported by a contingent of engineering and office staff. While AstraZeneca will hire scientists from leading research facilities around the world, many of the employees who operate the Bangalore facility will be from India.

Together with the existing R&D center, the new PR&D facility is an earnest attempt to address a neglected disease common to India and the rest of the developing world. Currently, AstraZeneca is the only major drug company to have established an R&D center and PR&D facility to develop new drugs in India.²⁸

Impact

As with many pharmaceutical-related investments, the financial benefit of the new project is expected to occur – over an extended period of time – once the drug has been created, approved, and released onto the market. Meanwhile, AstraZeneca has made significant investments in creating social impact through the project.

To date, AstraZeneca has invested over \$50 million in its Bangalore-based facilities, including \$15 million to build the PR&D laboratory and \$40 million in the R&D center for construction, equipment, and research programs on drug discovery. The total employment created through AstraZeneca's India operations is anticipated to exceed 400 in 2008. This number includes 300 manufacturing staff from an existing drug formulation plant, 90 scientists from the R&D center, and 80 scientists who will fill the new PR&D center by mid-2008. This estimate does not include staff and engineers for the new PR&D facility.²⁹

AstraZeneca's inclusive business model approach in India has created jobs across a range of skill levels – from highly-skilled scientists and engineers to auxiliary and support staff. Moreover, AstraZeneca continues to create greater economic opportunity through related and supporting industries. These opportunities are the product of value chain linkages in the form of distributing, supplying, outsourcing, and collaborating agreements with local firms. For example, AstraZeneca has outsourced some of its scientific work to third-party Indian firms.

AstraZeneca's inclusive business model in Bangalore has created a "strategic cornerstone" that serves as a platform for complementary strategies that magnify its economic opportunity impact. For example, beyond the company's core activities, AstraZeneca has supported education and training opportunities through organized seminars, symposia, and workshops.

Sudhir Nambiar, the director of the PR&D facility, commented, "Depending on the Bangalore team's performance during the coming year, the center may get a pilot plant with enough capacity to support human trials."³⁰

AstraZeneca's continued expansion may increase incentives for other pharmaceutical companies to open or expand operations in India. This would create a multiplier effect in which all parties involved, into the lower-income strata, benefit.

5.3 CREATING INCLUSIVE BUSINESS MODELS: GLAXOSMITHKLINE'S VOLUNTARY LICENSES

Background

Voluntary licenses form part of the inclusive business model strategy through which pharmaceutical companies can create economic opportunities. Voluntary licenses (VLs) are formal permissions granted by patent holders of branded drugs through which manufacturers in developing countries can produce and sell generic versions. Since generics are often cheaper than their branded counterparts, or have wider distribution, VLs create better access to drugs. By allowing generics manufacturers the legal right to produce drugs they would otherwise lack access to, VLs can foster local business development, job creation, and improved public health.

GlaxoSmithKline (GSK) has been a leader in the field of voluntary licensing, having granted eight VLs to date to generics manufacturers in South Africa and Kenya. "I think we've granted more voluntary licenses than most other players in the industry," says Jon Pender, Director of Government Affairs at GSK. "We have taken a very progressive attitude in dealing with this challenge." All of GSK's licenses have been for anti-retroviral (ARV) drugs used to treat HIV/AIDS.

Motivations

A combination of business and philanthropic needs drove GSK's decision to initiate voluntary licensing of its ARV drugs. First, according to Pender, the company simply recognized that licensing was the right thing to do, given AIDS' massive toll in the developing world. Second, providing tangible solutions to the AIDS pandemic helped improve the company's reputation and its relationships with strategic stakeholders at a time when the pharma industry was under significant pressure to act. Finally, the agreement helped preserve the company's business model, which relies heavily on a strong intellectual property rights regime. "People did not fully understand our constraints, and we needed to protect the fundamental business model. Providing the licenses allowed us to address the global health challenge and protect our intellectual property without compromising patent rules," explains Pender.

The recipient companies also reaped numerous benefits from the agreement. GSK's products were commercially attractive to the licensees, since they could access rights to produce first-line ARVs, and generate revenues leading to increased profits. For companies like Aspen Pharmacare, establishing a relationship with a major multinational pharma company paved the way for additional partnerships with other companies. The agreements also allowed the local generics companies to contribute to the local economy, address a critical public health challenge in their countries, and highlight their own social responsibility.

Activities

GSK has issued eight voluntary licenses to date, starting with Aspen Pharmacare in South Africa in 2001. The other companies are Cosmos in Kenya (2004), Biotech Laboratories (2004), Feza Pharmaceuticals (2004), Cipla Medpro (2004), Universal Coporation Limited (2005), Adcock Ingram (2005), and Ranbaxy (2006), all in South Africa. GSK's licencees are all producing their own versions of GSK's ARVs rather than manufacturing on GSK's behalf. Consequently, GSK's key responsibility is to ensure that the generics manufacturers are capable of producing to global quality standards. To ensure this, GSK undertakes a rigorous due diligence process before selecting each licensee. Each recipient company is selected on the basis of its technical capabilities, and any technology transfer for the manufacturing process is built into the licensing partnership. The responsibility to ensure that the products are of good quality lies with the licensee and with the local regulatory authorities. As a result, once the agreement is in place, there is not a significant need for skills transfer or technical assistance. Licensees usually buy the necessary active pharmaceutical ingredients for the drugs from India or China, then produce the treatments and work with local regulatory agencies to obtain approval before selling to local markets.

