GLOBALIZATION AND THE INDIAN PHARMACEUTICAL INDUSTRY

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Dependency theory and the critics of globalization are generally critical of multinationals' operations in the Third World. Drug multinationals have been criticized for monopolizing a very profitable industry; repatriating huge profits out of the Third World through transfer pricing, royalty payments, and dividends; producing profitable lines such as cough syrups and vitamin pills instead of lifesaving drugs; making Third World doctors prescribe unnecessary drugs; spending three times more on sales promotion than on research; and not allowing the national sector of the industry to grow in most developing countries. The bargaining school, on the other hand, believes that prolonged contact between the multinationals and the host country works to the advantage of the latter in the long run. It posits that after the multinational has remained in the host country for some time, a shift in the bargaining power of the two will be brought about, and the initial advantage enjoyed by the multinational will shift in favor of the host country.

The objective of this paper is to test the validity of some of these propositions by analyzing the case of the pharmaceutical industry in India. In particular, the study will focus on an analysis of the monopoly enjoyed by drug multinationals in independent India and how the state succeeded in bringing about a basic change in the structure of the industry. The pharmaceutical industry in India has gone from a state of total dependence on transnational firms in the first two decades of independence to one of relative self-reliance in the 1980s and early 1990s, mainly because of the emergence of a strong national sector and the state control and regulation of the industry. A survey of the growth of the pharmaceutical industry in the last five decades, within the framework of government control and regulation of the various segments of the industry, will suggest that there is a real possibility of the development of technological capability in a research-intensive industry in India. At the same time, the case study will also indicate the limitations of the Indian state in influencing the behavior of drug multinationals.

FOUR PHASES IN THE DEVELOPMENT OF THE PHARMACEUTICAL INDUSTRY
The pharmaceutical industry in India has gone through four distinct phases between 1950 and 1995, and it is only in the last phase that the national sector of the industry has acquired the capability to compete with the multinationals and that the country has achieved a degree of self-reliance not found in most Third World countries.

**Phase I (1948-1968): Toward the Multinational Monopoly of the Industry**

Most of the leading transnational drug companies established their trading and manufacturing operations in India in the 1950s. The monopoly of the new drug technology by a handful of transnational firms led to their entry into India either as subsidiary companies or as collaborators with Indian entrepreneurs. Although these firms began by importing the finished drugs and simply marketing them, they slowly moved, under the government's pressure, to the importation of formulations in bulk drugs and started processing them into tablets, capsules, and syrups.

The pharmaceutical industry in India has been broadly planned by the government, which has rigid control over every stage of licensing, import, collaboration, and extension. Because the drug market was expanding and the national sector was almost nonexistent, the government encouraged the trading and manufacturing activities of the foreign firms in the beginning. To meet the growing demand for drugs, the government granted "permission letters"/no-objection letters/registration certificates to 15 leading transnational firms, which allowed them to manufacture 364 items (360 formulations and 4 bulk drugs) in the country. These permission letters were in the nature of "blanket orders which allowed the unit to manufacture drugs and pharmaceuticals. In many cases neither the capacities nor the drugs that a unit can produce were mentioned." Such a liberal policy led to a substantial growth of the foreign firms. Though the initial investment of most of these firms was small compared to their turnover, they succeeded in building up large reserves and assets within the country. Glaxo Labs, for example, with an original equity of Rs.150,000, had a turnover of Rs. 120 million by 1973, and its reserves stood at Rs. 48 million.

The liberalization of licensing policy and of the economy in the mid-1960s, although short-lived, gave further impetus to the growth of the foreign sector. In 1966, the government, responding to the prevailing shortages of the various commodities, permitted drug manufacturers to diversify into the manufacture of "new articles." The following year, it also allowed them to expand production of licensed or registered capacities up to 25 percent without any
amendment to the licenses under the Industrial Development and Regulations Act (IDRA).

The structural imbalance that was taking place in the industry was emphasized by the government during the drafting of the Second Five Year Plan. It was found that the industry was formulating medicines solely from imported bulk drugs and there was no in-country production of new drugs such as antibiotics, antidiabetics and most vitamins. The Pharmaceutical Enquiry Committee was appointed in 1953 to examine the structural imbalance in the industry and to suggest remedial measures. The committee, which submitted its report in 1954, highlighted the importance of producing bulk drugs from basic stages and recommended that no licenses should be granted unless the production of basic drugs formed part of the license. This recommendation, along with those related to foreign collaboration, foreign capital participation, distribution, and prices, led to a rapid and diversified growth of the industry in the ensuing decades.

One of the suggestions of the government to the industry, based on the recommendation of the committee, was that the production of basic drugs could be phased out through penultimate stages to a total integration in a period of five years. Foreign firms, however, did not comply. The government was becoming increasingly aware of the reluctance of foreign firms to start manufacturing bulk drugs from basic stages in India, and it recognized the inability of the Indian private sector to undertake the manufacture of such drugs because of the Patent Law and for want of the requisite know-how.

The government therefore decided to establish a basic drug industry in the public sector. Although the Industrial Policy Resolution of 1956 grouped the pharmaceutical industry under the category (B) where both state and private industry could operate, it was the state that was to establish new undertakings in "Antibiotics and other essential drugs" with a view to accelerating their future development. The new industrial strategy adopted in the Second Five Year Plan further emphasized the important role that the public sector was to play in the industrial development of the country. In the Nehru-Mahalanobis strategy of industrialization, investment in basic and heavy industry was given the top priority. With a view to making the country self-reliant in antibiotics and other essential drugs, two public sector firms were established: the Hindustan Antibiotics Limited (HAL) in 1954 and the Indian Drug and Pharmaceutical Limited (IDPL) in 1961, with a total investment outlay of Rs. 56 crores.

