

ASPECTS OF DRUG INDUSTRY IN INDIA

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FOREWORD

This report attempts to highlight some of the central issues involved in the important areas of health and drugs in the developing world, primarily in the context of the Indian experience.

Beginning with a brief description and analysis of the current health scene in India and the formidable obstacles in the path of altering the current health-care status quo (Chapter 1), the report goes on to examine the role of drugs and the drugs industry in the developing world vis-a-vis the commonly accepted objective of providing health for all by the year 2000 A.D. laid down at the International Conference on Primary Health Care at Alma-Ata, USSR, September 1978 (Chapter 2). This role is examined in the light of the recent experience of some developing countries like Tanzania, Sri Lanka and India.

Chapter 3 focusses attention on the marketing malpractices of the large drug companies in India (both Indian and foreign companies), in freely selling drugs that have either been banned or restricted in the West owing to their harmful, sometimes even fatal, effects on the health of the consumers.

Chapter 4 presents a detailed analysis of the key issues involved in the lively controversy of brand names v/s. generic names that is currently raging in India. A strong case is made out for introducing generic names for over 100 essential drugs of mass consumption.

Chapter 5 gives a brief historical account of the development of a modern drugs industry in India and the West, with a particular emphasis on the role of the Western multinationals operating in India.

Chapter 6 studies the existing policy of the Indian Government, and its implementation, towards regulating the operations of these local multinational companies.

Chapter 7 assesses the contributions and the failures of the Central Government-owned public sector organisations in India vis-a-vis the role assigned to them in the basic economic policies of the country.

Chapter 8 covers the crucial policy of comprehensive price and profit controls in the Indian drug industry along with an evaluation of its effectiveness in practice.

Finally, the report raises some fundamental economic and political issues involved, and the likely trends and prospects in the near future, in the operation of the "mixed" industrial economy of India characterised by extreme inequality and poverty on the one hand and an abysmally low rate of growth on the other.

1981.

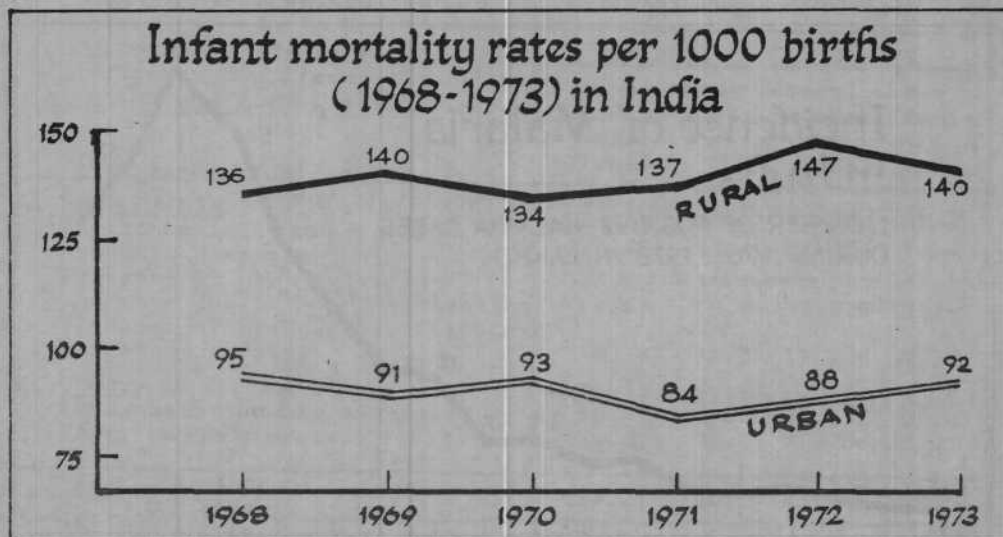
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THE HEALTH SCENE IN INDIA

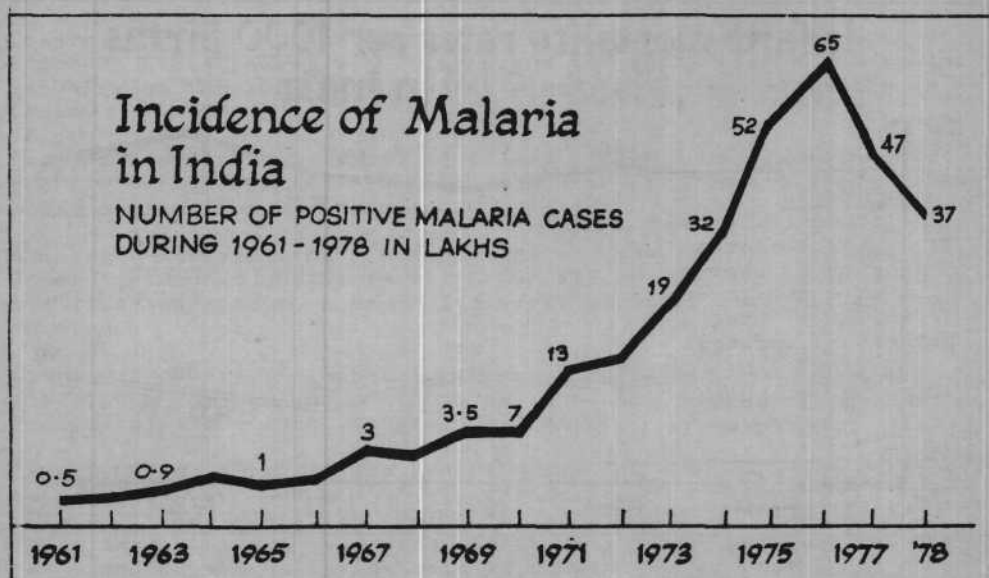
After 30 years of 'socialist planning', the health scene in India remains unrelentingly depressing. By now, it has become unequivocally clear that the health establishment of the country as it has developed over the past three decades is totally incapable of meeting the health needs of the majority of the people.

The following are some salient features of the health scene in India culled from various sources:

- The mortality rate of the rural population is, on an average, twice as high as that of the urban population.
- There is one doctor for every 3,000 Indians; but 80% of the doctors work in the urban areas whereas 80% of the people live in the rural areas.
- Children under 5, comprise 16% of the rural population; but the deaths in this age-group account for over 50% of all deaths in the villages.
- The infant mortality rate in rural areas is around 140 per 1,000 live births accounting for about 30% of all deaths. (See Chart below).



- The haemoglobin level of the average Indian woman is far below normal requirements. Malnutrition further disables her causing more anaemia, weakness — — — . The sex ratio in the population declined from 950 females per 1,000 males in 1946 to 930 in 1971 due to the worsening health of Indian women.
- About half of the world's 20 million T.B. patients are Indians and over one-third of the 10 million leprosy patients in the world are Indians.
- Over 13.5 millions, or 2% of the total population, suffer from pulmonary tuberculosis despite a nationwide T.B. control program launched in 1949. Filariasis, or elephantiasis, afflicts another 14 million Indians.
- Water-borne diseases — cholera, typhoid, gastroenteritis — afflict innumerable millions, killing at least 1.5 million people every year.
- Malaria, which was practically wiped out by 1960, staged a dramatic comeback in the 1970s. Every year there are 3 million new cases of malaria of which an estimated 40% or 1.2 million die from its onslaught. (See Chart below).



Of the 9 million blind persons in the country, about 5 million are curable. In addition, 45 million persons are reported to be otherwise visually impaired. 25,000 children go blind every year owing to vitamin A deficiency and 3 million children suffer from other forms of this deficiency: night blindness, dry eyes and rough skins.

What are the reasons for this depressing state of affairs?

It is clear, even from the above sketchy listing of some major hazards, that the root cause of widespread ill-health and disease is that genuine development, in terms of the most minimum amelioration of the living conditions of the masses, is simply absent in this vast country. This monumental failure is not primarily due to poor growth rates in national income or public health outlays but a complete lack of commitment on the part of the health establishment—the Government, the medical profession, the health bureaucracy—to improve the living conditions of the masses.

The Table below shows the pattern of diseases in India and the deaths caused by them during the year 1970.

PATTERN OF DISEASES AND DEATHS CAUSED BY THEM: 1970 (a)

Type of Diseases	DISEASES		DEATHS	
	Total number (millions)	Per Cent	Total number (thousands)	Per Cent
A. Preventible	<u>48.10</u>	<u>36.0</u>	<u>81.367</u>	<u>56.5</u>
Environmentally caused or promoted diseases	23.23	17.4	16.426	11.4
Diseases of poor nutrition	14.82	11.1	11.299	7.8
Diseases due to non-immunisation	4.67	3.5	33.936	23.6
Diseases of pregnancy, childbirth and early infancy	5.38	4.0	19.706	13.7
B. Others	<u>85.11</u>	<u>64.0</u>	<u>62.562</u>	<u>43.5</u>
Diseases of bodily systems	50.49	38.0	30.296	21.0
Other major diseases	34.62	26.0	32.266	22.5
Total (A + B)	133.21	100.0	143.929	100.0

Note: (a) Compiled from the State-wise data generally referring to 1970 or the nearest year whenever the 1970 data are not available.

SOURCE: Central Statistical Organisation, Government of India, Statistical Abstract of India: 1974, New Delhi, 1976.

Reproduced from: "Standard of Living of the Indian People", May 1979, Centre for Monitoring Indian Economy (CMIE), Bombay.

On analysis, the data presented above reveal some significant features:

1. Over 56% of the deaths in India, resulting from disease, are preventable. In other words, one out of every two deaths are "unnecessary".
2. The preventable diseases, which generally afflict the poor, constitute 36% of all diseases in the country but they account for 56.5% of all deaths. This indicates the fatal vulnerability of the poor to these diseases, particularly infants and women as we shall see below.
3. Diseases due to non-immunisation such as tuberculosis, whooping cough, diphtheria, measles, polio, etc. constitute only 3.5% of all diseases but account for almost 24% of all deaths. This is one of the causes of the very high infant mortality rates in the country.
4. Similarly, while the diseases of pregnancy, childbirth and early infancy constitute 4.0% of all diseases, they account for almost 14% of all deaths. The victims here are again infants and women.

The following excerpts vividly highlight what is, or is not, going on.

"India's rich can get the best medical facilities while the poor crowd outside clinics where often few modern aids exist." (1)

"The problem of malnutrition is closely linked with that of poverty, large family size, unemployment, illiteracy, lack of environmental sanitation and hygiene and safe drinking water." (2)

"The infrastructure of sub-centres, primary health centres and hospitals built up in the rural areas touches only a fraction of the rural population. The concept of health in its totality, with preventive and promotive health care services in addition to the curative, is still to be made operational." (2)

The article titled "Health For All By The Year 2000?"* in Science Today, May 1981, gives some quantitative estimates of the problem of water supply and sanitation:

* Saroj S. Jha, Prof. Head, Dept. of Preventive and Social Medicine, Topiwala National Medical College, Bombay.

"Two lakh villages (over one-third of the total number of 5.8 lakh villages) in this country, covering a population of 160 million (from a total population of over 680 million) are yet to be provided with potable water supply facilities. Ninety-eight per cent of rural households do not have latrines. One-third of the 40 million households still use a system of sewage where human excreta is collected manually and disposed off unhygienically to pollute water sources and food. Seven million households use the open ground for defecation to breed hookworms and other parasites. (Brackets inserted by me.)

"It is said that 80 to 85 per cent of all illnesses in this country, especially the waterborne ones, will disappear merely with an improved water supply and sanitation programme."

Couple this with grossly inadequate nutrition and you have a health disaster of continental dimensions.

"According to official statistics available, 60 million of our children (or over 20% of all children below 14 years of age) are malnourished.* About 1 lakh of them die of the effects of malnourishment every year while the others, who escape death, suffer various handicaps and ailments ... Many go blind; others become victims of crippling diseases -- nutrition surveys indicate that 80 to 90 per cent do not get vitamins and minerals which are essential for their normal growth; -- (Bracket inserted by me.)

"The worst sufferers are the children below six years of age, 60% of whom suffer from severe anaemia and protein - calorie deficiency. No wonder that 40% of the total deaths occur in the below six years age group."(3)

Describing the existing health care set-up in the country, the Sixth Plan document says that it has been primarily pre-occupied "with the promotion of curative and clinical services through city-based hospitals, which have, by and large, catered to certain sections of the urban population."(2)

* Out of 77 million children, below the age of 5 years, 37 million or 48%, suffer moderate to severe forms of malnutrition. See "Health for all by 2000 A.D.?" by M. Jeremiah, Deccan Herald, 18th February, 1981.

"Despite the high yearly turnout of about 11,000 medical graduates and growing unemployment among them, there are no doctors available to serve the rural primary health centres/hospitals in several States." (2)

The problem is further compounded by the built-in urban and elitist bias in modern medical education. As Halfdan Mahler, Director-General of the WHO, says in his article "The Meaning of 'Health for All by the year 2000'";

"Most of the world's medical schools prepare doctors not to care for the health of the people but to engage in a medical practice that is blind to anything but disease and the technology for dealing with it." (4)

"They prepare their students for certain high, obscure, ill-defined, and allegedly international "academic standards" and for dimly perceived requirements of the twenty-first century, largely forgetting or even ignoring the pressing health needs of today's and tomorrow's society." (4)

The type of medical education imparted to medical students in India is not any different: "--, as a recent committee on medical education reform pointed out, the curricula does not reflect health needs, is not community-oriented and does not teach students how to function as part of a health team. Despite the overwhelming evidence in favour of a firm system of primary health care, three-fourths of the health budget is poured into expensive specialist services benefitting less than one-fourth of the population." (5) We have already seen the disastrous results of this criminal neglect of a vast majority of the people.

Talking about the alternative health strategy required, and the role of the doctor in it, to promote health for all, Halfdan Mahler says:

"If we want a system which is accessible to all members of the community, which is concerned with the promotion of health in the whole community, and in which major decisions concerning health are taken and implemented by the community, the doctor will have to become only one component of a team whose every member does what he or she has been trained for and which is oriented towards identifying and solving the priority health problems of the community.

"But here we face a dilemma. The existing community of health professionals tends to oppose the establishment of such a health system." (4)

Take for instance the case of India. In an ICMR - ICSSR symposium report, Alternative Approaches to Health Care (ICMR, New Delhi, 1977), Dr. N.H. Antia explains why the Indian medical profession has a vested interest in the status quo:

"Having been for almost two decades a teacher and a specialist in one of the largest and oldest medical colleges of the country, the author is convinced that the chief beneficiary of the present system of medicine is the medical profession and not the public, despite the fact that the latter contributes Rs.80,000 towards the education of each doctor.... Let it be quite clear that the vast majority of the medical profession has neither, by training or interest, the ability or the desire to deliver the type of health service that the vast majority of the people of this country evidently need.

"What the country needs is a simple, cheap but effective community health service with emphasis on prevention and health education and not a sophisticated, personalised and expensive 'illness service' which is being provided." (6)

Attempts to alter the urban, elitist bias of the medical establishment have met with fierce resistance. In 1980, the Left Front government of West Bengal proposed a scheme to start 6 new medical schools in the State to train "barefoot doctors" for service in the rural areas. The State unit of the Medical Council of India denounced the scheme saying it would only churn out 'quacks' unfit to properly diagnose and treat the patients.

Instead of spending on new medical schools, the MCI suggested, the State government should spend more funds on improving the conditions of the existing colleges (7) The experience of several other States in medical education reform has been no different.

The attitudes and biases of the health bureaucracy manning the health and welfare programmes at the grass-roots level are no better. There is simply no commitment to the welfare of the afflicted masses. Professor D. Banerji, of The Centre of Social Medicine and Community Health, Jawaharlal Nehru University, New Delhi, a man of wide experience in health care operations in the rural areas passes this bitter judgement on the "health bosses":

"Even today, three-fourths of the tuberculosis patients who are literally knocking at our doors, pathetically entreating us to help them, are still being thrown out with a bottle of useless cough mixture.

"Why is this so? The simple answer is that those concerned with the programme do not care much about the plight of these unfortunate people, except for a few politicians shedding an occasional crocodile tear. The vast masses of the people do not concern them. They are concerned about what is called the informed public - the elite - the lobbies of politicians, _____ of bureaucrats, _____ of rich people, _____ of drugs and medical equipment industries, _____ of professionals and _____ of foreign consultants and advisers."

"The vast masses of people continue to suffer. In the early seventies, a Union Health Minister had very aptly summed up the situation _____. He said, 'Let us face it. There are two types of medical services in the country. One is for the classes, and the other is for the masses!'. (8)

The conclusions are obvious. Merely increasing the plan allocations for rural health and communicable diseases will not have much impact (though this is also necessary in view of the small percentage of national resources devoted to public health in India: See Table on following page) without radical changes in the entire health machinery—in the type of men who man the key positions at different levels of the bureaucracy, in the formulation of health strategies that would not alienate and obligate the poor, as at present, but instead seek their active participation and involvement and, ultimately, in the very nature of the political leadership that would not churn out endless slogans of welfare rhetoric but instead develop a genuine program to build a strong, healthy community. Till then, health for all will always remain "a dream."

EXPENDITURE ON HEALTH IN INDIA:
1970-71 TO 1978-79

Year	Health Expenditure (Rs. crores)			Health Expenditure (As % of GNP)			Per capita health expenditure (Rs.)
	Private	Public	Total	Private	Public	Total	
1970-71	612 (74)	211 (26)	823 (100)	1.6	0.5	2.1	15
1971-72	734 (75)	247 (25)	981 (100)	1.7	0.6	2.3	18
1972-73	798 (74)	278 (26)	1,076 (100)	1.7	0.6	2.3	19
1973-74	841 (74)	297 (26)	1,138 (100)	1.4	0.5	1.9	20
1974-75	941 (72)	359 (28)	1,300 (100)	1.4	0.5	1.9	22
1975-76	1,011 (69)	441 (31)	1,455 (100)	1.4	0.6	2.0	24
1976-77	1,285 (71)	517 (29)	1,802 (100)	1.6	0.7	2.3	29
1977-78*	1,314 (72)	511 (28)	1,825 (100)	1.5	0.6	2.1	29
1978-79*	1,376 (72)	535 (28)	1,911 (100)	1.5	0.6	2.1	30

* Estimated by CMIE.

SOURCE: Central Statistical Organisation, National Accounts Statistics, New Delhi, various issues.

Reproduced From: Standard of Living of the Indian People, May, 1979. Centre for Monitoring Indian Economy, (CMIE) Bombay.

Note:

- 1) Government expenditure on health in India accounts for barely half-a-percent of the gross national product or national income.

- 2) The meagre percentage of national resources devoted to public health reflects the neglect by the Government of a vital aspect of the quality of life of the common people.
- 3) Public health expenditure as a percentage of GNP needs to be raised to at least 4.5%.
- 4) But, these larger outlays must be accompanied by the designing of preventive, community-oriented and promotive health-care services which alone can meet the needs of the masses.

HEALTH FOR ALL AND THE DRUGS INDUSTRY

The role of drugs in the eradication of disease in the developing countries is limited. The root causes of the diseases and disabilities widely prevalent in these areas are environmental and socio-economic—poor sanitation and unhygienic practices, unprotected supplies of drinking water, inadequate and inaccessible health infrastructure, abject poverty and malnutrition, low levels of education and literacy. Undoubtedly, modern drugs have a valuable role to play: they can completely cure many of the diseases prevalent in the developing world. But they cannot prevent their recurrence if the causative factors listed above continue to operate.

Drugs are essentially curative in nature. What is most important for good health are the preventive measures that would eliminate the emergence of disease at its source. It is estimated that even in the developed countries, self-care and self-responsibility on the part of the people account for 50-60% of all health care. (1) Thus, what people really need, first and foremost, in the poor societies is clean drinking water, latrines, schools and land, not urban hospitals with their wonder drugs. (2)

Modern medicines and drugs cover only a small minority of the people in the poor societies. In India, only 15-20% of the population is covered by drugs. So it is not surprising that the average per capita expenditure on pharmaceuticals in many poor countries is less than U.S.\$1. The most minimum drug needs of these societies simply go unmet.

The Table on the following page shows the average per capita consumption of drugs in India for select years from 1950-51 onwards.

In order to widen the extremely narrow coverage of the population serviced by modern drugs and medicines, poor countries require to mass produce and distribute at low prices a few (about 30 or so according to WHO's estimate) essential drugs sufficient to meet the basic requirements of a majority of their people.

"Essential drugs, which can cope with the overwhelming majority of the problems even in relatively sophisticated societies, number around 200. But for the villager and the urban slum-dweller great miracles can be achieved with fewer than 30 well-chosen drugs. Without these drugs, the primary health care programmes cannot work" says Halfdan Mahler of WHO. (1)

But this is precisely where the interest of the drugs industry wanes. The drugs industry, both foreign and indigenous, is concerned with profits first, like any other business; not with the health needs of the majority of the people, though their publicity campaigns would like us to believe otherwise.

AVERAGE PER CAPITA CONSUMPTION OF DRUGS IN INDIA: 1950-85

Period	Drug Production (Rs. crores)	Population (Millions)	Annual Per Capita Consumption (Rs.)
<u>Pre-Plan</u>			
1950-51	15	359	0.42
<u>First Plan</u>			
1951-52	20	365	0.55
1955-56	35	393	0.89
<u>Second Plan</u>			
1956-57	54	401	1.35
1960-61	70	434	1.61
<u>Third Plan</u>			
1961-62	85	444	1.91
1965-66	150	485	3.09
<u>Annual Plans</u>			
1966-67	175	495	3.54
1968-69	200	518	3.86
<u>Fourth Plan</u>			
1969-70	235	529	4.44
1973-74	380	579	6.56
<u>Fifth Plan</u>			
1974-75	408	591	6.90
1977-78	900	629	14.31
<u>Annual Plans</u>			
1978-79	1,050	641	16.38
1979-80	1,150	654	17.58
<u>Sixth Plan</u>			
1980-81	1,200	684*	17.54
1984-85 (Targets)	2,450	743*	32.97

* As per 1981 Census.

"Still, the speed of the essential drugs programme is too slow,---. We need, --- to overcome normal marketing pressures, which impede progress. A startling example of such constraints occurred at one conference when the industry spokesman said that the production of vaccines and sera is so competitive that they were losing interest in it. What conclusion can you draw from that? When you want health for all and want to prevent 6 million children dying from tuberculosis, whooping cough, diphtheria, measles and polio every year, then you need to vaccinate 100-120 million children every year. In order to get that you need a vaccine price that is low. But when the price is low, you cannot get the products. So the conclusion is that

we can no longer treat these vital components of people's health as normal commodities in the market-place." (1)

The Director of the Office of Health Economics, U.K., George Teeling-Smith, a drugs industry-backed organisation, summed up the situation succinctly: "They are businessmen, not bishops." (3)

Almost all the worldwide R & D in drugs is being conducted in the multinational corporations (MNCs) in the developed countries. A negligible portion of these research efforts are directed towards the diseases rampant in the developing world. Out of an estimated U.S.\$2 billion spent annually on drugs R & D in the world, barely \$70 million or 3.5%, are spent on research in tropical diseases. The reason is obvious. The low purchasing power of an estimated one billion poor people in the developing countries, who are severely exposed to these diseases, renders the profit profile of such efforts unattractive. For example, the U.S. Walter Reed Army Research Institute is the only organisation in the world that has been screening drug compounds for anti-malarial properties. It got interested in malaria because of the Vietnam war, to safeguard the health of American military personnel. (4)

Some vital measures, like the list of essential drugs prepared by the WHO, centralised bulk purchasing of these essential drugs by national agencies, introduction of generic names in preference to brand names, cheap standardised packaging of a limited, but sufficient, number of products, need to be implemented rigorously in poor countries in order to provide essential drugs at low prices to a much larger proportion of their people. But, in almost every country, the large pharmaceutical firms have consistently opposed such policies. It is a measure of the enormous power and influence they wield that they have generally been successful.

"Developing countries found it very difficult to formulate national drug policies because of the resistance of the medical specialists or the general physicians, who were often influenced by the international drug industry.* But highly expert physicians assembled by WHO from around the world have said that a concept like essential drugs is perfectly valid" says Mahler of WHO. (1)

The experience of some developing countries, like Tanzania, Bangladesh and Sri Lanka, whose drug industries are almost wholly controlled by the MNCs of the West, is highly instructive. In the following sections, we shall examine the impact these corporations have had on their national drug policies and the health of their people.

* In this report, we shall come across many instances of the 'close' ties between the medical profession and the drugs industry in different countries.

Tanzania's Experience With The Multinationals

Dr. John S. Yudkin, a British physician, has worked for several years in Tanzania and has studied the impact of drug multinationals on the health situation of many countries round the world. He has observed that drug expenses account for a very large portion of the total health budget in most underdeveloped countries. In Tanzania, it accounted for 22% in 1977 and was estimated to reach 40% by 1980-81. In Thailand and Bangladesh, it was as high as 55%. Yudkin found that a substantial portion of this money is spent on highly expensive and inappropriate drugs with insufficient funds being left over for dispensaries and health care centres. (3)

For the treatment of hookworm, for example, a common parasitic disease in most third world countries, 1000 doses of tetrachloroethylene (TCE) cost 0.60 shillings (8 U.S. cents) in Tanzania, in 1972. Against this, only 100 doses of Alcopar (a brand name for bephenium) cost 80 shillings (U.S.\$ 11). The difference in costs (130 times) far outweigh any advantages, real and imagined, that Alcopar may offer over TCE. (4) Another example, from Tanzania, is that of ferrous sulphate tablets, to be taken by severely anaemic patients, regularly for 6 months. The cost of a tablet course worked out to 1.20 shillings (18 U.S. cents) while one iron-rich Imferon injection cost 30 shillings (U.S.\$ 4.20). (4)

Over 75% of the Tanzanian government's drug budget is used by official hospitals. According to Yudkin's study, "much of the spending, especially in larger hospitals, is not on life-saving drugs." An extravagance index measuring the proportion of patients treated with expensive drugs when cheaper alternatives are available without detriment to the therapeutic effectiveness—constructed by Yudkin, showed that the Muhimbili Medical Centre (a leading hospital of the country) topped the list with 39%. "The money spent at Muhimbili Medical Centre each year on Avafortan, Baralgan, Valium and Melleril could protect half a million children against malaria" according to Yudkin. (4)

Yudkin's detailed investigations of the operation of drug companies showed that 147 drug company representatives working in Tanzania spend an estimated £ 1.07 millions a year "to persuade 600 doctors to prescribe the company's drugs" which exceeds the medicine faculty's £ 860,000 annual budget "used to educate doctors in every other sphere, including how to use drugs properly." And ultimately, these astronomical sums spent by the companies on promotion have to be borne by Tanzanian consumers. (5)

There is one drug company representative for every four doctors; in Britain the ratio is 1:20. And doctors are strategic in Tanzania: each doctor controls drugs buying worth £ 11,500. "A lot of money is under the control of a few people" says Yudkin. The companies have used all the promotional ruses one could think of: free gifts,

company parties, free drug samples, support for medical research and equipment. (5) To put it bluntly, the foreign drug firms had literally bought over the Tanzanian doctors.

Dr. Leader Sterling, the then Minister of Health of Tanzania, observed that the drug company representative had distorted the drug purchasing pattern of his country. And many of these representatives now working with drug firms were trained by the government itself as medical assistants. (5)

Yudkin also found a "double standard in promotion" by the drug companies. On comparing the African Monthly Index of Medical Specialities (MIMS)—commonly used as a prescribing guide—with the British MIMS, he saw that "for many drugs in the African MIMS the stated indications (symptoms) are more numerous, and the side effects, contraindications and precautions given are fewer than in the British version." (5)

Yudkin recommended that the Tanzanian government should rationalise its drug purchasing policies: restrict the number of drugs to be purchased and order by generic instead of proprietary names. Such a rationalisation was expected to result in an annual saving of £1.5 millions a year.

