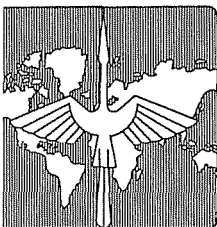


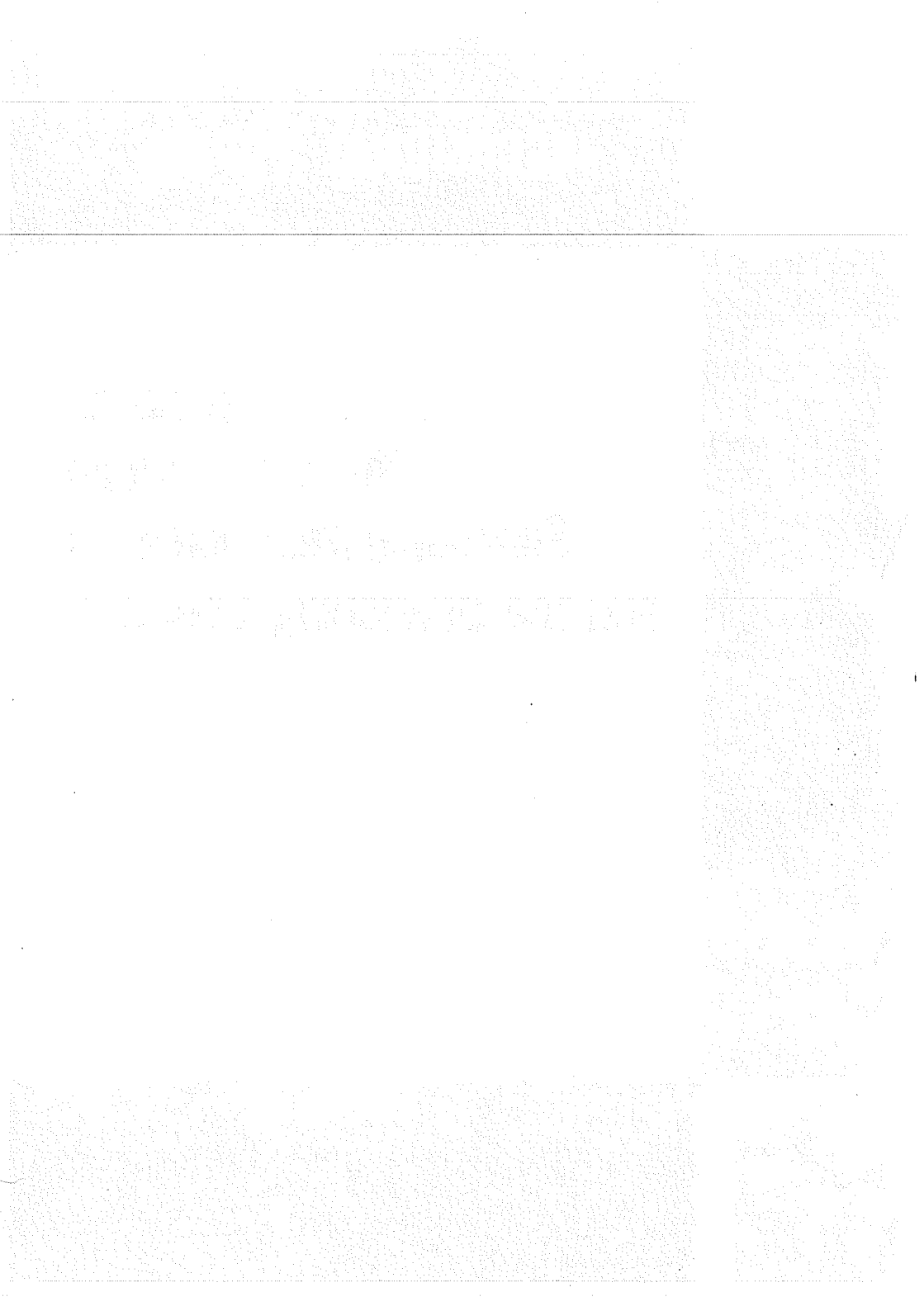
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**Trademarks,  
the International  
Pharmaceutical Industry,  
and the Developing Countries**

