Case Study

Sharing Power How Merck and the WHO have sustained a fragile balance of power in their battle against river blindness

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SHARING

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RENDA COLATRELLA, an executive of the multinational pharmaceutical giant Merck & Co., remembers being stunned at a meeting back in 1996 by a proposal made by a colleague at the World Health Organization (WHO). Since 1987, Merck and the WHO had been partners in an innovative program to eliminate onchocerciasis, a leading cause of blindness in the developing world. Merck's donations of its breakthrough drug Mectizan, with the WHO's technical support, had already saved millions of Africa's poor from the scourge known as "river blindness," using distribution by mobile drug-delivery teams of health professionals from numerous nongovernmental organizations. Though it was an unsustainable method in the long run to treat the estimated 120 million people at risk of contracting the disease across 35 countries,1 it had been quite successful

over its first nine years of operation.

But at the 1996 meeting, in Geneva, the WHO's research team was proposing a radical and untested delivery strategy that Colatrella feared could upset the whole effort: to let local communities select their own health workers – usually lay volunteers with unproven capacity and reliability – to distribute the drug and monitor patient care.

To Colatrella's Western sensibilities, the proposal was unfathomable. "It defied every protocol we lived by, starting with the fact that trained physicians administered prescription drugs, lay people did not," she recalls thinking. "I nearly fell off my chair." What if the local, typically illiterate workers improperly dosed the medication, she worried, or failed to accurately record adverse reactions? The Food and Drug Administration, to which Merck ultimately answered as a U.S. company, could pull the plug on the program altogether.

And what if Mectizan seeped into

How can organizations in public-private partnerships, with very different cultures and missions, find common ground on critical issues of strategy?

What are the chief concerns of corporate donors, and how do they influence decision making in public-private partnerships?

When should partners attempt to exert, cede, or compromise control over program decisions?

What are some principles to guide successful power sharing in partnerships?

by JONATHAN B. LEVINE





the black market, finding uses it wasn't approved for? Any negative impact on patients' health would be devastating - and surely damage Merck's reputation, turning its good intentions into a PR nightmare. Colatrella glanced across the meeting table at her Merck colleague, Charlie Fettig, then-senior marketing director for anti-infectives. She read his reaction on his face: "No way, José." He later added to her, privately, "This will never fly."

But fly it did. In fact, over the past decade, the WHO's community-directed treatment (CDT) strategy, pioneered by the Mectizan Donation Program (MDP), has become a fixture of mainstream public health delivery



Eye lesions (left) and skin nodules (right) are symptoms of river blindness.

throughout the Third World. Moreover, with its free doses of Mectizan to treat and prevent the blindness-causing eye lesions of onchocerciasis, MDP has become one of the most lauded public health achievements of the 20th century for its coverage of an unprece-

Merck executives Brenda Colatrella and Charles Fettig were surprised by the WHO's plan to let local health workers distribute Mectizan for river blindness.

dented number of beneficiaries.2

MDP, starting in 1987, was not only the first program to give away a prescription drug over a sustained period. It also pioneered the now-common cross-sector partnership model that forged standards of cooperation between private enterprise and multiple levels of public organizations. The legendary program has since spawned an entire industry of public-private drug-donation initiatives, from Pfizer's efforts to combat trachoma, to Novartis' work in leprosy, and GlaxoSmithKline's in malaria and lymphatic filariasis.

Yet, for all of the partnership's acclaim, Merck's uncharted journey with the WHO, along with the World Bank and dozens of NGOs and national health ministries, has given rise to a number of conflicts over the last 18 years that could just as easily have shut the program down. How these organizations with radically different experience and motivations found common ground over controversial issues such as CDT is a study in the fragile balance of power sharing. As in any strong partnership, the success of the MDP is rooted in the art of knowing when to exert, cede, or compromise control over critical decisions.

Typically, the dynamics have centered on the response of Merck, as the donor, to its partners' occasional requests. The ensuing debates over Mectizan strategy invariably have tested the company's patience, budget, and policies – just as they frequently left its partners wondering how long Merck's "unlimited" commitment would last. In hindsight, a simple guiding principle has served the partners well: "If we stayed focused on the needs of the program, rather than on what was desirable or politically convenient for any given partner, then the right decisions got made," says Colatrella, senior director for contributions at Merck. But that tenet would not always seem so obvious in the heat of debate.

