

5 Corruption in the pharmaceutical sector



A young medicine vendor from a so-called ‘ground pharmacy’ offers black market drugs to clients in a street in Libreville, Gabon, 29 August 2003. (Desirey Minkoh/AFP/Getty Images)

The pharmaceutical sector faces many challenges that are not addressed in this volume, including patterns of research and patent systems that do not seem to be meeting all public health needs, particularly in eradicating devastating tropical diseases. Corruption adds a potentially deadly element when patients cannot afford extortion payments for the drugs they need, or they are sold counterfeit medicines.

In this chapter, Jillian Clare Cohen argues that heavy government regulation in the pharmaceutical chain – while essential to safeguard the population against sub-standard drugs and unfairly priced goods – makes this sector particularly prone to corruption. In recent years, much discussion has centred on the close ties between physicians and the pharmaceutical, biotechnology and medical device industries – which, when unchecked, can lead to corrupt practices. Jerome Kassirer highlights the conflicts of interest that may arise when doctors feel indebted to drugs representatives, or when scientists are on the payroll of companies whose drugs they are hired to evaluate.

Efforts are being made to improve the situation. Representatives of the pharmaceutical industry and of physicians describe the voluntary codes set up to reduce potential conflicts of interest. Civil society and concerted efforts by courageous regulators can help curb corruption in the pharmaceutical industries – both legal and counterfeit – as the experiences from India, Thailand and Nigeria show.

Pharmaceuticals and corruption: a risk assessment

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Pharmaceuticals are indispensable to health systems. They can complement other types of health care services to reduce morbidity and mortality rates and enhance quality of life for many patients. Because pharmaceuticals have curative and therapeutic qualities, they cannot be regarded simply as ordinary commodities. Access to medicines is often about life and death. This is illustrated most dramatically in sub-Saharan Africa where almost 30 million people are infected with HIV/AIDS and the majority lack access to anti-retroviral therapies.

In a broader context, access to essential medicines has become a central topic at the international policy-making level where it is increasingly viewed as a fundamental right, with human rights law placing obligations on states to ensure access.² This includes duties on governments to ensure that pharmaceutical systems are institutionally sound and transparent and that there are appropriate mechanisms to reduce the likelihood of corruption, which can deny medicines to those in greatest need.

A major conundrum in international drug policy is the fact that, despite international aid and a plethora of programmes devoted to improving pharmaceutical access, there is a morally worrying ‘drug gap’. The WHO continues to estimate that one-third of the global population lacks regular access to essential medicines.³ A number of determinants contribute to this drug gap, including market failures, government inefficiencies, poverty and corruption.

For example, OECD countries generally devote US \$239 in annual spending on drugs per head, compared to less than US \$20 in developing countries and US \$6 in sub-Saharan Africa.⁴ Pharmaceuticals are the largest public health expenditure after personnel costs in most low-income states, and often the largest household health expenditure of all.⁵ One of the most important differences between industrialised and developing countries is that in the latter pharmaceutical expenditures are anywhere from 50–90 per cent of total individual out-of-pocket expenditures.⁶ In such countries, illness is a major cause of household poverty. Corruption exacerbates this drug gap: when officials accept kickbacks for purchasing medicines, pharmaceutical expenditure is reduced and fewer of the right drugs get to the right people when they need them.

Many determinants are responsible for disparities in access to medicines, but little research has been devoted to just how corruption impacts on drug availability. Fortunately, this area is gaining interest and a number of studies have begun to address this issue.⁷ The pharmaceutical system is susceptible to corruption for a variety of

reasons. One of the most significant is the degree of government involvement in its regulation: studies from other sectors have found that the incidence of corruption is noticeably higher when the state retains a major involvement in the economy and its bureaucracy is pervasive.⁸ Without robust institutional checks, government regulators can make discretionary decisions rather than decisions based on uniform criteria. In addition, wide information asymmetries exist between patient and physician (see Chapter 1). Patients trust their doctor to prescribe the most effective drug for their condition, but the doctor's decision as to which drugs to prescribe may be influenced by pressure from pharmaceutical companies. There are often poorly documented processes in the quality control system that can lead to the manufacture of sub-standard drugs. This occurred in Brazil when a well known pharmaceutical manufacturer was found to

Box 5.1 US pharmaceutical company fined for payments to charity headed by Polish health official¹

In June 2004, the pharmaceutical company Schering-Plough agreed with the Securities and Exchange Commission (SEC) to pay a fine of US \$500,000 for violations of the books and records and internal controls provisions of the Foreign Corrupt Practices Act (FCPA).

According to the SEC's findings, the Polish subsidiary of the New Jersey-based company, Schering-Plough Poland (S-P Poland), made payments amounting to approximately US \$76,000 between February 1999 and March 2002 to a foundation for the restoration of Silesian castles, the Chudow Castle Foundation. The foundation was run by the director of the Silesian Health Fund,² one of 16 regional state-run Polish health authorities which provides funding for the purchase of pharmaceutical products by hospitals and other medical centres.

The SEC alleged that these payments were made to induce the director to buy S-P Poland's products for his health fund. It alleged that, in order to conceal the nature of the payments, the S-P Poland manager deliberately set them at or below his approval limit and provided false medical justifications for them in documents submitted to the parent company's finance department.

Although the SEC conceded that the foundation was a bona fide charity and that the donations were made without the knowledge or approval of the US parent company, it charged that the parent's internal controls were inadequate to detect and prevent the financial irregularities committed by its Polish subsidiary. Although the SEC did not go so far as to state that the payments were bribes, it did find that the manager viewed them as necessary, in order to influence the action of the government official.

This case highlights that companies should not only have clear policies covering charitable donations, their permitted amount and approval procedures, but should conduct due diligence across their organisation. The case also underscores the aggressive stance of the SEC in holding suppliers accountable for the actions of their subsidiaries.

Transparency International

Notes

1. This text is based on Wilmer Cutler Pickering Hale and Dorr LLP, *Foreign Corrupt Practices Update*, 30 June 2004, www.wilmerhale.com
2. *Rzeczpospolita* (Poland), 11 June 2004.

have manufactured sub-standard contraceptives.⁹ Finally, the pharmaceutical market is so lucrative that it attracts entrepreneurs who are both honest and, more perplexingly, dishonest. All of these factors expose the pharmaceutical system to the possibility of corruption.

This essay focuses primarily on the role of government, since state intervention, particularly through regulation, is vital to the pharmaceutical sector. There are two central reasons why governments regulate the pharmaceutical market: first, to ensure that health policy and other governmental interventions, such as quality assurance of drugs and fair drug pricing, enhance the health of the population; and second, to ensure that industrial policies strengthen economic competitiveness of the pharmaceutical sector and improve innovation and efficiency. These two objectives can sometimes lie at cross-purposes. If regulators are subject to pressure from commercial groups, health objectives can be compromised.

Key decision points

The pharmaceutical system is technically complex and replete with a number of ‘core decision points’.¹⁰ Each decision point needs to function optimally so that the system as a whole offers good-quality, cost-effective, safe and efficacious medicines. Figure 5.1 shows key processes in the selection and delivery of pharmaceutical products and illustrates the potential for corruption that exists at any one of its decision points (post-manufacturing) unless there are solid institutional checks and balances in place. For example, procurement is particularly susceptible to corruption unless there are open bidding processes, good technical specifications, and consistent and transparent

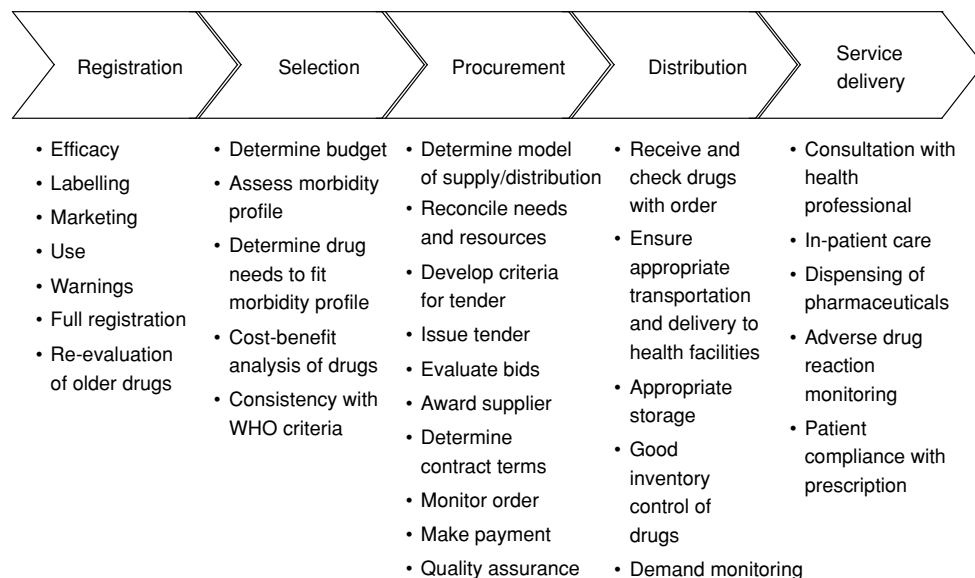


Figure 5.1: Key processes in the selection and delivery of pharmaceutical products

procedures for redress if needed. While the design of good institutions with oversight is crucial for the reduction of corruption, there is also a significant role for civil society. If community groups closely monitor pharmaceutical companies and regulators, there is a greater likelihood that corruption can be caught or even prevented out of fear of disclosure (see Boxes 5.2 and 5.3).