Hindustan Antibiotics Limited, set up with the technical assistance of WHO and the financial assistance of UNICEF, started production in 1955 and was the first company to manufacture a number of lifesaving antibiotics from basic stages: penicillin, streptomycin, Sulfhate, ampicillin, anhydrous, gentamicin. The
other public sector firm, IDPL (which is the largest in the Third World, with total
turnover of Rs. 117 crores in 1973), was set up with Soviet technical and financial
assistance. It has five plants: an antibiotic plant at Rishikesh, a synthetic drug plant
at Hyderabad, a surgical instruments plant at Madras, a formulation plant at
Gurgaon, and a drug and chemical intermediates plant at Muzaffarpur. The IDPL
antibiotic plant, equipped to produce eight different antibiotics and with an initial
installed capacity of 290 tons per year, is one of the largest in Asia. The synthetic
drug plant at Hyderabad, having an initial installed capacity of 851 tons of sulfa
drugs and other synthetic drugs, is again one of the largest of its kind in Asia. The
company claims to meet some 40 percent of India’s requirement for essential bulk
drugs.\textsuperscript{iv}

The establishment of the two public sector firms for the production of
antibiotics and bulk synthetic drugs marked the beginning of India’s move toward
self-reliance in basic drugs. It had the effect of reducing the country’s technological
dependence on foreign firms in the long run. The industrial strategy of the Second
Five Year Plan was thus crucial for India’s self-reliance in drug and pharmaceuticals
and other industries. This, along with the policy of sectoral reservation announced
by the government in the Drug Policy of 1978, made the Indian pharmaceutical
industry much more self-reliant than that of any other country in the Third World.

**Phase II (1969-1978): Effort to Curb the Monopoly of Drug Transnationals**

As discussed earlier, the transnational firms had an extremely favorable
climate in India, and they attained a position of dominance in the drug industry in
the first two decades of independence. Their success could be attributed partly to
the antibiotics and synthetic drugs that they introduced in the Indian market.
However, the patent law concerning drugs prevented the Indian firms from entering
into synthetic drugs. One finds, therefore, that by 1970, there were not more than
two Indian private companies: Standard Pharma and Alembic Chemical Works\textsuperscript{v}
that had taken the initiative in the production of penicillin and other antibiotics. The
RBI survey covering the period 1960-70 also shows that foreign subsidiaries were
particularly important in the pharmaceutical industry. Thus, the government’s
effort in the second phase was to curb the monopolistic position of the foreign firms
by enacting legislations.

In 1970, the government withdrew the concessions it had granted to
foreign firms in 1966 permitting them to diversify. Such diversification as had
already taken place between 1966 and 1970 was required to be regularized by
specific applications for “carrying-on-business” licenses (COB licenses). The Hathi
Committee Report (1975) found that 12 foreign companies and five Indian
companies had obtained COB licenses covering 215 formulations and 20 bulk
drugs. More important, some of the most profitable drugs, such as Librium and
Valium, the two largest-selling tranquilizers in the world at the time, were marketed in India under COB licenses. In January 1972, Indian firms were permitted to increase their licensed capacities on the basis of maximum utilization of plant and machinery and to diversify up to 100 percent. Furthermore, the government, by enacting antimonopoly legislation, subjected the expansion of foreign and large Indian firms to the new set of laws.

There seems to have been a sudden shift in the government policy following Indira Gandhi's split of the Congress Party and her massive electoral victory in 1971. In order to bolster Gandhi's leftist image, her government moved quickly to curb the growth and monopoly power of big business and industrial houses in general and the foreign firms in particular, by emphasizing the need to develop self-reliance and a strong national sector over economic considerations such as economies of scale and efficient utilization of scarce resources.

In the late 1960s, following the Report of the Monopolies Inquiry Commission (1964) and the Reports of Hazari (1966) and the Industrial Licensing Policy Enquiry Committee (1969), which reviewed the industrial licensing system, the government came to the conclusion that the existing licensing apparatus was not effective in controlling the monopoly and concentration of economic power in a few hands. As a result, the Monopoly and Restrictive Trade Practices Act (MRTP Act) was passed in 1969. This act sought to check the expansion of large industrial houses with gross assets exceeding Rs. 20 crores in interlinked undertakings or of dominant undertaking with assets of more than Rs. one crore (the definition of dominance being a market share exceeding 33 percent until 1982 and exceeding 25 percent until it was abolished in 1990s).

The enactment of the Foreign Exchange Regulation Act (FERA) in 1973 put further restrictions on foreign equity holdings, which had to be diluted to a maximum of 40 percent of the total holdings except in the case of core sector industries (as listed in Appendix I of the 1973 policy statement). The Industrial Licensing Policy, however, included drugs and pharmaceuticals in the list of core industries, which allowed both MRTP and FERA companies to participate in the growth of the industry. Once again pragmatism prevailed over ideological considerations. The projection made by the planning commission that there would be a large expansion in the production of pharmaceuticals during the Fifth Five Year Plan—a 100 percent increase in the production of formulations and a 400 percent increase in the production of bulk drugs—underlined the importance of the active participation of all the sectors allowed by the government at this stage.

The pharmaceutical industry had become highly visible by the early 1970s. A few instances of overpricing by drug multinationals, reported in the press and journal articles, led to an intense debate in Parliament between 1971 and 1973.
Recalling the investigations made by the Kefauver Committee in the United States and the Salisbury Committee in the United Kingdom into the workings of the pharmaceutical industry, including the question of drug prices, suggestions were made that the questions of the transnational firms' stronghold in this industry, the performance of the public sector units, and the prices of locally produced drugs should be examined by an expert committee.

In response, a Committee on Drugs and Pharmaceutical Industry (popularly known as the Hathi Committee) was set up under the chairmanship of Jaisukhlal Hathi in February 1974. Although the committee had 14 members including three influential Congress members of parliament—Yashpal Kapur, Vasant Sathe, and C. M. Stepan—it did not include any representatives from the industry. The committee's report, submitted in April 1975, is the most comprehensive document on the Indian pharmaceutical industry. It recommended a policy of sectoral reservation in order to provide a leadership role to the public sector and to foster and encourage the growth of the Indian sector.

Despite such regulatory measures, the growth of the industry was spectacular in the 1970s. There was between 13 and 22 percent turnover annually and the foreign firms continued to dominate the industry.

**Phase III (1978-1985): The Emergence of a Strong National Sector**

The third phase witnessed a dramatic decline in the foreign sector's share of the industry and a rapid growth of the Indian private sector. The policy of sectoral reservation adopted in the New Drug Policy of 1978 gave the necessary protection that the latter needed in order to grow and to compete technologically with the foreign sector. The developments during this period must also be viewed against the achievements India had made in science and technology during 25 years of independence.

