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GlaxoSmithKline in Brazil: Public-Private Vaccine Partnerships

As the first quarter of 2012 drew to a close, Martin Andrews, senior vice president of GlaxoSmithKline's (GSK) vaccines business, prepared an annual report to investors. Vaccines generated 15% of GSK's 2011 sales and had grown at an average of 18% annually since 2005. Emerging markets were at the forefront of this growth, with vaccine sales rising by a striking 38% in 2010, although partly from the rapid global response to the threat of H1N1 (swine flu).¹ Analysts considered vaccines sales in developing countries with significant unmet medical needs as critical to the company's future, especially when considering forecasts for prescription drug sales to level or even decline in Europe and North America.

Vaccine innovation and global access featured prominently in the ambitions of foundations seeking low-cost solutions to public health dilemmas in developing countries and were central to a United Nations' Millennium Development Goal of reducing childhood mortality by two-thirds. At the same time, vaccines were the focus of a growing number of public-private partnerships (PPPs). Lauded for the mutual benefits they provided to firms and the public, especially in resource-constrained developing countries, PPPs also were criticized as giveaways to multinationals that put a market price on public goods. Thus while PPPs could build good will and open access to markets in developing countries, success depended on how they were implemented, communication between partners, and sustaining public good will.

Andrews reflected on the implementation of a major collaboration between GSK and Brazil's Foundation Oswaldo Cruz (Fiocruz) announced in 2009. Under the PPP, GSK was transferring manufacturing technology and know-how for a sophisticated pediatric vaccine that prevented meningitis and pneumonia, and jointly funding research and development for a new vaccine against Dengue fever. Entering the third year of the initial ten-year agreement, Andrews was pleased at the positive press the PPP had received in Brazil, the United Kingdom, and internationally. But he also worried about long-term revenue as Fiocruz took over vaccine production. As the terms of the PPP became better known, other countries sought similar deals, which had the potential to stretch GSK's technical resources and exacerbate downward price pressure on vaccines. Was it a good strategy to incentivize rapid uptake of GSK's most innovative vaccines, knowing that sales would be lost at the end of the contract in countries with leading long-term growth potential? In the meantime, CEO Andrew Witty was seeking ways to focus GSK's activities and to manage a growing portfolio of ever more complex deals in developing countries around the world.

Professor Arthur A. Daemmrich and Research Associate Ian McKown Cornell of the Global Research Group prepared this case. HBS cases are developed solely as the basis for class discussion. Cases are not intended to serve as endorsements, sources of primary data, or illustrations of effective or ineffective management.

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GlaxoSmithKline

GlaxoSmithKline was created through the December 2000 merger of Glaxo Wellcome and SmithKline Beecham, respectively the product of mergers and acquisitions among British and American pharmaceutical firms dating to the 19th century.² The merger made GSK the largest pharmaceutical company in the world, with a market capitalization of £130 billion (\$193.5 billion).³ Post-merger, GSK also had over-the-counter health and cosmetics businesses in its portfolio.

Sir Andrew Witty had succeeded Dr. Jean Pierre Garnier as CEO in May 2008. Garnier, CEO of SmithKline Beecham prior to the 2000 merger, was a high profile leader especially known for his controversial stance regarding HIV-AIDS drug pricing (later reversed when Garnier played a leading role in brokering a deal to provide HIV drugs at cost to African countries) and British shareholder opposition to his compensation.⁴ Yet, he left GSK with a promising pipeline of 33 drugs in late-stage development and solid financial results despite a global economic downturn.

Witty brought a British executive leadership style in contrast to Garnier and was expected to move towards greater centralization of the diversified firm.⁵ In his first three years as CEO, Witty extended GSK's biological drug research through several acquisitions and increased the company's emphasis on emerging markets, vaccines, and consumer healthcare.⁶ Under a significant restructuring program, GSK reduced its sales force in the United States and Europe, and shifted research spending from depression and pain to Alzheimer's disease, multiple sclerosis, Parkinson's disease, and vaccines.