Registration

The first decision point in the pharmaceutical chain is registration, which was originally introduced to protect patients from catastrophes like the thalidomide cases in the 1950s, and evaluates a drug's efficacy against a specific disease and its possible side-effects. The process regulates the labelling, marketing, usage, warning and prescription requirements for a drug. Registration procedures need to be transparent and applied uniformly, and should leave no room for individual discretion. The registration process should guarantee drug safety and efficacy, but these guarantees risk being eroded by the pharmaceutical industry lobby. A high-profile inquiry into risks posed by the pain pills Vioxx, Bextra and Celebrex in 2004 highlighted already existing concerns regarding the US Food and Drug Administration's (FDA's) capacity as an unbiased regulatory body (see 'The corrupting influence of money in medicine', page 88). Critics point to the fact that between 1997 and 2004, 12 major prescription drugs, with a market value of billions of dollars, were recalled by the FDA or withdrawn by companies. According to Sheldon Krinsky of Tufts University, the rise in for-profit clinical trials, fast-tracking of drug approvals, government-industry partnerships, direct consumer advertising and industry-funded salaries for FDA regulators has contributed to degrading the institutional integrity of the FDA, suggests 'regulatory capture' of the FDA by the pharmaceutical industry to some degree and also illuminates the need for the institution to demonstrate more independence from its stakeholders.¹¹ Meanwhile, in low-income countries, regulatory agencies are often weak or non-existent due to lack of resources.

Selection

Drug selection processes should ensure that the most cost-effective and appropriate drugs for a population's health needs are chosen fairly. The WHO Model List of Essential Medicines is a helpful framework in this regard for most developing countries because it establishes priority areas of treatment and covers the most common diseases.¹² But this can open a new avenue for corruption since manufacturers have a strong interest in getting their products selected as essential medicines. If institutions are weak and individuals have incentives to engage in corrupt activities, the selection process can be replete with kickbacks and payoffs so that drugs on a national drug list may not necessarily reflect appropriate and cost-effective drugs (see 'Corruption in hospital administration', Chapter 3, page 51).

However, there are methods that can reduce the likelihood of corruption in the selection process and promote sound, evidence-based decision-making. The pharmaco-economic techniques used by Australia and the Canadian province of British Columbia

have proved helpful in ensuring that objective decision-making takes place if the correct models and techniques are employed. Pharmaco-economics, or outcomes research, uses cost-benefit, cost-effectiveness and cost-utility analyses to compare the economics of different pharmaceutical products, or to compare drug therapies with other medical treatments.

Drug selection committees must be composed of impartial persons with the appropriate technical skills. Their members must be obliged to declare any conflicts of interest, and meetings should be regular and well publicised so that the public can observe proceedings. Minutes of meetings should be posted on the Internet and decisions clearly justified. In the event of a potential breach, an appeal process must be in place that ensures due process.

Final selection criteria should be based on discussions and acceptance by key prescribers, and the WHO criteria for selection should be used as a basis for decision-making. These are: relevance to the pattern of prevalent diseases; proven efficacy and safety; evidence of performance in a variety of settings; adequate quality, including bio-availability and stability; favourable cost-benefit ratio in terms of total treatment cost; and preferences for drugs that are well known to have good pharmaco-kinetic properties. Lastly, all drugs listed on a government essential medicines list should be identified by generic name.

Procurement

Procurement is the principal interface between the public system and drug suppliers, and its goal is to acquire the right quantity of drugs in the most cost-effective manner. This involves inventory management, aggregate purchasing, public bidding contests, technical analysis of offers, proper allocation of resources, payments, receipts of drugs purchased and quality control checks.

Procurement is often poorly documented and processed, which makes it an easy target for corruption. Drug procurement is even more vulnerable to corruption than contracting in other sectors. This is due to several factors, including: the method to determine the volume of drugs needed is often subjective; there are difficulties in monitoring quality standards in drug provision; suppliers use different prices for the same pharmaceutical products and can artificially inflate prices; some marketing practices by pharmaceutical companies induce demand for products; and an additional challenge is posed by emergency situations, which call for speedy and adequate intervention.

The best protection against corruption is open, competitive procurement that prevents personal discretion in the selection of suppliers, and requires clear criteria for the selection and process of winning bids. However, procurement procedures require ongoing monitoring, including reviews from the inspector general's office.¹³

Strong oversight mechanisms can drastically reduce corruption. A World Bank study from 2001 examined the use of an electronic bidding system for pharmaceutical purchases in Chile.¹⁴ Contrasting the innovative Chilean system to other procurement practices, the authors argued that outcomes are greatly improved by the adoption of good incentive structures for public officials and the reduction of informational asymmetries through the posting of drug prices on the Internet.

A comprehensive study of corruption in the pharmaceutical system in Costa Rica found that in many cases competition was reduced, or procedures were followed incorrectly.¹⁵ Some health care professionals and pharmaceutical company executives alleged that participants in public tenders had on occasion colluded to extend the purchasing cycle as long as possible. This was done by submitting frivolous appeals, which were then extensively contested by both sides, or by delaying the delivery of drugs for unfounded reasons. The effect of these long delays was the eventual depletion of the social security system's inventory resulting in direct purchases from private suppliers. These purchases were then made at much higher unit prices than would be obtained through formal bidding processes. Studies from Argentina and Bolivia show that increased transparency and citizen participation in the procurement process can reduce corruption and cut costs considerably (see 'Corruption in hospital administration', page 52).

Distribution

Distribution in the pharmaceutical system ensures drugs are allocated, transported and stored appropriately at all points where they are to be dispensed. This involves central and regional warehouses, pharmacies and service floors. Information must flow easily through every level of the system to control inventory movements and deliveries. In addition, the system requires storage facilities, including refrigeration units, to guarantee the integrity of the drugs and good security to minimise the risk of theft. The electronic monitoring of transport vehicles and careful checking of delivery orders against inventories of products delivered are some of the methods that can reduce this likelihood.

In one Central American country, inventory records showed that stocks of oral antibiotic eye treatment and other products were intentionally oversupplied because government purchasers received commissions for their orders.¹⁶ This demonstrates one way that corruption can drain public expenditure on pharmaceuticals and have the greatest impact on the poor.

Service delivery

Service delivery involves the participation of physicians, pharmacists, nurses and other health care providers who diagnose patients and identify what drugs a patient should consume to treat a particular disease. This is the decision point at which patients should experience the benefits of the entire system. Here physicians prescribe, pharmacists dispense and nurses administer drugs to treat patients. Health providers ideally utilise evidence-based practice to provide effective therapy to their patients.

The interface between the pharmaceutical industry and physicians is an area that is particularly susceptible to corruption, as service delivery can be influenced by the marketing practices of the pharmaceutical industry (see 'The corrupting influence of money in medicine', page 86).

Some physician–industry interaction is necessary to educate doctors about the therapeutic qualities of new drugs. However, there is compelling evidence that suggests that the motivation is often not health education, but profit maximisation. A 2000

study by Wazana found that physician interaction with the pharmaceutical industry was associated with increased requests for additional drugs on hospital formularies and changes in prescribing practice.¹⁷ The influence of industry on physicians is an issue of concern in both developed and developing countries. But it can be particularly dangerous in developing and transition countries where doctors make paltry salaries and may rely heavily on gifts (both monetary and material) from the pharmaceutical industry to supplement their livelihood.

