

7. The Last Mile Problem

Getting drugs to patients and ensuring their effective use represents a major challenge, especially in poor countries. High prices can make a drug unaffordable to all but the wealthiest patients. Defective transport and storage systems can make a drug unavailable to many population groups. Lack of trained and motivated medical practitioners can lead to poor diagnosis and dispensing practices. Poverty and lack of understanding can lead to weak adherence by patients to treatment regimes. The HIF will directly address the problem of high prices and give HIF registrants strong incentives to support initiatives to reduce non-price barriers to access and rational use.

WHAT IS THE LAST MILE PROBLEM?

The last mile problem refers to the challenge of ensuring that available medicines of good quality are (1) accessible to and (2) correctly used by the people who need them. A global system for pharmaceuticals such as the HIF needs to address this point carefully, since a large proportion of the global population lives in areas in which the last mile problem is acute.

Accessibility

As highlighted throughout this book, one main barrier to access to available drugs is price. When manufacturers' prices are lower, then the prices consumers are charged through both public and private distribution systems will also be lower. Affordable manufacturers' prices are therefore crucial to improved access.

But manufacturers' prices are not the sole determinant of the cost to the consumer. Import duties, port clearance charges, inspection fees, pharmacy board fees, central and regional government taxes, storage and transportation costs, and wholesale and retail mark-ups add substantially to the manufacturers' price.¹ These supplementary costs are not always passed on to the consumer in their entirety, since the state or the nonprofit sector may provide subsidies to consumers. But in this case the financial burdens placed on the state or the nonprofit sector are increased by high prices. Even where supplementary costs are only par-

tially passed on to consumers, they can significantly affect the affordability of essential medicines.

Price, while crucial, is not the only determinant of access. In many low-income countries, weak health infrastructure significantly limits the extent to which essential drugs are accessible. For example, Ministries of Health are often reluctant to distribute drugs to hospitals and health clinics if they believe these facilities lack the trained and motivated medical staff or the physical assets needed to ensure that the drugs are properly stored, prescribed and dispensed.² Alternatively, a Ministry of Health's administrative systems may be such that it is not able to manage the efficient distribution of the drugs that are available to it, resulting in shortages, particularly in less accessible parts of the country. Weaknesses in transportation systems and drug management practices can also result in spoilage, thereby compromising the quality of available drugs.³ On the demand side, weak infrastructure often imposes significant costs and time burdens on poor people in need of health treatment. For example, patients may have long distances to travel, and in many countries, "informal payments" or bribes are required to obtain access to subsidized medicines (Lewis, 2007).

Rational Use⁴

The second main element of the last mile problem is the failure to use correctly the drugs to which patients do have access. The WHO estimates that worldwide

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50 percent of all medicines are prescribed, dispensed, or sold incorrectly, and that about half of all patients do not take medicines as directed (WHO 2004b, 75). This incorrect use exacts a huge toll in increased morbidity and mortality, in addition to the toll exacted by lack of access. Estimates suggest that between 60 and 90 percent of household health expenditure in developing countries is on medicines (DFID 2006, 1). Poor prescribing and dispensing practices, and weak adherence by patients to treatment requirements, means that much of this spending brings little in the way of health benefits. It can actually be harmful, increasing the likelihood that certain diseases will develop resistance to the drugs that are used to treat them.⁵ These problems occur not only in developing, but also developed countries.

If you don't have compliance, you might as well not have the medicine. There also has to be follow-up and testing.

Bill Clinton

Common types of incorrect medicine use include (WHO 2004b, 76):

- use of too many types of medicines per patient (polypharmacy);
- prescription of antimicrobials in inadequate dosage or for inadequate periods or the prescription of antibiotics for non-bacterial infections (the WHO estimates that around two-thirds of all antibiotics worldwide are sold without prescription);
- use of injections where oral formulations would be better, increasing the transmission of hepatitis, HIV/AIDS and other blood-borne diseases;
- failure to prescribe in accordance with clinical guidelines (survey data show that between 1990 and 2004 only around 40 percent of primary care level patients in Africa, Asia, and Latin America were treated in accordance with clinical guidelines for a number of common conditions, with no improvement over this period; WHO 2006c, 2); and
- inappropriate self-medication, often of prescription-only drugs.