While GSK is open to discussing VLs with other partners, it is also realistic about the challenges and benefits of these arrangements. The company considers it vital to choose the most appropriate licensees – those who can ensure the sustainability of supply, encourage safe use of the drugs, and ensure the medicines go to the patients who need them, rather than being diverted to wealthier markets.³¹

Impact

The VL's impact has already been seen in terms of building local ARV manufacturing capability. In 2005, GSK shipped 126 million ARV tablets. In 2006, the company shipped just 86 million tablets, yet total shipments increased to 206 million, as shipments from the locally-licensed manufacturers provided the balance of 120 million tablets.³²

GSK has also benefited through improved stakeholder relations. "We have seen a lot of interest from informed stakeholders, such as Oxfam, the investor community, and political leaders," says Jon Pender. "While it's difficult to say exactly how much public opinion has changed due to the VLs specifically, it's the overall package of our activities in this area that has made a difference in our reputation."

Since GSK is not directly responsible for the generic manufacturing process once a license has been issued, the company does not currently track the impact on licensees beyond their production volumes. However, conversations with Aspen Pharmacare identified several tangible benefits for the generics manufacturer. "We are probably the single biggest generic supplier to sub-Saharan Africa," says Stavros Nicolaou, senior executive at Aspen. "Today ARVs contribute about 7–8% of our total revenue, up from 0% before the agreements." In addition, the licensing agreement has allowed Aspen to apply lessons learned from its initial experience with GSK to more sophisticated partnerships it later established involving technology transfers for drugs in additional therapeutic areas (see Lilly case study for more detail). "We've gone from rudimentary licensing agreements and immunity of suits to more advanced technology transfer partnerships, and have learned along the way, as no two technology transfer agreements are the same," comments Nicolaou.

In addition to direct impact on licensee companies, the VLs also have multiplier effects in other markets that are connected to those companies. Since many of these African manufacturers import their raw materials from companies in India and China, the economic impact of the VLs extends to those companies and countries as well.

The Role of Collaboration

One of the key lessons GSK learned through the licensing process was that partnerships with generics manufacturers involve multiple steps and almost always take longer than originally planned. Hence, proper planning, well-developed timelines and milestones, and realistic expectations from the beginning are all important. Pender also notes that personal relationships are critical in establishing business partnerships. "The individuals who are involved on both sides can make a big difference in the partnership," explains Pender. "You need to enter into dialogues with many different kinds of stakeholders and need to build trust in that process. The personal relationships and trust allows you to weather the challenges in the process."

Aspen's experience working with GSK has helped it identify best practices for other local manufacturers seeking to establish similar partnerships going forward. Aspen's relationship with GSK has not only helped position the company as a partner of choice for other Western pharma companies, but has also helped build its internal capabilities and its reputation with the United States Food and Drug Administration. Says Nicolaou of Aspen, "We've learnt a lot through experience, since sometimes you only find the errors six months down the line. We're a lot smarter now. We're in a better position to gain experience from future partnerships and technology transfers."

5.4 CREATING INCLUSIVE BUSINESS MODELS: TECHNOLOGY TRANSFER IN ELI LILLY'S MDR-TB PARTNERSHIP

Background	<p>Technology transfers are another example of an inclusive business model strategy through which pharmaceutical companies can create economic opportunities. Technology transfers by Western pharmaceutical companies to developing country drug manufacturers play an important role in creating new jobs and expanding business opportunities for local drug manufacturers. Eli Lilly's effort to address multi-drug-resistant tuberculosis (MDR-TB) by transferring the manufacturing technology of their two TB drugs – cycloserine (Seromycin[®]) and capreomycin (Capastat[®]) – is a prominent example in this category. MDR-TB is a drug-resistant strain of TB that has emerged over the last several years as a result of poor adherence to TB treatment by patients in developing countries. The WHO estimates that more than 400,000 new cases of MDR-TB are diagnosed each year.³³</p> <p>Started in 2003, the Lilly MDR-TB Partnership is a unique public-private health initiative with the goal of controlling and ultimately eliminating multi-drug-resistant tuberculosis. As part of this philanthropic initiative, Lilly has made the manufacturing technology for its two MDR-TB drugs, capreomycin and cycloserine, available to pharmaceutical companies in some of the countries with the highest MDR-TB burdens: China, India, Russia, and South Africa. As a key component of this technology transfer, Lilly partners with Purdue University to provide training and expertise to locally-based pharmaceutical companies to help ensure that high-quality manufacturing processes are in place and that the companies are well positioned for long-term sustainability.</p>
Motivation	<p>The MDR-TB partnership and the resulting technology transfer agreements are philanthropic activities undertaken by Lilly to tackle the threat of the deadly disease. “We have no in-house infectious disease drug discovery group, so this is truly a philanthropic effort,” explains Dr. Gail Cassell, Vice President for Scientific Affairs and Distinguished Research Scholar for Infectious Diseases at Lilly. Although the partnership is a philanthropic activity, it is unique in that it capitalizes on Lilly's core competency as a drug manufacturer to transfer technical capabilities to the developing world. While creating economic opportunity for the manufacturing partners was not the primary goal of the MDR-TB initiative, it is an important outcome of the technology transfers: “Our direct intent initially was not for the promotion of economic opportunity or development in the countries, but certainly it is a positive outcome of our activities,” adds Cassell.</p> <p>In addition to taking advantage of the company's R&D resources, the partnership also delivers business value to Lilly. Transferring its production capacity to Aspen allows Lilly to devote its research and development resources to products that support its core business strategy. As a 2004 case study by the African Institute of Corporate Citizenship observed, “Through this initiative, Eli Lilly demonstrates how a company's investment can be managed to actualise the benefits to society in a situation where the entity has other overriding interests preventing it from following through with the investment/product on its own.”³⁴</p>
Activities	<p>Lilly has established technology transfer agreements with companies in the four countries with the highest MDR-TB burdens – South Africa (Aspen Pharmacare), China (Hisun Pharmaceutical), India (Shasun Chemicals and Drugs), and Russia (SIA International) – as well as a partnership with Purdue University in the United States. In addition to supplying the necessary manufacturing technology and expertise to produce cycloserine and capreomycin, Lilly provides financial assistance for the purchase of equipment and conversion of manufacturing facilities, and technical training for the different steps in the manufacturing process. Lilly's partnership with Purdue University brings foreign scientists and plant managers from recipient companies to the university for training in manufacturing skills and good business practices. This partnership provides a powerful example of how multinational companies partnering with institutions in their own countries can also help create economic opportunities in other countries.</p>
Impact	<p>Lilly's technology transfer activities are creating positive financial and operational impacts at all of the beneficiary companies. In South Africa, Aspen Pharmacare manufactures both cycloserine and capreomycin. Aspen sold its first batch of cycloserine to Botswana in 2005, and is currently preparing to open a new facility with a capacity of 4 billion capsules per year. In 2006, the company also began construction of a plant to produce capreomycin, funded in part</p>

