



Merck and river blindness: A case study in ethical dilemma

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Abstract

Ethics is that greyish zone of human behaviour that lies between the law on the one hand and the common courtesy on the other. It is not mandated by law. You do not have to be ethical. It is a moral obligation.

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Introduction

Merck & Co Inc is one of the world's largest pharmaceutical products and Services Company. Headquartered in Whitehouse station, New Jersey, Merck has over 70,000 employees and sells products and services in approximately 150 countries. Merck had revenues of \$47,715,700,000 in 2001, ranked 24th on the 2002 Fortune 500 list of America's largest companies and 82th on the Fortune 100 list of the Best companies to Work for.

In the late seventies, Merck research scientists discovered a potential cure for a severely debilitating human disease known as river blindness (Onchocerciasis). The disease is caused by a parasite that enters the body through the bite of black flies that breed on the rivers of Africa and Latin America.

Disease spectrum

The parasite causes severe itching, disfiguring skin infections and finally total and permanent blindness. This is known as AMBLYOPIA.

In order to demonstrate that it was safe and effective, the drug needed to undergo expensive clinical trials. Executives were concerned that because they knew that those who would benefit from using it could not afford to pay for it even if it was sold at a cost. Merck research scientists argued that was not too promising from a medical standpoint to abandon. Executives relented and a seven year clinical trial proved the drug both safe as well as efficacious. A single annual dose of Mectizan, the name Merck gave to the drug kills the parasites inside the body as well as the flies that carry the parasites.

Once Mectizan was approved for human use, Merck executives explored third party payment options with the WHO, the US Agency for International Development, and the US Department of State without success. Four United States Senators went so far as to introduce legislation to provide US funding for the worldwide distribution of Mectizan. However, their efforts were unsuccessful. No legislation was passed and no US government funding was made available. Finally Merck executives decided to manufacture and distribute the drug for free.

Since 1987, Merck has manufactured and distributed over 700

million tablets of Mectizan at no charge. The company's decision was grounded in its core values:

1. Our business is preserving and improving human life.
2. We are committed to the highest standards of ethics and integrity.
3. We are dedicated to the highest level of scientific excellence and commit our research to improving human and animal health and the quality of life.
4. We expect profits but only from work that satisfies customer needs and benefits humanity.
5. We recognize that the ability to excel—to most competitively meet society's and customers' needs and aspirations—depends on the integrity, knowledge, imagination, skill, diversity and team work of employees, and we value these qualities most highly.

Merck's dilemma

Because of the devastation the disease causes, Merck decided to produce the drug even though it would not financially profit from doing so. When no government or aid organization stepped forward to buy the drug, Merck pledged to supply the drug free forever. When Merck recognized that no effective mechanism existed to distribute the drug, they went far beyond industry practice and organized a committee to oversee the distribution. Hailed as one of the best managed US companies, Merck believes that such decisions serve its own long run interests.

It took \$200 million in research and 12 years to bring the drug into the market; the decision to pursue research is a complex one. Since resources are finite, dollars and time have to go to projects that hold the most promise, in terms of both making money so that a company can continue to exist and alleviating human suffering. This is an especially delicate issue when it comes to rare diseases, when drug companies' investments could probably never be recouped because the number of people who could buy the drug is so small. The problem with developing a drug to combat river blindness was a flipside of the "orphan" drug dilemma. There were certainly enough people suffering from the disease to justify the research, but since it was a disease afflicting people in some of the poorest

parts of the world, those suffering from the malady could not pay for the medication. In 1978, Merck was testing Ivermectin, a drug for animals, to see if it could effectively kill parasites and worms. During this clinical testing, Merck discovered that the drug killed parasite in horses that was very similar to the worms that caused river blindness in humans. This, therefore, was Merck's dilemma, the Company scientists were encouraging the firm to invest in further research to determine if the drug could be adapted for safe use with humans, but Merck knew it would likely never be a profitable product.

Merck's ethical leadership

Although the decision by Merck to develop this drug for no profits is an old one, it is still a great example of corporate social responsibility and ethical leadership. Merck did this long before the CSR was fashionable.

Reputational utility of Merck

The outcomes for the patients are tremendous and with the growing media attention, Merck was on the verge of catapulting into ethereal fame in an overriding manner. Hence reputational utility far surpassed its personal utility. That was the beauty of selfless philanthropy.

At the same time scientists who are the main human resource of Merck feel good while innovating some new drug molecule. Yet some opportunity cost is also there in the form of drugs not discovered because the scientists were working passionately on this project of Mectizan. Merck took the decision in terms of the question of philanthropy.

