/Nillions for Viagra, Dennies for Diseases of the Door

KEN SILVERSTEIN

Why are pharmaceutical companies willing to invest millions of dollars on drugs that reduce wrinkles or that eliminate our pets' anxiety—and not on drugs that would eradicate life-threatening illness afflicting Third World populations? The answer is related to how global economic stratification affects the availability of health care—those who can pay get what they need and want from the medical institution, and those who can't may not.

Put another way, the lure of high profits encourages pharmaceutical companies to place a priority on developing "lifestyle" drugs like Viagra, Rogaine, or even antidepressants for pets over developing drugs for infectious diseases such as malaria or river blindness. And, as Ken Silverstein argues, until it is profitable for them to do so, pharmaceutical companies are unlikely to change their priorities to research, develop, and introduce affordable drugs to disadvantaged populations.

Imost three times as many people, most of them in tropical countries of the Third World, die of preventable, curable diseases as die of AIDS. Malaria, tuberculosis, acute lower-respiratory infections—in 1998, these claimed 6.1 million lives. People died because the drugs to treat those illnesses are nonexistent or are no longer effective. They died because it doesn't pay to keep them alive.

Only 1 percent of all new medicines brought to market by multinational pharmaceutical companies between 1975 and 1997 were designed specifically to treat tropical diseases plaguing the Third World. In numbers, that means thirteen out of 1,223 medications. Only four of those thirteen resulted from research by the industry that was designed specifically to combat tropical ailments. The others, according to a study by the French group Doctors

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Without Borders, were either updated versions of existing drugs, products of military research, accidental discoveries made during veterinary research or, in one case, a medical breakthrough in China.

Certainly, the majority of the other 1,210 new drugs help relieve suffering and prevent premature death, but some of the hottest preparations, the ones that, as the *New York Times* put it, drug companies "can't seem to roll . . . out fast enough," have absolutely nothing to do with matters of life and death. They are what have come to be called lifestyle drugs—remedies that may one day free the world from the scourge of toenail fungus, obesity, baldness, face wrinkles and impotence. The market for each drug is worth billions of dollars a year and is one of the fastest-growing product lines in the industry.

The drug industry's calculus in apportioning its resources is coldblooded, but there's no disputing that one old, fat, bald, fungus-ridden rich man who can't get it up counts for more than half a billion people who are vulnerable to malaria but too poor to buy the remedies they need.

Western interest in tropical diseases was historically linked to colonization and war, specifically the desire to protect settlers and soldiers. Yellow fever became a target of biomedical research only after it began interfering with European attempts to control parts of Africa. "So obvious was this deterrence... that it was celebrated in song and verse by people from Sudan to Senegal," Laurie Garrett recounts in her extraordinary book *The Coming Plague*. "Well into the 1980s schoolchildren in Ibo areas of Nigeria still sang the praises of mosquitoes and the diseases they gave to French and British colonialists."

US military researchers have discovered virtually all important malaria drugs. Chloroquine was synthesized in 1941 after quinine, until then the primary drug to treat the disease, became scarce following Japan's occupation of Indonesia. The discovery of Mefloquine, the next advance, came about during the Vietnam War, in which malaria was second only to combat wounds in sending US troops to the hospital. With the end of a ground-based US military strategy came the end of innovation in malaria medicine.

The Pharmaceutical Research and Manufacturers of America (PhRMA) claimed in newspaper ads early this year that its goal is to "set every last disease on the path to extinction." Jeff Trewhitt, a PhRMA spokesman, says US drug companies will spend \$24 billion on research this year and that a number of firms are looking for cures for tropical diseases. Some companies also

provide existing drugs free to poor countries, he says. "Our members are involved. There's not an absolute void."

The void is certainly at hand. Neither PhRMA nor individual firms will reveal how much money the companies spend on any given disease—that's proprietary information, they say—but on malaria alone, a recent survey of the twenty-four biggest drug companies found that not a single one maintains an in-house research program, and only two expressed even minimal interest in primary research on the disease. "The pipeline of available drugs is almost empty," says Dyann Wirth of the Harvard School of Public Health, who conducted the study. "It takes five to ten years to develop a new drug, so we could soon face [a strain of] malaria resistant to every drug in the world." A 1996 study presented in *Cahiers Santé*, a French scientific journal, found that of forty-one important medicines used to treat major tropical diseases, none were discovered in the nineties and all but six were discovered before 1985.

Contributing to this trend is the wave of mergers that has swept the industry over the past decade. Merck alone now controls almost 10 percent of the world market. "The bigger they grow, the more they decide that their research should be focused on the most profitable diseases and conditions," one industry watcher says. "The only thing the companies think about on a daily basis is the price of their stocks; and announcing that you've discovered a drug [for a tropical disease] won't do much for your share price."