by Lilly. As a result, South Africa's profile as a manufacturing and pharmaceutical base is expected to be boosted. Enhancing Aspen's manufacturing capacity has generated new jobs and may also enhance South Africa's balance of payments through additional revenues from exports.

The partnership with Lilly has enabled Aspen to provide a skilled labor base and develop new skills for the local labor pool. Noting that the pharmaceutical industry is highly automated, Stavros Nicolaou, Senior Executive at Aspen, comments that these initiatives have led to some job creation in South Africa, a country saddled with a high unemployment rate. "From a human resource point the most impressive aspect of these arrangements has been the ability to retain and grow new skills, all of which contribute to the expanding of the South African economy and in particular in stemming the tide against the devastating pandemics of HIV, AIDS and TB." Aspen's relationships with Western companies such as Lilly and GSK helped the company secure approval as a United States Food & Drug Administration drug manufacturer. Due to the technology transfer, the company is now able to produce drugs from molecules which they did not have access to earlier. "These types of partnership have given us increased volume in our factories – without that, you can't be competitive," explains Nicolaou.

The Chinese manufacturer Hisun Pharmaceutical produced its first batch of the capreomycin active ingredient in May 2006. Hisun is also building a second facility to produce vials of the capreomycin final drug in early 2009. Shasun Chemicals and Drugs in India has validated its manufacturing process for cycloserine, and dispatched its first order to Aspen in February 2006. Finally, the Russian manufacturer, SIA International, is Lilly's newest drug-manufacturing partner and is one of Russia's largest pharmaceutical companies. SIA will supply both Lilly MDR-TB drugs.

The transfers may also have multiplier effects on the developing world manufacturers, allowing them to expand to other products beyond MDR-TB utilizing the resources from the partnerships. "We would make the case that now that we've transferred the technology to them, and we have enhanced their capabilities through training, they now have other opportunities to produce other products that will be in compliance with Good Manufacturing Practices [GMP]," says Cassell.

Lilly recently announced a new not-for-profit early-stage drug discovery effort for TB, which Cassell hopes will enable the company to engage scientists and pharmaceutical companies in low-income countries, particularly those countries with high disease rates. "This could improve their capabilities and provide economic opportunities for them individually, and possibly lead to collaborations with companies in their countries," she notes.

The Role of Collaboration

An important lesson from Lilly's technology transfer activities is that it is possible for pharmaceutical companies to enter into complementary agreements with generic manufacturers that lead to better economic and health impacts for developing countries. The Lilly MDR-TB Partnership represents a true win-win scenario. For Aspen, it provides an opportunity to expand the company's market share in South Africa and other African markets. For South Africans, the activities provide opportunities for new jobs, increased incomes, and better protection from a deadly disease. And Lilly is able to concentrate its research efforts on its core business areas, while gaining reputational benefits as a good corporate citizen.

Comments Cassell, "We feel it has been a very important and impactful philanthropic effort, and clearly it has increased access to treatment for this unbelievably complex disease. We are glad that we made the decision to invest in this area. We would encourage other pharmaceutical companies to use this model – transferring manufacturing know-how to developing countries. It increases access to medicines and also increases technical capabilities in these countries so there are opportunities for economic development."

Lilly's partnership with Purdue has had an impact not only on the generics manufacturers but also on the university itself. The partnership has been able to leverage other resources to achieve this additional impact. For example, a Purdue alumnus donated funding to establish a GMP center on campus. The center provides training for Lilly's manufacturing partners in GMP, but is also available to Purdue's students, allowing them to gain an appreciation for the need to involve both public and private sectors in these efforts. Says Cassell, "There's a lot of merit in partnering with universities who have manufacturing abilities and are interested in solving problems related to medicine access in developing countries."

5.5 HUMAN CAPACITY-BUILDING: ABBOTT, GLAXOSMITHKLINE, PFIZER, AND NOVO NORDISK

Background

Human capacity-building initiatives are part of the second tier of activities through which companies enhance economic opportunity in developing countries. Multinationals and other large companies can participate in building human capacity by supporting vocational training or professional development programs, technical support, networking assistance, or mentoring time. Initiatives that target human capacity-building for health care workers are strategic philanthropic investments because pharmaceutical companies rely on highly skilled care providers for the adoption and uptake of their products.