In 2011, GSK reported £27.4 billion in sales from pharmaceuticals, vaccines, and a portfolio of consumer health, nutritional, and cosmetics products. (See Exhibits 1 and 2 for GSK sales data.) Operating profits were strong at £8.4 billion. Underlying sales grew by 4%, but with significant variation by sector. Pharmaceuticals grew only by 2%, whereas vaccine sales grew by 11%, and consumer healthcare by 5%. Sales were flat in the United States, declined by 4% in Europe, but grew by 15% in emerging markets and by 10% in the Asia Pacific region.⁷

The company employed 96,500 people globally (down from over 103,000 in 2007) and invested £3.9 billion in R&D. In 2011, 3 new compounds gained regulatory approval and GSK announced late-stage clinical trial success with 9 compounds. In the previous three years, GSK had gained U.S. Food and Drug Administration (FDA) approval of 16 drugs and vaccines, putting it ahead of its competitors.⁸ But GSK faced challenges from upcoming patent expirations and pricing pressure from governments, especially in European markets.⁹ Vaccines offered an attractive complement to small-molecule drugs, since the company could demonstrate healthcare value to payers when people avoided other more expensive treatments. Furthermore, the complex manufacturing and distribution steps necessary to deliver vaccines safely made it difficult for generics to compete. With the support of governments, health foundations, and other NGOs, GSK's vaccines were included in immunization campaigns in 182 countries worldwide. (See Exhibit 3 for GSK's vaccine sales.)

GSK in Emerging Markets

Emerging markets, a category used by GSK to group countries other than the United States, Western Europe, Canada, Japan, Australia, and New Zealand, generated sales of £5.3 billion in 2011. The segment was growing rapidly, yet operating margins were notably lower, averaging 31% in contrast to 69% in the United States.¹⁰ Latin America was the fastest growth sector, increasing by over 40% between 2009 and 2011. China and Russia followed with growth of 21% and 20%, respectively. In 2011, vaccines comprised nearly a quarter of all pharmaceutical sales in emerging markets. Reporting

to investors, Witty identified himself as an “extreme bull” on emerging markets overall.¹¹ GSK’s future, he held, involved diversification of revenue streams away from “white pills in Western markets,” including through vaccine sales in developing countries.¹²

Least Developed Countries In least developed countries (LDC), GSK capped prices of patented medicines at 25% of the average across Western Europe. Additionally, GSK had committed to reinvest 20% of profits from LDC sales into local health infrastructure. A dedicated business unit created in 2009, called Developing Countries and Market Access, oversaw GSK’s activities and set policies for access, pricing, and investment. The company also participated in the Advance Market Commitment (AMC), a financing mechanism supported by the Bill and Melinda Gates Foundation, UNICEF, and the Global Alliance for Vaccines and Immunizations (GAVI).¹³ Associated with the AMC, GSK planned to provide 300 million doses of pneumococcal vaccines over a ten-year period.¹⁴

Middle Income Countries For middle-income countries, notably Brazil, Russia, India, and China (BRICs), GSK had announced “flexible pricing strategies.” GSK’s goal was to grow product sales while also broadening the overall pharmaceutical market by making prescription drugs affordable. Flexible pricing was an attempt to balance pricing for a growing middle class while not ignoring large populations living in poverty. The GSK middle-income strategy relied partly on strategic partnerships, including a 2010 acquisition of a leading Argentinian laboratory and an alliance with the Russian vaccine producer JSC Binnopharm.¹⁵

Competitive Landscape GSK’s competitors also were active in emerging market countries, with similar growth goals. For example, Novartis announced plans in 2009 to grow sales in emerging markets to 20% of its total by 2012 through acquisitions and by expanding manufacturing of branded generics.¹⁶ Sanofi-Aventis likewise expected emerging markets to make up a larger component of sales, though it was targeting generic drugs and consumer health products to offset an anticipated decline in branded pharmaceuticals.¹⁷ Others, such as Johnson & Johnson, employed a more decentralized corporate model and were advancing diverse health initiatives targeted at HIV, tuberculosis, birth safety, and intestinal worms in developing countries.¹⁸

As Andrews reviewed GSK’s vaccine sales (see Exhibit 4), he focused on Brazil and the international good will engendered by the PPP with state-run Fiocruz. He noted: “The major trend is the huge unmet need in emerging countries. A lot of people don’t have access to vaccines that need them, but they will be able to afford them soon. At the same time, there is zero tolerance for errors in manufacturing quality. It takes large capital investments to get new vaccines into production, and continual monitoring and investment to keep the quality high. So there is a robust outlook for the vaccine industry, but you have to have regional innovation and scale to make money in this market.”

Brazil

The fifth-largest country in the world, Brazil had a largely urbanized population of 195 million. Over 26% of the population was under 14 years old and 3.5 million children were born annually. Notorious for its history of oscillating macroeconomic policies and periods of rampant inflation, Brazil in the 2000s achieved political stability and enjoyed a decade of strong growth. Between 2000 and 2010, real GDP grew by an annual average of 4% to \$2.28 trillion, making Brazil the 8th largest economy in the world. Extreme income inequality was reduced, and some 30 million Brazilians joined the middle class.¹⁹

The Brazilian government was deeply involved in the economy, ranging from ownership and control of state-owned enterprises to minority positions in firms considered of strategic importance.