That comment came from a public health advocate, but it's essentially seconded by industry. "A corporation with stockholders can't stoke up a laboratory that will focus on Third World diseases, because it will go broke," says Roy Vagelos, the former head of Merck. "That's a social problem, and industry shouldn't be expected to solve it."

Drug companies, however, are hardly struggling to beat back the wolves of bankruptcy. The pharmaceutical sector racks up the largest legal profits of any industry, and it is expected to grow by an average of 16 to 18 percent over the next four years, about three times more than the average for the Fortune 500. Profits are especially high in the United States, which alone among First World nations does not control drug prices. As a result, prices here are about twice as high as they are in the European Union and nearly four times higher than in Japan.

"It's obvious that some of the industry's surplus profits could be going into research for tropical diseases," says a retired drug company executive, who wishes to remain anonymous. "Instead, it's going to stockholders." Also to promotion: In 1998, the industry unbuckled \$10.8 billion on advertising. And to politics: In 1997, American drug companies spent \$74.8 million to lobby the federal government, more than any other industry; last year they spent nearly \$12 million on campaign contributions.

Just forty-five years ago, the discovery of new drugs and pesticides led the World Health Organization (WHO) to predict that malaria would soon be eradicated. By 1959, Garrett writes in *The Coming Plague*, the Harvard School of Public Health was so certain that the disease was passé that its curriculum didn't offer a single course on the subject.

Resistance to existing medicines—along with cutbacks in healthcare budgets, civil war and the breakdown of the state—has led to a revival of malaria in Africa, Latin America, Southeast Asia and, most recently, Armenia and Tajikistan. The WHO describes the disease as a leading cause of global suffering and says that by "undermining the health and capacity to work of hundreds of millions of people, it is closely linked to poverty and contributes significantly to stunting social and economic development."

Total global expenditures for malaria research in 1993, including government programs, came to \$84 million. That's paltry when you consider that one B-2 bomber costs \$2 billion, the equivalent of what, at current levels, will be spent on all malaria research over twenty years. In that period, some 40 million Africans alone will die from the disease. In the United States, the Pentagon budgets \$9 million per year for malaria programs, about one-fifth the amount it set aside this year to supply the troops with Viagra. For the drug companies, the meager purchasing power of malaria's victims leaves the disease off the radar screen. As Neil Sweig, an industry analyst at Southeast Research Partners, puts it wearily, "It's not worth the effort or the while of the large pharmaceutical companies to get involved in enormously expensive research to conquer the Anopheles mosquito."

The same companies that are indifferent to malaria are enormously troubled by the plight of dysfunctional First World pets. John Keeling, a spokesman for the Washington, DC–based Animal Health Institute, says the "companion animal" drug market is exploding, with US sales for 1998 estimated at about \$1 billion. On January 5, the FDA approved the use of Clomicalm, produced by Novartis, to treat dogs that suffer from separation anxiety (warning signs: barking or whining, "excessive greeting" and chewing on furniture). "At Last, Hope for Millions of Suffering Canines Worldwide," reads the company's press release announcing the drug's rollout. "I can't emphasize enough how dogs are suffering and that their behavior is not tolerable to owners," says Guy Tebbitt, vice president for research and development for Novartis Animal Health.

Also on January 5 the FDA gave the thumbs up to Pfizer's Anipryl, the first drug approved for doggie Alzheimer's. Pfizer sells a canine pain reliever and arthritis treatment as well, and late last year it announced an R&D program for medications that help pets with anxiety and dementia.

Another big player in the companion-animal field is Heska, a biotechnology firm based in Colorado that strives to increase the "quality of life" for cats and dogs. Its products include medicines for allergies and anxiety, as well as an antibiotic that fights periodontal disease. The company's Web site features a "spokesdog" named Perio Pooch and, like old "shock" movies from high school driver's-ed classes, a photograph of a diseased doggie mouth to demonstrate what can happen if teeth and gums are not treated carefully. No one wants pets to be in pain, and Heska also makes drugs for animal cancer, but it is a measure of priorities that US companies and their subsidiaries spend almost nothing on tropical diseases while, according to an industry source, they spend about half a billion dollars for R&D on animal health.

Although "companion animal" treatments are an extreme case—that halfbillion-dollar figure covers "food animals" as well, and most veterinary drugs emerge from research on human medications—consider a few examples from the brave new world of human lifestyle drugs. Here, the pharmaceutical companies are scrambling to eradicate:

Impotence. Pfizer invested vast sums to find a cure for what Bob Dole and other industry spokesman delicately refer to as "erectile dysfunction." The company hit the jackpot with Viagra, which racked up more than \$1 billion in sales in its first year on the market. Two other companies, Schering-Plough and Abbott Laboratories, are already rushing out competing drugs.