Eyes on the Prize

From the outset, Merck and the WHO had a strong foundation for cooperation. New Jersey-based Merck was one of the largest and most admired research-driven pharmaceutical companies in the world. The Geneva-based health agency of the United Nations, for its part, had a long history in Africa of battling river blindness, caused by parasitic worms, by attacking carrier black flies with aerial spraying. By the early 1980s, the WHO had helped Merck set up clinical trials in Africa for ivermectin, the compound that would become Mectizan, and their ongoing dialogue about pricing and distribution built mutual respect that would later contribute to the MDP.3 Merck even offered to have the WHO take over Mectizan's entire distribution strategy. Given the company's unfamiliarity with Africa's remote terrain and limited medicaldelivery channels, it was hardly prepared on its own.

But by 1987, when Merck's then-CEO Roy Vagelos formally committed to donate unlimited supplies of the drug, neither organization felt equipped to go

The Mectizan Donation Program Experience

Principles in Partnership Power Sharing

- Put aside individual collaborators' agendas and stay focused on the goals of the partnership.
- Whenever possible, allow those who are most affected by a decision to determine their own needs and priorities.
- To resolve knotty disputes, use the invaluable services of an independent advisory entity of unquestioned expertise, whose sole mandate is to further the partnership's goals.
- Find ways to nurture important relationships, especially in the face of disagreement.
- Insist on being convinced of a partner's proposition with the clearest evidence possible, rather than allow decisions to be made against your better judgment. Mutual buy-in creates stronger relationships based on trust rather than power.
- Work to understand the other partners' structures, processes, and requirements to avoid being blindsided by unanticipated requests.
- Deploy your most knowledgeable and credible representatives available to balance the expertise from your strongest partners.
- Expect the unexpected: Be prepared to respond to constantly changing partner needs.

it alone. "It was the end of the Cold War, and neither of us wanted to get caught up in the politics of deciding which countries would receive the drug," Fettig recalls. To field those sensitive

tion of the drug based strictly on medical need – and thereby insulate the partners from any conflicts of interest. To head the committee, Vagelos recruited Dr. William Foege, the venerated former

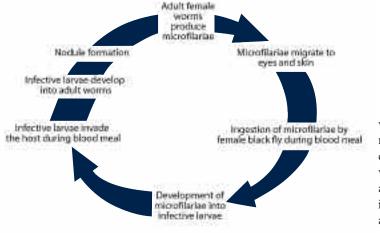


Focusing on the needs of the program, rather than on what was desirable for the partners, meant the right decisions got made.

issues, Merck set up the Mectizan Expert Committee (MEC), a panel of seven eminent public health and tropical disease authorities. The MEC would advise Merck on responsible use and distribu-

director of the Centers for Disease Control and Prevention, where he'd led the global campaign to eradicate smallpox.

However, Foege's strong leadership, along with an independent MDP secre-



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activities, lulled Merck management into a false sense that the program would run itself. "There was a naive expectation, or wishful thinking, or both, that we could just step out of day-to-day planning," recalls Colatrella. "So we never foresaw issues like community-directed treatment evolving in the field that would require decisions by M

tariat set up to carry out daily

would require decisions by Merck. But it soon became a constant effort to keep on track, and we learned we couldn't just throw money and medicine at it and wash our hands of operations. Unanticipated needs always came up."

Leap of Faith

To appreciate Merck's approach to engaging with partners, it helps to understand its corporate culture. As a visible giant in a tightly regulated industry, insiders have always been highly conservative and averse to anything that would risk the company's image. "Protecting the corporate reputation has always been paramount," recalls Fettig,

who retired in 2000. Colatrella, who took on increasing responsibility for the program's oversight over the years, saw it as her job to be skeptical, if only to make sure the program didn't come back to haunt Merck. A second characteristic, typical in many corporate cultures, is arrogant thinking. "We had to learn to constantly suppress the tendency to think that the way we did things was the right and only way," Fettig says.

No wonder, then, that when the WHO introduced its controversial community-directed treatment strategy in 1996, Fettig and Colatrella resisted. In initial methods of distributing Mectizan, mobile teams of professional healthcare

workers from NGOs and primary care centers would decide every detail: who would receive the drug, how and when it would be administered and communicated, and importantly, who would provide medical supervision. Under CDT, however, those decisions would be left to local communities to tailor to their own needs.