Sri Lanka's Attempts To Rationalise Drug Purchases

Sri Lanka's experiment at rationalising its drugs industry is highly instructive. It shows how the multinationals can stage formidable obstacles in the path of a determined government and, ultimately, win the protracted battle.*

The Sri Lanka government of Mrs. Sirimavo Bandaranaike set up a centralised bulk drugs purchasing agency, the State Pharmaceuticals Corporation (SPC), in 1972, authorised to purchase pharmaceuticals for the whole country. It also drew up a list of a limited number of essential drugs—a few hundred instead of the thousands of drugs on the market—and abolished branding of prescription drugs. Doctors were required by law to prescribe only by generic, or commonly accepted, names.

The SPC commenced operations in the second half of 1972 and imported some 52 categories of drugs, through worldwide tenders. It is estimated that Sri Lanka paid 40% less for these 52 drugs in the second half of 1972 (U.S.\$ 290,000) as compared to the first six months of the same year (U.S. \$ 485, 000). For example, 23 brands of the

* The detailed account of this experiment is based on Sri Lanka's Experience With Bulk Purchasing, Chapter 5, from Drugs And The Third World by Anil Agarwal.

antibiotic tetracycline were imported in the first half of 1972 at an average cost of U.S.\$ 16.92 per 1000 capsules. The SPC, after evaluating 44 tenders, bought tetracycline for U.S.\$ 6.33 per 1000 capsules, a saving of 63%. Similarly, the savings on chlorpromazine were as high as 86% for the same period. (See Table below)

COMPARISON OF AVERAGE PRICES OF SOME DRUGS IMPORTED BY THE PRIVATE SECTOR IN FIRST HALF OF 1972 AND BY THE SPC IN SECOND HALF OF 1972

Drug	No. of suppliers to the private sector.	No. of offers to the SPC.	Private Sector Average Purchase Price (A) (in U.S.\$)	SPC Purchase Price (B)	B as % of A
Tetracycline	23	44	16.92	6.33	37
Penicillin V	1	8	11.52	5.01	43
Ampicillin	1	16	8.30	2.47	30
Erythromycin	3	16	13.90	3.75	27
Chlorpromazine	2	10	3.79	0.52	14

Source: UNCTAD, Case Studies in Transfer of Technology: Pharmaceutical Policies in Sri Lanka, June 1977.

Prompted by its spectacular success in so short a period of time, the SPC began importing some key raw materials required by its private drug companies, both foreign and indigenous. Many multinationals were forced to lower the transfer prices at which they supplied these materials to their subsidiary concerns operating in Sri Lanka. The West German giant, Hoechst, cut down its prices for tolbutamide (a T.B. drug) from \$40.62 to \$19.24 — a saving of 53%. And Polfa of Poland supplied the same drug for only \$2.52 — a saving of 94% over the Hoechst price! (See Table on the following page).

The SPC took all the necessary precautions such as 'bioavailability' tests,* inviting tenders from a few reputed companies only, strict quality control, quick recall of drugs from the market found to be defective, and so on. But despite its best efforts and resounding success, the SPC continued to face a barrage of criticism from the multinationals and the Sri Lankan medical establishment. At times drugs manufactured by the foreign companies were found to be sub-standard (tetracycline of Roche, malt syrup of Burroughs-Wellcome). But the doctors, who enthusiastically publicised the defective drugs of local small-scale firms, kept mum over similar shortcomings of such larger firms. A study at the Colombo General Hospital found

* See "Who Needs Brands", Chapter 4 Pg.38 of this report for the meaning of 'bioavailability'.

COMPARISON OF TRANSFER PRICES PAID BY MULTINATIONAL SUBSIDIARIES TO THEIR PARENT COMPANIES IN 1972 AND THE PRICES PAID BY THE SPC IN 1973 FOR THE SAME RAW MATERIALS.

Raw Material	Private Sector Supplier (1972)	SPC Supplier (1973)	Private Sector Transfer Price (A) (in U.S.\$)	SPC Purchase Price (B)	B as % of A
Tolbutamide	HOECHST (W.Germany)	HOECHST (W.Germany)	40.62	19.24	47
		POLFA (Poland)	40.62 (HOECHST price)	2.52	6
Paracetamol	STERLING (U.K.)	RHONE POULENC (France)	3.24	2.76	85
Chloro-propamide	PFIZER (USA)	PLIVA (YUGOSLAVIA)	126.21	9.46	8
Tetracycline	PFIZER (USA)	HOECHST (W.GERMANY)	98.87	19.72	20
Aspirin	GLAXO (UK)	POLFA (POLAND)	1.16	0.99	85
Ampicillin	BEECHAM (Singapore)	BEECHAM (Singapore)	569.90	95.11	17

Source: UNCTAD, Case Studies in Transfer of Technology: Pharmaceutical Policies in Sri Lanka, June 1977.

Note: The operation of the transfer price mechanism in world trade, resorted to by the multinationals, is of profound significance. High transfer prices which bear no relation to production costs or internationally competitive prices are used to extort high profits incognito. They result in abnormally high material costs of production as shown in the accounts of the subsidiaries that are used to evade price and profit control policies of the local governments. They also enable the multinationals to show low paper profits in high-tax countries and high profits in low tax-countries.

that bacterial resistance in patients to tetracycline imported by the SPC was not due to bad quality but due to excessive dosage prescription by Sri Lankan doctors who, apparently, believed that SPC's tetracycline was not as effective. In fact, SPC imported the tetracycline from Hoechst and it was tested, both before and after encapsulation, by the Health Ministry.

In 1974, during a cholera epidemic, Pfizer refused to heed the Sri Lankan government's request to formulate badly needed tetracycline capsules from the bulk material supplied by Hoechst, and readily available in SPC stores. Sri Lanka had no option but to airlift expensive emergency supplies of formulated tetracycline. When the government, disgusted by the anti-national behavior of the foreign companies, decided to nationalise the foreign companies, the U.S. ambassador to Sri Lanka reminded the Prime Minister that the United States was the principal food donor to her country. The government promptly changed its mind. Also, a programme to locally manufacture 34 essential drugs was abandoned.

After the Jayawardene government came to power in 1977, the private sector was once again allowed to import drugs, along with the SPC, under brand names, to prevent the consumer being "tied down to types of drugs dictated by the State."

Thus ended Sri Lanka's experiment to introduce "rationality into the irrational world of drugs."

Distorted Pattern of Drugs Produced In India

In an UNCTAD study, prepared by the Jawaharlal Nehru University and the Indian Council of Scientific and Industrial Research (ICSI), on technology transfer in the Indian pharmaceutical industry, a comparison of the pattern of diseases and the pattern of drugs production shows "the inappropriateness of the drugs produced in India for catering to the needs of the masses." (6)

The Tables on the following pages present data on

- a) The pattern of deaths and illnesses as revealed by the number of patients treated in Indian hospitals and dispensaries during 1962-64, (pg.19), and
- b) The major drugs produced in India for treating such illnesses. (pg.20).

The Table on the pattern of diseases and deaths shows that infectious, parasitic and respiratory diseases are the major types of illnesses in India. But most of the drugs required to combat them are produced in very small quantities and the demand has to be met from imports. The Table on the pattern of drugs produced shows that of the 51 drugs marketed in India to combat the 3 major categories of disease, 28 have to be imported. Anti-malarials like primaquin and trimethoprim are not produced at all in India. Further, though chloroquin is produced in India its imports exceed local production although malaria is a common disease among the poor. Similarly,

even though cholera vaccine is being produced in India for over 40 years now, its indigenous production is inadequate during epidemics. And the production of vaccines against flu, mumps, measles and poliomyelitis is 'non-existent'. (6)

An analysis of 7,399 formulations, out of the total of 15,000 formulations, being marketed in India in 1972 by all large-scale units (accounting for 85% of total formulations production) and a few small-scale units showed that vitamin preparations accounted for 15% of the total number of formulations—"the largest single group of drugs marketed." (6). (See Table on page 22). Tonics, nutrients or "deficiency" drugs (9%), tranquillizers and sedatives (5%), expectorants (5%) accounted for another 19% of the total number of finished products sold. All these items, together accounting for over 34% of the total, are vigorously sold to the rich under popular trade-marks with high-pressure advertising and sales promotion campaigns. Most of the basic ingredients required for these preparations have to be imported. For example, in the case of cough syrups and tonics "none of the basic ingredients in these formulations is produced in India". (6)

CAUSES OF DEATH AND ILLNESS IN INDIA: 1962-1964

Cause	Cause as per cent of:	
	Deaths	Illnesses
Infectious and parasitic diseases	14.42	16.9
Diseases of respiratory system	13.37	11.3
Diseases of early infancy	13.34	0.4
Senility and ill-defined conditions	12.91	(14.55
Diseases of circulatory system	9.27	(
Diseases of digestive system	9.24	5.7
Allergic, endocrine, metabolic and nutritional diseases	8.65	1.1
Accident, poisoning etc.	6.83	14.1
Diseases of nervous system	4.67	11.4
Neoplasms (cancers)	4.20	0.8
Diseases of genito-urinary system	1.08	9.8
Pregnancy, childbirth, etc.	0.85	3.0
Congenital malformation	0.73	-
Diseases of skin, tissues etc.	0.33	10.8
Mental and psychoneurotic disorders	0.11	0.2
	100.00	100.00

Source: Compiled from data published yearly by Central Bureau of Health Intelligence, Directorate General of Health Services, Ministry of Health and Family Planning, Government of India.

Reproduced From: UNCTAD, "Case Studies in the Transfer of Technology, The Pharmaceutical Industry in India", U.N. 1977.

DISEASE PATTERN AND DRUG PRODUCTION

No.	Disease (1)	Drug (2)	Whether produced in India* (3)
I. Infectious and parasitic diseases:			
a)	Dysentery of all forms	Emetine hydrochloride Dehydroemetine Halogenated oxyquinolines Metronidazole Enterovioform Siosteran Diloxanide Furoate Ampicillin Cephalothin	yes yes yes yes yes no no no no
b)	Malaria	Chloroquin Amodiaquin Primaquin Triethoprim	yes yes no no
c)	Cholera	Prophylactic vaccine Chloramphenicol Tetracycline Furazolidine	yes yes yes no
d)	Parasitic infection of alimentary canal		
	Giardiasis	Quinacrine Piperazine	no yes
	Ascariasis	Piperazine Thiabendazole	yes no
	Enterobiasis	Piperazine Pyruvium pamoate	yes no
	Ankylostomiasis	Tetrachloroethylene 3pheniumhydroxy naphthoate	no no
	Tapeworm	Quinacrine Niclosamide	no no

* All products are marketed in India.

Contd...

DISEASE PATTERN AND DRUG PRODUCTION (Concl.)

(1)	(2)	(3)	
II. Respiratory system			
a) General illness	Aminophylline	no	
	Theophylline	no	
	Ephedrine	yes (small qty)	
	Phenobarbitone	yes	
	Adrenaline	no	
	Corticosteroids	yes (small qty)	
	b) Tuberculosis	Streptomycin	yes
		Isonicotinic acid hydrazide	yes
		Para amino salicylic acid	yes
		Thiacetazone	yes
Ethambutol		no	
	Pyrazinamide	no	
	Ethionamide	no	
III. Diseases of the central nervous system			
Sedative	Phenobarbitone	yes	
	Phentobarbitone	no	
	Thiopentone	no	
Tranquillizers	Potassium bromide	no	
	Meprobamate	yes	
	Chlorpromazine	yes	
	Diazepam	no	
Anti-convulsants	Amitryptline	no	
	Primidone	no	
	Hydantion derivs	no	
	Phenurone	no	

Source: Compiled from Central Bureau of Health Intelligence, Directorate General of Health Services, Ministry of Health and Family Planning, Government of India.

Reproduced From: UNCTAD, "Case Studies in The Transfer of Technology, The Pharmaceutical Industry in India," U.N. 1977.

ANALYSIS OF PRODUCTS OF INDIAN PHARMACEUTICAL INDUSTRY:1972

Sr. No.	Products (Group-wise)	No. of formulations in the market	% of total
1.	Vitamins - Multivitamins	308)	
	Vit. B. complex	406)	
	Vit. B. 12	126)	<u>1,134</u>
	Others	294)	<u>15.3</u>
2.	Tonics, nutrients or deficiency drugs		685 9.3
3.	Tranquilizers and sedatives		376 5.1
4.	Expectorants, cough syrups, decongestants		340 4.6
5.	Analgesics and antipyretics		296 4.0
6.	Antibiotics: Pencillin and salts	99)	
	Chloroamphenicol	155)	
	Streptomycin	82)	
	Tetracycline	115)	527 7.1
	Neomycin	28)	
	Others	48)	
7.	Anti-infectious: Sulphas	320)	
	Anti-TB Drugs	223)	
	Antidysentery	185)	
	Antimalarial	133)	
	Antifilarials	48)	
	Anthelminetics	66)	<u>1,068</u>
	Antileprosy	20)	<u>14.4</u>
	Antifungal	19)	
	Antiseptic	54)	
8.	Steroids and hormones		354 4.8
9.	Anti-histamines		151 2.0
10.	Antiacids		113 1.5
11.	Anaesthetics (local and general)		88 1.2
12.	Laxatives and purgatives		69 0.9
13.	Anti-inflammatory drugs		75 1.0
14.	Alkaloids		445 6.0
15.	Galenicals (crude drug extracts)		55 0.7
16.	Inorganic elements and compounds (excluding iron preparations)		146 2.0
17.	Sera and vaccines		49 0.7
18.	Enzymes		104 1.4
19.	Household remedies (dexture, gripe water, etc)		180 2.4
20.	Others		1,144 15.5
	Total:		7,399 100.0

Source: Compiled from product information given in Indian Pharmaceutical Guide 1972, 10th edition (Pamposh Publications, New Delhi.) Reproduced from: UNCTAD, "Case Studies", UN 1977.

While anti-infectious and antibiotic drugs account for 21% of the total, their production generally falls short of the quantities required to treat the widely prevalent diseases cured by them. (6)

An analysis of the value of drug formulations produced reveals the same pattern. In 1976, the total value of drug production in the country was Rs. 700 crores. Vitamins, tonics, health restoratives and enzyme digestants accounted for 25% of the total value of Rs. 700 crores, antibiotics 20%, anti-T.B. drugs 1.4% and sulphonamides 1.3%. (7)

The study concludes "that in the planning of drug production in India, the pattern of diseases is not given enough attention. Instead, transnational corporations have transferred technologies for the manufacture of products that are suited to the disease pattern of the western world to meet the demand originating from a relatively small section of well-to-do consumers in India. This has occurred because these "patent protected" and "branded" products earn a much higher profit margin than the generic products required by the poor." (6)

HEALTH OR WEALTH?

In our discussion on health and the drugs industry, we saw that the blind pursuit of profits by the drug firms conflicts with the basic health requirements and economic conditions of poor societies. We saw how the operations of the multinationals in Tanzania and Sri Lanka can have intolerably high social and economic consequences. We have also seen that modern drugs and medicines cover only a tiny fraction of the overall population of poor countries and that the multinationals, who are unduly guided by the profit motive, cannot meet the needs of a wider segment of the population.

In this chapter, we shall probe the widespread practice of freely selling irrational and downright harmful drugs, which are either banned or restricted (through appropriate statutory warnings) in the West, by the multinational companies in Third World countries. Valuable investigative work done by many individuals and organisations in different countries round the world has disclosed the extent to which these companies can go in their obsessive pursuit of profits. We shall restrict ourselves largely to Indian examples, but most of them, and many more, are applicable to other developing countries also.

These examples tell a vivid tale of the criminal neglect by the drug companies of the wider health concerns of individuals, of systematic propaganda that either exaggerates, or lies, about the good effects on health of many products while ignoring their adverse side-effects and potential hazards. There is also a growing suspicion that the people of the developing countries are in fact being used as 'guinea pigs' for extensive testing of certain drugs which is now virtually impossible to do in the developed countries with strict drug control laws and organised consumer protection movements.

For example, recent reports from the West state that a large multinational has administered Depoprovera - a long term contraceptive - to 7,000 women in Bangladesh and is keenly awaiting the results. The Food and Drugs Administration (FDA) of the U.S. banned the drug following its carcinogenic effects on beagles. It has also banned the distribution of Depoprovera by U.S. aid agencies abroad. (1)

There are many reasons why these blatant malpractices continue unabated in most developing countries.

1. Ineffective, inadequate and corrupt drug control machinery in most developing countries facilitates easy introduction of harmful drugs in their markets.

Every State in India has its Food and Drugs Administration. With a few exceptions, most of these are badly managed with poor testing facilities and lack of trained personnel. They are also subject to administrative interference and political pressures: the bane of the entire public sector in India. Many of its members "are bought over or infiltrated by large multinational corporations".(2) Further, the policies of different FDAs are often contradictory leading to confusion and chaos that is quickly capitalised by these companies.

For example, when the Maharashtra FDA banned Amidopyrine (an analgesic banned in over 20 countries due to its harmful effects on the production of blood and potential carcinogenic effects), the multinational company concerned obtained a court's stay order allowing it to market the drug on the ground that the same products were allowed to be sold by the other FDAs in their respective States.(2) In August 1980, an estimated 33 formulations containing amidopyrine were being manufactured and sold by some 20 manufacturers in the country without any warning of its dangerous side-effects. Some of these better-known firms are Sandoz, Ciba-Geigy, Suhrid-Geigy, Unichem, Ethnor, Themis and Indon. The Drug Controller of India had issued an order in January 1979 asking the manufacturers to gradually withdraw amidopyrine formulations from the market. But the notification did not carry any specific deadline and the companies, "reluctant to lose their market share ---- have merrily continued to produce and market amidopyrine-containing preparations without even an additional warning about the drug's side-effects." (3)

Apparently, Sandoz and Ciba have, rather belatedly, developed substitute products but they have not been able to produce and market them as the Government has not yet issued a fresh licence for these "new articles."

Why can't the Drug Controller ban amidopyrine with immediate effect or, at the least, set a deadline for its withdrawal? According to one view, 'partly' because it should be first withdrawn from the Indian Pharmacopoeia! (3)

Another recent example is a list of essential drugs prepared by the Tamil Nadu government for its medical hospitals. A number of analgesics, like phenacetin, amidopyrine and analgin in oral dosage form, found on this list, were considered "harmful combinations" and had been disallowed by the Central Government. (See Chapter 4, page 48 for a list of these items) These examples highlight the utter mismanagement and ineffectiveness of the drugs control administration in India.

2. The enormous power and influence wielded by the drugs industry in the developing countries enables it to stall, tone down and even overcome the orders and regulations proposed by several organisations, committees and individuals.

For example, in India, various committees suggested a ban on the sales of tetracycline syrups and steroids in asthma remedies but these have not yet been approved by the Drug Controller. (2)

Another example is the proposal to limit the minimum and maximum quantities of vitamins in tonics and other preparations, according to the norms laid down by WHO. The Union Government had issued a notification as far back as July 1978 compulsorily limiting the content of vitamins, but it has not yet implemented it. Since October 1978 the implementation of the notification has been extended 13 times. The latest extension is upto 31 August 1981. (5)

3. The pharmaceutical industry in developing countries does not have to face lawsuits and pay damages to the affected parties as it has to do in the developed countries. The principal reason for this is the poor level of consumer awareness and absence of well-organised consumer protection movements. And, of course, the ability of the large firms to resort to stalling tactics and tamper with the legal processes in developing countries must not be underestimated.
4. In a situation like this, one would expect the local doctors to play a critical social role in controlling the excesses of the drug firms. But we have already seen the 'close' ties between the medical profession and the drugs industry in some developing countries like Tanzania and Sri Lanka in Chapter 2.

Charles Medawar, Director of Social Audit Ltd., London, a non-profit, action-research group, in his study "Insult or Injury?" based on field research has this to say: "Probably the single most important part of drug promotion in the third world is sampling - that is giving doctors free samples of companies' products. In India, according to the Hathi Committee (1975), the scale of sampling has been 'lavish' and has 'degenerated into a rat race among manufacturers.' Sampling has a particular significance in India since the large majority of GPs dispense the drugs they prescribe and may therefore charge their patients for drugs they have acquired free ... We are reliably and widely informed in India that sampling abuse had enabled some doctors to acquire 'literally roomfuls of drugs' which were later sold to wholesalers. We heard also of doctors who had accepted substantial gifts from drug companies - including reportedly refrigerators, air conditioners and cars. What was not clear was the extent to which corrup-

tion had reached the medical profession as a whole - as opposed to a few malpractitioners. One senior marketing executive we spoke to - who had every incentive to play down the situation - said after some thought that he considered the number of doctors who were honest to be 'a microscopic minority'. Others thought this more or less exaggerated..." (13)

Dr. Zafrullah Chowdhury, who runs the People's Health Centre serving a rural population of 110,000 near Dacca, Bangladesh said in an interview in Washington D.C. with Jonathan Ratner and William Taylor of the Multinational Monitor: "Many doctors have a direct financial interest in the status quo. The foreign companies have reached an agreement with the government that they can dispense 10 percent of their total production as samples. But they don't give free samples to every doctor. Instead, they single out the "top" hundred, those that can look smart, doctors who will wear a tie even in the hot summer. Yes, only the very prestigious doctors. The doctors then sell the samples." (6)

"There is one more area of direct financial interest by doctors. As I mentioned earlier, several of the multinationals have local shareholders. Take the case of Pfizer, which is partially owned by Bangladeshis. There are only 45 shareholders in the entire country, all private capital. Of these 45, 44 are either doctors or doctor's wives. ICI is a similar case." (6)

Besides, the general practitioners mostly depend on the promotional literature of the large companies to keep abreast of the latest pharmacological developments rather than on medical journals. Needless to add, most doctors do not possess the competence to critically evaluate the chemical structure and therapeutic/pharmacological dynamics of new drugs and their combinations in diverse therapeutic groups. Thus, the doctors are largely dependent on the companies' promotional campaigns for vital pharmacological information. (See Chapter 4: Who Needs Brands, Pg. 49)

"A survey conducted in Delhi showed that 80-80% of the general practitioners after leaving medical college depended solely on drug representatives of the pharmaceutical companies for their information" on the latest pharmacological developments, according to Dr. D.S. Saksena a cardiothoracic surgeon in Bombay. (7).

A large number of people in developing countries resort to self-medication for a variety of diseases and ailments. This is coupled with the fact that the chemist shops are generally not manned by pharmacy graduates, as for example in India. The dangers of this practice are obvious: it can lead to improper

dosages and inappropriate or even harmful drugs being consumed by the people.

But the drug companies in developing countries not only accept widespread self-medication, but encourage it. A U.S. report on self-medication in Latin America states that the companies defend this hazardous habit by arguing that "a strict system of prescription control would force people to spend their health money on doctors with nothing left over to buy the drugs the doctor prescribes." (8) It is obvious that rampant self-medication in developing countries suits the vested interests of the multinationals.

Below we shall examine specific cases, mostly from India, of the "double standards" in the marketing of irrational and even harmful drugs, of different categories, by the larger firms, particularly the foreign ones.

ANTIBIOTICS

In the late 1960s, it was found that the antibiotic drug chloramphenicol or chloromycetin causes a rare but fatal disease called aplastic anaemia. (2) This disease results in the reduction of blood-cell production by bone-marrow and ultimately it completely stops producing blood leading to death.

In the USA, the FDA limited the production and marketing of chloramphenicol in the light of its widespread abuse. It also made it statutory for companies to issue warnings of the likely hazards of this drug. And its use was restricted to typhoid and a certain type of flu caused by bacterial infection. (9)

But in India, this antibiotic is widely used for common disorders like amoebic dysentery and the common cold. This abuse carries the danger of the typhoid germs developing resistance to the drug which then becomes ineffective when administered to a typhoid patient. In Mexico, during a typhoid epidemic, 2,000 typhoid patients treated with chloramphenicol died. In India, over a 100 strains of typhoid germs were found to be resistant to 3 or more antibiotics. (9)

Further, intramuscular injections of chloramphenicol have no therapeutic effectiveness. (1) This warning on the product packs is also statutory in the U.S.A.

But in India, injectable chloramphenicol formulations are easily available on the market without any warning. (9)

In Bangladesh, in 1979, a combined injection of penicillin and streptomycin, a potentially harmful drug combination, was very popular with the unqualified practitioners, who even prescribed it for cuts and bruises, as well as for every sort of infection. (10)

It could be easily bought over the chemist's counter. Dr. Martin Schweiger, who works in the rural villages, outlines the dangers: "The biggest problem is that there is high incidence of TB in the community and streptomycin is a front-line drug for its treatment. If patients have been, as they are, exposed to streptomycin when they are in the pre-clinical stage of TB, it means when the disease develops clinically it will be untreatable by one of the main-line drugs. Patients are very likely to die as a result of this. Bangladesh is not rich enough to start rushing into all the second-line drugs because the first one has been wasted." (10)

"World antibiotics experts, too, stress that streptomycin should be kept in reserve principally for the treatment of tuberculosis, and indeed, the Bangladesh government has moved to ban these combinations next year. There has been such a ban in the United States for ten years, yet the company that dominates combined antibiotics sales in Bangladesh is American: Pfizer." (10)

"In response to our inquiries about its continued use and promotion, Pfizer's representatives in Bangladesh and in the USA said that the drug is cheap and effective and that they operated within the law of the land; they denied its unqualified use. But, as Dr. Martin Schweiger says, 'The law may be one thing; ethics are quite another'". (10)

Another antibiotic with potential hazards is tetracycline. If this drug is administered to children before the formation of all their permanent teeth, their teeth develop a yellow-grey stain with greater susceptibility to decay. (2) It also gets incorporated in the child's bones as calcium orthophosphate which may be harmful to bone growth. (1) In Britain, it is recommended that tetracycline should not be used for children upto 12 years of age.

In the West, pediatric formulations of tetracycline are banned and the world leader of this product, a western multinational, stopped its distribution there. But this same product is marketed by this same company all over the Third World, including India, in large quantities, for children of all ages. (2)

HORMONES

In 1942, the German-Israeli gynaecologist, Dr. Bernhard Zondek, described his discovery for "hormonal treatment of amenorrhoea" or absence of menstruation, in the Journal of American Medical Association. The principle was simple: a woman who misses her period, due to reasons other than pregnancy, would menstruate if administered female hormones viz. oestrogen and progesterone. (11)

In the 1950s and 60s, synthetic female hormones were widely used to carry out "hormonal pregnancy tests" (HPTs) to decide whether a woman with delayed menses was pregnant or not. (1)

In 1969, Roussel of the U.K. withdrew its product named Amenorone from the British market when statistical analysis showed a significant correlation between HPTs and foetal abnormalities. (11)

In 1975, these sex hormonal preparations were banned in the U.S.A. by the FDA which did not find sufficient evidence of their effectiveness and had the following to say:

"Sex hormones should not be used in early pregnancy for any purpose. Such use of these hormones may seriously damage the foetus --- including heart and limb defects."(11)

An empirical study carried out by Dr. B. Palaniappan of Kilpauk Medical College, Madras on 160 women (20-40 years old), who had missed their periods ranging from 35 to 40 days, showed that HPT drugs do not induce 'withdrawal bleeding' in all women who miss their periods and are not pregnant. He came across the case of a woman from Madras, who had taken this drug in early pregnancy, in order to terminate it. Instead, she gave birth to conjoined twins: a monster known as Cephalo Thoracophagus in the medical jargon.(11)

These hormones can also lead to an unintended termination of pregnancy.