Moreover, the government sought to direct private sector investment through industrial policy coordinated among the Ministry of Planning, the Ministry of Trade, Commerce and Development, and the national development bank, Banco Nacional de Desenvolvimento Econômico e Social (BNDES).²⁰ The country also was characterized by high costs of doing business for the private sector. A “Brazil cost” arose from high interest rates, inefficient and high taxes, poor infrastructure, red tape, and the country’s large informal sector.²¹

Health System and Insurance

Universal access to medicine was guaranteed under Brazil’s constitution, which declared “health care is a right of all citizens and a duty of the State.”²² The publicly funded health system, Sistema Único de Saúde (SUS) had difficulty meeting patient needs due to limited resources, especially of medicines, equipment, and skilled personnel. Since SUS had an annual budget of only R\$60 billion, patients encountered long wait times for appointments, inconsistent care, and delays in getting prescription drugs. SUS nevertheless purchased 50% of medical equipment, 90% of vaccines, and 25% of pharmaceuticals sold in Brazil.²³ Government officials published annual reference prices for pharmaceuticals, and new drugs had to be priced at or below the minimum of 10 comparator countries.

Total public spending on health was growing rapidly thanks to a major new primary care initiative; in 2011, federal, state, and municipal governments spent a combined R\$167.1 billion on public health. However, due to expensive pension commitments, health appropriations only equaled 13.7% of revenue raised from social security taxes.²⁴ Of the 9% of GDP spent on health in 2011, 47% came from the government, while 53% came from private expenditures.

Despite improvements to SUS in the 2000s, Brazilians with financial means increasingly purchased private insurance. Accompanying the growth in Brazil’s middle class, the number of people covered by private or supplementary insurance grew by nearly 50% between 2000 and 2010, from 30.7 million to 45.6 million.²⁵ While private insurance paid for hospital treatment and physician visits, it typically did not cover drugs. Overall, Brazilians paid 80% of prescription drug costs out-of-pocket, making them more price-sensitive than in most countries.

Disease Profile

Brazilians suffered from a complex mix of diseases related to the country’s large size, a diverse geography that included the Amazon rainforest, and significant wealth inequalities. Thus Brazil ranked alongside poorer developing countries with a maternal mortality rate of 58 deaths per 100,000 births and an infant mortality of 21.2 deaths per 100,000 births. Infectious diseases were prevalent, including dengue fever (311.5 cases/100,000), tuberculosis (29.1 cases/100,000), hepatitis (19.7 cases/100,000), and meningitis (10.3 cases/100,000). Thanks to a major government commitment in education and treatment, the prevalence of HIV/AIDS was a comparatively low 6 cases per 100,000 inhabitants. (See **Exhibit 5** for additional Brazilian health indicators.)

Other health indicators aligned Brazil to more developed countries. The leading cause of death was circulatory disease (30%), while cancer (15%) and respiratory diseases (10%) also were prevalent. Diabetes and other diseases associated with diet and lifestyle were growing in incidence as the country grew wealthier. It was estimated that there were 30 million Brazilians with hypertension and 20 million with diabetes.²⁶

Pharmaceutical Market

For 2012, analysts projected Brazil's pharmaceutical market at R\$61 billion (\$37 billion).²⁷ Responding to pharmaceutical sales growth of 10.5% annually since the mid-2000s, domestic firms expanded production capacity, began to invest in research and drug development, and established new commercial relationships across Latin America.²⁸ Multinational pharmaceutical firms also identified Brazil as a top prospect for acquisitions and direct investment. The market was in flux, with rapid shifts underway among the top firms (see **Exhibit 6**). The Brazilian government, however, had sent mixed signals concerning intellectual property protection, an issue of particular concern to multinational firms. Most notably, through the contentious compulsory licensing in 2007 of the Merck AIDS drug, efavirenz, the Brazilian government demonstrated its willingness to use "public interest" provisions under domestic law and the WTO agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to secure supplies of a patented drug at significantly lower cost.²⁹ Nevertheless, many global pharmaceutical firms were expanding existing production facilities and considering larger research and development investments in the country.

Depending on their ailments, Brazilians could choose among three distinct types of drugs: patented name brands, branded generics, and generics. Patented, or original branded drugs were mostly developed and marketed by large multinational pharmaceutical companies. Typically not reimbursed by SUS or most private insurers, brand drugs could be prohibitively expensive for poorer and even middle-class Brazilians. Branded generic drugs, termed *similares*, had come off patent but sold under a name brand. They were especially popular in Brazil for offering the price benefits of generics while giving quality guarantees associated with branded drugs.³⁰ Generic drugs were legally manufactured in Brazil by any licensed firm once the original patent had expired.

