How Public–Private Partnerships Handle Intellectual Property: The PATH Experience

STEVE BROOKE, *Commercialization Advisor, Commercialization and Corporate Partnerships, PATH, U.S.A.*
CLAUDIA M. HARNER-JAY, *Commercialization Officer, Commercialization and Corporate Partnerships, PATH, U.S.A.*
HEIDI LASHER, *Principal, Lasher Consulting, U.S.A.*
ERICA JACOBY, *Senior Program Associate, Commercialization and Corporate Partnerships, PATH, U.S.A.*

ABSTRACT

PATH is an international, nonprofit organization that creates sustainable, culturally relevant solutions, enabling communities worldwide to break longstanding cycles of poor health. By collaborating with diverse public and private sector partners, PATH helps provide appropriate health technologies and vital strategies that change the way people think and act. PATH's work improves global health and well-being. Over the past 28 years, PATH has demonstrated that public–private partnerships (PPPs) can effectively address unmet public health needs, particularly when managed with a clear understanding of both public and private sector objectives. Indeed, collaboration between public sector and private sector partners is an especially valuable way to develop and advance appropriate health technologies for use in developing countries. When developing and managing PPPs, PATH recognizes that intellectual property (IP) is an especially important component in the range of variables that affect the economic, technical, and programmatic feasibility of a new health technology intervention. Our goal, therefore, is to incorporate IP considerations as a fundamental part of the PPP process. We seek to manage IP strategically to avoid or quickly overcome any IP-related roadblocks. Using three case studies, this chapter illustrates PATH's strategies for private sector collaboration, as well as PATH's approaches to managing IP.

1. INTRODUCTION

In many parts of the developing world, public health services reach less than 50% of the population. Weak infrastructure, poor living conditions, limited individual and public resources, extreme environmental conditions, population growth, new migration patterns, violent conflicts, and a host of other conditions all pose challenges to achieving "health for all." While healthcare for people in the developing world over the past quarter century has improved enormously, recently there have been significant setbacks: the AIDS epidemic and development of resistant strains of diseases, to name a couple. Continued growth in populations and decaying infrastructure due to lack of reinvestment have exacerbated the problem.

In this context, improving the effectiveness of healthcare services requires responsive, constantly evolving public health initiatives that can harness recent advances in biotechnology to solve difficult healthcare problems in developing countries. For example, new vaccines for meningitis, malaria, and rotavirus would greatly reduce the impact of these deadly diseases, which kill millions of people each year in developing countries. New, rapid diagnostic tests would detect conditions at the point of care, allowing treatment and counseling before the client has left the clinic. Heat stable and multivalent vaccines, prefilled injectors, and ice-free cooling would enhance health services and improve the effectiveness of immunization programs.

Brooke S, CM Harner-Jay, H Lasher and E Jacoby. 2007. How Public–Private Partnerships Handle Intellectual Property: The PATH Experience. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

© 2007. S Brooke, et al. *Sharing the Art of IP Management:* Photocopying and distribution through the Internet for noncommercial purposes is permitted and encouraged.

1.1 *Why are public–private partnerships so critical for health technologies?*

Our experience suggests that one of the best ways to ensure that appropriate, affordable health technologies are developed and made available in developing countries is through public–private partnerships, or PPPs. Globally, most new health technologies come from the research and development efforts of private industry. Commercial enterprises not only have the expertise, capacity, and resources to carry a product forward to market, they also have strong market-driven incentives to do so. Unfortunately, this drive to pursue projects with the highest potential profit means that private companies usually do not put a high priority on products and services for developing countries. Markets in those countries are often unstable, and so perceived risks diminish projected return on investment. Pharmaceutical companies, for example, would rather invest in products that are targeted to large, lucrative therapeutic markets than pour research dollars into malaria or AIDS vaccines.

Without private sector collaboration many badly needed public health products/ideas simply fail to come to fruition. By itself, the public sector lacks the capacity, resources, and experience to design, develop, produce, and distribute most new technologies. The "technology challenge" for public sector health organizations, therefore, is to shift market forces enough to attract private sector involvement in developing appropriate, cost-effective healthcare technologies and to make them available to resource-poor populations. To accomplish this, the public sector must co-invest in necessary and suitable technologies, reduce risk, and invigorate private commercial investment through effective PPPs.