A key cause of incorrect use is the lack of suitably qualified medical personnel available to developing country health systems. Recent figures show that the number of health workers per 1,000 people was only 2.3 in Africa and 4.3 in South & East Asia, compared to 18.9 and 24.8 in Europe and the Americas respectively.⁶ Moreover, many developing-country health workers are poorly trained and paid and are not given adequate administrative support. This in turn contributes to low morale and a high incidence of absenteeism. This problem is especially acute in rural and remote areas. Health facilities that are understaffed or staffed by inadequately trained or motivated workers are very poorly placed to meet the requirements of rational drug use (Das, Hammer, and Leonard 2008). The WHO estimates that 57 countries suffer critical shortfalls of doctors, nurses, and midwives that prevent these countries from meeting even the most basic standards of health care (WHO 2006d, 5, 11–12).

This human-resource crisis is complicated by the fact that in many low-income countries staff salaries take up an inordinately large share of the health budget, leaving insufficient funds for non-staff requirements such as vaccines, essential drugs, diagnostic tools and infrastructure maintenance. Public sector health payrolls are often poorly administered, and phenomena such as so-called ghost workers (people who are on payrolls but do not provide the relevant services) result in significant inefficiencies. Resource-constrained countries are confronted with the need to reduce the share of the wage bill in their health budgets while increasing the number and quality of health professionals, particularly in poorer areas. In many cases, greater efficiency in the use of existing resources, while necessary, will not be sufficient to remedy these problems entirely. There is no escaping the need for significantly larger amounts of resources to be made available to developing country health sectors.⁷

While public sector and not-for-profit private providers are key parts of the health sector in most low-income countries, the for-profit private sector—particularly in the form of private drug outlets—is often the first point of call for large parts of the populations of these countries when they fall sick. In Cambodia, for example, it is estimated that more than 70

percent of the population first approach private drug sellers when they fall sick, and that 75 percent of legal antimalarials are sold through the private sector. In Senegal, four private wholesalers linked to pharmacies and chemists represent nearly 65 percent of all sales of antimalarials (Institute of Medicine 2004, 40–41).⁸ Worldwide, an increasing share of health care is being delivered through the private sector (WHO 2006c, 4).

Especially in low-income countries, governments often regulate private-sector drug outlets poorly. Even where suitable regulations and licensing procedures exist, the supervisory and enforcement support needed to ensure compliance is often lacking. Coupled with poor training of staff in private drug outlets, these regulatory, supervisory and enforcement shortcomings result in poor diagnosis and dispensing practices, and subsequently in the sale of unnecessary or contra-indicated drugs or incomplete courses of medication. This wastes resources, compromises successful treatment, and can lead to adverse patient reactions and the development of drug-resistant disease forms. The incentives that private sellers have to maximize sales regardless of clinical requirements add to the likelihood of incorrect use. These incentives are present not only in the private sector, but apply where the prescribing and dispensing functions are combined, as is sometimes the case in some public health facilities in low-income countries. This point notwithstanding, survey data available to the WHO show that, in developing and transition countries, the use of medicines is significantly worse in the private than in the public sector (WHO 2006c, 4).⁹

Even where drugs are correctly prescribed, they are often sold in inappropriate packaging, with inadequate instructions for patient use, or both. This creates serious problems when patients are illiterate or ill-informed about the implications of not taking medication as directed. This is particularly problematic with respect to medicines whose partial completion is often sufficient to relieve symptoms. The result is a serious problem with patient adherence to the requirements of their drug treatment. Drug prices are also a factor in lack of patient adherence to treatment regimens. Poor patients may purchase

insufficient amounts of the medicine, in an attempt to economize.

A 2006 WHO report suggests that, unless effective action is taken, the problem of incorrect drug use is likely to get worse. This is so for two reasons. First, an increasing share of health care worldwide is being provided through the private sector. In developing countries and countries in transition to a market economy, provision through the private sector is likely to result in a higher incidence of incorrect drug use than provision through the public sector, which is important given the prominence of private drug sellers as a first point of call. Second, many large-scale initiatives to treat diseases of major public health importance, such as malaria, HIV/AIDS, and tuberculosis, concentrate primarily on access and give insufficient attention to the problem of irrational use (WHO 2006c, 4).