Exposing Merck to the risks of decisions by unproven lay health workers, including improper dosing and reporting, black market diversion, and a lack of professional oversight, seemed too much for Fettig and Colatrella to even consider. As it turned out, their fears weren't totally unfounded. A few years after CDT began, Mectizan would be linked to a rare death in Cameroon where no medical professionals were present to intervene. "As corporate decision makers, we wanted proof that CDT could work" without incurring such risks, Fettig explains. But of course, for all of the WHO's extensive research into the concept, "No one could give any



A lesson on river blindness and the correct use of Mectizan to treat it in an African village.

guarantees. And with growing field support at the NGOs for a more sustainable drug-delivery system, we were under mounting pressure to adopt the strategy," he adds.

Over the following year, three key factors convinced Fettig and Colatrella to reconsider. First, with each passing month, field data confirmed that Mectizan was extremely safe, supporting the premise that nonprofessionals could administer the drug without serious risk (rare instances like Cameroon aside). Indeed, treatment couldn't have been easier: It required only one simple dose in tablet form, once a year, and presented minimal side effects. "To its credit, the WHO recognized Mectizan was uniquely suited to trial the CDT strategy," Colatrella says.

Second, members of the Mectizan Expert Committee – with far more public health experience than Merck – came to strongly support the strategy. This led Merck senior management to defer to the MEC. After all, had Merck disputed their call, it would have undermined the authority the company itself had set up to oversee the program.

Third, WHO experts and others worked hard to find solutions to Merck's biggest objections. National task forces designed a ledger system to help field workers record patient data. NGO partners devised effective means of training illiterate volunteers, such as educational plays and skits from Helen Keller International. The MEC and MDP secretariat patiently designed a form to accurately record adverse reactions.

In the end, "Merck's skepticism was a good voice of caution," says Dr. Björn Thylefors, a 26-year eye-disease veteran at the WHO, and head of the MDP secretariat since 2001. "It pushed everyone to carefully prepare the implementation. We only had one chance to get it right, since the program would have been irreparably damaged if done badly. Merck's firm stand was essential to the



Local health workers distribute Mectizan in a village in Togo.

formula for good partnership."

With safeguards in place to minimize the risks, Merck finally agreed that the program's need for sustainable distribution was more important than the company's own policies and rules. "It was a leap of faith, but we had to accept that our ways of working were preconceived for Western medicine and inappropriate for the reality of getting the drug out to the remotest parts of Africa," Colatrella admits. "The bottom line was, without assured distribution, our very goal of eliminating the disease would have been in jeopardy."

The CDT debate yielded another important lesson: Target communities must not simply buy into program deci-

sions made by donors; they must take ownership of them. Before CDT. Merck – like most donors - took the attitude that outside professional care had to be *provided for* poor communities. But local health workers in some 62,000 communities across Africa and Latin America have since proven they're not only capable of responsibly dispensing Mectizan, they're also better at it. By harnessing local commitment and social networks, they nearly doubled coverage in many countries to as much as 87 percent after adopting CDT,4 while infection rates in some dropped from over 50 percent to near zero.5 The episode not only taught Merck the

value of yielding to the wisdom of trusted partners, but it also left a far richer health delivery system by challenging them to perfect their game.

Protecting the Relationship

If Merck's aversion to risk led it to challenge the WHO's aggressive CDT strategy, the health agency's own cultural quirks have occasionally created tensions in the partnership as well. In particular, the WHO has always been sensitive to associating with the private sector. As steward of the will and politics of its 192-member national health ministries, it has routinely sought to steer clear of any conflict of interest, or even the appearance of influence, par-

ticularly from the forprofit pharmaceutical industry. Although the MDP's success has won over many at the WHO to partnering with private industry, Thylefors says, "There are still voices there today who prefer to control many programs" with outsiders, including the drug donation initiatives.

One particular inci-

dent in the early 1990s, followed by others over the years, was seen by many as a thinly veiled attempt by the WHO to distance itself from Merck by seizing more control over the MDP. Its director of African operations at the time proposed stockpiling Mectizan under his own program's distribution center in Burkina Faso. A strong and vocal personality, the director argued that local storage would make the tablets available faster for emergency response. But when Merck investigated shipment data, it found no significant delays had ever held up urgent requests.

Moreover, shipping the drug en masse, rather than sending individual country orders through the Mectizan Expert Committee's standard application process, would have undermined its authority – Merck's only source of objective guidance – and relegated the company to a backseat player in its own program. Stockpiling also would have gutted many of the tracking and reporting procedures that helped make the program successful, not to mention exposing sup-

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River blindness is a serious problem not only in Africa, but in Latin America as well. Villagers (above) receive Mectizan from health workers such as this woman (right).

plies to diversion and misuse. "Once the drug was on the ground, we'd have lost control over where it went, how it was used,

and by whom," says Colatrella. Not only were there no urgent needs warranting the proposal – there were plenty of reasons to reject it.

