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PHARMACEUTICAL POLICIES IN SOUTH ASIA:
IMPLICATIONS FOR SELF-RELIANT DEVELOPMENT
AND GLOBAL INTERDEPENDENCE

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Nalini Malhotra

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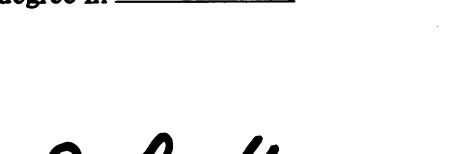

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PHARMACEUTICAL POLICIES IN SOUTH ASIA: IMPLICATIONS FOR SELF-RELIANT DEVELOPMENT AND GLOBAL INTERDEPENDENCE

By

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ABSTRACT

PHARMACEUTICAL POLICIES IN SOUTH ASIA:
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The present structure of the global pharmaceutical industry is one in which the bulk of the research and development, production and marketing of drugs is undertaken by a few western transnational corporations. This has significant socioeconomic consequences for developing countries that are striving toward self-reliant development and symmetric global interdependence. A comparative study of the pharmaceutical policies of India, Pakistan and Sri Lanka indicates their diverse attempts to overcome dependence on foreign companies. Data for this sociological study were collected largely from government documents, company reports, secondary analyses, and resports published by international agencies. An analysis of the successes and failures of pharmaceutical policies in the three case-studies suggests that pharmaceutical self-reliance cannot be meaningfully understood unless examined in light of a country's vulnerabilities as an actor with, and within, a world system. Recent trends indicate modest efforts to strengthen regional solidarity among developing countries with regard to their pharmaceutical policies.

Dedicated to Ram and Raj Malhotra,

and to the loving memory of

Gokal Chandra Malhotra

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Although the depth of my gratitude to a few individuals can never be fully expressed in words, I take this opportunity to acknowledge their contributions to this thesis. My sincerest appreciations are extended to Dr. John Useem, Professor of Sociology and Dr. Ruth Hill Useem, Professor of Sociology and Education, Michigan State University. Dr. John Useem, my major advisor and chairperson of my guidance committee, has extended himself beyond the call of duty in guiding the development of my intellectual thought not only during the writing of this thesis, but throughout the course of my graduate studies at Michigan State University. Dr. Ruth Hill Useem's patience, understanding, and tolerance have been unmatched by anything I have witnessed before. Both of them have unfailingly shown keen interest in helping me overcome the various kinds of academic pressures normally imposed on graduate students. The extent of their assistance reaches far beyond the field of academics alone. I express my heartfelt thanks to both of them.

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My initial interest in the subject of this thesis developed out of discussions I had with Dr. Zahir Ahmed Quraeshi, Assistant Professor of Marketing, Western Michigan University, over his research on the pharmaceutical industry in Pakistan. Since then, Dr. Quraeshi has commented extensively on earlier drafts of this thesis, and has introduced me to a great deal of the literature on the world-wide pharmaceutical industry. I would like to acknowledge his contributions to this thesis.

I thank professors and colleagues of mine who have directly, or indirectly, contributed to the development of the ideas expressed in this thesis by exposing me to their own ideas and insights throughout the course of my graduate studies at Michigan State University.

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CHAPTER I

INTRODUCTION TO THE STUDY

Theoretical Background to the Study

The second half of the twentieth century has witnessed substantive growth in the literature on development/underdevelopment within the social sciences. This is partly due to the emergence of new independent nations on the geo-political map in the period following the Second World War. The problems facing these countries in their attempt to modernize, captured the interest of social scientists worldwide. In the 1950s and 1960s, the academic community, most notably in the West, contributed to theory building, data collection and analysis of the structure and performance of less developed countries (LDC's). Their theoretical contributions were influenced by a number of factors: their concern for the modernization of LDC's, awareness of the complex interdependencies which bind these societies to their own, Western and Communist political and economic involvement in the newly independent nations, and the new opportunities for comparative, cross-cultural research and analysis of LDC's opened up.

Analysis and empirical research in cross-cultural social science have been guided by various conceptual frameworks, some of which are complementary, while others represent diverse sets of assumptions about the process of development. At this point, I will

attempt only to briefly summarize the general concepts and assumptions underlying these analytic frameworks, and the policy recommendations they lend themselves to, realizing that I am not detailing all the complexities of, and variations within, these general frameworks.

The dominant paradigm of the 1950s and 1960s has been referred to by a number of labels; "modernization" theory (Eisenstadt, 1966), "liberal development theory" (Chirot, 1977; Bodenheimer, 1971), "development-convergence" (Kumar, 1979). This paradigm holds the basic premise that various societies are at different stages of development, some more industrialized than others. Growth is perceived as unilinear with the assumption that the less industrialized nations will develop along the pattern of the more industrialized ones (Eisenstadt, 1966; Lerner, 1958; Rostow, 1962). Since poverty and wealth are related to internal characteristics of a society, any effort to modernize the less industrialized countries will begin with internal reform. Such reform can be achieved by internalizing Western values--a modern, rational work ethic, the "need to achieve"--by evolving new institutions and organizations, and by patterning existing ones along the lines of those in industrialized nations. Specific attention is paid to the role of educational, political and economic institutions in the move toward modernity. Formulated in this manner, the framework establishes the basis for a multi-disciplinary approach toward the study of modernization.

The diffusion of science and technology from the industrialized countries to their less industrialized counterparts is an important component of the framework. Proponents emphasize greater

inter-societal communication linkages between scientific communities through the mechanisms of collaborative research ventures, cross-cultural exchange of students and scholars, the developing of literacy and educated classes, and technical assistance programs. Perceived within this perspective, transnational corporations (TNC's) are one of the newer major conveyors of capital, technology, and managerial skills to LDC's, all three of these being prerequisites for large-scale industrialization.

The more recent dependency framework (articulated in the last decade or so) presents a direct challenge to the earlier modernization paradigm (the dominant paradigm for almost a quarter of a century). Rather than assume the "harmony of interests" between the industrialized nations of Western Europe and Northern America ("metropoles") and the less industrialized nations of what is generally known as the "Third" and "Fourth" Worlds ("satellites"), dependency is inherently a conflict model on both the international and domestic levels (Bodenheimer, 1971). The basic premise of this paradigm is that development and underdevelopment are inter-related consequences of the same historical process, the expansion of capitalism within a global system (Frank, 1971, 1972; Galtung, 1971; Wallerstein, 1974). Hence, according to proponents of this framework, the core nations have industrialized more rapidly than, and often at the expense of, peripheral nations who remained for centuries exporters of primary raw materials and agricultural products. The paradigm rejects the earlier evolutionary models which perceive underdevelopment as a transient stage of the process already

completed by industrialized nations, and attributes underdevelopment to the specific functions which LDC's have fulfilled as peripheral nations within a world system. Further, the dependency paradigm is a radical departure from the modernization paradigm with respect to diffusion of capital, science, technology and Western values. Whereas the latter perceives the diffusion of foreign capital and aid as positive contributions to development, dependency proponents interpret these as mechanisms of the dominant powers or interests in the international system which generate dependency and hinder development. Consequently, TNC's are viewed as sophisticated, indirect mechanisms by which subtle control over peripheral societies can be exercised, as opposed to earlier direct forms of control through military force and colonial possessions (Emmanuel, 1972; Galtung, 1971). Other points of contention with TNC's in this theoretical tradition concern their role in creating cultural dependency by diffusing Western values and consumption patterns to peripheral host countries, in fostering economic dependence by using raw materials and cheap labor in exchange for "highly" priced finished products mostly manufactured in plants localized in core countries, in wielding political influence on development policies in the periphery, combined with their reluctance to meet the technological needs of peripheral societies.

The emerging scientific and political elite in less advanced societies, in close cooperation with the international scientific community, are recognized as the prime movers of the development process in the older modernization tradition. Within the dependency paradigm, however, the emergence of an indigenous, new

elitist social class (whether industrial, entrepreneural, bureaucratic, technical, or professional) that maintains strong Western ties, is antithetical to the process of development. These "bridgeheads" have a "vested interest" in, and benefit from, the existing structure of the international system. In return for carrying out certain functions on behalf of foreign interests, these classes enjoy a privileged position within their own societies, based largely on economic, political, scientific-technological, or military support from overseas, and are thereby instrumental in perpetuating "dependent" development.

The dependency framework has also recently been subjected to much criticism and re-evaluation by scholars from a variety of traditions; by Marxian standards, the framework is not sufficiently structuralist in orientation, and especially tends to ignore the internal dynamics of class conflict; liberals question the feasibility and desirability of the goals and values and the means for fulfilling them as specified or implied within the dependency paradigm; writers within the dependency paradigm itself are constantly developing new concepts and empirical research methods in their search for a new paradigm.

To summarize then, the major points of divergence within the two frameworks, modernization is inherently a consensus model, dependency a conflict model. Whereas the first advocated scientific, technological and capital diffusion, the other rejects it. The earlier modernization perspective assumes unilinear growth, the dependency perspective stipulates that growth in core countries

occurs at the expense of growth in the periphery, with the establishment of a new power hegemony in the periphery that benefits the core. Nation-states comprise the unit of analysis in the former framework; the latter's is the global system. Broadly speaking, modernization proponents have used indices of development based on education, per capita income, GNP, level of industrialization, health welfare and physical well-being, energy consumption, quality of life, as just some examples. Dependency writers have focused on power, control over the means of production, equality/inequality, class, balance of payments, and international wage differentials, to mention some examples. The one method takes as its starting point the existing situation of development/underdevelopment in any country; the other historically traces the origins of developed/dependent structures to their interaction in a world capitalist economy.

Juxtaposed in this manner, these two frameworks appear to have little in common. However, to categorize all writers within these frameworks in terms of such polarized extremes is to mistakenly overlook significant advances made in social science theory building. Faced with an increasing awareness of the interdependence of nations, and of the complex patterns and consequences of such interdependencies, scholars within the older modernization tradition are re-evaluating earlier concepts and values, and in large part acknowledge multilinear patterns of growth, asymmetrical interactions between industrialized and less industrialized nations, many gradations in between the "rich versus poor" dichotomy, and greater differentiation between institutions than earlier paradigms had projected. This later

re-conceptualization of the earlier modernization paradigm is more commonly known as the "developmental" paradigm. Likewise, distinctions exist among dependency writers between the "less radicals" (Fagen, 1978; Sunkel, 1976; Cardoso, 1973) and the "more radicals" (Bodenheimer, 1971; dos Santos, 1970; Frank, 1971, 1972). On reflection, it is apparent that even though "dependencia" arose in Latin America as a radical challenge paradigm, the less radical "dependency" paradigm incorporates many of the "nation-building" ideas of the modernization tradition as "interim policies." This is largely because the "dependencia's" greatest weakness lies in its unspecific policy implications. Although almost all the writers who share the perspective are in general consensus that there must be a "socialist revolution," there seems to be little agreement as to who will lead this, when it should take place, and in what form (violent, nonviolent). Socialism is generally recognized by them as the end-state, but what transpires between now and then is left open to much debate and speculation. Import substitution, "inward-oriented" growth (as opposed to outward, export-oriented growth), nationalization of the private sector (Turner, 1973), withdrawal from the world capitalist economy, the strategy of "seizing the chance" in periods of global economic contraction (Wallerstein, 1974), are some of the measures available to peripheral nations. However, such recommendations leave many questions unanswered. For example, are peripheral and semi-peripheral countries constrained to wait patiently for the "moments of contraction" in economic cycles before they can "seize the chance," or can they hasten the process through their own or

combined initiative? Once they have withdrawn from the capitalist world economy, what is the next step? How are they to obtain goods, capital, and technology to embark on a program of inward-directed growth?

In relationship to the preceding discussion, it is appropriate to mention some of the other conceptual frameworks that address these questions in part or full. The "science and technology" framework (Crane, 1972; Hagstrom, 1965; Speigel-Rosing, 1977; Moravcsik, 1977; Useem and Useem, 1955) has been given its impetus from the older development tradition. As already mentioned in describing the development paradigm, the science and technology framework emphasizes the diffusion of research, science and technology to less industrialized countries, the education and training of scientists, and greater cross-societal communication between scientific communities, international institutes and research centers, as goals for societal and international development. Another perspective related to, but quite different from, the science and technology framework is the "appropriate technology" (AT) perspective. AT is important to mention in that it attempts to present an alternative to less industrialized countries in their effort to break away from dependent development and toward self-reliance, defined more modestly in terms of less industrial and technological growth than envisaged in the paradigms discussed earlier.

The "appropriate technology" approach has gained fervor in some circles (Dickson, 1974; Eckaus, 1977; Morrison, 1978; Schumacher, 1973) in what Morrison (1978) has described as a "growing worldwide

social movement." It has also generated considerable opposition in segments of the third world countries. Although the movement predates the establishment of OPEC in 1974, it received a boost following the oil embargo that exposed the vulnerabilities of non-petroleum producing nations, and the ensuing asymmetrical interdependence. The concept has also arisen largely as an outgrowth of the 1960s Environmentalism in the West, and the disenchantment with 'hard,' capital-intensive technology transfers in the less industrialized countries. The theme, generally, is "small is beautiful": small-scale, low capital, de-centralized, needs-related, labor-intensive, "ecologically sound" technology over large-scale, capital-intensive, centralized, 'elitist,' "ecologically unsound" alternatives (Morrison, 1978).

Appropriate Technology is a response to the failure of "trickle down" models, by advocating technological self-reliance at all levels--whether it be for the individual household, local community, or nation-state--assuming, somewhat unjustifiably, according to Morrison (1978:24), that "the combination of natural resources necessary for self-sufficiency is somewhat evenly distributed among the world's nations, and in meeting basic needs each nation's population puts equal pressure on these resources."

Certainly the approach presents a practical alternative to developing countries. But is it necessarily a desirable alternative? Is it possible to consciously place limits on technological growth, that has its own determinisms (Ellul, 1964; Goulet, 1977)? The approach essentially shares the same 'national development' concerns of the development and dependency perspectives, but differs

substantially in its goals and underlying values. Appropriate Technology envisions the stabilization of global development at a level close to basic needs, while material abundance is the image of the other two perspectives. An underlying current of the dependency framework is resource "exploitation," AT's is resource "utilization," and in this respect is similar to development models. Where AT differs with developmentalism, and is in consensus with the dependency concept, is in its rejection of high specialization in resource development, structural differentiation and the international division of labor. However, AT takes a step further than dependency writers would venture, in also rejecting economies of scale, and the substitution of energy for labor. Full employment and the soft, technology society are ends in themselves, according to the AT approach, as opposed to economic productivity per se. The implications for a policy that is unsympathetic towards TNC's is evident within this model.

Another emerging analytic framework, still in the process of development, is the "global" framework or "transnational perspective." This framework attempts to provide an ideologically free approach in addressing issues of universal concern (environmental, demographic, etc.). The primary actors that identify global problems and that are responsible for world reform are the transnational scientific community, and institutions and groups that transcend political boundaries. The concepts emphasized in this paradigm reflect the reality of an increasingly interdependent global system and the growing numbers of transnationally-oriented scholars (Brown, 1978;

Mazrui, 1975; Goulet, 1976). The global framework transcends aforementioned ones, in encompassing all mankind in its unit of analysis. It also stresses those values that receive universal consensus, with less focus on those that lead to conflict between nations. Perceived within this framework, international organizations, like the United Nations and its subsidiaries, play an important role in fostering the harmonious co-existence of all of mankind, while cross-cultural research centers contribute internationally acceptable solutions to global problems.

Having identified several analytically distinct (and not so distinct) frameworks, and having compared them to find both similarities and differences, it becomes increasingly clear that none of these is exclusive. Conflicting interests is as much a process of, and prerequisite for, development as is international cooperation and consensus (Rummel, 1979:283). Thus, in his philosophical piece, Rummel maintains:

> . . . my view is that cooperation and conflict are not polarities but complements--that they are intrinsic parts of the same social process among nations. Cooperation and conflict are multidimensional. They are separate dimensions reflecting phases in the process of building a mutual society, a structure of common norms, expectations and laws.

The fact that somewhat diverse frameworks exist in social science research for the study of development does not necessarily constitute a problem. Since none of these frameworks is complete in and of itself, taken together they address many problems, and provide various policy alternatives, certain features of which may also be combined to form a package. Thus, appropriate technology fills a

void in dependency theory; mainly, it provides one alternative to how less industrialized countries who choose the inward-directed path can achieve self-reliance in products that satisfy those basic needs they previously depended on TNC's to provide. The implications of the goals of AT amount to, simply, for countries to limit their needs (or wants) to what small-scale, indigenous industry can provide, and thereby become self-reliant.

The problem of defining self-reliant development is perhaps the single most vexing issue for scholars writing on independence/dependence/interdependence. Are there universal, objective criteria by which to evaluate self-reliance, or is the term relative to each society? Thus, can a nation based on small-scale industrial growth and labor-intensive technologies be compared to a highly industrialized, capital-intensive one in terms of self-reliance? Does a nation achieve self-reliance by being able to provide its population with basic subsistence needs defined in terms of clothing, food, shelter, and freedom from disease, or by being able to satisfy wants defined in terms of energy resources, defense and space exploration? Does the definition of self-reliance expand parallel to a country's growth to incorporate <u>wants</u> in addition to <u>needs</u>? Was the United States self-reliant before (and after) the OPEC oil embargo in 1973-74? Is it possible to view nation-states as self-reliant and yet interdependent? And finally, how can countries that are not self-reliant even by minimal standards maintain symmetric interdependencies with nations that are self-reliant by much higher standards? Evidently, there are no easy answers. Leaders, politicians, economists,

sociologists, technical experts and administrators have been struggling with these issues for years. In this paper, I make no claim to providing any ready answers. I do not even claim to simplify the problem; empirical reality dictates that the solutions cannot be simplified, but can only be made more complex. What I do hope to achieve in this study is to provide an understanding of the problem and its complexities by raising these questions against one empirical situation: the pharmaceutical industry in South Asia.

The Pharmaceutical Industry in South Asia

The pharmaceutical industry provides a good basis for posing the issues, addressed above. First, the choice of this industry rests on the premise that it comprises one among a few "priority" sectors for development and for minimal self-reliance, in that it fulfills a subsistence-level need for freedom from, and control of disease, and consequently, 'good' health and physical well-being. Second, ironic as it may appear, the pharmaceutical industry constitutes a classic case of asymmetric interdependence, whereby the developing countries are largely dependent on foreign drugs (especially through TNC's) to supply most of their pharmaceutical needs.

The pharmaceutical industry arouses the interest of sociologists at a number of different levels. The special problems of LDC's--poverty, malnutrition, lack of food purification and quality control facilities, low sanitation, and ignorance--have aggravated the spread of disease, especially in rural sectors, and have bestowed

heavy responsibility on the medical supplies industries. Within the development perspective, the pharmaceutical sector is significant with respect to these social problems, and raises questions pertinent to "nation-building," industrialization, pharmaceutical research and development, medical delivery systems, health-related professions, and the role of the state vis-a-vis the private sector in providing medical care to the population.

A study of the transnational pharmaceutical industry would arouse the interest of scholars writing within the dependency framework. Many of the features associated with economic and social dependence are embodied in a striking form in the pharmaceutical industry. The drug industry is unique in that it is marked by an unusual degree of market power, indicated by the concentration of production within a few industrialized countries, the ability of leading pharmaceutical TNC's to exercise price discrimination, to obtain higher returns on investments than do other manufacturing industries, and to employ marketing tactics to strengthen firms' market positions. The implications of this market power are more serious in the case of the pharmaceutical industry, because of the unique position that it occupies in terms of its human and social importance (Lall, 1975).

The pharmaceutical sector raises important questions for writers within the science and technology framework. Because the industry is primarily research-intensive (rather than capital- or labor-intensive: research costs occupy the largest percentage of investments), the establishment of local and international research

and development sectors, the role of the scientific community (Moravcsik, 1977; Mulkay, 1977; Skolnikoff, 1977; Useem et al., 1979), and pharmaceutical technology transfer versus alternative technologies (Bibile, 1977; Lall, 1975; Wortzel, 1971) pose some pressing issues for research.

The AT approach directly challenges development and dependency approaches with respect to the role of technology in the process of development. Implicit within the more conservative writings of the latter two approaches is the notion that the lack of 'hard,' industrial technology in less industrialized countries is a factor contributing to their underdevelopment. AT assumes that a heavy technology society is the antithesis of development. Technology transfers from the more industrialized to the less industrialized countries, therefore, is not the solution, but the problem of the development process. Posed within the context of the pharmaceutical industry, the questions are complex. The pharmaceutical TNC's often have been criticized for conducting research on the health problems of only developed countries, and of spreading these 'high' research costs to less industrialized countries in the form of higher prices for drugs. A second common source of criticism has been that the drugs that have been marketed in the developing countries have been unsuitable to the disease patterns of these countries, and have reflected Western drug consumption patterns. Therefore, can developing countries manufacture, or cheaply purchase, alternative technologies more suitable to their own needs? Moreover, since appropriate technologies have often come

to be associated with "second-rate" technologies, does the concept (AT) apply to the pharmaceutical industry in that cheaper alternatives could be substituted for modern medicine without any sacrifice of effectiveness?

Assuming that 'good' health for all mankind is a universal goal, the policy implications that stem from the global (or transnational) perspective are quite explicit. In order to control and eliminate certain globally common diseases, specialized centers of medical research and development would need to be established, recruiting highly skilled and trained members of the transnational scientific community. By waging a worldwide battle against diseases that could have afflicted all of mankind (for example, cholera, tuberculosis, smallpox) without the necessary preventative measures that have been taken, the World Health Organization (WHO) has almost totally wiped these diseases off the face of the earth.