Irrational use also occurs in developed countries. As Avorn (2004) notes, there is a paucity of reliable clinical trials comparing the risks and benefits of different medicines, and at the same time, pharmaceutical companies' marketing muscle sometimes leads to poor prescribing choices by clinicians.

Pharmaceutical Companies, the Current Patent System, and the Last Mile Problem

Under present arrangements, pharmaceutical companies have little incentive to do anything about the last mile problem, particularly in poor countries where this problem is most acute. Typically drug manufacturers sell their products to public health authorities or private wholesalers well removed from consumers of the product, and do so at a price designed to maximize profits.¹⁰ Nonprice factors associated with the accessibility of their product and issues relating to its correct prescription and use are matters that manufacturers have little incentive to address, for two interrelated reasons. First, these problems are complex and difficult to address in many developing countries. And, second, the financial gains pharmaceutical companies might reap from helping to resolve such problems—higher sales volumes flowing from wider accessibility and better outcomes—are, under

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current remuneration arrangements, uncertain and likely to be small. (In fact, correct and effective use of a medicine may *reduce* demand for it).

It might be argued that pharmaceutical companies should not be given a role in tackling the last mile problem because they are ill-equipped to deal with it, especially with respect to issues such as systemic problems in the health systems of low-income countries. That pharmaceutical companies are poorly equipped to deal with such issues is true but unsurprising, given the lack of incentives that they currently have to address them. The important question is whether such companies could help solve the last mile problem if they were provided with a very different set of incentives.

PHARMACEUTICAL COMPANIES, THE HEALTH IMPACT FUND, AND THE LAST MILE PROBLEM

Rewarding pharmaceutical companies on the basis of their product's health impact changes their relationship to the last mile problem in a fundamental way. Far from having no interest in this problem, Health Impact Fund registrants would have a strong incentive to address it, since their profits are based on their product's health impact. How will companies respond to the last mile problem with respect to the drugs they have registered with the HIF?

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Lack of Access: Price and Nonprice Factors

Consider first lack of access due to unaffordability. As detailed elsewhere in this book, HIF registrants will be required to sell their product worldwide within a price window ranging between the average and marginal cost of production and distribution as determined by the HIF. Furthermore, registrants will have strong incentives to try to reduce wholesale and retail

mark-ups on their products, and to use their lobbying power with politicians to ensure that taxes and other government charges are kept to a minimum. It is therefore reasonable to expect that the retail prices of HIF-rewarded medicines will be within the reach of a very large proportion of those who need them.

The incentives of suppliers of HIF-registered medicines are quite different from those of suppliers of patented medicines outside the HIF. HIF-registered drugs sell at very low prices and are more likely to have many highly price-sensitive customers. A small addition to the retail price can deter a large number of patients at a significant cost to the registrant in terms of reduced payments from the HIF. Thus, retail mark-ups and taxes, which both increase the price to the patient, may substantially reduce the registrant's profits. As a result, HIF registrants will be strongly motivated to lobby for reduced taxes and also to monitor and try to restrict retail mark-ups. These incentives are much weaker for suppliers of patented medicines not registered with the HIF. Such medicines sell at much higher prices, where variations in mark-ups and taxes typically have smaller effects on the number of patients buying the product. And their suppliers will therefore not be as interested in controlling mark-ups and taxes.

What about lack of access caused by nonprice factors? Take the case where a country's health ministry is unwilling to purchase a particular drug, or willing to purchase it only in relatively small amounts, because it considers that the necessary medical and logistical support to administer the drug effectively does not exist in parts of the health system, or because the ministry's drug distribution system is not up to the task of distributing the drug effectively. How would the HIF registrant respond? At present, developing country governments, supported by aid donors, are directing large amounts of time and money to strengthening public health systems, including procurement and distribution systems. Much of this work is being done through so-called Sector Wide Approaches (SWAs) and similar sector-focused programs, in which donors work with governments to develop a comprehensive health-sector budget, providing a framework within which government and donor funds are prioritized, disbursed, and ac-

counted for. If systemic shortcomings in the health sector were adversely affecting the widespread accessibility of its HIF-registered drug, a pharmaceutical company might well be prepared to provide financial and other support to a SWAp designed to address these problems, though the company would understandably be focused on issues relating to the distribution of its own product.