GSK employed 1,100 people in Brazil in manufacturing, pharmaceuticals, and consumer healthcare divisions.³¹ The company had two production plants in Brazil that supplied the domestic market and produced exports for 11 other Latin American countries. In 2010, GSK's sales in Brazil reached R\$2.2 billion (\$1.2 billion), reflecting 22% compounded annual growth since 2006.³²

Competitors to GSK in Brazil included a mix of multinational firms and domestic manufacturers. Some domestic firms benefitted from government support through subsidized loans from BNDES and from large multi-year contracts to deliver medicines to the public healthcare system.³³ Multinationals were expanding in Brazil largely through acquisitions. For example, Sanofi-Aventis bought Medley, Brazil's third-ranked pharmaceutical firm in 2009, raising its sales to R\$3.3 billion (\$1.8 billion). Likewise, Pfizer's 2009 sales of R\$1.5 billion (\$0.8 billion) were poised to grow after the firm acquired a significant stake in a generic drug producer, Laboratório Teuto Brasileiro.³⁴ Overall, firms appeared to be experimenting with a variety of strategies in the Brazilian market, ranging from partnerships to acquisitions, and from branded prescription drugs to generics and diverse OTC health products. One commonality for foreign firms was the growing importance of manufacturing in Brazil and recognition that government officials sought evidence of long-term commitments to the country.

Vaccines

Intentionally infecting patients with a mild or attenuated form of a disease to build immunity gained physician acceptance after Edward Jenner used cowpox to inoculate against smallpox in 1796. Yet, nearly a century would pass before the next major vaccine was developed (for cholera in 1879). Louis Pasteur initiated the first large-scale systematic vaccine research program in the 1880s. Vaccines

subsequently became integral to the growth of pharmaceutical firms in the late 19th century.³⁵ In the 20th century, a complex mix of foundations, public health authorities, and private firms sponsored research and testing of new vaccines for diseases such as polio. In other cases, for example the MMR vaccine, pharmaceutical firms took the lead in development and testing. However, the role of vaccines in the industry declined considerably in the 1970s and 1980s. A combination of costly liability suits, few major research breakthroughs, and declining sales led companies to reduce or abandon vaccine research.³⁶

A series of legal reforms and market changes made vaccines attractive to pharmaceutical firms and small biotechnology ventures in the 1990s and 2000s. First, the 1986 U.S. National Childhood Vaccine Injury Act limited manufacturer liability and established a compensation fund for those harmed by vaccines. Second, a concerted public policy push by the WHO and other international health bodies improved vaccination rates in emerging markets, notably in the BRICs. Third, health insurers globally began covering annual flu shots and governments in the United States, Europe, and elsewhere made large annual vaccine purchases, resulting in predictable sales for manufacturers. Firms invested in research and a new generation of sophisticated vaccines became available for hepatitis, human papillomavirus (HPV), and other conditions.³⁷

Since they were given to healthy children and adults to prevent disease, vaccines faced an elevated safety threshold for regulatory approval and underwent extensive quality inspections. Concerns regarding the ethics of using children in clinical trials often made it hard to test experimental vaccines in the population targeted for eventual use. Once approved, even rare adverse events were sufficient to prompt product withdrawals. Vaccine manufacturing also was subject to stringent oversight. Typically formulated as biological treatments given as injections, vaccines could cause allergic reactions from stray proteins or other impurities. As a result, regulations required individual batch testing and certification by government inspectors with considerable expertise.³⁸

Despite being subject to stringent regulation, vaccines had a legacy of public suspicion.³⁹ Opposition to the smallpox vaccine emerged in England and the United States starting in the mid-1800s, and anti-vaccination leagues fought mandatory vaccination against tuberculosis, pertussis, and other diseases in the 20th century. Repeatedly discredited by medical authorities, worries of a putative link between vaccination and autism had a largely temporary impact on vaccination coverage in developed countries in the 2000s.⁴⁰

The GSK – Fiocruz Public Private Partnership

The PPP Model

Involving a negotiated division of resources, responsibilities, and rewards between governments and private sector firms, PPPs gained in popularity in the 1990s.⁴¹ In theory, PPPs could deliver public goods more efficiently and at a lower cost than either governments acting without profit incentives or private firms acting without government-based legitimacy and public access. Governments could avoid large capital investment and administrative costs; thereby avoiding tax increases to pay for new initiatives. Private firms could benefit from the scale of public purchases. Notable PPP agreements included private administration of transportation infrastructure, municipal water services, and health care delivery.⁴²