1.2 *What has PATH learned about PPPs?*

In the past two decades, the public sector has learned that the commercial sector can very effectively produce and distribute high-quality goods at low cost. It has also learned that before deciding to get involved in a project, the commercial sector must perceive a reasonable return on its investment and an acceptable level of risk. Acting as a "bridging agency," PATH helps to reconcile these differences by leveraging its technical innovation, knowledge of markets in developing countries, understanding of commercial imperatives, and experience of managing intellectual property (IP). PATH negotiates mutually beneficial solutions for both the public sector and private entities. Through public–private partnerships, the costs and risks of development are shared—and sometimes entirely funded by PATH with funds from donors, private foundations, and governments—at the early stages of a project, which helps private companies see the potential for a reasonable return on their investment. In return, PATH can guide technology development towards meeting the priority health needs of resource-poor populations.

Acting as a "value-added" intermediary between industry and the public sector, PATH has been involved in successfully commercializing and advancing over 50 new technologies for public health in developing countries over the past 28 years.

1.2.1 *Prioritizing availability, accessibility, and affordability*

Typically, a project will begin by clearly identifying a need or gap in the health system of a developing country that a new technology, at least in part, can address. PATH identifies potential partners, demonstrates the value of the technology, and forms collaborations with commercial companies to become codevelopers and/or sustainable suppliers of the technology to the developing world. Alternatively, the commercial company may own a technology that can be adapted for use in a developing country. In these cases, PATH may approach the company to collaborate or gain access to their technology. Within these partnerships, PATH aims to meet three objectives:

1. **Availability**: To guarantee supply for the developing world. Initially, PATH works to ensure that the company has adequate capacity to supply demonstration projects and/or clinical trials. Later, a company must be able to meet potential demand in targeted countries. Over the long term, companies must have capacity to meet

wider public sector demand in relevant developing countries.

2. **Accessibility**: To ensure that the product is available through distribution channels that actually reach target populations. Although many vulnerable populations get their services through public sector channels, they also access healthcare through private sector channels. PATH helps facilitate access to both channels by working with traditional government health services and by creating alliances with social marketing groups that are able to reach target populations more broadly.
3. **Affordability**: To create health products that the developing world can afford. PATH will often negotiate with partners to agree upon different prices for different markets (that is, tiered pricing by country, or between private sector versus public sector consumers). PATH also conducts cost-effectiveness studies to help decision-makers understand the value of the new product in relation to other potential health products.

1.2.2 *Principles for collaboration with private sector partners*

Once PATH has identified potential private sector partners, it follows a process of due diligence to examine a potential partner's operations and management and to verify material facts. Such upfront diligence significantly increases the chance of a successful partnership and assists planning. PATH needs to decide, for example, whether a company has enough resources to dedicate to a project, whether the company is stable and financially viable, whether the collaboration is appropriate given its current situation, and whether the company represents the best choice for a PATH partnership. Due diligence is an accepted—and often required—practice in the private sector, and it helps ensure the sustainability and impact of PATH's PPPs.

In addition, PATH professionals have a responsibility to preserve PATH's integrity and status as a publicly funded nonprofit, nongovernmental organization and fulfill this responsibility by evaluating partnerships with respect to nine principles for private sector collaboration.[1] From the perspective of IP management, the following two principles are most important:

1. **Clear link to mission.** PATH's collaborations with private sector companies must positively affect the availability, accessibility, and affordability of important health products for public health programs in developing countries.
2. **Recognition of private sector needs.** PATH recognizes the company's need to benefit commercially, which ensures a sustainable commitment to the collaboration. PATH's goals for availablity, accessibility, and affordability of products for developing country public health programs will likely be met if PATH's expectations of the private sector collaboration are realistic and take into account the full range of costs necessary from product development to commercialization.