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## INTRODUCTION

There are several reasons why an examination of the impacts of trademarks in the pharmaceutical industry on the developing countries is opportune. First, the nature of supply and consumption is strongly conditioned by the trademark system. Second, the pharmaceutical sector is the most important internationally as far as the registration of trademarks is concerned - what happens here has a powerful influence elsewhere. Third, an internationally recognised alternative to brand names<sup>1</sup> as an identification method, namely the use of generic names, exists and is in fact used to varying degrees by different countries. This implies that policies which wished in any way to restrict the role of trademarks could be constructed upon a solid foundation. Fourth, very few industries exhibit the compelling social significance which is a hallmark of pharmaceuticals and few involve the complex pattern of relations associated with the industry. Medical doctors, pharmacists, individuals as patients, the social services, and the large chemical groups are all intimately concerned with the directions this industry has taken and might take in the future. As an introduction which simultaneously confronts the reader with several of the bedrock issues, the following paragraphs elaborate briefly the four reasons for interest that have just been given.

The value of drug production in 1971 has been estimated at approximately \$21 billion (excluding the socialist countries of Eastern Europe and China - important exceptions since they may be significant sources of supply for several generic drugs). About 10 per cent of this output was produced in developing countries, with a high concentration in India, Brazil, and Mexico which accounted for some 56 per cent of the developing country total.<sup>2</sup> Though developing countries have some 70 per cent of the world's population they account for only 20 per cent of world consumption<sup>3</sup> with per capita figures probably not in excess of \$5 in Latin America and perhaps between \$1 and \$2 in Asia and Africa. Yet, due to the highly unequal distribution of income, this consumption corresponds to limited segments of the population only - the Hathi Committee in India estimated that only around 20 per cent of the Indian population uses modern drugs.<sup>4</sup>

The number of products, and still more the variety of presentations under which they are sold, is very high in almost all countries. Statistics on the number of

presentations indicate that in Belgium there were 9,000 on the market; in France 8,500; in Federal Germany 24,000; in Italy 21,000; in Spain 12,400; in the UK 9,000; in the USA anywhere between 14,000 and 35,000; and in developing countries, Brazil 14,000; Colombia 15,000; India 15,000; and it has been said that in Mexico there may be as many as 80,000 items on the market.<sup>5</sup> Given the striking degree of product differentiation, it is scarcely surprising that promotion costs as a proportion of sales are also high, usually accounting for at least one-sixth and sometimes greater than one-quarter of sales.<sup>6</sup> *The costs of promotion are well in excess of those for research and development, often by a factor of 3 or more: above all else pharmaceuticals is a marketing intensive industry.*

Studies in various countries have underlined the pivotal role played by the pharmaceutical sector as a user of the trademark system. Thus a study of *Ethiopia* found that around one-third of all trademarks registered were in pharmaceuticals;<sup>7</sup> an analysis of 845 contracts deposited with the National Register of Contracts for the Licence and Transfer of Technology in *Argentina* in 1972 and involving trademarks (either alone or linked with patents and technical assistance) showed that pharmaceuticals was a dominant sector;<sup>8</sup> for *Mexico* an examination of a sample of 618 contracts containing trademarks and accepted for registration by the government between 1 February 1973 and 31 December 1975 showed pharmaceuticals as one of the principal industrial branches involved;<sup>9</sup> while in *Ireland* calculations based on the international (Nice) classification of trademarks demonstrated that

on average, registrations for the chemical classes 1-5 together make up about 40 per cent of the total registration each year. This is over twice the number coming forward from any other identifiable industry grouping (e.g. engineering classes 6-12 include only 15-18 per cent of registrations). Even food, drink and tobacco taken together do not produce more than about 20 per cent of annual registrations. Taking individual classes, the number of registrations in Class 5, which includes pharmaceutical substances, has consistently been the largest with a comfortable margin over the next biggest class... Trademarks in the pharmaceutical class appear to be uniquely important. The sheer numbers of applications to register in Ireland for Class 5 far outweigh those for any other class -

they generally account for around 20 per cent of the total number in any one year.<sup>10</sup>