India had made sustained efforts in building a fairly elaborate institutional and infrastructural base in science and technology and had acquired indigenous capacity, which enabled the government to strive for a greater degree of self-reliance. For example, whereas India had a corps of roughly 375,000 scientists and engineers in 1956, the number had increased to a million by 1979 out of which 140,000 scientists and engineers were engaged in organized R&D. Moreover, it had established a network of laboratories which allowed Indian scientists to undertake innovative and adaptive process and product research in a large number of disciplines (metallurgy, chemistry, electronics, medicines, etc.). In the pharmaceutical industry, private industry, not the CSIR labs, had already demonstrated that it had the capacity to develop process technology through in-house R & D if the proper environment were created by the government (e.g., by
drastic revisions in the Patent Law). The government responded favorably and gave the Indian sector the necessary protection, which accelerated the growth and development of this sector.

The Indian Patent Act, drawn up by a joint committee of the two Houses of Indian Parliament in 1970, was an important step taken by the government to break the monopoly of drug multinationals. The act, which replaced the old Indian Patents and Designs Act of 1911, lowered the period of validity of patents in general from 16 to 14 years, and of patents in the field of food, drugs, and medicines to a period of seven years, and raised the scales of fees payable for renewing the patent. An important feature of the new law is the provision that grants patent protection only to processes and not products. The rationale was that product patents allowed companies to gain a monopoly market by combining drugs and chemicals in different formulations. Indeed, the legislation, inspired by the reports of various enquiry committees, diluted patent rights in an effort to promote local development work, process research, and manufacture. Other important provisions of the act were:

1. to broaden considerably the grounds for the issue of compulsory licensing;
2. to give the Controller wide powers in determining the terms of settlement;
3. to allow the unrestricted use of patented inventions by the government for its own purposes; and
4. to provide for the automatic endorsement of patents in the field of foods, drugs and medicines and patents for the methods or processes for the manufacture or production of chemical substances with the words "licenses of rights" after a period of three years from the date of sealing of the patent.

The provisions of the act were thus far-reaching and reflected the thinking of policymakers in the late 1960s, particularly Prime Minister Indira Gandhi. Addressing the 34th World Health Assembly in Geneva in May 1982, she reiterated the stand she had taken more than a decade before with these words: "The idea of a better-ordered world is one in which medical discoveries will be free of patents and there will be no profiteering from life and death." Although the analysts and policymakers do not agree on the pros and cons of the Patent Act, and the debate still continues, it will be useful to examine the salience of the act for the development of the national sector in the Indian pharmaceutical industry.

It is a widely accepted view that the enactment of the Patent Act has contributed significantly to the growth of the national sector, both public and private, in the Indian pharmaceutical industry. The managing director of a leading Indian company has described it as "the most significant milestone in [India's] aim to achieve self-sufficiency and self-reliance in the drug industry." Indeed, the decade following the implementation of the Patent Act in 1972-73 witnessed unprecedented progress and development of bulk drug manufacture by both the
private (Indian) and public sector drug companies. Using indigenously developed technology, the national sector of the industry began to produce a number of bulk drugs and their formulations such as ampicillin, amoxycillin, erythromycin, ethambutol, metronidazole, propranolol and trimethoprim. By 1984, the contribution of the national sector of the industry had reached 65 percent of the drug formulations and 83 percent of the bulk drug production in the country, and this sector also contributed to over 65 percent of the exports of drugs and pharmaceuticals from India. In 1983-84, this sector produced Rs. 295 crores' worth of bulk drugs as compared with Rs. 60 crores by the foreign sector and Rs. 1,000 crores' worth of formulations as compared with Rs. 760 crores by the foreign sector.

The growth of the national sector was further accelerated by the New Drug Policy (NDP) announced by the Janata government in March 1978. The NDP, which was based primarily on the recommendations of the Hathi Committee Report, divided drugs into three groups for purposes of reserving items for production by various sectors. Whereas the production of 17 essential drugs was reserved for the public sector and production of 27 items was reserved for the Indian sector, public and private, 64 items were open for licensing to all sectors, including the foreign sector.
The NDP imposed restrictions on the growth and expansion of FERA companies. Those firms not manufacturing bulk drugs and those producing "low technology drugs" were required to bring down their foreign equity holding to 40 percent; however, those foreign companies producing "high technology" drugs were allowed to retain foreign equity in excess of 40 percent subject to dilution formulas linked to expansion projects. In the case of product mix, the FERA companies were required to maintain a ratio of 1:5 in the production of bulk drugs to formulations, whereas the ratio for Indian companies was 1:10. Furthermore, FERA and MRTP companies were required to make 50 percent of their bulk drug production available to nonassociated formulatees (the ratio being 40 percent and 30 percent for the public and Indian companies, respectively).

The NDP achieved at least one of its major objectives, namely, the growth of the national sector. In the post-1978 period, there has been an enormous growth of wholly owned Indian companies. The Operational Research Group (ORG) Survey of retail sales between 1980 and 1986 has consistently ranked five Indian companies among the top ten, with Sarabhai Chemicals ranking first or second in the last seven years. Other Indian firms such as CIPLA, Cadilla, Lupin, and Ranbaxy have emerged as major pharmaceutical manufacturers since 1979-80. There has been, for example, a three-fold increase in the sales turnover of CIPLA between 1979 and 1985. The progress that the company has made in the manufacture of bulk drugs and intermediates has been partly due to the government bias against foreign firms in granting industrial licenses for drugs even in the category open for all sectors. In the much publicized controversy over Glaxo's application for the manufacture of salbutamol, an antiasthma drug, the government decided to grant the license to CIPLA, which had indigenously developed the technology.