2. HOW DO PATH'S PPPS HANDLE IP?

Given its mission, PATH has an inherent interest in managing IP to achieve maximum public health benefits. PATH's approach to IP management has common themes for all projects. PATH professionals review the existing and competing IP rights of all partners, negotiate with partners over the exact terms of ownership for all IP generated over the course of the project, agree on what happens if the partnership terminates before the project's completion, and specify responsibilities for protecting project IP generated by partners and PATH. After a technology is developed, IP is managed in the context of a commercialization strategy and a licensing plan.

Within each of these activities are myriad complexities that influence the specific strategies and tactics PATH adopts to negotiate IP. Perhaps the best way to understand PATH's approach to handling IP, then, is through case studies. Two of the following case studies, the first involving cervical-cancer screening diagnostics and the second involving a meningitis vaccine, are well along the product development pipeline. In these projects,

IP is managed to *advance specific products* through subsequent stages of development and commercialization leading to use in developing countries. A third case study, involving vaccine stabilization, describes technologies in an earlier stage of R&D that will become *components* of final products rather than complete products themselves. In this case, PATH is pursuing the development of a portfolio of technologies simultaneously in order to distribute risk and ensure progress toward a successful outcome. IP is managed to *advance the technology portfolio,* with the understanding that technologies developed over the course of the project will become important components of future final vaccine products.

2.1 *Cervical-cancer-screening tests: two is better than one*

Although cervical cancer is preventable, about 200,000 women die each year from it—often in their most productive years. Pap-smear screening programs help keep cervical cancer rates relatively low in wealthier countries; however, the success of these screening programs rely on regular visits to healthcare facilities, expensive pathology laboratories, and follow-up visits. Due to the cost, implementation challenges, and the complexity of properly screening and treating women in developing countries, the Pap-smear method has had only a limited impact in these areas. Not surprisingly, more than 80% of new cervical cancer cases occur among women living in developing countries.

2.1.1 *How the public and private sectors came together*

Because cervical cancer affects women in developed countries and developing countries, private industry had already invested in research to improve diagnostic screening tools for human papillomavirus (HPV), the virus is associated with over 99% of cervical-cancer cases. However, these commercial enterprises had not taken an interest in adapting their technology to make it more affordable and appropriate for developing-country health settings. This would have required a large investment in both product development and clinical studies—for a market that can afford prices that are only a fraction of those in developed countries. Hence, investing in HPV diagnostic technology for public sector markets in developing countries would never be a top priority for a commercial entity.

In 2003, PATH received funding from the Bill & Melinda Gates Foundation for its Screening Technologies to Advance Rapid Testing (START) project. This project includes support for clinical studies involving over 22,000 women in China and India, as well as support for developing low-cost, easy-to-use, culturally acceptable tests for cervical cancer screening. Since the private sector had already developed relevant technologies, and since PATH possessed useful data, a PPP was a logical choice. Two testing formats appeared promising, so PATH orchestrated partnerships with two companies to develop the test formats to detect HPV (one using DNA, and the other using a biomarker protein).

Both companies in the PPP are working to create a test that is safe, accurate, affordable, simple to use, and acceptable to women and healthcare providers. Tests will be based on a cervical swab provided by a healthcare provider or a vaginal swab obtained by the woman herself. Health workers with minimal training and equipment should be able to process either test in one day. Both tests are expected to have a higher than 90% accuracy rate in detecting cervical precancer or cancer (the Pap-smear test has a 55%–65% accuracy rate). This means that women who get tested only once in their lifetime, using one of the new methods, will still have a high probability of avoiding cervical cancer disease.