The US authorities have recently demonstrated concerted efforts to address inappropriate marketing practices by some pharmaceutical companies. In 2001, TAP Pharmaceutical Products was required to pay one of the largest fines in the industry's history, with the government demanding US \$875 million for civil liabilities and criminal charges.¹⁸ Other governments are introducing stricter laws and regulations. For example, in April 2005 a report by the UK's House of Commons Health Select Committee on 'The Influence of the Pharmaceutical Industry' recommended greater transparency in drug regulation processes, reduction in the excessive promotion of medicines, tougher restrictions on physicians to avoid inappropriate prescribing and an end to Department of Health relationships with the drugs industry in favour of the Department of Trade and Industry.¹⁹ Following press accounts of the free trips pharmaceutical companies offer medical doctors and the lavish parties thrown for them, the Deputy Mayor of Social Affairs and Public Health of Helsinki, Paula Kokkonen, banned all trips funded by the pharmaceutical industry for the capital's medical doctors.²⁰

In view of the potential for undue influence on prescribing behaviour, global standards have been developed and a number of professional bodies, including pharmaceutical industry associations, have enacted codes of conduct that detail best practice in minimising corruption (see 'Promoting trust and transparency in pharmaceutical companies', page 92, and 'Fighting corruption: the role of the medical profession', page 94). Whether such guidelines have made an impact is questionable. The WHO issued its Ethical Criteria for Medicinal Drug Promotion in 1988, but a 1997 WHO roundtable discussion concluded that inappropriate drug promotion is still a problem in developing and industrialised countries.²¹ Even though the criteria have been disseminated widely, their effective implementation is a major problem, as governments need to revise legislation and regulation, and to promote them forcefully in medical schools and associations.

While self-regulatory codes of conduct may be beneficial, they should not delay meaningful reform in terms of external, enforceable regulations. Current voluntary codes are not audited or enforced with meaningful penalties, or overseen by independent and objective observers.²² More robust policies are needed to address the serious conflicts of interest that arise in the service delivery segment of the pharmaceutical system.

Counterfeit medicines: the bad and the ugly

When institutions are weak and unable to regulate the pharmaceutical sector accurately, they increase the opportunities for corruption, including the manufacture of counterfeit drugs, a problem that precedes the first decision point in the pharmaceutical chain

in Figure 5.1. For example, regulators may receive kickbacks to ignore makers of counterfeit products, or customs agents may be paid to turn a blind eye to their import or export.

In 2001, China had roughly 500 illegal medicine manufacturers and Laos around 2,100 illegal medicine sellers. In Thailand, sub-standard medicines account for 8.5 per cent of those on the market.²³ India plans to introduce the death penalty for the manufacture or sale of counterfeit medicines that cause grievous harm. 'Profiting from spurious drugs that might harm or kill innocent people is equivalent to mass murder', said Health Minister Sushma Swaraj recently.²⁴ Meanwhile, an estimated 192,000 people died last year in China because of fake drugs.²⁵ Regulatory bodies in the South need resources to root out corruption and stem the flow of counterfeit drugs. The success of Nigeria's National Agency for Food and Drug Administration and Control is one example of what can be achieved through strong leadership (see page 96).

Moving forward: how to do better?

Corruption in any one of the critical decision points in the pharmaceutical system can be harmful to a country's ability to improve the health of its population by limiting access to high-quality medicines and reducing the gains associated with their proper usage. While corruption affects the entire population, it is typically the poor who are most susceptible when officials hoard drugs, or waste resources on the wrong kind of medicines. Good governance is therefore a sine qua non for ensuring better access to essential medicines.

Greater transparency in the pharmaceutical system will help to improve drug access. Honest assessment of the institutional robustness at all core decision points in the pharmaceutical system is the first necessity. Governments need to know what areas of the system are less than optimal and vulnerable to corruption. There is a need for more monitoring of how pharmacies, hospitals and health care providers are reimbursed for drugs. Further research is needed to determine what systems offer the best incentives for providers to behave honestly and control fraud. Second, consumer groups and other third parties need to be vigilant about monitoring both the public and private pharmaceutical systems to ensure they are directed towards the public interest.

While international statements and professional guidelines on best practice are well intentioned, they are meaningless unless they are properly enforced. Individual governments must have the courage to enact and, most importantly, to implement policies and processes which encourage ethical behaviour and punish firms and individuals for corrupt actions. If this happens, hopefully we will see a change for the better in terms of ensuring that people in need get the right drugs at the right time.

Notes

1. Jillian Clare Cohen is assistant professor in the Leslie Dan Faculty of Pharmacy at the University of Toronto and Director of the Comparative Program on Health and Society at the University of Toronto's Munk Centre for International Studies.

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4. WHO Medicines Strategy: Framework for Action in Essential Drugs and Medicines Policy 2002–2003. (Geneva: WHO, 2000), www.who.int/medicines/strategy/strategy.pdf
5. Ramesh Govindaraj, Michael Reich and Jillian Clare Cohen, 'World Bank Pharmaceuticals Discussion Paper' (Washington DC: World Bank, 2000).
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7. For example, the World Bank, the WHO and USAID have all commissioned studies in recent years on the issue of corruption in the pharmaceutical system.
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19. The UK parliamentary report is available at www.parliament.the-stationery-office.co.uk/pa/cm200405/cmselect/cmhealth/42/42.pdf
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21. See the Drug Promotion Database website at www.drugpromo.info/about.asp#1
22. The Code of Marketing Practices of Canada's Research-Based Pharmaceutical Companies from January 2005 is a case in point. See www.canadapharma.org/Industry_Publications/Code/code_e05Jan.html (accessed 15 March 2005).
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The corrupting influence of money in medicine

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Pharmaceutical, device and biotechnology companies have created new drugs and devices that have prolonged the lives and improved the health of millions of people. Many interactions between academic scientists and industry have been responsible for such advances, and these collaborative research projects should be encouraged. Yet the

collaborations sometimes go beyond research and merge into marketing by physicians who become paid company consultants or speakers. The financial relationships between the pharmaceutical industry and physicians yield a subtle form of corruption, one that escapes legal supervision and challenges.

My comments apply principally to the United States, but the manifestations are similar in countries all over the world. In recent years, the pharmaceutical, device and biotechnology industries have spent some US \$16 billion annually in the United States on marketing to physicians.² Of this, more than US \$2 billion was spent on meals, meetings and events alone.³ Companies seek to influence doctors with US \$ 1,000–5,000 honoraria (or more) to participate in their speaker's bureaus and hire them as well paid consultants and members of their advisory boards. They also bombard doctors with journal ads, and almost 90,000 friendly drug salesmen.⁴ They pay academic physicians to help them develop educational materials and befriend medical students and doctors with gifts of textbooks, stethoscopes, and free lunches and dinners. Such payments can lead some physicians to act in their own best interests rather than in the interests of their patients. There can be a fine line between legitimate marketing outlays by a pharmaceutical company and an unethical practice. But when compensation to salespeople and medical professionals translates into higher sales revenues, the temptation to cross the line becomes especially great.

The enticements on offer by pharmaceutical companies

The attempt to seduce young people is particularly worrisome. Some years ago, I witnessed a typical drug company-sponsored lunch at an academic medical centre. Two well dressed pharmaceutical representatives had brought food for a regular teaching conference for the house staff. One by one, house officers and medical students arrived to join a buffet line and were greeted warmly by the male 'drug rep' with 'How was your weekend?' or 'How're you doing?' These reps were obviously a familiar presence. The line moved slowly because it took some time to scoop up the food, and the two drug reps used the opportunity to make a sales pitch. One was stationed strategically at the beginning of the line, and the other at the end. The reps were describing two of the company's popular new (and expensive) products, as well as recommendations for dosages.⁵ The seduction moves on to the dinner hour as well. One evening in a pizza parlour, I observed a resident with his team of interns and students enjoying pizza and beer with a drug representative. There were two 'costs' for the free food and drinks. The resident had to listen to the drug rep's sales pitch during the meal, and at the end of the party he was given a pile of reprints to take back to the rest of his team.

These trinkets and meals are simply marketing ploys, intended at minimum to ingratiate the drug rep to the doctor, perhaps to raise awareness of certain products and, at the other extreme, to create a sense of indebtedness. Such indebtedness is problematic, however, because the physician's obligation to the drug salesman or his company often conflicts with his obligation to his patients. The prescribing practices of physicians have been examined in a few studies in relation to some kind of exposure to a drug company promotion.