In India, till 1979, there were 16 HPT drugs marketed by several foreign companies, freely prescribed for pregnancy tests by doctors to an estimated 180,000 women every year, (11) easily available over-the-counter at drugstores without prescription and without any warning of their potential hazards. Following an uproar in certain sections of the press, the companies were compelled to carry warnings on their products which were then allowed to be marketed despite insufficient evidence of their effectiveness and with far more safer alternatives available.

Another category of sex hormones with dangerous side-effects are the anabolic steroids which are analogues of the male hormones. The use of these steroids was a craze in the West when they first appeared; they promised the consumer greater weight and muscle mass. With prolonged use, it was discovered that they impart male characteristics to females, result in loss of libido in both males and females and genital atrophy. (1) Children were found to be more vulnerable to these adverse effects.

The use of anabolic steroids is restricted in the West, but freely marketed in Third World countries with impunity by the multinationals. In India, their preparations are sold as "growth tonics" for infants and children. (2)

John S. Yudkin's report on Tanzania, "Provision of Medicines in a Developing Country", discussed in Chapter 2, found that anabolic steroids are promoted in the African MIMS as treatment for malnutrition, weight-loss and kwashiorkor (brand: Decadurabolin, company: Organon); as appetite stimulants (brand: Winstrol, Winthrop);

for exhaustion states (Primobolan Depot, Schering; Dianabol, Ciba-Geigy) and for 'excessive fatiguability' in school children (Disnavit, Ciba-Geigy).

Similarly, in the case of female sex hormones, the indication given for Primodos (Schering) — a high-dose oestrogen - progestagen combination — since 1974, in Britain, is for the diagnosis of secondary amenorrhoea of short duration for women who are not pregnant. In the African MIMS, Primodos as well as Menstrogen (Organon), Norlutin (Parke-Davis), Paralut (Wallace), and Discron (British Schering) is prescribed for diagnosis of pregnancy. The package insert of Primodos does not make any mention of the risks of teratogenicity (i.e. foetal malformation).

ANCOLOXIN

A study by Charles Medawar of the Social Audit Ltd., U.K., titled "Social Audit - Insult or Injury", enquired into the marketing and advertising of British food and drug products in developing countries. He found that Ancoloxin, an anti-nausea drug made by Glaxo, was sold in India without any warning of its hazards to pregnant women. This warning is of critical importance: women in early pregnancy use anti-vomiting drugs as a cure for morning sickness. In the USA, this drug carries statutory warnings against its prescription to "women who are or may become pregnant". But detailed product literature of Ancoloxin in India "did not hint at the need for special caution in pregnancy or the possibility of teratogenicity". (12) Following this disclosure, the managing director of Glaxo in India, J.S. Khambata, had to admit to his company's double standards, albeit, in extremely mild words: "an administrative failure — the only one that has to some extent besmirched our proud record". (13) The wide range of similar "failures" all over the Third World clearly indicate that these are not mere "administrative" failures, but mostly moral failures; and failures of this type are not accidental oversights, and therefore exceptions, but seem to be part of a systematic attempt to manipulate and exploit "human frailty" and ignorance.

ANALGESICS

Analgesics, or 'pain-killers', are widely used by a large number of people in almost every country. They are easily available and the users generally make the purchase decision independently, without resorting to the doctor.

The basic, essential-ingredient of every analgesic is aspirin (acetylsalicylic acid) which relieves pain, lowers fever and also has anti-inflammatory properties. Tablets containing aspirin alone are very cheap and highly effective.

However, in India, various products combining aspirin with other analgesic ingredients, that are either harmful or are used in such low quantities that they are therapeutically ineffective, have been

freely sold. One common ingredient combined with the basic aspirin component of analgesics is phenacetin.

There is sufficient evidence to show that its "prolonged use, or use in large doses, may cause kidney damage (papillary necrosis and pyelonephritis) resulting in death." (14) The drug companies justify its use in analgesic combinations under the garb that it reduces the toxic effect of aspirin. But clinical studies show that phenacetin exposes the patient "to a much wider spectra of toxicity which in case of a pre-existing kidney disease, may even be fatal." (14) Prolonged use of phenacetin is also found to cause diseases of the haemoglobin in the blood such as methaemoglobin-aemia, sulphaemoglobinaemia and, in rare cases, haemolytic anaemia. (14)

Phenacetin has been withdrawn in the U.S.A. over 20 years ago but continues to be widely used in India as for example in the form of A.P.C. (aspirin, phenacetin, caffeine) formulations (1) marketed at present under 19 different brand names. (See Chapter 4, Pg. 52).

Caffeine, found in tea and coffee, is not an analgesic either directly or indirectly. It is a cerebral stimulant that induces wakefulness and reduces fatigue. But a study, by 3 eminent Indian pharmacologists, of the major analgesic combinations available in 1977, in India, showed that none of them contained even 60 milligrams of caffeine (a dose equivalent to a cup of tea) necessary to provide the "cerebral stimulation". The pharmacologists concluded that: "The therapeutic presumption is ridiculous: and adding one more drug is a form of medical gimmickry." (14)

A close look at the Table on the next page will tell you the whole story.

As can be seen in the Table, the price of the different tablets ranges from 6 to 24 paise. Against this, a tablet containing aspirin alone cost only 3 paise in 1977. This clearly shows that in their blind pursuit of profits, the companies do not hesitate to actively promote and peddle irrational, ineffective and even harmful concoctions of mass consumption drugs.

The authors of the study summed up the situation perceptively:

"Why is the patient asked to pay more for preparations which include a more toxic substance like phenacetin, and for six of the brands to which are added other ingredients in less than their effective doses? This is not only a therapeutic facade but also economic exploitation of the patient." (14)

POPULAR BRANDS, AVAILABLE OVER THE COUNTER, OF COMBINATIONS
OF ASPIRIN WITH PHENACETIN, CAFFEINE, CODEINE AND OTHER DRUGS.

Aspirin Preparation and Manufacturer	Aspi- rin (mg)	Phena- cetin (mg)	Caff- eine (mg)	Code- ine (mg)	Other Ingredients Name	mg.	Approx. price per tablet in paise
1. Aspro-microfined, Nicholas	350		20*				8
2. Apistin, Khandelwal	225	1507	30		Chlorpheni- ramine M	2*	6
3. Codopyrin, Glaxo	250	2507		8			14
4. Cafiaspirin, Bayer	300		30				6
5. Micropyrin, Ind. Schering	350		20*				8
6. Micropyrin-C Ind. Schering	350				Vit. C	25**	14
7. Anacin, Whitehall G.M.	389		16.2*		Quinine S	8.1**	7
8. Dristan, Whitehall G.M.	230	977	16*		Phenyleph- rine Phenindamine Tartarate-Vit.C	5 10 20**	18
9. Apidin, I.D.P.L.	277	1627	32	6.5*			12
10. Capremin, Glaxo	230	1607	30		Phenylephrine ChlorpheniramineM	10 2*	20
11. Verindon, INDON	250	2007	1.5**		Phenobarbital	16	10
12. Colithen-CPA, Fairdeal	230	1507	30		ChlorpheniramineM	4	15
13. Daprisal, S.K.F.	160	1607			Dexamphetamine S Amylobarbitone	5 32	18
14. Vaganin, Warner	250	2507	32	7*			24
15. Codalgin, Treatment H.P.	260	2607		8	Atropine S Phenobarbitone	0.3 20	17

† Inclusion not recommended, because of high toxicity.

* Quantity less than the minimum required to be effective.

** Very low quantity.

SOURCE: The Times of India, August, 1977.

HYDROXYQUINOLINES (VIOFORM)

This group of drugs is commonly used in anti-diarrhoeal remedies and these drugs are freely sold over-the-counter without prescription in India e.g. Mexaform tablets of Ciba-Geigy, a Swiss multinational, which almost wholly commands the Indian market. As early as 1975, in Japan, a link was first established between enterovioform and brain and eye damage. As many as 30,000 Japanese consumers of this drug suffered this damage. After this drug was banned, such disorders disappeared completely. (15) In early 1981, a Japanese court, definitively concluded that several people had suffered from partial or severe forms of blindness (myelo-optic neuropathy) because they had consumed enterovioform and ordered the companies to pay them compensation. (1)

For years it had been promoted as an ideal "holiday anti-diarrhoeal". (16) In 1977, following the distressing reports from Japan, a leading medical journal of the U.K., 'Lancet', had this to say, rather belatedly: "The time has come to halt the free sales of clinoquinol (i.e. enterovioform) and similar drugs for vague intestinal ailments and to demand good evidence before their use for other purposes is allowed to continue." (15)

"The scientific evidence for the value of clinoquinol in the treatment or prevention of travellers' diarrhoea is scanty." (15)

By 1977, the drug was already banned in Japan, Norway and Sweden and available on prescription only in West Germany, France, Denmark and Finland.

But today, this drug continues to be widely sold in India with warnings of their dangerous side-effects written in fine print. (1) After such hard evidence of their doubtful utility and definite potential for disastrous damage, the continued production and distribution of this drug on a mass scale has no justification.

It is a clear example of the criminal neglect of the wider health problems of the people by the entire health establishment - the industry, the doctors and the government - of the country.

In 1977, Dr. P.C. Pandiya of Jaipur Medical College and the then President of the Pharmacy Council of India, along with Drs. J.S. Bapna and S.K. Patni of University College of Medical Sciences, New Delhi cautioned against the widespread abuse of enterovioform and other similar preparations, so widely prevalent in India, in the following words: "The Indian brand of 'Mexaform' contains two more drugs (besides iodochlorohydroxyquinoline the basic drug) — phenquone and oxyphenonium — and has come to be used not only due to traveller's diarrhoea but diarrhoea of all descriptions including that due to indigestion, ---". (17) (Bracket inserted by me)

They further observed that the dramatic relief brought about by Mexaform was not due to its basic ingredient viz. iodochloro-hydroxyquinoline, but due to "oxyphenonium which reduces the spasm of the intestines and bowel movements and thus markedly reduces abdominal pain and discomfort." The basic drug "has to be taken for some time before it is effective. With some individuals it (i.e. Mexaform) has become a habit or even a panacea of all abdominal ills." (17) (Bracket inserted by me)

They concluded that the widespread abuse of Mexaform and other similar drugs to check non-specific diarrhoeas and abdominal discomforts "has to be viewed seriously in the light of the reports on the toxic action of iodochlorohydroxyquinoline". (17) They suggested that the free distribution of these drugs should be restricted and they must be sold on prescription only.

THE CRAZY WORLD OF TONICS

'Health' tonics are a craze with the affluent in the cities with their supposedly hectic, energy-consuming life-styles. Feeling tired? Pop a pill or gulp down a spoonful and it will keep you going (nobody knows where!).

The most commonly used tonics are multi-vitamin preparations with highly excessive quantities of vitamins.

Incremin C, the famous growth tonic with the Giraffe logo, contains an important amino acid lysine which the human body cannot synthesise by itself. However, a teaspoon of Incremin contains only about 300 milligrams of lysine when just a handful of peas contains about 1800 milligrams of lysine. The advertising slogan that Incremin turns "extra eating into extra growth" is medically unsubstantiated and at best a half-truth. The quantities of vitamin constituents of Incremin are absurd: 10 times more vitamin B1, 25 times more vitamin B12, 2 times more vitamin B6 than required by the body daily. (18)

The daily requirement of the human body of vitamin C is about 50 milligrams, of vitamin B1 one milligram and some others in minute quantities of a few micrograms. Against these well-established norms, most tonic preparations contain between 10 to 50 times the minimum requirements (19) which are simply excreted away by the body - a colossal waste of valuable nutrients in a poor country. Further, most vitamins are needed in small amounts to stimulate the processes of normal metabolism, they are not energy-giving in themselves.

It is almost certain that the high-potency multivitamin formulations consumed by the well-fed are almost wholly rejected by the body. For example, the daily requirements of vitamin C can be obtained from a single fruit or a salad helping. Vitamin A, supplied by green, leafy vegetables, is stored in large amounts

by the body for proper vision. Vitamin D is naturally synthesised by the skin from daily sunlight. Despite all these simple facts, the craze for 'health' tonics continue unabated. (19)

Why? Manohar S. Kamath in his article in The Daily Magazine provides the answers:

"The real culprits behind the 'tonic craze' are the manufacturers of such formulations. The principal reason for their hard selling of such products is the fact that the tonics and vitamins fall in 'category four' of the Drugs Price Control Act, which means that there is no limit on profits made on these preparations ---. With easy pickings and a readymade market, no wonder then that every new company entering the pharmaceutical world wants to market its own brand of tonic rather than any life-saving drug!" (19)

Explaining how the 'tonic craze' is the result of systematic campaigns of the large companies, he says:

"The first part of the plan was the mounting of an intensive sales campaign to influence doctors on the need for tonics in their day to day practice. This was followed by free sampling" (19)

"The other part of the marketing gimmickry in selling tonics was by directly advertising in the mass media, to catch the public eye. Slogans like "Do you feel tired at the end of the day? You need ---". Or "A woman needs iron every day" gradually made a deep impact on the people until many were psyched into believing that they could not do without a tonic." (19)

Waterbury's Yellow Label Tonic, a brand leader in the Indian tonics market, contains only 3 milligrams of iron per teaspoon just 1/10 of which may be absorbed by the body. The Indian Council of Medical Research (ICMR) recommends at least 10 milligrams for women. The producer claims that this tonic stimulates appetites and builds bodies. But chemical analysis has revealed that it has 10% alcohol content which is the real appetite-stimulant! (18)

We have noted that these tonics are not consumed by the poor but mainly by the relatively rich whose ordinary diet adequately meets their vitamin and other requirements. In recent years, evidence has grown that the excessive vitamins may not simply be discharged by the body but may even cause severe disorders. Prolonged consumption of excessive vitamin C may form kidney stones, excessive vitamin A may cause diseases of the hair, skin and liver and vitamin D in excess may cause disorders of the kidneys and bones. (19)

And the consequences of prescribing expensive, irrelevant vitamin preparations to the poor can assume monstrous dimensions, as the following experience of a medical worker in Bangladesh shows:

"Every prescription we saw written out -- always included a vitamin preparation as well. I remember once when our gardener came to us with a list of drugs the doctor had written out for him when his child had a discharge from the ear - it included, not one, but three antibiotics, and three vitamin preparations. That was going to cost him several hundred taka (and the average wage in Bangladesh is 8 taka a day), but he was going to find it. He was going to borrow it, he was going to steal it - because his child was sick". (10)

Vitamin tablets and injections are "big sellers" in Bangladesh accounting for at least 25% of the total drugs sales and regarded as "good medicine." Dr. Martin Schewiger, a health worker in the rural areas of Bangladesh, has this to say regarding the vitamins craze in that country:

"The biggest single problem is malnutrition and that is not treatable by drugs at all. It is treated with food. If we give tablets, the feeling may very well be: "We can't remember all the junk the health workers have just told us, but these tablets three times a day are all we need" -- and this may have written the death sentence for a lot of children." (10)

Take this further example from South-East Asia. In the U.K., Sanatogen is marketed as a 'nerve tonic' for old women who believe in its doubtful ability to tranquillise. But Sanatogen Powder is marketed to students in Malaysia who believe in its ability to stimulate their minds. "Worried about exams?" says the advertisement. Sanatogen will give you "greater energy and concentration". Can a drug both stimulate and sedate? (20)

Thus, the sheer irrationality and deliberate exploitation of consumers through this sinister "tonic racket" is obvious. The fact that many such 'rackets' continue unabated is a measure of the enormous influence and power of the large pharmaceutical corporations not only in India but in many other countries, particularly the developing ones.

More than 20 years ago, the following words were spoken before the Kefauver Committee hearings on drugs in the U.S.A:

"The incidence of disease cannot be manipulated and so increased sales volume must depend at least in part on the use of drugs unrelated to their utility or need, or in other words, improperly prescribed. Human frailty can be manipulated and exploited and this is fertile ground for any one who wishes to increase profits. The enormous sales of so-called tranquillisers are only a small part of the crop reaped from this ground. The pharmaceutical industry is unique in that it can make exploitation appear a noble purpose." (21)

WHO NEEDS BRANDS?

One of the most sensitive issues in the drugs industry is that of brand names for its products. It is not difficult to see why: brands lie at the very foundation of the monopolistic market position of large companies, particularly the foreign companies.* The drugs industry is characterised by strong product and promotional competition rather than price competition. Every large manufacturer tries to create strong market preferences for his products by means of "high-pressure" advertising and promotion campaigns aimed at generating long-lasting brand preferences. These preferences blunt the edge of price competition enabling a particular producer to maintain high prices as well as a high sales volume. (For a detailed discussion on the nature of competition in the drugs industry see Chapter 8, pgs. 87-90)

The Meffauer Committee (87th US Congress hearing on Monopoly and Anti-trust (Drugs) 1961) reported that innumerable branded products were being sold at prices ten times higher than their equivalent generic products.** In 1970, in the UK, a small British manufacturer was selling the generic equivalent of Librium (a patented, branded tranquilliser sold by Hoffman-La Roche) at prices 25% lower than Roche, but its market share for this product was barely 3%. In Italy, prices even 30% lower could not make any dent in the 80% market share of Roche. And, in India 1972, the selling price of Librium was about Rs.16/- per 100 tablets when generic equivalents marketed by small producers cost only Rs.1.50 per 100 tablets. (1)

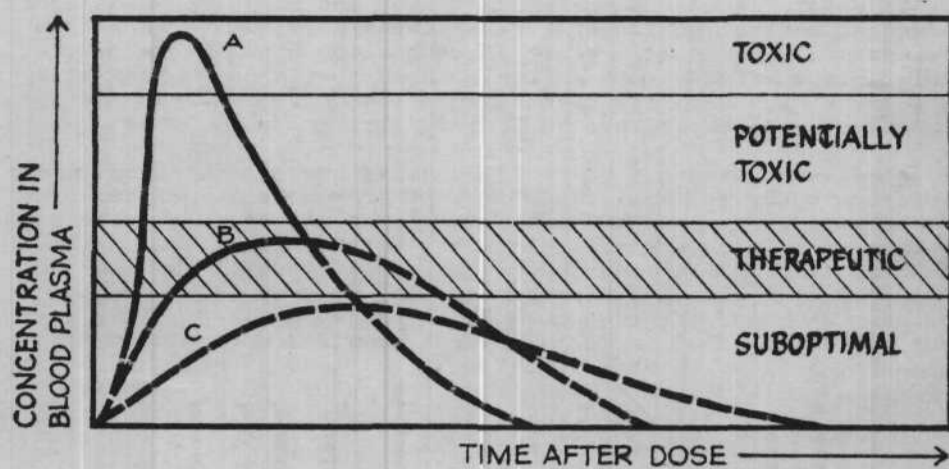
The Table on pages 40-41-42 compares the prices of some important drugs sold in India under brand names with that of their generic equivalents. The Table clearly shows that (a) the branded drugs are more expensive than their equivalent generic products for all the 8 items covered here and (b) the maximum brand prices range from 102% to 158% of the maximum generic prices of these 8 listed drugs. (2)

* A "foreign company" in India is defined as a company with foreign shareholding exceeding 40% of the total share capital. However, in this report, the term "foreign company" generally includes companies with some foreign shareholding even if it is less than 40% except where otherwise specified.

** Generic name is a commonly accepted name of a drug e.g. Aspirin. Brand name is a proprietary name of a particular company e.g. Aspro of Nicholas. Chemical name describes the chemical structure of the drug compound e.g. 'Acetylsalicylic Acid'.

Thus, it is not surprising that the multinationals are against the very concept of generic names for their formulations. The industry's arguments for brand names are mostly exaggerations and distortions of the relevant facts. Let us closely examine some of the important ones.

1. The problem of 'bio-availability': The case for generic names of drugs assumes equal patterns of bio-availability. This is an untenable assumption, according to the larger pharmaceutical firms.



Type of variation of bio-availability of drug formulations, depending on the nature of auxiliary ingredients, particle size and method of formulation. All 3 drug formulations, A, B, and C, release the same total dose into the bloodstream, but drug A is released so quickly that it reaches toxic levels, while drug C is released so slowly that it never reaches the level at which it has any effect. Only drug B is medically useful.

Source: UNIDO, Monograph No. 10, *Appropriate Industrial Technology for Drugs And Pharmaceuticals*, Pg. 23.

Bio-availability is the rate at which a drug's active ingredients are released and absorbed into the bloodstream in order to perform their therapeutic actions effectively. Even if two products are chemically identical, they need not be clinically or therapeutically equivalent. (See Chart above). Their pharmacological action can get significantly altered in the process of formulation.

COMPARATIVE PRICES OF IMPORTANT PRODUCTS SOLD UNDER GENERIC NAME VS. BRAND NAME

Sl. No.	Name of the Bulk Drug	Product Marketed (Name & Composition)	Whether Generic Name or Brand Name	Marketed by	Pack	Price	Price Per Unit (Rs.)	Maximum Brand Price % Maximum Generic Price (%)
1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
1.	Tetracycline Hcl.	Tetracycline caps.(250 mg)	Generic	IDPL	10x10	47.88	0.479	121
		Achromycin caps.(250 mg)	Brand	Cynamid	4	2.32	0.580	
		Hostocycline caps.(250 mg)	Brand	Hoechst	10x10	48.80	0.488	
2.	Ampicillin Trihydrate	Ampicillin caps. (250 mg)	Generic	Smith Street	10	9.94	0.994	158
		Ampillin caps. (250 mg)	Brand	Lyka	16	22.27	1.392	
		Roscillin caps. (250 mg)	Brand	Ranbaxy	4	6.30	1.575	
3.	Analgin	Analgin tabs. (0.5 gm)	Generic	IDPL	10x10	18.27	0.183	109
		Novalgin tabs. (0.5 gm)	Brand	Hoechst	10x10	20.00	0.200	

Contd

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	
4.	Chloramphenicol	Chloramphenicol caps. (250 mg)	Generic	Pharmakab	100	35.00	0.350	111	
		Chloramphenicol tabs. (250 mg)	Generic	Mac Labs.	12	3.53	0.294		
		Enteromycetin caps. (250 mg)	Brand	Deys Medical	12	4.21	0.351		
		Paraxin caps. (250 mg)	Brand	Boehringer Knoll	10	3.50	0.350		
		Chloromycetin caps. (250 mg)	Brand	Park-Davis	12	4.63	0.390		
5.	Benzathine Penicillin G.	Benzathine Penicillin G (6 lacs, 12 lacs, 24 lacs)	Generic	HAL	6 lacs	2.03	2.030	107	
					12 lacs	3.66	3.660	104	
					24 lacs	6.54	6.540	102	
		Penidure - LA 6, LA 12, LA 24 (6 lacs, 12 lacs, 24 lacs)	Brand	John Wyeth	6 lacs	2.17	2.170		
					12 lacs	3.80	3.800		
					24 lacs	6.70	6.700		
6.	Prednisolone	Prednisolone tabs. (5 mg)	Generic	Deys Medical	10	1.82	0.182	118	
		Wysolone tabs. (5 mg)	Brand	Wyeth Labs.	10	2.15	0.215		

contd....

COMPARATIVE PRICES OF IMPORTANT PRODUCTS SOLD UNDER GENERIC VS. BRAND NAME (Concl'd.)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
7.	I.N.H.	Isoniazid tabs. (100 mg)	Generic	Albert David	1000	29.74	0.030	103
		Isoniazid tabs. (100 mg)	Generic	Days Medical	1000	29.58	0.030	
		Isoniazid tabs. (100 mg)	Generic	Haffkine	1000	26.62	0.027	
		Isonex tabs. (100 mg)	Brand	Pfizer	1000	30.38	0.031	
8.	Iodochlory- hydroxyquino- line	Iodochlorydro- xyquin tabs. (250 mg)	Generic	Haffkine	100	7.88	0.079	114
		Entero-Vioform tabs. (250 mg)	Brand	Ciba- Geigy	50x10	42.08	0.084	
		Enteroquinol tabs. (250 mg)	Brand	East India	20	1.84	0.090	

SOURCE: Indian Pharmaceutical Guide 1980.

Reproduced from: "Generics' Policy" by P.K. Ghosh, The Economic Times,
15 April, 1981.

There are at least some 32 factors (particle size and shape, nature of the inert ingredients, pH i.e. hydrogen ion concentration level, type of coating, flavouring, etc.) that can affect bio-availability.

It is true that bio-availability is a genuine problem. But the number of drugs for which this is so is highly limited. A study of antibiotics by a non-profit organisation called the Council on Economic Priorities (CEP) found no evidence of bio-availability being a real medical problem for injectable medications. (3) In an attempt to establish the magnitude of the overall problem of bio-availability, a report was prepared by a panel set up by the Office of Technology Assessment (OTA), a congressional investigative body of the USA. The panel concluded that about 85 to 90% of chemically equivalent products presented no problems of therapeutic equivalence and could be used interchangeably. (3) Studies in the U.K. have shown that only 42 drugs present the problem of bio-availability. (1) Moreover, the Hathi Committee stated in its report that bio-availability can even vary from batch to batch of the same manufacturer. (4)

We can conclude in the words of Dr. Sanjaya Lall, an Oxford scholar of transnational corporations, who said in an UNCTAD study of the pharmaceutical industry that the bio-availability argument "enables the companies to get away with a great deal of profitable obfuscation". (1)

2. Brands provide incentive for R & D. for marketing new drugs: The Chairman of Pfizer Ltd., India, Mr. S.V. Pillai, states in his annual report to the shareholders that "almost all major new drug discoveries are introduced under brand names and no company which has a new research product will be willing to market it under a generic name". In other words, the industry wants sufficient rewards, in the form of high prices and high sales for its new products, brought out by costly research efforts, through the agency of brands and patents.

An editorial in a leading financial daily takes the veiled threat of Mr. Pillai seriously indeed stating that "the people will be deprived of the fruits of drug research conducted here or abroad" as a consequence of the Government's recent decision to abolish the brand names of 5 essential single-ingredient drugs as well as new single-ingredient drugs that may be introduced in the future.

A close look at all the relevant facts, however, will give us quite a different picture.

First and foremost, countries where most of the research in drugs is conducted spend far more on sales promotion than on R & D. The Kefauver Committee studied the data for the 22 largest drug firms in the USA. It found that sales promotion accounted for 24% of their combined turnover in 1959, whereas R & D accounted for a mere 6%. In absolute terms, the entire US drug industry spent \$750 million on

sales promotion in 1959, while the total funds available to all medical schools in that year amounted to only \$200 million! (5) The same pattern continues till today with R & D expenditures accounting for 1/3 to 1/4 of promotion expenditures in the U.S.A. (1)

In India, on an average, annual R & D expenditures account for barely 1.5% of total industry sales. (See Table below). Against this, we may expect the total marketing and promotional expenditures of the larger companies to be at least 10% of their sales.

RESEARCH & DEVELOPMENT (R & D) OUTLAYS IN THE INDIAN DRUGS INDUSTRY IN RECENT YEARS

Year	R & D Expenditure	Formulations Production	R as % of P
	(R)	(P)	
1972-73	5.86*	300	1.9
1973-74	6.28*	380	1.6
1974-75	7.29*	408	1.8
1975-76	8.00*	560	1.4
1976-77	10.50+	700	1.5
1977-78	12.00+	900	1.3
1978-79	14.75+	1050	1.4

* Handbook of Research & Development Statistics 1976-77, Department of Science & Technology, Government of India.

+ Organisation of Pharmaceutical Producers of India (OPPI) Estimate.