In any field generic names, i.e. words or phrases which describe objects of a particular kind, either acquire the status of 'standard words' through repeated and familiar usage, or are created expressly to serve that purpose - it is the latter which has occurred with pharmaceuticals. Drugs can be defined by a chemical name consonant with standard nomenclature in chemistry; in many instances, however, the resulting names are very long and involved. With the increase in numbers and complexity of drugs, names simpler than the chemical ones were adopted and included in national pharmacopoeias, such as those of the UK and the USA. International distribution of drugs, however, resulted in a situation where different names were employed in different countries, a situation both confusing and potentially dangerous. The World Health Organisation was thus requested to assist in the establishment of a list of acceptable 'International Non-Proprietary Names' - this has been done and is adopted by most countries and quoted in the national pharmacopoeias. *It is these non-proprietary names which are known as generic names and the drugs sold under these names as generic drugs; fairly well known examples are tetracycline, chloramphenicol and diazepam.* It is against this background that brand names in the pharmaceutical field must be seen, for whereas the laboratories were the ones whose work provided the basis for the selection of generic names, they also invented the brand names. Solomon Garb, professor of pharmacology at the Albany Medical College, giving evidence before the Kefauver Committee, had this to say about the origin of generic names: *Not only are the generic names creations of drug companies themselves, but after making them complex and unpronounceable, these same companies proceed to cite their complexity as an argument for the use of their simple trade names.*<sup>11</sup> Thus the confusion which the generic names were originally intended to eliminate has been re-introduced on a greatly amplified scale via the proliferation of trademark names. As Walter Modell, editor of the *Journal Clinical Pharmacology and Therapeutics* observed during the Kefauver Committee hearings:

Trademark names often introduce confusion in an already difficult and complex subject by providing more than one name for the very same drug. Sometimes there are as many as 25 proprietary synonyms which have been created for the non-proprietary

names of drugs they use. Thus, it is possible in a discussion between two specialists in the same field for neither to know that each is talking about the same drug. Imagine the dilemma this can create for the less expert, the student and the general practitioners.<sup>12</sup>

The modern pharmaceutical industry is a comparatively recent phenomenon:

The big chemical groups have become interested in the pharmaceutical industry mainly since the 1930s when the active ingredients began to be manufactured more and more from synthetic substances and less from substances of vegetable or animal origin. Similarly, industries with experience in fermentation were led into involvement with the pharmaceutical industry following the discovery of the antibiotics and their use in the 1940s.<sup>13</sup>

During the same period a dramatic change occurred regarding purchase of medicaments - in several countries the State is the major buyer, with its payments being in part financed by workers' contributions to social insurance schemes. There is thus a peculiar market situation where the decision maker (the doctor) is distinct from the user (the patient) who in turn is not the one who directly meets the bill.<sup>14</sup> Thus the usual mechanisms encouraging economy are not present whilst publicity is directed far more at the doctor than the user. Both the direct and indirect costs inherent in this situation have their implications for health policy as a whole. Expenditure on drugs represents around 10 per cent of total health care disbursements in an average industrialised country but may be of the order of 15 to 20 per cent in a developing country - what could be saved on drugs could be a valuable injection elsewhere in the system.

Shifts in the pattern of supply and purchase have been accompanied by major changes in the roles played by various professional and other groups.