Another Indian firm, Ranbaxy Laboratories, doubled its sales turnover in three years (from Rs. 3,695 crores in 1983 to Rs. 7,099 crores in 1985), and the ORG survey has ranked it as ninth in 1983 and sixth in 1985. The company's leading product, Compos, a tranquilizer reserved for the Indian sector under the NDP, captured the market of Valium and Librium marketed earlier by the foreign firm, Roche. The drug output of Lupin Laboratories has recorded a similar growth pattern: Its bulk drug output alone increased from Rs. 3.74 crores in 1983 to Rs. 10.33 crores in 1985 and reached Rs. 30.50 crores in 1987.

The range of products manufactured by the Indian sector has also become increasingly sophisticated in recent years. A number of these firms have undertaken the production of bulk drugs and have started producing high-technology drugs, which until recently was the domain of foreign firms. For example, Standard Medical and Pharmaceutical Limited, a relatively new Indian company, announced in February 1987 that it would manufacture cephalxin, an advanced antibiotic not
produced by any other Indian or foreign company. Cephalexin is considered to be superior to many semisynthetic penicillins including ampicillin and amoxycillin in its efficacy in treating penicillin-resistant infections and gastrointestinal disorders. The technology of this drug has been indigenously developed by the scientists of Standard Medical, which indicates the maturity attained by this sector.

Government policy has had a positive effect on the outflow of foreign exchange because of remittances and the import of raw materials. The multinational companies have been criticized for taking more out of the Third World by way of profits than they bring in as investable capital. It would therefore be useful to compare the foreign exchange earnings of the multinational firms through exports with their remittances abroad by way of dividends. Table 1 reveals that the foreign exchange earnings of the international companies located in India totaled more than three times their remittances by way of dividends, which was about Rs. 8 crores per annum. For an earlier period (1970-75), the Hathi Committee Report had found the remittance of profits by multinationals to be Rs. 5 crores annually, which was "less than the actual exports by firms having foreign equity of more than 50 percent."

The government's introduction of the system of "drug canalization", the importation of bulk drugs through the use of a government agency, the state Chemical and Pharmaceutical Corporation (CPC), in order to prevent transfer pricing and to ensure a reliable supply of raw materials to indigenous manufacturers at fair prices, further curtailed one of the worst abuses that multinationals have been accused of practicing in most Third World countries. The CPC started importing essential raw materials on a bulk purchase basis, pooled them with the same raw materials produced domestically by the public sector company (IDPL), and distributed the pooled stock to domestic manufacturers at a pooled (fair) price. The system, which worked well according to most industry analysts, was designed to counter the transfer pricing methods used by drug multinationals importing active ingredients and drug intermediates from parent companies. These constraints imposed by the government on the behavior of drug multinationals in India hardly resemble the situation found in most Third World countries. Case studies of the multinational drug firms in the Third World have shown weaker government regulations in a number of African and Latin American countries. An early 1980s study of Mexico's steroid industry suggests that foreign control of the industry has wider implications for the country; it "restrict[s] the choice among local development options.

The 1980s witnessed a rapid decline in the shareholding of the transnational subsidiaries. A comparison of the foreign shareholding in the period before and after the enactment of FERA/NDP is quite revealing. The official statistics indicate that up to March 1964, over half the foreign subsidiaries operating in India had a 100 percent foreign ownership, which remained as high as one-third
of all the subsidiaries between 1964 and 1970. In 1974, a year after the enactment of the FERA, the total number of drug companies holding foreign equity was 66.

Table 1
Export and Remittances of International Drug Companies (Rs. in Lakhs)

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<th>1979</th>
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<tr>
<td>Export</td>
<td>2,909.52</td>
<td>2,541.50</td>
<td>2,514.43</td>
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<tr>
<td>Remittances</td>
<td>813.55</td>
<td>786.64</td>
<td>789.16</td>
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<tr>
<td>Net Gain</td>
<td>2,095.97</td>
<td>2,754.86</td>
<td>2,725.27</td>
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Source: Minister's Answer to Lok Sabha unstarred Question No. 2570 on August 3, 1982 (for remittances), Annual Reports of International Companies and Basic Chemicals, Pharmaceuticals and Cosmetics Export Promotion Council (for export).

of which 10 had 100 percent equity holding, 24 held 50 to 59 percent equity and 15 held 40 to 50 percent. The number of companies holding equity below 40 percent was only 17. As late as 1978, when the NDP was announced, there were 31 FERA companies. By contrast, by the late 1980s, there were only half a dozen FERA companies--Bayer, Johnson & Johnson, Roche, Wyeth, IEL and Sandoz--in the drug sector. There was also a significant decline in the market shares of the FERA and ex-FERA companies to be discussed later in this chapter. Therefore, the foreign sector has been reduced to a position of minor partner in the Indian drug and pharmaceutical industry.


The above discussion suggests that by the mid-1980s the pharmaceutical industry in India had grown into a vertically integrated manufacturing enterprise producing almost all essential drugs and meeting the country's requirements of formulations in full and of bulk drugs very substantially. Moreover, the Indian pharmaceutical industry was no longer dominated by multinationals, which was unquestionably due to the New Drug Policy and the Patent Law. Do these developments in the pharmaceutical industry provide enough evidence to support the dependency hypothesis that states intervention and regulation of an industry in the Third World would not only reduce dependence on foreign multinationals but also facilitate the growth of the national sector in the industry? As the following discussion will suggest, it would be a mistake to conclude that India has succeeded
fully in overcoming its dependence on drug multinationals. The situation is much more complex than what dependency theory would have us believe about the possibility of “dependency reversal” due to state intervention. Nor does the Indian case fully support the proposition of the bargaining school that states prolonged contact with the multinationals necessarily results in increased bargaining for the host country. On the one hand, the analysis in the previous section partially supports the hypothesis that the regulation and control of the multinationals will allow the growth of the national sector and eventually reduce dependence on the multinationals. On the other hand, the inadequate production of drugs in India in the 1990s and the liberalization in price increases, delicensing, and broad-bandingxxi to encourage market economy, and India’s signing of the Uruguay Round with its controversial TRIPS provisions, will suggest that in the Third World there is a definite limit to state intervention and control of an industry that is highly research-intensive and in which there is a high level of product obsolescence.