Baldness. The top two drugs in the field, Merck's Propecia and Pharmacia & Upjohn's Rogaine (the latter sold over the counter), had combined sales of about \$180 million in 1998. "Some lifestyle drugs are used for relatively serious problems, but even in the best cases we're talking about very different products from penicillin," says the retired drug company executive. "In cases like baldness therapy, we're not even talking about healthcare."

Toenail fungus. With the slogan "Let your feet get naked!" as its battle cry, pharmaceutical giant Novartis recently unveiled a lavish advertising campaign for Lamisil, a drug that promises relief for sufferers of this unsightly malady. It's a hot one, the war against fungus, pitting Lamisil against Janssen

Pharmaceutical's Sporanox and Pfizer's Diflucan for shares in a market estimated to be worth hundreds of millions of dollars a year.

Face wrinkles. Allergan earned \$90 million in 1997 from sales of its "miracle" drug Botox. Injected between the eyebrows at a cost of about \$1,000 for three annual treatments, Botox makes crow's feet and wrinkles disappear. "Every 7½ seconds someone is turning 50," a wrinkle expert told the *Dallas Morning News* in an article about Botox last year. "You're looking at this vast population that doesn't want frown lines."

Meanwhile, acute lower respiratory infections go untreated, claiming about 3.5 million victims per year, overwhelmingly children in poor nations. Such infections are third on the chart of the biggest killers in the world; the number of lives they take is almost half the total reaped by the number-one killer, heart disease, which usually strikes the elderly. "The development of new antibiotics," wrote drug company researcher A.J. Slater in a 1989 paper published in the Royal Society of Tropical Medicine and Hygiene's *Transactions*, "is very costly and their provision to Third World countries alone can never be financially rewarding."

In some cases, older medications thought to be unnecessary in the First World and commercially unviable in the Third have simply been pulled from the market. This created a crisis recently when TB re-emerged with a vengeance in US inner cities, since not a single company was still manufacturing Streptomycin after mid-1991. The FDA set up a task force to deal with the situation, but it was two years before it prodded Pfizer back into the field.

In 1990 Marion Merrell Dow (which was bought by German giant Hoechst in 1995) announced that it would manufacture Ornidyl, the first new medicine in forty years that was effective in treating African sleeping sickness. Despite the benign sounding name, the disease leads to coma and death, and kills about 40,000 people a year. Unlike earlier remedies for sleeping sickness, Ornidyl had few side effects. In field trials, it saved the lives of more than 600 patients, most of whom were near death. Yet Ornidyl was pulled from production; apparently company bean-counters determined that saving lives offered no return.

Because AIDS also plagues the First World, it is the one disease ravaging Third World countries that is the object of substantial drug company research. In many African countries, AIDS has wiped out a half-century of gains in child survival rates. In Botswana—a country that is not at war and has a relatively stable society—life expectancy rates fell by twenty years over a period of just five. In South Africa, the Health Ministry recently issued a report saying that 1,500 of the country's people are infected with HIV every day and predicting that the annual deathrate will climb to 500,000 within the next decade.

Yet available treatments and research initiatives offer little hope for poor people. A year's supply of the highly recommended multi-drug cocktail of three AIDS medicines costs about \$15,000 a year. That's exorbitant in any part of the world, but prohibitive in countries like Uganda, where per capita income stands at \$330. Moreover, different viral "families" of AIDS, with distinct immunological properties, appear in different parts of the world. About 85 percent of people with HIV live in the Third World, but industry research to develop an AIDS vaccine focuses only on the First World. "Without research dedicated to the specific viral strains that are prevalent in developing countries, vaccines for those countries will be very slow in coming," says Dr. Amir Attaran, an international expert who directs the Washington-based Malaria Project.

All the blame for the neglect of tropical diseases can't be laid at the feet of industry. Many Third World governments invest little in healthcare, and First World countries have slashed both foreign aid and domestic research programs. Meanwhile, the US government aggressively champions the interests of the drug industry abroad, a stance that often undermines healthcare needs in developing countries.

In one case where a drug company put Third World health before profit—Merck's manufacture of Ivermectin—governmental inertia nearly scuttled the good deed. It was the early eighties, and a Pakistani researcher at Merck discovered that the drug, until then used only in veterinary medicine, performed miracles in combating river blindness disease. With one dose per year of Ivermectin, people were fully protected from river blindness, which is carried by flies and, at the time, threatened hundreds of millions of people in West Africa.