It is a commonplace that the tasks that the pharmacist is called upon to undertake have changed dramatically over the past quarter century. From being a craftsman who made medicines, the pharmacist has become a distributor of medicines made by manufacturers.<sup>15</sup>

The squeeze on the pharmacist is in sharp contrast to the internationalisation of the guild type organisation which defends the interests of doctors. As the medical hierarchy has become more pronounced, so the



corporations producing pharmaceuticals have devoted ever more resources to coaxing the upper echelon of that hierarchy into buying the brand name drugs. Since, as I will stress again later, the training doctors receive (both during and after qualification) is woefully weak regarding pharmaceuticals, the publicity of the corporations tends to be the decisive factor influencing prescribing habits. Despite the large number of firms engaged in pharmaceutical production in most countries, the demand is met by a small percentage of corporations who are much the same from place to place. Thus, although roughly 5,000 companies are registered for pharmaceutical production in the OECD countries, some 50 corporations (a bare one per cent of the total) account for 80 per cent of sales. It is the publicity emanating from these enterprises which is the truly powerful voice.<sup>16</sup>

This, in broad sweeps of the brush, is the canvas on which trademarks appear. In the next section I discuss in more detail the key role of brand names in the sector; the third section analyses certain key policy initiatives taken (or proposed) quite recently, and, in the light of these, looks again at some of the arguments advanced in favour of brand names. The concluding section offers some suggestions on policies which might be considered in developing countries.

#### THE IMPACT OF TRADEMARKS IN THE PHARMACEUTICAL SECTOR

What are the effects, direct and indirect, of the brand name epidemic? They may be summarised under the following headings:

##### 1.

##### *Cost*

There are huge price differentials between products sold by brand names and those sold under their generic titles. Lall has reported that

The Kefauver Committee uncovered innumerable instances of branded products being sold at prices up to 1,000 per cent higher than others in the United States with no effect on the market shares held by the large companies. In Roche's case, a small British firm supplies its equivalent of Librium, under a compulsory licence, at prices 25 per cent lower than Roche but had not been able to capture even 3 per cent of the market for the drug by 1970;

... in India, Librium was sold in 1972 at Rs. 16.00 (per 100 tablets of 10 mg each) when generic name equivalents were available from small producers for prices as low as Rs. 1.50.<sup>17</sup>

Likewise a study of 7 antibiotics *no longer protected by patents* in the US showed that the branded drugs were priced well in excess of their generic counterparts and that in 5 of the 7 cases the market was dominated by the highest priced drug. Thus

Abbott's Erythrocin holds a 60 per cent share of the erythromycin market although it sells to drugstores for \$12.96 for a hundred 250 mg tablets, while Sherry Pharmaceutical Company sells a non-branded version for \$5.70. Pfizer's Terramycin holds 99 per cent of the market for oxytetracycline even though drugstores pay \$18.10 for a hundred 250 mg capsules, while they could get it through smaller manufacturers for as little as \$1.90.<sup>18</sup>

Recounting the experience of the State Pharmaceuticals Corporation of Sri Lanka, Bibile shows that in 1972 'the private sector imported 23 brands of tetracycline at an average price of \$16.92 per 1,000 capsules. By 'shopping around' the Corporation purchased tetracycline at \$6.33 after considering 45 offers.'<sup>19</sup> Even among the brand name articles there are considerable differences in price across countries; 'recent data show that Librium and Valium are at present sold to different developed countries at price differences of nearly 600 to 1,000 per cent.'<sup>20</sup> *There can be no doubt that restriction of legal drug sales to generic items, and the purchase of these through bulk buying agencies, would result in substantial savings of foreign exchange for the developing countries, particularly if joint purchasing could be effected by the smaller developing countries.*

## 2.

### *Distortion of Information*

Drug sales are of two sorts, over-the-counter and on prescription from a physician (the 'ethical' drug sales). Since medical doctors are not systematically subjected to post-university training dealing with new products and their therapeutic value, pharmaceutical companies become the major source of knowledge. While they do provide some information about their products which is genuinely valuable, this is mixed with a high content both of misleading information and failure to provide relevant details, the social consequences of which are

serious. The publicity effort has been described as follows:

The object is to make a lasting impression on the memory of the doctor, who only knows about 80 to 200 medicines, depending on his special line. A more specific goal is to bring the physician to prescribe a given brand name rather than the corresponding generic name, since several companies may sell a given drug under different brand names and the drug may be sold under its generic name as well, at a far lower price.<sup>21</sup>

The diseases for which the drug is recommended are known as its *indications*; and conversely, those against which it should not be used are called its *contra-indications*.