Despite their potential benefits, PPPs were often undermined by prolonged negotiations, shifts in government priorities associated with leadership changes or competition among political parties, and public opposition to perceived handouts to firms. Governments entering into PPPs encountered

fierce protests out of fears that costs for public goods would rise and that poorer citizens would be excluded from services. The apparent outsourcing of regulatory responsibilities troubled critics, who warned, “PPPs may achieve cost reductions at the price of democracy and equity.”⁴³

Private sector participants also had to manage uncertainty associated with PPP deals. As national political priorities shifted, private providers could be left with large sunk investments. Even under a stable administration, the government had disproportional leverage to restructure project terms. PPPs were even more subject to post-hoc renegotiation in cases where more than one firm was paired with a government, or when more than one government was part of the agreement.

Fiocruz

The Fundação Oswaldo Cruz (Fiocruz) was established in 1900 as the Instituto Soroterápico Federal with a mandate to improve public health in Brazil through applied medical research.⁴⁴ It was renamed for founding director Oswaldo Cruz in 1908, after he gained international recognition for his efforts to improve sanitation in Rio de Janeiro and for supporting a program of mandatory vaccination against smallpox in 1904. Six days of rioting took place during the Revolta da Vacina, a populist uprising that originated in opposition to urban reforms but was fueled by reports of side effects from the vaccine program.⁴⁵ The institute in its early years also was home to Carlos Chagas, famous for identifying the eponymous disease and its route of transmission. In subsequent decades, Fiocruz built an international reputation for tropical disease research.

Fiocruz maintained its mission to “promote health and social development, to forge and disseminate scientific and technological knowledge, to be an agent of citizenship.”⁴⁶ The institute operated a large campus in northern Rio de Janeiro and four smaller technical-scientific hubs elsewhere in Brazil. Scientists, physicians, and public health officials working at Fiocruz carried out medical research, treated patients in an on-site hospital, manufactured drugs and vaccines, trained a variety of health specialists, and carried out public health programs. Fiocruz also had a close relationship with national public health officials and the SUS, offering guidance on policy and scientific issues. It employed 4,500 people and operated with an annual budget of R\$1.6 billion (\$800 million).⁴⁷

From Supplier to Partner

For decades, GSK supplied active ingredients for vaccines and drugs that Fiocruz’s biologics manufacturing division, Bio-Manguinhos, converted into pills or injections. Under a 1985 “technical collaboration,” GSK started to share manufacturing know-how for a polio vaccine. Then, in the late 1990s, the Brazilian health ministry sought suppliers for Hib (*Haemophilus influenzae* type B) vaccine, used to prevent a variety of dangerous infections striking children, including meningitis, pneumonia, and infections of blood, bones, and joints. Breaking with GSK’s initial plan to just sell the vaccine ingredients, a five-year deal was reached in 1998 under which GSK transferred Hib technologies, starting with packaging and formulation but eventually moving upstream to the complete vaccine. In exchange, Brazil purchased the vaccine from GSK at a negotiated price for the duration of the technology transfer. The incidence of Hib meningitis in Brazil subsequently declined by 98% and by 2009, the country had achieved comprehensive immunization against Hib diseases (see **Exhibit 5**).

Building on the experience gained under these agreements, GSK and Fiocruz signed a technology transfer deal in early 2008 for an advanced vaccine against rotavirus. A multi-year staged plan was followed, starting with packaging and gradually expanding to include manufacturing know-how and technologies to produce the bulk product. When announcing the deal, the Brazilian government projected manufacturing 50 million doses of the rotavirus vaccine and reaching the full population

within five years, even as costs would decline by \$20 million per year once domestic production reached full scale.⁴⁸

The Synflorix and Dengue Research PPP

In August 2009, GSK and Fiocruz announced a major new PPP combining technology transfer to manufacture a vaccine preventing pneumococcal infections with joint funding to develop a vaccine against Dengue fever. *Streptococcus pneumoniae* infections were responsible for blood infections, pneumonia, and meningitis, mostly striking infants and children. Globally, it was estimated that pneumococcal infections caused 14.5 million episodes of serious disease and 826,000 deaths in children up to age 5.⁴⁹ While the diseases resulting from the infection were individually treatable through new and costly antibiotics, treatments failed to reach many patients in time. Developing an effective vaccine had involved years of research and testing due to variation among over 90 distinct serotypes of the *S. pneumoniae* and the biology of the immune system. Responses to existing vaccines did not develop until after age 2, leaving infants especially vulnerable. GSK's development of Synflorix in the mid-2000s, which could be administered to infants, thus offered a significant benefit over existing treatments or other vaccines. But to make the drug required sophisticated chemical and biological manufacturing; Antonio Barbosa, vice director for production at Bio-Manguinhos, noted: "It is the most complex vaccine in the world today."⁵⁰