The Tariff Commission found that in the year 1966-67, only 11 companies in India spent more than Rs.1 lakh on R & D annually. These 11 companies together spent only 1.9% of their total turnover on research during 1966-67. The percentages ranged from the lowest level of 0.26% of sales (Glaxo) to a maximum of 6% of sales (Ciba-Geigy). (6)

An analysis of the combined income, production and expenditure accounts of 52 medium and large public limited drug companies (each with share capital of at least Rs.5 lakhs) published by the Reserve Bank of India in May 1980, reveals that these drug firms spent extremely small sums on R & D during the 3-year period 1975-78. (7) (See Table on the following page.)

The Table clearly shows that the 52 drug companies covered under the RBI study spent between 10 to 12 times on selling commissions and advertising as compared to what they spent on R & D.

A COMPARISON OF EXPENDITURES INCURRED ON R & D,
ADVERTISING AND SALES COMMISSION BY 52 DRUG COMPANIES.

Item	1975-76 (in Rs. lakhs)	1976-77 (in Rs. lakhs)	1977-78 (in Rs. lakhs)	1975-76 (as % of Value of Production.)	1976-77 (as % of Value of Production.)	1977-78 (as % of Value of Production.)
Expenditure On:						
1. R & D	107	136	156	0.3	0.3	0.4
2. Marketing Costs on: (a+b)	1317	1462	1534	3.8	3.7	3.6
a. Selling Commission.	631	656	694	1.8	1.7	1.6
b. Advertising.	686	806	840	2.0	2.0	2.0
3. 2 $\frac{1}{2}$ 1 (no. of times)	12	11	10			

Source: "Finances of Medium and Large Public Ltd. Cos., 1977-78", RBI BULLETIN, May 1980.

The Levraj Kumar Committee, which investigated the profitability of multinational drug firms during the 1970s, found that their R & D outlays accounted for only 0.83% of their total costs, with the exception of only 2 companies (most probably Ciba-Geigy and Hoechst Pharmaceuticals). Against this, sales promotion, administrative and overhead expenses accounted for 33% of their total costs which was unduly high as compared to other industries. (8)

Second, brand names provide a powerful impetus to imitative or "me-too" product research. (3) Thus, there is a considerable wastage of the already low R & D outlays of the industry. It has been estimated that, worldwide, genuine new pharmaceutical products are created at the rate of only around 6 a year. (3) The rest are 'new' only in that they are trivially different from existing products in their therapeutic action, while sufficiently so in terms of their chemical structure to masquerade as 'new' research products. According to studies conducted in the USA, out of 5386 'new' products introduced in the market between 1948 to 1963 (over 350 a year), only 11% were new chemical entities not previously known. Most of the remaining were either duplicates or slight variations of existing compounds. (1) Again, in 1972, in USA, out of 1500 drug patents filed only 45 or 3% were new, some 1305 or 87% were imitative. (1) A former director of research at Squibb, USA, estimated that 25% of his company's research

funds were spent on "worthwhile" projects, the remaining 75% on "me-too" drugs and unimportant combination products. (3)

Third, as far as India is concerned, the multinationals have largely avoided conducting original R & D on any significant scale in areas of vital concern to the country because they find it more profitable to obtain technological innovations and new products from their parent organisations abroad. (For a more detailed discussion of the superficial and inadequate R & D activities of these firms in India, see Chapter 5, pgs. 50-65 and Chapter 6, pgs. 67-68 of this study).

The Mathi Committee notes that "barring a few, other multinational companies have been taking the line that basic innovational research for new drugs involving co-ordination between multi-disciplinary teams of scientific workers requires giant outlays and top-grade research scientists. According to them, research should be concentrated in the parent organisation functioning abroad rather than be dissipated in many countries." (4)

Moreover, most of the 'new' research products are introduced in the country more than 10 years after their introduction in the developed world markets. A majority of the 7500 drug formulations produced in India were commercialised in the West before 1950⁹ (9) Thus by the time a new drug is introduced in India, the foreign company has already recovered its R & D investment on that drug, and there can be no justification for the argument that high prices of drugs are necessary to recoup large research outlays.

A paper, presented by B.V. Rangarao of Jawaharlal Nehru University for the International Seminar on Technology Transfer, titled 'Foreign Technology in the Indian Pharmaceutical Industry', analyses the adverse impact of multinationals on the indigenous research efforts. The author notes that the research results of the local subsidiary are normally sent to the parent organisation where they are converted into a technological achievement and re-imported back into the country at high costs. Similarly, local research efforts are directed away from areas more relevant to local needs. (10)

Finally, there is a total neglect, on the part of the parent organisation whose profit calculations are based on a global scale, of research activities aimed at developing effective therapeutic agents against the diseases more prevalent in the Third World. On a worldwide scale, an estimated \$2 billion are spent annually on R & D in drugs of which less than \$70 million, or 3.5%, is spent on tropical diseases. (1) At the same time, over 1 billion poor people in the world, or about 30% of the world's population, are extremely vulnerable to these diseases.

Most of the research in this field was done in the early 20th century when the western countries were themselves struggling against such infectious diseases both at home and in the occupied colonies in the Third World. In the last 30 years, there has been considerable neglect even in basic research on the biology of tropical disease parasites which was called "a disgrace" by Jacques Monod, the Nobel prize-winning French molecular biologist. (1)

3. Brand names are "the best and most effective means of providing responsible identification of finished drugs, so as to give the greatest assurance of reliability and predictability in drug therapy." (11)

In fact, brand names lead to a chaotic proliferation of products on the market, a large number of which are irrational, harmful or of doubtful utility. A study published in 1974 found that for the 700 different prescription drugs available in the U.S.A., there existed some 20,000 brands i.e. on an average 30 brands for each drug. (3) In the U.K., it was estimated that against 1,000 essential drug compounds or bulk drugs listed in the Monthly Index of Medical Specialities (MIMS) some 30,000 to 40,000 branded drugs were being marketed. (1)

In developing countries, the situation is still worse. Many such countries have found that only 1 to 2% of the drugs on their markets are essential for meeting the basic needs of their people. The Joint Mission Hospitals Equipment Board Ltd. (ECHO), which supplies essential drugs to Christian mission hospitals around the world, found that about 25 generic drugs were adequate for most patients in some 98 hospitals all over the Third World. (1)

In India, at present, some 20,000 branded medicines are on the market, a large number of which are considered irrational and not commensurate with prescribed dosage requirements. The basic bulk drugs used for their formulation number only 400. The Hathi Committee considered just 117 generic drugs (0.6% of the number of drugs currently marketed) sufficient for satisfying the basic requirements of the country. (4)

In 1980, a high-powered sub-committee, set up by the Drugs Consultative Committee (DCC—a statutory body consisting of State Drug Controllers and members of the Central Drug Control authority) to examine the therapeutic effectiveness of 34 categories of fixed-dose combination drugs, concluded that 23 (68%) of these categories were either irrational, therapeutically useless or outright harmful. Out of these 23 categories, 16 or 70% were judged by the Committee to be harmful and it recommended that they should be "weeded out immediately" in the public interest. The remaining 7 were judged to have no therapeutic rationale but at the same time had no harmful potential. The Committee suggested their production should be discontinued gradually. In addition to these, the Committee found

that popular drug combinations such as penicillin with streptomycin, tetracycline with vitamin C, atropine with analgesic antipyretics and vitamins with tranquillisers were potentially harmful. The implementation of the Committee's report banning these 23 drugs would endanger more than 1,000 branded formulations on the Indian market! It is not surprising that the industry swiftly denied the validity of the Committee's findings.

The table below gives a list of 19 categories of fixed-dose combinations to be "weeded out immediately." (12)

List of 19 Categories of Fixed-Dose combinations that should be Banned.

1. Steroids.
 2. Chloramphenicol.
 3. Ergot.
 4. Vitamins with anti-inflammatory agent and tranquillisers.
 5. Atropine in Analgesic Anti-pyretics.
 6. Analgin.
 7. Yohimbine and strychnine with testosterone and vitamin.
 8. Iron with strychnine, arsenic, yohimbine.
 9. Phenacetin.
 10. Tetracycline, analgin with Vitamin C.
 11. Chloramphenicol with streptomycin.
 12. Penicillin with streptomycin.
 13. Ayurvedic drugs with Modern drugs.
 14. More than one Anti-histaminic .
 15. Penicillin with sulphonamides.
 16. Anti-histaminic with tranquilliser.
 17. Vitamins and Analgesics.
 18. Vitamins in Anti-TB drugs.
 19. Tranquillisers, Anti-histaminics and Analgesics.
-

Source: 'Surya India', May 1981.

In 1971, a committee of experts set up by the Food and Drug Administration (FDA) of the USA to evaluate 2,000 multi-ingredient preparations marketed in that country found that a majority of them (60%) did not possess therapeutic efficiency. (10)

The Mathi Committee extensively investigated the consequences in India of using brand names. "Brand names have been responsible for putting up a large number of unnecessary and often irrational formulations in the market." Analysing further the consequences of this absurd product proliferation, it states: "This has resulted in excessive use of drugs particularly under the names 'tonics' containing vitamins in excessive quantities. Multiple drug combinations in amounts far in excess of what is required result in colossal national wastage of drugs. This could be substantially reduced if the brand names are eliminated." (4)

A peculiar feature of the drugs industry is that the consumer is 'captive'. He normally does not possess sufficient knowledge to make his choice from a bewildering array of branded products available on the market. It is his physician who makes this choice for him. However, the confusion is no less for the prescribing physician too: it is virtually impossible for him to make a rational evaluation of the thousands of price and quality alternatives the market is flooded with. Further, most doctors can hardly find enough time to keep abreast of all the latest pharmacological developments in their respective fields through the scientific journals. Thus the doctors mainly depend on the information provided by the large manufacturers as part of their promotional campaign. As one would expect, much of this information transmitted through beautiful pamphlets and company medical representatives (the ubiquitous salesmen of the drugs industry), is of doubtful objectivity. In the enthusiasm to promote their products, many 'ifs' and 'buts' of vital importance are simply left out in the promotional literature.

At the Kefauver Committee hearings several prominent witnesses testified in the manner in which tranquillisers were being promoted by the large U.S. drug firms:

"Either in the course of legitimate investigation or in the search for a new promotion device it is found that a drug which is claimed to be effective in relieving anxiety, produces in rats specific, objectively measurable changes in a particular area of the brain. Now this is an interesting scientific finding but in the present state of our knowledge, its significance is unknown. To the promotion people, this lack of significance is unimportant since it is both intriguing and impressive. It is presented in an ad or brochure, complete with accurate anatomical illustrations of the brain beautifully executed in vivid colours. This is coupled with the claim that the drug relieves anxiety. The usual response of the average practitioner who is not, and is not expected to be, an expert in neurophysiology is to associate the two and assume they support each other. To the expert, however, any attempts to relate the claim to the finding is absurd since there is no known relationship between human anxiety and this finding. It is no more absurd to relate the claim to this finding than to the finding that the drug when given to cats make their tails curl up and form a square knot. The latter is obvious, the former is not. Because it is not, the impressive but irrelevant fact is carefully presented in vivid form. The classifying facts are equally carefully omitted." (5)

The advantage from the continuance of the brand system to the prominent, larger firms is obvious: it enables them to maintain their strong foothold in the market. The Hathi Committee report bluntly states that "the organised sector has maintained dominance over the drug market principally through their branded products containing multiple ingredients." (4)

Further, the experience of many countries proves the existence of long-lasting preference for particular brands especially those under which the product was introduced for the first time. Even after their patents expire, they continue to enjoy a marked consumer/physician loyalty. The prices of these are also found to be among the highest compared to other similar, therapeutically equivalent products available on the market. (3) Is it surprising to find the entrenched, large companies vociferously defending their rights to use brand names, albeit, on the most noble-sounding pretexts?

Under Indian conditions, another consequence of this chaotic, bewildering array of branded formulations is that it renders the task of administering effective price control extremely difficult if not impossible. With tens of thousands of products on the market, coupled with a price control policy as comprehensive as it is in India, the hands of the concerned price fixing authorities are too full for them to monitor and respond quickly and effectively to continuously changing market conditions. Thus the elimination of brand names (at least for the 117 essential drugs listed by the Mathi Committee), by introducing an element of standardisation, would go a long way in making this vital instrument of Government regulation and direction of the drugs industry successful.

4. Another pet argument of the large drug companies is that brand names represent the manufacturer's guarantee of high quality and sustained reliability of his product. If brands are abolished, this will open up the "flood-gates" of sub-standard and even spurious drugs on a massive scale particularly in a country like India which lacks an efficient and vigilant drug control machinery.

It is true that the larger firms are able to maintain high quality standards of their products. Most smaller units, with low volumes of production, cannot afford in-house testing laboratories with elaborate quality control equipments. They generally resort to commercial labs for the testing of their finished products. Also, it is not possible for them to develop a quality control system built into the entire process of production right from the raw materials to the finished products stage.

However, to say that with the abolition of brand names the prominent firms would lose all incentive to maintain high quality of their products is clearly untenable. First, brands or no brands, it is a basic responsibility of all firms, large and small, to satisfy the minimum statutory standards of quality for a sensitive product group like drugs and medicines. This has nothing to do with the brand vs. generic names issue. Secondly, if the larger firms lose incentive to maintain quality standards higher than the legally required minimum, the extra benefits, if any, that may be gained by the consumer would be far outweighed by the extra costs that he has to bear in the form of higher prices of the branded products. And, as is well-known, a significant proportion of these higher prices—20% according to one estimate—is accounted for by the promotional expenses incurred by these large firms in promoting their particular brands.

to challenge the notification in a court of law. On 21 July 1981, Hoechst Pharmaceuticals obtained a stay from the Delhi High Court against the Government order abolishing one of its brand names, "Novalgin", which is an analgin, from 1 August 1981. (13) In all, 3 multinational companies - Hoechst, Pfizer and Cyanamid India - have filed cases challenging the Government's order. (14)

The Mathi Committee had recommended the abolition of brand names for 13 drugs to start with. But the Government decided to do so for only 5 drugs. The idea is to gain experience from a limited scheme of introducing generic names, before extending it to more and more essential drugs of mass consumption. An analysis of the analgesics market, for instance, reveals the extent to which the Government's January notification is limited in scope and effectiveness. At present, aspirin is marketed under 8 brand names, aspirin + caffeine under 7 brand names and aspirin + caffeine + phenacetin (popularly known as A.P.C.) under 19 different brands. (15) The Government's order prohibits only the 8 brand names under which the single-ingredient aspirin (or acetylsalicylic acid) is marketed. The remaining 26 brands are multiple-ingredient drugs and are not affected by the order.

The WHO experts committee, which prepared the list of essential drugs, considers aspirin alone to be therapeutically equivalent to all these multiple combinations as well as to analgin. We have already seen in Chapter 3 of this report, that most of these analgesic combinations are a mere "medical gimmickry" and "economic exploitation of the patient." To top it all, aspirin alone is the cheapest of the lot: the price per unit of analgin is 6 times that of aspirin (See Table below). The cost of the brand 'Kenalgescic' of Sarabhai is almost 8 times that of the aspirin sold by Haffkine, apparently due to the additional 30 milligrams of caffeine which is not an analgesic at all, but a cerebral stimulant amply available in a single cup of tea which is approximately equivalent to a dose of 60 milligrams of caffeine!

Drug	Producer	Name under which Drug is Marketed	Price Per Unit (Paise)
1. Aspirin (300 mg)	Haffkine	Aspirin (Generic)	2.84
	Boots	Aspirin (Generic)	3.60
2. Aspirin (300 mg) + Caffeine (30 mg)	Nicholas	Aspre (Brand)	7.75
	Sarabhai	Kenalgescic (Brand)	22.00
3. Analgin (500 mg)	Haffkine	Analgin (Generic)	18.24
	IDPL	Analgin (Generic)	18.27
	Hoechst	Novalgin (Brand)	20.00

Source: Indian Pharmaceutical Guide, 1980.

Reproduced from: "Drugs: Abolishing Brand Names" by S. Viswanathan, Business India, September 28 - October 11, 1981.

But the drugs industry, both Indian and foreign, will have none of it. It at once dubbed the Government order "arbitrary and highly discriminatory". (13) It has raised certain technical, legal issues under the Drugs and Cosmetics Act, 1940 and under the Trade and Merchandise Marks Act, 1958. (15,16) The Hathi Committee had already recommended in its report that suitable amendments should be made under both these Acts. But the Government failed to do so before issuing its notification. All the arguments that we have examined here, were once again raised by the industry from its standard repertoire of debating points.

The case filed by Hoechst has been adjourned for hearing till 24 August 1981 by the Delhi High Court. The Court's decision will have profound consequences for the drugs industry -- and for the 'common man'.

THE DEVELOPMENT OF THE DRUGS INDUSTRY IN INDIAHISTORICAL BACKGROUND

The allopathic system of medicine was introduced in India by the British. For centuries, the indigenous systems of Ayurveda, Unani and Siddha were practiced and are still accepted by a majority of the people and recognised by the Government. (1)

In the 19th century, Indian medicinal plants and herbs (e.g. cinchona bark, poppy pods, nux vomica seeds) were sent to Great Britain where they were processed into tinctures and ointments and shipped back to India. (1) At the turn of the century, in 1901, the late Acharya P.C. Ray pioneered the first Indian drug factory, Bengal Chemical and Pharmaceutical Works, Calcutta for the manufacture of galenicals and other simple drugs. (2) This was also the first unit to start indigenous manufacture of the basic drug Tetanus Anti-toxin in 1930. (3)

Towards the end of the 19th century, the germ theory of disease and its possible immunisation, got well-established in Western Europe with the path-breaking work of Louis Pasteur. At the turn of the century, several top British medical scientists came to India to study tropical diseases—the biggest enemy of the imperial armies. They set up the first State-owned enterprises in the colony viz. Haffkine Institute, Bombay (1904); Central Research Institute, Kasauli (1905); King Institute of Preventive Medicine, Madras (1904); Pasteur Institute, Coonoor (1907); which conducted research into local diseases and produced sera and vaccines to fight cholera, typhoid and small-pox. Upto the beginning of World War II, besides the production of sera and vaccines, the Indian drugs industry made little progress. Most of the British companies sold their products in India either through their branches or through established British trading houses. The Indian units were few in number and could not make any significant impact. (1,2)

Most important, the technological revolution in therapeutics was proceeding rapidly in the West.

The landmark was the year 1935, when Gerhard Domagk of Germany discovered a new substance called Prontosil (a red dye) while he was studying the anti-bacterial properties of dyes for I.G. Farben industries. Following Paul Ehrlich's path-breaking concept of artificial, chemical substances that could act like natural anti-bodies in killing the specific bacteria without harming the host tissues, Domagk found that his red dye was effective against a wide range of bacterial diseases. French scientists of the Louis Pasteur Institute soon disclosed that it was not the dye but its ingredient called sulfanilamide that killed the germs. (4)

The next important development was the introduction of penicillin, the first antibiotic, in the mid-40s following the accidental discovery by Alexander Fleming in 1928 of its germ-killing properties. Thus began the "therapeutic revolution" of the century with its "magic bullets."

The technological revolution in therapeutics resulted in the structural transformation of the existing drug firms in the West. In the 1930s, the major firms produced the whole range of medicines needed for the physician's use. The firms did not engage in research and development, the nature of technology was simple and sales promotion was not focused on a particular product but on the quality of the full product line. Producers of bulk drugs sold their products to packagers who supplied essentially the same drugs to the pharmacist and the physician. By the late 1950s, the drug firms had undergone a sea-change in their structure and operations. They now specialised on particular products, combined production with intensive research and development (R & D) activities, and vigorously marketed finished product packs under brands and patents with attractive packaging—all within a single corporate structure. (4)

During the 1940s and 50s, the age of 'wonder drugs' had truly set in with the introduction of important new drugs such as sulpho-namides, penicillins, streptomycin, tetracycline, corticosteroids and innumerable others which greatly increased the range and subtlety of therapeutics. With this also increased the scale and complexity of drug technology and R & D, both largely under the control of the large, integrated corporations which now took on a multinational character.

Cessation of drug imports during the two World Wars gave some impetus to the local industry in India. (2) For example, during World War II, some progress was achieved in the manufacture of phyto-chemicals (processed from plants and herbs); also a number of small firms were established for the manufacture of simple preparations and formulations. Some synthetic drugs were also being made, and the production of formulations was increasing rapidly largely from imported bulk drugs and late intermediates. (2)

However, the local industry was in no position to meet the rapid technological advances made in the West after World War II. Indian medicinal products were quickly replaced in the export markets and took a severe beating in the local market itself from foreign producers. Soon, more foreign firms began trading operations in India and some started formulating finished products, imported in bulk from their principals, into tablets, capsules, syrups, etc. (2)

From those early years of independent India, the drugs industry today has come a long way indeed. The western multinational drug companies played a vital role either directly, or through collabo-

rations, in developing a modern pharmaceutical industry in the country. Beginning with elementary processing of imported drug chemicals and finally to the indigenous manufacture of many of these basic drug compounds themselves, the Indian industry today manufactures a wide range of sophisticated anti-biotics, hormones, vitamins and synthetic drugs. The policy of protection and the provision of a seller's market prodded the foreign firms to convert their trading concerns into manufacturing units. Production increased rapidly from an insignificant Rs.10 crores in 1947-48 to Rs.150 crores in 1965-66 to an estimated Rs.1200 crores in 1980-81 (see Table below). The 1960s also marked the beginning of rapidly growing exports. In the 14-year period ending 1973-74, exports increased about 10 times (see Table on the following page).

TRENDS IN THE PRODUCTION OF BULK DRUGS AND FORMULATIONS.
(in Rs. crores)

Year	Bulk Drugs (B)	% change over previous year	Formu- lations (F)	% change over previous year	B as % of F
1947-48	N.A.*	-	10	-	-
1965-66	18	-	150	-	12
1974-75	90	-	408	7.4	22
1975-76	130	44.4	560	37.3	23
1976-77	150	15.4	700	25.0	21
1977-78	164	19.3	900	28.6	18
1978-79	200	22.0	1050	16.7	19
1979-80	226	13.0	1150	9.5	20
1980-81	240**	6.2	1200**	4.3	20

* Not Available

** Estimates

Below, let us quickly summarise the salient features of the historical development of India's drug industry:

- At the dawn of independence, the modern drugs industry in India was virtually non-existent.
- What little progress in local manufacture as had taken place was no match to the vast technological and financial resources of the Western multinationals in the post-war period.
- These multinationals, starting with trading and simple processing activities, gradually developed a modern drug industry in India, either singly or through financial/technical collaboration with local entrepreneurs, over a period of 2 decades or so.

TRENDS IN EXPORTS & IMPORTS OF PHARMACEUTICALS: 1960-61 TO 1973-74

Year	Exports* (E)	Imports (I)	E as % of I
1960-61	154.80	1759.92	9
1961-62	154.63	1778.38	9
1962-63	167.01	1461.00	11
1963-64	154.80	1314.13	12
1964-65	415.75	1292.93	32
1965-66	379.51	1380.33	27
1966-67	377.09	1740.81	22
1967-68	332.79	1752.20	19
1968-69	399.97	1749.66	23
1969-70	600.29	1830.28	33
1970-71	846.48	2426.80	35
1971-72	962.50	2655.68	36
1972-73	1032.24	2322.20	44
1973-74	1494.92	2639.29	57

* excluding medicinal castor oil.

Source: Multinationals And Indian Export; Chapter III; page 42.

Today, the pharmaceutical industry has come a long way both in terms of the volume of production as well as its diversified composition.

We will now carry out a detailed examination of the successes and weaknesses of the modern Indian drug industry that has been developed largely with the help of foreign technology, know-how and capital.

WHY SHOULD THEY MAKE BULK DRUGS?

At the outset, it must be remembered that the basic chemicals industry in India had hardly been developed in the pre-independence years. In the West, the development of the chemicals industry, particularly the dyestuffs industry in the earlier years, preceded the development of the drugs industry. And, it is the basic chemicals industry which supplies the raw materials needed for bulk drugs manufacture.*

* A "bulk drug" is the basic, active chemical ingredient of a drug formulation. "Drug formulation" is the finished product which is directly consumed and contains in addition to the active drug compound other ingredients such as diluents, binders, flavouring/colouring agents (as in tablets), gelatin shells (capsules), chemical bases and waxes, preservatives (ointments) and so on.

Thus the nascent drugs industry in India was dependent on the multinational corporations for the supply of the bulk drugs which were then fabricated into dosage formulations. And it is the bulk drugs sector, the "base plank" of the industry, which is highly capital intensive and requires sophisticated technological and research inputs on a sustained basis.

It was only the large, multinational corporation that had the requisite technological know-how and the vast resources to develop the bulk drugs sector. Either singly or in technical/financial collaboration with Indian entrepreneurs, the foreign companies were in a position to establish bulk drug manufacture on a large scale. Initially, no doubt, there was no alternative to importing basic chemical intermediates from abroad but this dependence could have gradually decreased with the simultaneous growth and diversification of the Indian chemicals industry in the 1960s.

But this is precisely where national developmental needs were at variance with the profit motive of the foreign companies. It was far more profitable for these concerns to import the bulk drugs and late drug intermediates from their parent companies, often at monopoly prices that had no relation to the ruling international prices, and formulate them into finished dosage packs sold under popular brand names. And formulation technology is relatively simple and well-known; it could have easily been adopted by the medium and even small-scale Indian firms. Thus, "division of labour" with the larger firms, mostly foreign, concentrating on bulk drugs production on a massive scale and supplying part of this, after meeting their own formulation requirements, to the smaller firms, mostly Indian, would have been the optimal pattern of development for the drugs industry.

But in practice, the multinationals, far from promoting "backward integration" into bulk drugs manufacture, in fact impeded the rapid local manufacture of galenicals and such simple drugs by means of their monopolistic control of the raw materials under the international patent system. Their primary interest was, and remains till today, to import the basic drug ingredients, often at inflated prices, and fabricate them into fast-selling, finished products sold under popular brand names. Thus, even the formulations sector that got established in the country continues to remain under the domination of the foreign companies whether with foreign majority or minority equity ownership.

The Mathi Committee states that: "Formulation activity represents the high pay-off sector of the pharmaceutical industry and bulk drugs manufacture gives comparatively low profits." "The ratio of capital invested to sales turnover in the formulation sector averages 1:2.6 with an upper limit of as high as 1:7.5. It is estimated that a purely formulation unit recovers the entire invested capital in a 2-4 year period. On the other hand, in bulk drugs production, under

the best of circumstances, sales turnover to capital ratio does not usually exceed the 1:1 figure and in many cases, in the early development stages, this ratio is much lower." (2)

And this is precisely what most foreign companies did in those halcyon days of "pragmatic" Government policies: they quickly recovered their invested capital from simple manufacturing and trading activities in the formulation sector. The Mathi Committee observes that: "Within a period of twenty years, multinational companies attained a position of dominance in the drug industry. Their success could be partly attributed to the anti-biotics and synthetic drugs which they introduced in the market. The Patent Law concerning drugs prevented Indian companies from entering into the field of synthetic drugs. Multinational companies had an extremely favourable climate in this country when they commenced operations. They managed for a good length of time with a meagre capital investment, pushed up the sales of their products, remitted profits to their principals abroad and built up substantial reserves. Government's policy permitted payment of royalty even on drug formulations. Whatever basic drugs they manufactured were mostly utilised for captive consumption. High prices were maintained for their drugs for several years. Added to this, money-spinning tonics and household remedies which they could market on the basis of "Permission Letters" and "COB Licences" swelled their profits." (3)

According to some estimates, upto 80% of the present output of many foreign drug companies comprises of simple household remedies and inessential formulations. Essential drugs like insulin, anti-leprosy drugs, anti-TB drugs, cholera vaccine account for only 30% of the value of formulations sold by many large firms. (5)

"However, in recent years, some of the multinational units did enter the field of bulk drug production ---. Even so, they were usually highly selective and chose low-tonnage, high money-value bulk items and started to manufacture these, frequently from penultimate or near penultimate intermediates imported, usually, from the corresponding principals, at high costs. This position is only slightly better today." (3)

"It is evident that it is the Indian and Indian majority sector, and in particular the two public sector units, that have made the major contribution in the critical area of bulk drugs production which constitutes the base plank of the pharmaceutical industry." (3)

There have been several instances of foreign firms producing certain drugs from imported raw materials even when indigenous materials are available. For example, in 1962 a foreign company commenced production of tolbutamide for which the raw material was almost wholly imported. But the Haffkine Institute was making the same drug in small quantities from only 15-20% of imported materials. (6) In 1961, an Indian unit started production of 600 kgs. of chloro-

propamide and was sued by a foreign firm challenging the patent of this local unit. In 1962, this Indian firm imported about 50% of its material input. But another foreign firm, which was licensed for undertaking chloropropamide production in 1965 (capacity: 10,000 kgs.), was found by the Tariff Commission to be importing 89% of its raw material input in 1967. (6) Such examples can be multiplied.