It should be emphasized that the kind of support here envisaged would in no way represent the outsourcing of responsibility for a country's health system to pharmaceutical companies. Clearly, governments should take primary responsibility for public health systems. But just as bilateral and multilateral aid donors can participate in SWAps without absolving home governments of their responsibilities, private companies could play a constructive supporting role as well. It might be objected that pharmaceutical companies with substantial resources at their disposal and with big financial rewards at stake might skew the implementation of a SWAp in their own favor, potentially undermining the process of priority setting which the SWAp is designed to facilitate. Such dangers would doubtless exist, but the composition of a SWAp, which normally includes a number of major donors as well as the home government, would act as a strong countervailing force.

The involvement in a SWAp of a commercial company with a specific and relatively narrow area of interest might also bring significant advantages. SWAps and similar initiatives are sometimes criticized on the grounds that, insofar as they involve cooperation between a several agencies directed at the achievement of broadly-specified goals, they lack the individualized accountability needed for success. It is a short step, the argument goes, from everyone being responsible for everything to no one being responsible for anything at all (Birdsall 2007, 2; Easterly 2006, 14–15). A pharmaceutical company continually questioning how the work being undertaken through the SWAp is overcoming obstacles to the competent use of its drug—obstacles that are likely to be endemic and therefore relevant to essential medicines generally—could play a constructive role in keeping SWAp members focused on the need to undertake rigorous priority-setting for health-sector

expenditure and to support this with practical, solution-oriented programs. Insofar as the HIF, by tying reward to health impact, aligns the financial interests of HIF-rewarded companies and the health interests of relevant population groups, such companies could strengthen the accountability of the health system to patients by forcefully representing their interests within SWAps and similar programs.

While SWAps are designed to incorporate all major players in the health sector, they typically are more representative of the public than the private sector. They rarely include private for-profit drug retailers, for example, even though these outlets often play a major role in the distribution and sale of vital drugs in low-income countries. Manufacturers of HIF-rewarded drugs would therefore have strong incentives to ensure that private distribution systems were as efficient as possible in getting their drugs to private outlets.

In addition, the incentives that companies would have to ensure good handling, diagnostic, dispensing, and labeling practices in relation to their drugs would in turn lead them to support improved public regulatory and supervisory systems, because the alternative of developing and running alternative systems themselves, or contracting them out to private sector agencies, would not be cost-effective. In other words, HIF registrants would be motivated to support the development of an effective public regulatory system.

The following section discusses in greater detail the incentives that drug manufacturers would have to address rational use issues.

HIF-rewarded Companies and Rational Use

Rewarding pharmaceutical companies on the basis of the health impact of their products clearly gives these companies a pressing interest in how their drugs are actually used. In order to promote a drug's health impact, a company will want all those who need the drug to have timely access to it in the right amounts, will want the quality of the drug to be good, and will want the drug to be used properly by patients. HIF

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registrants would have strong incentives to work toward achieving these conditions.

Rewarding pharmaceutical companies on the basis of health impact gives these companies a pressing interest in how their drugs are actually used.

There are a variety of measures that are being or could be taken through the public sector to encourage rational use of essential drugs. These include:¹¹

- the establishment of a national body to develop an essential medicines use policy;
- the development of a national essential medicines list;
- the preparation of clinical guidelines for treatment of specific diseases;
- the preparation of standard operating procedures to govern pharmaceutical management tasks relating to specific drug treatments;
- the establishment of drug and therapeutics committees in hospitals and health clinics;
- continuing in-service medical education;
- strengthening regulation, supervision, audit and feedback mechanisms, including pharmacovigilance systems;
- improving public education about medicines and their use; and
- providing sufficient funds to facilitate the availability of medicines and suitably qualified and motivated staff.