The extent of a drug's indications is no academic question. If, for example, a drug is recommended and used for a disease against which it is not effective, then the disease, perhaps serious, will be left untreated. In addition, and despite the ineffectiveness of the drug, the person using it still runs the risk of its toxic effects. Even if the drug is effective, the person may be subjected to unnecessary risks if a less toxic drug would do the job as well.<sup>22</sup>

It has been noted that in Brazil, for example, Ambra-Sinto, a combination of chloramphenicol and tetracycline, was, according to the package insert, recommended for more than 80 different conditions. Ledogar has stressed that the foreign marketing practices of US pharmaceutical transnationals in Latin America are open to severe criticism on this score. 'Just as manufacturers are often quick to recommend a drug for a new indication, they can be very slow to modify or remove outdated indications from their foreign labelling and promotion.'<sup>23</sup>

Doctor María Dolores Torres Pons estimates that 7 out of 10 prescriptions in Spain may be erroneous on account of the distortion in supply of information and the inadequacy of the pharmacological training of doctors to cope with the biases. She says:

From the discovery of penicillin to the present day, an infinite number of antibiotic products have been isolated and synthesized even though many of them have had to be rejected because they are toxic or ineffective. Nevertheless, this great proliferation of substances has brought with it such a confusion that the utilisation of antibiotics, at

least in hospitals, may not be adequate, sometimes because they are administered in excess and on other occasions because their use is unjustified... To all qualified personnel, but most especially to doctors, propaganda concerning the distinct pharmaceutical preparations and forms that invade the market arrive constantly.<sup>24</sup>

Thus the information provided by the drug companies meets very low standards of objectivity due to the need to stimulate sales of brand name products; doctors are not trained to assess pharmacological data on a regular and reliable basis; and there is a dreadful lack of official provision of information on drugs. These depressing and dangerous features of the market are present both in developed and developing countries but of much greater severity in the latter.<sup>25</sup>

## 3.

*Habit Creation*

Without question the purpose of the whole advertising exercise is to convince the doctors of the importance of prescribing the brand name drug.<sup>26</sup> Their resistance to change has been concisely described by the UK Monopolies Commission:

Doctors become accustomed to prescribing a drug under the brand name by which it has been introduced to them by the innovator. They are not easily persuaded to prescribe under a different brand name; few of them will do so before the drug is felt to have been well-established for some considerable time, and in practice this may mean not before the patent has expired.<sup>27</sup>

In fact the suggestion that practices will alter when the patent lapses is probably optimistic since the brand name will remain in force as will the selling apparatus that goes with it.

The consequences of habit formation at the doctor level were thrown into sharp relief by Wickremasinghe and Bibile in their report which led to the creation of the State Pharmaceuticals Corporation in Sri Lanka. They pointed out that

Tetrex, Tetracyl, Tetrarco, Hostacycline, Upcyclyne, Ambramycin, Probacycline, Achromycin, Hcyclyne are all trade names under which the antibiotic tetracycline is available. A patient with a prescription for Achromycin will go from one chemist to another and be told that the drug is out of stock

whereas the chemist would have the same drug under other brand names. One patient had a prescription for pentazocine under one of its trade names - Fortral. Since pentazocine is not sold in this country as Fortral, a special user's licence was obtained and the drug airlifted to find that pentazocine had been available all the while under the trade name of Sosegon, manufactured by the same company which sells it under the name of Fortral in other countries.<sup>28</sup>

Habits built up at the doctor level carry over to patients, on the one hand, and local producing firms (if any) on the other. The patient retains the brand name and if, in future, he has the same complaint and can purchase without prescription, the chances are he will ask for the trademark product he used originally. In her study of Egypt, Handoussa stressed that even when licence contracts with transnationals had terminated and it was possible to manufacture a product under any name whatever, including the generic name, 'local firms choose brand names that are as close as possible to the original foreign brand name'.<sup>29</sup> A mythology has been woven around the name to such a degree that doctors, patients and domestic producing enterprises cease to act as independent decision-making agents but instead follow blindly the verbal sign-posts laid out with such ease by the name makers. Aries reports that the Institut Pierre Bessis in France tried to find out what's in a name.