Merck soon found that it would be impossible to market Ivermectin profitably, so in an unprecedented action the company decided to provide it free of charge to the WHO. (Vagelos, then chairman of Merck, said the company was worried about taking the step, "as we feared it would discourage companies from doing research relevant to the Third World, since they might be expected to follow suit.") Even then, the program nearly failed. The WHO claimed it didn't have the money needed to cover distribution costs, and Vagelos was unable to win financial support from the Reagan Administration. A decade after Ivermectin's discovery, only 3 million of 120 million people at risk of river blindness had received the drug. During the past few years, the WHO, the World Bank and private philanthropists have finally put up the money for the program, and it now appears that river blindness will become the second disease, after smallpox, to be eradicated.

Given the industry's profitability, it's clear that the companies could do far more. It's equally clear that they won't unless they are forced to. The success of ACT UP* in pushing drug companies to respond to the AIDS crisis in America is emblematic of how crucial but also how difficult it is to get the industry to budge. In late 1997, a coalition of public health organizations approached a group of major drug companies, including Glaxo-Wellcome and Roche, and asked them to fund a project that would dedicate itself to developing new treatments for major tropical diseases. Although the companies would have been required to put up no more than \$2 million a year, they walked away from the table. Since there's no organized pressure—either from the grassroots or from governments—they haven't come back. "There [were] a number of problems at the business level," Harvey Bale, director of the Geneva-based International Federation of Pharmaceutical Manufacturers' Association, told *Science* magazine. "The cost of the project is high for some companies."

While the industry's political clout currently insures against any radical government action, even minor reforms could go a long way. The retired drug company executive points to public hospitals, which historically were guaranteed relatively high profit margins but were obligated to provide free care to the poor in return. There's also the example of phone companies, which charge businesses higher rates in order to subsidize universal service. "Society has tolerated high profit levels up until now, but society has the right to expect something back," he says. "Right now, it's not getting it."

The US government already lavishly subsidizes industry research and allows companies to market discoveries made by the National Institute of Health and other federal agencies. "All the government needs to do is start attaching some strings," says the Malaria Project's Attaran. "If a company wants to market another billion-dollar blockbuster, fine, but in exchange it will have to push through a new malaria drug. It will cost them some money, but it's not going to bankrupt them."

^{*}Eds. Note: AIDS Coalition to Unleash Power

Another type of "string" would be a "reasonable pricing" provision for drugs developed at federal laboratories. By way of explanation, Attaran recounted that the vaccine for hepatitis A was largely developed by researchers at the Walter Reed Army Institute. At the end of the day, the government gave the marketing rights to SmithKline Beecham and Merck. The current market for the vaccine, which sells for about \$60 per person, is \$300 million a year. The only thing Walter Reed's researchers got in exchange for their efforts was a plaque that hangs in their offices. "I'll say one thing for the companies," says Attaran. "They didn't skimp on the plaque; it's a nice one. But either the companies should have paid for part of the government's research, or they should have been required to sell the vaccine at a much lower price."

At the beginning of this year, Doctors Without Borders unveiled a campaign calling for increased access to drugs needed in Third World countries. The group is exploring ideas ranging from tax breaks for smaller firms engaged in research in the field, to creative use of international trade agreements, to increased donations of drugs from the multinational companies. Dr. Bernard Pécoul, an organizer of the campaign, says that different approaches are required for different diseases. In the case of those plaguing only the Southern Hemisphere—sleeping sickness, for example—market mechanisms won't work because there simply is no market to speak of. Hence, he suggests that if multinational firms are not willing to manufacture a given drug, they transfer the relevant technology to a Third World producer that is.

Drugs already exist for diseases that ravage the North as well as the South—AIDS and TB, for example—but they are often too expensive for people in the Third World. For twenty-five years, the WHO has used funding from member governments to purchase and distribute vaccines to poor countries; Pécoul proposes a similar model for drugs for tropical diseases. Another solution he points to: In the event of a major health emergency, state or private producers in the South would be allowed to produce generic versions of needed medications in exchange for a small royalty paid to the multinational license holder. "If we can't change the markets, we have to humanize them," Pécoul says. "Drugs save lives. They can't be treated as normal products."

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Questions

- 1. Why have drug companies focused almost exclusively on lifestyle drugs? What are some potential negative outcomes of this on the health of people throughout the world?
- **2.** According to Silverstein, is it appropriate to put the blame solely on drug companies for their neglect of vaccines that would help people in Third World nations? Why, or why not?
- **3.** Pretend that you have ten minutes to talk to the president of a major pharmaceutical company. What would you say to him or her about developing treatments for tropical diseases that afflict people in Third World countries?
- 4. Visit the Doctors Without Borders website (www.doctorswithoutborders. org) and the World Health Organization website (www.who.int/homepage). What can one learn from these websites about world health problems and priorities? Is what you learned consistent with the claims made by Silverstein in this article? Explain.