While several countries have implemented or are implementing some of these policies, data from the period between 1999 and 2003 shows that a significant number of countries fail to make use of many of the options available to them. Of member states reporting to the WHO:

less than 60% had monitored the use of medicines in the previous two years; about 50% had undertaken a public-education program on use of medicines in the previous two years; about 40%

supported independent, continuing medical education for prescribers and had established a medicines information centre; 30% to 40% had drug and therapeutic committees in most hospitals and regions; in about 60% clinical guidelines had been updated in the previous five years; just over 70% had a national essential medicines list but only 30% used this list for insurance reimbursement; and only 60% to 70% trained their prescribers in the essential medicines concept, pharmacotherapy, rational prescribing and the application of clinical guidelines. (WHO 2006c, 4)

While these measures are of broad scope, and have impacts beyond the distribution and use of any particular drug, a HIF registrant might support one or more of them directly or use its influence to advocate for their introduction or expansion by relevant governments. We have already suggested that a strengthened regulatory and supervisory system is something that would interest an HIF registrant, and a pharmaceutical company may well be able to mobilize the resources needed to make a significant difference to the reach and performance of these systems. Registrants might also be willing and able to provide financial resources—which in other circumstances might be directed to marketing—to improve the pay and conditions of health workers in those areas of the system that suffer from acute human resource shortages, to improve pre-service or in-service training of front-line health care workers, or both, to the extent that such expenses supported the increase in the use of their products leading to higher payments from the HIF.¹² Registrants might find it attractive to provide funding for consumer education campaigns.

It is worth considering that pharmaceutical manufacturers provide services to encourage rational use in developed countries, because the high prices they charge make it worthwhile for them to do so. They have large numbers of sales representatives whose job it is to provide clinicians with relevant informa-

tion on their products. They support pharmacies in providing supplementary information to patients, and they engage in very expensive patient education campaigns. To be sure, much of the current marketing to doctors and patients is designed not so much to inform as to persuade (this is especially true when competing firms offer similar products in a given therapeutic class). However, some current marketing is informative and valuable. Because the HIF is designed to provide large rewards only to first-in-class medicines, with small rewards for follow-on products, the extent of competitive marketing is likely to be small, but firms will still have incentives to engage in informative promotional activities.

Promotional activities by pharmaceutical firms to doctors and patients have been widely criticized. Firms whose only reward is a high price, regardless of the therapeutic outcome, have an incentive to encourage as much use as possible of their product, and this had led to promotional spending that has not been useful and may even have been harmful to patients. Whether a drug is actually indicated for a patient does not affect the profit earned by a monopolist. It should be recognized that the incentives for HIF registrants will be somewhat different from those of nonregistrants in two significant ways.

First, the HIF only offers high rewards per unit for products that have a high impact per unit. Thus, the motivation to increase sales will be strongest for those products which are really therapeutically important, not those with the highest price. The incentive to sell products that are less therapeutically effective than older alternatives will be very low, since the HIF payments for such products will also be very low.

Second, the HIF will assess health impact, including how the product is used in practice. If sampling of prescribing practice—whether through private drug retailers or government clinics—shows that the drug is being sold inappropriately, the HIF will take that into account in determining the health impact of the medicine, and the assessed health impact will fall, rather than rise, because of such sales. To be sure, the HIF will not be able to measure health impact perfectly, and there will evidently be challenges as firms attempt to expand sales volumes inappropriately. But overall it is important to recognize that

some of the less attractive outcomes of pharmaceutical promotion will be avoided for HIF-registered drugs because the reward is based on health impact, not simply on price times volume. These benefits of better-aligned incentives with respect to pharmaceutical promotion apply equally to developing and developed countries.