The government’s decision to delicense 94 bulk drugs and related formulations in 1985 brought an end to the sectoral reservation system introduced in the New Drug Policy in 1978. While the NDP did result in the growth of the national (private) sector of the industry and the Drug Price Control Order (DPCO) of 1979 made the price of drugs in India among the lowest in the Third World,xxii they also had many negative consequences for the industry. The most important among them was the consistent shortfalls in the level of production of drugs, especially essential drugs, in the years following the implementation of the DPCO.

The DPCO brought under its control the price of 347 bulk drugs, of which about 225 were domestically produced. It divided the price-controlled formulations into four categories.xxiii Categories I and II consisted of essential drugs, and the markups which included distribution cost, promotional expenses, trade commission, and the manufacture’s margin were fixed at 40 percent and 55 percent, respectively. Category III formulations, considered less essential, carried a markup of up to 100 percent, and category IV formulations were outside price control. It has been estimated that "4,000 formulations, marketed in 25,000-odd packs" were brought under the control of the 1979 DPCO.xxiv

The drug manufacturers, particularly the FERA and ex-FERA companies, responded by diverting their production into nonessential and decontrolled products, thereby flooding the Indian market with category IV formulations such as "unnecessary" vitamins, tonics, mineral supplements, and cough and cold preparations, which are top-selling drugs and account for a large percentage of the total market for drugs in the country.xxv It is not surprising, therefore, that by the early 1980s, the Indian pharmaceutical industry was producing between 40,000 and 60,000 formulations, most of which were considered superfluous and some harmful.xxvi The multinationals’ share of the production of simple formulations far
exceeded that of the national sector. Discussing the proliferation of drugs in India, a commentator observed that "backed by an aggressive advertising and marketing campaign, the drug companies have successfully promoted the concept of a pill for every ill, even if imaginary." This has resulted in the shortfall in production of several essential drugs such as antibiotics, sulphas, analgesics, corticosteroids, anti-T.B. drugs, antimalarials, cardiovascular drugs, and anesthetics.

The total imports have increased from Rs. 16.14 crores in 1970-71 to Rs. 162.16 crores in 1983-84. Imports of bulk drugs in the same period have gone up from Rs. 11.52 crores to Rs. 123.06 crores, and the proportion of bulk drugs in total imports is around 75 percent since 1980. The government objective of self-sufficiency in drug production was thus far from being realized. According to many analysts, this situation came about mainly because of the new pricing policy of the government. Nitya P. Anand, the former director of the Center of Drug Research Institute (CDRI), Lucknow, was one of the vocal opponents of the government pricing policy. He believed that the market forces alone, not price control, could bring the prices down. Therefore, he argued that "major changes were needed in the existing pricing policy, as the low mark-up was unrealistic."

From the beginning there were skeptics within the government who doubted the usefulness of the policy of price control. On the eve of the announcement of the DPCO, Nitya Anand sent a long telegram to the concerned ministry (the Ministry of Petroleum and Chemicals) urging the government not to announce the DPCO in 1979. As the Director of CDRI and a consultant to the UNIDO and other international agencies for many years, Anand had actively participated in the formulation of the DPCO and was dissatisfied with its provisions, especially with markups in category I and II drugs. The reservations expressed by him and many others were not unfounded. As it turned out, the critics of the NDP proved to be more farsighted than the supporters of the policy. The implementation of the DPCO soon resulted in the distortion of the production of essential drugs. Due to the serious shortfalls in production, the Sixth Five Year Plan targets had to be revised downwards to Rs. 500 crores from Rs. 665 crores for bulk drugs and to Rs. 1,950 crores from Rs. 2,400 crores for formulations and even the revised plan targets were not achieved. The magnitude of the shortfall in production in the Sixth Five Year Plan period was quite serious compared to the production figures of the Fifth Five Year Plan; the latter had not only attained the production target of bulk drugs but it also exceeded the target by 57 percent in formulations, mainly because of the high tempo of growth produced by the industry between 1975 and 1979.

The production of the wholly owned Indian private companies was far below the target. Out of 27 items reserved for them, production of 19 bulk drugs had been inadequate to meet the country's total requirements in the early 1980s. The shortfalls in production were not only in the private sector but also in the public sector, the record of the
public sector had been far from satisfactory. The production data on different sectors of the industry further reveal that of the 17 drugs reserved for the public sector, the production of almost all of them had been below the targets set for them, and in the cases of three reserved items—morphine, polio vaccines and sulhamethoxy-pyridazine production had not even commenced. The public sector, in general, was also suffering from high cost of production mainly because of technological obsoleteness a subject to be addressed in the following chapter.

Public discussion of the New Drug Policy and the DPCO (1979) started shortly after they went into effect. The government started receiving complaints from the industry and consumers, and several MPs belonging to both the ruling party and the opposition parties started raising questions in Parliament regarding the unavailability of many essential drugs, lower capacity utilization by many companies, and the proliferation of "irrational drugs" in the country. The government responded by setting up the National Drug and Pharmaceuticals Development Council (NDPDC) in 1983 for the purpose of reviewing the working of the drug policy of 1978 and to suggest necessary changes toward formulating a new policy. The main objective was to find ways to increase the production and ensure availability of essential and lifesaving drugs in abundance. NDPDC, which had representation from the industry but not from people and consumer groups, submitted a report in 1984, which formed the basis of the 1985 delicensing decision of the government and the 1986 drug policy.

