SELECTED SUMMARY

Drug deals

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This article provides an overview of the excesses of the pharmaceutical industry in the US.

Profits

While justifying high prices by the high risk of failure of new drugs, the industry consistently reports higher profits than any other industry, 17% vs 3.1% for all the other industries on the Fortune 500 list – hardly a sign of high risk. The high profits reflect the exorbitant prices, particularly in the US, where, unlike most countries, there is no governmental mechanism to regulate drug prices. Thus, all top 10 pharmaceuticals (5 European and 5 US); generate most of their profits in the US. Moreover, in the US, while the majority of the patients who are covered by some form of an employer-assisted insurance plan get lower prices as insurance companies bargain for significant price reductions, the uninsured poor pay the highest prices for drugs.

"Me-too" drugs

The main R&D of the industry is targeted at manufacturing and selling "me-too" drugs that are low-risk minor variations on successful drugs marketed by themselves or others, sometimes "gimmicks" to extend their monopoly. These drugs are cheaper to develop and, with an established market, less of a gamble to manufacture. Mostly tested against placebo, these "me-too" drugs rarely offer an advantage over existing drugs. Yet many me-too drugs are covered by patent and thus more expensive than the older drugs that are no longer covered by patents. From 1998 through 2003, 379 of the 487 drugs approved by the US Food and Drug Administration were "me-too" drugs.

The main industry justifications for these me-too drugs are a) the drugs offer a choice to patients who do not respond well to a drug already on the market; and b) competition reduces prices. These claims have no merit. These new drugs are rarely tried against others in the class and never in people who do not respond to other older drugs in the same group.

Marketing

Drug companies spend "35% of their sales on marketing and administration and ... only 11-14% on R&D". A sizable part of the marketing is spent on "education of medical professionals" which is really inappropriately persuading doctors to prescribe their drugs. A significant portion also goes to persuade the affluent that "they are suffering from conditions that need expensive long-term treatment" such as "generalised anxiety disorder," "erectile dysfunction," "premenstrual dysphoric disorder", etc. As Dr Angell says, drug prices are "high to cover their marketing costs – and their outsize profits."

Influence on the medical profession

Most continuing medical education activities are primarily supported by drug companies who often use this opportunity to influence the prescribing habits of doctors. These activities are paid for from the advertising budgets of these corporations. "The industry also provides students, house officers and physicians in practice with meals, trips to exotic locations and many other blandishments." The industry and the medical profession have developed guidelines to regulate this behaviour but there are enough loopholes to get around them.

Political muscle

The drug industry contributes heavily to political campaigns and maintains one of the largest lobbies in Washington to assure that most of the laws passed promote the industry's interests. This has paid dividends: law makers have legalised manoeuvres to extend patent protection; industry uses data from publicly-funded research at little or no cost; laws bar consumers from importing lower cost name-brand drugs from other countries, and so on. Last year, as the Congress passed a law that would provide prescription drugs to the elderly at a subsidised rate, the drug industry managed to write into the law a clause that prohibits the administrators of the programme from negotiating with the industry for lower prices – something that all health insurance companies, the HMOs and even the Veterans Administration in the USA do routinely.

Commentary

During the second half of the twentieth century, the western pharmaceutical industry, often using research performed at universities and government institutions, revolutionised medical therapy. With few exceptions (e.g. digitalis and aspirin), every drug we prescribe today was introduced in the last 50 years. These new therapies have contributed to an increase in our life span and have reduced pain and suffering. It is only during the last 20 years or so that the corporate drive for profits has overcome scientific endeavour and led to unethical practices in the industry.

How is this article relevant for India?

In the 1970s, after decades of debate, the government of India restricted patents only to process and not products to encourage development of an indigenous pharmaceutical

industry. The nascent Indian pharmaceutical industry, with low overhead, rapidly grew to be the third largest in the world (1). Today, despite the low pricing, the profitability of the Indian pharmaceutical industry is second only to that of information technology (2). India has also exported its cheaper drugs to third world countries helping their populations immensely.

The Indian pharmaceutical industry is not much better than its western counterparts. For example, if Angell considers 14% of sales allocation to R&D insufficient, how would we rate the 2-3% for the Indian industry (3) and that too by just a handful of firms of the 30,000-plus in the market? Even potentially profitable areas such as development of drugs based on our indigenous systems of medicines (Ayurvedic, Unani, Siddha) remain unexplored. There has been scarce basic research on indigenous plants with medicinal properties. While the western pharmaceutical industry is criticised for doing little research on diseases prevalent in poor countries such as malaria, our pharmaceutical corporations have not done any better.

Unique to the Indian pharmaceutical scene is the presence of a large number of irrational drug combinations and substandard and spurious drugs. This reflects a lack of coordination in licensing and regulatory oversight by the center and the state authorities. The Mashelkar Committee report (4) calls for a thorough overhaul of our drug regulatory structure to curb these shortcomings and to encourage drug research but its recommendations are yet to be implemented.

The marketing and lobbying tactics in the West are being duplicated in India (5, 6, 9). Whether these tactics will succeed in influencing the decisions of the government to the detriment of the people is an open question.

Are Trade-Related aspects of Intellectual Property Rights (TRIPs) likely to have a major impact on drug prices?

Diametrically opposite views have been expressed in the media. Without data that the industry is reluctant to divulge, who do you believe? The government claims that pharmaceutical prices are unlikely to change because 97% of the drugs manufactured by the Indian pharmaceutical industry are generic drugs. (7). On the other hand, Siddharth Narain (8) quotes D G Shah, secretary of the Indian Pharmaceutical Alliance, "If the US pharmaceutical industry is saying that 40% of the market is eligible for patent, on what basis is the Minister saying that only 3% will be eligible?"

There are other factors that will impact what the Indian patient will pay.

Ultimately, it is the doctor who prescribes a drug to a patient and it is she/he who will have to keep the costs in mind when writing prescriptions. Alas, the practicing doctor relies on the medical representative to keep her/his medical knowledge current. And the detail man is always going to push his drugs using incentives to encourage prescription of his products (9).

Moreover, in India, it is often not the doctor but the pharmacist who recommends a drug to the patient. Pharmaceutical companies may offer more remuneration to a pharmacist for stocking only their higher priced items rather than generics (9).

Undoubtedly, under TRIPs, the cost of new drugs will increase markedly. However, when new drugs are essential and life-saving (eg treatment of HIV or cancer), the government has the option of enforcing mandatory licensing. India may find support for such an action even in the USA (10). Will the Indian government withstand the pressures from western pharmaceutical industry in the interest of its people? This remains to be seen.

When liberalisation of trade began in early 1990s, the Indian manufacturing industry was fearful that they would be swamped by competition and many wanted protection for indigenous firms. We have seen that external challenges forced Indian corporations to invest more to upgrade their products. It is not inconceivable that TRIPs may stimulate our pharmaceutical firms to their outlay on R&D and focus on diseases that affect our population. India may have an edge particularly in biotechnology and may be able to exploit its intellectual capital to develop new therapies (11).

To promote basic and clinical research, to sustain quality drug manufacture, and to detect and eliminate spurious and dangerous drugs from the market, the government of India must implement the recommendations of the Mashelkar Committee Report (4) forthwith and establish an overarching National Drug Authority.

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