Further, there are several instances where it would be cheaper to import the drug itself rather than to import its late intermediates and then locally 'manufacture' the final drug. (See Table on pgs. 62 and 63).

These distortions in the production pattern have had profound consequences in the vital area of indigenous technological development. Despite rapid growth in the overall volume of production and the impressive range of diversification achieved, the Indian drugs industry continues to depend on the developed countries for technological progress. In other words, it has failed to develop the technological ability to generate, on its own, new products and processes essential for self-sustained development. Let us closely examine how this continuing relationship of technological dependence is brought about and maintained.*

TECHNOLOGY? R & D? WHY BOTHER, WHEN...

Firstly, the foreign drug companies who dominate the industry have totally neglected basic research and development in this highly knowledge-intensive industry. In 1973, only 20 companies out of some 116 or so large-scale companies conducted some R & D activities. (7) Of these, only 3 firms seemed to have the resources to conduct basic research.** The total expenditure on R & D in recent years barely accounts for 1.5% of the total value of production of the industry. Today, from among the foreign companies, only Ciba-Geigy and Hoechst have adequate R & D establishments and they have yet to make a significant contribution. (8)

It is very important to understand the vital role R & D plays in technological development. That technology has to be imported in the

* Also refer to the discussion on R & D in Chapter 4, pages 43-46 and on 'high technology' activities of the multinationals in Chapter 6 pages 67-68 to get a comprehensive picture of this important aspect.

** The term "basic research" in India usually implies fundamental and innovational process or product research.

initial stages of an industry's development is obvious. But to enable the imported technology to take root in the country, R & D on a continuing basis is a must. In the drugs industry, R & D in the initial years would concentrate on product stabilisation and more appropriate product packaging under tropical, warm weather conditions. (1) Gradually, the focus would shift from product modification to process modification: adapting the production processes to local raw material and factor input availability to cut down costs and become competitive. Finally, the industry would develop the ability to generate innovative products and processes on its own in an independent manner. That the drug industry has not shown any interest in this genuine, long-term process of technoindustrial development is evident from the abysmally low percentages of its revenues devoted to R & D expenditure year after year (see Table below). And, as we observed earlier in Chapter 4, at present, the large foreign drug firms spend only 0.83% of their total costs on R & D against 33% for sales promotion, administration and overhead expenses. (9)

RESEARCH & DEVELOPMENT (R & D) OUTLAYS IN
THE INDIAN DRUGS INDUSTRY IN RECENT YEARS (in Rs. Crores)

Year	R & D Expenditure (R)	Formulations Production (P)	R as % of P
1972-73	5.86*	300	1.9
1973-74	6.28*	380	1.6
1974-75	7.29*	408	1.8
1975-76	8.00*	560	1.4
1976-77	10.50+	700	1.5
1977-78	12.00+	900	1.3
1978-79	14.75+	1050	1.4

* Handbook of Research & Development Statistics 1976-77, Department of Science & Technology, Government of India.

+ Organisation of Pharmaceutical Producers of India (OPPI) Estimate.

Besides, the transfer of Western technology through direct foreign investment was largely restricted to formulations and simple process technology rather than technology derived from basic research. This was the logical outcome of the foreign companies' primary obsession with the production and sale of highly profitable formulations.

Thus, even out of the meagre amounts allocated to R & D, a substantial portion of it is spent on superficial improvisation of existing products with a view to further enhancing their saleability. An examination of R & D priorities in the multinational firms shows that maximum importance is given to packaging research,

IMPORTED INTERMEDIATES AND THEIR COSTS

Name of drug	Basic Chemicals for manufacture	Intermediates for manufacture in India	Cost of imported intermediates in Rs. per kg.	Cost of drug if imported in Rs. per kg.	Remarks
(1)	(2)	(3)	(4)	(5)	(6)
Chloramphenicol	Benzaldehyde and Nitroethanol or p-introaceto phenone, Bromine and Hexamethylene tetramine	Amino-diolactive base. (last-but-one stage) or p-nitroamino diol (penultimate stage)	332))) 335)	100	All the other chemicals necessary for production from basic chemicals are available in India
Chloroquin	M-chloroaniline, formic acid, and diethyl melonate	4,7 dichloro-quinoline and 4 amino-diethyl aminopentane (penultimate stage)	187))) 56)	128	All basic chemicals are indigenously available and an Indian firm had started production independently, but could not continue.

Contd

IMPORTED INTERMEDIATES AND THEIR COSTS (Concl'd.)

(1)	(2)	(3)	(4)	(5)	(6)
Sulphapyridine	Acetanilide, Chlorosulphonic acid and amino-pyridine	Acetyl amino-benzene sulphanyl chloride and aminopyridine diene (penultimate stage)	43	Not marketed	This sulphadiazine drug produced in the private sector is obsolete abroad, but very costly in India.
Chlorthiazide	M-chloroaniline, chlorosulphonic acid and ammonia	5, chloroaniline, 2,4 disulphamide and formic acid (penultimate stage)	37	No imports	All basic chemicals are indigenously available

Source: B.V. Ranga Rao, "Pharmaceutical Industry in India: Status and Perspectives", Jawaharlal Nehru University, New Delhi, 1975.

Reproduced from: UNCTAD, "Case Studies in the Transfer of Technology, The Pharmaceutical Industry in India," U.N., 1977.

then to product/process research and least to basic research. A slightly better ordering of R & D priorities is found in the wholly Indian firms starting with process research to product development. (7) Again, there can be genuine doubts as to how meaningful things like 'product development' really are. In Chapter 4 of this report, we have seen how a large part of research activities, even in the developed countries, consists of "me-too" or imitative product research rather than on genuinely new products. (4)

"At best these laboratories appear to be taken in nature, probably like 'after-sales-service' units, to look into complaints, and for information dissemination, market research and quality control work. Meaningful contribution by way of transfer of technology to the drug industry from these laboratories is hard to conceive" say Ramachandran and Rangarao while describing the overseas R & D establishments of U.S. multinationals. (1) We have already seen in Chapter 4 that the policy of the multinationals is to concentrate basic research activities in the parent or sister organisations in the West rather than "dissipate" them in many countries. (2)

Besides, whatever technology that was transferred to the country had a number of restrictions. The rigid terms and conditions — long duration of collaboration agreements, disallowing transfer of technology from one local firm to another and so on — greatly impeded the indigenous growth and diffusion of technology in the industry. (7) Further, there were restrictions on marketing the products in the world markets. For example, a 1968 Reserve Bank survey of foreign collaborations in the Indian industry showed that 26 or 50% of the 52 collaborations operating in the drug industry had export restrictions. (6) In 1974, however, this proportion declined from 50% to 32% with 19 out of the 60 collaborations having export restrictions. (6)

It is hardly surprising, that the Indian drugs industry continues to depend on the Western multinationals for technological advance. And the rate at which technology is progressing in the post-war years the gap is becoming wider and wider. Though, outwardly, the industry seems to have 'advanced' fairly rapidly in about 20 years or so, its potential for independent, self-sustaining development remains stunted. The fundamental weaknesses in the structure of the industry — low indigenous technological potentials and continuous dependence on the developed economies, drain of resources in the form of continuing imports of bulk drug materials and royalties on the latest know-how and the accompanying lack of integration and transformation of the production pattern — will continue to operate for a long, long time to come. This then is the heavy price the country has paid, and is paying, for its dependence on the multinationals for the development of its drugs industry.

We may end this Chapter with the following observations of the Mathi Committee:

"The Committee is fully aware of the fact that foreign companies in India with the commanding position they have attained in the drug industry today and with the technological and other resources which they can command from their principals abroad may produce all the bulk drugs that are needed by the country well within the time schedule ... But the big question that we should ask is: What would it cost the country if the future development of the drug industry is entrusted primarily to the foreign sector of the industry? In response to a query raised by the Committee as to why the member firms of the Organisation of Pharmaceutical Producers of India (an organisation which is dominated by foreign companies and firms with foreign interests), have not shown adequate interest in the manufacture of bulk drugs, the reply received from the Organisation stated that its members "are in a position to further expand their production of bulk drugs provided such expansion is immediately sanctioned by government without attaching any condition." This proviso pithily sums up the attitude of multinational companies. It implies that Government should not ask them to bring down progressively their foreign equity, that no condition should be imposed to the effect that a portion of the bulk drugs manufactured by them should be distributed to the manufacturers for being processed into formulations, that no export obligations should be stipulated and, lastly that the cost of the bulk drugs and the prices of the formulations produced by them should not be investigated by government agencies and fixed."

REGULATING THE MULTINATIONALS IN INDIA

In order to bring the operations of the multinational drug companies in line with national needs and priorities, the Government outlined its policy towards the foreign companies, with equity participation exceeding 40%, in the New Drug Policy announced in March 1978 following the report of the Hathi Committee submitted in April 1975.

GOVERNMENT POLICY

Some of the key features of this policy towards the foreign companies are as follows: (1)

- Foreign companies engaged only in the manufacture of formulations must be directed to bring down their foreign equity forthwith to 40% i.e. become 'Indian' companies.
- Foreign companies engaged in the manufacture of bulk drugs not using high technology* must also reduce their foreign equity to 40%.
- Foreign companies manufacturing bulk drugs involving high technology will be allowed to retain foreign equity exceeding 40% upto a maximum of 74% depending upon the proportion of the total turnover from such high technology drugs and activities related to Appendix I or the "core sector" of the Industrial Licensing Policy, 1973.
- The Government, vide Article 14 of the new drug policy, redefined 'drugs and pharmaceuticals' listed in Appendix I to mean
 - A. drug intermediates from the basic stage for production of high technology bulk drugs, and
 - B. high technology bulk drugs from the basic stage and formulations based thereon with an overall ratio of bulk drug consumption from own manufacture to formulation from all sources of 1:5.
- A list of bulk drugs was also drawn up reserving 25 bulk drugs for the public sector and 23 drugs for the Indian sector (public and private). No foreign companies will be given a licence for these reserved bulk drugs.

* See the following page for a discussion on what constitutes "high technology"

In future, foreign companies will be given a new licence, including capacity expansion licences, only for high-technology bulk drugs and formulations linked to them, subject to the condition that they supply 50% of their bulk drugs production to non-associated formulators. They must also maintain the ratio of 1:5 between their bulk drugs consumption (from own manufacture) and formulations production (from all sources).

With regard to regularisation of production in excess of the licensed quantities, the highest production achieved in any year during the 3 years preceding 31 March, 1977 will be the basis of regularisation. In the case of foreign companies, this will be further subject to their supplying 50% of total bulk drugs production (including regularised excess production) to non-associated formulators, and maintaining the 1:5 ratio between bulk drugs and formulations production. No regularisation will be permitted to foreign companies for excess production in household remedies.

WHAT IS "HIGH TECHNOLOGY?"

It was in the context of this new policy towards the multinationals that the Government appointed the K.V. Ramanathan Committee in 1978 to identify the foreign drug companies engaged in the production of one or more bulk drugs using high technology. The report was submitted in October 1979.

The Committee divided the bulk drugs produced into 4 categories:(2)

- 1) Bulk drugs based on fermentation through microbiological processes.
- 2) Those produced through synthetic chemical processes.
- 3) Those extracted from plant or animal sources.
- 4) Those that do not come under any of the above 3 categories.

For the first category, the Committee decided that the development of high-potency strains of microbes used for the production of antibiotic bulk drugs and the extraction and purification processes involves "very intricate technology and maintenance of well-controlled operation parameters, which would qualify such products as involving high-technology in case these are produced from the basic stage."

For the second category, technology involving continuous sequential synthesis resulting in reduced costs, better quality, lesser pollution etc. as well as stereospecific synthesis technology for reduction of specific drugs without involving selective separation would also qualify as high technology.

For the third category, only the special processes used to extract active ingredients conforming to strict specifications or to increase their yields would qualify as high technology.

For the fourth category, products like catguts, sutures, etc. produced from animal or plant materials would qualify as high technology drugs only if the production processes involve very intricate techniques and operations.

The Committee studied the operations of the 45 foreign drug firms with foreign equity exceeding 40% in 1978-79. The Committee found that out of these 45 firms, only 22 were producing bulk drugs involving high technology in varying proportions to their total turnover. (3) (See Table on the following page giving the full list of these 22 companies.) The rest were either pure formulators: 7 or did not make any bulk drugs involving high technology: 16. The Committee had studied the bulk drugs production processes of 24 companies in great detail involving 207 bulk drugs. It found that only 127 of these bulk drugs involved high technology. Out of these 24 firms, Richardson Hindustan Ltd. and Whiffen India Ltd., with foreign equities of 55.97% and 50% respectively, were not found to be producing any high technology bulk drugs. (3)

As can be seen in the Table, the foreign equity participation varies widely for the 22 companies from 100% for Burroughs Wellcome & Co. to 75% for Pfizer to 50% for Hoechst and 45% for Geoffrey Manners.

Few of the 22 companies listed above have a high proportion of high-technology bulk drugs in their total product-mix of bulk drugs. Pfizer has 10 such drugs out of a total of 11, Wyeth Laboratories 25 out of 28, Sandoz 8 out of 10, Hoechst 9 out of 20 and Glaxo 11 out of 34. (3) Also, very few companies have a large portion of their value of production contributed by high technology bulk drugs.

DILUTING GOVERNMENT POLICY

The 7 foreign drug companies, involved in purely formulation activities, were directed by the Government to dilute their foreign equity to 40% in 1978 itself. By August 1981, all these companies - Nicholas of India (100%), Abbot Laboratories (100%), C.E. Fulford (100%), Smith Kline & French (100%), Indian Schering (88.6%), Anglo-French Drug Co. (80%) and Carter Wallace (49.46%) - had diluted their foreign holdings to 40%. SKF took the longest to comply with the government's order after protracted "negotiations" for over 3 years. (5)

But regarding the 21 foreign companies* making at least one or more high technology bulk drugs which comprise the most important segment of the foreign sector, the Government has yet to order their equity dilution. According to the strict criteria being applied by

* Out of the 22 high technology companies identified by the Ramnathan Committee, Suhrid Geigy producing 8 bulk drugs of high technology has completely withdrawn its foreign equity and is now a 100% Indian company.

LIST OF 22 FOREIGN COMPANIES EMPLOYING HIGH TECHNOLOGY
ACCORDING TO THE RAMANATHAN COMMITTEE

COMPANY	EQUITY (%)
<u>Foreign Equity 41% to 49%</u>	
1. Geoffrey Manners & Co. Ltd.	45
2. Suhrid Geigy	47.5
3. Organon (India) Ltd.	49
4. Uni-Sankyo Ltd.	49
<u>Foreign Equity 50% - 59%</u>	
5. Hoechst Pharmaceuticals Ltd.	50
6. Warner-Hindustan Ltd.	50
7. Alkali & Chemical Corpn. of India Ltd.	56.15
8. Bayer (India) Ltd.	51.37
9. Cyanamid India Ltd.	55
10. Boots Company (India) Ltd.	53
<u>Foreign Equity 60% - 100%</u>	
11. E. Merck (India) Pvt. Ltd.	60
12. Merck Sharp & Dohme of India Ltd.	60
13. May & Baker (India) Ltd.	60
14. Sandoz (India) Ltd.	60
15. Ciba-Geigy of India Ltd.	66
16. Wyeth Laboratories Ltd.	74
17. Johnson & Johnson Ltd.	75
18. Glaxo Laboratories (India) Ltd.	75
19. Pfizer Ltd.	75
20. Parke-Davis (India) Ltd.	83.33
21. Roche Products Ltd.	89
22. Burroughs Wellcome & Co. (India) Pvt. Ltd.	100

the FERA Committee, a foreign company can retain a maximum of 74% foreign equity only if not less than 75% of its total turnover is from high technology activities and exports and 51% if not less than 60% of the total turnover is from such activity. (3) It is expected that only 2 out of the 21 companies viz. Roche Products (89%) and Parke-Davis (83.3%) will be able to retain their foreign equity at 74%. Most of the 12 companies with foreign equity of 60% and above (See Table on page 71) will have to reduce it to between 50% and 60%. For example, though Glaxo manufactures a number of high technology bulk drugs, a substantial part of its turnover is accounted for by inessential, consumer products e.g. baby food.* It is expected that Glaxo may have to dilute its foreign equity from 75% to 51%. (6)

* For a break-up of the drugs and non-drugs sales of the 22 companies listed in the Table on page 71, see Chapter 8, pgs.106-108 of this report.

To ascertain how much of the turnover of the concerned companies arises from high technology activities and exports, the Government had asked them to submit detailed data. According to some reports in August 1981, the companies have already submitted the data to the Government "many months ago". But the Government has not yet taken any action. (5)

Why has the Government been dragging its feet on the dilution issue over more than 3 years after taking a policy decision in March 1978 and almost 2 years after the high technology committee submitted its report in October 1979? It is highly probable that the 'row' created by the multinationals against the strict norms to be applied for equity dilution has been successful. These companies have challenged the competence of the Ramanathan Committee to decide on what constitutes high technology. They have even questioned the 'jurisdiction' of the Committee to identify companies engaged in high technology bulk drugs manufacture, when it was appointed to identify only those companies not engaged in high-technology manufacture (7)

According to the FERA committee, only Article 14 of the New Drug Policy of 1978 which redefined the term 'drugs and pharmaceuticals' appearing in Appendix I of Industrial Licensing Policy 1973 (See Pg.66 of this Chapter) should be considered for deciding the permissible limit of foreign equity for all foreign companies.

According to the foreign companies, only Article 17 of the 1978 policy should be used to decide on the equity limit of existing foreign companies. Article 17 states: "In respect of foreign drug companies currently engaged in Appendix I activity on drugs and formulations, the value of turnover which will be considered as such Appendix I activity will consist of (A) the value of bulk drugs sold by them to non-associated formulations, plus (B) the value of formulations not exceeding 5 times the value of their total bulk drug production." (1)

In other words, the turnover relating to Appendix I i.e. the core sector activity, should not be computed on the basis of high technology bulk drugs but all bulk drugs. The FERA committee dismissed this argument of the multinationals as "ridiculous" because the principle that only high technology products should be included in the core sector applies to all industries.

The following item appearing in The Economic Times, March 12, 1981 ably sums up the essence of the controversy:

"Take two companies manufacturing 20 items each. One makes 19 high-technology items and 1 low-technology item. The other makes 19 low-technology items and 1 high-technology item.

LIST OF 22 FOREIGN DRUG COMPANIES (AUGUST 1981)

COMPANY	EQUITY (%)
<u>Foreign Equity 41% - 49%</u>	
1. Geoffrey Manners & Co. Ltd.	45
2. Organon (India) Ltd.	49
3. Uni-Senkyo Ltd.	49
<u>Foreign Equity 50% - 59%</u>	
4. Hoechst Pharmaceuticals Ltd.	50
5. Warner-Hindustan Ltd.	50
6. Alkali & Chemical Corpn. of India Ltd.	51.38
7. Bayer (India) Ltd.	51.37
8. Cyanamid India Ltd.	55
9. Richardson Hindustan Ltd.	55.97
10. Boots Company (India) Ltd.	53
<u>Foreign Equity 60% - 100%</u>	
11. E. Merck (India) Pvt. Ltd.	60
12. Merck Sharp & Dohme of India Ltd.	60
13. May & Baker (India) Ltd.	60
14. Sandoz (India) Ltd.	60
15. Ciba-Geigy of India Ltd.	65
16. Wyeth Laboratories Ltd.	74
17. Glaxo Laboratories (India) Ltd.	75
18. Johnson & Johnson Ltd.	75
19. Pfizer Ltd.	75
20. Parke-Davis (India) Ltd.	83.33
21. Roche Products Ltd.	89
22. Burroughs Wellcome & Co. (India) Ltd.	100

"Can both these companies be treated on a par for the purpose of equity dilution? No, asserts the FERA committee. The foreign drug companies contend that even if a company makes only one high-technology item among its total products its total turnover should be treated as Appendix I activity.

"The FERA committee says the principle that high-technology items alone form the core sector activity which is applicable to all industries cannot be diluted in favour of the drug industry.

"Foreign drug industry sources hint at the possibility of certain companies challenging the FERA committee's decision if it seriously affects their equity positions." (7)

According to reports appearing in April 1981, the Government was reported to be "contemplating a change in the norms of foreign equity in the pharmaceutical industry". Following protests from the companies, the "current thinking" of the Government is that "the recommendations of the high-technology committee need not be the

sole basis for deciding the extent of foreign equity." (8) After 2 years of non-implementation of its policy decisions made 3 years ago, now the Government has discovered that in "quite a few cases" the conclusions of the high-technology Committee do not conform to "the realities of the situation." (8) The technological 'realities' of drug production or the political 'realities' of the Indian economy?

GOVERNMENT'S HELPING HAND

Unauthorized installation of capacity in excess of licensed capacity has been going on for years in the drugs industry as in many other industries. The Tariff Commission which went into this question extensively in the 1960s found that the drug companies had made a mockery of the industrial licensing policy of the Government and there was no relationship between licensed and installed capacities. (9) Many units had installed capacities far in excess of licensed capacities — in certain cases 10 times the licensed capacity; many had installed capacities far lesser than the licensed capacity and many had not installed any capacity for years after having obtained the necessary licences. What is worse, the Commission found that no penal action was taken against any firm. (9) The manner in which the D.G.T.D. has handled these matters is vividly portrayed in the following examples furnished by the Tariff Commission:

1) VITAMIN B-12 AND VITAMIN B-12 (b)

"The total licensed capacity is 25 kg. while the installed capacity is 64 kg. in the case of Merck Sharp and Dohme. When the unit approached Government for the regularisation of its increased capacity it was informed that this could be done only if it was prepared to reduce the price. Since the unit was not prepared to reduce the price no regularisation of the capacity was made. As against the licensed capacity of 25 kgs. for both the drugs, the unit manufactured 53.6 kgs. in the year 1967. It appears that no restrictions were placed in the way of the unit producing more than its licensed capacity. The refusal to recognise the fait accompli was therefore inconsequential so far as production was concerned. Had the unit been subjected to restrictions which would have resulted in its not exceeding the capacity for which it is licensed or at the most 25% over and above the licensed capacity, that is a total of 31.25 kg., it could be considered that Government's disinclination to increase the capacity owing to the intransigence of the unit in the matter of reduction of price, bore fruit, but in the present case it was not possible to discern any advantage that may have resulted from this approach." (9)

2. PENICILLIN

"Alembic Chemical claimed an installed capacity of 50 MMU as against a licensed capacity of 20 MMU. The D.G.T.D. has mentioned that the

production of penicillin by this unit was well above the licensed capacity and this was helpful in meeting the increasing demand. Notwithstanding this, the party was told that keeping in view the total capacity of the manufacturer and the fact that licences were held both in the public and private sector against requirements by the end of the Fourth Plan period, in regard to the progress of the licensed units, it was not possible to regularise the additional capacity. Government would however have no objection to the additional production over and above the licensed capacity being exported. This presents certain very complicated issues with regard to the licensing of capacities. On the one hand it is recognised that the installed capacity of the unit was higher than that licensed; it is also stated that this no doubt proved to be helpful in meeting the increasing demand. But, it has been simultaneously stated that it was not possible to recognise this fact." (9)

3. CHLORPROPAMIDE

"Pfizer produced 12.21 tonnes of this product in 1966. It claims an installed capacity of 5 tonnes and the licensed capacity is only 1.5 tonnes. The clarification received from Government on this discrepancy was that the proposal of the unit for expansion of its capacity for manufacture was not approved as its output was not up to the licensed capacity, and it was suggested to it that it can submit its proposal for expansion after it had been able to fully utilise the licensed capacity for at least a period of one year. This introduces a new feature in the matter of licensing of capacities. While the D.S.T.D. recognised that the proposal was for expansion of capacity for the same product, it mentioned that such expansion is allowed only if it becomes fait accompli and the performance justifies the expansion. This would mean that if the unit is allowed to increase the capacity and show higher production and then is asked to come up to Government for the regularisation of its higher capacity, Government then has the choice to recognise it or to refuse recognition, subject to the diverse criteria adopted by Government in such matters. If the expansion is refused, the unit does not stand to lose anything. It goes on producing at the higher rate and most probably it continues to get the necessary foreign exchange for raw material. Licensing of units for capacities is thus likely to be rendered infructuous. On the other hand, if Government were to deter the unit from increasing its production, the outlay on expansion would be a dead loss." (9)

These examples need no comment.

Let us now move to early 1980. With the coming to power of the Indira Gandhi Government, the Organisation of Pharmaceutical Producers of India (OPPI), which represents the interests of the large, foreign companies,* launched a Rs. 2 lakhs advertising campaign

* including companies with foreign equity less than 40% of total equity.

spread over 15 publications criticising the previous Government's drug policy. The main target was the 1978 decision to freeze the output of drug companies at the highest level achieved in any year during the 3 years preceding 31 March, 1977. The main argument (or was it a threat?) of the OPPI was that this decision would lead to a 25% fall in the output of bulk drugs as well as formulations at a time when many drugs were in short supply due to inadequate indigenous production. (10)

"OPPI Media Blitzkrieg", a report appearing in Business India (February 18 - March 2, 1980) correctly predicted that "the publicity campaign launched by OPPI is certain to sway official opinion, already somewhat sympathetic—thanks to the minister in charge of pharmaceuticals, P.C. Sethi—in its favour." (10)

In August 1980, the industry ministry, announced an excess capacity regularisation scheme for 34 industries including drugs and pharmaceuticals which recognised installed capacities as on 1 September, 1980 as the basis for regularisation. (11) This was in clear contradiction to the March 1978 drug policy of the petroleum and chemicals ministry which stipulated regularisation of excess production over the licensed capacity on the basis of the highest production achieved in any year during the 3 years preceding 31 March, 1977.

In May 1981, the Department of Chemicals and Fertilisers was reported to have designed a 'new' regularisation scheme. "The new scheme proposes to regularise installed capacity as licensed capacity in the case of companies which have achieved 60 per cent and above capacity utilisation in any of the three years preceding 1980. In the case of others with less than 60 per cent capacity utilisation, the licensed capacity will be the highest production achieved during the three years preceding 1980." (12) And this is precisely what the OPPI desired: "If there is to be a freeze on our output at all, it should be at the highest annual output produced in the triennium prior to 1980, not 1977". (10)

Other elements of the earlier policy, such as supplying part of the bulk drugs output to non-associated formulators and restricting formulations to bulk drugs output at certain stipulated ratios, were, however, retained.