In one, 40 physicians who requested additions to their hospital's drug formularies were compared to 80 who had not requested any new drugs.⁶ Statistically, doctors who requested the additions were 9 to 21 times more likely to have eaten free meals provided by the companies, to have accepted drug company money to attend or speak at a company-sponsored symposium, or to have received research support from the companies. An independent review (in the same study) indicated that the newly requested drugs had little or no advantage over the drugs already available.

Another study of the prescribing practices of 10 physicians who had attended company-supported symposia in resort locations showed a two- to threefold increase in the physicians' use of the drugs in the months after their trip.⁷ Interestingly, a majority of physicians attending the symposia claimed that they would not be influenced by the enticements; most dismissed the possibility – defying common sense – that all of these efforts by industry could affect them.

Financial conflicts of interest in medical research

Fundamentally, big business and physicians alike are involved in a charade. The drug companies say that marketing helps to educate doctors so they can prescribe drugs more appropriately. At the same time, the companies press their drug salesmen to push the newest products, and they allow their surrogate intermediaries, the medical education companies, to advertise their services as 'persuasive' education. And the physician-recipients of drug company largesse act as if they were immune to its influence.

Physician–industry involvement is widespread. A 1996 survey showed that half of full professors and lesser fractions of more junior faculty who conduct life science research have substantial financial arrangements with industry, and disclosures at medical meetings and in published journal articles confirm the widespread involvement.⁸ During my tenure as editor-in-chief of the *New England Journal of Medicine*, we only allowed physicians to write review articles and editorials if they had no financial conflicts with a company whose products (or their competitors) were featured in the article. Finding authors without such conflicts became progressively more difficult during the 1990s and, by the end of the decade, we often had to reject several prominent potential authors before we found one who had no conflicts. Finally, an industry-connected legal group admitted the extent of involvement. It wrote: 'It is widely acknowledged that most of the top medical authorities in this country, and virtually all of the top speakers on medical topics, are employed in some capacity by one or more of the country's pharmaceutical companies.'⁹

Several specific examples will illustrate the problem: one involving practice guidelines; the second, a human research study; a third involving radiological diagnosis; and the fourth, a decision by the Food and Drug Administration (FDA).

Four case studies from the United States

The National Cholesterol Education Program at the National Institutes of Health regularly updates its practice guidelines when new data become available. The latest,

reported in July 2004, was a combined effort of the American Heart Association, the American College of Cardiology and the National Institutes of Health. These three organisations selected nine individuals to analyse all the clinical trials that had been published since the previous guidelines and come up with new recommendations. The group was impressive. It consisted of a nutritionist, the chief of the molecular disease branch at the National Institutes of Health, a well known pharmacologist, a former president of the American Heart Association and other well regarded cardiologists. Their recommendations included greater lowering of low-density lipoprotein (LDL) with diet, exercise and treatment with statins. Later, it was revealed that seven of the nine participants had financial arrangements as paid speakers or consultants for companies that make statins. They had these arrangements not with just one company, but three to five of them. These connections made it difficult to know whether the relations of these high-level physicians with the statin manufacturers may have influenced their recommendations.¹⁰

In 1999, a 17-year-old boy died at the University of Pennsylvania four days after receiving genes imbedded in a common cold virus. The boy had only a mild deficiency of a particular enzyme, but was participating in the research because he thought the results might help others. Neither he nor his parents had been told that the experiment had previously shown some toxicity; nor were they told that both the principal investigator and the university had financial stakes in a company that might have benefited from the outcome of the work. The principal investigator denied that money had anything to do with his decision or the institution's decision to move ahead with these studies.¹¹

An interesting study was reported in the journal *Academic Radiology* in 2004. It was a re-analysis of 492 chest X-rays read by 30 radiologists employed by law firms who were suing companies for people exposed to agents that damage the lungs. To explain the findings, I will call these 30 the 'hired' hands. The authors of the study had the same chest X-rays re-read by six radiologists who were not paid by lawyers. I will call these radiologists the 'independents'. All 36, the hired hands and the independents, were certified 'B' readers by a federal agency, meaning that they all had undergone the same training to interpret chest X-rays. The results are interesting: the hired hands diagnosed 96–97 per cent of films as abnormal, whereas the independents said only 4–6 per cent were abnormal. The hired hands said none of the films were completely normal, whereas the independents said 38 per cent were normal. One does not need a chi square test to appreciate the gross discrepancy in these interpretations.¹²

In mid-February 2005, an advisory panel of the FDA met to assess whether the risk-benefit profile of various Cox-2 inhibitors made by Merck and Pfizer warranted removing the drugs from the market. This was a highly visible decision because of the increased risk of cardiovascular complications of some of the drugs, especially Vioxx, and because of Merck's decision only weeks before to take Vioxx off the market. The 32-person panel voted 31:1 to keep Celebrex on the market; there seemed to be little controversy about this decision. However, the votes on Bextra and Vioxx were much closer. The panel voted 17:13 to keep Bextra on the market, and 17:15 to allow Vioxx to return to the market. But there was a hitch: it was later learned that 10 of the panel members had financial ties to both companies that made these two drugs, and that

these company-paid physicians had voted 9:1 in favour of keeping both drugs on the market. If none of these conflicted panel members had voted, the recommendation would have been not to allow either on the market. The votes would have been 12:8 opposed for Bextra and 14:8 opposed for Vioxx. Bextra has since been removed from the market, but both Vioxx and Bextra could return if the FDA follows the advisory board's recommendations.¹³ The FDA decision will affect millions of people as well as the enormous profits of two major pharmaceutical companies.¹⁴

Though these examples are worrisome with respect to their effect on patient care, and cannot be condoned from an ethical construct, none constitutes either fraud or overt corruption. None is punishable by legal means and any sanction would have to come from state or professional organisations, but these bodies rarely impose any (see below). Each example strongly suggests a pattern of overt bias, but the problem with each is trying to assess an individual's motivation. One possibility is that none of the tilt towards company products was intentional, yet the close ties between physicians and companies yielded biased recommendations in some subconscious way. It is even possible that the recommendations these physicians made were completely objective, and that anyone else with the same expertise would have come up with exactly the same conclusions. Finally, it is possible that some doctors on industry payrolls are knowingly greedy and that they are intentionally profiting at the expense of the validity of information that doctors use in their daily practices. In the latter case, we must assume that they perceive the consequences of their actions on patient care to be negligible. These examples illustrate the essential problem with financial conflicts of interest: we don't know what to believe.¹⁵

A threat to the public's trust

Extensive analyses of the effects of financial conflicts of interest have documented its corrosive influences on patient care, medical information and the public's trust in the profession.¹⁶ These huge financial subsidies can influence the validity of the information that doctors use every day in their practices. It tends to distract faculty into emphasising profitable research and to neglect their teaching duties. It replaces openness with secrecy, 'privatises' knowledge and replaces part of the social commons by commercialising discovery. It has also created a culture in which the design of studies is sometimes jiggered to create positive results; in which unfavourable results are sometimes buried; in which communication of results is sometimes hindered for commercial reasons; and in which bias in publications and educational materials has sometimes gone unchecked.¹⁷ All of this amounts to a serious threat to public trust in medicine. These financial conflicts can undermine the faith of the public in medical research, threaten government funding, reduce enrolment in clinical trials and damage the trust between patients and their doctors.

In the United States, some progress has been achieved in dealing with financial conflicts. The Association of American Medical Colleges has issued new guidelines for individuals and institutions,¹⁸ while many medical schools are now in the process of revising their conflict-of-interest policies. The National Institutes of Health, in response

to a public outcry about important financial connections of several of its senior scientists, issued strict guidelines in 2005 that effectively limit investigators from having these associations.¹⁹ The United States Congress has also expressed an interest in the concerns raised here.²⁰ The pharmaceutical companies and the American Medical Association have both issued guidelines about physician engagement in company programmes, but neither has precluded marketing of products by physician-consultants or speakers.

Far more work on this is needed. All gifts from the industry should be prohibited, even items that might be considered useful in a doctor's practice or education. Consultations with industry for anything except scientific matters should also be prohibited, while marketing by physicians of drugs or devices in which they have a financial interest should be outlawed. Physician participation in company-sponsored speaker's bureaus should be excluded. Clinical practice guideline committees and FDA advisory panels must contain a minority of individuals with financial conflicts of interest. Positions of journal editors, officers of major professional organisations and leaders of medical centres and academic institutions should be preserved only for individuals without conflicts. Given that complete elimination of all financial conflicts of interest is unlikely, the full disclosure of relevant financial conflicts on an easily searchable website should be introduced.