There is a range of issues relating to improved drug use where additional research is needed (see ICIUM 2004). HIF registrants can be expected to have a strong interest in supporting efforts aimed at: identifying key factors that prevent the acquisition of knowledge about appropriate use of medicines leading to changed behavior on the part health care workers and patients; determining how information on poor-quality drugs can best be communicated to the general public; identifying which strategies are most effective in encouraging health care providers in both the public and private sectors to adhere to standard treatment guidelines; developing simple tests that can be used by community health workers, dispensers or drug sellers to detect counterfeit drugs; and identifying how best to conduct improved drug use information, education and communication campaigns for consumers.¹³

A number of initiatives have already been undertaken that seek to improve the way in which private drug retailers in low income countries do business. HIF registrants could well improve compliance with the correct use of their drugs by helping to scale-up such initiatives. The fact that these initiatives exist and are having a positive impact means that HIF registrants would not have to start from scratch. Replication (with due attention to the specifics of local conditions), scaling-up, and promoting sustainability would be the main challenges they would face. These are undoubtedly significant challenges, but developing new initiatives from scratch would be more difficult still.

One example of a private-sector focused program is the accredited drug dispensing outlet (ADDO) program in Tanzania (Mbwasii et al 2005). The goal of this program is to improve access to essential drugs and other pharmaceutical services in rural and peri-urban areas where there are few if any registered pharmacies. Nonpharmacy drug shops are the

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most numerous outlets for essential drugs in Tanzania, but they often fail to meet minimum standards. A program of accreditation by the Tanzanian Food and Drug Agency was introduced to encourage these retailers to improve standards concerning products, premises and staffing. Key program elements included: (1) training courses for dispensers and owners; (2) incentives for owners, including legal approval to sell a limited range of prescription drugs, a marketing campaign financed by the program, access to microfinance and links to health financing schemes; and (3) a regulatory system using local government officials trained and deputized as officials of the drug regulatory authority to ensure compliance with regulatory requirements. An evaluation of the program found that it had significantly improved access to essential drugs and encouraged better use of these drugs by consumers. It is noteworthy that this program, while targeting private drug sellers, is strongly linked to the public sector through the regulatory system.

Instead of accreditation, Ghana has trialed a franchise model to improve the performance of licensed chemical sellers (LCS), the first-line providers of medicines in 60 percent of medicine sales (Mensah 2005). Poor dispensing practices of LCSs were common due to a combination of inadequate technical knowledge and the distorting effect of the profit motive. With technical support from the US nonprofit health consultancy Management Sciences for Health, the Ghana Social Marketing Foundation established a franchisor to build the capacity of existing LCSs to enhance access to quality essential medicines. Franchisees operate under the name of CAREshops, and receive training and supervision to produce a uniformly high quality of service. Advocates claim that the CAREshop franchise has improved both the accessibility of essential drugs and the quality of pharmaceutical care and services that franchisees provide their customers.

Similar initiatives have been undertaken in Kenya (Ombogo 2005). Child and Family Wellness Shops (CFWS) operate under a tightly controlled license and focus on a short list of infectious diseases referred to as “treatable killers,” such as malaria, respiratory infections, diarrhoea, TB, and worms. They also treat opportunistic infections associated with AIDS.

CFWS outlets may only stock and prescribe medicines purchased from the franchisor, which includes in its formulary only those treatments that have been approved by the Kenyan Ministry of Health. There is an approved price list to which CFWSs must adhere. CFWSs are increasing their focus on prevention through the aggressive promotion of bed nets, vaccination, and condoms.

It is possible to make significant gains in access and correct usage of vital medicines by supporting small enterprises that are already in the business of selling drugs.

Initiatives such as these suggest that it is possible to make significant gains in access and correct usage of vital medicines in low income countries by supporting small enterprises that are already in the business of selling drugs. The resources that pharmaceutical companies have at their disposal could have a major impact on the reach of these organizations and on the quality and amount of training and other support provided to their owners and staff, at least in relation to HIF-registered medicines. The involvement of pharmaceutical companies could also help to address two of the key problems with initiatives of this kind, namely how to sustain them over time and how to scale them up effectively. HIF registrants with an ongoing interest in the health impact of their products would have strong incentives to ensure that improvements in dispensing and related practices did not disappear as initial enthusiasm for them wanes.