The case studies below provide detail on the human capacity-building programs operated through the philanthropic arms of several multinational pharmaceutical companies, including Abbott, GlaxoSmithKline, Pfizer, and Novo Nordisk.

Abbott and Abbott Fund

Abbott and Abbott Fund's program to strengthen health care systems in Tanzania is a comprehensive philanthropic initiative aimed at meeting the needs of people with HIV/AIDS and other lifelong diseases. Launched in 2001 as a public-private partnership with the Government of Tanzania, the initiative has helped to modernize facilities, train staff, improve hospital and patient management, and expand capacity for HIV/AIDS testing and treatment at over 90 hospitals and rural health clinics across the country. To date, Abbott Fund has invested more than \$50 million in the initiative, in addition to providing the technical expertise of Abbott employee volunteers to address a range of critical health areas.

A central component of the Tanzania initiative is its focus on developing human capacity: to date, over 10,000 professional and community-based health care workers have been trained in HIV care and treatment, voluntary HIV counseling and testing, laboratory equipment operation, hospital information technology, and hospital management. The training programs have had a significant impact on local health care infrastructure. Staff working at facilities funded through Abbott's initiative operate one of the most extensive hospital IT systems in East Africa to track health history, referrals, test results, and drug prescriptions. At Muhimbili Hospital, the national teaching hospital, a strong management team has increased hospital revenues by more than 50% in the first two years since the program began. Access to care has also improved as a result of the training program. About one in three people enrolled in the government's national HIV treatment program receive services at a facility that has benefited from Abbott Fund improvements.

Evidence of increased economic opportunity for program participants is more difficult to document. As Reeta Roy, Vice President of Abbott Fund and Divisional Vice President, Global Citizenship and Policy at Abbott explains, "Our program metrics align with our objectives to improve health care services." Roy emphasizes that while Abbott's main goal in designing its initiatives is to expand access to quality health care, program investments have helped create an enabling environment for the poor to manage their assets. "We have observed that investments in health care enhance livelihood options for low-income families. However, quantifying this impact is challenging."

Abbott and Abbott Fund's work in Afghanistan is another example of a high-impact human capacity-building program. The goal of this program is to improve maternal and infant health in a country that has the second-highest maternal and infant mortality rate in the world. The program also has an explicit emphasis on increasing economic opportunity for program participants.

Through its partnership with Direct Relief International and the Afghan Institute of Learning (AIL), Abbott Fund has provided more than \$230,000 in grants to support two nine-month intensive nurse/midwife/health educator workshops in Herat and Kabul. All 19 women from the program's first graduating class are utilizing the skills they obtained, with 11 graduates working at local hospitals and health centers. 16 additional women completed desk and/or clinic training and are qualified as health educators and science teachers. The success of the program created significant demand for health training among the women in the community, resulting in twice as many applicants as spaces available for the next training session. The program also revealed tremendous need for general health education by women in the community. Based on these findings, a new program was initiated this year by AIL, and Abbott provided a grant to support 15 community health workshops in Herat and Kabul provinces. Four of the 15 have

already been completed. Additionally, a third party recently approached AIL and Abbott in hopes of replicating the workshops in the surrounding areas of Bamiyan.

Abbott also donated \$3.2 million in products (including nutritionals, vitamins, and antibiotics) for distribution at three clinics associated with the program. This comprehensive support has more than doubled the capacity of these clinics to serve women and children, and has enabled the clinics to reallocate funds used for purchasing products to delivering services. Within the first year of the program, the three clinics saw a significant increase in their capacity to serve patients. Compared to baseline, the clinics treated 56% more patients, increased reproductive health services by 17%, and vaccinated more than three times as many patients as before the program began.

The Abbott Fund programs have had multiplier effects in developing countries. By strengthening public health systems and improving individual health, the programs have fostered an environment that enables individual and community economic development. “The private sector and foundations have an important role as change agents in international development,” Roy explains. “While the lives that we touch gain from programs we support and from our expertise, our companies benefit by learning how to operate in new and challenging environments.”

GlaxoSmithKline

Similar to Abbott’s Afghanistan program, GlaxoSmithKline (GSK) sponsors several initiatives aimed at training nurses, midwives, and other health care workers to provide primary and maternal care for people in developing countries. GSK’s Thai Nursing program was the longest-running of several initiatives throughout southeast Asia, having trained 500 nurses over a five-year period in subjects including primary care, health care prevention and promotion, patient home visitation, disease management and control, and health promotion campaigns.

The Thai program’s goal of increasing economic opportunity for women is particularly important in the context of the Thai economy, notes GSK’s Vice President of Global Community Partnerships, Justine Frain. “In Thailand, the nursing training program provides a much-needed opportunity for underprivileged young women who might otherwise have turned to prostitution. Our program enables them to develop skills that will allow them to go back to villages in rural areas and carry on working there and use their skills to work as nurses.”

Graduates from the Thai nursing program are now working in 85 community hospitals and 24 public health centers in 40 provinces across Thailand. While corporate funding for the program is now complete, the Thai Royal Family was so impressed by the results that it partnered with the local GSK office to continue offering the training courses.

GSK has funded a similar program in Viet Nam aimed at improving access to care for women from ethnic minority groups. Students in that program train for six months in subjects including prenatal care, midwifery, infectious disease prevention, and social work. Upon graduation, they return to work in isolated rural villages, where they report to provincial health services.

A critical success factor in both programs, according to Frain, is GSK’s commitment to working with locally-based non-profit partners to execute the training programs. “Our principle is to try to identify an organization that can provide services and deliver the program in a particular location, because what you would deliver in Thailand is different from what you’d do in Indonesia.” Additionally, where GSK has local company offices, staff in those offices are also involved in the program design and implementation. “It’s very arrogant to go in and think we can do something on their turf without their insight and involvement.”