Among the various areas of the drug policy, the council paid special attention to the operation of price controls. It recognized that the pricing system was distorting the production pattern because of the shift in the production away from the more essential category I and II formulations, which carry a lower markup. The 1984 NCAER study also found that the pricing policy of the government was the major impediment to the growth of the industry. Based on the data collected from 23 companies, the study concluded that the break-even markup of the sample units ranged from 63.3 percent in 1978 to 62.5 percent in 1980. Thus the mark-up prescribed by the DPCO (1979) for certain categories of formulations (I and II) was lower than the break-even markup. On the question of the government's pricing policy, therefore, there emerged a consensus in the industry, and throughout the early 1980s there was an intense lobbying effort on the part of both the national sector (through IDMA: Indian Drugs Manufacturers Association) and the multinationals (through OPPI: the Organization of the Pharmaceutical Producers of India) to change the existing drug policy. Both sectors of the industry have argued vigorously that the profitability in the industry had been declining and was at an all-time low in 1985-86. The profitability of the industry as a whole had decelerated rather sharply from 15.47 percent in 1969-70 to just 4.0 percent in 1985-86.
The concerted lobbying by the industry coupled with the shortfalls in the production of essential drugs led to the revision of the drug policy announced by the government in December 1986. This revision raised the markup called Maximum Allowable Post Manufacturing Expenses (MAPE), the difference between the cost of production and the final selling price on a small number of essential drugs from rather unattractive levels (40 and 55 percent) to a profitable 75 to 100 percent and cut the categories under which drugs are grouped from three to two. According to the 1986 Drug Policy, whereas for the FERA companies the ratio of bulk drugs to formulations had been raised from 1:5 to 1:4, the ex-FERA companies were treated for the first time as national companies. In order to liberalize the industry, broadly in accordance with the general liberalization of the economy, the government decided to dismantle physical controls. The decision taken under the liberalized Drugs (Price Control) Order (DPCO) of August 1987 to slash the number of bulk drugs and their formulations governed by price controls by more than half from 371 to 166 was a move in that direction.

### Table 2
**Profitability in the Pharmaceutical Industry**

<table>
<thead>
<tr>
<th>Profitability before Tax as Percentage of Sales</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>1969-70</td>
<td>15.47</td>
</tr>
<tr>
<td>1971-72</td>
<td>10.19</td>
</tr>
<tr>
<td>1972-73</td>
<td>8.53</td>
</tr>
<tr>
<td>1974-75</td>
<td>10.7</td>
</tr>
<tr>
<td>1975-76</td>
<td>10.4</td>
</tr>
<tr>
<td>1977-78</td>
<td>11.7</td>
</tr>
<tr>
<td>1978-79</td>
<td>12.0</td>
</tr>
<tr>
<td>1978-80</td>
<td>12.4</td>
</tr>
<tr>
<td>1980-81</td>
<td>8.8</td>
</tr>
<tr>
<td>1981-82</td>
<td>8.0</td>
</tr>
<tr>
<td>1982-83</td>
<td>7.5</td>
</tr>
<tr>
<td>1983-84</td>
<td>6.7</td>
</tr>
<tr>
<td>1984-85</td>
<td>5.8</td>
</tr>
<tr>
<td>1985-86</td>
<td>4.0</td>
</tr>
</tbody>
</table>

**Sources:**
- 1974-75 to 1980-81: RBI Bulletins
- 1981-82 to 1983-84: NCAER Study
- 1984-85: A. F. Ferguson Survey
- 1985-86: OPPI estimates
These changes in the government policy were made primarily to encourage investment in the industry in order to meet the projected demand of drugs by the turn of the century, as computed by IDMA, NCAER, and the planning commission. NCAER has estimated the demand for drugs by the year 2000 at Rs. 16,000 crores. To meet this projected demand, it was thought that the industry must grow at an annual rate of 15 to 20 percent. With the public sector out of the reckoning, the government had very little choice but to attract the private sector “with the carrot of higher profits being the lure for increased investment and production.”

However, it would be a mistake to conclude that there is no effective control of the industry by the government. Based on a survey conducted by ORG in 1987, it was estimated that 72.8 percent of the formulations market will remain under price controls, a reduction of just 3.2 percent from the old DPCO. It is a testimony to the effectiveness of the pressure exerted by consumer groups, intellectuals, and many experts in the field of community health and social medicine who wanted to maintain the effective control of the government over the industry.

**CONTRIBUTION OF THE NATIONAL SECTOR VS. THE MULTINATIONALS**

In recent years, the wholly owned Indian companies have emphasized the contribution made by the national sector, which includes the public, private, and small-scale industry companies as compared with the international companies (both FERA and ex-FERA). They emphasize that the national sector has achieved all-around growth in the production of bulk drugs and formulations while the contribution of the international companies in the production of formulations has been quite disproportionate to their production of bulk drugs. Such claims are supported by the growth figures of the private national sector of the industry.

The senior managers and the managing directors of the two leading national companies I interviewed (CIPLA and Ranbaxy) were emphatic in pointing out the positive effect of the Patent Law and the sectoral policy of the government on the growth of the private national sector of the industry. In general, they argued that the national sector, including the public sector, has made the country “not only self-sufficient in a number of essential and life-saving drugs such as Ampicillin, Sulphamethoxazole, Trimethoprim, Metronidazole, Ethambutol etc., but has also helped India emerge as a major exporter of these drugs the world over.” The international companies, on the other hand, claim that their contribution to the development of the industry is crucial because they have brought to India the latest drug technology from the parent companies and, in many cases, without paying any royalty or technical fee. These competing claims, however, are not mutually
exclusive. In fact, there is enough empirical evidence cited by both in support of their claims.

The role of the government's sectoral policy in the growth of the national sector has already been noted. However, a few important developments must be underscored. By 1986, the national sector was contributing about 83 percent of the bulk drug production, of which 60 percent was by the private national sector. The country has thus become self-sufficient in a number of bulk drugs, and some of these drugs are now exported to sophisticated Western markets. Some of the large Indian companies such as Sarabhai Chemicals, Unichem, Alembic, Cadilla, CIPLA, and Ranbaxy have grown to the extent of successfully competing with the very best of the international companies in terms of the quality, quantity, and efficacy of drugs manufactured. Many of these companies have their factories approved by the U.S. FDA so that they could export their products to the markets of the developed countries. A few national sector companies, notably Sarabhai Chemicals and IDPL, have been selling turnkey plants and technical and training services to other developing countries.

In the manufacture of formulations, the share of the Indian sector increased from 58.29 percent in 1976-77 to 70.61 percent in 1984-85, while that of the foreign sector declined from 41.71 percent to 29.39 percent over the same period. Compulsory licensing under the Patent Law, as already discussed, was largely responsible for the progress made by the Indian private sector. For the first time it became possible for the Indian companies to manufacture drugs legally although they were still under patent in the developed countries by paying not more than 4 percent royalty on total sales to the original patent-holder. A number of lifesaving drugs still under patent in the West, such as rifamycin (an anti-T.B. drug) and salbutamol (an antiasthma drug), are now being manufactured by Indian companies from basic stages. Such possibilities were unthinkable until the revised Patent Law went into effect in 1973.