Merck's value system

Merck says that it values people over profits. And it has acted like this indeed. Otherwise, there is no use of creating a lot of cynical employees who do not respect their organization's culture.

If you do not mean it, please do not say it! And it goes pretty well for individuals too.

Extra mile mentality of Merck

It is pertinent to note that Merck wanted to pursue research. And it did succeed after many millions of dollars and a decade of pain and privation. But that was worth it. They came up with a wonder drug for river blindness but alas! no one was ready to take this. Not even the government.

The company took an extraordinary decision- to distribute the drug for free to all who needed it forever or till the time river blindness was eradicated! And that was not the end of the show for the company. The biggest challenge was to transport the drug to the remotest possible areas where it was needed the most. They designed their own network and logistic support.

Their philanthropy programme is being emulated by other companies as well. Merck remains one of the most philanthropic companies of US. There was another outcome-when AIDS became a world health problem, the company's experience with the distribution of Mectizan in Africa helped. Although AIDS drugs were more complicated, the company could call on its experience to direct these new efforts.

Merck voluntarily recalled Vioxx a few years ago, after learning that it caused cardiovascular problems in patients who took it for 18 months or more. The recall created uproar and lot of lawsuit. Merck fought them, because of its claim that it had done no wrong. But after winning more cases that it lost, it finally settled the remaining cases and it moved on its trajectory of ethical excellence.

Lessons learnt from Merck

On October 21st 1987, Merck &Co decided to donate newly discovered drug molecule to combat River Blindness. Merck took this decision collaborating with international experts in parasitology and WHO. This decision came twelve years after the discovery of Mectizan and seven years after its clinical trials in Dakar, Senegal.

Merck chairman Raymond V Gilmartin has reaffirmed company's commitment to donate as much Mectizan as necessary for as long as necessary to treat river blindness and to help bring the disease burden down and under control as a public health problem.

Mectizan has taught us about how to mobilize resources in successful public/private partnerships to address significant health problems so as to significantly reduce disease burden over long term.

Effective treatment requires only one annual dose, easily administered with no major side effects. Some of the critical success factors for this achievement are as below:

1. The need to focus scientific and clinical research resources on feasible targets for clearly important health priorities.
2. The importance of partnerships among public and private sector organizations including Non Governmental organizations to control a dreadful disease.
3. The essential role of distribution mechanisms and healthcare infrastructure in ensuring that medicines like Mectizan reach those who need them.

Health impact and capacity building for future programmes

Since the inception of MDP, around sixteen million children around the world have been spared the risk of infection due to spraying programme combined with Mectizan treatment. The World Bank report says that 25 million hectares of arable land have been recovered enough to feed 17 million people. More than 60,000 cases of blindness have been prevented.

The cooperative nature of programme has helped to strengthen the primary care system in many countries where Mectizan has been delivered: in fact the delivery strategy and treatment guidelines have resulted in the delivery of other health services e.g. Vitamin A in the Central African Republic and diagnosis of other conditions such as cataracts.

Donation programmes offer a mechanism for providing access to care and treatment which should be evaluated on a case by case basis.

The Merck Mectizan Donation Programme which has helped millions of people in the developing world is an instructive case, reminding us that even when medicines are free, questions of infrastructure, transparency, distribution, logistics, partnership and sustainability structure the prospects for long term health benefits.

Sustainability

Mectizan also shows that for a donation programme to succeed in a significant way, commitments to ensure sustainability are as critical as promises to supply product. The MDP case also suggests that donation programme should, where possible, be integrated into the country's health system. For example, onchocerciasis control efforts in endemic countries have been supported by training of local (country and community level) health workers in the distribution, administration and monitoring of Mectizan treatment. Similarly, treatment strategies of lymphatic filariasis can benefit from the existing delivery structure for river blindness where the two diseases co-exist. The involvement of the local political leadership and opinion leaders is of paramount significance for long term programme sustainability and overall success in diminishing disease burden in developing countries.

The height of magnanimity-the Merck way to Processual affordances

George W Merck, the company's president from 1925 to 1950, summarized the core values of Merck thus:

"Medicine is for the people. It is not for the profit. The profits follow, and if we have remembered that, they have never failed to appear. The better we have remembered that, the larger they have been."

In total, approximately 30 million people in 32 countries are now treated annually with Mectizan. Merck reports that it has no idea how much the entire programme has cost but estimates that each pill is worth \$ 1.50. The United Nations reports that River Blindness May Soon Be Eradicated.

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