Pfizer

Pfizer’s sponsorship of the non-profit Infectious Diseases Institute (IDI) in Uganda offers another example of a capacity-building initiative that indirectly enhances economic opportunity for people in developing countries. Originally constructed with financial and technical support from Pfizer, IDI’s mission is to build capacity in Africa for the delivery of sustainable, high-quality care and prevention of HIV/AIDS and related infectious diseases through training and research. The Institute is a major center for training African medical professionals in advanced HIV/AIDS management techniques. Training programs offered through IDI include:

- an intensive, three-week HIV/AIDS course for physicians which includes lectures, bedside and clinical teaching, clinical case discussions, journal clubs, and group project work;

- one- and two-week multi-disciplinary courses targeting nurses, midwives, clinical officers, counselors and laboratory technicians; and
- modular courses on more specific topics offering health care workers from different backgrounds and workplaces the opportunity to develop skills based on the needs of their home institutions.

Since 2004, the state-of-the-art facility has trained more than 1,400 health care providers from 26 African countries.

Although data regarding the placement of training program graduates is unavailable, a 2005 survey showed that 98% of IDI alumni were providing anti-retroviral therapy and other forms of care for people living with HIV/AIDS. Perhaps even more significantly, 100% of survey respondents said they had trained other health workers in HIV care, with each alumnus sharing their new skills with about 20 health workers per month. As one IDI graduate put it:

“We have been running an opportunistic infections clinic but we discovered that we didn’t have enough doctors and nurses who were capable of managing HIV. I contacted the Government, which agreed to send me for this training. The information I have got within this short period of time is more than enough. I have learnt a lot about management of opportunistic infections and ARVs. There was also a train-the-trainer aspect, so I will be able to go and train others. Since we don’t have enough doctors and nurses who are capable of managing ARVs, definitely I will be a resourceful person.”³⁵

Novo Nordisk

Novo Nordisk established the World Partner Project (WPP) in 2001 in response to the WHO’s four recommendations for dealing with chronic diseases. The purpose of the initiative is four-fold:

- to improve the outcomes of diabetes therapy;
- to fulfill Novo Nordisk’s social responsibility;
- to address the ongoing public debate criticizing the pharmaceutical industry; and
- to find models for improving the global treatment of diabetes in the world’s developing countries to benefit both patients and the company.

The WPP initiative is currently active in eight countries: Bangladesh, Malaysia, Tanzania, Zambia, El Salvador, Costa Rica, China, and India. This case study focuses on WPP’s presence in Bangladesh.

The WPP’s main partner in Bangladesh is the Diabetes Association of Bangladesh (DAB), which is the main provider of diabetes care in the country, with a network of hospitals and clinics serving about a third of the diabetes population. One of WPP’s key activities in Bangladesh is a distance-learning program originally developed for doctors working in DAB clinics and later expanded to doctors at most public and some private clinics in rural areas. Many of these physicians did not have access to continuing medical education opportunities given their remote locations. Over the past five years, the WPP program has provided training in diabetes prevention and care to more than 400 doctors. A similar program was developed for nurses, utilizing a train-the-trainer approach that has created a ripple effect on nurse training in the country. To date, more than 100 nurses have participated in the program.

These programs have improved the skill sets of hundreds of medical professionals in Bangladesh and have also had a significant impact on the general awareness level regarding diabetes prevention and care in the country. Peter Gerhardsson, Vice President of Corporate Responsibility for Novo Nordisk, explains, “The success here has been that we’ve really gotten many of these countries to realize that they have another chronic disease problem that will hit them harder ten years from now. There’s a success in awareness-building.” This educational outcome also has implications for Novo Nordisk’s future business interests in developing countries. “We’re always looking at the business opportunity. In some countries, we may not currently have a large market presence, but the need for infrastructure is there. The business opportunity will come later.”

5.6 INSTITUTIONAL CAPACITY-BUILDING: INTERNATIONAL FEDERATION OF PHARMACEUTICAL MANUFACTURERS AND ASSOCIATIONS

Background

Institutional capacity-building efforts form part of the second tier of activities through which health care companies create economic opportunity. Types of activities in this tier include technical support, financial support, networking assistance, strategic planning advice, and in-kind resources. The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) is developing a collaborative, industry-based approach to building health care management and infrastructure capacity in developing countries through education and training programs. This effort provides an excellent example of an institutional capacity-building initiative with high potential for both social and business impacts.

The IFPMA is a non-governmental organization that represents national industry associations and companies in the pharmaceutical, biotech, and vaccine industries. One of IFPMA's main objectives is to contribute industry expertise and foster collaborative relationships and partnerships with international organizations, national institutions, governments, and non-governmental organizations that are dedicated to the improvement of public health, especially in developing and emerging markets.³⁶ To that end, the organization recently created a working group, called the Partnership Taskforce, that will develop collaborative initiatives aimed at addressing bottlenecks in the drug development, manufacturing, and distribution systems in developing countries. The three main areas of engagement include:

- building institutional capacity;
- improving supply chain management; and
- establishing an industry network for research and development for neglected diseases.

This case study focuses on industry efforts related to institutional capacity-building, which has a direct impact on economic opportunity in developing countries.