The data on growth of the industry further reveal that the production of bulk drugs has increased at a rate higher than the rate of growth in production of formulations. The rate of growth of bulk drugs between 1970 and 1984 is 19.5 percent while that of formulations is only 12.5 percent. This is mainly because the formulations market is highly competitive and the Indian manufacturers find it difficult to compete with the brandname drugs marketed by international firms. As a result, a number of Indian private sector units, both in the organized and unorganized sectors, have concentrated on the production of bulk drugs.

Notwithstanding the growing share of the national sector in the production of both bulk drugs and formulations, the performance data of the Indian sector between 1980-81 and 1984-85 reveal that in the reserved categories (i.e., items
reserved for both the public sector and the Indian sector) it failed to achieve the targets set in this regard; the national sector's production of most of the essential bulk drugs under categories I and II was consistently far below the target for four consecutive years.

Another problem with the national sector has been the horizontal growth of the small-scale sector. According to the DPCO (1979) small-scale companies with annual turnovers of up to Rs. 5 million were exempt from price control. Although the price control did not directly apply to the small-scale drug manufacturers, they were brought under the scheme indirectly by being required to follow the "leader price" principle: the price charged by the most efficient manufacturers in the country for the particular product. This was done, in accordance with government policy, to encourage the small-scale sector in each industry. The small-scale manufacturers were required only to register with the state government instead of securing industrial licenses from the Ministry of Industry (DGTD). (It has therefore been very difficult to get reliable data and statistical information about this sector of the industry.) The NDPDC found that a large number of small companies floated associated companies, allegedly to circumvent the provisions of the DPCO. Such developments were obviously not in the interest of the growth of the industry.

The multinationals have emphasized their contribution to the production of basic drugs in India. They claim to have introduced a number of basic drugs dating back to the 1950s, including liver extract from Rallies (1941); INH from Pfizer (1956); vitamin A from Glaxo (1958) and Roche (1959); prednisone from Glaxo (1958), MSD (1959), and Wyeth (1963); vitamin B-12 from MSD (1959); and amodiaquin from Parke-Davis (1959). Since the enactment of the NDP, multinationals maintain, international companies have continued to manufacture the high technology bulk drugs used in category I and II formulations, from basic and intermediate stages. For example, in the late 1980s, Glindia launched a new drug, Normadate, which was an entirely new and unique concept in cardiovascular treatment.

After the announcement of the NDP, however, the international companies started concentrating on the production of category III (with 100 percent markup) and category IV (outside price control) drugs. They emphasized that the low markups in categories I and II were the reason why they found it necessary to reduce the production of drugs in the essential categories and correspondingly increase the production of more profitable drugs. Despite such a move on the part of the international firms, they are still considered crucial for the future development of the industry and in meeting the demand of drugs and pharmaceuticals in India. Neither the public sector nor the wholly owned Indian companies have ever suggested the nationalization of the multinationals. Perhaps it is a recognition of the fact that in the area of high technology, India cannot do without the multina-
tionals. In fact, what is ailing the public sector pharmaceutical companies in India is technological obsolescence, and serious efforts are being made to overcome that. It has been acknowledged that the latest and most efficient drug technology is available from the multinationals, but they do not want to sell it at any price without having financial participation in a company. This has led the government to consider the possibility of allowing the multinationals to have equity share in a public sector company, an idea selectively implemented since the late 1990s. The multinationals' strength in the area of technology and marketing has also allowed them to continue the domination of the lucrative formulations market in return for meeting the government's requirement of producing a certain proportion of high-technology bulk drugs.

THE LIMITS OF THE TWO THEORIES

Based on the knowledge of the growth and development of the pharmaceutical industry in India, we can make some generalizations and examine the validity of the two theories we set out to verify in the first chapter. It is of utmost significance to note that the multinationals, which dominated the industry for three decades in independent India, have been reduced to the level of junior partners, so far as their shares of the total production of both bulk drugs and formulations are concerned. The domination of the multinationals in the first two phases lends support to some of the hypotheses of dependency theory: their profitability was high, they concentrated on the manufacture of simple formulations as opposed to bulk drugs and were reluctant to produce drugs from the basic stages, their R&D investment was low, and there were reported cases of transfer pricing. But the analysis of the third and fourth phases presents problems for dependency theory as well as for the bargaining school. The nationalist phase, which witnessed the unprecedented growth of the national sector, making it the largest segment of the industry, seems to fit the dependency reversal prescriptions advanced by a few dependency theorists. Yet, the shortfall in production in public and private national sectors made the government decide to eliminate many restrictions on multinationals imposed in the third phase.

If the hypothesis of the bargaining model, on the other hand, were to be applied, one would expect a gradual increase in the power of the state vis-à-vis the multinationals. To some extent, it happened in the 1970s: The revision of the Patent Law (1970), the NDP (1978), and DPCO (1979) were steps taken by the state to increase its regulatory and bargaining power. But the drug policies announced by the government in December 1986 and the DPCO the following year, mainly guided by the consideration of growth in the industry, seem to suggest a slight erosion in the bargaining power of the state.
CONCLUSION

What emerges from our analysis of the effect of government policies on the structure, profitability, sectoral growth, and production in the Indian pharmaceutical industry is that it is neither a categorical validation of the dependency hypotheses nor a clear confirmation of the assumptions of the bargaining school. Sensitive to the possible threats of multinationals to its national autonomy, the Indian government tried to control the expansion, growth, profitability, and ownership of the multinationals through legal and administrative measures. As a result, most of the criticisms found in the empirical studies on the behavior of the drug multinationals in the Third World—high profits, transfer of inappropriate technology, hindering the development of indigenous technology, transfer pricing, and so on do not apply to India.