Out of 139 drug units asked to furnish capacity and production data for regularisation, 114 units have applied till now. (12) But the Government has yet to identify their excess production, more than 3 years after the policy was first announced in March 1978. Meanwhile the companies go on producing as they like in excess of licensed capacities, with the Government engaged in bureaucratic exercises to legitimise, ex-poste, the violation of its own basic, economic policies.

THE ROLE OF THE PUBLIC SECTOR

With the private sector of the drugs industry dominated by the foreign multinational corporations, either directly or through collaborations, and the perverse effects of such an arrangement on the developmental potential of the local industry, the public sector companies obviously have a vital role to play in offsetting the distortions in production and technology brought about by the large private firms.

CONTRIBUTIONS

The major contributions of the public sector units to the indigenous drugs industry are as follows:

1. They pioneered the production of bulk drugs in the country which was neglected by the private sector owing to the high investment and relatively (to formulations) low profitability entailed in such activity.

2. Almost the entire output of the public sector units comprises of important bulk drugs. In 1978-79, it produced bulk drugs worth Rs.49 crores or about 25% of the total bulk drugs production, and only Rs.60 crores worth of formulations or about 6% of the total formulations production. On the other hand, the foreign sector produced about 28% of bulk drugs and 44% of formulations. More significantly, for the public sector, the value of bulk drugs production as a percentage of its formulations production works out to 82%, for the Indian sector 22% and for the foreign sector only 12%.

SECTORWISE PRODUCTION OF BULK DRUGS & FORMULATIONS: 1976-77, 1978-79

(Rs. in crores)

Sector	1976-77				B as % of F	1978-79				B as % of F
	Bulk Drugs		For- mulations			Bulk Drugs		For- mulations		
	(B)	%	(F)	%		(B)	%	(F)	%	
Public a	49	33	47	7	104	49	25	60	6	82
Indian b	28	19	241	34	12	75	37	340	32	22
Foreign c	63	42	292	42	22	56	28	460	44	12
Small- scale d	10	7	120	17	8	20	10	190	18	10
Total	150	100	700	100	21	200	100	1050	100	19

(See notes on next page)

- a. "Public Sector" includes drug manufacturing companies owned by the Central Government.
- b. "Indian Sector" includes private sector companies with Indian shareholding ranging from a minimum of 60% to a maximum of 100% of the total share capital.
- c. "Foreign Sector" includes only those companies with foreign shareholding exceeding 40% of the total share capital.
- d. "Small-scale Sector" includes the thousands of small firms with original, fixed investment not exceeding Rs.10 lakhs (the investment ceiling being revised from time to time).

3. The minor bulk drug production efforts of the foreign sector appear exaggerated in value terms. This is because the multinationals concentrate on low-tonnage, high-rupee-value bulk drugs, as pointed out by the Hathi Committee. And only some of these are essential and technology intensive. Sectoral analysis of 5300 tonnes of bulk drugs produced in the organised sector of the industry by the Hathi Committee reveals that the foreign subsidiaries and majority ownership units having 38% of the total capital investment produced only 11% of bulk drugs in physical terms while recovering as much as 27% of the total bulk drugs production in value terms. (1) (See Table below).

SECTORAL ANALYSIS OF BULK DRUGS PRODUCTION: PHYSICAL QUANTITY AND RUPEE VALUE.

Ownership/control cluster	No. of units	Capital investment (Rs. lakhs)	Quantity (tons)	Value (Rs. million)
<u>Cluster I</u> Foreign subsidiary and majority ownership	27 (34.2)	332.0 (37.6)	600 (11.3)	190 (27.1)
<u>Cluster II</u> Joint venture with foreign minority ownership	12 (15.1)	118.6 (13.5)	3200 (60.4)	270 (38.6)
<u>Cluster III</u> Indian wholly-owned firms	38 (48.1)	164.2 (18.6)		
<u>Cluster IV</u> Public Sector	2 (2.5)	267.2 (3.3)	1500 (28.3)	240 (34.3)
Total	79 (100.0)	882.0 (100.0)	5300 (100.0)	700 (100.0)

SOURCE: Report on The Committee on Drugs And Pharmaceutical Industry, April 1975, Ministry of Petroleum & Chemicals, Govt. of India.

4. It is estimated that in 1976-77, 67% of IDPL's bulk drug output, and 50% of HAL's, was sold to formulators in the private sector who make good profits on the finished products. (2) Besides, much of the public sector formulations output is supplied to government institutions and hospitals. For example, in 1976, 50% of HAL's bulk penicillin output was sold to the multinationals and the other 50% was formulated and sold to government health institutions. (3)

5. The formulations are often sold to government institutions and hospitals at prices below market prices. For example, in 1978, IDPL was supplying tetracycline to hospitals at Rs.35 per 100 capsules compared to Rs.48 per 100 capsules it charged in the open market. Similarly, it supplied oxytetracycline at only Rs.36.64 against its market price of Rs.58. (4)

Further, before the advent of IDPL, the large companies with powerful foreign interests, used to sell tetracycline at around Rs.106-118 per 100 capsules in the 1960's. By 1978, the price had fallen to Rs.55-63 with IDPL charging the lowest price of only Rs.48 per 100 capsules. (4)

However, despite the many valuable contributions made by the public sector there still remain fundamental weaknesses in its overall performance which allow the multinationals to continue their domination of the Indian market and which generally inhibit the growth potential of the industry.

FAILURES

In 1954, the first public sector unit, the Hindustan Antibiotics Ltd. (HAL), was set up with American (Merck) collaboration. In 1956, its plant at Pimpri, near Pune was the first to produce penicillin in India. However, from the very beginning HAL has been beset by a number of problems. To some extent these are inevitable for a new entrant pioneering the production of new bulk drugs on a large scale in the country. However, the technical, marketing and financial problems of HAL seem to be 'eternal' with the result that the primary objectives of setting up public sector drug units — mass production of bulk drugs to make the country self-sufficient, to reduce the import burden and technological dependence on the multinationals, and to free the drug market from the overall domination of the multinationals — remain unfulfilled. Today, HAL, continues to suffer massive financial losses (see Table on the following page) and is plagued with utter mismanagement and underutilisation of capacity.

HAL: CONTINUING LOSSES (Rs. CRORES)

Year	Net Sales	Net Loss (-)	Loss As % of Sales
1974-75	6.63	-3.28	50
1975-76	9.45	-2.92	31
1976-77	13.77	-0.68	5
1977-78	13.97	-2.22	16
1978-79	16.17	-1.97	12
1979-80	17.10	-2.98	17
1980-81	26.00*	-3.00*	11

* Estimates

HAL's output of penicillin and streptomycin remained stagnant between 1959 to 1967. Use of obsolete technology was an important reason for this stagnation. (2) In January 1976, a technical agreement was signed with Toyo Joza Co., Japan for increasing the productivity of the penicillin plant. In Phase I, the production was to increase by 50% without any significant increase in inputs. In fact, production went up by 100% in this phase. (3) In the more important Phase II, penicillin production was to rise by 300% after modifying the existing equipment to the needs of the new Japanese strain. However, production actually increased from 74 mmu (million mega units) to only 117 mmu, or by 58%. The experience with high-yielding strains of streptomycin was no different: the productivity increases were only marginal. (5)

The company's efforts at developing its own technological innovations, have been characterised by inadequate planning. Production of Hamycin, an anti-fungal antibiotic developed by HAL's own research efforts, had to be discontinued in December 1974. A 1000 kgs. a year capacity plant was set up in the 1960s. In 1970, only 17 kgs. was produced and this further plummeted to 0.2 kg in 1974 before the plant was shut down. The reasons were the rapid deterioration of the product as well as high toxicity. These should obviously be studied adequately, before launching production, through quality control tests. Instead, HAL spent lakhs of rupees on an inadequately tested product. (5)

Take the story of Ampicillin as another instance of poor back-up to the company's technological achievements. Ampicillin is derived from a drug intermediate known as 6 A.P.A. which in turn is processed from penicillin I crystals. A Rs.3-crore plant for the manufacture of ampicillin from penicillin I was set up following the progress made by HAL's R & D division in ampicillin technology. But instead of backing up these achievements further with adequate investment, HAL produces ampicillin from imported 6 A.P.A. under technical collaboration with American Home Products. (5)

Another disaster story is that of Vitamin C. Almost 2 decades ago, the Government decided to produce Vitamin C indigenously. HAL was

given a licence in 1961 to take up its production. However, in 1968, the Vitamin C plant was still being "designed". (6) It was eventually commissioned in 1973 with technical know-how from the National Chemical Laboratory, Pune. You may say, better late than never. But you would be mistaken. The plant has yet to produce commercially viable Vitamin C on any significant scale: in 1979-80 its output was only 17 tonnes against an installed capacity of 125 tonnes! At present, it is reported to be still under "trial runs". (7) And note the double loss to the economy: the high capital costs due to incredible delays in commissioning the plant, on the one hand, and the abysmally low level of output from the capacity eventually installed, on the other.

The Indian Drugs and Pharmaceuticals Ltd. (IDPL) was established in 1961 with Soviet technical collaboration and loan assistance to make a significant breakthrough in the production of a wide range of antibiotics and synthetic drugs. It started production in 1968-69.

IDPL too faced teething technical problems in its early years. Use of obsolete technology led to low levels of productivity. For example, the streptomycin strain supplied by the Soviets yielded only 8-10 thousand units, whereas the strain supplied by Glaxo to HAL yielded 18,000 units. (2) To overcome the technological obstacles, IDPL bought sophisticated technology from Farmafim of Italy for 5 antibiotics of mass consumption: penicillin, tetracycline, erythromycin, doxycycline and ampicillin. It was expected that this would enable the country to quickly attain self-sufficiency in these essential drugs.

But what is the position today? The following excerpts from a recent news item in The Times of India vividly highlights the mess IDPL is in:

"The monthly loss on account of underutilisation of capacity is estimated at about Rs.1.5 crores. Of the total loss, the Rishikesh antibiotic plant of IDPL alone is responsible for a loss of over Rs. 1 crore every month. During the period April - June this year (i.e. 1981), Rishikesh accounted for a total loss of Rs.3.5 crores out of a total of Rs.4.3 crores for the organisation as a whole.

"It may be interesting to note that the rate of capacity utilisation of the Rishikesh plant after the transfer of the latest (Italian) technology is around 30%. With the Soviet technology it had been possible to attain 85-90% capacity utilisation. At present, the Gurgaon formulation plant is operating at 15-20% capacity, the surgical instrument plant at Madras at 30% and the Hyderabad semi-synthetic drug plant at 65%.

"IDPL has also bungled in the implementation of its expansion plan. On account of delays, the project cost (of expanding antibiotics production with Italian technology) had gone up from the original

estimate of Rs.15.3 crores to Rs.27 crores. This revised cost does not include the expansion plan for streptomycin, grisonofulvin and ceaphlorodin which formed a part of the scheme when the original estimate was prepared.

"IDPL has had to pay an interest \$50,000 to Farmafin for delays in technology transfer." (8) (Brackets inserted by me).

And this is not happening for the first time. The Committee on Public Undertakings (1973-74) found that ever since its inception, the IDPL has shown inadequate project management and poor planning and implementation. (9)

During the trial runs, the Italian strains yielded outputs higher than the minimum required under the agreement. But after the trial runs, the yields fell to low levels despite IDPL personnel having undergone training in Italy to ensure quick absorption of the new technology.

"This dismal performance of IDPL is evidently the upshot of poor management of personnel, plant and materials. Inquiries here have revealed that IDPL has the unique distinction of rewarding inefficiency. A number of people, not of proven skill, have been promoted and confirmed as chief plant executives." (8)

IDPL JOINS THE LOSERS (in Rs. crores)

Year	Net Sales*	Net Profit (+)/Loss (-)
1974-75	45.84	+ 2.49
1975-76	58.52	+ 3.55
1976-77	73.56	+ 4.11
1977-78	79.15	+ 7.56
1978-79	73.20	+ 0.01
1979-80	67.76	- 7.19
1980-81		- 13.00
1981 (April to June)		- 4.30

* Including sales of canalised drugs.

Owing to the poor production performance of the public sector, the Government is reportedly thinking of 'de-reserving' 25 bulk drugs (mostly antibiotics, sulpha, drugs and some vitamins) reserved for production in the public sector under the March 1978 drug policy.

Take for instance Vitamin B1 and Vitamin B2. Both these vitamins are reserved for the public sector. During 1979-80, IDPL's capacity utilisation for vitamin B1 was 41% and for vitamin B2 31%. This necessitated heavy imports of these drugs far in excess of the low domestic levels of production. Again, IDPL has not been able to utilise even 50% of its capacity for key antibiotics like tetracycline and streptomycin. (10)

Low overall levels of production of several important antibiotics — for which the average capacity utilisation is around 60% for the past several years — such as penicillin, ampicillin, streptomycin and erythromycin has resulted in heavy imports. In 1978-79, antibiotics imports alone amounted to Rs.18 crores and sulpha drug imports amounted to Rs. 3 crores or so. In 1979-80, HAL's production of streptomycin declined to 91.06 tonnes from 100.26 tonnes in 1978-79 while that of penicillin increased only marginally to 117.19 mmu from 116.80 mmu during the same years. (11) And the overall turnover of IDPL fell to Rs.68 crores in 1979-80 from a level of Rs.73 crores in 1978-79. (See Table above).

BIRDS OF A FEATHER

Besides the production of bulk drugs of vital importance to the country, another important area of the public sector's operation is in the field of canalised bulk drug imports. The major objectives of canalising the imports of some 45* critical bulk drugs/intermediates were:

1. to obtain concessional terms of supply and lower prices through bulk purchases on world markets,
2. to ensure equitable supplies of raw materials at uniform prices to local formulators including the small-scale units,
3. to regulate the introduction of new drugs in the Indian market, and
4. to generally protect the indigenous production.

The central canalising agency for drug imports in the country is the State Chemicals and Pharmaceuticals Corporation (CPCO, a subsidiary of the State Trading Corporation (STC). The Indian Drugs & Pharmaceuticals Ltd. (IDPL) plays an important role in the distribution of the drugs imported by the CPC and also of those manufactured by itself in limited quantities.** In such cases, the IDPL operates a pool of the imported and indigenously produced stocks to be distributed at the weighted average price of the two type of products.

The Chavda Committee (April 1978), went into the specific question of reportedly higher import prices for canalised drugs as compared to the prices at which actual users could import the same drugs. Though the Committee was also to go into the general question of import prices of drugs being higher than the corresponding indigenous prices, it regretfully noted that it could not "make any meaningful study of comparative prices" because of inadequate data provided to it. And this cannot be merely an accident: it is very likely that much of the sensitive information regarding the imports of private firms was suppressed by the vested interests. For example, the Committee had the following to say about the 6 lists of comparative prices of bulk drugs supplied to it:

* during 1977-78

** There were 16 such items out of the 45 canalised drugs/intermediates during 1977-78.

"None of the 6 lists contained complete information in regard to the 45 canalised items ---. While list 3 gives certain information about the prices of private imports of vitamin B1 (mono & Hcl), vitamin B2, vitamin B6, chloroquin, etc. lists 5 and 6 give the impression that no imports of these items were made by private importers. Again, while the c.i.f. price of tetracycline imported by Gujarat Export Corporation in the month of November 1977 has been shown at Rs.300/- per kg. list 5 does not include this information at all." (12)

On analysing the actual expenses incurred by the CPC for the 9-month period (April to December 1977), the Committee found that the CPC charged a total of 3.46% more than the actual expenses incurred under the following 3 heads: clearance charges on c.i.f. price (1.48% excess), Letter of Credit (L.C.) opening charges and voyage interest on c.i.f. price (1.68%) and distribution charges on landed cost i.e. c.i.f. + customs duty + other charges, (0.30%). The Committee concluded that there was "a clear case for downward revision of the percentages" charged by CPC which would bring about "a substantial reduction" in the issue prices of canalised bulk drugs, perhaps of about 20%, and the formulations based on them. (12)

The Table on page 34 - 35, as prepared by the Committee, shows the adverse effects on the formulations prices, which the final consumer has to ultimately bear, due to canalisation through CPC/IDPL.

It seems, from the above evidence, that the canalisation of vital bulk drugs has been used to make handsome profits from the monopoly control of imported stocks by the State agencies!

There are even more interesting anomalies. The Committee was keen on investigating the excessively high notified prices of the anti-malarial drug Trimethoprim. It found that the import price (c.i.f) of trimethoprim was \$55.75 per kg. or about Rs.461 per kg. Taking the CCI & E's prescribed formula of 191% over the c.i.f. price for CPC, the issue price of the drug works out to Rs.881 per kg. But the BICP took Rs.1075 per kg. as the base price for its calculations and stipulated the issue price at Rs.2000 per kg! And look at the dubious argument of the Department of Chemicals & Fertilisers to explain away this anomaly: "the artificially propped loaded prices were to serve as an incentive (sic) to Burroughs Wellcome to reduce their prices and to act as deterrent to the payment of subsidy to Burroughs Wellcome which would have resulted from a pooled price"! (12)

Surely, if the Government has to sacrifice the consumer to give "incentive" to Burroughs Wellcome, it does not hesitate to violate its own price fixation formulas.

c.i.f.: cost, insurance, freight; CCI&E: Chief Controller of Imports and Exports; BICP: Bureau of Industrial Costs and Prices.

The basic purpose of canalisation is to equitably distribute cheaper imported drugs to local formulators, including the small-scale sector, at uniform rates, thus putting those who charge unduly high prices at a competitive disadvantage. But, if the Government were to carry its woolly logic of "incentives" to its conclusion, then, in every case, it would have to keep the canalised drug prices close to the artificially high prices charged by the multinationals and thus join them in the collective loot of the consumer. In the case of Trimethoprim discussed above, the Committee concluded that "such artificially propped-up prices were resorted to protect the interests of M/s. Burroughs Wellcome & Co., who manufacture the products from penultimate or intermediate stage chemicals." (12) What else can explain why, in the first instance, Burroughs Wellcome should be allowed to manufacture trimethoprim formulations. The imported penultimate materials used by the company cost the same or even higher than the imports of the finished drug itself in terms of foreign exchange! (12)

Consider the following antics of the IDPL. The Committee found that in 1977-78, the IDPL made a surplus of Rs.117 lakhs on the distribution of bulk drugs, both canalised as well as those from its own indigenous production. The Committee was apprehensive that "this surplus will be utilised for off-setting IDPL's losses" i.e. ultimately the consumer would have to bear the burden of IDPL's inefficiencies. A classic case of the public sector 'exploiting' the consumer is to be found in IDPL's distribution of the bulk drug Sulphaguanidine. The price of the indigenously produced drug by IDPL itself was fixed at Rs.89.74 per kg. which was insufficient to cover its production costs. During 1974-75, 105 tonnes of sulphaguanidine were imported at a total cost of Rs.66.75 lakhs or Rs.63.57 per kg. The pooled price at which the drug was sold by IDPL was fixed at Rs.115.61 per kg. During the subsequent years, this drug was not imported at all owing to IDPL's adequate indigenous production. But the drug was kept on the canalisation list and the 783 tonnes of sulphaguanidine produced by IDPL during the four-year period 1974-75 to October 1977) was sold at the pooled price of Rs.115.61 per kg. with an extra profit of over Rs.2 crores! (12)

The Committee found a number of other cases where the prices fixed by IDPL were unduly high. For example, the distribution price for imported Griesofulvin to be sold by IDPL was fixed at Rs.4925 per kg., when the ex-godown price of the drug was only Rs.1300 per kg. (12)

Take these further examples of price fixation which make little sense, at least in terms of the underlying economic rationale. The pooled price of Frusemide, manufactured indigenously by Hoechst, was fixed at Rs.1741 per kg. when its import price was much lower. But, in the case of Indomethocin, when M/s. Mermaid Chemicals were willing to sell their indigenous production for only

EFFECT ON PRICES OF FORMULATIONS DUE TO PROCUREMENT OF BULK DRUGS FROM CPC/IDPL VIS-A-VIS ACTUAL IMPORTS.

Drug	C.I.F. Price (Rs./Kg.)	Landed Cost of Direct Imports to Actual user (Rs./Kg)	Final Price if Bought from CPC/IDPL (Rs./Kg)	Extra cost to user (Rs./kg)	Formulation price per unit (Rs.)	Formulation price per unit (Rs.)	Extra Price Consumer pays. (Rs.)	Percentage Increase in Price paid by consumer (%)
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
Ampicillin Trihydrate (Cap. of 250 mg. each)	627 (Sept, 1977)	1120.06	1593.00	472.94	56.00 (100%)*	79.65 (100%)*	23.65	42.25
Chloramphenicol Powder (250 mg. each)	105 (April 1977)	333.30	632.00	299.58	14.16 (70%)*	26.897 (70%)*	12.74	89.95
Chloroquine Phosphate (250 mg. each)	248 (Aug. 1977)	445.44	462.24	16.80	17.02 (60%)*	18.48 (60%)*	0.66	3.70
Doxycycline Hcl. (100 mg. each)	1410 (Dec. 1977)	2513.80	4320.00	1806.20	50.20 (100%)*	86.40 (100%)*	36.12	71.84

Contd....

EFFECT ON PRICES OF FORMULATIONS DUE TO PROCUREMENT OF
BULK DRUGS FROM CPC/IDPL VIS-A-VIS ACTUAL IMPORTS. (Concid).

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
Erythromycin Sterate (250 mg. each)	561 (Oct. 1976)	1002.58	1404.00	401.42	43.86 (75%)*	61.42 (75%)*	17.56	40.03
Trimethoprim Sulphametho- xazole (80 mg. + 400 mg Tabs)	547 189 (Nov. 1977)	977.66 340.42	2160.00 432.00	1182.34 91.58	42.87 (100%)*	69.12 (100%)*	26.25	61.23
Oxytetracyc- line Hcl. (Cap. of 250 mg)	234	420.52	808.92	388.40	21.02 (100%)*	40.45 (100%)*	19.43	92.43

* Mark-ups.

Source: Chavda Committee Report on Canalization of Drugs & Pharmaceuticals, April 1978.

Rs.1400 per kg., their production was not pooled with the Indomethocin imported by M/s. Merck Sharp & Dohme (an American multinational) at the fancy price of Rs.3000 per kg! (12) In other words, in the case of Indomethocin the efficient producer (Mermaid) was penalised, while in the case of Frusemide the "inefficient" producer (Hoechst) was rewarded. Either way, the consumer paid the price!

The Committee concluded that the primary objectives of canalisation, viz. lowering prices of essential drug formulations based on canalised materials and establishing a uniform level of such prices in the market, have not been fulfilled.

What are we to make of all this? Has the public sector been created to bring down prices of essential items of mass consumption by flooding the markets with plentiful supplies produced at reasonable cost or to defraud the ultimate consumer by making him pay for its poor efficiency and dismal performance? The *raison d'être* of the public sector organisations in the drugs industry is to check the private sector companies' tendencies to distort the pattern of production away from essential, life-saving drugs and exploit the consumer by charging unduly high prices. But if the public sector itself joins the league of the 'profiteers', whose excesses it is supposed to counter, then we might as well wind up the public sector.

We may briefly summarise the major failures of the public sector as follows:

- The 2 major public sector manufacturing units, HAL and IDPL, have remained in a perpetual state of crisis since inception, particularly HAL.
- They have failed to make the country self-sufficient in several, vital bulk drugs of mass consumption which continue to be imported in large quantities.
- They have shown poor production levels, idle capacities and huge financial losses. They are plagued by a host of managerial and technical problems.
- A fundamental failure of the public sector has been its inability to smoothly absorb and adapt imported technology, not to speak of developing its own, independent technological dynamism. The public sector units, like their private sector counterparts, continue to depend on foreign sources for sophisticated technology.
- Canalisation of some important bulk drugs through the public sector organisations has failed to achieve the basic objectives of lower and uniform prices. In fact, the public sector has often fixed very high prices of several canalised items with utter disregard of the consumer's interest thus violating the basic economic policies of the country.

CONTROLLING PRICES AND PROFITS

It may be interesting to note that historically, State regulation of the drugs industry in India started due to complaints of sub-standard and spurious drugs imported from abroad. The Drugs Enquiry Committee was set up in 1930 to go into the problem of ensuring proper quality standards of the drugs sold in the country. Its recommendations submitted in 1931 ushered in legislation for drug control on a comprehensive basis. (1)

In recent times, the most controversial piece of Government regulation is the one concerning pricing. Before we go into the specific aspects of price controls in the Indian drugs industry, it will be useful to discuss the structural characteristics of the industry in general.

THE NATURE OF COMPETITION

In almost every country, the drugs industry comprises of thousands of small units, most of them locally owned, which contribute about 20% of the total output of drug formulations. Almost all the small units are engaged in purely formulation activities. The formulation of drugs does not involve sophisticated technology or large capital investments and hence there are no significant entry barriers faced by these small firms.

In India, there are over 5,000 small-scale drug manufacturers. The Table on the following page gives the State-wise distribution of all licensed drug manufacturers in particular years. The large-scale organised sector comprising some 139-odd firms or so, accounts for 82% of the total formulations sales.

The larger units come to dominate the formulations market owing to the tremendous heterogeneity of the products of the drugs industry. However, a large part of this heterogeneity is contrived or artificially created by the companies in their attempts to increase their individual sales. For example, as we have observed in Chapter 4, in 1974 for the 700 different prescription drugs available in the U.S. market there existed 20,000 different branded names— an average of 30 "different" products for the same drug. (2)

The reason for this bewildering maze of thousands of products is that the drug industry is characterised by intensive product competition among the giant companies. The major drug companies of the world give maximum emphasis to the continuous development of new products in their R & D efforts. No doubt, people all over the world have greatly benefited from these innovations. However, product competition has given rise to 2 major disadvantages: (2)

1. It largely eliminates price competition whereby the consumer is deprived of the important benefit of lower drug prices. The

STATEWISE DISTRIBUTION OF THE LICENSED DRUG MANUFACTURERS IN SELECT YEARS.

State	1969-70	1977-78	1979-80
Andhra Pradesh	172	232	274
Assam	12	28	N.A.
Biher	39	198	119
Gujarat	140	298	375
Haryana	*	78	96
Himachal Pradesh	9	13	18
Jammu & Kashmir	5	12	17
Karnataka	56	94	105
Kerala	52	86	128
Madhya Pradesh	109	210	219
Maharashtra	736	1956	2135
Meghalaya	-	2	2
Nagaland	-	-	-
Orissa	24	90	95
Punjab	106	80	92
Rajasthan	51	82	143
Tamil Nadu	199	333	442
Tripura	4	5	8
Utter Pradesh	198	352	N.A.
West Bengal	255	523	679
UNION TERRITORY			
Chandigarh	-	5	7
Dadra & Nagar Haveli	-	4	2
Delhi	81	113	149
Goa, Daman & Diu	8	35	35
Pondicherry	2	14	16
Mizoram	-	358	-
TOTAL	2257	5201	5156

* Included in the figure for Punjab.

Source: All India List for Licensed Drugs & Cosmetics Manufacturers compiled by the Drugs Controller (India), Directorate General of Health Services, Government of India.

sales promotion and advertising campaigns are so geared that they shift attention away from prices to particular product characteristics and advantages, some of which are real, some grossly exaggerated and some purely mythical. The massive sales promotion outlays necessitated by the intense product rivalry account for a large part of the industry's turnover (between 1/3 to 1/4 of U.S. industry sales for example). Needless to add, these costs are ultimately recouped from the consumer. Also, the companies come to depend heavily on a few products for a large volume of sales.

This leads to low price elasticity of sales at such large volumes. Further, a price reduction by one company easily provokes retaliatory action from the competitor leading to mutual destruction if the 'price wars' go unchecked.

2. It adversely affects the composition of R & D outlays by the large firms with substantial sums being spent on superficial product changes with a view to enhancing saleability. (See Chapter 4, pg.45-46 for a more detailed exposition of this effect.)