Motivations

The basic business imperative to maintain cost-effective and efficient operations provides a main motivation for engagement in institutional capacity-building initiatives in developing countries. Companies' ability to develop, produce, and distribute high-quality medicines in a timely manner is heavily dependent upon the existence of a robust and well-managed health care infrastructure, which does not exist in many developing countries. In those countries, limited local capacity for directing clinical trials, registering and regulating drugs, and conducting quality assurance activities has restricted companies' ability to operate effectively. In some countries, the delay in bringing new drugs to market can be years, and products often reach stores with limited shelf life remaining. In addition, says Stefanie Meredith, Director of Public Health Partnerships for IFPMA, "If industry is going to develop new products for diseases in the developing world, it needs to be able to do the clinical trials appropriately, efficiently, and ethically. Most countries have limited experience with this, so this is an area that needs to be better organized and built up." Significant improvements in the areas of health care management and government capacity are necessary in order to address these challenges and improve the business environment for pharmaceutical and other health care companies.

The social consequence of limited access to medicine for people living with treatable diseases provides an equally compelling case for engagement in institutional capacity-building initiatives. Notes Meredith, "The top priority here is meeting an unmet medical need. Some of these efforts are things that only industry can offer – their core competencies around training, supply chain management, etc. They should be able to have a significant social impact in addition to the economic benefit."

The IFPMA taskforce on institutional capacity-building offers a powerful example of an initiative that leverages companies' core competencies to create both business and social impacts in developing countries. Ultimately, increased local capacity will result in a better business environment for companies, increased economic opportunities for local residents, and expanded access to medicines and related health care services for citizens of the affected countries.

Activities

The IFPMA created the Director of Public Health Partnerships position in the fall of 2006 to help member companies think and act more strategically around public health issues. What had been missing in companies' strategies to date was not action, notes Meredith, but rather coordination and collaboration. "What we've been talking about since [the taskforce was launched in] March is, what can we do collaboratively that uses core competence and will have an impact. Every company has done something good and useful, but the initiatives are all bilateral. To have an impact on public health, we have to look at what can be done in a collaborative fashion."

Meredith began by establishing a taskforce comprised of industry players who were interested in exploring ways of engaging more strategically and collaboratively in developing countries. "We started off with several key questions: what are the needs in these countries, where are the gaps, what are you willing to do and what can we contribute?" explains Meredith. The taskforce members identified several areas of need where the industry was well-suited to make an impact through collaborative action. Those areas – capacity-building, supply chain management, and drug discovery – are now the focus for the Partnership Taskforce, and industry participants have been identified to lead each effort.

The capacity-building subgroup identified three areas of need on which its efforts will focus: clinical trial capacity, drug registration and regulation capacity, and quality assurance capacity. Each of these processes is a key step in the path from drug discovery to drug distribution; efforts to increase local skill and competence in each process will directly improve companies' ability to bring drugs to market in a timely and efficient manner.

The subgroup identified the scarcity of professional education and training opportunities for government health agency employees as the major impediment to increased institutional capacity. The subgroup is now exploring a range of opportunities to engage in training clinicians, scientists, and other workers. Training in clinical trials and quality assurance, for example, could be developed by the companies and offered in their labs, and mentors could be made available to support trained staff in their home countries.

A specific challenge facing the capacity-building subgroup relates to industry engagement in training drug registration and regulation workers. As Meredith notes, "Industry knows where the regulatory problems are, but we can't train regulators. We can help find the funding to pay for the training, though. We can spend some time at the WHO where they are looking at their own programs." This collaborative approach to institutional capacity-building allows member companies to achieve their desired impact without creating a conflict of interest.

The work of the capacity-building subgroup is designed to bolster local and national health care management and infrastructure through expanding training opportunities for local scientists, clinicians, and government workers. "We believe that countries deserve the best possible training to manage these functions themselves in partnership with the industry companies," says Meredith.

Impact

The IFPMA taskforce is still in its earliest stages of information gathering and program design; however, it has already gained momentum among industry members. Recognizing that conversations about industry engagement in developing countries are often challenging and fraught with concerns over company image, Meredith was careful to establish a good working environment to encourage participation among industry partners. "The second meeting brought in more people than the first, and since then there's been even more interest. People in different companies have heard that the meetings were successful and that they provide a good environment." Securing buy-in from additional companies will allow taskforce programs to reach greater scale, leading to increased impact on the ground.

Taskforce members have begun to research other models of institutional capacity-building (e.g., the European Clinical Trials Development Program), and plan to implement a few pilot training programs in the near term.

Measuring the impact of these pilot programs and other initiatives that will follow them, however, is likely to prove difficult, according to Meredith. "If you are donating a drug, you can look at how many people are treated, but as we get further along than drug donations, it's a slow process to measure impact. If you're building capacity, that takes longer than three to five years. You can measure something from perceptions and communications, but it's a proxy and not particularly useful."

**The Role of
Collaboration**

An important lesson IFPMA learned early on in the initiative relates to the importance of incorporating cultural awareness into the work of a global partnership. “I did the same presentation to several companies in Europe and the United States, and their reactions were totally different. What I’ve learned is that we need to understand each other better. We need to learn about each other’s different processes, legal restrictions, intellectual property rules, etc.,” says Meredith. Gaining a better understanding of each partner’s operating environment and its related competitive advantages and limitations is essential to the taskforce’s ability to leverage each partner’s core strengths to improve the overall effectiveness of the group.

A best practice in developing institutional capacity-building programs is to ensure that new efforts complement rather than duplicate any existing initiatives, and that new partners work collaboratively with agencies and organizations that are already active in specific fields. “We have to bear in mind that there are other initiatives going on around clinical trial capacity-building. We must look at how to work with other major partners – WHO and the UN Special Programme for Research and Training in Tropical Diseases (TDR) are clearly big players. They can help in endemic countries. We need to work with other programs that are addressing this issue, and look at what they’re doing and complement and expand what’s already happening.”