In a study of a sampling of the French population they discovered, for instance, that medicines ending in 'il' were regarded as modern and for brief mild illness. Medicines ending in 'ol' were old-fashioned, not very potent and for mild illness. Medicines ending in 'al' are also old, but they are strong and for serious illness. Medicines ending in 'ian' and 'an' are modern and potent.<sup>30</sup> To have created such a picture speaks volumes for the advertising skills of the pharmaceutical companies, yet its implications are hardly conducive to the welfare of the developing countries.

#### 4. Wasteful Advertising

Wherever modern drugs are sold, an extraordinary array of selling devices is used, ranging from medical representatives, to free samples, to literature of all kinds,

to business gifts, to sponsored conferences, to medical journals in effect controlled by the companies, to ... and the list could go on. Senator Kennedy described the situation in the USA as follows: '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 science and medicine - comparative information, analysis of risks and benefits of competing products.'<sup>31</sup> The medical representatives are the key figures in this network and the most expensive element in the advertising budget.

There are 9,000 of these in France and 8,000 in Federal Germany and Italy, 1,700 in Belgium. Their function is to call on the doctor in his consulting room or hospital, to explain the merits of the medicines presented, to hand him printed literature, free samples on request, and business gifts. In France such a representative, on average, meets 160 to 180 doctors per month, gives to each one 1.25 medicines and mentions 2.6. The cost per visit is between Fr.Fr. 60 and Fr.Fr. 100. General practitioners receive 27 representatives per month and specialists 14.<sup>32</sup>

A Brazilian legislator, Senator Ferreira, who is himself a doctor, recently conducted his own survey of the plague of salesmen:

He was visited on 18 of the 21 days by a total of 69 salesmen. He was given 452 free samples of drugs (after refusing extra quantities so as not to distort the counting); he received 25 gifts, including coffee-pots, notebooks, plastic bags.<sup>33</sup>

The use of free samples is rampant. When given to doctors the quantities are almost always sub-clinical, i.e. sufficient to start but not to sustain treatment. They serve to imprint the name in the mind of the doctor and serve as an indirect source of income for him. In the USA

several witnesses testified that it was not uncommon for recipients to swap these samples at their local pharmacies for other items, sometimes for their personal use. And it was also testified that some pharmacies removed the word 'sample' from these products and sold them as part of their regular inventory.<sup>34</sup>

While the cash value of the samples may be negligible to a doctor in the USA it may not be so insignificant to a doctor in a developing country: *yet these samples are being paid for by the purchasers of the drugs, through*

*the higher prices charged.*

Free samples, however, are not limited to doctors - they are also given to hospitals and sometimes to other organisations or groups. The relevance of this practice was taken up by the UK Monopolies Commission when it examined the behaviour of Roche Products Ltd (the British subsidiary of Hoffmann La Roche) in its supply of Chlordiazepoxide and Diazepam (under the brand names of Librium and Valium) to the UK National Health Service. The Commission stated

the fact that the company was able to make free supplies of the reference drugs available to the hospital service and the armed forces also, in the Department's opinion, reinforced the view that prices to the pharmaceutical services were too high. Such free samples, the Department said had three effects. First, a potential competitor would be discouraged since he would normally attempt to establish his initial sales in the hospital market; secondly, hospital doctors would prescribe Roche Products' branded reference drugs and this precedent would tend to be followed by the patient's general practitioner when the patient returned to his care; and thirdly, hospital staff would tend to regard the company's products as causing the smallest increase in the hospital's drug bill and would not be so readily aware of the cost of treatment of patients returned to the general practitioner's care. The Department says that, in accepting the company's offer of free supplies of reference products for the hospital service and the armed forces, it was made clear that the Department did not accept as fair or reasonable the company's refusal for an indefinite period to discuss non-hospital prices.<sup>35</sup>

The quotation drives home the basic feature of the free sample and free supply system. It is not philanthropy: *its purpose is to establish barriers to entry for competitors and thereby allow prices to be higher than they otherwise would be.* Hence we have an extremely expensive, socially wasteful, advertising complex whose function is to restrict competition and maintain prices at levels way in excess of those that could prevail in a more rational framework.