Skeptics might argue that pharmaceutical companies would use their substantial resources to encourage private outlets to maximize the sale of their drugs, even when sales were harmful to patients. But, so long as reward is determined by health impact, such conduct would be counter-productive. Provided the HIF is able to measure health impact effectively, drug companies would not be rewarded for sales of their product to those who derive no benefit from it. They would therefore have no incentive to pressure retailers to maximize sales of their product. But they would have incentives to ensure that retailers make sound judgments about where their products were

likely to be beneficial, as well as to dispense their products and explain use requirements to customers in a way that increases the likelihood that they will be used correctly. They would also have incentives to find ways of encouraging consumers to use their products as directed, and to support the development of systems to monitor use.

These initiatives could be further strengthened, for example by introducing treatment registers to record basic patient information (age and gender), diagnoses made and drugs and dosages given. It has been shown that, with proper incentives, private retailers can be relied upon to acquire this information. Relatively simple computer-based analysis of this information can identify problems such as use of third- rather than first-line treatments of malaria, poor handling of diarrhoea through high usage of antibiotics or low usage of oral rehydration salts (Chalker 2005). Again, while pharmaceutical companies seeking HIF rewards would be focused on monitoring the use of their particular drugs (where the use of their drugs would be counter-productive, their concern would be that these drugs not be used), they may well find that the best means to do this is to support the establishment of systems that are able to monitor drug use.

CONCLUSION

Neither the current patent system nor other methods of incentivizing the development of new drugs, such as prizes and limited Advance Market Commitments, will provide pharmaceutical companies with adequate incentives to ensure that the drugs they produce are (1) accessible to all those who stand to benefit from them, and (2) used by consumers to good effect (defined not merely in terms of effect on the patient but also on the broader human population). These factors of accessibility and rational use constitute the last mile problem, which is a severe impediment to reducing the burden of disease, particularly (but by no means exclusively) in low-income countries. While significant efforts are underway to tackle last mile issues in both the public and private sectors of developing countries, there is little evidence of

major successes, although a number of smaller-scale initiatives have shown promise.

By tying reward to health impact, the Health Impact Fund gives participating pharmaceutical companies strong incentives to address last mile issues. HIF registrants will be required to sell their products at a price determined by the HIF, and they will have incentives to use their financial and lobbying power to keep taxes and other charges and mark-ups that increase prices throughout the distribution chain to a minimum.

Ensuring that available drugs are used correctly is a more complex problem, since it involves difficult systemic challenges. Properly trained and motivated front-line health workers must be in place in sufficient numbers to be reachable by patients. These workers must be supported by sound management and administrative systems and be subject to effective regulatory and supervisory mechanisms. While HIF registrants will not be able to fix all of these systems, they will have incentives to address weaknesses particularly relating to their registered drugs, and it is likely that some of the resulting administrative improvements will apply to other drugs as well.

HIF registrants will be incentivized to maximize the health impact of their drugs and will find it profitable to engage in activities that increase correct uses, and reduce incorrect uses, of their products. HIF-rewarded companies can thus be expected to bring their considerable energies and resources to bear on some of the most difficult problems besetting the health systems of developing countries. This injection of energy from the private sector toward solving these problems may be just what is needed to enhance the efforts already underway.

In developed countries, where the last mile problems are less severe, HIF registrants will be motivated to increase the awareness of their products among physicians and patients to ensure appropriate prescribing and use.