This paper will attempt to examine these issues in the context of the pharmaceutical industry in South Asia. The discussion of these issues from a variety of conceptual frameworks will demonstrate the inability of any one framework, in and of itself, to address all these issues, and thereby make a case for the need to combine these paradigms and apply an integrated approach to comparative, cross-cultural social science research with respect to an understanding of dependent, independent and interdependent social structures.

Scope of the Study

The geographical focus of the study has been narrowed to three case-studies of South Asian countries: India, Pakistan and Sri Lanka. A comparison of the pharmaceutical industry in these three countries is of interest for a number of reasons. Firstly, each of these countries differs with respect to pharmaceutical manufacturing. The United Nations Industrial Development Organization (UNIDO, May, 1969) working groups on the Establishment of Pharmaceutical Industries in Developing Countries divides countries into five developmental stages with respect to pharmaceutical manufacture. Stage 1 consists of "developing countries with no pharmaceutical product manufacturing." Stage 2 is "developing countries whose pharmaceutical industry is in an early stage." Countries in Stage 3 have been described as "developing countries with a well-established pharmaceutical sector aiming at a certain level of backward integration for, at least, certain product lines (engaged in bulk drug manufacture)." Stage 4 is composed of "developing countries having reached a high level of self-sufficiency, oriented toward full integration at least for the main sectors of the pharmaceutical industry (starting the development of medicinal clinical manufacture)." The most advanced countries "with a well established pharmaceutical industry" comprise Stage 5. Sri Lanka is classified in Stage 2; Pakistan in Stage 3 and India in Stage 4.[1]

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[1]Although these countries have made much progress since these data were collected by UNIDO in 1969, no recent re-classification of these countries along these lines has appeared in print. The absence of such a conceptualization, indeed, reflects in part the influence

The distinctions made between these three countries with respect to the degree of sophistication of their pharmaceutical industries are important from the perspective of applied theory and policy in the social science tradition. Earlier literature in the social sciences has reflected a tendency to over-generalize policy options for a less industrialized country as applicable to all or most "other less industrialized countries." Societies have otherwise been classified into "metropolis-satellite"; "core, semi-periphery and periphery"; "North" and "South"; "industrialized-less industrialized"; "developed-underdeveloped"; or have been generally referred to as the "Third World" and "Fourth World." While such concepts are convenient for purposes of generally classifying societies on a continuum, it is easy to lose sight of the fact that such concepts tend to obscure and over-simplify structural differences between societies. There is, therefore, a greater need for sensitivity to the specific socio-historical, economic, political and technological situations of a society for designing and applying policies toward achieving self-reliance. The diverse policy choices that India, Pakistan, and Sri Lanka have had to face in achieving pharmaceutical self-reliance exemplifies the complex differences (social, political, historical, economic, technological, etc.) between the less industrialized countries.

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of new challenges to the "stages of growth" analyses. However, such a classification has proven useful in the absence of other data by providing some uniform basis to assess where pharmaceutical production was at in each of these countries in 1969.

A selective comparison of the pharmaceutical industries in India, Pakistan, and Sri Lanka is relevant at another level. There are certain factors that are common to all three countries: they share similar disease patterns and pharmaceutical needs; they are culturally very similar; historically, all three have been British colonies until 1947; and all three have embarked on nation-building efforts since independence in 1947. Thus, by keeping these "variables" (health needs, culture, history and number of years since independence) "controlled" for, it is possible to obtain insight into what other structural conditions and variables are partially responsible for the different directions these countries have taken in their policies, and what directions they are contemplating for their future growth.

The pharmaceutical industry in South Asia, as in much of the developing world, has witnessed great penetration of its markets by foreign drug companies. In an effort to limit dependence on foreign drugs and achieve control over drug research, production and marketing in their countries, legislators in LDC's have taken various measures to restrict TNC practices, ranging from tariffs, import regulation and substitution, restrictions on patents and licenses, drug registration in a national formulary, replacing brand names with generic names, to the formulation of state-controlled prûchasing, manufacturing and distribution agencies. The first case to be discussed in this paper is that of India which has restricted patents, emphasized backward integration, import substitution and foreign collaboration rather than sole ownership by foreign firms. Pakistan, the second case, created a National Formulary which made up a list of all drug

products that could be manufactured and sold in Pakistan, and abolished the use of brand names in the marketing of drugs. The third case, Sri Lanka, introduced the State Pharmaceutical Corporation that invited quotations on tenders, and purchased drugs through TNC's and foreign governments through a system of "bid-buying." Each of these will be described in greater detail in a later chapter.

What is theoretically significant in the three case studies is that each sharply brings to focus the implementation of national goals for development and their interplay within and with an international economic system. The convergence and conflict of interests are most evident in these various policies that have addressed not only the structure of local industry, but also its interaction with transnational actors. An understanding of the socio-economic conditions, both national and international, leading to the success of some programs in some countries, and of the conflicts, again national and international, leading to the failure of other programs in these and other countries, is important for its contributions to theories of development and dependency in the social sciences.

Methodology and Limitations of the Study

If number of publications is any indication at all, scholarly interest in the pharmaceutical industry has been on the steady incline ever since the pricing and promotional practices of the industry have been subject to severe criticism and scrutiny by the Kefauver Senate Committee Hearings (1960s) and the Nelson Senate

Subcommittee on Monopoly (1967) in the United States, triggering off a chain of similar investigations in other countries (Sainsbury Committee, 1967, and Monopolies Commission, 1973, in the United Kingdom; Haathi Committee, 1975, in India). One effect of these investigations has been to somewhat polarize writers on the pharmaceutical industry so that there are extremely emotional critics (Lall, 1975; Steele, 1964) on the one hand, and those who are advocates of pharmaceutical TNC's (Reekie, 1975; Schwartzman, 1975) on the other. These radical differences of opinions have not presented as much a problem for research as would first appear; on the contrary, they have had the positive impact of demanding that the arguments be weighed and the controversies thought through with care. Hence, I have tried to present various sides of the arguments, and assess the alternatives, based on the available empirical evidence.

The writers in the field of the pharmaceutical industry have predominantly been trained in business administration and economics, propelled by an interest in TNC's and their role in a global economy. Some have been natural scientists, chemists, and others in the medical profession, concerned with chemical properties, bio-equivalence of drugs, and side-effects of active ingredients. Some stem from international organizations (United National Conference on Trade and Development [UNCTAD]; United Nations Institute for Technology and Research [UNITAR]; United Nations Industrial Development Organization [UNIDO]; and Organization for Economic Cooperation and Development [OECD]) that have published extensively on technology and its transfer to developing countries. Significantly few

contributions have been made by social scientists (other than economists). Where these studies do exist, they have generally taken the form of social-psychological analyses of delinquency, drug dependence and drug abuse. Only in the last decade or so have sociologists been increasingly interested in the structure and functioning of TNC's, and their role in perpetuating development, dependence, and interdependence. Since the pharmaceutical industry presents a unique case-study among other TNC's (for reasons mentioned earlier), sociologists are only beginning to bring their analytic frameworks and concepts to this problem. This study, therefore, presents somewhat of a first step in this direction.

One of the major problems faced in cross-cultural, comparative analyses is the lack of cross-culturally comparative data. This study is no exception with regard to the three regional case-studies used. Although a great deal has been written on the pharmaceutical industry in India, and has been available to me, much relevant data has been published in Indian journals with little or no circulation outside that country. I have relied heavily on secondary analyses, government documents and company reports. Data on the pharmaceutical industry in Pakistan (particularly for the period 1972-76) has been made readily available to me by another researcher (Quraeshi, 1978) in the form of special medical press releases, Pakistani newspaper and journal articles, government reports, and interviews with doctors, chemists, pharmacists, and leaders in government and industry (in cases where confidentiality posed no problem). The data on Sri Lanka are relatively weak. Although a few published materials and secondary

analyses do exist, they all largely draw from the same major source of information on the pharmaceutical industry in Sri Lanka (Bibile, 1977), thereby representing similar perspectives. I have therefore tried to employ discretion in interpreting these data.

The structure and functioning of TNC's is widely accepted as one of the most mystified areas of research. Data on intra-company transfer prices and profits are generally unavailable, and published company reports on profits are suspiciously regarded as being conservative estimates. Data on actual breakdown of investments by TNC's into various sectors (research and development, promotion, production, etc.) have often been speculative. Such problems make comparisons between TNC's and local firms difficult in terms of research and development expenditures as percentage of profits, cost of drug production, economies of scale, and so on. This study is, undoubtedly, restricted by the unavailability of these data.

Study Format

After having mentioned in this chapter some of the major conceptual frameworks developed by scholars of social change, Chapter II then provides a brief historical background of the origins of the world-wide pharmaceutical industry. The salient features of the industry are then discussed according to the following framework: (a) research and development (including technology transfers, patents, the role of the scientific community); (b) pharmaceutical production (including specialization, concentration, backward integration); and (c) marketing and promotion (including pricing, brand

and generic names, advertising, and regulation). The views expressed by various actors--government, the local private sector, TNC's, the medical profession, chemists and pharmacists, and international agencies--are presented, where possible, with regard to each of the above mentioned issues.

In Chapter III the various features of the pharmaceutical industry are discussed more specifically in conjunction with the case-studies of India, Pakistan and Sri Lanka. The pharmaceutical industry in each of these countries, together with the various legislative measures taken, are examined in relation to these countries' goals for achieving self-reliance.

Chapter IV presents an evaluation of the information presented in earlier sections, and weighs the policy alternatives available to these countries at various levels, whether nationally, regionally, or as actors within an interdependent global system.

CHAPTER II

SALIENT FEATURES OF THE PHARMACEUTICAL INDUSTRY

The History of Modern Drug Therapy

One of the great modern revolutions in drugs began in 1935 when a group of German scientists and physicians led by Domagk announced the discovery of Prontosil, a red dye that treated systemic microbial infections without ill effects to healthy parts of the body (Cooper, 1966; Silverman and Lee, 1974; OECD, 1969). This breakthrough triggered a chain of discoveries of chemotherapeutic and antibiotic agents, most notably penicillin, streptomycin (1943), chloramphenicol (1947), and tetracycline (1953). The increased demand for drugs in World War II, and the impetus given by major drug discoveries, led to greater public and private investments in drug research, quality control procedures and bulk manufacturing in England, France, Germany and the United States (Silverman and Lee, 1974). Many of the leading pharmaceutical corporations of present times (for example, Pfizer of the United States, and Hoffman La Roche of Switzerland) emerged during the post-World War II era as leading producers of drugs.

The degree of profitability for a firm directly corresponded to the number of drugs they could innovate and successfully market. Consequently, high research expenditure was required for the firm to stay in business, and pharmaceutical companies were quick to

appreciate that their research programs could only be financed by spreading these costs over large markets. Thus, companies expanded their operations to overseas markets (OECD, 1969). The limited domestic market for such Swiss producers as Ciba-Geigy, Hoffman La Roche and Sandoz made it necessary for them to seek markets abroad. Soon after, companies from other countries, including Japan (Fujisawa, Tanabe, Takeda) and Holland (AKZO), had made their entry into world markets. The mid-twentieth century hence signalled the rise of the present transnational structure of the pharmaceutical industry. By 1973, companies from the United States, Japan, Switzerland, Germany, France, the United Kingdom and Holland relied heavily on overseas markets, as indicated in Table 1.

The total world market for human medicines in 1969 was $14,363 million, of which the demand for drugs in Third World markets comprised $3,514 million. The National Economic Development Office (HMSO, 1972) has projected the demand to increase considerably by 1980 as new drugs are discovered, population increases, and per capita consumption of drugs rises. Their estimates have been summarized in Table 2.

In 1968, the less developed countries alone (Latin America, Asia, Near East and Africa) consumed 53.6% of all United States pharmaceutical exports (Pharmaceutical Manufacturers' Association, FACTBOOK, 1973).

As these data indicate, the transnational pharmaceutical companies have emerged as the major producers and suppliers of commercially marketed drugs in the second half of the twentieth century.

TABLE 1.--Overseas Sales Volume as a Percentage of Total Sales Volume of Major Multinational Pharmaceutical Companies (1973).

Company	%	Company	%
Abbott	35	Merck & Co.	45
Astra	51[a]	E. Merck	42
AKZO	88	3M	40
American Home	29	Pfizer	52
Beecham	58	A. H. Robins	28
Banyu	N.A.	Rhône-Poulenc	22
Boehringer-Ingelheim	62	Roussell-Uclaf	50
Boehringer-Mannheim	N.A.	Richardson-Merrell	56
Bayer	67	Sterling Drug	38
Bristol-Myers	24[d]	Sandoz-Wander	97
Clin-Midy	N.A.	Squibb	33
Ciba-Geigy	98	Schering-Plough	41
Cyanamid	32	Schering AG	58
Dow	46	Shionogi	N.A.
Eisai	N.A.	Smith, Kline	31[a]
Fujisawa	5	G. D. Searle	31
Glaxo	56	Sankyo	N.A.
Hoffman La Roche	90[c]	Syntex	100[b]
Hoechst	58	Takeda	5
ICI	84[a]	Tanabe	N.A.
ICN	67[a]	Varta	12
Johnson and Johnson	22	Upjohn	38
Lilly	33	Wellcome	90[a]
Morton-Norwich	9	Warner-Lambert	42
Montedison	N.A.	Yamanouchi	1

SOURCE: Barrie G. James, The Future of the Multinational Pharmaceutical Industry to 1990 (New York: Halsted Press, 1970), pp. 251-52.

[a]Pharmaceuticals only

[b]Panama based.

[c]Estimate.

[d]International Pharmaceutical Marketing, Sogen-Swiss Corp. (New York, 1973).

N.A. = Not Available.

TABLE 2.--World Market for Medicines: Projection of Demand, 1969-1980 (in millions of dollars)

	Total World Market	Third World Market
1969	$14,363	$3,514
1980	37,399 - 48,680	8,533 - 11,522

SOURCE: National Economic Development Office, Focus on Pharmaceuticals (London: HMSO, 1972).

They are concentrated in a few market economies, and the leading market shares are further concentrated within a few companies even within these countries. One of the major reasons contributing to the dominant market positions of a few companies has been their ability to engage in risky, capital-intensive research and development, leading to drug innovations protected by patent laws.

Contrasted to this situation, the developing world as a whole accounts for a small proportion of the global output of commercial pharmaceuticals. Thus, around 1971, the share of developing countries to total drug production was only 10% (Lall, UNCTAD, 1975), while the developing market economy supplied 85.7%, and the Southern European countries 4.3%. This meant that developing countries were dependent on foreign sources to supply their pharmaceutical needs. This is more evident when we compare the market share of pharmaceutical TNC's with local manufacturers within developing countries (see Table 3).

TABLE 3.--Market Shares of Foreign and Local Pharmaceutical Companies (in percentages).

Country	Year	Share of Market (percentage)	
		Local	Transnational
Brazil	1969	22	78
Argentina	1969	35	65
Peru	1964	5	95
Philippines	1966	20	80
India	1969	25-35	65-75
Venezuela	1970	10	90

SOURCE: Tom Heller, Poor Health, Rich Profits: Multinational Drug Companies and the Third World (Nottingham: Spokesman Books, 1977), p. 3.

The implications of such dependence on foreign sources has been severe for developing countries. In 1971, industrialized countries had a positive balance of $924 million in their trade in pharmaceuticals, whereas less industrialized countries had an adverse balance of $674 million (Lall, UNCTAD, 1975:8). At another level, developing countries have been concerned about the proliferation of drugs reflecting consumption and disease patterns in industrialized countries, and the cost that they have had to bear for expensive research and development unsuited to their own needs (Illich, 1976; Lall, 1975). This concern has been translated into more intensive efforts to reduce dependence on foreign drug imports and to increase

backward integration in the private sector. Since progressive strides have been taken to develop pharmaceutical technology in developed countries in comparison to what has been the case in less industrialized countries, the problem for the latter becomes one of how to close the "gaps in technology," either through technology transfers, or through increased local research and development efforts. It is therefore necessary to turn our attention to the process of pharmaceutical research and development, and to examine what implications this has for developing countries.

Pharmaceutical Research and Development

The long-term success of a pharmaceutical company depends primarily on the extent and the success of its research and development, and on the extent to which the products of this research and development can be successfully marketed. The rate of pharmaceutical innovation reached its peak between 1951 and 1960 as the accelerated growth of research and development spending resulted in an increasing flow of new chemical entities (Schnee and Caglarcan, 1978:93). However, there has been a steady decline in the volume of all new drug products and new chemical entities in the 1960s (Schnee et al., 1978; Schwartzmann, 1975; de Haen, 1967 and 1975).

New drugs can be classified into four categories (de Haen, 1967, 1975): (a) a new chemical entity indicates products that are new, single-chemical entities not previously known, including new salts; (b) duplicate single products are those which are put out by various manufacturers; (c) compounded products are any products having

more than one active ingredient; and (d) alternate drug forms are products previously marketed in tablets and now offered in capsules, ampules, liquids, etc. Table 4 shows the decline in new product introductions in the "ethical drug" industry between 1950 and 1974.

Critics of the industry cite the relatively small number of new products as evidence that the industry is becoming more inefficient. They maintain that the "pharmacological revolution" of the 1950s has been replaced by a new era of "molecular manipulation" presenting little or no therapeutic benefits over existing drugs. A Health, Education and Welfare (HEW) task force on prescription drugs (1968:12) concluded that:

> Since important new chemical entities represent only a fraction--perhaps 10 to 25 percent--of all new products introduced each year, and the remainder consists merely of minor modifications or combination products, then much of the industry's research and development activities would appear to provide only minor contributions to medical progress.

According to those who hold this perspective, these minor drug modifications do not provide significant clinical advantages over already existing drugs. These "me-too" drugs may offer, for example, slightly more rapid absorption, which Silverman and Lee (1974:39) claim may be of more interest to statisticians than to clinicians. The molecular manipulation issue involves the development of a molecule pharmacologically similar to that of a profitable rival, but distinct enough to obtain patent protection. Thus, research is often geared toward patentable inventions and not toward essential but non-patentable drugs (Steele, 1967:1911-1914). Because of the commercial advantage to the drug company in duplicating

TABLE 4.--New Product Introductions in the Ethical Pharmaceutical Industry, 1950-1974.

	Total New Products	New Single Chemicals	Duplicate Products	Compounded Products	New Dosage Forms
1950	326	28	100	198	118
1951	321	35	74	212	120
1952	314	35	77	202	170
1953	353	48	79	226	97
1954	380	38	87	255	108
1955	403	31	90	282	96
1956	401	42	79	280	66
1957	400	51	88	261	96
1958	370	44	73	253	109
1959	315	63	49	203	104
1960	306	45	62	199	98
1961	260	39	32	189	106
1962	250	27	43	180	84
1963	199	16	34	149	52
1964	147	17	29	111	41
1965	112	23	18	71	22
1966	80	12	15	53	26
1967	82	25	25	32	14
1968	87	11	26	50	21
1969	62	9	22	31	12
1970	105	16	50	39	23
1971	83	14	40	29	30
1972	64	11	35	18	30
1973	74	19	37	18	17
1974	83	18	42	23	26
Total	5587	717	1306	3564	1686

SOURCE: Paul de Haen, Ten Year New Product Survey, 1950-1960; Non-Proprietary Name Index, Vol. VI (New York: Paul de Haen, Inc., 1967); New Products Parade, 1973-1974 (New York: Paul de Haen, Inc., 1975), cited in Schnee and Caglarcan, "The Changing Pharmaceutical Research and Development Environment," in The Pharmaceutical Industry, edited by Cotton and Lindsay (New York: John Wiley and Sons, 1978), p. 94.

successful new drugs, research tends to be duplicative. Molecular manipulation stimulates applied, rather than basic research, thereby limiting the number of new therapeutic discoveries.

The industry view is that molecular manipulation is a perfectly legitimate and efficient tool in medical chemistry and that its use has often led to the discovery of important new therapeutic compounds, most notably hydrocortisone, methicillin, and ampicillin (Schnee and Caglarcan, 1978; Reekie, 1975). They maintain that this kind of research activity does not "waste" resources any more than other kinds of research and development efforts, and while being equally prone to the elements of risk and failure, the activity does possess a record of innovative success.[2]

Another controversy relating to pharmaceutical research has centered around the role of the pharmaceutical industry in discovering new drugs. The issue surfaced frequently at the Kefauver Hearings in the United States. The industry claimed credit for having discovered most drugs. Critics maintained that most of the drugs discovered by the industry were in fact derived from discoveries which had been made by academic and non-industrial scientists.

Schwartzman (1975), Schnee (1971) and Seife (cited in Schwartzman, 1975) have conducted independent studies on the origins of drug discoveries in the United States, and conclude that the

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[2]Beckman (1962:72-77) has compiled "an impressive but not exhaustive" list of useful drugs that "would not exist today if someone had not tinkered with the molecular structure of another drug already in use, or sought by synthetic means to develop useful congenors of such a drug"; Harry Beckman, "In Defense of Tinkers," The New England Journal of Medicine 267 (July 12, 1962).

pharmaceutical industry discovered the majority of all new drugs discovered between the periods 1935-1970 (see Table 5 which presents Schnee's findings). Schwartzman further maintains that a decrease in industry's investment in drug research is not likely to be made up by government or other non-industry research. The reason he puts forward is:

> Academic scientists generally are attracted by research into underlying scientific principles, and are put off by the often routine evaluation of compounds required by the search for new drugs. Moreover, because academic laboratories are concerned with the advances of knowledge within separate disciplines, their staffing is rarely multi-disciplinary, whereas multi-disciplinary staffing is needed in the search for new drugs (p. 18).