### 5. *Influence on Government Decision-Making*

In an environment where so much depends on certain pivotal groups, such as medical doctors, and certain pivotal administrative bodies, such as the Ministry of Health, taking decisions in favour of particular brand name products rather than others, it is scarcely surprising that there is heavy pressure by the companies to make sure the steps taken are favourable to them. Brazil and India, the two developing countries where the greatest amount of drug production takes place, bear ample witness to the pressures.

Sources within the Brazilian parliament recently called for an investigation into the compromising relationship between multinational pharmaceutical companies and the nation's drug control agencies. A parliamentary investigating committee was reportedly given an internal document of the Swiss firm Ciba-Geigy containing a list of 135 public officials in the SNFMP (Brazil's National Service for the Control of Pharmaceutical Products) and other licensing agencies who were to receive small 'gifts' and 'donations' from the company.

#### In India

one of the modi operandi is to employ highly qualified and highly paid 'medical advisers' - brilliant young men who could have been the pride of their profession had they chosen to practise it, instead of seeking comparative ease and higher lucre toeing the line of the multinationals... The function of these 'medical advisers' seems to be to prepare literature on 'branded' drugs, arrange conferences for popularising them and to liaise with government agencies to sell the ideas of the multinational firms to them. A recent report published in the *Washington Post* and reproduced in local journals shows how one multinational company influenced the higher echelons in our government in accepting a contraceptive pill. But for the publication of this report in a foreign journal, this incident would not have seen the light of day in this country. In such matters the 'medical advisers' play a significant role. This local brain drain is no different from the drain one often hears about when technical and scientific people leave this country in search of fortunes abroad.<sup>37</sup>

These direct pressures for the purchase of specific drugs form only part of the story. For while the companies are engaged in promoting brand name sales, to some



extent in competition with each other, they also act together to defend their joint interests in reserving the structure of the industry. In the UK the Sainsbury Committee, which in the middle 1960s investigated the relationship of the pharmaceutical industry with the National Health Service, had asked for stringent controls over the industry's marketing practices but this was never implemented. Similarly the Macgregor Committee, which had existed as an official body to examine the crucial question of the effectiveness of drugs, was disbanded in 1970 and no new group has been established in its place. Lang concludes 'All the evidence points to the conclusion that the ABPI [the drug industry's pressure group] wields too much influence, has accumulated too much expertise, and has become too entrenched in the bureaucracy of the government for the elected representatives of the people to deal with it effectively.'<sup>38</sup>

Shortly after the publication of the Hathi Committee's report on the pharmaceutical industry in India, in April 1975, there were already reports of response.

Furious lobbying had preceded, and has followed, the submission of the report. The pharmaceutical industry - especially the powerful foreign sector of it - clearly has its interests at stake here... the foreign drug companies are already influencing the direction of the decisions by taking a tough stand. While Press and Parliament will discuss the Hathi Committee's policy recommendations for total or partial takeover of these companies, the foreign companies have been actively lobbying for the issue of new licences for their expansions. Twelve applications for substantial expansion are in fact pending with the government; the drug firms seem confident that all these will be cleared in due course.<sup>39</sup>

Under these circumstances it seems doubtful that the wider implications of the brand name syndrome receive the consideration they deserve: it is all too easy for partial and biased decisions to be taken by those regularly subjected to the bombardment of pressures from the small number of producers whilst the voices of the consumers scarcely are to be heard.

6.