2.1.2 *PATH's management of IP*

When negotiating with partners, PATH often finds it helpful to articulate the different roles and responsibilities and the expected durations of the various phases involved in the project. For the START project agreements, there was the R&D phase, which would last approximately five years, and the commercial sales phase, which would last 10 years from the date of first sale. In the R&D phase, PATH assumed responsibility for seven primary activities:

- funding a portion of each industry partners' direct R&D costs
- providing biological samples during research
- conducting market and industry assessments
- conducting some key product development tasks, specifically with lateral flow technology
- conducting program and product cost-effectiveness studies
- developing for the new tests an evaluation framework for public health program use
- conducting multicenter, multicountry (India and China) clinical evaluations of the performance of the new test that would be suitable for the compilation of data required for product registration in those countries

In turn, PATH's industry partners agreed to:

- conduct product development activities as outlined in their agreements
- assemble and protect any needed IP
- manufacture and supply the products for clinical evaluations
- finalize the products for registration and commercial supply

Each of PATH's private sector partners in this project already controlled key IP for the technologies included in its respective diagnostic test. This eliminated the need to broker IP for reagents from multiple parties. However, the two partnerships are more complex when it comes to creating PATH's backup IP rights if either industry partner were to decide not to go forward. In one agreement, PATH obtained, under certain backup conditions, a long-term supply agreement to the partner's key reagent, as well as the ability to sublicense others to produce a final diagnostic test incorporating this reagent. In the other agreement, the industry partner agreed to appoint a third party to manufacture and supply the diagnostic test if it does not want to continue commercialization. The latter partner would never be comfortable allowing its core background IP to move out of its direct control, so rather than asking the company to grant PATH rights to background IP, PATH focused on ensuring continued supply. Both agreements set pricing targets that are significantly lower than anything currently available.

Following the successful completion of research, development, and validation, PATH's industry partners will be responsible for obtaining the necessary regulatory approvals and for manufacturing and selling the test at an affordable price in India, China, and other developing countries. By the end of 2008, two easy-to-use, inexpensive, and appropriately designed diagnostic products to detect cervical precancer and cancer should be available in developing countries.

2.1.3 *Key insights*

All projects come with their own unique challenges, particularly when multiple partnerships are involved. In the case of the START project, PATH was able to avoid some common pitfalls by carefully selecting its partners. For example, because PATH came forward with links to clinical researchers and policy-makers, and because it had a solid understanding of the specifications that any new cervical-cancer-screening test would need, PATH was able to attract two top-tier industry partners that had the expertise and capacity to move product development forward. These partners were attractive to PATH because they owned proprietary control of the key reagents needed for their specific technologies. This allowed the project to avoid the even more uncertain, complex, and lengthy negotiations necessary to bring multiple IP holders into a workable product development project.

PATH also provided access to well-characterized, highly sought-after clinical specimens from countries outside the industry partner's normal research networks. In addition, PATH offered the opportunity for major field-based clinical assessments of final products, assessments that would be sufficient for product registration in those countries. As a result, the two industry partners realized that working with PATH would provide a unique opportunity to reengineer their product (in the case of one partner) or develop a new product (in the case of the other partner) to address lower-price market segments, thus gaining valuable inroads into the challenging but attractive markets of India and China. Without

the PATH program incentives, it is unlikely that either company would have undertaken these major efforts to adapt and develop their technologies for use in developing countries.

2.2 *Meningitis vaccine: a new model for vaccine development*

Meningitis, also referred to as spinal meningitis, is an infection in the fluid that surrounds the brain and spinal cord. When caused by a bacterial infection, the disease can be quite severe and may result in brain damage, hearing loss, learning disabilities, and death. Epidemic meningitis has been present on the African continent for about 100 years.

Over the last 20 years, countries located in Africa's "meningitis belt," roughly located between Senegal and Ethiopia, have depended on a disease control strategy involving surveillance and, once outbreaks are detected, reactive mass immunization campaigns using meningococcal polysaccharide vaccines. These interventions are massive, expensive, and disruptive, and they deflect scarce resources from public health efforts to control other diseases. Moreover, recent studies have shown that after an epidemic has begun, follow-up mass vaccinations are ineffective at preventing meningitis.