Government spokesmen and academia responded by indicating that the major research and development efforts of the industry has been designed to produce drugs that have a large consumer market, would ensure a good volume of sales, and secure monopoly privileges in the form of patents. Thus the industry has neglected research on drugs related to rare but deadly diseases (for example, cancer). Further, compared to total pharmaceutical research and development investment in the United States, the percentage spent by the pharmaceutical industry is relatively weak. Data for the United States is quite striking. Table 6 shows that the industry contributed 26% of total expenditures on medical research in 1960, and the proportion has been declining ever since, compared to government expenditures that have increased by almost five times in the same period.

The controversies are relevant to developing countries contemplating backward integration in their pharmaceutical sector. The

TABLE 5.--Schnee's Distribution of Drug Discoveries, Selected Periods, 1935-1970 (in percent).

Periods of Introduction	Sources of Innovations		
	Industry	Universities	Other
	---------- Unweighted Distribution ----------		
1935-49	52	34	14
1950-62	69	16	15
1963-70	82	9	9
	--------- Distribution Weighted by Sales ------		
1935-49	33	66	1
1950-62	82	8	10
1963-70	85	8	7
	---------- Distribution Weighted by --------- Medical Importance		
1935-62	52	37	11

NOTE: In Schnee's table the classes include "innovator and discoverer" and "foreign firm," as well as "universities, hospitals, or research institutions" and "other." Here "innovator and discoverer" and "foreign firm" are grouped under "industry"; "other" includes a few cases where the discoverer was a domestic company which was not the innovator.

SOURCE: Jerome Schnee, "Innovation and Discovery in the Drug Industry," in Mansfield, et al., Research and Innovation in the Modern Corporation (New York: W. W. Norton, 1971), p. 178.

TABLE 6.--U.S. Expenditures on Medical-Related Research, by Source of Funds, 1960, 1965, 1970 and 1972 (in millions of dollars).

	1960[a]	1965	1970	1972[b]
Total	$ 798	$1,715	$2,499	$3,102
Government	471	1,229	1,740	2,223
Federal	488	1,174	1,664	2,144
State and Local	23	55	76	79
Private	121	158	193	211
Foundations and Health Agencies	76	88	108	124
Other Private Contributions	12	25	32	33
Endowment	19	19	19	19
Institutions' Own Funds	14	26	34	35
Industry	206	328	566	668
Industry as Percentage of Total	26	19	23	22

SOURCE: David Schwartzman, The Expected Return from Pharmaceutical Research (Washington, D.C.: American Enterprise Institute for Public Policy Research, 1975), p. 48.

[a]Data for 1960 are recorded here as in the original source. However, the author's calculations reveal inaccuracies in totalling these numbers. Accurate figures are unknown.

[b]1972 figures for industry represent budget amounts rather than actual expenditures; other 1972 figures are NIH estimates of actual expenditures.

debates bring to surface the much larger issue of the role of the public and private sectors, and the degree of responsibility that should be assigned to each. Is the state-controlled or state-regulated industry more efficient in drug production and research than the private one? And, more importantly, which system is most effective in distributing drugs to the largest segment of the needy population? Reekie's (1975) position on this issue is clearly pro-industry. He asserts that since members of the pharmaceutical market are best informed regarding the supply and demand of medicines and patients' needs, and since they have the most to lose if pharmaceutical products are inadequate (the physician in terms of his patient's health, and the industry in terms of profits), they therefore have the greatest incentive to make correct decisions relating to the production and consumption of medicine. Those concerned with the industry's practices, on the other hand, realize that physicians are often unaware of the potency, quality and side-effects of drugs, resulting in the over-use and mis-use of drugs--clinical, social, and cultural "iatrogenesis" (Illich, 1977)--and that the profit motive of the industry transcends most other social considerations. With reference to state participation in pharmaceutical research and development (in the United Kingdom), the Sainsbury Committee (1967) said:

> Nationalisation would have a strong tendency to lead to the central direction of research. We can see no reason why this should produce the best results; we doubt indeed whether it would be efficient. There may be an element of economic waste in competitive research but the evidence we have obtained leads us to believe that without such competition there would be a slower rate of discovery and innovation.

> This is not, in our view, the type of industry which would better serve the public interest under nationalisation.
>
> We therefore do not recommend nationalisation of this industry.

The recommendation may be appropriate for a country like the United Kingdom, with highly trained specialists and an advanced pharmaceutical private sector. But the evidence needs more careful examining in the case of a less developed country where, often, scarce resources cannot risk even "an element of economic waste," and where "competitive research" is minimal or even nonexistent (for example, in Sri Lanka).

The cost of pharmaceutical research has increased substantially over the years, with diminishing rates of return. Schwartzman (1975) estimates that the research and development cost of a new chemical entity in the United States was $1.3 million in 1960 as against $24.4 million in 1973. The increase in prices of goods and services used by research laboratories accounted for 68 percent of the increase. Therefore, the increase in costs of research and development, for reasons other than price increases, was 1,015 per cent (Schwartzman, 1975:48). Several studies indicate that the 1962 Drug Amendments in the United States contributed markedly to this effect, by attempting to restrict industry profits, shorten patent life, and by placing other strong regulatory controls on the drug industry (Peltzman, 1973; Schwartzman, 1975; Reekie, 1975). Advocates of government regulation indicate that these price increases in drugs have been inflated by the pharmaceutical industry, since the latter tend to conceal promotional and marketing expenditures as part of research and development investments.

Pharmaceutical research is considered by the industry to be a high-risk, time-consuming activity. Joseph Stetler, of the Pharmaceutical Manufacturers' Association (United States), states (1967):

> The development and marketing of new drug products is an uncertain enterprise at best. The percentage of the sales dollar which the research-oriented drug companies spend to discover and develop new products is by far the highest of any American industry. Only one out of 6,000 compounds tested by the drug companies turns out to be a marketable product, and even then it can reach the market only after years of animal and clinical testing. In addition, a competitor's new or improved product can appear at any moment to overshadow or make obsolete a profitable product perfected at great cost.

A HEW task force (1968), on the other hand, was "unable to find sufficient evidence to support the concept of the drug industry as a potentially risky enterprise," since the oligopolistic structure of the industry is protected by patent laws, thereby discouraging competitors.

Patents

Closely related to the issue of research and development is the question of patents. The patent system is of special significance to the drug industry, since in the nature of the industry a new innovation is fairly copiable by competitors, and much of the discussion of the system has revolved around its effects in the industry. In the field of pharmaceuticals, there are basically three types of patents, namely process, product, and application (use) patents. The form of patent protection and its duration varies from country to country. For instance, the United States allows both process and product patents; Pakistan, India, Argentina, Switzerland grant only

process patents; a few more, notably Italy, Brazil and Korea grant neither process nor product patents. The usual duration of a drug patent is 17 years in most developed countries, but is shorter in many developing ones. India grants patents for a duration of seven years only.

By far the greatest concentration of patents in developing countries is in the chemical sector, and especially in the pharmaceutical branch. An examination of 3,513 patented processes or products for Colombia showed that 2,534 of them belonged to the pharmaceutical industry and the rest mainly to the textile and chemical industries (UNCTAD, 1975b). One reason for this is that patent protection is a very important incentive for scientific progress in medicine, since new drugs can be quickly imitated and marketed by competing firms who have borne none of the costs of research, safety testing, clinical evaluation and initial marketing in which the innovating firms have invested. Michael H. Cooper (1966), perhaps the most vocal advocate of strong patent pharmaceutical protection, maintains that patents encourage continuity in research. They are the means by which a firm gains the funds for its future research, rather than a 'reward' for its past efforts. He attacks Italy, which grants no patents, for "legalized theft of the world's stock of intangible research knowledge," and indignantly states: "In effect the world is paying for Italy's drugs. Italy is making no contribution to the overhead of the discoveries developed abroad, thus others must clearly pay more to make good the innovator's loss." Another of his concerns is that most imitating companies are not in

full possession of the patent holder's or innovator's knowledge and experience, and may produce drugs that are health hazards.

The international patent system has recently encountered much criticism (Group of 77, UNCTAD, 1977; Penrose, 1973; Vaitsos, 1976; UNCTAD, 1975b), emanating mainly from a dependency framework. Concern for revising the protection of industrial property has been both at the national and international levels. An UNCTAD report (1975b) concluded:

> The available evidence suggests that the international patent system is not, in its present form, proving to be of benefit to the developing countries and that it is instead having a negative effect on their development. . . . Patent laws and practices of developing countries, following international standards, have legalized an anamolous situation which had come to act as a reverse system of preferences granted to foreign patent holders in the markets of developing countries.

Vaitsos (1976:86) argues that the "existing system of patents . . . has been constructed so as to protect the interests of the patent holders, who are in most cases, nowadays, the transnational enterprises." Thus, in most developing countries, the vast bulk of patents is held by foreign companies. An estimate for 1972 puts foreign ownership of patents in developing countries as a whole at 84 percent, with many individual companies having even a higher figure (UNCTAD, 1975b).

A large percentage of foreign ownership of patents presents no serious problem in and of itself, insofar as these patents are used toward meeting the basic health needs of the patenting countries. The problem arises when the interests of those holding the patents does not coincide with those granting the patents. Critics of the

patent system maintain that such conflicts of interest are present in that practically all patents granted in developing countries are never worked in their territories. As such, patent protection is divorced from innovative and from investment activity; consequently, it blocks the use of technology to directly work the patented products or processes, grants monopoly privileges to a few transnational enterprises, and covers innovations not directed to local needs. Data presented in Table 7 shows that 90 to 95 percent of the patents were almost entirely unused in production in developing countries in 1972.

TABLE 7.--Patent Holdings in Developing Countries by Ownership and Use, 1972.

Item	Number of Patents Held (in thousands)	Percentage Distribution
World Distribution:		
Developed Countries	3,300	94
Developing Countries	200	6
	3,500	100
Distribution in Developing Countries:		
Held by Nationals	30	16
Held by Foreignors	170	84
		100
of which		
Used	10 - 70	5 - 10
Not Used	150 - 160	90 - 95

SOURCE: United Nations Conference on Trade and Development, The Role of the Patent System in the Transfer of Technology to Developing Countries (TD/B/AC.11/19/Rev.1) (New York: 1975), p. 41.

Measured against the costs, the patent system also offers benefits to developing countries by (a) creating a favorable climate for foreign investment; (b) protecting domestic innovation; (c) fostering foreign innovation in drugs which have their main markets in developing countries; and (d) facilitating the licensing of domestic firms (Lall, 1978b). Further, (e) developing countries receive income from the "basic" and "annual" fees charged to the patent holders (UNCTAD, 1975b). Not all these benefits are equally significant. Regarding (a), studies indicate that firms invest heavily in countries which grant no pharmaceutical patents (for example, Brazil, Italy). With respect to (e), the UNCTAD report shows that in the developing countries for which information was available (includes India and Sri Lanka), "the broad level of annual fees is much lower than that in the developed countries, and the progression in the increases of the fees over time is much less sharp" (UNCTAD, 1975b:59-62). The other three benefits mentioned, (b), (c), and (d), carry weight in their claims.

Strides toward pharmaceutical self-reliance in developing countries must address the issue of patents. The system of patents impacts national policy both with and within an international system. The alternatives available to developing countries are somewhat constrained by these factors. Keeping the benefits and disadvantages of the patent system for developing countries in mind, Lall (1978b) suggests that in countries with very little industry, a case may be made for weakening the patent system considerably in order to receive the benefits of cheap drug imports. In countries

with a developing pharmaceutical industry, a case exists for keeping the system with a number of safeguards so that its potentially restrictive effects on domestic development are minimized. In countries engaged in major research and development, the case is clear for a fairly strong patent system. Similarly, Lall suggests that developing countries should offer weak patent protection for innovations designed primarily for developed countries. For innovations developed primarily for developing markets, patent protection would be stronger, guaranteeing a fair return for the innovator. Although Lall's recommendations appear theoretically sound and socially just, problems may be anticipated in enforcing these recommendations as policies. Developing countries may face resistance from groups adversely affected by a revision of the international patent system (for example, pharmaceutical TNC's whose products currently hold a monopoly on patent privileges).

Pharmaceutical Technology, Appropriate Technology, Technology Transfers

The preceding discussion illuminates some of the formidable barriers facing developing countries in their move toward pharmaceutical self-reliance. How are legislators to encourage research and development investments, suited to their own needs, limit investments on minor drug modifications, decrease foreign dominance and monopoly practices, and obtain technology at costs they can afford without jeopardizing firms' incentives to invest and innovate? In other words, at what point can the convergence of interests between pharmaceutical TNC's and developing countries be optimized? From

the point of view of the developing country, this would involve taking stock of their own pharmaceutical facilities, and assessing to what extent TNC's can fill their technological gaps. From the point of view of the TNC, it would involve identifying what the needs of developing countries are, and trying to penetrate local markets in these areas. However, the basic contradiction exists, in that a country's therapeutic needs do not always correspond to its commercial need. Thus, drugs that present a high volume of sales and require fairly simple production techniques are commercially more viable than drugs that are required to counteract less frequently occurring diseases, that may require lengthy research and manufacturing processes. Much of the responsibility for meeting these latter drug needs rests, at present, with the respective country.

The origins of the pharmaceutical industry have shown that heavy research and development investments were requisite for establishing a pharmaceutical industry. Developing countries today need not necessarily contend with these requirements for capital in that they can benefit from the research and development tradition of TNC's. The manufacture of many widely used drugs (antibiotics, aspirins, cough and cold preparations, syrups) require what has now become "stable technology," involving standardized, relatively simple procedures, available to even small manufacturers in developing countries. Hence a pharmaceutical company today can support itself without incurring major capital expenditures on research and development, even though it may not be able to obtain monopoly privileges

granted to those who make innovative contributions. Until they can stimulate and afford their own research and development efforts, developing countries may rely on foreign sources for new pharmaceutical technologies, granting patents, where appropriate, for only new chemical entities (as also discussed earlier). All this assumes, of course, that developing countries are content, for the time being, with "intermediate technologies" and drugs that are considered somewhat obsolete in the developed world because of the rapid turnover in drugs. And the question still remains as to how developing countries are going to stimulate local research and development efforts.

This is an ideal point to pause for a while and consider a model for development that addresses not the how, but, more basically, questions the why of heavy research and development programs. If low capital, decentralized, small-scale technologies close to basic needs is the goal of the Appropriate Technology model, in the case of the pharmaceutical industry, how is one to identify what are the basic health needs? Although protection against infectious and parasitic diseases (dysentery, malaria, cholera, tapeworm) and diseases of the respiratory system (tuberculosis) constitute major areas of concern for the developing world today, social factors like increasing industrialization, urbanization and overpopulation may yet reveal symptoms of new diseases (mental and psychoneurotic disorders, cancer, cardio-vascular diseases) commonly associated with such social change. Clearly then, a commitment to appropriate technology in the pharmaceutical sector must correspond to appropriate technology

policies overall, including all other sectors. The issue of defining basic needs will be taken up again in another section that discusses the development of an essential drugs list and a National Formulary.

The issue of whether low-capital, small-scale firms are economically viable in the pharmaceutical industry has been open to much debate. The economies and diseconomies of scale of large and small pharmaceutical companies constitutes an area for research in itself. Various studies relating size of firm to research and development output and size of research and development effort to innovative output, have presented conflicting conclusions (Comanor, 1966; Grabowski, 1976; Monopolies Commission, 1973; OECD, 1969; Reekie, 1975; Schnee, 1971; Schwartzman, 1975). Reekie (1975:114-118) discusses these controversies in more detail. Although the debate remains unresolved, the issues involved merit the close attention of those contemplating the appropriate technology model of development.

Encouraging to the proponents of the appropriate technology model is the growing realization in recent years that traditional, indigenous medicines have not been fully explored or appreciated in modern, science-based therapy. Local botanical products and animal organs have tremendous potential for use as raw materials in industrial pharmaceutical production. Local production can therefore exploit this resource by developing appropriate technologies for the extraction, purification, formulation and packaging of these materials. India has already made steps in this direction, and UNIDO is promoting

international cooperation among developing countries to promote industrial development based partly on medicinal plants.

Drug Products and Pharmaceutical Production

The concentration of drug production within a few developed countries (already described on pages 26-30), illustrates the dependence of developing countries on these few developed countries. Even within the leading drug producing countries--United States, Japan, Germany, Switzerland, and the United Kingdom--the production of pharmaceuticals is largely concentrated in ten leading drug companies that account for nearly one quarter of world pharmaceutical output (Lall, 1975). Developing countries and Southern European countries therefore import four to five times more drugs than they export.

Pharmaceutical manufacturing technology consists of two components: raw material (active ingredient) manufacture, and dosage form fabrication. Raw material manufacture involves a variety of processes, ranging from chemical synthesis to fermentation and testing procedures, which may be quite complex. The technology of dosage form fabrication, on the other hand, is less sophisticated, requiring relatively simple equipment and easy-to-follow procedures. Tablets or capsules can be formulated, regardless of active ingredient, using essentially the same procedures.

Countries at various stages of pharmaceutical development (according to the UNIDO classification mentioned on page 17) have a number of alternatives available to them as regards supplying

pharmaceuticals to their populations. They may either import finished products; they may import finished or semi-finished bulk medicinal chemicals and then finish and/or package these locally; they may expand or establish 'self-sufficient' manufacturing facilities; or they may use some combination of all the above alternatives (Deering, UNIDO, 1970:31). While some countries have little or nor manufacturing facilities, other countries (India, Mexico, Brazil) have acquired facilities representing 60 percent of the technology required to produce bulk chemicals of the essential pharmaceuticals.

Although there is disagreement regarding economies of scale in research and development activity (mentioned earlier), most writers agree that formulation and packaging facilities can be economical with quite small markets. However, economies of scale are important in the production of bulk chemicals and antibiotics, so that developing countries can only undertake economical production if they have large markets. This is evident in that India has been able to establish a viable manufacturing sector, while constraints (in terms of market size) appear in Sri Lanka.

The United Nations Industrial Development Organization (UNIDO) has published specific guidelines for the "Establishment of Pharmaceutical Industries in Developing Countries" (ID/35, 1970) listing the resources required by those countries contemplating the establishment of a pharmaceutical sector. These include adequate supplies of chemical raw materials, semi-finished products, raw materials of vegetable origin, raw foodstuffs, packaging materials, adequate supplies of water and electrical power, transport conditions,

trained professionals and a specialized staff, and an adequate economic base (Valashek, UNIDO, 1970:53). UNIDO aids developing countries in establishing local pharmaceutical sectors by undertaking the "planning of the enterprise, the initiation of its operation, the development of production, training of the staff needed, organization of marketing and ensuring that there will be adequate motivation for management" (UNIDO, 1970:52).

In addition to these conditions and pre-requisites for manufacturing drugs, another very important consideration involves monitoring the quality of drugs. Great quantities of drug production alone, without adequate quality control, will not guarantee the sale of drugs, particularly since foreign companies have strengthened their market power on the basis of their ability to publicize their superior quality control techniques. More importantly, unmonitored drugs will more likely be health hazards, rather than cures. The World Health Organization (WHO) has established a code of basic standards to be adopted in manufacturing practices, and published in an "International Pharmacopoeia: Specifications for the Quality Control of Pharmaceutical Preparations" (1967).

Drug monitoring is crucial not only to ensure that standards of safety and quality have been met, but also to evaluate the therapeutic equivalence of similar compound ingredients. Hence, "chemically equivalent" drugs may not be either "biologically equivalent" or "clinically equivalent."[3]

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[3]The Health, Education and Welfare task force makes distinctions between these three as follow (HEW, 1968:3):

In addition to these considerations, the creation of a National Formulary (NF), is one of the basic tasks of any drug industry. The need for such a list is evident in the case of India when one notices the inappropriateness of the drugs marketed to the disease patterns of the country (as noted in Table 12, pp. 78-79). The issue facing most legislators is: Who is to be responsible for drawing up the drug priorities? Will the consumers themselves dictate which drugs are to persist through their purchasing vote in the market place, determining the supply of drugs? Obviously, when 80 percent of the population can demonstrate no effective demand to influence supply and demand (as in India; Haathi Committee, 1975), such a policy is biased toward the few who have such purchasing power. Besides, the decision to consume drugs does not rest with the consumer, but with the physician (and often the pharmacist). The nature of medicines is such that consumers cannot make rational choices about the effectiveness of one medicine over another (unlike other consumer goods, for example, clothes or soap) without expert guidance. Should doctors then be responsible for determining priorities? To some degree, yes. But another problem rests

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Chemical equivalents: Those multiple-source drug products which contain essentially identical amounts of the identical active ingredients, in addition to dosage forms, and which meet existing physicochemical standards in the official compendia.

Biological equivalents: Those chemical equivalents which, when administered in the same amounts, will provide essentially the same biological or physiological availability, as measured by blood levels, and so forth.

Clinical equivalents: Those chemical equivalents which, when administered in the same amounts, will provide essentially the same therapeutic effect as measured by the control of a symptom or a disease.

in the inadequate flow of information to physicians, whereby "detail-men" from private companies make visits to physicians to promote their own products. Moreover, since there are few physicians and pharmacists in rural areas, many of the diseases prevalent there go undetected and unreported. Evidence regarding the proliferation of 'irrelevant' drugs indicates that the industry itself is not to be entrusted with ultimate responsibility. The efficiency and expertise of government bureaucracies has often been challenged. Pharmacologists and bio-chemists provide some hope, although the counter-argument is that they are concerned primarily with basic, rather than applied research. Obviously, the answer is not easy, and calls for a combination of expertise from all of these sources. But it is clear that the responsibility must lie with an elitist group--the administrative, scientific, technological and professional elite, ruling out the possibility of mass, democratic decision-making. It is therefore the responsibility of this group, coordinated perhaps by the government, to set the guidelines and priorities for drug manufacture, based on India's health needs.