It is difficult to understand why the standards on conflicts of interest in medicine should be lower than those of other professions, such as the media. Reporters for the most ethical media outlets such as the *New York Times* and CNN are not allowed to accept any gifts, meals, honoraria or paid consulting arrangements.²¹ This is an exceptionally high standard, but one medicine must adopt. The bar must be raised if we are to maintain the public's trust in medicine.

Notes

1. Jerome P. Kassirer is distinguished professor at Tufts University School of Medicine and adjunct professor of medicine and bioethics at Case Western Reserve University. He was editor-in-chief of the *New England Journal of Medicine* from 1991 to 1999.
2. *Boston Globe* (US), 10 March 2004.
3. Jerome P. Kassirer, *On The Take: How Medicine's Complicity With Big Business Can Endanger Your Health* (New York: Oxford University Press, 2004).
4. B. Darves, 'Too Close for Comfort? How Some Physicians are Re-examining their Dealings with Drug Retailers', *ACP Observer*, July/August 2003.
5. *Journal of the American Medical Association* (US), 284(2156–7), 2000.
6. *Journal of the American Medical Association* (US), 271(684–9), 1994.
7. *Chest* (US), 102(270–73), 1992.
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9. D. J. Popeo and R. A. Samp, comments of the Washington Legal Foundation to the Accreditation Council for Continuing Medical Education concerning request for comments on the 14 January 2003 draft: 'Standards to Ensure the Separation of Promotion From Education Within the CME Activities of ACCME Accredited Providers', Washington Legal Foundation, 2003.
10. *Washington Post* (US), 1 August 2004.
11. *Washington Post* (US), 30 December 2001.
12. J. N. Gitlin, L. L. Cook, O. W. Linton and E. Garrett-Mayer, 'Comparison of "B" Readers' Interpretations of Chest Radiographs for Asbestos-related Changes', *Academic Radiology* 11(843–56), 2004.

13. Despite the FDA ruling in February 2005 in favour of allowing Vioxx back on the market, at this writing Merck had decided against its return.
14. *New York Times* (US), 25 February 2005.
15. Kassirer, *On The Take*.
16. *Ibid.*, and Sheldon Krimsky, *Science in the Private Interest: Has the Lure of Profits Corrupted Medical Research?* (Lanham: Rowman and Littlefield, 2003).
17. *Ibid.*
18. Association of American Medical Colleges (AAMC), 'Protecting Subjects, Preserving Trust, Promoting Progress I: Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research', AAMC Task Force on Financial Conflicts of Interest in Clinical Research, December 2001; 'Protecting Subjects, Preserving Trust, Promoting Progress II: Principles and Recommendations for Oversight of an Institution's Financial Interests in Human Subjects Research', AAMC Task Force on Financial Conflicts of Interest in Clinical Research, October 2002.
19. www.nih.gov/about/ethics_COI.htm
20. waysandmeans.house.gov/hearings.asp?formmode=view&id=2933
21. 'Ethical Journalism: Code of Conduct for the News and Editorial Departments', *New York Times* (US), January 2003.

Promoting trust and transparency in pharmaceutical companies: an industry perspective

Harvey Bale¹

The twentieth century saw enormous improvements in overall health care standards in the developed world. Yet in both the developed and developing worlds, patients are still in need and are waiting for treatments, cures and vaccines for AIDS, cancer, diabetes, heart disease, Alzheimer's disease and many hundreds of other debilitating and life-threatening conditions. Even older diseases, once thought conquered or controlled, such as tuberculosis, malaria and polio, are re-emerging as clear and present dangers because of resistance to existing treatments or failings in immunisation programmes. Biological resistance to current treatments for HIV/AIDS infections is on the rise, making it imperative that industry and governments continue to fund heavily research into this as well as other diseases.

According to surveys by member associations of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA), industry currently spends more than US \$50 billion in research and development into finding drugs and vaccines annually worldwide. The industry is subject to a high degree of government regulation at every nearly stage of its activity. The large interface between industry and government throughout the life cycle of medicinal products poses continuous risks of corruption. Before clinical trial tests can begin, government must approve them. Before a drug is approved after such trials, another formal approval is needed in every country where the drug or vaccine is to be used by patients, physicians and nurses. Many countries set prices – another government decision. Before companies invest they need to have their ideas and innovation protected against copiers – another government function. Furthermore, where poor countries are concerned about certain epidemic threats, like

HIV/AIDS or malaria, companies work with governments and NGOs to find ways to get medicines to those who cannot afford them. Governments must be involved, from customs authorities to regulators to health ministry and local officials, to ensure the medicines get to intended patient groups. All of these points of governmental intervention raise the possibility of corrupt practices entering to distort and damage the development and delivery of new drugs and vaccines to patients.

Corruption in the pharmaceutical supply chain can take many forms: products can be diverted or stolen at various points in the distribution system; officials may demand 'fees' for approving products or facilities, for clearing customs procedures, or for setting prices; violations of industry marketing code practices may distort medical professionals' prescribing practices; demands for favours may be placed on suppliers as a condition for prescribing medicines; and counterfeit or other forms of sub-standard medicines may be allowed to circulate. While corruption carries economic costs, corruption adds further costs to the end goal of patient well-being.

Given the impact of corruption, the IFPMA and other industry bodies have taken significant steps to address the dangers of corruption. But the industry and other stakeholders must intensify efforts to prevent and avoid abuses.

The need to minimise the chances of corruption in the distribution chain is well illustrated by the diversion of heavily discounted GlaxoSmithKline (GSK) anti-retroviral (ARV) HIV/AIDS drugs from Africa to Europe unearthed in the summer of 2002. GSK had committed to providing its full range of ARVs at not-for-profit prices to the world's poorest countries. These prices were, on average, 70 per cent less than developed world prices. Registration of special 'access' packs in target countries would have taken between 6 and 18 months. With the HIV/AIDS epidemic spreading quickly, GSK was anxious to respond to the global crisis as quickly as possible. GSK's initial consignments to Africa were therefore dispatched in European packaging. The medicines had originally been sold by GSK at not-for-profit prices to an NGO and the procurement arm of a ministry of health, for distribution to African HIV patients. In the beginning of the sales programme, the company had not received approval for box designs to differentiate the countries to which they were destined – as such approvals take time; and some of the ARVs were diverted by West African public officials, almost undetected, back into the European market, with traders making substantial profits and patients in Africa being denied access to the medicines they desperately needed. Prosecution is under way for those involved in this scheme, which should help send the signal that this behaviour cannot be tolerated. In the meantime, GSK has developed 'access' packages for its main ARVs that are differentiated from developed country packs.

Another area where the industry has been active in recent years is in strengthening its product-promotion practices. The prescribing behaviour of medical professionals, who are frequently paid poorly under national health care systems, may be affected by the compensation offered by suppliers for administering their products or services, rather than by the interests of their patients. Though the direct evidence is thin that prescribing behaviour is directly and significantly affected by trips and gifts from the industry, there are cases that involve travel including coverage for spouses, despite

the fact that the IFPMA Code and various national codes forbid spousal travel to be sponsored by companies to educational symposia. Companies belonging to the IFPMA adhere to a marketing and promotion code that requires that companies refrain from offering inappropriate hospitality or gifts to medical professionals that would tend to 'influence them in the prescription of pharmaceutical products'. The IFPMA Code is supplemented by its national member associations, by individual company ethical marketing codes and by a variety of measures that seek to redress the situation when violations of the codes occur. The code is based on self-regulation, but its application is obligatory. These codes are activated by complaints that are made to IFPMA or its member associations by physicians, other medical professionals or other interested parties, and violations are accompanied by publicity or fines paid in some countries.

Transparency is important in many other areas. Significant new initiatives have been introduced over the past two years regarding the pharmaceutical industry's approach to clinical trials. In a few cases, companies have been accused of disclosing and publishing only favourable clinical results. To increase the transparency of companies' clinical trials undertaken to develop new drugs and vaccines – and recognising that there are important public health benefits associated with making clinical trial information more widely available to health care practitioners, patients and others – easily accessible web-based clinical trial registers have been set up by companies to publicly record relevant details of the trials they are conducting. Beginning in summer 2005, the industry is making public the results of all clinical trials that have taken place and also information on those just being initiated, from the first stage of patient registration and enrolment through to final outcomes. At the same time, to make trial information easily accessible to those seeking information, the IFPMA is establishing a web-based search portal, linking the various clinical trial registries for information on ongoing clinical trials and databases for the summary results of completed clinical trials. This one-stop location will simplify and ease access for patients and medical professionals to the company registries and data.