Unfortunately, while the public health need for a meningitis vaccine in Africa is great, no manufacturers have been willing to develop an affordable, effective group A meningococcal vaccine. In the 1990s, when more than 100,000 people died in Africa from a group A meningitis outbreak, there was also a group C meningitis outbreak in the United Kingdom, which resulted in 1,000 deaths. By 2001, three vaccine manufacturers had developed group C meningococcal vaccine for the United Kingdom. No vaccine for group A, however, had been developed.[2]

2.2.1 *How the public and private sectors came together*

The disease-specific components for a highly effective group A meningococcal conjugate vaccine existed before the PATH/World Health Organization (WHO) Meningitis Vaccine Project began. The conjugation technology also existed, which was a key production process step—it chemically links the two components, which makes the vaccine highly immunogenic and effective in young children, provides long-lasting protection, and decreases carriage and transmission rates. Yet no one was bringing these components together to develop and produce a meningococcal A vaccine. The challenge was to develop a program capable of motivating a vaccine producer to take a risk on an indigent market unable to pay high prices for the meningococcal A vaccine.

To address this challenge, in 2000 WHO commissioned an independent assessment of existing IP on conjugation technology and of the costs for project development and production for a group A or group A/C meningococcal conjugate vaccine intended for Africa.[3] The assessment showed that development was feasible and that a vaccine costing around US$0.40 per dose was possible—a price that health managers in sub-Saharan African countries were willing to pay. Soon after, the Bill & Melinda Gates Foundation awarded PATH a ten-year grant to establish, in partnership with WHO, the Meningitis Vaccine Project, which will advance the development, production scale-up, testing, licensure, and introduction of conjugate meningococcal A vaccines for Africa.

2.2.2 *PATH's management of IP*

The Meningitis Vaccine Project brought three critical partners to the table: SynCo Bio Partners B.V., which supplied meningococcal polysaccharide A (one of the two main components of the vaccine); the Serum Institute of India Limited (SIIL) to supply tetanus toxoid (the second main component of the vaccine) and to scale-up the manufacturing processes for the final vaccine; and the U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research to transfer their conjugation technology. This consortium was a new model for vaccine development: a key raw material came from one source, the technology from another, and the final scale-up for production from another. Moreover, it included a north-to-south transfer of technology and capacity.

PATH first negotiated a nonexclusive license for the FDA conjugation technology from

the U.S. National Institutes of Health Office of Technology Transfer (on behalf of the FDA), which PATH then sublicensed to SIIL. To protect the charitable mission of the project, PATH and SIIL agreed that if SIIL were to cease developing or producing the vaccine, SIIL would transfer to PATH the manufacturing know-how developed during their collaboration to enable another manufacturer to make the vaccine. SIIL also granted back to PATH a nonexclusive, sublicensable license to SIIL-owned technology necessary to make the vaccine. In addition, the PATH-SIIL agreement set out an explicit initial pricing of US$0.40 per dose for sales to the public sector. PATH's agreement with SIIL also includes explicit procedures and remedies should SIIL not meet public sector demand or charge the public sector more for the vaccine than the maximum agreed-upon price.

2.2.3 *Key insights*

It is somewhat unusual for vaccine manufacturers to accept a nonexclusive sublicense for a key production process such as a conjugation technology. However, the PPP and technology transfer gave SIIL incentive to accept this. First, since no manufacturer had been willing to make this vaccine, SIIL considered the risk that a competing manufacturer would step forward to use nonexclusively available FDA technology for a group A meningococcal conjugate vaccine was very small. Second, although SIIL is one of the world's leading vaccine manufacturers and had prior research experience working with conjugation technology, both SIIL and PATH knew they would be facing complex development challenges and an aggressive timetable. To help address these challenges and make the project more attractive to SIIL, PATH formed a technical team composed of the FDA inventors and other industry and government experts, who creatively and efficiently helped the Meningitis Vaccine Project surmount the inevitable technology scale-up and standardization hurdles. Third, the U.S. National Institutes of Health Office of Technology Transfer (NIH OTT) would have likely required higher up front fees, milestone payments, and higher royalty rates if PATH and/or SIIL had demanded an exclusive license to the conjugation technology. By nonexclusively in-licensing the conjugation technology under lower-cost terms and bundling it with further technology transfer support, pharmaceutical development, and clinical trials funding, PATH provided a package that would allow SIIL to keep the finished vaccine price at the targeted US$0.40 per dose, even after paying royalties to the NIH OTT. At this price, the new vaccine would cost less than current expenditures in hyperendemic areas, even before adding lost livelihood income and disability savings.