The related problem becomes, how is one to define basic health needs? Is the drug list to be prepared on the basis of what were, in the past, the most frequently sold drugs? Again, this would only encompass the 20 percent who had purchasing power. Besides, consumption patterns may reflect drug dependence, over-use or under-use of drugs. An alternative method is to analyze the occurrence and frequency of diseases based on past experience, but this method again misses out on those cases of diseases that go undetected,

unreported, and untreated. And who is to predict what new diseases make their appearances in the future, and which drugs become impotent as a result of resistances built in the body to those drugs through their constant use? Is the industry to concentrate its efforts in the manufacture of commonly spread illnesses--such as colds, fever--that are widespread but not fatal, or on rare but fatal diseases like cancer? These issues provide dilemmas not only for policy-makers in developing countries, but are shared throughout the world.

Efforts to provide a priority drug list for developing countries have been undertaken by UNIDO and WHO (WHO, 1977). This "rationalized drug list" (rather than an "essential drug list") allocates different priorities to different kinds of drugs, based on therapeutic need, efficacy and cost. All the drugs contained within the list would be provided within the country, but would be grouped into three categories according to priority.

> First-line drugs would be the main drugs needed by the primary health-care units of the country. These products would be relevant to the diseases of wide prevalence and would include pharmaceuticals needed for preventive care. Such drugs would number 50 to 60 and would meet 80 to 90 percent of total health needs of developing countries.
>
> Second-line drugs would be available at district or regional hospitals and would be needed for cases that have not responded to first-line drugs or that are so severe that second-line drugs should be used immediately; they would also be needed for less prevalent conditions. This list may be longer than the first, but the quantities needed would be much less.
>
> Finally, the third-line drugs would be available only for specialized tertiary care. What is usually meant by basic drugs refers to first-line drugs, while all the drugs taken together may be called the "rationalized list" of drugs (Lall, UNIDO, 1978:30-31).

> The basic list in this case is defined by the prevalence of illness, therapeutic effectiveness, available resources and cost. The list does not correspond to the pattern of domestic production of drugs, since production is governed by different criteria (comparative advantages, skills, scale, technology, etc.). However, many of the basic drugs are fairly standard and unpatented, and the technology for their production already exists in the developing world (Lall, 1978).

It is quite evident that although the manufacturing of pharmaceuticals is quite a complicated venture, such international bodies as the United Nations Organization and its agencies have standardized, to a great degree, the process and established guidelines for the benefit of developing countries. But the economic constraints (TNC's power to influence policies in host countries), and social constraints (peoples' reliance on indigenous medical practitioners, foreign companies, or household remedies) may still persist.

If we grant that many of the above-mentioned constraints are overcome and the establishment of a local pharmaceutical industry is indeed possible, one must further question whether it is necessary or even desirable? Must every nation-state establish its own pharmaceutical industry within its boundaries? With regard to environmental factors, the potential for such development in each country is not totally impossible because of the very nature of drugs and their active ingredients.[4] The manufacturing of drugs does not depend totally on any one non-renewable raw material or natural

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[4]Although climatic conditions and temperatures do vary from region to region, and do effect the effectiveness of drugs, temperatures can be controlled under laboratory and storage conditions.

resource (as petroleum does on non-renewable crude), nor are there significant concerns that the natural resources are concentrated primarily within a few countries (as crude is largely in the Middle East). Active ingredients required for various drugs can be chemically synthesized, or developed from animal and vegetable extracts, of which no particular country has any significant monopoly over others. The possibilities of a "pharmaceutical embargo" occurring similar to the OPEC oil embargo of 1973-74 are therefore somewhat diminished. But in spite of decentralized raw materials, the pharmaceutical industry is still one sector in which a few TNC's have been able to maintain a great degree of monopolistic power, largely because of their research and development capacities and the economies of scale of large-scale production.

One possibility for an emerging drug firm in a developing country to compete in a global market is to specialize its manufacturing to one therapeutic submarket. Within the total drug market, there are a number of sub-markets (analgesics, antihistamines, contraceptions, cough and cold preparations, hormones, laxatives, psychotropics, vitamins and nutrients, etc.), and the medicines produced to satisfy the demand in any one sub-market are of little or no value to satisfy the demand in others. Within each sub-market or therapeutic grouping, there will be a number of medicines available to the patient, each of which will be appropriate to a greater or lesser degree to be used as a treatment for the patient's ailment. There is consequently much scope for competition within the various sub-markets but for very little between them.

Although major drug TNC's are diversified into the production of a number of drugs in various sub-markets, much of their volume of sales depends largely on one therapeutic sub-market. For example, Hoffman La Roche's tranquilizers--Valium and Librium--comprised the greatest percentage of its sales volume.

The question yet remains as to whether each nation-state should seek to develop its own pharmaceutical sector to balance their reliance on a few foreign-owned TNC's. The answer to this question must vary according to the specific situation of each country. With respect to economic considerations, cost efficiency will more likely accrue to countries with larger populations (like India), and most economies of scale can be attained by the larger TNC's. Data presented earlier, however, indicate that the savings in cost obtained by TNC's are not always passed on to the consumer. On the other hand, if countries with large populations[5] do contemplate establishing a local pharmaceutical industry, population size does not guarantee the sales of drugs, since factors other than price may be equally important in determining the use of drugs. A large percentage of the population may rely on homeopathic medicine and other indigenous cures. Home remedies are often extremely popular among rural, and even urban, people in many developing countries. Besides,

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[5]It is difficult to define how large is "large," and what the appropriate ratio is between market size and volume of drug production, to obtain optimum economies of scale in production. However, it may be safe to assume that by any measures, India's population is large enough (600 million) to obtain economies of scale in drug production, and Sri Lanka's is relatively small (14 million).

there are many forms of ill health for which there may not be any readily available drug cures. For example, although malnutrition constitutes a common problem in developing countries, there is no better cure than food and nutrition intake. Some may argue that vitamins, tonics and other diet supplements can help ameliorate malnutrition. But one must keep in mind that these diet supplements are often considered a luxury by those who cannot afford a daily subsistence diet. Also, other infrastructure (storage and transportation of drugs, dispensaries, etc.) may not be available to maintain an effective medical delivery system. Besides the purely economic considerations, the scientific-technological issues must also be addressed. For instance, does each country have a competent scientific community, and if so, what is their relationship to the technological infrastructure of the country? Can the technological infrastructure meaningfully absorb the skills and expertise of these professionals or will this community look overseas for more advanced research and employment opportunities in collaboration with the global scientific community? These are all important considerations.

Perhaps most important of all, one must address the issue of the <u>distribution</u> of drugs to the largest segment of the needy population, in contemplating the development of a local pharmaceutical manufacturing sector. Thus, are drugs more available to the largest segment of the population in an industrial structure that is wholly nationally owned, foreign-owned, or some combination of national and foreign ownership (contractual agreements, licences, joint-ventures, etc.)? Many countries have engaged in collaborative agreements with

TNC's for largely technological and economic reasons. Surprisingly, I have come across no research on the effects of these different kinds of industrial structures on the distribution of drugs to the population. Price efficiency and volume of drug production are important factors determining the distribution of drugs, but as already indicated, not the only ones.

One of the main reasons for establishing a local pharmaceutical industry (rather than relying on imported drugs) by a developing country is to achieve self-reliance, overcome dependence on foreign drug companies, develop "national pride," and to be able to interact symmetrically in a world market. However, if drugs are not distributed to the largest possible proportion of the needy population, but are only consumed by an urban, wealthy minority, even the establishment of the most technologically sophisticated industry cannot be taken as a substitute for national self-reliance. The issue of self-reliance will be taken up in more detail in Chapter IV.

Pharmaceutical Marketing and Promotion

The pharmaceutical industry is also unique with respect to its exceptionally high marketing expenditures. Data indicate that the leading pharmaceutical firms spend more on promoting their brand name than on research and development, even in countries where most of the world's pharmaceutical research and development is performed. The following statistics are self-descriptive. In the United States, marketing expenditures range from three to four times research and development expenditures and account for up to one-third of the value

of sales. Altogether, promotional expenditures in the pharmaceutical industry in the developed countries in 1970 exceeded $3 billion (Lall, 1973).

Prescribed drugs are consumer products of a very special kind, because the actual consumer of drugs neither determines the demand for, nor does he choose the products he will purchase. Consumers have but one responsibility regarding the acquisition of prescribed drugs--that of paying for the products selected for them by someone else. It is the physician, therefore, with whom both the consumer of drugs and the prescription drug company are especially concerned. The particular prescribing decisions of practitioners can make the difference between a sale or none at all for a particular manufacturer.[6] Consequently, the bulk of the manufacturer's promotional efforts goes into persuading them to prescribe by brand names rather than by generic names. It is naturally the aim of each drug company to promote its own brand names and to draw the least attention to price differences between these and generic products. This is done by means of an immense paraphernalia of modern marketing, which has earned the industry considerable notoriety. As Senator Edward Kennedy puts it:

> What we have is a system of hard sell, rather than a system of objective information dissemination; we have salesmen instead of analysts; we have the tools of selling--gimmicks, gifts, bonus deals--rather than the tools of

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[6] In many developing countries, however, prescription drugs are often sold "over-the-counter," or are "prescribed" to the patient by a pharmacist.

science and medicine--comparative information, analysis of risks and benefits of competing products.[7]

Silverman (1974), a critic of "heavy" promotional expenditures, estimates these expenditures (including "detailmen's" salaries) in the United States to be about 20 percent of corporate sales. The TNC's use much the same strategies in promoting their products in LDC's. In Pakistan, drug promotion is mainly directed at 8,500 practicing physicians, and the promotional expenditure per physician was Rs. 3,798 in 1972 (Quraeshi, 1978). Critics of such promotion maintain that this expense is unjustified in a country that had a per capita income of Rs. 700 at the time. The industry justifies such expense on the grounds that they are 'educating' the medical profession, a claim that is not totally unfounded in developing (and developed) countries. Hence, in Pakistan, as in many other countries, these 'detailmen' provided the major--and in many cases the only--source of drug information for doctors.

The very speed of introduction of new products, and slight variations of existing ones, competing brand names, coupled with a lack of information from non-industry sources on comparative costs and effectiveness of drugs, have left the medical profession almost totally dependent on the drug firms themselves for information, which is not always objective. Furthermore, physicians in developing countries are often trained along the lines of their counterparts

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[7]Senator Edward Kennedy, Statement before the U.S. Senate Subcommittee on Monopoly, Competitive Problems in the Drug Industry (Washington, D.C.: Government Printing Office, 1972), p. 792.

in developed countries, whereby they become familiar with international brand names. The physicians (and their patients) also have a strong prejudice in favor of foreign as compared to domestic producers, sometimes justifiably reinforced by the fear that some local products are of inferior quality. Handoussa,[8] writing about Egypt, and the Haithi Committee (1975), writing about India, remark that even on termination of licence contracts with TNC's, "local firms choose brand names that are as close as possible to the original foreign brand name."

With regard to the United States, Dr. James Faulkner of the Massachusetts Medical Society says:

> . . . medical education has failed to grasp the significance of the vast proliferation of new drugs which has taken place over the last couple of decades . . . the practicing physician finds himself obliged to choose between a bewildering array of drugs for which competing claims are made and more often than not he finds himself not only ill prepared to make correct judgments but at a loss to know where to turn for unbiased information. . . . It is indeed deplorable that so much of what the medical student and the practitioner learn about drug therapy comes to them from pharmaceutical firms who are actively promoting their own products.[9]

Consequently, in the United States, drug advertising and the promotional materials supplied by drug firms are subject to review by the Food and Drug Administration, which is responsible for assuring that the claims made are accurate and substantiated by

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[8]H. A. Handoussa, "The Pharmaceutical Industry in Egypt" (Ph.D. dissertation, University of London, 1974), p. 141, cited in Lall, UNCTAD, 1975.

[9]Dr. James Faulkner, Statement before the U.S. Senate Subcommittee on Monopoly, Competitive Problems in the Drug Industry, Part 10 (Washington, D.C.: Government Printing Office, 1972), p. 4054.

evidence. Testimony presented before the U.S. Senate (1968) indicates, however, that the agency has had continuous problems in policing the promotional programs of many manufacturers. There is little doubt that the companies' representatives do have a significant impact in influencing the physician's prescribing methods.

Regarding the marketing of "ineffective" drugs, recent investigations in the United Kingdom showed that several TNC's were selling several hundred drugs, costing at best several millions of pounds, which had been withdrawn from the American market by the FDA as "lacking evidence of effectiveness." There are cases in which drugs disapproved by the FDA in the United States were being sold in developing countries by TNC's (Dowie, 1979).

A drug can be "overeffective" in the sense that it possesses, for example, a five percent advantage of efficacy over an alternative but costs, say, a hundred times more. If a new drug represents only a very slight improvement, for instance, in terms of fewer possible adverse reactions compared with older and much less expensive drugs, Friebel (UNIDO, 1970:34) argues that from the viewpoint of the health needs of a poor country, the less effective (older) drugs may be more appropriate, since many more patients could thus receive therapeutic treatment which would compensate for the slightly greater occurrence of side effects. If doctors had more objective information on the side effects of drugs, and on comparative prices, they would perhaps more carefully scrutinize the promotional strategies used by the drug supplies industry. Friebel, however, assumes that price fluctuations alone determine the demand and

supply of drugs, and does not consider the social factors affecting the consumption of drugs (discussed earlier on pages 56-57).

Price Discriminations and Higher Profits

Pricing policies of TNC's have concerned governments in both developed and developing countries. In the United States, both the Kefauver Senate Committee Hearings and the Nelson Senate Subcommittee on Monopoly addressed the issue of drug prices and profits, and the comparative efficacy of brand-name drugs and their lower cost generic counterparts. The Senate reports show that the leading drug companies engage in substantial price discriminations among different purchases within the same or in different countries; they charge much more than smaller drug companies for practically identical products; they consistently earn profits that seem to exceed the limits of a "fair return" on investment. An example is that of Hoffman La Roche's Valium and Librium, two of the leading tranquilizers which account for 90 percent of the sales of tranquilizers in the United States. Data show that Librium and Valium are sold to different developed countries at price differences of nearly 600 to 1,000 percent (U.S. Senate, Competitive Problems, 1972).

The Issue of Brand Versus Generically Named Drugs

List prices, which are often the basis for comparing the costs of different products, are not always the actual prices charged retail distributors, because of discounting and other sales and

promotional considerations. Yet, even after list prices are adjusted for these factors, wide differences in the prices asked for competing brands of drugs remained. To take the case of the two drugs whose prices were frequently discussed in the Hearings before the Subcommittee on Monopoly--reserpine and sodium secobarbital (generic names), data show that, generally speaking, products marketed under trade-name designations, usually by larger firms, tended to be higher priced than products sold by smaller companies who sell drugs under generic names. (Smith Kline and French sold reserpine under the brand name Eskaserp ar $46.00 per 1000 tablets of 0.25 m.g. each, whereas the same quantity was sold by Darby under its generic name at 59¢; U.S. Senate, 1972:10). Price differentials existing among competing branded products sold by larger firms sometimes were also of major proportions. For example, the price charged for CIBA's Serpasil (brand name for reserpine) at $33.50 per 1000 tablets of 0.25 m.g. each is nearly four times that of Lilly's brand of reserpine, sold under the trade name Sandril, at $9.12 for the same quantity (U.S. Senate, 1972:10).

In Italy, where there is no patent protection, seven firms were selling at prices 30 percent lower than Roche without making a dent on Roche's 80 percent share of the market. In India, Librium was sold in 1972 at Rs. 16.00 (per 100 tablets of 10 m.g. each) when generic name equivalents were available from small producers for prices as low as Rs. 1.50.

The appeal of brand named drugs (whether backed by patent protection or not) is so strong that the big drug producers can

charge whatever price the market will bear. These prices have little relation to the cost of production or to prices charged by smaller competitors. Table 8 shows the comparative prices of drugs between multinational and other firms.

Data indicate that the pharmaceutical industry earns consistenly higher returns on investment of the order of 20 to 25 percent, as compared to an average of 10 to 15 percent for other industries as a whole (Silverman and Lee, 1974). It is ironical that consumers must pay high prices for a product that satisfies basic priority needs, particularly in countries where people have low purchasing power. An educated, urban minority are the major consumers of drugs in India (Haathi Committee, 1975).

The industry justifies its pricing policies by maintaining that their brand names provide an assurance of quality products, and that they need to support their research and development efforts. Both these claims are not invalid, as is brought out in the discussion of the generic names policy adopted by Pakistan in Chapter III.

Implications for Sociological Theory

The features of the pharmaceutical industry just described throw light upon issues that are of concern to sociologists of social change. TNC's have been identified as subtle mechanisms of imperialism within the dependency paradigm (Turner, 1973) whereby they transfer "surplus" capital from the periphery to support the core. Galtung (1971) further conceptualizes this process as a series of cores and peripheries whereby the elite in developing countries

TABLE 8.--Selected Drug Price Comparisons--Multinational and "Other" Firms.

Chemical Name	Trade Name	Price per Kilo in U.S. $	
		"Other"	Multinational
Chlordiazepóxido	Librium	$18.90 - 20.00	$1,250.00
Diazepan	Valium	30.00 - 45.55	2,500.00
Sulfafurazol	Gantricín	7.20 - 8.75	35.00 15.00
Nitrazepan	Nogadón	108.70	2,088.00
Ampicilina	Pentrexil	162.50 - 200.00	420.00
Tetracilina Base	Bristaciclina	23.50 - 26.00	110.00
Erytromycina	Ilosone	100.00 - 145.50	375.56
Prometacina	Deinal	17.75 - 21.00	140.00
Indometacina	Indocid	72.50 - 110.00	320.00
Metrenidiázol	Flagil	11.15 - 14.80	38.00
Acetazolamida	Diamox	13.50 - 16.85	53.00
Tolbutamida	Rastinón	2.40 - 3.20	28.00
Furosemida	Lasix	77.00 - 100.00	1,177.00
Cloranfenicol	Chloromycetin	13.00 - 15.95	80.00

SOURCE: C. V. Vaitsos, Intercountry Income Distribution and Transnational Enterprises (Oxford: Clarendon, 1974). Data collected for the Colombian government.

(cP) maintain a vested interest in supporting international capitalist relations at the expense of the less privileged classes in the periphery (pP). Similarly, the "internal colonialism" is also manifested in core nations, whereby the "bourgeoisie elite" (cC) benefit at the expense of the Western lower classes (pC), leading to a complex pattern of dominant-subordinate relationships both inter- and intra-nationally. In Galtung's definition:

> Imperialism is a relation between a Center and a Periphery nation so that
>
> (1) there is a harmony of interest between the center in the Center nation and the center in the Periphery nation,
>
> (2) there is more disharmony of interest within the Periphery nation than within the Center nations,
>
> (3) there is a disharmony of interest within the periphery in the Center nation and the periphery in the Periphery nation.

Within Galtung's scheme, TNC's are among one of the international organizations that link the Center to the Periphery in the contemporary phase of neo-colonialism. If one is to go by this scheme, then many of the described features of the pharmaceutical industry remain unexplained. For example, the pricing and promotional practices and research activities of the industry have come under much criticism in developed countries as much as in less developed cones. The Kefauver Committee Hearings exposed the worldwide restrictive business practices of pharmaceutical TNC's. Price differentials between equivalent drugs and even the same drugs exist within developed countries as within less developed ones. Galtung's

scheme tends to simplify what is in reality a much more complex network of conflicting and consensual relationships.

Implicit within the statement that TNC's are modern mechanisms of economic imperialism is the assumption that there is a harmony of interest between corporate executives and the elites in developing and developed countries. If so, then how is one to explain the attempts to regulate the transnational pharmaceutical industry both within the core and periphery through stern legislative measures? On the other hand, if one assumes that the activities of TNC's are not consistent with the interest of policy makers in developed and developing countries, then why have policy makers in these countries not joined forces to restrict business practices? Part of the confusion in making any such conclusive statements from Galtung's schemata arises because of the lack of a definition as to which elites he is referring to: government legislators (political elites), the intellectual elites, corporate executives (economic elite), the scientific-technological elite, or even some combination of all these. The issues surrounding the pharmaceutical industry and the debates between various groups--elite and non-elite--give insight into the complexity of "center-peripheral" conflicting and consensual relationships, and the interaction of TNC's with this system.

Using an economic analysis, if the elites in the core and periphery are indeed the owners of the means of production, that is, the corporate executives, in Galtung's framework, then clearly in the case of the pharmaceutical industry they have formed a

particular enclave of people with interests not entirely identical to other groups in developed, developing countries and international organizations insofar as these latter groups have expressed concern over the operations of the pharmaceutical industry in their own country and overseas.

The dependency framework has tended to thus over-simplify the patterns of symmetric and asymmetric interdependencies both between and within nations by emphasizing only one dimension of global interactions: conflicting, dominating-dependent relationships between cores, semi-peripheries and peripheries. By focusing on the economic relationships between these three groups (both globally and nationally) the dependency paradigm has also minimized the distinction between the various kinds of elites (economic, political, technocratic and intellectual) which each play different and significant roles in influencing policy at various levels. That the distinction between these elites is important to make will be further demonstrated in the next chapter when the roles of each of these actors in relation to the pharmaceutical industries in India, Pakistan, and Sri Lanka are discussed.