5.7 RULE-SHAPING: MERCK'S COMPETITIVENESS INITIATIVE IN LATIN AMERICA

Background

Rule-shaping constitutes the third tier of activities through which health care companies can create economic opportunity. The types of activity in this tier include helping to optimize policy and regulatory frameworks related to the business environment in developing countries, for example in the areas of tax, intellectual property, and innovation. Merck's Competitiveness Initiative for Latin America is one such example.

Launched in 2004 in collaboration with the United States Council on Competitiveness, the initiative aims to promote competitiveness in the region, with initial emphasis on projects that support the development of the life science sectors in Mexico and Brazil. Merck (known as Merck Sharp & Dohme, or MSD, outside the US) has had a presence in Latin America and the Caribbean since 1915, and operates in nearly all of the region's 35 countries. MSD activities span from clinical research, manufacturing, sales, and marketing to supporting policies that promote innovation. MSD employs several thousand people throughout the region.

Motivations

Strategic business motivations led Merck to set up this ambitious program. In the long term, a healthier and more prosperous Latin America provides greater opportunity for Merck by creating more disposable income, leading to increased expenditure on health care. In addition, Merck's involvement in specific partnerships through the Competitiveness Initiative allows the company to position itself as a partner of choice for future collaborations with local governments, businesses, and civil society. "We see ourselves as long-term investors and corporate citizens in these markets, which necessitates investing in sustainable health care solutions, economic development, and advocating for a policy and scientific environment that better fosters innovation," says David Greeley, who, until recently, headed up Merck's public affairs and policy efforts for Latin America.

Social impact is also an important motivation for Merck. "We were in part influenced by some of the work of Jeffrey Sachs and the World Health Organization's Report on Macroeconomics and Health. Our long-term vision is formed on the basis that health is a driver of economic development rather than an output of it," explains Clemens Caicedo, Senior Director of Latin America Policy at Merck. The conditions that foster business innovation, such as the protection of intellectual property rights, are beneficial to local scientists and businesses as well as for research-based multinational companies such as Merck. Overall, says Caicedo, "We see this competitiveness initiative as being perceived in the national interest of countries in which we are investing, thereby creating a constructive win-win relationship with countries south of our border."

At a time when Western pharmaceutical companies have come under scrutiny in developing countries, the initiative provides a powerful example of how pharma can have positive impact on local businesses, and ultimately, the citizens of these countries. The initiative is a unique opportunity to build brand equity for Merck in Latin America leading to future commercial success.

At the same time, though, Greeley notes that an initiative like this needs to be positioned properly *within* the company to garner internal buy-in. "Because some of these activities are designed to produce long-term impact, and we are often looking for immediate results and facing quarter-by-quarter pressures, demonstrating return on investment can sometimes be challenging. It has to be framed in a way internally so that we get widespread support."

Activity Description

Over the last four years, Merck has invested about \$1 million a year in the initiative. The company has taken a long-term, business approach to this initiative, as demonstrated by its placement within the International Policy and Latin America business units.

While the company's effort to encourage innovation in the life sciences will eventually encompass much of Latin America, the initiative initially focused on Mexico and Brazil. Merck sees these countries as holding an enormous potential to incubate clusters, and anticipates that the life sciences will take a prominent role in innovation initiatives in these two countries. Merck is partnering with the Council on Competitiveness in order to bring innovation programs to the region. The initiative also takes advantage of local partners in both Mexico and Brazil. In addition to these two countries, exploratory contacts are ongoing in Chile, Colombia, and Costa Rica.

In Mexico, the initiative partners with Instituto Mexicano para la Competitividad (IMCO) to support the development of a vibrant cross-border life sciences sector, which would improve hemispheric competitiveness in the face of global competition. To date the initiative has established a steering committee of key US and Mexican business, scientific, and government leaders, conducted a study assessing the regional and national policy environment for life sciences innovation, and, along with The National Academy of Medicine, launched the annual “Awards on Innovation in Health and Food” program. In 2007, a new partnership was established with the University of California at San Diego to explore research capability in the life sciences in four regions of Mexico and link the scientific communities of these regions with San Diego. The objective is to accelerate patenting, technology transfer, and business development plans for their own discoveries while improving business links with the San Diego life science cluster.

In Brazil, Merck works with Movimento Brasil Competitivo (MBC) to promote the improved performance of existing Brazilian life sciences technology parks, expand the development of a vibrant and globally competitive life sciences sector, and raise awareness of the value of innovation. The initiative has published two major studies: *Competitive Brazil: An Essay on Brazilian Competitiveness* (2005) and *Mechanisms of Innovation and Competitiveness: An Analysis of Brazilian Technology Parks* (2006). MBC also collaborated with the World Bank on the Bank’s Doing Business in Brazil (2006) report, which evaluates current regulations and their impact on facilitating or hindering business transactions in Brazil.

Following the Brazilian government’s decision to issue a compulsory license for one of Merck’s HIV/AIDS drugs in April, 2007, the company is now re-evaluating its short-term investment in this area. However, Merck remains committed to keeping an open dialogue with the government and scientific community in Brazil consistent with its view as a long-term investor in the country.

Ultimately, the Competitiveness Initiative is designed to fill the critical gap in business operations and innovation that will lead to expanded economic opportunities in the region. “If we can connect the chain from basic research all the way to commercialization by teaching local businesses to patent their products, attract venture capital funding, and market their innovation, then we can fill the gap that’s there right now,” says Caicedo.