2.3 *Creativity and flexibility accelerate vaccine stabilization technologies*

The global health community is trying to make vaccines available to all the world's children, but this commitment is stressing an already fragile cold chain: the distribution network of equipment and procedures used to maintain vaccine quality from the vaccine manufacturer to the recipient. While strengthening and expanding existing cold-chain capacity is one option for reducing these stresses, improving vaccine thermostability—the inherent ability for vaccines to withstand extreme temperatures—is likely to be the more effective and sustainable approach. In recent years, stabilization technology has advanced so far that it could reduce the reliance of vaccines on the cold chain and facilitate expanded delivery options. These products could reduce the logistical burden of vaccine delivery, reduce vaccine waste, improve safety, and facilitate extended coverage.

2.3.1 *How the public and private sectors came together*

Vaccine producers typically seek to obtain sufficient product stability to meet the standards of developed countries. This means that vaccines typically require storage at frozen (–20° C) or refrigerated (2–8° C) temperatures. Some heat-sensitive vaccines (such as measles, BCG, and yellow fever vaccines) must be lyophilized (freeze-dried) in order to achieve this level of stability. Vaccine producers have been reluctant to further improve thermostability to reduce reliance on the cold chain for two main reasons. First, there

is no perceived need for such products in developed countries where cold chain breaks are infrequent. This means that vaccine producers would rely solely on developing country sales to recoup their development investment. Second, the commitment of vaccine purchasers to buy stabilized vaccines for use in the developing world is uncertain—especially at higher prices.

In the absence of a market for thermostable vaccine products, PATH initially investigated the feasibility of stabilizing vaccines with funding from the U.S. Agency for International Development (USAID) under a program called HealthTech: Technologies for Health. In 2003, PATH received funding from the Bill & Melinda Gates Foundation to investigate the technical, programmatic, and market feasibility of stabilization technologies. PATH is pursuing a portfolio approach to the project, working with a range of private sector companies and universities to accelerate the development of different stabilization technologies that could be applied to a variety of vaccines. PATH has also developed its own proprietary technology to protect vaccines against freeze damage (U.S. and Patent Cooperation Treaty [PCT] patent applications are pending). As certain technologies show themselves to be more promising than others in terms of availability, accessibility, and affordability, the portfolio will be narrowed. When the technologies are mature enough to transfer, vaccine producers will need to help validate and scale up the technologies for commercial production.

2.3.2 *PATH's management of IP*

The primary focus of PATH's IP management strategy for the vaccine stabilization project has been to keep options open by holding some ownership of the new IP generated with partners. This makes it possible to move forward with the technology if the partner is unwilling and to improve the efficiency of research within the portfolio (that is, use the project IP with other partners). Since the landscape of patents in the stabilization field is fairly crowded, the strategy also involves creating partnerships with those that hold foundational IP to which others may eventually need access.

In practice, this strategy requires a great deal of creativity and flexibility. In many cases, for example, PATH and its partner jointly own project IP. Moreover, in certain circumstances, access to background IP is negotiated at the start. This is ideal because it gives PATH control without jeopardizing the partner's access. However, two specific partnerships illustrate the extremes of managing IP. On one end of the spectrum is a technology that PATH created in-house and is developing in collaboration with a partner. Since PATH owned the technology, it was able to negotiate full ownership of all improvements, even those to which the partner may contribute. On the other end of the spectrum, a private sector partner maintained very tight control over its proprietary IP. Rather than accept funding from PATH, the company tested its technology against the applications of interest to PATH, assuming the entire R&D burden in order to fully control the IP. In this case, PATH was able to obtain *an opportunity* to negotiate access to their IP in the future. Although not ideal structurally, this collaboration allowed PATH to build a relationship with a partner whose technology may be important to other technologies in the portfolio. This may allow PATH to avoid a potential roadblock to access in the future.