CHAPTER III

THREE CASE-STUDIES OF THE PHARMACEUTICAL INDUSTRY IN SOUTH ASIA

Introduction

The previous section summarized some of the major issues associated with medical research and development, pharmaceutical production, promotion and distribution. These issues, when posed as policy question, are complex and perplexing globally and nationally. The issues, however, when analysed within the various paradigms, vary in their emphases and their priorities with regard to social change policies and goals. Hence, research and development and technology transfer are of particular relevance to the literature on the relationship between science, technology and development. The policy questions, framed within this perspective, concern identifying the person who is to define the direction of medical research. What proportion of the research and the research expenditure of drugs is to be borne in a country by the public sector, private sector, or transnational bodies? Are there limits to technological growth within the pharmaceutical industry, and if so, how are they defined? Posed within the developmental perspective, priority issues concern the production of drugs, the establishment of local pharmaceutical firms, and educating the population on hygiene and health care. The following are some examples of the questions that need to be raised. Is

large-scale production more efficient than production in small scale firms? How can production costs and drug prices be held at "affordable" levels without harming research and development incentives? The issue of pharmaceutical distribution is particularly emphasized within the dependency perspective, whether it be the distribution of drugs both intra- and inter-nationally or the distribution of resources, technology, and the capital that ensues from pharmaceutical production.

The above statement is not intended to give the impression that each of these perspectives addresses only those questions that are mentioned in relation to them. By the very inter-related nature of these issues, it is not meaningful to discuss one without mention of the others. For example, any analysis that deals with the transfer of pharmaceutical technology without addressing the alternatives of local drug production, alternative technologies, international interdependence and trade, the patterns of drug, capital and resource distribution, and the mechanisms of technology transfer, is incomplete. The perspectives, however, do differ in the degree of emphasis they attach to each of these issues. The three countries to be analyzed in this section, India, Pakistan and Sri Lanka, have, likewise, placed varying degrees of emphasis on these issues with regard to their policies for self-reliance, in keeping with their particular levels of pharmaceutical development and their specific needs.

Although the emphases may differ, there appears to be a fair consensus among writers within the various perspectives, and among legislators within various countries, as to what the pharmaceutical

needs of developing countries are. Ideally, the product structure of the pharmaceutical industry should correspond to the disease pattern of the country, the price structure should match the income levels of the population, and drugs should be available to all who may require them. That this has not been the case so far, and most particularly in the developing countries, has already been shown in Chapter II. This chapter will then discuss the attempts made by India, Pakistan and Sri Lanka to achieve something corresponding to this ideal situation.

The Case of India

The modern pharmaceutical industry in India dates from the British colonial period. British pharmaceutical manufacturers opened trading branches and agencies in India and kept India as a preserve for their finished products until the 1940s. British manufacturers and traders shipped out from India chemical raw materials and shipped back to India extracts and other medical preparations for general prescription. With the remarkable pharmaceutical discoveries in the post-World War II period, non-British firms, mainly from the United States and Switzerland, also entered the Indian market.

With the advent of independence, the government of India set up a Pharmaceuticals Enquiry Committee which made recommendations designed to promote the growth of the pharmaceutical industry in India. The pharmaceutical industry was designated as among the priority areas for development, and as a field where both private and public enterprises were allowed to act side by side. The national

Indian policy also recognized the importance of foreign investment and the import of technology for rapid industrialization, and encouraged foreign enterprise to begin manufacturing finished products in India.

On the basis of the classification scheme suggested by the UNCTAD secretariat (UNCTAD, 1972a), the Indian Council of Scientific and Industrial Research in collaboration with Jawaharlal Nehru University analyzed the present ownership of pharmaceutical firms in India along four categories: (1) full majority foreign ownership, (2) foreign minority ownership, (3) Indian full ownership, (4) public sector undertakings. Table 9 shows the pattern of ownership in 1971-72 in India, by number of units. Although the table shows the predominance of Indian-owned units in both the large-scale (units with a minimum investment of Rs. 10 million in plant and equipment) and small-scale (units with less than Rs. 0.75 million investment in plant and equipment) sectors, the industry is clearly under the dominance of foreign firms because of their disproportionately large share in the turnover of drugs. Hence, in 1971-72, 25 units with full or foreign majority control accounted for more than 50 percent of the gross turnover of Rs. 2,960 million. The two public sector undertakings in the pharmaceutical industry (Hindustan Antibiotics Ltd., and Indian Drugs and Pharmaceuticals Ltd.) contributed Rs. 200 million (UNCTAD, 1977:7). Moreover, while foreign-controlled firms maintain a considerable share in the market for pharmaceuticals, they contribute a relatively small proportion to the manufacture of the basic ingredients used in the production of modern drugs. Table 10

TABLE 9.--Ownership Pattern of Pharmaceutical Units, 1971-1972, by Number of Units.

	Large-Scale Sector		Small-Scale Sector		Total	
	Number	Percentage	Number	Percentage	Number	Percentage
Full Majority Foreign Ownership	25	21.6	9	0.4	34	1.4
Foreign Minority Ownership	20	17.2	12	0.5	35	1.3
Indian Full Ownership	69	59.5	2303	99.1	2372	97.2
Public Sector	2	1.7	--	--	2	0.1
TOTAL	116	100.0	2324	100.0	2440	100.0

SOURCE: Ministry of Petroleum and Chemicals, Report of the Committee on Drugs and Pharmaceutical Industry in India (New Delhi, 1975).

TABLE 10.--Distribution of Bulk-Drug Production by Different Ownership Group.

Type of Ownership	Number of Units	Capital (Rs. million)	Bulk-Drug Production	
			Quantity (tons)	Value (Rs. million)
Full/Majority Foreign Ownership	27 (34.18)	332.0 (37.64)	600 (11.32)	190 (27.14)
Minority Foreign Ownership	12 (15.19)	118.6 (13.46)	3200 (60.38)	270 (38.57)
Fully Indian Owned	38 (48.10)	164.2 (18.61)		
Public Sector	2 (2.53)	267.2 (30.29)	1500 (28.30)	240 (34.29)
TOTAL	79 (100.00)	882.0 (100.00)	5300 (100.00)	700 (100.00

NOTE; Figures in parentheses are percentages.

SOURCE: United Nations Conference on Trade and Development, "Case Studies in the Transfer of Technology: The Pharmaceutical Industry in India." Study prepared by the Jawaharlal Nehru University and the Indian Council of Scientific and Industrial Research [New Delhi, India] (UNCTAD, TD/B/C.6/20, 1977:8).

shows that foreign fully owned/controlled units account for a little over 34 percent of the number of bulk drug producers and almost 38 percent of total investment but contributed only about 11 percent of the total tonnage of bulk drug production.

Such a pattern of foreign monopolistic ownership is inconsistent with India's own goals for self-reliance and self-sustaining development. As the Development Council (Drugs and Pharmaceuticals), Director-General of Technical Development, Government of India, 1973:20) has phrased it, "The indigenous manufacture of raw materials is a key phase in the planned development of a self-sustaining industry. Basic manufacture, was, therefore accorded top priority in the initial development of the industry."

Furthermore, the dependence on foreign drugs is further unsatisfactory for India in that these drugs do not reflect India's basic health needs and disease patterns. Table 11 shows the causes of deaths and illness in India between 1962 and 1964. Although infectious and parasitic diseases are most widespread, followed by diseases of the respiratory system, Table 12 indicates that India did not locally manufacture many of the basic drugs required for the treatment of these diseases.

Pharmaceutical Research and Development

The data indicate the inappropriateness of the drugs marketed in India for catering to the needs of the masses. Drug imports reflect Western consumption patterns, resulting in a gap in drugs required for treatment of a wide spectrum of local illnesses.

TABLE 11. Causes of Death and Illness in India, 1962-1964.

Cause	Cause as Percent of Deaths	Cause as Percent of 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	(
Diseases of circulatory system	9.27	(14.5 (
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
TOTALS	100.00	100.00

SOURCE: UNCTAD, TD/B/C.6/20, 1977:35).

TABLE 12.--Disease Pattern and Drug Production.

Disease	Drug	Whether Produced in India[a]
INFECTIOUS AND PARASITIC DISEASES:		
Dysentery of All Forms	Emetine hydrochloride	Yes
	Dehydroemetine	Yes
	Halogenated oxyquinelines	Yes
	Metronidazole	Yes
	Enterovioform	Yes
	Siosteran	No
	Diloxanide Fureate	No
	Ampicillin	No
	Celphalothin	No
Malaria	Chlorequin	Yes
	Amodiaguin	Yes
	Primaquin	No
	Triethoprim	No
Cholera	Prophylactin vaccine	Yes
	Chloramphenicol	Yes
	Tetracycline	Yes
	Furazolidine	No
Parasitic Infection of Alimentary Canal		
Giardiasis:	Quinacrine	No
	Piperazine	Yes
Ascariasis:	Piperazine	Yes
	Thiabendozole	No
Enterobiasis:	Piperazine	Yes
	Pryruvimium pamoate	No
Ankylostomiasis:	Tetrachloreetheylene	No
	Bepheniumhydroxy naphthoate	No
Tapeworm:	Quinacrine	No
	Niclosamide	No

TABLE 12.--Continued.

Disease	Drug	Whether Produced in India[a]
RESPIRATORY SYSTEM:		
General Illness	Aminophylline	No
	Theophylline	No
	Ephedrine	Yes (small qty)
	Phenobarbitone	Yes
	Adrenaline	No
	Corticosteroids	Yes (small qty)
Tuberculosis	Stremptomycin	Yes
	Isonicotinic acid hydramide	Yes
	Para amino salicylic acid	Yes
	Thiacetazone	Yes
	Ethambutol	No
	Pyrazinamide	No
	Ethionamide	No
DISEASES OF THE CENTRAL NERVOUS SYSTEM:		
Sedative	Phenobarbitone	Yes
	Phentoborbitone	No
	Thiopentone	No
	Potassium bromide	No
Tranquillizers	Meprobamate	Yes
	Chlorpromazine	Yes
	Diazepan	No
	Amitryptline	No
Anti-convulsants	Primidone	No
	Hydantion dervs	No
	Phenurone	No

SOURCE: Central Bureau of Health Intelligence, Ministry of Health and Family Planning, Government of India.

[a]All products are marketed in India.

Furthermore, foreign subsidiaries in India are not interested in research on drugs for tropical diseases as the global demand for such drugs, in their view, will not be sufficiently profitable (Haathi Committee, 1975:93). In India, per capita consumption of drugs is Rs. 6.00, and only 20 percent of the population consumes modern drugs (Haathi Committee, 1975) compared to $20+ per capita consumption in the United States and $15 in Japan (Wortzel, 1971:19).

In view of these conditions, India has realized that she must assume ultimate responsibility for research and development on drugs required for the treatment of local diseases. However, the research and development investment by the pharmaceutical industry in India, not even 1 percent of total sales in 1973, is very low in comparison to pharmaceutical research and development investments in developed countries, an average of 5.6 percent (National Science Foundation, NSF.68, 1966).

Research and development activities in the Indian drug industry have been classified into three areas, namely, public-funded research and development, public sector in-house research and development, and private sector in-house research and development (UNCTAD, 1977). The first of these, public-funded research and development, refers to the monies allotted for pharmaceutical research and development to various research institutes and medical colleges by the Ministry of Health and Planning and the Indian Council of Medical Research. Public sector in-house research and development refers to medical research, and the production of bulk drugs and intermediate products that are undertaken by public sector units. These units

were established after India's independence in 1947, when the government "adopted the principle that the production of basic drugs should be in the public sector at least partially if not totally carried on with a view to making common drugs available universally and to eliminating dependence on transnational corporations" (UNCTAD, 1977: 46). The third area of research, private sector in-house research and development, refers to pharmaceutical research and development undertaken by the foreign and national drug industries in India. Subrahmaniam (1971), in a study on the chemical industry as a whole, found that foreign-controlled drug companies spent less than one percent of their turnover annually on research and development in the host country. Some scholars (Rangarao, 1975; Lall, 1975), find problems with conducting local research and development in the present international structure of the drug industry. Rangarao finds that where research is successful at an initial stage, the results "are picked up by the large industrial research and development establishments abroad and converted into technological realities to be imported to India after a few years." Lall discovered that

> . . . many TNC's actively scout institutions engaged in pharmaceutical research and offer free equipment, chemicals and trips abroad to the research workers in exchange for an agreement that the foreign patents be granted to the TNC. The indigenous institution (say, in India) then receives a royalty on the active ingredient only, while the TNC markets the drug and collects profits on the whole value of sales. Furthermore, while the Indian patent is owned by the local institution, ownership by the TNC's of foreign patents effectively bars the development of exports of the new drug from India.

Over 90 percent of patents in the drug industry in India are held by foreign companies. This can be interpreted in two ways:

either the research and development efforts of Indian research laboratories are assimilated by foreign companies, as mentioned by Rangarao and Lall, or, the situation reflects one in which there is a low level of innovation by Indian firms. In either of these cases, the situation is one of foreign predominance in the Indian drug industry. This is ironical in view of the fact that India maintains a strict patent policy, because of her objections to the effects of the patent system, and also in keeping with her own industrial policy of import-substitution and self-reliance. A Patents Bill was passed in 1970 reducing the period of patent protection from 16 years to 7 years, ruling out product patents, and providing compulsory licensing after 3 years for a royalty not exceeding 5 percent of the value of production. Why does India grant patents at all? The Development Council (Drugs and Pharmaceuticals) of India maintains that some form of protection is required as an incentive to foreign companies to invest in India. Besides, the Italian case suggests that even if a country does not grant patent protection, foreign dominance prevails in the market, without transferring the benefits of technology and research and development. India is now relatively advanced (compared to other developing countries) in her production of pharmaceuticals. Her main weakness lies in her research and development capacity. In order to bring about further backward integration in this section, some form of patent protection is necessary to stimulate local enterprise, insofar as the rationale for granting patents is that it stimulates innovation. However, the proliferation of drugs in the Indian market not directly related to local health needs

calls for more discriminatory protection whereby stronger patents could be granted for relevant drugs, and weaker patents for less necessary ones, in a graded patent system.

Pharmaceutical Products and Production

The Development Council (Drugs and Pharmaceuticals) in India (1973) observes that the development of a pharmaceutical industry occurs in three different stages:

Step 1: Packaging of imported formulations

Step 2: Production of dosage formulations from imported bulk drugs

Step 3: Production of basic drugs, which generally follows this sequence:

Manufacture of common pharmacopeial preparations, which involve only simple chemical reactions, and production of galenicals, i.e., tincture and extracts.

Production of glandular preparations like liver extracts.

Production of biologicals like sera and vaccines.

Production of phyto-chemicals,

Production of synthetic drugs,

Production of antibiotics.

The Council further maintains that Indian pharmaceutical manufacturing is progressively integrated up to Step 3, although no producer is fully integrated in respect to all its products, but specializes in one or more therapeutic sub-markets. The Council also holds that the technology employed in production and quality control is of the level obtaining in the industrialized countries of Europe, the United

Kingdom, and the United States, because of the foreign collaborative agreements. The collaboration of TNC's with the Indian industry has assured that about 100 technicians and administrators are sent overseas each year to learn the latest technology, and diffuse these skills among their colleagues upon their return. Among the 65,000 people that were employed in the large-scale sector alone, in 1970, 10 percent were technically trained, "constituting the spearhead of a technological society" (Development Council, Government of India, 1973).

The very forces that the Development Council identifies as progressive for the pharmaceutical industry in India (foreign technical collaboration, a foreign-trained technical elite) have been perceived as causes of India's technological dependence, and the retardation of her local enterprise, by academicians (UNCTAD, 1977) and by trade union leaders (All-India Trade Union Workers, 1970). The argument is that the transfer of foreign trademarks, technology and patents have stifled indigenous research and development and local efforts at production. Examples of the "struggle between India and imported technology" abound, illustrating that where India had developed indigenous technology to produce certain drugs (anti-tubular, anti-leprosy, anti-diabetic, anti-malarial, and anti-dysentery drugs) foreign companies were licensed to produce these drugs at greater capacity, cometitively forcing Indian firms out of business (UNCTAD, 1977). The interesting pattern displayed here is that foreign companies have not produced (or have produced at low capacity) many of the drugs relevant to India's needs. But

when local efforts to initiate such production have been undertaken, the TNC's quickly better such efforts by producing these drugs in greater capacities. This may then be India's short-term solution to acquiring relevant drugs, but conflicts with her long-term goals of encouraging local production for self-reliance.

The alternative is to make short-term sacrifices for achieving long-term goals, by not licensing foreign companies to manufacture drugs where facilities are available locally, even though it may mean settling for less quantities of drugs initially. The government may also restrict the manufacturing capacity of foreign firms to supply only the amount not met by local industry. The problem of brand competition between foreign and local firms will still have to be solved, by ensuring adequate quality control of local drugs, or by distributing drugs by their generic names.

Why has India not nationalized her drug industry? This was a serious consideration in the mid-1970s, and foreign companies were threatened with nationalization. However, although there are indications that the intent is not lost altogether, the threat never became reality, partly because of pressure by TNC's, and partly because India did not yet have local facilities to be totally self-reliant. The transnational nature of the pharmaceutical industry itself dictates that no country can be totally self-sufficient with regard to pharmaceutical research and production. Dr. K. K. Raj, economist and Vice-Chancellor of Delhi University, advises against nationalization of the pharmaceutical industry in India, in that it is "premature to consider it at this stage," since one needs to be very careful not to

"over-stretch the limited managerial resources available to the public sector" (All-India Trade Union Workers, 1970:36-37).

Rather than take any extreme routes, like total nationalization of the industry on the one hand, and free play for private enterprise on the other, India has chosen a policy by which she combines the two and maintains both a private and a public sector in manufacturing pharmaceuticals. Although the bulk of production of drugs is in the private sector, the two public sector enterprises have been responsible for exports made to neighbouring countries. The role of the public sector is to regulate the free forces of demand and supply that would place consumers at a disadvantage in terms of high prices for drugs, and also for determining priority needs and a drug list for pharmaceutical production.

Pharmaceutical Marketing and Promotion

As with most other countries, the marketing of drugs is left entirely to the private manufacturers. This has led to the proliferation of branded products and formulations of the same drug, leading to greater promotional expenditures and confusion for the physician who must choose between a wide array of products. Thus Table 13 shows the number of formulations of various compounds that are sold in the Indian market. A government committee has estimated that the country's basic pharmaceutical needs can be satisfied by no more than 116 drugs, in contrast to the 15,000 that are marketed there at present (Haathi Committee, 1975).

TABLE 13.--Analysis of Products of Indian Pharmaceutical Industry (1972).

Products (Group-wise)		Number of Formulations in the Market
1.	Vitamins:	
	Multivitamins	308)
	Vitamin B complex	406)
	Vitamin B_{12}	126) 1,134
	Others	294)
2.	Tonics, nutrients or deficiency drugs	685
3.	Transquilizers and sedatives	376
4.	Expectorants, cough syrups, decongestants	340
5.	Analgesics and antipyretics	296
6.	Antibiotics:	
	Penicillin and salts	99)
	Chloroamphenicol	155)
	Streptomycin	82)
	Tetracycline	115) 527
	Neomycin	28)
	Others	48)
7.	Anti-Infectious:	
	Sulphas	320)
	Anti-TB drugs	223)
	Antidysentery	185)
	Anthelminetics	66) 1,068
	Antifilarials	48)
	Antileprosy	20)
	Antifungal	19)
	Antiseptic	54)
8.	Steroids and hormones	354
9.	Anti-histamines	151
10.	Antiacids	113
11.	Anaesthetics (local and general)	88
12.	Laxatives and purgatives	69
13.	Anti-inflammatory drugs	75
14.	Alkaloids	445
15.	Galenicals (crude drug extracts)	55
16.	Inorganic elements and compounds (excluding iron preparations)	146
17.	Sera and vaccines	49
18.	Enzymes	104
19.	Household remedies (dexture, gripe, water, etc.)	180
20.	Others	1,144
	TOTAL	7,399

SOURCE: UNCTAD, TD/B/C.6/20, 1977:38).

India is well-known for having relatively high drug prices. The government's general policy of heavy import substitution has led to manufactured products in general being expensively produced in the country, and which has obliged firms to buy costly chemicals from local sources. The cost of intermediate chemicals supplied by the public sector plants is high relative to international prices, and foreign firms often blame high retail drug prices on the high cost of their raw materials. However, the cost of raw materials is always such a small proportion of selling prices in this industry that it is difficult to be convinced by this argument. Besides, generic equivalents are marketed much more cheaply by smaller firms which use the same chemicals and raw materials. That production costs comprise a very small percent of actual sales price of drugs is brought out in statements made by Senator Kefauver in the United States Senate and before the Subcommittee on Antitrust and Monopoly of the Senate Committee on the Judiciary:

> Under the big drug companies' brand names, such as Reticorten or Rericortelone, these products are sold to druggists for around 18 cents a tablet and the suggested price to consumers is 30 cents a tablet. Yet the cost of production for these tablets including tableting, bottling and packaging is no more than 1.5 cents per tablet. . . . Or take the case of the wide-range antibiotics. . . . These are the drugs which cost the consumer around 50 cents a capsule and are prescribed for a wide variety of infectious diseases in adults as well as children. The largest selling product of this type, tetracycline, is sold to the druggist at around 30 cents a pill. Yet the average production cost, again including tableting, bottling and packaging, is less than 3 cents per capsule.