Merck has utilized multiple tools to publicize the value of its initiative, including brochures, panels, conferences, and press releases. Adequate and appropriate communication also plays an important role in positioning Merck as an expert and leader in promoting local business innovation in Latin America – a light that pharma is not usually viewed in. Comments Caicedo, “We need to do a lot of communicating about our activities, even during the process when projects are being formulated. That’s a best practice – to continuously communicate what we’re doing. It is sometimes even more effective when independent and credible third parties communicate about this initiative – so we pay attention to that as well.”

Impact

Given the long time horizon of the initiative, and its relatively short lifespan to date, substantial results are not yet available. MSD has won a number of external awards in the countries where it operates, including “Best Company to Work for,” “Most Admired Company,” and “Most Socially Responsible Company,” but it is difficult to attribute them directly to any single activity. While direct business impact is still to be determined, the initiative has allowed Merck to build strategic relationships in the region. For example, discussions about the initiative with local government officials have allowed the company to highlight some of the other challenges it faces in its operations, such as registration of its products. “The initiative has allowed us to develop even stronger and more mutually respectful relationships with policy-makers and other key decision-makers on issues that are important to us, with an understanding that we want to be long term investors in these countries,” comments Greeley. “Quantifying these relationships in terms of business impact, however, is always difficult,” he adds.

Recognizing the long time horizon for the initiative, Merck is only beginning to focus on measuring social or business impact. While the company values the impact its initiative creates, it recognizes that it is too early to begin impact assessments given that most of the activities have taken place in the last three years.

**The Role of
Collaboration**

While the partnerships between Merck, the Council on Competitiveness, and the local partners have been very fruitful, the initiative can benefit from the participation and resources of additional multinational corporations, and more importantly in the long run, from local businesses and venture capitalists. Unfortunately, due to the long-term nature of the impacts of an initiative like this, securing commitments from others has proven difficult. Many companies are focused on short-term results and need to see immediate return on investment to balance the cost of participating as a major player. The company has, however, formed partnerships in Mexico with local businesses that have begun to contribute to fund the Mexican initiative.

■ End Notes

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9. In addition to participating in rule-shaping, pharmaceutical companies may also engage in a variety of other activities aimed at reducing instances of counterfeit drugs, including utilizing technological tools or enforcing their own rules regarding drug distribution and wholesaling. Regardless of the strategy or strategies each company employs, the engagement of local and international regulatory bodies is essential.
10. "Brain drain" has emerged as an issue due to limited job opportunities for highly-skilled workers in many developing countries. Collaborating with local non-profits or governments to ensure the availability of attractive job options for trained workers (for example, at health care clinics, hospitals, and regulatory agencies) is one way that pharmaceutical companies can help maximize the local impact of their training programs.
11. As in developed countries, many pharmaceutical companies provide continuing education opportunities to physicians in developing countries, typically through their business unit budgets. Since these activities target highly skilled and already-employed workers, they are not the focus of this paper.
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■ List of Companies Interviewed

Abbott Labs	Reeta Roy, Vice President, Abbott Fund, Divisional Vice President, Global Citizenship and Policy; Susan Beverly, Manager, Global Citizenship and Policy
Aspen Pharmacare	Stavros Nicolaou, Senior Executive
GlaxoSmithKline	Justine Frain, Vice President, Global Community Partnerships; Jon Pender, Director of Government Affairs
International Federation of Pharmaceutical Manufacturers and Associations	Stefanie Meredith, Director of Public Health Partnerships
Eli Lilly	Gail Cassell, Vice President for Scientific Affairs and Distinguished Lilly Research Scholar for Infectious Diseases
Merck	David Greeley, Senior Director, Global HIV/AIDS Programs; Clemens Caicedo, Senior Director, Latin America Policy
Novo Nordisk	Peter Gerhardsson, Vice President, Corporate Responsibility
Pfizer	Sebastian Fries, Director, Strategic Planning, Africa/Middle East/Latin America

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FSG Social Impact Advisors is a 501(c)(3) nonprofit enterprise that provides consulting services to foundations, corporations, governments, and non-profits to develop strategies for increasing social impact and to measure the results achieved. FSG also publishes original research and leads action initiatives that advance the practices of philanthropy and corporate social responsibility. FSG was founded in 1999 by Professor Michael E. Porter and Mark R. Kramer as Foundation Strategy Group, LLC, and converted to non-profit status under its new name in 2006. With offices in Boston, San Francisco, Seattle, and Geneva, FSG's global team combines strategy consulting, evaluation, and research skills with a deep understanding of the non-profit sector. www.fsg-impact.org

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Under the direction of John Ruggie (Faculty Chair) and Jane Nelson (Director), the CSR Initiative at Harvard's Kennedy School of Government is a multi-disciplinary and multi-stakeholder program that seeks to study and enhance the public contributions of private enterprise. It explores the intersection of corporate responsibility, corporate governance, and public policy, with a focus on the role of business in addressing global development issues. The Initiative undertakes research, education, and outreach activities that aim to bridge theory and practice, build leadership skills, and support constructive dialogue and collaboration among different sectors. It was founded in 2004 with the support of Walter H. Shorenstein, Chevron Corporation, The Coca-Cola Company, and General Motors and is now also supported by Abbott Laboratories, Cisco Systems, Inc., InBev, InterContinental Hotels Group, Microsoft Corporation, Pfizer, Shell Exploration and Production, and the United Nations Industrial Development Organization (UNIDO). Visit the Initiative's homepage at <http://www.ksg.harvard.edu/m-rcbg/CSRI>

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