Under the transfer agreement, GSK would provide technology and know-how to manufacture Synflorix, including a manufacturing sequence of 8 distinct processes and some 200 quality control tests. GSK would sell the vaccine to Brazil's Health Ministry for use in government-sponsored immunization programs over a ten-year transfer period. The company planned to supply 13 million doses of Synflorix per year, though this quantity would be reduced in future years as the existing cohort of children was vaccinated. As reported in the trade press, "The price starts at €11.50 a dose and should drop to €5 in the final years (in Europe the vaccine sells for €35-40 a dose)."⁵¹ Over the same period, GSK would transfer technology to Fiocruz that would enable Bio-Manguinhos to produce the vaccine domestically. GSK also planned to train regulators in Brazil to inspect the manufacturing process and vaccine batches in light of its technical sophistication.

A second key element of the 2009 PPP involved collaborative research and product development at Fiocruz to develop a vaccine for Dengue fever.⁵² Endemic in over 100 countries, the Dengue virus was spreading rapidly and infected between 50 and 100 million people annually. Symptoms included severe fever, headaches, muscle and joint pain, and a skin rash similar to measles. In children and adults with weakened immune systems, the disease was life threatening. Speaking to the World Health Organization, Akira Homma, chairman of the Bio-Manguinhos policy and strategy council, predicted that the Dengue vaccine would consist of purified inactivated virus and would use GSK's adjuvant technologies to provide "rapid onset of durable protection."⁵³ GSK and the Brazilian government each pledged \$51 million to research and vaccine testing.⁵⁴

Speaking about the deal, GSK's president of emerging markets, Abbas Hussain, explained: "Brazil has excellent vaccine research facilities. This collaboration with Fiocruz is a key piece of our strategy to partner with emerging middle-income countries. Together we will be able to develop and make available new vaccines to benefit public health in Brazil."⁵⁵ Jean St  phenne, president and CEO of GSK Biologicals, underscored, "With Fiocruz's expertise, we can help to protect Brazilian children from pneumococcal disease today and collaborate on innovative technologies to address Brazil's public health needs over the coming years."⁵⁶

Leaders at Fiocruz likewise strongly supported the new PPP with GSK, not only as an alternative to market-based pricing, but also as a way to build greater technical know-how in manufacturing and sustain research budgets. Carlos Morel, director of the Center for Technological Development in Health at Fiocruz, observed, “Brazil is a huge purchaser. GSK will sell over \$1.5 billion of Synflorix vaccine as Brazil vaccinates all newborns. Both sides win.”⁵⁷ Carlos Gadelha, secretary for Science, Technology and Strategic Inputs at the Ministry of Health, described the mutual benefits: “The public market is the carrot, and technology transfer is the stick ... for big pharmaceutical companies to increase the legitimacy they need by offering an opportunity to support public health.”⁵⁸

Nevertheless, GSK Brazil’s president, Cesar Rengifo, noted challenges that accompanied GSK’s long-term commitments. “If you like emotions, Brazil is a good place to be, because you must be prepared for swings ... GSK is always trying to follow the government agenda, and adapting the strategy toward what the Brazilian government needs and what we believe is the future.”⁵⁹ Among the swings looming for GSK were other promising Dengue vaccines being developed worldwide.⁶⁰ If one proved effective at low cost, would Fiocruz continue the PPP, or would it be forced by the government to cancel collaborative research with GSK and seek out other partners?

The Road Ahead

In January 2012, representatives from the Bill and Melinda Gates Foundation, the World Health Organization, and 13 drug-companies, including GSK, pledged to eradicate ten of the world’s most destructive diseases by 2020. Plans mirrored the GSK-Fiocruz agreement: multinational drug companies would work with governments and local health institutes to provide low-cost drugs, transfer manufacturing technologies, and jointly undertake research into new medicines.⁶¹ Broadly, the PPP model in health care appeared to offer benefits from pooling resources and sharing information and expertise. Forms of “social partnerships” were emerging, beyond strictly commercial relationships.⁶²

Rengifo saw the PPP as key to the company’s competitive position in Brazil: “We are in the enviable position of having a headstart on other companies which may be trying to start partnerships from scratch.”⁶³ Anticipating a smooth presentation to investors, Andrews nevertheless prepared for challenging questions about the core business model GSK was advancing through PPP initiatives. Risks to the deal with Fiocruz seemed remote. But public opinion was never fully on the side of the pharmaceutical industry and rival pharmaceutical firms were pursuing partnerships with Fiocruz and public health authorities in other developing countries. Andrews knew that success with technology transfer for Synflorix and research into a vaccine for Dengue fever were fundamental to GSK’s success in Brazil, and important to its emerging market strategy overall.