Health care expenditures, and spending on innovative pharmaceuticals, will inevitably increase throughout the world. Whereas the past 20 years have seen an informatics revolution, the next quarter-century will witness major advances in the biosciences. Public confidence in the pharmaceutical industry is crucial and companies are taking significant steps through their member associations to maintain and improve public trust. To ensure that patients are able to benefit from medical advances, it is also important to ensure that access be addressed, and one way will be to help prevent the selective allocation of health care – by those in the public or private sector – on the basis of bribery and corruption.

Note

1. Harvey Bale is director-general of the International Federation of Pharmaceutical Manufacturers and Associations.

Fighting corruption: the role of the medical profession

*John R. Williams*¹

Physicians are human beings and, like everyone else, are subject to the temptation to put their own interests above those of others. As self-regulating professionals, they have less oversight than many other individuals and consequently more opportunity to conceal unethical behaviour. On the other hand, they belong to a profession that has high ethical standards and that encourages and expects its members to uphold these standards.

Physicians encounter corruption in health care at all levels: in government, hospitals and other health care institutions, and in their own practice. For the most part, they are among the victims of corruption, seeing resources that should go to patient care or professional development siphoned off for other purposes. In some cases, however, they may be beneficiaries of corruption, insofar as they personally receive part or all of the resources that have been designated for other legitimate purposes.

The extensive guidance for physician behaviour provided by their professional associations seldom includes a responsibility for dealing with corrupt practices by non-physicians. It is quite a different matter when it comes to themselves and their colleagues. The World Medical Association (WMA) International Code of Medical Ethics exhorts physicians to 'always maintain the highest standards of professional conduct ...; not permit motives of profit to influence the free and independent exercise of professional judgement on behalf of patients ...; deal honestly with patients and colleagues, and strive to expose those physicians deficient in character or competence, or who engage in fraud or deception'.² These general principles have been elaborated in detail in policy statements from the WMA and its national medical association members.

It should be noted that the word 'corruption' seldom appears in medical association policy statements. These deal with 'unethical' or 'unprofessional' behaviour and practices that cover a wide spectrum from impoliteness to various degrees of conflict of interest to euthanasia. 'Corruption' would be considered an extreme form of conflict of interest whereby physicians receive substantial personal benefit at the expense of others, whether individuals, institutions or society in general. Most professional guidance deals with 'softer' forms of conflict of interest where it is not immediately obvious that wrongdoing is involved.

In what follows, I describe activities designed to prevent or deal with such conflicts of interest between physicians and the pharmaceutical industry.

The conflicts of interest inherent in the relationships of physicians and industry are described elsewhere in this volume (see 'The corrupting influence of money in medicine', page 87). Beginning in the late 1980s, the World Health Organization (WHO), industry groups and national medical associations began to produce guidelines for such relationships. In 1988, the WHO Assembly adopted a resolution endorsing a set of ethical criteria for medicinal drug promotion.³ In 1991 the Canadian Medical Association adopted guidelines for physician-pharmaceutical industry relationships,⁴ followed by many other professional organisations, including the American Medical

Association in 1992,⁵ the Finnish Medical Association in 1993,⁶ the Australian Medical Association in 1994,⁷ the Israeli Medical Association in 2004⁸ and the World Medical Association in 2004.⁹ These guidelines deal with gifts to physicians, continuing medical education/professional development, industry-sponsored research and drug samples. Though their primary concern is to avoid conflicts of interest between physicians and patients, they are equally applicable to conflicts between the interests of physicians and those of society in general, for example regarding cost-effectiveness in prescribing drugs that are paid from public sources.

The principal reason why the WMA took so long to produce its guidelines is the great variation in access of physicians to continuing professional development activities throughout the world. In less developed countries, the pharmaceutical industry is often the only source of funding for physicians to attend conferences, whereas in wealthier countries such a relationship would be considered an unacceptable conflict of interest for physicians.

These guidance documents are directed to individual physicians, organisers of educational events and medical associations. Though they are ethical rather than legal in nature and therefore not generally binding, various mechanisms exist for turning them into enforceable rules, whether for those who offer conflict-of-interest incentives (for example, the pharmaceutical industry) or for those to whom they are offered (physicians and other health professionals). The pharmaceutical industry is increasingly subject to laws and regulations regarding its educational and promotional activities with physicians.¹⁰ In some countries medical conferences are not eligible for continuing professional development credits unless they follow strict rules for industry sponsorship.¹¹ Some physician licensing bodies are beginning to define acceptable limits for industry–physician relationships and warning physicians that overstepping these limits will result in disciplinary action. Progress in this area has been slow for several reasons; for example, the difficulty of monitoring physician relationships with industry and the need to address more serious instances of physician misconduct, such as murder and the sexual abuse of patients. Unless the medical licensing authorities define more precisely the rules for physician behaviour regarding conflicts of interest and can obtain extra resources to enforce them, the individual consciences of physicians will have to be the principal resource for identifying and dealing with conflicts of interest.

Several educational programmes are available to inform physicians how to avoid conflict-of-interest situations with industry. The American Medical Association has developed an on-line resource for self-study by physicians,¹² and a group of health care providers has developed the ‘No Free Lunch’ website¹³ to encourage their colleagues to maintain complete independence from industry in their clinical and educational activities. In the field of medical research, where there have been many reports of unethical conduct in recent years, educational resources for the responsible conduct of research are plentiful and many institutions now require researchers to demonstrate familiarity with the basic principles of responsible conduct of research.

The effectiveness of educational measures in this area is difficult to measure. Enforcement mechanisms may be somewhat more effective but are expensive to

implement. The best hope for improving physician behaviour is a combination of reasonable and well publicised standards; continuing education about the standards and their foundations (beginning in medical school and continuing at all other levels); peer pressure from colleagues and medical associations; stricter government regulation of industry involvement in medical research and practice; and the threat of disciplinary action for egregious breaches of the standards. However, unless all interested parties cooperate to address conflicts of interest in health care, it is unlikely that progress will ever be achieved.

Notes

1. John R. Williams is director of ethics at the World Medical Association. The views expressed in this article are his own, not those of the World Medical Association.
2. www.wma.net/e/policy/c8.htm
3. World Health Organization, *Ethical Criteria for Medicinal Drug Promotion* (Geneva: WHO, 1988).
4. www.cma.ca//multimedia/staticContent/HTML/N0/l2/where_we_stand/physicians_and_the_pharmaceutical_industry.pdf
5. www.ama-assn.org/ama/pub/category/4001.html
6. www.laakariliitto.fi/e/ethics/industry.html
7. www.ama.com.au/web.nsf/doc/WEEN-5GJ7MH
8. www.pharma-israel.org.il/eng/htmls/article.aspx?C1004=578&BSP=4
9. www.wma.net/e/policy/r2.htm
10. See Susan Chimonas and David J. Rothman, 'New Federal Guidelines For Physician-Pharmaceutical Industry Relations: The Politics Of Policy Formation', *Health Affairs* 24(4), 2005 and House of Commons Health Committee, 'The Influence of the Pharmaceutical Industry', 22 March 2005, www.parliament.the-stationery-office.co.uk/pa/cm200405/cmselect/cmhealth/42/42.pdf
11. For example, the Standards for Commercial Support of the US Accreditation Council for Continuing Medical Education, available at www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf
12. www.ama-assn.org/ama/pub/category/8405.html
13. www.nofreelunch.org/

The fight against counterfeit drugs in Nigeria

*Dora Akunyili*¹

The presence of sub-standard and counterfeit drugs on Nigeria's streets escalated after the distribution of pharmaceuticals was denationalised in 1968. The lack of proper regulation and monitoring meant that import licences were readily issued to non-professional companies and drug regulations were flouted with impunity. Companies producing quality drugs found it difficult to compete with those who skimmed on active ingredients, or relabelled expired drugs for resale. The result for the user of the fake pharmaceuticals was often prolonged illness, organ damage or death.