It is in the context of this intense product competition in a heterogeneous industry that the brand names and patents play a crucial role. The whole system of strong product differentiation in the drug formulations market rests on them. When a new product is developed by a company's R & D division, it is patented and given a new brand name. Patents, by preventing other firms from making the same product for a stipulated period of time, eliminate all forms of competition and give ample time for the company to recover its investments. Brands, by making a particular product clearly identifiable and differentiated, form the basis of the promotional campaigns of the company in its bid to create high brand-fidelity. It has often been found that long after patents expire, strong brand preferences continue to last enabling the innovator to maintain his dominant market share despite higher prices. (2) Thus both brands and patents are an integral part of product competition and they serve to eliminate price competition. The only sector where price competition plays an important role is that of unpatented, non-branded generic drugs available from a number of different producers. (2)

The general description above of the nature of competition in the pharmaceutical industry in the West broadly holds true for the Indian industry also. In fact, the adverse effects of the competitive dynamics of the Western multinationals assume different dimensions under the Indian situation. First and foremost, the developed economies at least get the full benefits of the large producer's R & D activities which account for about 10% of the industry's turnover. In the developing countries, the multinational subsidiaries merely introduce new products generated by R & D conducted in their parent or sister organisations in the West. In India, R & D expenditures average around 1.5% of the total industry sales in recent years. At present, out of the 22 foreign companies (with equity participation exceeding 40%) only 2, Hoechst Pharmaceuticals and Ciba-Geigy, have any significant R & D organisations; and they too have yet to make any major contributions. (For a detailed discussion on R & D and technology in the Indian drugs industry, See Chapter 4 pgs. 43 - 47 Chapter 5 pgs. 60-65 and Chapter 6 pgs. 67-68).

Second, the elimination of price competition, the intensive product rivalry accompanied by large selling costs and the consequent high prices of drugs, places them out of reach of a large

number of people in developing countries like India. It is in the context of these specific characteristics of the drugs industry that the Indian Government has evolved elaborate price and profit controls with a view to attaining a better harmony of private profit and social good.

The Hathi Committee has explained the rationale underlying price and profit controls in the Indian drugs industry in the following words: "The per capita consumption of modern drugs and pharmaceuticals in India is currently estimated to be Rs.6 per year and according to some estimates, only about 20% of the population use modern drugs. On a rough estimate it would appear that the total annual expenditure on drug formulations will probably be below Rs.30 per family where the family income is Rs.4,200 per year. The pricing of drugs is thus a socially important issue not because of its effect on the family budget but for certain other considerations. High prices of drugs, for instance, would affect the ability of the public hospitals to cater to the needs of the poor; but even here, it has to be recognised that the cost of medicines constitutes a relatively small proportion around 12 to 15 per cent of the total cost of the public health services. The reduction in the price of drugs, by itself, therefore, will not make much difference to the ability of the municipal or state agencies to provide medical facilities. The concern about drug prices, therefore, really arises from the fact that many of them are essential to the health and welfare of the community; and that there is no justification for the drug industry charging prices and having a production pattern which is based not upon the needs of the community but on aggressive marketing tactics and created demand. In other words the main objective of policy has to be to secure a better convergence of commercial considerations and social needs and priorities. The emphasis has to be on increasing the social utility of the industry particularly in the context of extreme poverty and the urgent need for extending as rapidly as possible certain minimum facilities in terms of preventive and curative medicines to the large mass of people both urban and rural." (3)

It is in the context of these peculiar characteristics of the drugs industry coupled with the particular social needs and objectives of the country that the control of prices and profits has to be judged. Conceptually speaking, price control is perfectly valid. However, whether it is effective in practice depends much on the manner in which the Government attempts to implement it and the responses of the industry.

PRICE CONTROL POLICY

The Indian drugs industry has been under some form of price control or another since almost 2 decades now. Drugs were first brought under price control in the wake of the Indo-China War of 1962 under the Defence of India Rules. The Drugs (Display of Prices) Order,

1962 and the Drugs (Control of Prices) Order, 1963 virtually froze the prices of drugs—many at very high levels—as of 1 April, 1963 for the next 7 years till the promulgation of the Drugs (Prices Control) Order, 1970 on 16 May 1970. A system of selective price increases of certain drugs with prior Government approval was, however, introduced in 1966—Drug Prices (Display and Control) Order, 1966.

The DPCO, 1970 marked the beginning of a highly systematic and comprehensive control of prices and profits in the drugs industry. Revisions in the prices of almost all drugs and formulations required prior Government approval. However the DPCO, 1970 failed to achieve its major objectives of lowering prices of several essential drugs, attaining uniformity of prices and ensuring adequate supplies of essential drugs at reasonable prices on a sustained basis.

In this report, we shall restrict ourselves mainly to an analysis of the Drugs (Prices Control) Order, 1979 and its operation over the last 2 years. Considerable material is available in various magazines, newspaper articles and reports on the implementation of the DPCO, 1970. An extensive and detailed discussion of this Order may be found in the Mathi Committee Report, April 1975.

Below, we shall discuss some of the major features of the Government's latest Drugs (Prices Control) Order, which came into effect from 1 April 1979, and how effective their implementation has been in practice.

1. The less essential the drug formulation or finished product, higher the mark-up allowed over the average direct or factory costs of production of some major, and supposedly more efficient, larger producers.

The cost-plus pricing formula used is roughly as follows: Price = (Material costs + Conversion costs + Packaging costs) + % Mark-up on the sum of these 3 cost elements.

Thus, in the main, selling costs, administrative expenses and profits have to be provided for from the stipulated mark-ups.

2. Over and above, the specific mark-ups fixed for different categories (40% for the most essential category I formulations, 55% for II, 100% for III), an overall, maximum pre-tax profit ceiling ranging from 8% to 13% of gross sales, including excise duty, depending on size of turnover, volume of bulk drugs production and R & D efforts, is also stipulated.

3. The prices fixed according to the formula described in 1. above, called "leader prices", have to be followed by all others including the small-scale units.

4. As far as bulk drugs are concerned, all those which are used in the fabrication of price-controlled formulations are subject to the DPCO.

Bulk drugs used for formulating category I & II drugs are allowed a post-tax return of 14% on net worth. Those used for category III formulations are allowed a 12% return.

The idea is to co-ordinate the 2 sets of prices: those of the bulk drugs and their formulations. And an added incentive of 2% is given to encourage the production of more essential bulk drugs.

1. The Government in its attempt to provide essential drugs of mass consumption at reasonable prices to the consumers has fixed lower mark-ups for more essential items. But, in practice, this has served as a disincentive to the increased production of more essential items. As in many other key industries such as cement, paper, aluminium, unrealistically low and rigid price fixation in the name of lowering prices of essential goods and protecting the 'common man' has led to exactly the opposite consequences: shortages and blackmarketing, which benefit only the hoarders, speculators and corrupt politicians.

Production and investment in the drugs industry have been severely affected over the past 2-3 years by the inability of the price-fixing authorities to effectively monitor, on a continuous basis, the price-cost variations of hundreds of bulk drugs and thousands of formulations covered under the different categories of the new DPCO. The result is long delays in announcing the revision of prices of end-products in an inflationary environment where the corresponding input prices are allowed to freely escalate.

Take for instance the situation prevailing in mid-1981. By June, 1981, prices of 85% of the 200 major bulk drugs and 25% of the formulations under the 3 categories had been revised. These revisions were based on costs prevailing in August 1980, and for some drugs the base taken was 1979. The industry was prompt in demanding further price revision on the basis of 1981 costs, on grounds of spiralling cost inflation during 1980-81. And by the time the officials work out the revised prices on 1981 costs, they would again be out-dated! Meanwhile, the much talked about "common man" has to run from pillar to post hunting for essential medicines.(1)

For example, insulin an essential drug used by diabetics has been in great demand but its production level has stagnated around 1,500 mmu for the last 2 years. (4) Similarly, the output of penicillin increased only marginally from 315 mmu in 1977-78 to 327 mmu in 1979-80. The story is the same for several essential drugs. Imports of several bulk drugs like anti-biotics, sulphas, steroids, anti-malarials, and anti-TB drugs have been rising on account of inadequate indigenous production. (5,6) During 1980-81, imports of bulk drugs may be around Rs.100 crores or just under half of the

value of bulk drugs production of Rs.240 crores. It is true that price is only one of the many critical elements affecting the volume of production in the Indian economy, but it is a very powerful element which can severely affect the incentive to produce. (The Table on the following pages give some sketchy data on recent trends in the production, imports and exports of drugs).

DECLINING TREND IN THE PRODUCTION OF BULK DRUGS AND FORMULATIONS IN RECENT YEARS. (Rs. crores)

Year	Bulk Drugs	% change over previous year	Formulations	% change over previous year
1965-66	18	-	150	-
1974-75	90	-	408	7.4
1975-76	130	44.4	560	37.3
1976-77	150	15.4	700	25.0
1977-78	164	19.3	900	28.6
1978-79	200	22.0	1050	16.7
1979-80	226	13.0	1150	9.5
1980-81	240*	6.2	1200*	4.3

* Estimates.

HEAVY IMPORT DEPENDENCE (Rs. crores)

Year	Imports of bulk drugs (I) (C.I.F. Value)*	Bulk drugs production (P)	I as % of P
1974-75	30	90	33
1975-76	39	130	30
1976-77	47	150	31
1977-78	84	164	51
1978-79	81	200	41
1979-80	80	226	35
1980-81	100**	240**	42

Source: Compiled from various sources.

Notes:

1. Most of our drug imports (about 85%) consist of bulk drugs.

* C.I.F. stands for Cost, Insurance, Freight.

** Estimates.

2. The country continues to depend very heavily on imports of bulk drugs (the 'base plank' of the drugs industry) more than 2 decades after the beginning of a modern drugs industry.
3. The major reasons for this continuing, costly import dependence are:
- the disinclination of the large, private sector companies, particularly the foreign-controlled ones, to undertake the large-scale manufacture of essential bulk drugs from the basic stage of the production cycle, often involving "high technology". Instead, they prefer to import the bulk drugs or their late intermediates, usually from their principals or collaborators abroad.
 - the inability of the 2 public sector corporations—HAL and IDPL—to at least maintain, if not rapidly expand, adequate levels of production of several essential bulk items from the capacities already installed at high capital costs.
 - the lackadaisical and adhoc manner in which the Government has implemented its basic policy decisions in the matter of prices, profits and production capacities.

POOR EXPORT PERFORMANCE

(Rs. crores)

Year	Formulations Exports (E)	Formulations Production (P)	E as % of P
1971-72	7.2	300	2.4
1972-73	7.4	360	2.1
1973-74	13.1	380	3.4
1974-75	19.2	408	4.7
1975-76	19.7	560	3.5
The above export figures are non-comparable to the export figures below.			
1975-76	16.4	560	2.9
1976-77	17.1	700	2.4
1977-78	16.7	900	1.9
1978-79	21.0	1050	2.0
1979-80	19.4	1150	1.7
1980-81	28.0*	1200*	2.3

* Estimates.

Source: Compiled from various sources.

(See Notes on the following page)

Note:

1. A substantial proportion of our exports (about 70%) of modern drugs consist of formulations.
2. Our formulation exports account for a negligible portion — about 2% — of our total formulations production.
3. The poor export performance coupled with the heavy import dependence of the modern drugs industry has resulted in a massive net drain of foreign exchange resources over the years.
4. Some important reasons for the poor export performance of the modern drugs industry are:
 - a) Considering the fact that the drug formulations market is largely dominated by firms with substantial foreign interests, it is not surprising to find that the industry has not launched a vigorous export drive. Exports are taken good care of by their parent and sister companies abroad.
 - b) As we have seen in Chapter 5, several technical collaboration agreements with the larger Indian companies contain export restrictions. The technology suppliers do not want to face any competition in world markets from their technology buyers.
 - c) The inability of the Indian companies — public and private — to compete with the multinational giants in the world markets.

2. The pre-tax margin of 8% - 13% on formulations sales should amount to at least 20% post-tax return on net worth (share capital + reserves) for several large companies which is fairly generous under Indian conditions. In practice, the average profitability of the industry has been far lesser owing to only partial compensation of cost increases allowed by Government in the form of corresponding price increases for a wide range of drugs, and the incredible delays in announcing price revisions under conditions of soaring inflation all over the world including India. However, this does not imply that the large, organised sector of the drugs industry suffers from poor profitability. In fact, the profit performance of the drugs industry compares very favourably with other chemical industries and even more so vis-a-vis the organised industrial sector as a whole despite the industry's propaganda to the contrary.

THE MYTH OF POOR PROFITABILITY

The Tables on the following pages compare the profitability of the pharmaceutical industry vis-a-vis some major chemical industry groups as reflected in the key profitability ratios of 201 chemicals companies (each with a paid-up capital of Rs.5 lakhs or more) covered in the RBI survey of the finances of 1720 large and medium public limited companies during the 3-year period 1975-78.(7)

An analysis of the Tables reveals the following important facets of the profit performance of the organised drug industry:

- a) At most, the price controls (under DPCO 1970) seem to have considerably depressed the overall post-tax margin on sales as measured by profits after tax as a percentage of net sales. (Table I).
- b) The companies appear to have offset this disadvantage by a rapid increase in net sales on a relatively narrow capital base. Despite the poor average post-tax margin on sales, the drugs industry managed to maintain attractive levels of return on net worth or owners' capital i.e. share capital + reserves. (Table II).

The ratio of net sales to net worth increased from around 2.5 in the early 1970s to 3.5 in the late 1970s. The larger companies could, therefore, maintain their average return on net worth at 16.5% despite a low net margin on sales of 4.6% in 1977-78 as compared to the return on net worth of 16.4% with a net margin on sales of 7.0% in 1970-71. (Table III).

And this seems to be a time-tested strategy of the larger companies: "But the fact remains that the industry was able to off-set part of the decline in profitability on sales by the increase in the volume of sales. Between 1968-69 and 1972-73 the total sales of formulations by foreign companies with more than 50 per cent foreign equity, increased by 69.2 per cent. The corresponding increase in the case of the Indian companies, however, was only 32.9 per cent and this is one of the reasons for the relatively sharper reduction in the profitability of some of the Indian companies." (3)

- c) The drugs industry ranks second highest in the chemicals industry in terms of return on net worth. But when ranked in terms of return on equity capital it ranks lowest among the profit-making chemical industry groups (Table IV). This means that the drugs industry has the lowest level of reserves and surplus (used for partly financing investment outlays) in relation to its equity capital as compared to other chemical industries.

The low level of reserves and surplus, in turn, is explained by the low proportion of profits after tax retained in business by the drug companies in India which have followed a very high dividends payment policy. The drug industry ranks the number one industry in the chemicals group for its dividend performance. The dividend pay-out ratio of the drugs group was 17% in 1977-78 as compared to the 14% average for the chemicals industry and only 11% for all industries in the same year. (Table IV).

TABLE-1: MARGIN ON NET SALES

Industry	No. of companies.	Profits Before Tax as % of Net Sales*				Profits After Tax as % of Net Sales*			
		1975	1976	1977	Rank	1975	1976	1977	Rank
		-76	-77	-78	(77-78)	-76	-77	-78	(77-78)
		(Pre-tax Margin)				(Post-tax Margin)			
Chemical Fertilisers	13	16.6	14.4	14.0	3	11.1	7.2	6.1	4
Dyes & Dye-stuffs	10	16.0	15.8	14.9	1	6.4	7.7	8.1	2
Man-Made Fibres	13	13.1	12.6	14.8	2	5.7	7.7	9.4	1
Plastic Raw Materials	11	2.0	2.6	3.4	8	-4.1	-2.3	-0.7	8
Other Basic Industrial Chemicals	44	10.1	10.2	11.5	5	4.8	5.6	6.3	3
Paints, Varnishes & Allied Products	15	6.1	9.2	9.1	6	2.5	3.3	3.1	7
<u>Medicines & Pharmaceutical Preparations</u>	<u>52</u>	<u>10.6</u>	<u>11.7</u>	<u>12.0</u>	<u>4</u>	<u>3.6</u>	<u>4.1</u>	<u>4.6</u>	<u>5</u>
Other Chemicals	43	9.5	8.7	8.3	7	3.6	3.2	3.5	6
Total: Chemical Industry	201	<u>11.5</u>	<u>11.3</u>	<u>11.5</u>		<u>5.3</u>	<u>5.2</u>	<u>5.4</u>	

* Net sales exclude excise duty, rebates and discounts and cess.

Source: Compiled by me from "Finances of Medium and Large Public Limited Companies 1977-78", RBI BULLETIN, May 1980.

- Notes: 1. The pre-tax margin on sales in the drugs industry is close to the average for the chemicals industry as a whole.
2. The post-tax margin on sales, however, does not compare favourably with most other chemical groups and falls below the average for the chemical industry as whole.

TABLE - II: RETURN ON OWNERS' FUNDS-PROFIT
AFTER TAX AS % OF NET WORTH*

Industry	No. of Companies	1975-76	1976-77	1977-78	Rank (1977-78)
Chemical Fertilizers	13	22.7	15.5	12.3	7
Dyes & Dyestuffs	10	17.6	21.5	19.6	1
Man-made fibres	13	9.0	13.2	15.0	4
Plastic Raw Materials	11	+	+	+	8
Other Basic Industrial Chemicals	44	10.4	12.8	14.7	6
Paints Varnishes and other Allied Products	15	12.4	17.5	16.5	2
<u>Medicines and Pharmaceutical preparations</u>	<u>52</u>	<u>12.0</u>	<u>14.6</u>	<u>16.5</u>	<u>2</u>
Other Chemicals	43	13.4	12.2	14.8	5
Total: Chemicals	201	13.5	13.8	14.6	
Total: All-Industry	1720	8.2	7.9	8.8	

* Net Worth = Paid-up share capital + Reserves & Surplus.
+ Numerator is negative.

Source: "Finances of Medium and Large Public Limited Companies, 1977-78", RBI Bulletin, May 1980.

Note:

1. The drugs industry compares very favourably with other chemical industries in terms of the profitability on owned capital or net worth.
2. The industry had the second highest level of return on net worth in the chemical industry in the year 1977-78.
3. The drugs industry's return on net worth when compared to the all-industry average makes it one of the most attractive areas for investment in the organised, industrial sector of the Indian economy.

TABLE - III: KEY PROFIT DATA

Item	42 Companies			52 Companies		
	1970-71	1971-72	1972-73	1975-76	1976-77	1977-78
1. Net Sales (Rs. lakhs)	18315	21422	24183	34096	39007	42729
2. Net Worth (Rs. lakhs)	7618	8477	9063	10287	11004	11970
3. Net Profit after tax (Rs. lakhs)	1250	1363	1411	1231	1609	1975
4. Net Sales/ Net Worth Ratio (no. of times)	<u>2.40</u>	2.53	2.67	3.31	3.54	<u>3.57</u>
5. Net Profit/ Net Sales (%)	<u>6.83</u>	6.36	5.83	3.61	4.12	<u>4.62</u>
6. Net Profit/ Net Worth (%)	<u>16.41</u>	16.08	15.57	11.97	14.62	<u>16.50</u>

Source: Based on RBI data.

Note:

1. The net worth turnover (net sales ÷ net worth) of the larger drug companies increased from around 2.5 times during 1970-73 to around 3.5 times during 1975-78.
2. The post-tax margin on sales declined from 6.8% in 1970-71 to 4.6% in 1977-78.
3. Because of 1. and 2. above, the industry ultimately managed to maintain its return on net worth, or owned funds, at 16.5% in both 1970-71 and 1977-78.

A simple arithmetical exercise might make the above analysis more clear:

Return on Net Worth (RNW)	=	$\frac{\text{Profits After Tax (PAT)}}{\text{Net Worth (NW)}} (\%)$	
	=	$\frac{\text{PAT}}{\text{Net Sales}} (\%) \times \frac{\text{Net Sales}}{\text{NW}}$ (no. of times)	
Now, in 1970-71: RNW=16.4%	=	6.83%	x 2.40
And, in 1977-78: RNW=16.5%	=	4.62%	x 3.57

TABLE - IV: DIVIDEND PROFILE

Industry	No. of compa- nies	Return on Equity Capital 1.				Dividend Pay-out Ratio 2.			
		1975 -76	1976 -77	1977 -78	Rank (1977 -78)	1975 -76	1976 -77	1977 -78	Rank (1977 -78)
Chemical Fertilisers	13	59.2	42.2	35.9	3	15.2	14.3	14.1	4
Dyes & dyestuffs	10	38.3	51.6	48.8	1	15.0	15.3	14.5	2
Man-made Fibres	13	23.6	33.5	38.0	2	9.6	12.4	13.7	6
Plastic Raw Materials	11	+	+	+		7.4	7.4	8.1	8
Other Basic Indust- rial Chemicals	44	23.7	27.2	32.8	5	10.9	12.2	13.3	7
Paints Varnishes and other Allied Products	15	21.7	32.8	33.5	4	11.7	15.0	14.0	5
<u>Medicines and Pharma- ceutical Preparations</u>	<u>52</u>	<u>25.0</u>	<u>28.8</u>	<u>32.0</u>	<u>7</u>	<u>16.4</u>	<u>16.2</u>	<u>16.9</u>	<u>1</u>
Other Chemicals	43	29.3	27.5	32.6	6	13.8	14.1	14.2	3
Total: Chemicals	201	30.4	31.0	33.1		12.9	13.5	14.0	
Total: All-Industry		18.1	16.7	18.6		10.0	10.6	10.8	

1. Profit After Tax less Preference Dividends as % of Equity Share Capital.
 2. Equity Dividends as % of Equity Capital. + Numerator is Negative.

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TABLE - IV: DIVIDEND PROFILE (Concl'd.)

Industry	No. of compa- nies	Proportion of Earnings Retained in Business 3,			Rank ('77 -78)
		1975 -76	1976 -77	1977 -78	
Chemical Fertilisers	13	73.5	65.4	59.8	3
Dyes & dyestuffs	10	60.3	69.4	69.3	1
Man-made Fibres	13	58.1	60.4	62.0	2
Plastic Raw Materials	11	0+	0+	0+	
Other Basic Industrial Chemicals	44	52.4	54.4	58.9	4
Paints Varnishes and other Allied Products	15	46.1	53.2	56.6	5
<u>Medicines and Pharmaceutical Preparations</u>	<u>52</u>	<u>33.9</u>	<u>43.3</u>	<u>46.8</u>	<u>7</u>
Other Chemicals	43	52.6	48.4	56.2	6
Total: Chemicals	201	56.5	55.1	56.7	
Total: All-Industry		43.0	34.9	40.3	

3. Retained Profits as % of Profits After Tax. 0+ Both numerator and denominator are negative.

Source: "Finances of Medium and Large Public Limited Companies, 1975-78", RBI BULLETIN, May 1980.

Note: (1) The return on equity capital in the drugs industry was the least in the chemicals industry in 1977-78 and falls consistently below the average for the chemical group during the period 1975-78. (2) However, the return on equity still compares very favorably with the all-industry level. (3) Despite the relatively low overall return on equity, the dividends yield per equity share was the highest for the drugs industry as compared to all other chemicals industries. (4) This is explained by the small proportion of earnings after tax retained in business by the drug companies as compared to the companies in other chemical industries. Thus, the drugs industry ranks the lowest among the profit-making chemical industry groups in terms of retaining net profits in business which are used for partly financing investment expenditures.

d) There is a clear trend of improvement in the profit performance of the drugs industry during the 3-year period 1975-78. However, it is likely that this trend was arrested or even reversed during the subsequent 3 years (1978-81) owing to the sharp rise in price inflation in the economy from 1979 onwards which was only partially met by the revision of drug prices. (See Table on Trends in Wholesale Prices of Drugs below).

Price controls in India have succeeded in considerably depressing the overall rate of increase in the prices of drugs and medicines. However, they have failed to achieve uniformity in the levels of prices and profits as we shall shortly see. The Table below compares the wholesale price index for drugs and medicines with that for all commodities and with the index for chemicals and chemical products.

TRENDS IN WHOLESALE PRICES OF DRUGS: 1970-71 to 1980-81
(Base: 1970-71=100)

Year	Drugs & Medicines	% Change over previous year	All Commodities	% change over previous year	Chemicals and Chemical products	% Change over previous year
1970-71	100.0	-	100.0	-	100.0	
1971-72	99.7	-0.3	105.6	5.6		
1972-73	101.0	1.3	116.2	10.0		
1973-74	101.8	0.8	135.7	20.0		
1974-75	108.8	6.9	174.9	25.2		
1975-76	118.7	9.1	172.9	-1.1		
1976-77	133.9	12.8	176.6	2.1		
1977-78	136.3	1.8	185.6	5.1		
1978-79	136.1	-0.2	186.4	0.4		
1979-80	135.2*	-0.7	217.6*	16.7	198.7*	12.1
1980-81	142.0**	5.0	269.1**	23.7	250.6**	26.1
<u>Annual Compound Growth Rate (%):</u>						
1970-71 to 1979-80	3.4		9.0		7.9	
1970-71 to 1980-81	3.6		10.4		9.6	

* Provisional

** Provisional as of March 1981.

Source:

- 1) Report: 1980-81, Ministry of Petroleum Chemicals & Fertilizers, Dept. of Chemicals & Fertilizers, Govt. of India, New Delhi.
- 2) RBI Bulletin, March 1981.

The official wholesale price data presented on the preceding page clearly show that the average annual rate of increase in the wholesale prices of drugs and medicines (3.6%) has not kept pace with the rise in prices of all commodities (10.4%) during 1970-81. The rise in the average prices of all chemicals and chemical products (9.6%) has also been much sharper than that of drug products.

The wholesale price index of drugs and medicines presented above has its limitations: it is derived from only a limited number of bulk drugs and finished formulations available in the Indian economy. But it does give a broad picture, howsoever crude, of the underlying trends in the relative prices of different products.

It is well-known that the prices of drugs were frozen at a high level in the 1960s and many large companies, particularly the foreign firms, earned back their original investments within a couple of years. Even after the DPCO (1970), many large companies managed to get hefty hikes in the prices of many essential drugs which were far sharper than the overall rate of inflation. Take for instance the following 3 examples:

Drug & Producer	Year & Price for same unit pack		% Increase
	1970	1978	
a. Sulphaguanidine, May and Baker	Rs. 13.31	Rs. 83.00	524
b. Sulphadiazine May and Baker	-	-	182
c. Insulin injections, Boots	Rs. 4.60	Rs. 11.39	248

Source: "The High Prices of Drugs" by K.C. Khanna, The Times of India, 17 October 1978.

Despite the comprehensive price control orders now in operation for over a decade, the retail prices of several essential drugs continue to vary sizably from manufacturer to manufacturer. Take for instance, the following examples pertaining to the year 1978:

Drug	Producer	Price Range of same unit pack	High $\frac{\text{₹}}{\text{₹}}$ (%)	Low
a. Ethambutol	Apollo British Pharm	Rs. 32.50 Rs. 80.50	248	
b. Ampicillin injections	Pharmed Ranbexy	Rs. 4.78 Rs. 11.88	248	
c. Mebendazole	Gufic Ethnor	Rs. 5.50 Rs. 13.75	250	
d. Mexamethasone	Impha Labs. H.Jules	Rs. 7.50 Rs. 23.00	307	

Source: "The High Prices of Drugs" by K.C. Khanna, The Times of India, 17 October 1978.

This pattern of wide variations in the prices of either identical or very similar products continues till today. For more recent data on such price variation, and its underlying causes, see Chapter 4, pgs.38, 40,42 and pg. 52 of this report.