Exhibit 1 GlaxoSmithKline Sales by Product Category and Location (in £ billion)

Business Group	2005	2006	2007	2008	2009	2010	2011
U.S. Pharmaceuticals & Vaccines	9.1	10.4	9.3	8.9	8.6	7.6	7.0
Europe Pharmaceuticals & Vaccines	5.5	5.5	5.6	6.5	7.1	6.5	5.8
Emerging Market Pharmaceuticals & Vaccines	1.4	1.5	1.9	2.3	2.9	3.6	3.7
Asia-Pacific/Japan Pharmaceuticals & Vaccines	2.2	2.2	1.7	1.9	2.6	3.1	3.2
ViiV Healthcare*	–	–	–	–	1.6	1.6	1.6
Consumer Healthcare	3.0	3.1	3.6	4.0	4.7	5.0	5.2
Other	0.5	0.5	0.6	0.8	1.2	1.0	1.0
Total	21.7	23.2	22.7	24.4	28.4	28.4	27.4

* ViiV Healthcare was established by GSK and Pfizer in 2009 with the mandate “to deliver advances in treatment and care for people living with HIV.” It was jointly owned (85% GSK, 15% Pfizer) and managed a portfolio of 10 widely approved drugs with a pipeline of 16 drugs in development. See: www.viivhealthcare.com, accessed February 2012.

Source: Adapted from GlaxoSmithKline, *Annual Report* (Brentford, UK: GSK, various years).

Exhibit 2 GlaxoSmithKline Sales by Division (in £ billion)

Division	2005	2006	2007	2008	2009	2010	2011
Pharmaceuticals	17.3	18.4	17.1	17.8	20.0	19.1	18.7
Vaccines	1.4	1.7	2.0	2.6	3.7*	4.3*	3.5
Consumer Healthcare	3.0	3.1	3.6	4.0	4.7	5.0	5.2
Total	21.7	23.2	22.7	24.4	28.4	28.4	27.4

* 2009 & 2010 figures include H1N1 (swine flu) vaccine sales.

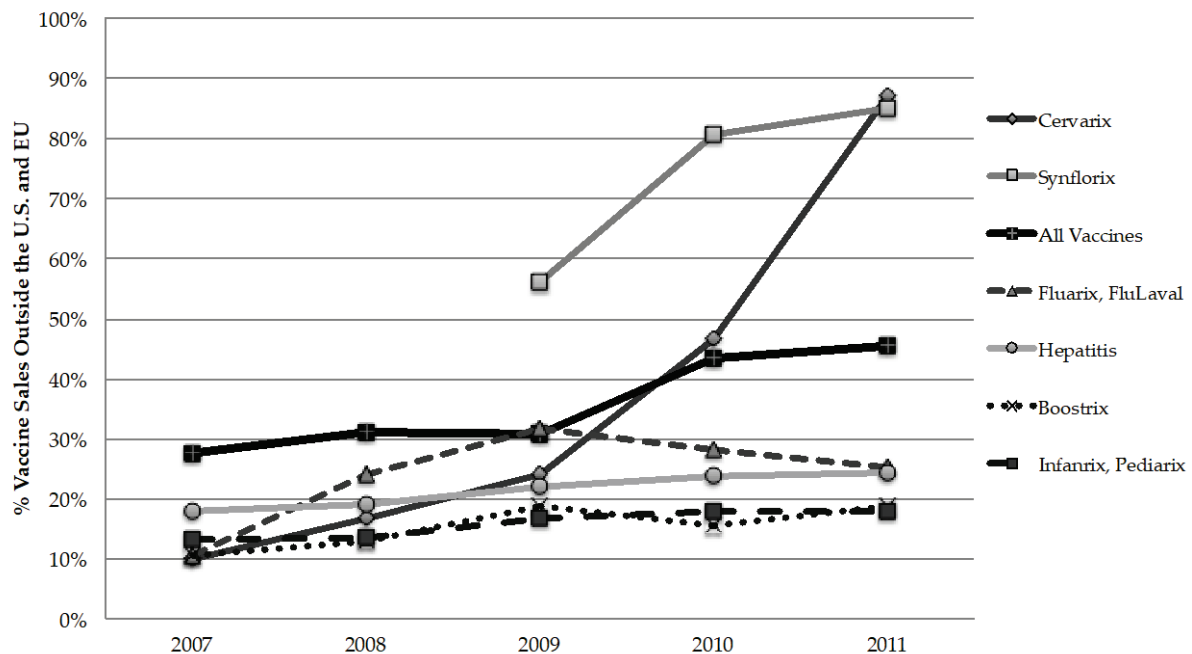
Source: Adapted from GlaxoSmithKline, *Annual Report* (Brentford, UK: GSK, various years).