In relation to India, the Kefauver Committee stated:

> India . . . does not grant patents on drug products, providing an interesting case example. Prices in India for the

> broad spectrum antibiotics, Aureomycin and Anchromycin, are among the highest in the world. As a matter of fact, in drugs generally, India ranks among the highest priced nations of the world--a case of inverse relationship between per capita income and the level of drug prices.

Evidence for the Joint Committee of the Indian Parliament on Patents Bill, testified to much the same kind of pricing pattern. Hence, Vitamin B_{12} manufactured by Merck Sharpe and Dohme was sold in India at Rs. 215 a gram; its international price was Rs. 32 per gram. Similarly, chloramphenicol manufactured by Parke-Davis was sold at Rs. 410 a kilogram in India whereas it was sold at Rs. 100 in the international market. Such a list of examples could continue indefinitely.

In 1970 the Government of India issued a Drug Price Control Order , based on the recommendations of a Tariff Commission study, conducted in 1966, to determine the prices of 17 basic drugs and their 69 formulations. The objective was to bring down prices of essential drugs, to provide incentives for backward integration into basic drugs, to develop research facilities, and to promote the overall development of the industry.

Under the Drug Price Control Order, the prices of the 17 essential bulk drugs and their formulations were fixed by the government, while the selling prices of all other drugs were frozen at the level prevailing immediately before the promulgation of the order. Subsequent price rises were considered on an individual basis upon application. The study conducted by the Jawaharlal Nehru University and the Indian Council of Scientific and Industrial Research (UNCTAD, 1977), reported that:

> As a result, prices for about 45 percent of the items were reduced, 36 percent were kept unaltered and increases were permitted for about 11 percent. The estimated annual benefit to the consumer by the control exercise was of the order of Rs. 200 million.

In a separate account of the effects of this Order, Lall (1974) maintains that it was, in fact, a failure. The pace of increase in drug prices quickened, in fact, after 1966 when the Tariff Commission investigation of prices was institutted. The 17 drugs accounted for only 9 percent of the total value of drugs marketed in India. The order had the perverse effect of inducing firms to increase the prices of their other drugs prior to 1970, leading to a rise in the overall drug price index of 12 points in 1970-71, the highest annual increase recorded since 1960. Hence, although objectives and policy were good, planning and implementation was faulty. Even though reductions in the prices of drugs are obtained for India, who will benefit from these lower prices? Clearly, it is the urban, upper-class consumers of modern medicine, who comprise only 20 percent of the population of India. Insofar as prices are one determinant of the demand for drugs,[10] reduced prices of drugs may render them within the means of a larger segment of the population. Yet, many of the most needy may still not be advantaged by lower drug prices since they are not informed of the benefits of modern medicine, and rely either

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[10]Some may hold that the demand for drugs is inelastic. I will argue that this proposition fails to make the distinction between various kinds of drugs needed for various kinds of illnesses. Although one can agree that the demand for life-saving drugs may well be inelastic, the consumption of drugs like tranquilizers, cough and cold preparations, vitamins, etc., will vary to some degree with fluctuations in the prices of these products.

on traditional medical practitioners, household remedies, or no therapy at all.

Whereas most of the pharmaceutical policies adopted by the Indian government mainly benefited only a select target market--the consumers of modern medicine--in the past, in recent years the government has increasingly sought to address the health needs of a larger population by exploring and supporting alternatives to modern drug therapy. Thus, a great impetus has been given to Indian systems of medicine, which form part of the National Health Service Programmes of the Government of India. Some of the institutions established to promote traditional systems of medicine include the National Institute of Ayurveda at Jaipur, the Central Council for Research in Indian Medicine and the National Institute of Homeopathy. Under the Fifth Five-Year Plan (1974-79), the Department of Health in India proposed to establish the National Institute of Unani and Nature Cure. Additionally, a Central Pharmacy was proposed to be established as a public sector undertaking "to cater to the requirements of drugs of the Indian System of Medicine and to increase all around availability" of drugs (Department of Health, Government of India, Report 1975/76). The Indian Government offered to finance State governments in developing pharmacies, herb gardens, etc., in their own States.

Programs designed to improve the quality of indigenous medicine are indeed essential in a country that has 184.6 million practitioners of traditional medicine as against 146 million physicians trained in modern drug therapy (see Appendix, Table 15). By

developing alternative systems of therapy, India has taken one more step toward reducing her dependence on foreign drugs.

The Case of Pakistan

The origins of the pharmaceutical industry in Pakistan can again be traced to the colonial period. British manufacturers had trading agencies in India, which was a captive market for mainly British finished drug products. After partition in 1947, although post-partition India had some leading multinational drug companies with some dosage form fabrication facilities, Pakistan did not, relying primarily on imported drugs.

This situation prevailed until the 1960s, when the government made a deliberate attempt to foster pharmaceutical manufacturing in Pakistan. The liberal foreign investment atmosphere existing at the time was an incentive for American, British, German and Swiss firms to establish subsidiaries in Pakistan. This situation, together with tariff regulations which protected the industry, led to the establishment of a dosage form fabrication pharmaceutical industry in Pakistan.

Until 1972, the major legislation controlling the production and marketing of pharmaceutical products in Pakistan was the Drugs Act (XXIII) of 1940, passed on April 10 of that year in British India (prior to partition) and adopted by the government of Pakistan. The Act was meant to regulate the import, export, manufacture, distribution and sale of drugs.

Although the Pakistani industry developed fairly rapidly in terms of dosage fabrication, it was and still is heavily reliant on imported raw materials and active ingredients. Pakistan lacks a necessary chemical base for the manufacture of active ingredients. Until the 1970s there were only a few drugs for which active ingredients were being manufactured in Pakistan.

Approximately 300 firms were competing in the Pakistani pharmaceutical market in 1971 (Quraeshi, 1978). These included foreign firms with established manufacturing facilities in Pakistan, Pakistani manufactureres, and foreign firms exporting finished products to Pakistan. Of the approximately 300 firms, 60 firms (20 percent) held approximately 95 percent of the market share in rupee sales in the years 1971 and in 1975. Among these, 30 companies (10 percent) accounted for approximately 85 percent of the rupee sales in drugs and medicines. The remaining firms (90 percent) accounted for only 15 percent of the sales. This kind of oligopolistic market structure is consistent with general patterns of the pharmaceutical industry world-wide.

The pattern is again systematic in that foreign TNC's controlled most of the market for drugs. Thus, of the 300 total registered firms, ten TNC's engaged primarily in dosage form fabrication, importing active ingredients from overseas, and accounted for about 54 percent of sales in that year. Of these firms, six were subsidiaries of United States companies, three were British, and one was German.

Consequently, the Pakistani pharmaceutical industry was very dependent on foreign imports because her own industry was not very developed. Thus, Pakistani firms engaged mainly in dosage form fabrication, and undertook practically no research and development activity.

Pharmaceutical Research and Development

The Pakistani Government, under Z.A. Bhutto, tended to accept the view that Pakistani consumers should not be made to pay for the results of innovation directed mostly at Western markets. Since they felt that many of the drugs marketed were minor molecular modifications of patented products, offering little clinical advantage over the original drug, the government introduced the National Formulary in 1972 to restrict the number of drugs and remove "non-essential" drugs from the market.

Pakistan also maintains stringent restrictions on patents. Product patents were not allowed and only process patents were granted. The government had sanctions against nonworking patents, and a patent could be revoked if the demand for the patented drug was not being met, or if it was found not to be in the public interest.

Pharmaceutical Products and Productions

The major legislative measure taken by the Pakistani government to increase local manufacturing of drugs was the Drugs (Generic Names) Act, 1972. The major objectives of this act were to reduce

the prices of drugs, encourage local manufacturing and price competition by abolishing all brand names for drugs and replacing them with generic names. The government had therefore drawn up a National Formulary (which was to include a list of 850 drugs) and to adopt generic names for drugs by September 23, 1972, later extended to March 31, 1973 because of pressure from industry (Gazette of Pakistan, Extra, Islamabad, Sept. 25, 1972). When the Generic Names Act was first introduced, about 200 drugs were granted exemptions, all of which were manufactured or imported by foreign sources. Between 1971 and 1975, more products were added to, or deleted from, the National Formulary, until by 1975 it included 1,200 drugs and exempted 300 others. The exemptions were granted because of the strong opposition to the policy from foreign manufacturers, some of whom threatened to close operations.

The policy of the government was such that <u>all</u> manufacturers could produce <u>all</u> drugs included in the National Formulary, so long as manufacturers restricted themselves to those products in the National Formulary, and marketed their drugs by generic names.

Many Pakistani firms sought licenses to manufacture drugs in the hope that, in the absence of brand names, they would be able to compete. Between 1972 and 1974, 13 manufacturing licenses were granted, and all to Pakistani local manufacturers (Quraeshi, 1978). However, many of these firms did not have production nor quality control facilities, and the licenses of 12 new Pakistani firms were cancelled by 1976, with many more pending stern action for manufacturing "sub-standard" drugs.

The issue of quality control is particularly important when undertaking legislative measures of the kind taken by Pakistan. In emphasizing standard quality, the Government focused on the chemical make-up of the drugs, and the quality of a product was related to how well it conformed to chemical specifications. However, the government failed to realize that both the chemical and the biological aspects of a drug need to be considered in ensuring product quality, since chemically equivalent drugs may not be therapeutically equivalent (as discussed on pages 50-51). The foreign countries used this factor (quality) as a major tool for maintaining, and indeed strengthening, their market power during the Generic Names Act. Thus, of the 29 leading manufacturers in Pakistan in 1971 (prior to implementation of the Act) the market share was 74.39 percent of all sales. The government's objective was to reduce the market share of these 29 manufacturers to approximately 25 percent by the end of 1975. However, by 1975 these 29 companies held 83.69 percent of the volume of sales, and thereby, the government fell dismally below its objective. The foreign companies and major Pakistani manufacturing firms emphasized the occurrence of sub-standard drugs among local manufacturers, leading to distrust of these drugs by the public and the physicians. By emphasizing their own quality control procedures, these companies were able to maintain their hegemony by initiating competition based on quality, rather than on price.

The policy of the Pakistani government should have been to assure that all other factors were equal, in order to promote classical price competition. However, even as late as 1975, there

were inadequate quality control facilities. For the four provinces of Pakistan, there were only 24 quality control inspectors in 1975. The Medical Gazette critically summed up the quality control facilities in Pakistan:

> The provincial laboratories were ill-equipped. . . . Drug inspectors . . . who are supposed to keep a regular check are neither fully qualified for the job, nor have adequate facilities according to international standards . . . . Provincial Health Departments in the four provinces have so far failed to regulate and maintain the standard of drugs (M.A. Khan, "Quality Control and Drug Research," Medical News, January 25, 1975:11).

The situation exhibits a case of piece-meal implementation of an otherwise powerful policy to regulate the monopoly of TNC's. The Generic Names Act of 1972 was then replaced by the Drugs Act (XXXI) of 1976 which was developed to regulate the import, export, manufacture, storage, distribution and sale of drugs. The major emphasis of this Act was on quality control and quality control procedures (Yusuf Kazmi, 1976).

Pharmaceutical Marketing and Promotion

Until 1972, brand names were used for the sale of drugs. There were some products available by generic name, although competition between Pakistani and foreign firms induced doctors to prescribe drugs manufactured by the latter. With the accession to power of Z. A. Bhutto in 1971, the Pakistani government embarked on a stated policy of controlling key industrial sectors. Because of the concerns regarding the market behavior of pharmaceutical TNC's, Pakistan chose to abolish brand names of all drugs and to allow them to be

promoted only under their generic names, thereby hoping to reduce the concentration of sales held by a few firms (all TNC's) and to accelerate price competition in the pharmaceutical industry.

The policy met with controversial reactions among the various affected groups. The Pakistani Pharmaceutical Manufacturers' Association (PPMA) that was composed of the leading foreign and domestic manufacturers, displayed active hostility to the Drugs (Generic Names) Act, 1972, in the form of resolutions, news releases, publicity in major newspapers and representation to the health authorities against the adoption of the proposals. They argued that the National Formulary had been "arbitrarily prepared," and had excluded a number of widely used active ingredients. They felt that the replacement of brand names with generic names shifted the responsibility of dispensing drugs from doctors to chemists who had little medical expertise. Regarding the proposal to import raw materials through the Trading Corporation of Pakistan (TCP, a government body), the PPMA argued that the TCP had neither the skill nor the facilities to be the central raw material purchaser of pharmaceuticals.

The Central Health Minister, Shaikh Rashid, was quoted as stating that "one of the medical firms approached him with an offer of Rs. 50 lakhs to dissuade him from going ahead with the scheme of banning the brand names of medicines in the country," a charge that was denied by the PPMA ("PPMA Denies Any Offer of Bribe to Minister," Dawn, April 27, 1972).

Shaikh Rashid also spoke of foreign pressure that was brought to bear on him in order not to make the switch over from brand to

generic names, but he was determined "not to yield." According to him, the United States and West German Ambassadors had asked him to withdraw the decision as the "business of medicines in their countries would be badly affected by this decision" ("Rashid Speaks on Foreign Pressure," Medical News, June 15, 1972). The West German Ambassador immediately denied having met with Rashid or of having pressured him, maintaining that he had only

> written him a letter containing the suggestion to consult local representatives of the pharmaceutical industry of Pakistan which was largely built up with foreign investments before the final formulation of those parts of the national health scheme which dealt with the pharmaceutical industry ("German Envoy Had Only Written a Letter to Rashid," Dawn, June 8, 1972).

The medical profession was divided over the issue of brand versus generic names for drugs, although many doctors showed reluctance to prescribe drugs under generic names, preferring to prescribe by brand names ("Prices of Several Drugs Increase," Dawn, May 26, 1972). A past president of both the Pakistan Medical Association and the British Medical Association expressed his reservations regarding the therapeutic equivalence of chemically equivalent drugs. He suggested that:

> by restricting the availability of drugs and by insisting on the use of generic names a doctor will be derived of the right to prescribe the drug of his choice. . . . By the use of generic names the initiative will pass from the doctor and the patient to . . . the chemist (Hamid Ali Khan, "An Appraisal of the People's Health Scheme," Medical News Supplement, April 22, 1972, p. 16).

The Pakistan Chemists and Druggists Association (PCDA) maintained that the Drugs Act, 1972, would have catastrophic consequences since generic names are not easily remembered, that quality may suffer,

that the policy would ruin chemists who had stocks left over after the deadline, and that it would cause massive unemployment ("Appeal to Mr. Zulfikar Ali Bhutto, President of Pakistan," Pakistan Times, August 9, 1972). Many chemists and druggists protested the deadline (October 20, 1972, later extended for six months) by which the Drugs Act would be enforced because it would not give them sufficient time to sell their stocks. In Lahore, hundreds of angry chemists and druggists kept their shops closed for twelve hours or more in protest.

Many employees in the health sector were laid off for indefinite periods as a result of the confusion surrounding the national health policy. The pharmaceutical workers' federation indicated that workers in the industry were faced with "retrenchment, termination of services, and dismissal" ("Workers Threaten to Take Over All Pharmaceutical Firms," Dawn, May 18, 1972). But rather than blame the government for this situation, they accused the industrial manufacturers of making the legislation an excuse to victimize workers.

The central government responded to the various criticisms of the policy by supporting the generic policy as a "revolutionary step . . . in the interest of the people" so that prices of drugs under generic names "will come for the first time within the easy reach of the common man." Furthermore, because of the rural health expenditure under the People's Health Scheme, there would be "a tremendous increase in the consumption of drugs and medicines."

Government estimates of expected price reductions of medicines ranged between 70 percent to 25 percent of the prevailing price in 1971. Whether a price reduction of this magnitude actually did take place is difficult to compute because of problems of measurement. First, after the introduction of the National Formulary, certain formulations, package sizes and strengths differed from those offerred prior to 1972, making price comparisons difficult. Second, many products that were offered prior to 1972 were discontinued after, and new ones were added. Also, some drugs need to be weighted greater than others because they are used more frequently, and price reductions in these drugs would present greater savings to the consumer than equal price reductions in less frequently sold drugs.[11] However, despite any measures, the prices of drugs

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[11]Quraeshi (1978) has tried to take these problems into consideration in calculating the price differences of drugs between 1971 and 1975 in Pakistan through three different estimates: (1) by comparing prices of 24 products (reasonably representative of the different therapeutic classes) with equivalent formulations offered in the same package size in 1971 and 1975 and calculating an "average" change in price for these products; (2) by comparing prices in the most frequently sold package forms of these 24 products for 1971 and 1975; and (3) by comparing the prices charged by a leading manufacturer for a drug in 1971 to the price charged by the same manufacturer for the same drug in 1975. On the basis of the first measure, Quraeshi concludes that between 1971 and 1975 there was an average price increase of 2.6 percent of all package forms for the 24 products included in the comparison. According to the second estimate, the percentage change in average price of the most frequently sold package forms ranged from -29.59 percent (for diazepam, a tranquilizer whose prices had long been under attack in many countries) to +208 percent for phenobarbitone (a barbituate). Only three products (of 24) registered price decreases of at least 25 percent (taking the most conservative estimate of the government), while there were price increases in two leading therapeutic submarkets, vitamins and cough and cold preparations. The third measure indicates that in all cases except two, foreign manufacturers led in unit sales of the most frequently sold package form in 1971 and 1975,

registered increases between 1971 and 1975, rather than reductions, as intended by the Pakistani Government.

These data indicate that the Generic Names Act, 1972, fell far below the goals set by the National government. The policy and its method of implementation raises some important sociological questions. Bhutto emphasized the 'socialist' goals of the Act--encouraging local production, redressing the imbalance in market shares between foreign and local manufacturers, and encouraging a more equitable distribution of drugs to a larger segment of the population by trying to reduce the prices of drugs--with a policy that was based on the concept of classical price competition in, what was in actuality, a free market economy. Hence, can any society that emphasizes the above-mentioned 'socialist' goals ever achieve these through the principle of a free market economy? The case of Pakistan, so far, suggests not, although one cannot help but speculate on how things may have been different had there been a vigorous effort to ensure comparable quality control standards between Pakistani local manufacturers and foreign manufacturers. Quality becomes an important issue because of the very nature of the pharmaceutical industry itself, unlike some consumer goods industries (for example, soaps, combs, stationary, etc.) where certain compromises in quality can be

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and, in general, the same foreign local manufacturer who led unit sales in 1971 was also the sales leader in 1975. Most frequently sold package forms of the leading manufacturers were priced higher in 1975 than in 1971. Further, the spread between the highest and lowest price of the most frequently sold package forms was greater in 1975 as compared to the price in 1971.

made without the drastic adverse effect that adulterated or low quality drugs would have on one's health.

The TNC's and leading local drug manufacturers widely advertised their superior testing and quality control procedures and tended to undermine public confidence in locally manufactured drugs (in some cases, justifiably so) through an immense paraphernalia of promotional literature, advertising, and frequent visits by "detailmen" to chemists, druggists, and physicians. Although generic names replaced brand names on packages, the leading manufacturers still maintained their identity by including trademarks, manufacturers' names and certain distinct colors and symbols to distinguish their products from those of other manufacturers, thus negating the basic rationale for the switchover to generic names.

It is also important to consider the oligopolistic nature of the transnational pharmaceutical industry and its impact on policies designed to promote a free market economy with pure competition. The leading TNC's have a competitive advantage over other manufacturers in the availability of capital resources which can be applied to sophisticated promotional techniques such as giving free samples, and recruiting skilled medical representatives. It is doubtful whether local manufacturers could successfully compete with dominant pharmaceutical TNC's in an open market on these terms. An alternative--but less ambitious--policy for the Pakistani government may have been to introduce the conversion to generic names in a gradual, phased out manner. Rather than encourage local manufacturers to compete in those therapeutic submarkets where TNC's maintain a

dominant market share, policies could have been designed to stimulate local participation in those therapeutic submarkets where TNC's have no particular economic interest (measured in terms of global demand) but which are consistent with the disease pattern of the country.

In relation to the above discussion, one can then pose another theoretically relevant question. With the increasing awareness of a complexly interdependent world-system, predominantly capitalist in nature, and the asymmetrical relationships between societies, regions, etc., in which the small, less industrialized countries are largely dependent on foreign enterprises for supplying many of their 'basic' needs, is it possible for countries like Pakistan to pursue socialist economic policies and yet maintain her dealings with dominant transnational enterprises, and will such policies aggravate or appease her vulnerabilities (economic and social)? Did Pakistan, given her peripheral position within the world-system, her therapeutic need for the benefits of research and development and technology developed overseas, and for drugs, have policy choices other than bargaining with TNC's within a regulated market economy? The same question can be posed again within the context of the pharmaceutical industry in Sri Lanka, and it is possible to compare how Sri Lanka dealt with the problem differently.

In recognition of the problems that arose in the implementation of the Drugs Act, 1972, the next legislative measure, the Drugs Act, 1976, enforced more rigid quality control procedures, warned of stern measures against adulterated drugs and regulated the

advertising of drugs and the labels of medicine packages. The earlier policy to convert brand names of drugs to generic names was modified to read "Single ingredient drugs shall be registered generally by their generic names while compound drugs shall be registered generally by their proprietary names" (Kazmi, 1976:12). The policy of the Pakistan government in 1976 was more comprehensive than that of 1972 in that it enforced "An Act to regulate the import, export, manufacture, storage, distribution and sale of drugs," rather than the earlier policy of limiting regulation to the production and promotion of pharmaceuticals.