Also considerable variations in the profitability of different sectors and of particular firms within each sector continue to prevail despite the DPCOs. Generally, companies with foreign equity participation have fared better than Indian companies. Obviously, private companies including several large foreign companies concentrating mainly on non-essential formulations fare the best because of the highest mark-ups available under the price order. Besides, the foreign companies have established an excellent reputation with their aggressive sales promotion and advertising strategies over the course of the last 2 decades which has enabled them to rapidly increase their volume of sales per unit of invested capital.

The Lavraj Kumar Committee, appointed by the Union Government in May 1978 to investigate the alleged high profitability of foreign companies, submitted its report in 1980. The Committee has reported that over the last 7 years, the profitability of the foreign drug companies has declined and can no longer be considered excessive. But, their profitability still compares favourably with many high-profit industries of the economy. (8) We too have seen a similar pattern in our comparative analysis of the RBI data covering both foreign and Indian companies.

The Committee further found that about 62% of the companies studied attained an average post-tax return on net-worth of 14% over the last decade in their total manufacturing activities. 3 companies

managed to earn a return as high as 20%. (8) It is well-known that a significant portion of the total sales of many foreign drug companies is contributed by non-pharmaceutical sales. This diversification into other fast-moving, high-value consumer goods, catering mainly to the affluent sections of society, have enabled them to maintain high, overall profitability rates. For the 22 foreign drug companies, currently holding foreign equity exceeding 40%, one-third of their total turnover was from non-drug activities, during the years 1972-73, 1973-74. (3) (See Tables on the following pages).

On the other hand, the profitability of the public sector undertakings which concentrate mainly on essential, bulk drugs production gets seriously affected. The Public sector gets the lowest rates of return on sales and capital employed, while many private sector companies, including several foreign companies, which concentrate mainly on non-essential items get either the highest mark-ups or do not come under any price control. The profitability structure inherent in the regulated price pattern favors the production of less important items.

Many large private Indian companies e.g. Alembic Chemicals (1980-81) and particularly the thousands of small firms are also reported to be adversely affected by price controls.

What the Mathi Committee concluded on the overall effectiveness of price control over 6 years ago still holds true: "While the operation of price control so far has certainly helped in preventing the emergence of very large or excessive profits by the drugs and pharmaceutical industry, it does not appear to have contributed materially to the emergence of a product or price pattern which is more in consonance with social needs or national objectives. For instance, in spite of the fact that the industry has been under some form of price control for over a decade, there are still fairly wide variations in the prices charged by different units for the same or similar formulations. Even more disturbing, however, is the fact that the structure of product pricing appears to have a bias in favour of greater profitability in respect of less essential formulations which are consumed by the more affluent sections." (3)

3. We have seen earlier, that economies of scale do not pose a major problem in the formulations industry, particularly beyond a given minimum size. Thus, formulation prices, worked out on the basis of the production costs of a few, generally large producers, can be applied to firms of all sizes. However, factors other than size such as the type of technology used and the particular product-mix, location of the plant, etc. do lead to differential costs of production. Hence, the concept of 'leader prices' puts all firms under a uniform straitjacket.

According to news reports appearing in 1981, most of the small-scale units in the country are severely depressed. However, this

DRUGS AND NON-DRUGS SALES OF 22 FOREIGN DRUG COMPANIES WITH FOREIGN EQUITY EXCEEDING 40% OF TOTAL EQUITY.
(in Rs. Lakhs)

Company	Foreign Equity % (as of Aug. '81)	1972/1972-73			1973/1973-74		
		Drugs	Non Drugs	Total	Drugs	Non Drugs	Total
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
FOREIGN EQUITY 41% - 49%							
1. Geoffrey Manners & Co. Ltd.	45.45	988.88 (71)	391.91 (29)	1399.99 (100)	1071.71 (70)	465.65 (30)	1536.66 (100)
2. Organon (India) Ltd.	49.49	245.45 (100)	- (0)	245.45 (100)	284.84 (90)	32.32 (10)	316.66 (100)
3. Uni-Sankyo Ltd.	49.49	7.7 (100)	- (0)	7.7 (100)	- (0)	- (0)	- (0)
FOREIGN EQUITY 50% - 59%							
4. Hoechst Pharmaceuti- cals Ltd.	50.50	1650.50 (90)	183.83 (10)	1833.33 (100)	1988.88 (92)	184.84 (8)	2172.22 (100)
5. Warner-Hindustan Ltd.	50.50	585.55 (85)	103.33 (15)	688.88 (100)	557.57 (87)	82.82 (13)	639.99 (100)
6. Alkali & Chemical Corpn. of India Ltd.	51.38	119.44 (4)	2578.78 (96)	2697.97 (100)	116.16 (4)	3000.00 (96)	3116.66 (100)
7. Bayer India Ltd.	51.37	289.22 (22)	1031.31 (78)	1320.20 (100)	311.11 (20)	1267.67 (80)	1578.78 (100)
8. Cyanamid India Ltd.	55.55	892.82 (84)	168.68 (16)	1060.60 (100)	999.99 (83)	202.02 (17)	1201.01 (100)
9. Richardson Hindustan Ltd.	55.97	508.08 (93)	38.38 (7)	546.46 (100)	643.43 (87)	95.95 (13)	738.38 (100)

Contd...

DRUGS AND NON-DRUGS SALES OF 22 FOREIGN DRUG COMPANIES WITH FOREIGN EQUITY EXCEEDING 40% OF TOTAL EQUITY. (Contd..)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
10. Boots Company (India) Ltd.	58	631 (96)	29 (4)	660 (100)	748 (96)	30 (4)	778 (100)
FOREIGN EQUITY 60% - 100%							
11. E. Merck (India) Pvt. Ltd.	60	380 (100)	- (0)	380 (100)	469 (98)	8 (2)	477 (100)
12. Merck Sharp & Dohme of India Ltd.	60	868 (100)	- (0)	868 (100)	1051 (100)	-	1051 (100)
13. May & Baker (India) Ltd.	60	664 (95)	34 (5)	698 (100)	907 (93)	65 (7)	972 (100)
14. Sandoz (India) Ltd.	60	713 (58)	513 (42)	1226 (100)	963 (62)	594 (38)	1557 (100)
15. Ciba-Geigy of India Ltd.	55	1331 (51)	1289 (49)	2620 (100)	1454 (47)	1668 (53)	3122 (100)
16. Wyeth Laboratories Ltd.	74	339 (100)	- (0)	339 (100)	393 (100)	- (0)	393 (100)
17. Glaxo Laboratories (India) Ltd.	75	1901 (61)	1195 (39)	3096 (100)	2331 (66)	1207 (34)	3538 (100)
18. Johnson & Johnson Ltd.	75	210 (59)	197 (41)	357 (100)	295 (60)	194 (40)	489 (100)
19. Pfizer Ltd.	75	2062 (85)	376 (15)	2438 (100)	2177 (85)	393 (15)	2570 (100)
20. Parke-Davis (India) Ltd.	83.33	1024 (100)	- (0)	1024 (100)	1062 (100)	- (0)	1062 (100)

Contd...

DRUGS AND NON-DRUGS SALES OF 22 FOREIGN COMPANIES WITH FOREIGN EQUITY
EXCEEDING 40% OF TOTAL EQUITY. (Concl'd.)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
21. Roche Products Ltd.	89	920 (100)	- (0)	920 (100)	928 (100)	- (0)	928 (100)
22. Burroughs Wellcome & Co.	100	322 (88)	45 (12)	367 (100)	391 (93)	29 (71)	420 (100)
TOTAL		16648 (67)	8120 (33)	24768 (100)	19138 (67)	9515 (33)	28653 (100)

Note: Figures in brackets are percentage shares of drug and non-drug sales in the total sales.

Source: Report of The Committee On Drugs and Pharmaceutical Industry, April 1975, Ministry of Petroleum Chemicals, Govt. of India.

is more due to inefficiency and utter mismanagement of most of these firms than due to the price policies of the Government.

4. In practice, the revision of the bulk drugs and formulations prices has not been effectively coordinated. By June 1981, prices of 170 out of 200 (85%) of the major bulk drugs had been revised. But, in the case of formulations, prices of only 25% of the products under the 3 categories had been revised. (4) In October 1980, prices of 13 essential bulk drugs were revised, mostly upwards. But the revised 'leader prices' of 30 different formulations based on them were not announced. (9) If the Government itself increases the input costs, but freezes the end-prices what would the producer do? He would withhold supplies and wait for the Government to increase his end prices. And what about the ailing consumer? Disease cannot 'wait' and he tries to obtain the medicines at any cost. The revised formulation prices were then 'shortly' announced in December 1980 with shortages in the intervening period. (10)

Secondly, the stipulation of a maximum ceiling of 14% for the post-tax return on net worth in the case of bulk drugs makes their production and sales far less attractive than that of formulations. The ratio of gross sales (including excise duty) to net worth in the case of formulations manufacture may range anywhere between 4.5 to 8.5 for different formulators. So if a formulator is allowed the minimum pre-tax margin of 8% on gross sales (from the range of 8% - 13% under the BPCD 1979) and has a minimum gross sales/net worth ratio of 4.5 he can easily earn a minimum post-tax return of 14% on net worth (assuming tax @ 60%). And if we assume a 10% pre-tax margin on gross sales and a net worth turnover of 6, the post-tax return on net worth would work out to 24% (again assuming tax @ 60%). It is very likely that several large companies are easily able to earn a minimum of about 20% return on net worth on their formulations sales.

Further, by increasing the net worth turnover i.e. the volume of sales per unit of net worth, the formulator can greatly enhance his profitability on net worth despite the low level of prescribed pre-tax margins on sales. (We have already examined this strategy of the larger drug companies in great detail on page numbers 96 and 97 above.) In other words, the return on owned capital can be maintained and even increased by expanding the sales volume fast enough. No such room for manoeuvre exists in the case of bulk drugs with their pre-determined ceilings on return on net worth. This acts as a further disincentive to bulk drug manufacture.

The foregoing analysis thus makes it clear that owing to the much higher ratio of sales to net worth in formulations manufacture as compared to bulk drugs manufacture, (and the proven ability of the larger companies to further raise this investment turnover over time), the production and marketing of formulations gives higher

rates of return on net worth despite the low, fixed margins on sales than bulk drugs manufacture which is more capital intensive and has fixed, maximum ceilings on the return on net worth.

The drugs industry, particularly the foreign sector, has strongly resisted the price control system. In early 1981, many foreign companies filed writ petitions against the DPCO (1979) contending that the prices fixed for certain drugs were arbitrary and unremunerative. (11) The industry's resort to the judiciary for "economic justice" is an interesting and new feature in this highly regulated industry. The outcome of these protracted battles with the Government will have important consequences for the future of price regulation not only in the drugs industry but in many other price-controlled industries.

'REAL' COSTS?

It is true that many foreign drug companies resort to the over-statement of their material costs in their bid to escape the rigid price and profit control of the Government. Take the recent case of Hoechst Pharmaceuticals concerning Baralgan Ketone bulk drug which raises serious doubts as to what are the 'real' costs of production.

In 1981, the Petroleum and Chemicals Ministry accused Hoechst of overpricing its popular drug, Baralgan Ketone (used for stomach aches), for the past 2 years since the DPCO (1979) came into effect. It was alleged that the company was selling Baralgan at the rate of Rs. 24,000 per kg. of the bulk drug. But the company itself had claimed only Rs. 8,000 per kg. when it submitted its production cost data to the Ministry. The Government had further reduced the amount claimed by the company to Rs. 1,810 per kg. when it announced the revised prices of formulations in December 1980. The company challenged the Government's calculations in a court of law and obtained a stay order. Pending the court's decision, the Government instructed the company to pay the difference between its declared price and its selling price running into a few crores of rupees: Rs. 3 crores according to one estimate. (12)

TRANSFERING PROFITS

An important technique by which the multinational companies overcome price and profit controls of local governments is that of "transfer pricing". This technique is very simple: the local multinational subsidiary buys intermediate products at varying stages of completion, from its parent company or other sister concerns abroad, at prices which often bear no relation to production costs or internationally competitive rates. To the extent that the material costs are thereby inflated, the paper or accounting profits are understated. This has often been resorted to in countries with strict price controls on end-products, high incidence of taxation, and considerable dependence on the foreign companies. These account-

ing manipulations are decided on by the parent corporation to maximize its overall profits on a global basis.

It is extremely difficult for national governments to monitor and regulate these transactions. In Europe alone, an estimated 1.5 million or more products, in various stages of completion, are involved in transfer price transactions. The detailed data regarding these transactions are inaccessible to outside authorities and it is impossible to make definitive conclusions about the extent of overcharging and extortion involved on a comprehensive basis.

As far as the Indian drugs industry is concerned, there have been many such instances of overpricing of materials by the multinationals. Imports of products and services by local multinational companies are always from their principals abroad. Even Indian companies with collaboration agreements often have to import from their foreign collaborators due to 'tie-in' clauses in the collaboration agreements. There is thus considerable scope for overpricing under the guise of technology transfers. For example, Librium was introduced in India by Roche at a price exceeding Rs.5,555 per kg. when a local firm could import it at Rs.312 per kg. or only 6% of the Roche price. Similarly, another foreign subsidiary was charging Rs.60,000 per kg. of dexamethasone which was brought down to Rs.16,000 per kg. on being pressurised by the Controller of Imports. (13) More recently, the Lavraj Kumar Committee's investigation on foreign drug companies, discussed earlier, found large variations between the maximum and minimum prices of drug materials of identical or similar specifications and packaging imported during the same time-periods by different firms. (8) The Committee recommended the setting up of a research cell either in the Petroleum & Chemical Ministry or the Bureau of Industrial Costs and Prices (BICP) to continuously monitor import prices, spot serious anomalies and seek clarification from the concerned importing firms and arrive at more economic ways of arranging such imports. (8) This reflects the inability of the Government machinery, at present, to stymie the attempts of the foreign drug companies to artificially inflate their material costs. And the Government cannot claim innocence in this regard after having realised long back, in 1969, about how Pfizer had extorted high prices on the country's purchases of tetracycline during the 14-year period 1953-67.

HEADS, I WIN; TAILS, YOU LOSE

In the 1950s, six U.S. multinational corporations - Pfizer, American Cyanamid, Bristol Myers, Dlin, Upjohn and Squibb - divided out the world market for tetracyclines and aureomycin among themselves to avoid competition and extort high prices. (14) The importing countries had no choice: these 6 giants controlled the entire world sales. Pfizer was allotted the Indian market. The Indian Government became aware of this 'game' the multinationals played through a U.S. Senate Committee's report in 1969 stating that these companies

had resorted to price collusion in their worldwide marketing of tetracycline drugs including the U.S. market.

The Government's calculations showed that the c.i.f. (cost, insurance, freight) value of imports of tetracycline during 1953-67 amounted to Rs.5.94 crores. It was estimated that the overcharging was to the extent of 40% on the f.o.b. (free-on-board) value of Rs.5.76 crores or Rs.2.30 crores. The U.S. Anti-Trust Laws permit triple damage suits and thus the Government could claim Rs.6.90 crores. And taking indirect damages into account, the total claimable damages were estimated to be Rs.10 crores or so. (14)

After almost 5 years of hesitation, the Indian Government filed a triple damage suit on October 11, 1974, on the advice of the Indian Embassy that a foreign government had the jurisdiction to file a suit in a U.S. court against the U.S. companies which had violated U.S. Anti-Trust Laws. Many other national governments - West Germany, South Korea, Philippines, Vietnam, Kuwait, Iran, Spain, Colombia - had also filed suits against these companies. (14)

The companies challenged the right of foreign governments to sue them (a) on behalf of their private importers and (b) as a "Person" as defined in the U.S. Laws. The U.S. Appeals Court rejected the latter objection of the companies but accepted the former. In January, 1978, the U.S. Supreme Court agreed with the judgement of the U.S. Appeals Court. (14)

Since the U.S. court judgements precluded the Indian Government from filing a damages suit on behalf of private importers, the Indian Government initiated a fresh exercise to calculate the imports made directly by the government institutions, companies and hospitals from the parent corporations abroad or their subsidiaries operating in India.

According to Indian Embassy officials in the U.S., Pfizer has overcharged the Indian government institutions by U.S.\$32 million during the period 1953-67. While 100 units of 250 mg. capsules of tetracycline sell for around \$6 in the U.S. market, the same quantity is now sold for \$22.54, or almost 3.8 times the U.S. price, in the Indian market. (15) According to another estimate, while the cost of production of 100 tablets of tetracycline varied between \$1.59 to \$12, the companies charged a uniform price of \$30.60 resulting in a retail price of \$51 to the consumer! (16,17) The total amount claimed by India for the above period is \$96 million (thrice the actual damage of \$32 million) claimable under the triple damages suit permitted under the U.S. Anti-Trust Laws.

The U.S. Government had itself sued these corporations for concerted price fixation and they had to pay an estimated \$232 million to U.S. nationals. (14) But they are fighting a protracted battle to avoid paying damages to foreign governments by seeking a legislative amendment to the Anti-Trust Law.

On 12 May 1981, the U.S. Senate Judiciary Committee passed a Bill denying the right to a foreign government to sue as a 'Person', i.e. as an ordinary American citizen can, in a U.S. federal court, unless it can prove that it has a domestic anti-trust law similar to the U.S. Law. And the Bill will have a retrospective effect. According to some news reports, among the Senators who voted for the Bill, six had received a total sum of \$9,500 from Pfizer for their elections campaign contributions in 1980. (16) A public citizen health group of America described the Bill as a "virtually unprecedented intervention in an ongoing judicial proceeding", "the worst kind of special interest legislation". (16)

This was just before the suit filed by India, West Germany, Philippines and Colombia in a Philadelphia Court was to come up for hearing on 1 June 1981. The total amount claimed by these 4 countries for actual damages amounts to over \$100 million. Besides exerting pressure on the Reagan Administration to pass the above Bill, the companies had allegedly tried to reach an "out-of-court" settlement with West Germany in order to isolate the 3 developing countries, including India, which by themselves would wield a much lesser clout. (17)

Following the passage of the Bill by the U.S. Senate Judiciary Committee, the Indian Embassy's Minister for Economic Affairs protested to the U.S. State Department in May 1981 in the following words:

"--- the government and the people of India were defrauded by U.S. drug companies on a large scale and overcharged huge sums of money in foreign exchange which could have been better utilised for improving health services in a developing country with scarce resources." (17)

As of June 1981, the Bill had yet to be passed by the full Senate and the House of Representatives to become law. If it is endorsed, India will not be able to collect even the \$32 million of the actual damages suffered by the country. The Monopoly and Restrictive Trade Practices Act of the Indian Government is not enforceable in Indian courts and does not provide for the accused to pay compensation to the affected parties. (15)

Earlier, the companies had made similar efforts to push legislation amending the Anti-Trust Law in a manner that would make it impossible for the foreign countries to collect damages. But at that time, the Carter Administration successfully thwarted the vested interests, and the U.S. State Department and Justice Department had made a case against these companies. (16) But with the coming to power of the Reagan Administration, well-known for its penchant for 'laissez-faire' economic policies, these same Departments have refused to challenge the proposed Bill which, according to the Indian and West German governments, amounts to the U.S. Government cover-

ing "unfair trade practices of the multinational companies." (17)

According to information available in August 1981, India agreed to an "out-of-court" settlement with the companies for U.S.\$0.8 million against actual damages of \$32 million and the total claimable damages of \$96 million! (18).

THE LARGER CANVAS

The basic challenge faced by developing countries like India is to increase the proportion of their people with ready access to essential drugs and medicines. But the requisite products are largely produced by the private firms which are guided mainly by the market forces. In a developing society marked by wide inequalities in income and asset ownership, these market forces of demand and supply result in a price and product pattern that caters to the requirements of a small minority—the relatively richer sections of society, accounting for about 15% to 20% of the total population, who have the requisite purchasing power to influence the major production and investment decisions of the private producers. The requirements of a large majority of the poor and destitute are simply bypassed. In terms of profits, vitamin tonics are more exciting to produce and market than cholera vaccines!

This basic contradiction, between the commonly accepted socio-economic goals (such as "health for all") and the logic of the market-place, has been officially recognised in India long ago. Two major policy instruments were designed to countervail and check the operation of the free market forces: (1) direct State intervention in economic activity through the establishment of the public sector undertakings, and (2) the regulation and control of the free market forces through various regulatory mechanisms such as industrial licensing, price and profit controls, fiscal incentives and disincentives, and so on. Both these policies, in the overall context of planned economic development, were expected to bring about a pattern of economic activity more in consonance with the broader socio-economic needs and goals of the whole society.

That the Indian economy has failed to achieve these lofty goals, despite much radical, populist rhetoric to the contrary, is unequivocally clear after the past three decades of "planned socialist development."

We have seen in our examination of the role of the public sector corporations in the drugs industry that they have failed to achieve some of their most basic goals such as developing an indigenous technological dynamism, providing adequate supplies of essential items at relatively low prices and reducing the market dominance of the large, private sector companies with strong foreign control. It is true that the large foreign-controlled corporations, having a virtual monopoly over technology in the world, are guided largely by commercial considerations and are often incapable of realising the fundamental social and economic goals of the country. The large, Indian private companies too are more keen on buying technologies wholesale from abroad and making quick gains in a protected domestic market rather than developing an indigenous technological potential through sustained R & D efforts. Much was expected from the large investments made in the public sector projects. But the

public sector too has failed to deliver the goods—it is suffocating in the morass of its own inefficiencies. In fact, the entire public sector, with a few, solitary exceptions, is almost wholly devoid of whatever little entrepreneurial initiative or creative dynamism the Indian economy possesses: these lie largely outside the State-owned organisations. Today, the most that is expected of them is the maintenance of adequate levels of production from capacities already installed, often at high capital costs, in a wide range of key industrial sectors, not to speak of rapid increases in new capacity and additional production. In a situation like this, it would be extremely naive to believe that nationalisation of the large private companies will 'solve' our basic problems. Thus the economic and technological dependence on foreign sources of technology and the private sector companies is bound to continue and increase over time, in the absence of any other concrete alternative open to the Indian economy at this juncture of its development.

The wide range of controls in the Indian economy have also failed to achieve their basic goals. Today, Government regulation of the organised industrial sector of the economy is:

- (1) depressing the trend rate of growth in the volume of industrial production in the long run, particularly in the case of the key intermediate products and the essential items of mass consumption, and
- (2) enabling the politicians and the bureaucrats to exact their "tithes" from the industrial economy.

The heavy corpus of India's labyrinthine regulatory statutes has failed to attain its major policy objectives, its *raison d'être*: a dynamic product and price pattern that subserves the wider social and economic goals. India's industrial economy thus finds itself in the quagmire of sluggish growth, wide inequalities and rampant corruption: the poor man's burden.

Take for example, the operation of price and profit controls in the drugs industry. What have they achieved over the past 2 decades or so? Basically, nothing. As we have seen, they have failed to alter the composition of output and the structure of prices in consonance with socio-economic priorities. All that they seem to have induced are short-run cyclical variations in the rates of profitability and the growth of output. The pattern is something like this: price controls depress profitability and production in the short-run, then the controlled prices are revised, both profits and production pick up, then again they slow down, till the next price revision, and so on.

In the long-run, there is no structural transformation of the production pattern but, instead, only a slowing down in the trend rate of growth of output. So eventually, we have neither rapid

growth nor equity. In fact, there is much evidence to show that the lower levels of prices fixed for more essential items have, instead, discouraged their production in favour of relatively inessential items that are free from price controls.

The above analysis raises more fundamental issues of India's political economy. Price controls are not magic wands that can transform the face of this country overnight. Price controls and bureaucratic regulation of the organised industrial sector cannot, by themselves, be effective in the longer run if they are not accompanied by a rapid, simultaneous transformation in all the key sectors and subsectors of an increasingly interdependent and integrated economy: institutional changes in agriculture such as land reforms, the establishment and strengthening of the social and economic infrastructure of the rural economy, raising the levels of productivity and organisation of household and non-household industries of the so-called unorganised or unregistered sector, the expansion in overall employment opportunities to an increasing number of people through more balanced regional development, and so on. In other words, unless the regulation of the organised industrial sector is accompanied by more fundamental processes of widespread social and economic transformation, large and rapid enough to make an effective dent in the overall structure of wide income inequalities and extreme poverty, all that regulation achieves in the longer run is to depress the growth rate of production without altering its "undesirable" composition. And unless these underlying conditions of extreme inequality and poverty are removed, the operation of market forces will continue to distort the pattern of production and investment with Government regulations merely acting as a drag on this inevitable outcome.

That the powers that rule India are congenitally incapable, and plainly unwilling, to bring about such "structural transformation" of Indian society is, today, obvious to almost all observers of widely differing persuasions. And, it is not difficult to see why, the politicians and bureaucrats are more enthusiastic about "controlling" the organised sector rather than initiating such structural changes: the former is more convenient, politically, and more rewarding, monetarily.

The question then is: should price and other controls be abandoned? Should the economy be "opened-up". What will be the outcome of the rising clamour of "open-up" the economy that can be heard more and more stridently from certain powerful sections of Indian society with each passing day? It is true that the so-called opening-up of the economy will lead to faster production growth rates and may even impart an element of competitive dynamism to India's over-protected, highly obsolescent industrial establishment. And the 'common man'—the largely urban, middle-classman, the petty white-collar clerk, certain sections of the industrial working class—will undoubtedly benefit, in varying degrees, from the expanding volumes of production.

In other words, all those sections of society who have the requisite means to maintain or increase their purchasing power (these undoubtedly include the urban-based, highly organised sections of the industrial labour force) will get tangible benefits, the fruits of vigorous capitalistic enterprise.

But what about those destitutes, numbering hundreds of millions, below the "poverty line", probably accounting for almost half of the total Indian population? What about the poverty-stricken masses, barely surviving at or a little beyond the margin of subsistence, who comprise another 25% of the Indian people? What about the large numbers of people struggling day and night in the 'unorganised' sectors of economic activity?

In other words, what about those sections of society who do not have the means to earn a decent living or at most maintain their extremely low levels of purchasing power?

Most likely, they will simply be bypassed. But everything will continue to be done in the name of the poor, the deprived, the weak: a modern ritual in this ancient land of rites and cults. The social tension and economic discontentment that is bound to increase over time will be repressed with brutal State power: economic laissez-faire will be accompanied with political absolutism, one supporting the other in a new symbiotic relationship. "Democratic socialism" and all the magnanimous myths of the Independence movement served the then emergent ruling classes well in quenching the rising expectations of the masses, in containing the social tensions and economic discontentment within tolerable limits, during the initial phases of industrial development in the post-Independence years: the "politics of accommodation". Now these very myths, the great illusory promises and "socialistic" policies are felt as an obstruction to faster growth and investment, as a cumbersome slough restricting the further development of those sections of society who have entrenched themselves in the "commanding heights" of the system during the past three decades of development.

The recent trends towards greater liberalisation of economic policies clearly indicate that the ideological pretensions of India's rulers, such as those of distributional justice, are rapidly evaporating and the emphasis is clearly shifting to rapid increases in the growth rate of production, higher efficiency of operations and the seeking of large productivity gains from investments already made whether in the public or private sectors. In other words, what the Government is attempting is the maximisation of returns from the economic structures that have been established since Independence by dismantling the older framework of policies which is now seen as a hindrance to future growth. What is important is that these developments have become inevitable considering the fact that the underlying foundations for an essentially

capitalist mode of development have been firmly laid, over the past 3 decades, despite what the radical sounding rhetoric and "socialistic" policy formulations would have us believe.

The stage is now firmly set for the economics of liberal capitalism and the politics of ruthless repression. The 70s was the decade of this transition, the '80s will be the decade of its culmination.