Exhibit 3 GlaxoSmithKline Vaccine Sales (in £ million)

Vaccine	2005	2006	2007	2008	2009	2010	2011
Boostrix (adult tetanus, diphtheria, and pertussis)	–	60	66	70	139	181	192
Cervarix (cervical cancer)	–	–	10	125	187	242	506
Fluarix, FluLaval (influenza)	–	–	320	215	211	241	230
Flu Pandemic (H1N1)	–	–	–	66	883	1,192	18
Hepatitis	444	479	529	665	665	720	688
Infanrix, Pediarix (pediatric tetanus, diphtheria, and pertussis)	431	511	543	682	649	700	690
Rotarix (rotavirus)	–	–	91	167	282	235	300
Synflorix (pediatric meningitis and pneumonia)	–	–	–	–	73	221	350
Total Vaccine Sales*	1,389	1,692	1,993	2,593	3,706	4,326	3,497

* Includes sales from vaccines not identified here.

Source: Adapted from GlaxoSmithKline, *Annual Report* (Brentford, UK: GSK, various years).

Exhibit 4 GlaxoSmithKline Vaccine Sales in Emerging Markets and Developing Countries

Source: Adapted from GlaxoSmithKline, *Annual Report* (Brentford, UK: GSK, various years).

Exhibit 5 Selected Health Indicators in Brazil

Indicator	1990	1995	2000	2005	2009
Economic					
Total health expenditure, % GDP	n/a	6.7	7.2	8.2	9.0
Total health expenditure, US\$ per capita (PPP)	n/a	412	494	695	943
Government / Private % total health expenditures	n/a	43 / 57	40 / 60	40 / 60	46 / 54
Out-of-pocket as % of private health expenditures	n/a	68	64	63	57
Health					
Life expectancy at birth (years)	67	n/a	70	n/a	73
Under-five mortality rate (per 1000 live births)	59	48	36	26	19
Hib (Hib3) immunization coverage of 1-year-olds (%)	n/a	n/a	90	96	99
BCG immunization coverage of 1-year-olds (%)	79	99	99	99	99
Measles immunization coverage of 1-year-olds (%)	78	87	99	99	99
Hepatitis B immunization coverage of 1-year-olds (%)	n/a	10	94	92	98
Diphtheria, tetanus, and pertussis immunization coverage of 1-year-olds (%)	66	81	98	96	99

Source: Adapted from World Health Organization, *Global Health Observatory Data Repository*, <http://apps.who.int/ghodata>, accessed February 2012.

Exhibit 6 Brazilian Pharmaceutical Market

1998 Rank	Company	Origin Country	2007 Rank	Company	Origin Country	2011 Rank	Company	Origin Country
1	Aventis	France	1	Sanofi-Aventis	France	1	Sanofi-Aventis	France
2	Novartis	Switzerland	2	Novartis	Switzerland	2	EMS Corp.	Brazil
3	Aché	Brazil	3	EMS Corp.	Brazil	3	Hypermarcas	Brazil
4	Bristol Myers Squibb	USA	4	Pfizer	USA	4	Novartis	Switzerland
5	Roche	Switzerland	5	Hypermarcas	Brazil	5	GlaxoSmithKline	United Kingdom
6	American Home Products ^a	USA	6	Aché	Brazil	6	Aché	Brazil
7	Johnson & Johnson	USA	7	Roche	Switzerland	7	Pfizer	USA
8	Schering Plough	USA	8	Merck	USA	8	Roche	Switzerland
9	Boehringer Ingelheim	Germany	9	Bayer	Germany	9	Eurofarma	Brazil
10	Pfizer	USA	10	GlaxoSmithKline	United Kingdom	10	Johnson & Johnson	USA

^a American Home Products was acquired by Wyeth in 2002, which was acquired by Pfizer in 2009.

^b Schering-Plough was acquired by Merck in 2009.

Note: Companies ranked by total prescription drug, vaccine, and other non-retail sales in Brazil.

Source: Adapted from IMS Health, MIDAS database, various years.

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