The Case of Sri Lanka

The emergence of modern medicine in Sri Lanka can be traced, again, back to the British colonial period which lasted for 150 years till 1947. The British evolved a health assistance scheme for the public sector in which they established a general hospital in Colombo and a number of district hospitals and dispensaries in the tea, rubber and coconut plantation areas. As in India, health care in Sri Lanka was (and still is) provided by both the public and private sectors, without any kind of comprehensive health scheme. The private sector was dominated primarily by indigenous medical practitioners in the rural areas, and a few practitioners of modern medicine in the major towns. By the mid-1970s, the number of modern medical practitioners had increased to about 1,000 in the private sector so that they provided 60 percent of health care in the private sector (Bibile, UNCTAD, 1977). There were about 2,200 doctors and

1,000 assistant medical practitioners employed by the public sector. Regarding indigenous practitioners (Ayurveda, Siddha and Unani), there were about 9,800 registered Ayurvedic physicians and 6,000 unregistered Ayurvedic physicians in the private sector, and about 300 Ayurvedic physicians in the public sector (Ministry of Health, Sri Lanka, 1974; also see Appendix, Table 15, p. 156). Health care in the public sector at present is under the aegis of the Ministry of Health, which provides almost 60 percent of the health services for Sri Lanka's approximately 14 million population (85 percent rural, 15 percent urban).

Pharmaceutical Research and Development

Sri Lanka is involved in negligible, if any, research and development activities in the pharmaceutical sector. The Marga Institute of Sri Lanka in collaboration with UNCTAD (1975a) has compiled a study analysing the mechanisms of technology transfers to Sri Lanka since 1945. They conclude that technology transfer agreements (between the private sectors in donor country and Sri Lanka, or inter-government agreements) have had tie-in clauses, restrictive practices and abuses of the contractual agreements, so that the actual transfer of technology was far below expectations or potential.

Pharmaceutical Products and Production

The expansion of the public sector health services took place after independence in 1947, with a concurrent rise in the size of the private sector. In this period, 1947 until the 1970s, there were

approximately 14 firms which were engaged in limited amounts of drug production, although most of their activities consisted of packaging and formulation of finished or intermediate "over-the-counter" drugs or non-prescription drugs. Most of the "ethical" or prescription drugs were imported in finished form. These imports were handled by 134 subsidiaries of foreign companies in the private sector, and by the Civil Medical Stores (now called the State Medical Stores) in the public sector.

Pharmaceutical Marketing and Promotion

Government regulation was first imposed on the public sector which operated on a relatively limited budget and suffered financial constraints as a result of physicians' prescribing practices which favored the more expensive brand-name products. In 1958, Senaka Bibile, then a professor of Pharmacology at the University of Colombo, was asked by the Minister of Health to advise the major public sector agency (namely, the Civil Medical Stores, renamed the State Medical Stores) on how to "rationalize" drug prescribing practices. Bibile recommended that the number of drugs used be limited to about 500 (1,000 formulations) that were 'needed,' and that they be listed under their generic names into a Hospitals Formulary. A Formulary Committee was appointed consisting of two physicians, a pediatrician, a surgeon and a pharmacologist. This Committee prepared the Formulary by reviewing the 1,000 drugs used in the public institutions, deleting obsolete or toxic drugs, and introducing new 'effective' ones.

Private sector imports were relatively unregulated until 1962, the year in which Sri Lanka experienced a severe adverse balance of payments, forcing the government to restrict imports on a number of goods, including drugs. Bibile notes, with some irony, "It is interesting that the principal motivation for these steps (regulation) came from economic and not therapeutic considerations" (Bibile, UNCTAD, 1977).

The Formulary Committee was asked to review and regulate the import of drugs through the private sector. This committee was then renamed the National Formulary Committee. It appointed a Drugs Subcommittee headed by Dr. N.D.W. Lionel, associate professor of Pharmacology, which reduced the number of drugs used from 4,000 (6,000 formulations) to 2,100 (3,000 formulations) (Lall and Bibile, 1977b). Thereafter, only those drugs could be imported or manufactured by the private sector that had been approved by the Drugs Subcommittee, although there was no restriction on the number of brands under which these could be imported, manufactured and sold. The prices of imports were also unregulated.

By 1970, the public sector purchased about 600 approved drugs on the world market by means of world tenders and "bid-buying" which ensured lower import prices than what the private sector paid for the 2,100 approved drugs imported under brand names.

The new government elected in 1970 made up of a coalition of three parties committed to a socialist ideology, recognized the "needless loss of foreign exchange on account of high import prices." Dr. S. A. Wickremasinghe (then a member of Parliament) and Professor

Senaka Bibile were appointed to review the import, manufacture and distribution of drugs on a national scale. They submitted their recommendations in 1971 regarding (a) the establishment of a state purchasing agency which would import all drugs required for the country with considerations to both quality and price, (b) reduction in the number of drugs imported, the use of generic names, and to amend patent laws (process patents would replace product patents) so as to obtain new drugs at the cheapest prices, (c) expand the frequency and circulation of the drug information publication The Prescriber, so that it could eventually replace drug advertising, (d) expand quality testing facilities in the Ministry of Health, and (e) to increase pharmaceutical formulation in the unutilized capacity of the 13 private factories (Wickremasinghe and Bibile, 1971).

Acting on these somewhat 'radical' recommendations, the government established the State Pharmaceuticals Corporation (SPC) in 1971 with Bibile as honorary chairperson. The SPC reduced the number of drugs in the private sector from 2,100 to 600, and almost entirely abolished brand names. The SPC began its work by a phased takeover of drug imports from 134 private sector importers during 1972 and 1973 and introduced a system of tender purchasing ("bid buying") for 65 percent of drugs.[12] This resulted in much lower

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[12]Pharmaceuticals were purchased by means of a world wide tender (WWT), restricted quotations (RQ), or monopoly quotations (MQ). The older, well established drugs like tetracycline, streptomycin, benzylpenicillin, etc., were purchased by means of world wide tenders. In 1975 such tenders comprised about 64 percent of SPC purchases. Restricted quotations comprised about 14 percent and monopoly quotations 22 percent of all purchases by the SPC in 1975. These are newer drugs or drugs where quality is critical, like cancer

prices for drugs and in considerable savings in foreign exchange (see Table 14). It demonstrates that the adoption of such a system placed Sri Lanka in a strong bargaining position vis-a-vis foreign companies which are now pressed to compete with one another to reduce their prices. Here is a classic case of a small, vulnerable country, committed to socialist goals, but using a "rational consumer" approach within a global free market economy. However, I will argue that such an approach was available to Sri Lanka, but Pakistan or India would not necessarily meet with comparable success if they were to adopt a similar policy. First, since Sri Lanka had no developed local manufacturing industry, her goals were much less ambitious than those of Pakistan or India, who sought further backward integration of their own industries through collaborative, contractual, etc. agreements with pharmaceutical TNC's. Sri Lanka's definition of self-reliance was far more modest, in that she sought to procure quality drugs at reasonable prices, at her particular 'stage of development.' Keeping in mind the relatively small size of Sri Lanka's population (14 million as against Pakistan's 70 million and India's 600 million) and the economies of scale that are important in drug manufacturing, further backward integration may not have been economically viable at all. The process of simple dosage form fabrication and packaging is economical even in small-scale factories, requiring no capital-intensive technologies. Her goal, therefore, was

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chemotherapy drugs. In a monopoly quotation there is only one known manufacturer for a drug and he is invited to quote a price. In restricted quotations there is more than one manufacturer and quotations are sought from manufacturers whose quality is assured.

TABLE 14.--Savings Achieved by the State Pharmaceutical Corporation Takeover of Finished Drug Imports (1972) (Ceylon rupees).

	Private Sector (First Half 1972)			SPC (Second Half 1972)			
	Suppliers	Average Weighted Price	Unit	Number of Tenders	Actual Price	Value of Purchase (Rs. 000)	Savings (%)
1. Tetracycline capsules (250 mg)	23	74.26	1000s	44	44.77	531.5	45.1
2. Chloramphenicol capsules (250 mg)	12	64.88	1000s	41	46.26	208.2	28.7
3. Sulphadimine tablets	7	22.62	1000s	31	11.60	112.7	48.7
4. Neomycin tablets	2	791.81	1000s	9	149.00	1.8	81.2
5. Phenylbutazone tablets L100 mg)	5	43.09	1000s	36	7.48	7.7	82.6
6. Phenylbutazone (200 mg)	8	79.88	1000s	37	11.76	33.2	85.3
7. Chloroquine tablets	6	41.68	1000s	34	28.23	14.1	32.3
8. Metronidazole tablets	5	170.02	1000s	21	22.26	17.7	86.9
9. Aspirin tablets	7	8.50	1000s	32	3.14	40.8	63.1
10. Chlorpromazine tablets (26 mg)	2	48.86	1000s	29	6.30	3.1	87.1
11. Hydrochlorothiazide tablets	1	139.40	1000s	3	10.98	3.3	92.2
12. Tolbutamide tablets	1	55.80	1000s	19	16.00	4.0	71.3

NOTE: Rate of exchange (1972): US$ = Ceylon rupees 6.18

SOURCE: Sanjaya Lall and Senaka Bibile, "The Political Economy of Controlling Transnationals: The Pharmaceutical Industry in Sri Lanka (1972-76)" in World Development, 5(8):691.

not to develop her own manufacturing capacities (at least at that time), and therefore, instead of having local manufacturers compete with TNC's in a market economy (as both Pakistan and India are attempting to do), she developed a process by which TNC's would compete with one another. Evidently, she may be exposing herself to new kinds of vulnerabilities within the global economy (for instance, the possibility of a "pharmaceutical cartel" similar to the oil embargo in 1973-74).[13]

This is not to suggest that there was no opposition to the drug policy that Sri Lanka adopted. The Wickremasinghe-Bibile report met with controversial reactions, and a great deal of opposition from various sectors (as described below). Thus, not all the recommendations were implemented, and some of the other recommendations were compromised. It is relevant to this discussion to recapitulate some of the events and reactions surrounding the socioeconomic and political environment in which this report was presented.

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[13]The possibility of such an embargo occurring in the case of pharmaceuticals is slender, as argued earlier in this paper (see page 54). First, no one country or group of countries maintains a monopolistic control over the raw materials that are required for the manufacture of active ingredients. Although a few TNC's do maintain competitive control over advanced pharmaceutical technology, a great deal of technology required for pharmaceutical manufacturing is 'stable,' and available to smaller manufacturing companies. Besides, alternative systems of therapy (traditional systems of medicine) exist in most developing countries and are being further developed. In the event of such an embargo, those most directly affected would constitute a largely urban minority: the consumers of modern medicine. The larger proportion of the population would either be only indirectly affected (as potential consumers of modern medicine) or not affected at all.

Sanjaya Lall and Senaka Bibile have presented an interesting account of the major 'actors' that were "directly or indirectly concerned with drug provision in Sri Lanka, and "that played a constructive or obstructive role in the implementation of the reform programme" (1977b:681).

The government that was elected in 1970 inherited a critical economic crisis and an adverse balance-of-payments from its predecessors. It was therefore supportive of the Wickremasinghe-Bibile recommendations as these would lead to savings in foreign exchange by restricting the number of drugs imported and their prices. However, the external debt of the country made it more vulnerable to "economic pressures from those opposed to the reform (in particular, the aid donor countries whose TNC's were threatened" (Lall, Bibile, 1977b). The Prime Minister, Bandaranaike, gave her full support to the SPC (until 1975), but with food shortages in the country, and political problems among various factions of her government, she backtracked somewhat from her strong support for pharmaceutical reform. It is interesting to note how food shortages retarded the policies of the SPC. In order to eradicate the food shortage problem, the Prime Minister accepted aid from Western countries and, therefore, had to weaken her prior strong stance against foreign pharmaceutical TNC's.

The members of the scientific community were the main intellectual force behind the reform. This community was composed of highly trained academicians and physicians.

The local manufacturing subsidiaries of TNC's opposed the reform. There were five large TNC's that had subsidiaries that were engaged in formulation and packaging of drugs in Sri Lanka in the 1970s (Pfizer, USA; Glaxo, UK, Warner-Hudnet, USA; Unical, for Burrough's-Wellcome, UK; and Reckitt and Colman, UK) which accounted for about 75 percent of all drug production. Two local companies that were producing under license for TNC's accounted for 22 percent of local drug production. The remaining seven companies were small locally owned ones that largely produced only skin applications (Lall and Bibile, 1977b). Joseph Stetler, President of the Pharmaceutical Manufacturer's Association (USA) wrote a letter to the Prime Minister of Sri Lanka and argued against the reforms. Further, when the SPC decided to purchase not only finished drugs, but also bulk chemicals for the production of a limited number of drugs locally (called the 34-drug programme) there was much greater resistance from TNC's. The five TNC subsidiaries absolutely refused to purchase their bulk chemicals from the SPC, and eventually the program was scaled down to include only fourteen drugs. Because of stern warnings from various government agencies, four subsidiaries agreed to comply to the fourteen drug program. Pfizer held out. In 1974, the SPC and the Minister of Industries recommended having Pfizer's subsidiary nationalized. Lall and Bibile recount how the U.S. Ambassador personally approached the Prime Minister on the issue with the result that Pfizer was not nationalized and the SPC was ordered to "continue negotiating" with Pfizer with no further

disciplinary action. Stetler again strongly advised the Prime Minister of Sri Lanka against taking measures against Pfizer.

Although local subsidiaries of TNC's opposed these reforms, certain foreign TNC suppliers welcomed these measures, since they are also competitive suppliers in the generic drugs market. (For example, Hoffman La Roche competes in both brand name and generic name drugs, selling both very expensive tranquilizers and very inexpensive vitamins).

The medical profession and professional organizations such as the Sri Lanka Medical Association (SLMA) were convinced that the brand name products of foreign manufacturers were superior to the local ones, and therefore opposed many of the recommendations of the Wickremasinghe-Bibile report. The physicians, chemists and pharmacists were not familiar with the generic name equivalents and preferred to prescribe and dispense well-known brand names.

As had happened in the case of Pakistan, the leading manufacturers emphasized their superior quality control facilities, and thus sought to maintain, or increase, their market power. However, the Government attempted to ensure that the public's confidence in products manufactured by smaller companies would not be undermined, and therefore imported only those drugs that had been screened for quality overseas (for example, by the FDA in the United States). Also, all drugs that had been disapproved by the FDA, but were still marketed in Sri Lanka, were removed.

The recommendations of the Wickramsinghe-Bibile report concerning the revision of the patent laws was not implemented.

Although the government did nothing to amend the strong process and product patent protection it offers, the SPC decided to buy patented drugs from non-patent observing sources. This resulted in financial savings for Sri Lanka. To cite one of the more extreme examples, one of Roche's patented drugs, Diazepam, was purchased from Ranbaxy (India) for less than $200 when the TNC quoted $7,760, which represented a savings of 97 percent (Lall and Bibile, 1977b). Although patent holders warned against this kind of practice, the process of fighting a court battle had been too cumbersome for them to take, particularly in an ideologically socialist country. Although one can critically question the ethics of such a measure, the SPC tended to rationalize it on the grounds that Sri Lanka receives no benefits from the TNCs' research and development investments so therefore should not be subjected to paying the costs of such investments.

The overall savings accruing to the Sri Lankan economy through her global purchases has been tremendous as was evident in Table 14. However, the life-span of the SPC tended to be short. Bandaranaike's government was replaced by a more right-wing party in 1977. But even when she was still in power, Bandaranaike's own initial support for the SPC's reforms dwindled in the mid-1970s, leading to disenchantment among the SPC's staff. Bibile and other staunch supporters of the SPC resigned from their positions when there was lack of support for the SPC from the Government.

CHAPTER IV

SUMMARY AND CONCLUSIONS: IMPLICATIONS FOR POLICY IN DEVELOPING COUNTRIES

The comparative case studies illustrate diverse attempts of three countries to achieve a degree of self-reliance in their pharmaceutical sector (and nationally). These three cases often have been referred to in academic circles globally as classic examples illustrating the successes/failures of developing countries in their dealings with TNC's.

Some generalizations can be made regarding the heritage of these three countries. India, Pakistan and Sri Lanka share similar cultural values and also have common disease patterns. All of them were previously British colonies, and achieved independence at about the same time in 1947. Since then, each was faced with immense concerns regarding nation-building and development. Sri Lanka inherited a plantation-based economy with tea, rubber and coconut being her main exports. The prices of these goods fluctuated according to global market fluctuations in demand and supply. An economic crisis occurred in the 1960s when the price of these goods fell on the international market concurrent with a food crisis, that instigated the government to diversify its industrial sector. Pakistan, in the chaos of partition from India, had to re-create a

new nation-state with political leadership. Most pharmaceutical facilities established by the British in the major cities had been located in the geographical area that became part of India after partition in 1947. India experienced similar "birth-pangs of a new nation" and inherited a pharmaceutical sector largely dependent on British manufacturers for modern medicine. All three have embarked on intensive economic and social development efforts through local effort, international technical assistance and by encouraging private foreign investment by foreign companies.[14]

The pharmaceutical industry in each of these countries was dominated by TNC's in terms of market shares, the proportion of patents held, and the ability to charge higher prices for their brand name products than what their local counterparts in the host country could charge. These all resulted in foreign exchange costs above what the foreign exchange earnings of these countries were. On the other hand, given the research-intensive high cost nature of pharmaceutical manufacturing and innovation, one can question whether these countries could have fulfilled their immediate (or even long-range) need for medical care resources without some form of foreign technical assistance or foreign investment.

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[14]Although Pakistan and India had opened their doors to private foreign investors by the 1950s and early 1960s, a similar trend in Sri Lanka was more slow in coming. The Marga Institute report (UNCTAD, 1975a) describes how TNC's were reluctant to invest in Sri Lanka because of the less profitable prospects of investing in Sri Lanka's economy which had a small population and a political uncertainty due to changes in ideology with changes in government. Sri Lanka therefore had to increase her efforts to assure TNC's that they would not be nationalized, provide strong patent protection and lower their trade tariffs and barriers.

As they became more aware of their growing dependence on foreign drugs, India, Pakistan and Sri Lanka have undergone dramatic reversals in policy from their earlier "open door" economies to increased public sector participation, government controls and regulations. Sri Lanka's policies have been more dramatic than either Pakistan's or India's. Policies designed to regulate the restrictive business practices of TNC's met with greater success in Sri Lanka than in Pakistan or India.

Sri Lanka had a lesser degree of foreign investment than did the other two countries. Most of her drugs were imported in finished form, so that there was little capital investment in manufacturing facilities within the country. Economically, Sri Lanka had less to lose than either Pakistan or India, both of which had immense capital investments in their pharmaceutical industries and in fees to technical consultants and TNC's, and in collaborative agreements with TNC's. Further, one could hypothesize that opposition from foreign TNC's to strong regulative policies would not be as strong in the case of Sri Lanka as in Pakistan or India, given the relatively small investments of TNC's in Sri Lanka, and her small market size. In addition, Sri Lanka's manufacturing facilities were at a preliminary stage, so the global technology for intermediate and basic drugs were stable and standardized and quite readily available from East European and developing countries (e.g., India, Brazil, and Italy) at relatively cheaper prices. The patents on these "stable technology" drugs have often expired, so that additional savings are obtained by not having to pay the greater costs of patented drugs.

This suggests the possibility that Sri Lanka will be "one step behind" and may not be able to bridge the so-called "technological gap" in the next few years.

India's experience in moving toward self-reliant development has been markedly different. In order to further expand the research and development base in her pharmaceutical industry and to reap the benefits of the latest drug innovations, India has as her competitors in the manufacturing of modern drugs, the advanced pharmaceutical TNC's. Her local manufacturers, therefore, compete with these "corporate giants." In many cases, however, the Indian government has undertaken the policy of encouraging local firms to collaborate with foreign ones (through joint ventures, contractual agreements, licensing, etc.) with a view to having foreign skills and technology transferred to local entrepreneurs. Although the Indian government had considered taking more radical steps against TNC's (like nationalization) these were rejected in favor of more moderate policies, as India did not have the resource base to implement more radical measures.

Pakistan also chose a policy by which she would encourage her local manufacturers to compete with the more advanced foreign drug companies in the production of pharmaceuticals, but at the same time she was largely dependent on foreign companies for the fruits of their research and development activities.

How are we to assess which of these countries made greater strides toward self-reliance than the other? Is India, with her pharmaceutical industry that has achieved sufficient backward

integration to incorporate research and development activities, more self-reliant than Pakistan's pharmaceutical industry, whose activities consist primarily of packaging and dosage formulation? Is Pakistan's pharmaceutical industry more self-reliant than Sri Lanka's which is based on an import economy? Thus, does greater backward integration in pharmaceuticals (from importation of finished products; to dosage formulation, packaging, etc.; to the manufacture of active ingredients; and finally, to applied, and then basic, pharmaceutical research and development) necessarily mean greater pharmaceutical self-reliance? Backward integration in this form almost certainly implies growth in the endogeneous pharmaceutical sector; but this is not to be confused with self-reliance, which incorporates not only growth but also 'social justice' and the equitable distribution of the products of this growth both within, and between, countries. The degree of backward integration in the pharmaceutical sector cannot alone be taken as an adequate measure of pharmaceutical self-reliance. Thus, if the ideal situation is one in which the product structure of the pharmaceutical industry corresponds to the disease pattern of the country, the price structure matches the income levels of the population, and drugs are available to all those who may require them, then a country like Sri Lanka, with little or no backward integration, can be as self-reliant as India is, despite the latter's more advanced industrial capacity.