In addition to IP management, the project's global access strategy makes concerted efforts to align partners along the vision of how the end products might be made available in developing countries. For such purposes, PATH developed a Preferential Technology Access Program, which is written into each partner's agreement. For example, partners must agree to license their technology on nonexclusive terms to vaccine manufacturers in order to maximize access, place a royalty cap on those licensing arrangements, and restrict licensing and milestone fees. The exact terms vary with each partnership. The goal is to enable access to these technologies as they move downstream in the development pipeline.

2.3.3 *Conclusions*

When it comes to upstream research projects, we know very little about which technologies will emerge as promising, which may need to be

eventually combined, and which may prove foundational for others. PATH's strategy has been to invest in a wide variety of promising approaches, promising to maximize the chances for success and integration and to negotiate some degree of access. PATH can thereby prevent those technologies that are emerging from the portfolio—and even technologies that already exist—from limiting the widespread adoption of stabilization technologies by vaccine manufacturers serving the developing world. This requires a constant reexamination of product scenarios and players. PATH uses as much flexibility and creativity as possible to move forward a market that in its absence would stall. ■

ACKNOWLEDGEMENT

Some of the writing in this chapter was borrowed from internal documents written under the HealthTech project, which was made possible by the generous support of the people in the United States through USAID under the terms of HealthTech Cooperative Agreement # GPH-A-00-01-00005-00. The ideas expressed in this chapter reflect the principles and goals of PATH and do not necessarily reflect the views of USAID or the U.S. Government.

STEVE BROOKE, *Advisor, Commercialization and Corporate Partnerships, PATH, 1455 NW Leary Way, Seattle, WA, 98107, U.S.A. sbrooke@path.org*

CLAUDIA M. HARNER-JAY, *Program Officer, Commercialization and Corporate Partnerships, PATH, 1455 NW Leary Way, Seattle, WA, 98107, U.S.A. charner@path.org*

HEIDI LASHER, *Principal, Lasher Consulting, 410 N Willson Ave., Bozeman, MT, 59715, U.S.A. heidilasher@yahoo.com*

ERICA JACOBY, *Senior Program Associate, Commercialization and Corporate Partnerships, PATH, 1455 NW Leary Way, Seattle, WA, 98107, U.S.A. ejacoby@path.org*

---

1 A full description of PATH's Guiding Principles for Private-Sector Collaboration is available online at: www.path.org/files/ER_gp_collab.pdf. Additional reading and relevant articles are:

Free MJ. 2004. Achieving Appropriate Design and Widespread Use of Health Care Technologies in the Developing World: Overcoming Obstacles that Impede the Adaptation and Diffusion of Priority Technologies for Primary Health Care. *International Journal of Gynecology & Obstetrics* 85(Suppl. 1): 3–13.

Free MJ. 1992. Health Technologies for the Developing World. *International Journal of Technology Assessment in Health Care* 8:4: 623–34.

Greenwood BM. 1999. Manson Lecture: Meningococcal Meningitis in Africa. *Transactions of the Royal Society of Tropical Medicine and Hygiene* 93: 341–53.

PATH. 2006. Global Partnerships for Malaria Control. *Directions in Global Health* 3:1. www.path.org/files/ER_directions_spr_06.pdf.

PATH. 2006. Eliminating meningitis in Africa. *Directions in Global Health* 3:2. www.path.org/files/ER_directions_summer06.pdf.

Ramsay ME, N Andrews, EB Kaczmarski and E Miller. 2001. Efficacy of Meningococcal Serogroup C Conjugate Vaccine in Teenagers and Toddlers in England. *Lancet* 357: 195–96.

Lloyd J. 2000. WHO Department of Vaccines and Biologicals. Technologies for Vaccine Delivery in the 21st Century. whqlibdoc.who.int/hq/2000/WHO_V&B_00.35.pdf.

2 Jódar L, FM LaForce, C Ceccarini, T Aguado and DM Granoff. 2003. Meningococcal Conjugate Vaccine for Africa: A Model for Development of New Vaccines for the Poorest Countries. *Lancet* 361: 1902–4.

3 See *supra* note 2.