NOTES

1. HAI (2004, 35–6) and HAI (2005, 26) indicate that mark-ups in the order of 100 percent, and sometimes substantially higher, are not uncommon. Detailed survey results on the components of retail prices of medicines in a number of developing countries are available at <http://www.haiweb.org/medicineprices/surveys.php>.
2. In 2006, the WHO drew attention to a global shortfall of 4.3 million health workers, with the worst shortages in the poorest countries. The Global Health Worker Alliance (GHWA) was launched at that time to tackle this issue. A GHWA taskforce has recently estimated that an additional \$2.6 billion a year is needed in Africa alone to train an additional 1.5 million health workers over a ten-year period. Documents detailing the scale of the health worker problem and proposed solutions are available at <http://www.ghwa.org/>.
3. UN Millennium Project (2005, 5–6) identifies inadequate national commitment to health care and inadequate human resources for health as two of the four primary reasons for lack of access to existing medicines in developing countries (the other two reasons it gives are inadequate financial resources from the international community and poorly coordinated international aid).
4. The earliest definition of rational use, formulated by the 1985 Conference of Experts on the Rational Use of Drugs held in Nairobi, included low cost to the consumer as a defining feature. Our discussion of the last mile problem includes cost primarily as a determinant of accessibility, although we acknowledge that cost can affect rational use by reducing the likelihood of poor patients completing full courses of medication.
5. The WHO identifies inappropriate prescribing and use as the primary cause of the growing resistance to antimicrobial medicines, which is a major challenge to public health around the world. This is exemplified by chloroquine resistance, which is now established in 81 of the 92 countries where malaria is endemic, necessitating the use of higher-cost second- and third-line treatments (WHO 2004b, 75, 87–8). Das, Hammer, and Leonard (2008) argue that, while access to health care in many low-income countries has improved, the quality of medical treatment, a function of both the competence of medical practitioners and the effort they expend on diagnosis, is exceedingly low, particularly for poor patients.
6. GHWA (2008b, 6) identifies a “massive shortfall in the production of health workers” as the key to the problem, compounded by other factors such as the impact of HIV/AIDS on the health workforce, international migration, poor wages and working conditions and political instability. “If all the doctors trained in Ethiopia in the last 30 years were still working in the country, there would be about one doctor per 10,000 population. In the United Kingdom, there is one doctor for about every 450 people.” Eyal and Hurst (2008) contend that the “brain drain” of doctors and other health workers from poor to rich countries is a major contributing factor and suggest ways of reducing it. Clemens and Pettersson (2008) argue that data on African doctors do not support this thesis.
7. The Global Health Workforce Alliance (GHWA 2008a, 5; 2008b, 3) calls on the World Bank, regional development banks, the IMF, and domestic finance ministries to show greater flexibility and initiative in finding ways to enable developing countries to increase health expenditure significantly without violating necessary macroeconomic disciplines. It also calls on relevant Ministries of Health to create the conditions for increased health spending by developing evidence-based and carefully costed health workforce plans. CGD (2007) and IMF (2007) discuss in detail the impact of IMF programs on health spending in poor countries.

- McKinley (2005) argues that larger levels of foreign aid need not, as is often feared, lead to domestic inflation or higher real exchange rates. Aid can be used effectively to increase domestic public investment and real resource transfers from abroad, although the increasing practice of using aid to build foreign currency reserves reduces the latter benefit. Ooms and Hammonds (2008) argue for more foreign aid to finance the “core content of the right to health.” They claim that providing this aid within a framework of rights and duties under international law—for which, they argue, there is substantial warrant—rather than as discretionary spending by well-off nations would mitigate the risk of it contributing to a new form of colonialism.
8. The situation differs in Zambia, where it is estimated that up to 70% of people seeking malaria treatment first go to the public sector healthcare providers (Institute of Medicine 2004, 36). This is indicative of the variability across developing countries in the mix of public and private healthcare service providers and drug retailers.
 9. The private and public sectors referred to here include not just medical practitioners but all those involved in dispensing medicines.
 10. Particularly for drugs treating high profile diseases such as HIV/AIDS, negative publicity generated by drug companies charging high prices in low-income countries can change this equation and give the companies an incentive to concern themselves with the impact of price on accessibility. Publicity about nonprice issues affecting access and irrational use is much less likely to change the incentives facing drug companies.
 11. These points are based largely on a list of core policies to promote rational drug use proposed by WHO (2004b, 88). For a discussion of standard operating procedures for ART, see Thuo and Wachira (2005). Pharmacovigilance is the detection, assessment and prevention of adverse drug reactions (see WHO 2004b, 89).
 12. Data contained in Das, Hammer, and Leonard (2008, 25–6) suggest that increasing the training that doctors receive does not necessarily lead to significant improvement in the quality of the care they provide. However, they refer (2008, 27) to the finding of Barber and Gertler (2007) that empowering women to demand better health care from their doctors can lead to a significant increase in effort and therefore in the quality of care.
 13. It is possible that the marketing skills of a pharmaceutical company, usually employed solely to promote its product, could have a major impact if put to the task of providing nonpromotional information about the importance of adhering to treatment guidelines.