Though counterfeit drugs remain a serious problem in Nigeria, the situation has changed since 2001 thanks to a combination of mass education campaigns targeted at potential users of counterfeit drugs, and a more rigorous testing and enforcement

regime. Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC) has been at the centre of these efforts. A baseline study conducted in April 2001, as the current NAFDAC directors took office, showed that 68 per cent of the drugs available in Nigeria were not registered with NAFDAC, which is taken as an indication of counterfeiting.² A repeat of the study in 2004 revealed an 80 per cent reduction in the level of counterfeit drugs in the country.

The manufacture of counterfeit drugs is a global problem, but opinions as to what constitutes counterfeiting vary from country to country, making it difficult to control. The WHO describes counterfeit medicine as one 'that is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products, and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.'³

In Nigeria NAFDAC has identified each form of counterfeit drug. These include drugs that contain no active ingredient but are made up merely of lactose, chalk or olive oil; herbal preparations that are toxic, ineffective or mixed with orthodox medicine; expired drugs that have been relabelled; drugs that are issued without publishing the full name and address of manufacturer; and drugs that have not been certified and registered by NAFDAC.

Corrupt officials protect counterfeiters

The counterfeiting of medicine is financially lucrative, as several organised crime syndicates have discovered. Moreover, it entails relatively low risks compared to narcotics or gun trafficking. The low risk may be deliberate: according to the WHO, corruption and conflict of interests are the driving forces behind poor regulation which, in turn, encourages drug counterfeiting. Corruption and conflicts of interests result in laws not being enforced and criminals not being arrested, prosecuted and convicted.⁴

An example of how authorities collude with organisations that fake or sell counterfeit drugs is the falsification of shipping manifests. In 2002, a 20-foot container of Napfen (ibuprofen tablets) imported through Apapa Port was falsely declared as containing motorcycle spare parts in order to evade NAFDAC regulations. The consignment was released by custom officials but later intercepted by NAFDAC officials. Similar-sized containers intercepted later that year contained hidden Gentamycin injections and Seven Seas Cod Liver Oil in one case, and Tramal capsules imported from Pakistan in a second. The drugs were discovered by the Port Inspection Directorate, which was established by the present NAFDAC administration.

Early on in the current administration, NAFDAC agents were themselves discovered to have engaged in corrupt practices in a series of high-profile cases. Two NAFDAC officials at Port Harcourt were dismissed and publicly reproached for releasing imported products without inspection in 2002. In Akwa Ibom state, two NAFDAC staff members were caught extorting money from the Nigerian Association of Patent Medicine Dealers and were dismissed in 2003.

Until recently, NAFDAC staff were allowed to collect cartons of expensive products as samples, which they could then sell off. This led to the practice of deliberate oversampling and sparked industry complaints. NAFDAC subsequently adopted clear sampling guidelines and disseminated information about correct sampling sizes to employees and the industry. New guidelines also prohibit NAFDAC staff from accepting free transportation, lunch or gifts from the companies they are inspecting. Instead, inspectors are provided with all the necessary resources to carry out their tasks.

The registration process produces another opportunity for corruption by NAFDAC staff. It is still common for it to take two years or more to register a product, although recent streamlining and automation of the process have shortened the process to two or three months in most cases. The lengthy exceptions are partly due to inefficiency, but corruption also plays a role, with NAFDAC staff dragging their heels and extorting bribes from applicants to speed up the process. Staff guidelines have been disseminated among industry members so that manufacturers might be less vulnerable to extortion. NAFDAC officers face suspension, demotion or dismissal if they are found to be corrupt.

Inadequate legislation contributes to the problem

Nigeria has a multiplicity of drug control laws that have become unwieldy, overlapping and sometimes conflicting. The result is a legal framework that fails to deter counterfeiters or that moves so slowly once allegations of wrongdoing have been identified that the suspect is rarely brought to trial.

Penalties for some offences related to counterfeiting are not commensurate with the severity of the crime. For example, the maximum punishment for contravening the decree on counterfeit or fake drugs and unwholesome processed food is less than N500,000 (US \$3,600), or a prison sentence of between 5 and 15 years. NAFDAC does not believe that this level of punishment deters offenders and is calling for amendments to the law.

Judicial authorities have on occasion failed to act against counterfeiters or importers of fake drugs, even when NAFDAC has provided evidence of wrongdoing. For example, a well known importer of fake drugs, Marcel Nnakwe, was arrested three times in 1997 for importing more than N19 million worth (around US \$137,700), but was protected by a judge who issued an interlocutory injunction restraining NAFDAC from taking any further action without court clearance.

One month after the present NAFDAC administration took office, a team of regulatory consultants and legal experts were invited to review existing obsolete laws and recommended detailed amendments. These have been reviewed and at the time of writing were before the National Assembly.

Discriminatory regulation by exporting countries

In many countries more lenient control of drugs for export has compromised the quality of drugs on the international market. A case that came to light in Nigeria recently involved the importation of poorly packaged, fake paracetamol tablets labelled 'not for use in Southeast Asia'. The poor regulation of exports from manufacturing countries

exposes those countries with non-existent or weak regulations to the dumping of counterfeit pharmaceuticals.

There are 84 pharmaceutical manufacturing companies in Nigeria, which together produce less than 30 per cent of the country's drug requirements: the rest is imported. Most counterfeit drugs are imported from Asia, more than 98 per cent from China and India. Nineteen pharmaceutical companies, mainly Indian and Chinese, were blacklisted and banned from exporting drugs to Nigeria in 2001, and a further 12 were debarred in 2004. NAFDAC recently prohibited the importation of products marked 'for export only'.

Other factors that militate against effective regulation and encourage counterfeiting include: ignorance and poor public awareness of the problem; the chaotic drug distribution system; misleading advertising; the demand for drugs exceeding supply; inadequate funding of regulatory authorities; lack of cooperation between government agencies; false declarations by importers; the sophistication of clandestine drug manufacturing; and the irrational use of drugs, making demand difficult to control.

NAFDAC's role and future

NAFDAC's dual strategy of creating a strong regulatory environment, while encouraging intolerance of counterfeit drugs through public enlightenment campaigns, seems to be working. Jingles, media interviews, public alerts and notices in the national press publicising drugs identified as fakes are helping to lift the shroud of secrecy from the problem.⁵ Efforts have been made to stop fake drug imports at source; surveillance at all ports of entry has been beefed up; many counterfeit drugs already in circulation have been mopped up by the agency; good manufacturing practices of local manufacturers are being monitored; and registration guidelines have been streamlined and are being strictly enforced.

But success comes at a cost. Testament to NAFDAC's achievements over the past few years is the vehemence with which corrupt manufacturers have sought to block our work. During my time as head of NAFDAC, my family and I have been the victims of numerous death threats and in December 2003 we narrowly escaped an assassination attempt.

Efforts to tackle counterfeit medicines must be redoubled. While national measures are working, the international community must realise that poor nations lack the funds, manpower and technology to fully address the problem. NAFDAC strongly advocates for harmonised regulation of pharmaceutical products on the international market and the establishment of an international convention for the control of counterfeit drugs similar to the one on psychotropic substances. The international community should recognise the control of counterfeit drugs as an international health emergency.

Notes

1. Dora Akunyili is director general of the National Agency for Food and Drug Administration and Control (NAFDAC), Nigeria. Her five-year mandate expires in April 2006. She was the winner of TI's Integrity Award in 2003.
2. Ijeoma Nnani et al., Baseline Study to Ascertain the Level and Quality of Unregistered Drugs on the Market (NAFDAC, 2001).

3. *WHO Drug Information* 6(2), 1992.
4. WHO (1999) *Counterfeit Drugs. Guidelines for the Development of Measures to Combat Counterfeit Drugs* (Geneva: WHO, 1999).
5. *Ibid.*, and D. N. Akunyili, 'Understanding the Problem: The African Perspective with Special Emphasis on Nigeria', Global Forum on Pharmaceutical Anti-Counterfeiting (22–25 September 2002), Geneva Switzerland.