Because of the evolution of an interdependent global system, highly advanced growth in every sector of the economy is not a venture

that is equally viable for every nation to undertake. Growth of an industrial sector in one country (like the pharmaceutical industry in India) may not be equally viable in economic terms for another (as for example, in Sri Lanka, where a population size of approximately 14 million, and an even smaller consumer market, would not be conducive to obtaining economies of scale in production). The problem for development for both scholars and planners is not so much one of how to promote industrial growth, but of how to resolve the seeming paradox of "self-reliance with interdependence." Hence, are the goals of self-reliant development and global interdependence complementary or conflicting? Although there are no straightforward answers, there are some insights to be gained by comparatively examining the issues in the context of the pharmaceutical industries in India, Pakistan, and Sri Lanka.

The only way in which a country can become self-reliant in her pharmaceutical sector without the concurrent development of her pharmaceutical industry is by maintaining a symmetric, interdependent relationship with other actors in a world system. However, to maintain symmetrical interdependencies between countries, there need also be reciprocal vulnerabilities. For instance, Sri Lanka's vulnerability in her pharmaceutical sector may be counterbalanced by her strength in another sector (for example, tea). She could then exchange tea for pharmaceuticals. With regard to reciprocal vulnerabilities, Mazrui maintains (1975) that "mature interdependence"[14]

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[14]"Mature interdependence" is what Mazrui calls the third stage of interdependence. The first and second stages are what he

is the stage when different parties

> must not only need each other--their different needs also must be on a scale that enables serious mutual dislocations in case of conflict. The combination of an egalitarian ethic and reciprocal vulnerability within a framework of wider technological and intellectual frontiers provides the essence of mature interdependence (Mazrui, 1975:39).
>
> . . . The principle of reciprocal economic vulnerability would help to consolidate genuine symmetrical interdependence. The price of such interdependence is the ability to harm each other as genuine equals. The fear of such reciprocal harm should help to deter irresponsible and one-sided ventures (Mazrui, 1975:53).

The situation, however, is far more complex than attempting to maintain symmetric interdependence and reciprocal vulnerabilities. Who, for instance, is to decide which products have greater or lesser priority than others? Does the United States need Sri Lanka's tea as much as Sri Lanka needs the United State's pharmaceuticals? What other countries are willing to meet the United States' demand for tea and Sri Lanka's demand for pharmaceuticals? If Sri Lanka decides to use her tea as an economic weapon by stopping exports of tea to the United States, is the action going to hurt Sri Lanka's economy more than it hurts the United States' economy?[15] Thus, it

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calls "primitive interdependence" and "feudal-imperial" interdependence," respectively. See Ali A. Mazrui, "The New Interdependence," in Guy F. Erb and Valeriana Kallab (eds.), Beyond Dependency: The Developing World Speaks Out, Overseas Development Council (September 1975), pp. 38-56.

[15]The same question is being raised, at present, in the context of the United States' withdrawal of grain supplies to the U.S.S.R. Has this loss of the Soviet market for grains hurt the U.S. economy more than the loss of U.S. grains has affected the Soviet economy?

is not difficult to see how extremely vulnerable Sri Lanka was when her determination to move toward "self-sustaining growth" in the pharmaceutical sector had to be compromised because of her lack of food supplies. This incident also makes it somewhat evident that all the industrial sectors of a society are complexly interrelated with one another and with the global economy. With global interdependence, there is also an increasing awareness of intranational interdependence between various sectors. Therefore, it is not meaningful to talk of "pharmaceutical self-reliance" without viewing it in the perspective of overall national self-reliance, and one's vulnerabilities in relation to the world system.

If all countries were to become reciprocally vulnerable, would this be a necessary and sufficient condition to ensure symmetrical interdependence, and consequently, self-reliant development? Reciprocal vulnerability is certainly a necessary condition for self-reliance, but not a sufficient one. Parmar (1975:6) addresses this issue when he maintains that self-reliant development cannot be measured simply in terms of a balance-of-payments sheet, but encompasses larger 'structural changes'

> . . . to promote social justice, to utilize the economy's most abundant resources, to engender public participation in the development process, to reduce the concentration of economic power, [and] to assist in the establishment of more egalitarian patterns of international economic relationships.

If these structural changes are indeed the goals of self-reliant development, one can then question the pharmaceutical policies of India, Pakistan and Sri Lanka. Most of the policies

undertaken by these countries have been largely motivated by managerial and economic, rather than social considerations.[16] Besides resulting in foreign exchange savings for the government, the price controls imposed on foreign pharmaceuticals directly benefit the upper- and middle-class minority that consumer modern medicine. Undoubtedly, these policies were also projected to benefit other socioeconomic classes who comprise the large majority of those who did not purchase modern medicine, by assuming that economies of scale in production, and hence reduced prices, would make drugs more affordable to the poor. However, there has been little or no follow-up research conducted to determine whether this occurs. Although data are available on per capita consumption of pharmaceuticals in various countries, the measure is inadequate in providing information on whether higher per capita consumption represents a wider distribution of pharmaceuticals by socioeconomic strata, or the increased consumption of those in the higher echelons who already were purchasers of pharmaceuticals. The unequal access of various socioeconomic strata to the benefits of modern drug therapy in part represents the failure of earlier "trickle down theories" in which proponents of the modernization paradigm assumed that the benefits of development received by an upper- and middle-socioeconomic class would filter down to also benefit the masses.

Many of the steps taken by India, Pakistan and Sri Lanka represent attempts made by each of these countries to overcome their

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[16] As also observed by Senaka Bibile in reference to Sri Lanka, quoted on page 108 of this paper.

dependence on foreign drugs and to develop effective means of bargaining with TNC's. Posed within the dependency paradigm, one may question whether it is possible for a less industrialized country to achieve self-reliant development so long as it remains a member of the capitalist world system. Parmar's views on the subject reflect a modification within the dependency paradigm and a move away from an earlier neo-Marxian approach as incorporated in the 'dependencia' literature. He maintains that within an interdependent global system,

> it would be a mistake to view developing countries' pursuit of self-reliant development as necessarily leading to their withdrawal from world economic systems and to the subordination of international trade to programs dealing with domestic and social policies (Parmar, 1975:4).
>
> . . . developing countries have good reasons to support the liberalization of trade and other changes in the economic relationships between North and South, providing that these links promote international economic justice and contribute to a process of self-reliant development (Parmar, 1975:17).

In Chapters II and III both the costs and the benefits ensuing to developing countries as participants in international trade were discussed. The severe economic and social costs incurred have motivated India, Pakistan and Sri Lanka to contemplate taking drastic measures against TNC's, but they have had to comprise their stance in favor of less radical policies because of their vulnerable position within the world system. All three countries have developed tools to bargain with TNC's whereby they can undermine their asymmetric vulnerabilities vis-a-vis TNC's. However, it is necessary to examine what further options are available to India, Pakistan and

Sri Lanka to enable them to interact as more egalitarian participants in a global system.

In exploring what options are available to developing countries other than continuing with the asymmetric relationships they currently maintain with pharmaceutical TNC's, one must not overlook the immense potential that exists in many of these countries for developing indigenous systems of medicine. Table 15 (Appendix A) presents data that show the proprotionately greater number of indigenous medical practitioners relative to the number of physicians and pharmacists in India, Pakistan and Sri Lanka. Data presented earlier in this paper also indicate that a large proportion of the population in these countries rely more on these indigenous practitioners for therapy than they do on physicians.[17] Recent trends in

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[17]On the topic of traditional medical systems in India, see G. Morris Carstairs, "Medicine and Faith in Rural Rajasthan," and McKim Marriott, "Western Medicine in a Village in Northern India," both in Benjamin D. Paul (ed.), Health, Culture and Community (New York: Russell Sage Foundation, 1955). Carstairs discusses the cultural and moral obstacles to the acceptance of western medicine by the villagers in rural Rajasthan. The villagers attributed causation and cure of physical illness to divine and supernatural forces. Carstairs maintains that the western medical practitioner will be unsuccessful in diffusing modern drug therapy so long as he fails to recognize, and adapt to, local cultural expectations. Marriott points to the conflict in roles between indigenous and western medical practitioners as obstacles to the spread of western medicine. Marriott concludes that indigenous folk-medicine flourishes in India far more than western medicine because of the former's "successful adaptation to the fundamentals of village social organization" (p. 250). The only time the villagers would consume western drugs was when these were offered free of charge in hospitals and government clinics, although they were willing to pay high prices in terms of money and gifts to faith healers, priests, etc.

These studies indicate that low prices of 'modern' drugs will not guarantee the diffusion of 'modern,' scientific drug therapy to rural areas unless accompanied by increased faith in the effectiveness of science-based medicine among the pre-literate rural population.

UNIDO and some countries (like India) indicate that Ayurvedic medicine is being given a new boost, and advanced research centers are being created to explore these possibilities. Many developing countries (like Sri Lanka) now employ trained and licensed practitioners of Ayurvedic medicine in their public sector enterprises. Questions need to be raised in future research endeavors exploring the extent to which therapeutic needs can be met by indigenous medical practitioners, and to what extent the expansion and development of this traditional sector provides a viable alternative to modern drug therapy. The expansion of traditional medicine reflects the goals of the appropriate technology movement: small scale growth, decentralization, and resource-utilization.

The last few decades have witnessed the growth of a new pattern of interdependence on the global scene. The leaders of developing countries have appealed for greater solidarity among themselves, emanating from their common disenchantment with prior international trade relations that operated to their disadvantage. This solidarity is reflected in their united appeal for a New International Economic Order, in their recommendations for the revision of the international patent system, in the creation of the Group of 77, the Andean Pact, and in the establishment of OPEC. This kind of solidarity among developing nations has created new options for countries that are the least industrially advanced. Intra-developing

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Moreover, for the rural population, prices of drugs are not the dominant factor influencing their choice of 'medical' therapy, as assumed by development planners in India, Pakistan and Sri Lanka, in their designing of pharmaceutical policies directed, predominantly, at price controls.

country transfers of technology provide strong competition to bilateral trade agreements between developed and developing countries, and to technology transfers from TNC's to developing countries. In the case of the pharmaceutical industry, the transfer of pharmaceutical technology between developing countries is gaining momentum, particularly since some countries like Brazil, India and Mexico possess 60 percent of the technology required for bulk chemicals in the list of essential pharmaceuticals (Lall and UNIDO, 1978b). Lall (UNIDO, 1978b:19-20) maintains that:

> These countries (Brazil, India and Mexico) are able to assist less industrialized countries in setting up and expanding their pharmaceutical industries, offering some advantages over the traditional process of transferring technology through transnational corporations, such as:
>
> (a) The terms they offer are extremely competitive. This is especially true of public-sector enterprises, which set up complete plants in other developing countries on a cost-plus-commission basis;
> (b) Practically no restrictive conditions are attached;
> (c) Equity participation by the seller of technology is usually kept to a minimum, enabling recipient countries to build up an independent industry;
> (d) Since enterprises in developing countries have little stake in brand names, the recipient can use the technology to sell the products under generic names. (However, as indigenous enterprises grow, they also tend to invest money and effort into developing brand-named products);
> (e) The technology may be better adapted to the conditions of developing countries in terms of scale, skills, capital intensity, formulation and packaging;
> (f) The developing country selling the technology can earn foreign exchange that would otherwise have gone to a developed country.

The transnational scientific community that comprise the membership of the international organizations (for example, the United Nations organization and its agencies, and the World Health

Organization, etc.) have perhaps been one of the foremost leaders in taking steps to resolve asymmetric interdependencies. UNIDO has committed itself to encouraging the transfer of technology between developing countries, and to promoting domestic production in these developing countries to enable them to be more self-reliant with regard to pharmaceuticals. Elsewhere, the Lima Declaration and the Plan of Action on Industrial Development and Cooperation (ID/Conf.3/31, Chapter IV) declared the pharmaceutical industry as one of the industries selected "for the negotiation of the relocation of productive facilities from the developed to the developing world." A resolution passed at the Fifth Conference of Heads of State or Government of Non-Aligned Countries (Colombo, Sri Lanka, 1976) seeks to enforce solidarity between developing countries, and consequently mitigate asymmetric interdependencies (see the text of the resolution in Appendix B). Perhaps the most unique proposal included in the resolution regards the creation of regional Co-operative Pharmaceutical Production and Technology Centers (COPPTECs). The United Nations Action Programme on Economic Co-operation (UNAPEC) has developed a Joint Task Force drawing members from the World Health Organization (WHO), United Nations Conference on Trade and Development (UNCTAD) and the United Nations Industrial Development Organization (UNIDO), to implement the resolution passed first in Colombo in August 1976, and later by the Group of 77 in Mexico (Lall and UNIDO, 1978b:3). These COPPTECs are designed

> to coordinate research and development, facilitate the transfer of technology, collect and disseminate information on pharmaceutical uses and prices and on the technological

> capabilities among member countries and also to coordinate the production and exchange of drugs between different member countries as well as between different regional centers.

In this regard, UNIDO has already prepared feasibility studies for the establishment of regional pharmaceutical plants. Acting on the recommendations of a study carried out by UNIDO and the Industrial Development Center for Arab States, the Arab Company for Drug Industries and Medical Appliances was established by fourteen Arab countries. Feasibility studies for cooperative antibiotic production by the Andean Pact countries have also been conducted by UNIDO. Because of the common pharmaceutical needs of India, Pakistan and Sri Lanka, the possibilities of strengthening regional cooperation in the field of pharmaceuticals between these countries are clearly immense.

In light of the emergence and strengthening of solidarity between developing countries, social scientists need to take fresh stock of what implications this has for global interdependence, national self-reliance and dependent development. As sociologists we need to refine our conceptual tools to understand not only bilateral conflicts between core and peripheral countries, but to also understand conflicting and complementary interactions between nation-states and other major global actors, such as TNC's, international agencies and transnational scientific communities. The emergence of new patterns of interdependencies warrant the incorporation of new focuses in framing research questions. Thus, are the goals of global interdependence, national self-reliance and regional solidarity

complementary or conflicting? Will regional solidarity intensify a North-South confrontation,[18] or will it lead to a more egalitarian interdependent relationship between developing and developed countries?

Goulet (1976:29) argues that two misconceptions regarding mutually interdependent growth need to be avoided. The first

> is unduly optimistic and imagines that a just order of mutual interdependence can be built in ways which will benefit everyone and cause loss to no one. Obviously, some areas of mutually compatible interests can be found; these should be consciously identified and developed. Nevertheless, a comprehensive strategy for restructuring the international order must deal with incompatible interests as well as with areas of agreement.

The second misleading view that he rejects is

> that any concessions made to oppressed groups will harm the privileged classes in their vital interests. This formulation ignores the fact that not all the interests of the latter are vital. Nevertheless, 'vital interests' must be redefined, because the present heritage of structural injustice is so heavy that no new 'social compact' founded on reciprocal solidarity can be obtained without entailing some losses to groups now privileged.

With the strengthening of regional solidarity, sociologists need to focus not only on relations between developed and developing countries, but also on relations between the developing countries themselves. Consequently, will regional solidarity undermine the goals of national self-reliance of weaker countries by creating new dominant-dependent relationships between developing countries, or

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[18] It is possible to envisage an egalitarian inter-dependence based on global conflict and hostile confrontation, provided there are reciprocal vulnerabilities. However, the goals of global inter-dependence are not so much to aggravate conflicts, but to develop mutual and complementary goals.

will it strengthen the position of more vulnerable nations by creating mutual support systems between cooperating countries? Whatever the answer to these questions, the implications are more promising for developing countries in that they are faced with newer policy options. The appeals for solidarity, self-reliance and mutual cooperation present alternatives to the existing system of asymmetric interdependence, and lay the corner-stone for building a new kind of moral order. We must look forward to a new set of research questions on the consequences of these changes on the social structure and culture of the scientific community and the institutions at the center of national societies in various kinds of interdependency.

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APPENDICES

APPENDIX A

MEDICAL PERSONNEL, NUMBER OF HOSPITALS AND BEDS IN INDIA, PAKISTAN AND SRI LANKA

TABLE 15.--Medical and Allied Health Personnel in India, Pakistan and Sri Lanka.

Country Occupation (Population in thousands)	Absolute Numbers of Medical Personnel	Medical Personnel per 10,000 Population	Population per Medical Personnel
I. INDIA, 1975 (598,097)			
Physicians	146,000[a]	2.4	4,100
Pharmacists	66,360[a]	1.1	9,010
Practitioners of traditional medicine	184,584	3.9	3,240
II. PAKISTAN, 1975 (70,260)			
Physicians	17,929[b]	2.6	3,920
Pharmacists	999[c]	0.1	70,330
Dispensers	9,787	1.4	7,180
"Ayurvedic doctors"	588	0.1	119,490
"Herb doctors"	33,214	4.7	2,120
"Homeopathic doctors"	13,679	1.9	5,140
III. SRI LANKA, 1972 (13,033)			
Physicians	3,251	2.5	4,010
Pharmacists	455	0.3	28,640
Dispensers	900	0.7	14,480
Medical Assistants	1,337	1.0	9,750
"Ayurvedic doctors"	10,116	7.8	1,290

SOURCE: Compiled by the author from data presented in World Health Statistics Annual, Volume III (Geneva: World Health Organization, 1977).

[a]Preliminary, approximate or estimated data.

[b]Number on the register. Not all working in the country.

[c]Incomplete data.

TABLE 16.--Hospitals, Other Medical Establishments and Number of Beds in India, Pakistan and Sri Lanka.

Country (Population in Thousands) Category of Establishments	Number of Establishments	Number of Beds	Population per beds	Beds per 10,000 Population
I. INDIA, 1969 (536,980)				
Total Establishments	14,286	331,633	1,620	6.2
II. PAKISTAN, 1975 (70,260)				
Total Establishments	1,345	33,948	2,070	4.8
Government Hospital Establishments	1,052	27,352		
Private Non-Profit Hospital Establishments	10	1,800		
Private Profit Hospital Establishments	283	4,796		
III. SRI LANKA, 1973 (13,249)				
Total Establishments	456	39,732	330	30.0

SOURCE: Compiled by the author from data presented in World Health Statistics Annual, Volume III (Geneva: World Health Organization, 1977).

APPENDIX B

TEXT OF THE "RESOLUTION ON CO-OPERATION AMONG DEVELOPING COUNTRIES IN THE PRODUCTION, PROCUREMENT AND DISTRIBUTION OF PHARMACEUTICALS," PASSED AT THE FIFTH CONFERENCE OF HEADS OF STATE OR GOVERNMENT OF NON-ALIGNED COUNTRIES HELD AT COLOMBO, SRI LANKA, 1976

APPENDIX B

"*The Conference,*

"*Recalling* the Non-Aligned Action Programme for Economic Co-operation among developing countries adopted at the Conference of Foreign Ministers of Non-Aligned countries in Georgetown in August 1972, and approved at the Fourth Summit held in Algiers in September, 1972,

"*Recalling* also the Economic Declaration of that Summit calling for the further strengthening of economic co-operation among developing countries,

"*Noting* the inclusion of the production and distribution of medicine and medical substances in the Lima Programme for Mutual Assistance and solidarity as an additional area of co-operation among developing countries,

"*Bearing in mind* the possibilities for joint action by developing countries, identified in the study commissioned by UNCTAD on major issues in the transfer of technology to the developing countries in the pharmaceutical industry,

"*1. Endorses* the recommendations of the Group of Experts on Pharmaceuticals which met in Georgetown in July 1976 and which proposes among other things:

"*(a)* The preparation of a list of priority pharmaceutical needs of each developing country and the formulation of a basic model list of such needs as a general guideline for action by the developing countries;

"*(b)* The establishment of a national buying agency to undertake the purchase and supply of pharmaceuticals;

"*(c)* That in the context of the revision of the industrial property systems, consideration be given to excluding pharmaceutical products from the grant of patent rights or alternatively the curtailment of the duration of patents for pharmaceuticals;

"*(d)* The elimination, wherever possible, of brand names and the acoption of the generic names for pharmaceuticals; and provision of information only from official sources;

"*(e)* The establishment by each developing country of its own pharmaceutical industry as appropriate, beginning with formulation and packaging and building up to more complex production activities;

"*(f)* The creation of regional Co-operative Pharmaceutical Production and Technology Centres (COPPTECs), as proposed by UNCTAD and UNIDO, in order to draw up drug lists, to co-ordinate research and development, facilitate the transfer of technology, collect and disseminate information on pharmaceutical uses and prices and on the technological capabilities among member countries and also to co-ordinate the production and exchange of drugs between different member countries as well as between different regional centres;

"2. *Invites* the relevant international organizations such as UNCTAD, UNIDO, WHO and UNDP to assist in the achievement of the objectives outlines in operative paragraph 1 above with particular regard to the establishment of appropriate National Pharmaceutical Centres in developing countries and Regional Co-operative Pharmaceutical Production and Technology Centers (COPPTECs) among them.

"3. *Decides* further that the co-ordinator of the trade, transport and industry sector of the Non-Aligned Action Programme for Economic Co-operation among developing countries should take the necessary follow-up action to ensure early implementation of the provisions of this resolution."

SOURCE: "Resolution on co-operation among developing countries in the production, procurement and distribution of pharmaceuticals," Fifth Conference of Heads of State or Government of Non-Aligned Countries, Colombo, Sri Lanka, 1976, A/31/197 (Annex IV: Political and Economic Resolutions NAC/Conf. 5/S/Res.25), cited in Sanjaya Lall and United Nations Industrial Development Organization, The Growth of the Pharmaceutical Industry in Developing Countries: Problems and Prospects (New York: United Nations, 1978), pp. 29-30.