The Patent Act (1970), especially its provision of compulsory licensing, and the policy of sectoral reservation in the NDP (1978) did contribute significantly to the growth and expansion of the national sector, both public and private. Once the new Patent Law, which allowed process patent only, went into effect in 1973, it became possible for Indian companies to manufacture the patented drugs legally by paying 4 percent royalty on sales to the patent holder, or to manufacture the patented drug themselves through a different process. Many companies decided to develop their own process through in-house R&D instead of paying the royalty; they did so by simply altering the molecular structure of a drug. The introduction of the system of "drug canalization" almost eliminated the problem of transfer pricing so widespread in the pharmaceutical industry. The foreign exchange earnings of the drug multinationals were much higher than their remittances by way of dividends.

By 1984, multinationals had been dislodged (to use a term from Dennis Encarnation's study) from their dominant position to become junior partners in the industry. In that year, the national sector's contribution to the total production of formulation and bulk drugs had reached 65 percent and 83 percent, respectively. The range of products manufactured by the Indian sector also became sophisticated, and its contribution to the growth of bulk drug production was significant. The private national sector seems to have benefited most from the protective policies of the government. In less than a decade, the private national sector reached maturity and became competitive with the foreign sector in a highly research-intensive industry. Many private sector Indian firms acquired the technological capability to manufacture bulk drugs from the basic stages.

However, sectoral reservation and price control created many problems for the industry in the ensuing years. While DPCO (1979) had made the price of drugs in India among the lowest in the Third World, the pricing policy of the government became the major impediment to the growth of the industry. The low markups in
categories I and II drugs led to the multinationals' shift of production from essential and lifesaving drugs to more profitable nonessential drugs in categories III and IV. The low production of essential drugs resulted in a ten-fold increase in their import between 1970 and 1984. The problem was recognized by the NDPDC and NCAER study and addressed in the 1986 Drug Policy, which reduced the categories under which drugs are grouped from three to two and increased the markup in the essential drug category (from 40 to 55 percent to 75 to 100 percent). It was expected that a reasonable profit margin in the production of essential drugs and the end of sectoral reservation with the government decision in 1985 to delicense 94 bulk drugs and related formulations would encourage new investments, which would help the industry attain 15 to 20 percent annual growth rate in order to meet the projected demand for drugs.

Although the government policies have succeeded in dislodging multinationals in the drug and pharmaceutical industry, the strategies adopted by the latter were such that many of the intended benefits of government control and regulation were not realized, which frustrated policymakers as well as consumer groups and intellectuals. The complexity of the situation is mainly due to the nature of the industry, which is research-intensive and has a high rate of technological innovation and obsolescence. The salience of the multinationals in drugs and pharmaceuticals, not only in India but all over the Third World, is closely related to their domination of the latest technology.

NOTES


ii. These formulations included household remedies containing vitamins and minerals, many of which did not require a doctor's prescription, such as cough mixtures, ring worm ointments, health salts, gripe mixtures, laxative tablets, eye drops, malted tonics, digestive tablets, ointments for burns and piles, tonics containing calcium, alcohol-based tonics, and others.


viii. Other countries that allowed only process patents are: Australia, Brazil, Bulgaria, Canada, China, Chile, Czechoslovakia, Denmark, former East Germany, Hungary, Italy, Japan, Netherlands, Pakistan, Poland, Spain, Sweden, Switzerland, former Soviet union, and Yugoslavia.

ix. The most important among them was the Ayyangar Report (1959), which argued for abolishing the existing Indian Patent and Design Act of 1911. The old patent act had been amended from time to time, one of the notable amendments being the provisions introduced in 1952 relating to the compulsory licensing of patents in the field of food or medicines at any time after the sealing of the patent. See N. Rajagopala Ayyangar, *Report on the Revision of the Patents Law* (New Delhi, 1959).


xii. The Managing Director of CIPLA, Dr. Y. K. Hamied, in an address to a gathering in Pune on December 2, 1983, to commemorate the transfer of technology for manufacture of vinblastine and vincristine from NCL to CIPLA.

xiii. In India, unlike some other countries—China, for example—the burden of proof of infringement is on the patentee even for a process patent; this is practically impossible to prove in the case of imported items.


xvi. Hathi Committee Report, p. 98.


xx. Bayer and IEL are not strictly drug companies because drugs comprise less than half their turnover.

xxi. Broad-banding means that the description of items of manufactures in the Industrial License would be in terms of broad characteristic categories instead of rigidly defined specific products. For example, if a drug company gets industrial licence/permission for the production of penicillin, it can produce all types of penicillins and chemically related analogues like ampicillins, and others. See S. K. Jain, *The Drug Policy 1987-88* (Delhi: India Investment Publication, 1987), p. 78.
This book is a collection of all the documents, statements, and press notes related to the drug industry that were issued by the government since 1973.

xxii. According to OPPI (Organization of Pharmaceutical Producers of India), drug prices in India are lower than those prevailing in most developing and developed countries, mainly because of government price control since the early 1960s.


xxv. It is interesting to note that 30 percent of the total sales of Glaxo—the name was changed to Glindia in 1987—consisted of baby formula.


xxix. Personal interview in Lucknow on September 19, 1986.

xxx. Communicated to the author in a personal interview on September 19, 1986.


xxxii. The NCAER study has been widely accepted as an objective study of the industry. P. L. Narayana, The Indian Pharmaceutical Study: Problems and Prospects (New Delhi: NCAER, 1984), p. 158.

xxxiv. Cited in Ibid., p. 38.


xxxvi. This point was emphasized by Pfizer managers in a personal interview on October 6, 1986. Unlike many international firms such as Glaxo (Glindia), Pfizer does not pay any royalty or technical fee to the parent company.

xxxvii. *Guidelines for Industries*.


xli. The criteria adopted for classification of bulk drugs were defined by the government Committee on High Technology in March 1982. Although the definition adopted was quite exhaustive, it involved 12 different criteria. Some of the committee members expressed their dissatisfaction with the government decision. For example, Nitya P. Anand, a member of the committee, told me in a personal interview that because of the way high and low technology drugs were defined, it became possible for multinationals to get most of their drugs classified in the category of high technology drugs.

xlii. K. Jayaraman's "Multinationals: Sinners or Sinned Against?" (unpublished paper, Bombay, 1986) provides a list of category I/II bulk drugs manufactured by FERA and non-FERA companies.


xliv. When multinationals are involved in intrafirm trade (i.e., trade between