However, it was clear to Colatrella that simply saying no to the African director, one of the most powerful figures in public health and a key client and advocate of the program, was not an option. An unceremonious rebuff could easily have destabilized the partnership, and her managers constantly reminded her, she says, that "the company's relationship with the WHO was

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much bigger than MDP." So Merck redoubled efforts to minimize emergency response times – redirecting shipments or borrowing tablets from other countries when necessary to assure that shortages wouldn't develop. MDP then asked the WHO for a plan to protect supplies against diversion and other risks. When it never delivered, the proposal quietly faded away.

As with CDT, Merck in the end put the program needs ahead of political concerns – in this case standing its ground despite the risks. But by taking goodwill actions to mitigate the WHO's perceived problem, it also protected one of the key relationships underlying the partnership. The African director never mentioned the incident again.

The Virtue of Compromise

Knowing how far to bend to a partner's request is a refined skill. But sometimes

knowing the proper response doesn't make the job any easier. Eight years into the Mectizan partnership, a number of NGOs timidly requested that Merck reformulate and repackage the drug. For years field workers had quietly complained that its 6mg tablets, wrapped in foil packs of 100, caused considerable waste when they had to be cut into halfdoses for small children. The discarded foil also posed an untenable environmental problem as volumes grew. Their request for 3mg units in bottles of 30, 100, 200, and 500, plus smaller foil packs, would solve those problems, plus better accommodate communities of different sizes. "We didn't feel we could possibly ask Merck for more on top of what was already a donation," says Catherine Cross, manager of international relations for Sight Savers International. "But the field requests were becoming hard to ignore."

What the NGOs figured was an effort of perhaps several months, however, turned into a nearly three-year ordeal. It required Merck to retest potency stability for the new formulation and persuade its manufacturing division to make the packaging changes - idling expensive foil machinery in the process. It also had to get clearance from regulatory authorities, set up a new bottling line, and produce new labels and physician circulars. "We felt blindsided." recalls Colatrella. "The NGOs made a very good case, and we completely understood once we heard it. But it meant asking other divisions of the company to do things that would impact their own operations and performance goals, and it was hard to justify the costs. Yet if we hadn't cooperated, it would have appeared that we lacked commitment to needs in the field."

After putting off the decision for nearly a year, Merck finally compromised on 3mg tablets in bottles of 500 only. The solution wasn't ideal, but it satisfied the partners. More important, Cross says, "Merck's willingness to listen



Merck's willingness to listen disarmed the partners' early view of the company as an ogre "with horns and a tail."

for having the essential elements of part-

armed many of the partners' early preconceptions of the company as a controlling ogre "with horns and a tail." The virtue of compromise not only solved the problem but also strengthened the partners' trust and won Merck allies for future challenges.

and accommodate" them totally dis-

Constructive Conflict

All partnerships come with conflicts. By most accounts from partners to the Mectizan Donation Program, it has done a far better job than most in turning those potentially destructive differences into constructive collaborations. Indeed, nearly all 34 respondents from 21 international organizations involved in MDP agreed in a recent survey that "conflict is resolved skillfully" in the partnership and that "consensus-building is performed well."6

The experiences above offer some basic guidance in sharing the power in partnerships. The lesson of the community-directed treatment decision suggests deferring to the position in a conflict with the greatest expertise, as long as partners trust each other and risks can be mitigated. On the contrary, the Mectizan stockpiling episode implies it's best to stick to your guns – as did Merck where there's no hard evidence for a proposal or when the risks are greater than the rewards. However, compromise is the obvious path when both sides of an issue have equally strong arguments, as in the tablet reformulation dilemma.

Still, even the best instincts in sharing decision making can't compensate nership success in place. In the case of MDP, top management of all the partners genuinely bought into its goals; the expertise and reputation of members of the Mectizan Expert Committee, as a critical decision-support mechanism, was unassailable; the drug itself turned out to be highly efficacious, safe, and simple to administer; and as respondents to the recent survey acknowledged, all partners shared the program's single and clear vision of eliminating the disease of river blindness.

No pat set of principles, of course, can assure harmonious decision making. But as Colatrella puts it, "There's nothing wrong with insisting on being convinced" of a partner's position. In the long run, taking the time to reach agreement creates stronger relationships based on trust rather than power. \square

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