Box 5.2 Corruption in the Ministry of Public Health, Thailand¹

The Rural Doctors Forum (RDF)² of Thailand traces its origins to the student demonstrations of 1973 and an ideological commitment to serving the rural public. This political commitment initially placed it in a difficult position in relation to the government. Towards the end of the 1970s, however, the head of the RDF was given a position in the Ministry of Health, which increasingly came to accept the Forum as a means of resolving the problems involved in decentralising health services to the rural areas.³

In 1998, the RDF departed from its role of supporting the ministry's work to expose corruption in the procurement of medicines and medical supplies. It claimed that its members had been ordered by the central authorities to procure supplies from some companies, rather than others, at prices two to three times higher than normal. It also alleged that senior administrators had put in place a regime that fostered corruption by cancelling medicine price ceilings and changing budgeting arrangements so as to make provincial-level officials, rather than officials in individual hospitals, responsible for procurement. The latter move made it easier for administrators in central government to interfere with the procurement process for personal gain.

The RDF's chairman wrote an open letter to the prime minister asking for an investigation. The RDF and another professional association, the Rural Pharmacists Forum (RPF), began to collect evidence on corruption and encouraged their members to step forward as witnesses. They also approached existing networks of NGOs, including the Drug Study Group and Consumers Protection Group, to form a coalition of 30 organisations against medical supplies corruption. The coalition provided information to the media and the public, and petitioned the court to force the country's National Counter Corruption Commission to release information on the case. The court decided in its favour and the information was released.

The committee set up to investigate the case confirmed that there was indeed corruption among politicians and civil servants in the ministry.⁴ It recommended that the procurement system be reformed to promote transparency and accountability, and that those guilty of corruption be punished through a free and neutral committee. Two ministers resigned as a result,⁵ and several senior and mid-level officials were dismissed or reprimanded. Rakkiat Sukthana, Public Health Minister at the time of the scandal, was later found guilty of accepting bribes from drug companies, and began serving a 15-year prison sentence in November 2004.⁶

Despite this victory, there continue to be calls for other politicians and high-level officials to face legal sanctions.⁷ It was widely felt that the committee's recommendations for reforming the procurement system to prevent corruption were ignored.⁸ But the improved coordination among civic organisations, which previously knew little about each other's work, is likely to help them to promote transparency and exert pressure on government in future.⁹



The role of the RDF and RPF in the case was particularly important because of the position of members of the associations in the Ministry of Public Health. Most were medical professionals and had privileged access to information, such as changes in budget allocations, yet were able to maintain their independence, rather than being drawn into the corruption.¹⁰ This degree of independence can be attributed both to the fact that many rural doctors were involved in public health NGOs, and to the RDF's history as a force for public health reform.¹¹

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Notes

1. This essay draws from N. Trirat, 'Two Case Studies of Corruption in Medicine and Medicine Supplies Procurement in the Ministry of Public Health: Civil Society and Movement Against Corruption', Institute of Development Studies, UK: Civil Society and Governance Programme Working Paper, 2000; S. Wongchanglaw, 'Case Study: Citizen Mobilisation in the Fight Against Corruption: The Case of Health-Care Funding in Thailand', paper written for the Open Government Forum held in Seoul, February 2003, see www.thinkcentreasia.org/documents/healthcarecorruptionthailand.html; U. Tumkosit, 'Two Case Studies of Corruption in Medicine and Medicine Supplies Procurement in the Ministry of Public Health: A Framework of Relationships between Civil Society and Good Governance', Institute of Development Studies, UK: Civil Society and Governance Programme Working Paper, 2000.
2. Sometimes referred to as the Rural Doctors Society.
3. Trirat, 'Two Case Studies of Corruption'.
4. Wongchanglaw, 'Case Study'.
5. Dr Rakkiat (alternative spelling, Rakkied) Sukthana resigned on 15 September 1998 and Deputy Public Health Minister Teerawat Siriwanasarn resigned on 20 September 1998.
6. *The Nation* (Thailand), 2 November 2004.
7. Pasuk Phongpaichit, 'Corruption, Governance and Globalisation: Lessons from the New Thailand', Corner House Briefing 29, 2003, www.thecornerhouse.org.uk/item.shtml?x=51987
8. Trirat, 'Two Cases of Corruption'.
9. Wongchanglaw, 'Case Study', and Tumkosit, 'Two Case Studies'.
10. 'In one sense, it [the RDF] is inside the ministry it is attacking ... But in another sense, the Rural Doctors Society is not an official part of the ministry structure. It is just a *chomrom* (club).' See C. Noi, 'Six Rules for Fighting Corruption', *The Nation* (Thailand), 15 November 1998. Available at www.geocities.com/changnoi2/ruraldoc.htm
11. Trirat, 'Two Cases of Corruption'.

Box 5.3 Malpractice in the Office of the Drug Controller in Karnataka, India¹

The Karnataka *Lokayukta* (KLA) is a statutory judicial body charged with improving standards of public administration in the state of Karnataka, India. Although other Indian states also have *lokayuktas*, the KLA is exceptional in that it is better funded – its annual budget for 2002–03 was around Rs72 million (around US \$1.7 million) – and is proactively led by a high-profile retired judge, Justice Venkatachala. It is able to investigate grievances and complaints against public bodies through the police, and direct the relevant authorities to take corrective action when a grievance is justified. Its actions in the health sector have included paying unannounced visits to hospitals to check for bribes being paid, and requesting hospitals to display citizens' charters detailing which drugs are available, the fees for services, and what kind of facilities and services are offered.

NGOs occasionally make vital contributions to the KLA's investigations. A medical doctor and activist from Drug Action Forum (DAF), a group aiming to raise awareness about



drugs promotion and policy, made a complaint to the KLA in 2003, alleging malpractice in the Office of the Drug Controller (ODC). A preliminary investigation revealed a number of irregularities. The office's mandate is to ensure that only authorised drugs of specific quality are sold. Many drugs were found to be sub-standard, but the test results were only available after several months and no action had been taken to withdraw them. Nor had any action been taken against the companies manufacturing the drugs. In this way, sufficient time had passed for all of the sub-standard drugs to be sold to the public.

It was discovered that companies that paid bribes were allowed to circumvent drugs standards, and those that refused to pay were harassed. Other irregularities included non-enforcement of price controls and accepting kickbacks. The ODC's remit also included granting licences to blood banks, but it did this with little regard for enforcement of standards or monitoring. The investigation found that a complaint had been filed about a blood bank in the district of Gulbarga that had provided HIV-positive blood; no action was taken in response.

The KLA responded to these findings by calling a meeting of over 50 officers from the ODC. It was claimed at the meeting that each drugs inspector was required to give Rs20,000 (around US \$460) every six months to the Drugs Controller, who then passed it on to the Minister of Health.² Hearings were open to the media, with politically damaging consequences for former ministers who had also been implicated. In a bid to limit the damage, the ODC suspended the three officers who were cooperating with the inquiry, but the KLA threatened to hold the government in contempt of court for obstruction of justice if it did not reinstate the men and protect them from further harassment.

The KLA's final report of the investigation called on the government to suspend the ODC's top three officials, but did not implicate the Minister of Health.³ The three officials were duly suspended on grounds of misconduct and dereliction of duty in October 2004.⁴ The *Lokayukta's* powers have limitations: it is not able to remove someone from office without the permission of central or state government, or of a senior official in the same department as the accused. It therefore depended on pressure from the public, via media exposure, to push the government into acting on its recommendations. It is not yet clear whether this pressure has been sufficient to bring about sustainable reform in the ODC.

DAF's involvement in the case was instrumental. There are obvious difficulties for ordinary individuals who make a complaint to a judicial body like the KLA. The judicial process is slow and cumbersome, and can seem daunting. Patients may lack information about their entitlements or health standards, and may fear losing access to services if they file a formal complaint. Moreover, expert pressure groups like DAF can provide the detailed information that may be necessary in order to proceed with an investigation.

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Notes

1. This essay draws from two articles by Asha George, 'We Need to Fix This Leaky Vessel' and 'Small Steps Ahead' published in *Humanscape Magazine* 10(9) 2003, and 10(10) 2003, respectively. See www.humanscape.org/Humanscape/new/sept03/weneedto.htm and www.humanscape.org/Humanscape/new/october03/smallsteps.htm The issues were uncovered by Anuradha Rao, in 'Karnataka Lokayukta: Initiatives in the Public Health Sector: A review', Mimeo, Bangalore: Public Affairs Centre, 2003.
2. *Humanscape Magazine* 10(10), 2003.
3. *Deccan Herald* (India), 1 October 2003; *The Hindu* (India), 1 October 2003.
4. *Deccan Herald* (India), 3 October 2004. The officials were the Drugs Controller, Anand Rajashekar, the Additional Drugs Controller, H. Jayaram, and the Deputy Drugs Controller, B. G. Prabhakumar.