#### *Inappropriate Consumption*

When the criteria are those of commerce rather than public welfare, and where in any case the commercial impetus

involved emanates from markets whose needs are very different from those of the majority of people in recipient countries, it is scarcely surprising that drugs are misused. The extremely high proportion of branded to generic drugs as well as the elevated prices both operate against the existence of a set of drugs relevant to the health needs of the population as a whole and available at prices, in quantities and at the locations in the country which will allow them to be used as required. Given that the resources which can be spent on drugs are severely limited in developing countries ( and everywhere else for that matter) the relation between the cost of a drug and its clinical efficacy is of critical significance in determining what set of drugs should be used. A newer drug might have fewer possible adverse reactions than an older one but may be far more expensive. If many people need treatment their prospects of getting it will be greater if supplies are restricted to the older drug.<sup>40</sup>

Wickremasinghe and Bibile put the point in their discussion of the management of pharmaceuticals in Sri Lanka.

A good example is the use of the aspirin type of analgesic drugs. The current consumption of this type of drug is 130 million tablets annually, of which 50 million are used by government hospitals and dispensaries and 80 million in the private sector. The 80 million is made up of 60 million tablets of 'Disprin' and 20 million of aspirin, 'Aspro', buffered aspirin, 'ASC' pink tablets and paracetamol. Clinical trials indicate that all these preparations do not have significant advantages over aspirin with regard to efficacy and adverse reactions. Furthermore, aspirin tablets are far cheaper and more stable than the other analgesic preparations mentioned. Aspirin tablets will, therefore, be adequate to meet situations where this type of analgesic treatment is required. For a small number of people who cannot tolerate aspirin, paracetamol tablets will be required. Manufacture and import could therefore be restricted to aspirin tablets and paracetamol tablets and the price to the public would be considerably reduced.<sup>41</sup>

Unfortunately the inappropriate consumption is not confined to that of well-established drugs. The testing of pharmaceuticals goes beyond the laboratory - a key part consists of clinical trials or, to put it bluntly, giving the drugs to people and watching for any unexpected effects which might be detrimental to their health. In the

developed countries the regulations governing this kind of activity are growing steadily more severe. Governments are not permitting the drugs to be given to members of the human population until ever more stringent tests have been carried out beforehand. Due to the substantial differences in laws among countries, regulations in practically all countries of the developing world are far more lax. So the corporations are shifting their clinical testing to the developing world; the laboratory work is performed in the industrialised countries and the use on humans begins in the developing world. To the massive bias inculcated by the social misfit nature of ordinary drug consumption is added the adoption of developing countries as the places where new drugs, as likely as not but of little relevance to the social needs of those countries, are first tried out.

These six aspects of the industry: cost; distortion of information; habit creation; wasteful advertising; influence on government decision-making; inappropriate consumption; arise from the presence of market power as manifested by the dominant members of the ruling oligopoly of corporations. Much attention has been given to technical knowhow as a source of this power. Whatever may have been the role of this knowledge some time ago, it has ceased to be the salient feature of the industry. Now it is marketing which has become the pivot on which relatively the heaviest expenditures are made. 'But all of this expenditure by the pharmaceutical company would be to no avail unless the doctor was able to identify and specify that company's product; hence the importance of the registered trade mark, the exclusive use of which is the right of that company and no other.'<sup>42</sup>

#### THE POLICY CONTEXT

It is scarcely surprising that, faced with the manifold difficulties described above, certain steps are being taken (or proposed) in at least some developing countries to tackle the problems. The possibilities have recently been given clear expression by the Non-aligned Countries, at the Fifth Conference of Heads of State held in Colombo in August 1976. Just prior to the Colombo meeting a Group of Experts on Pharmaceuticals had met at Georgetown and on the basis of their report<sup>43</sup> the Heads of State passed a *Resolution on Co-operation among Developing Countries in the Production, Procurement and Distribution of Pharmaceuticals*.<sup>44</sup> In the first operative paragraph

of that resolution the following points, among others, are made:

(The Conference...)

1 *Endorses* the recommendations of the Group of Experts which met at 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) the elimination, wherever possible, of brand names and the adoption of the generic names for pharmaceuticals; and provision of information only from official sources.

These three *interrelated* proposals form the backbone of what has happened so far and provide the central elements of future measures.

#### *Actions in Developing Countries*

(i) *Sri Lanka*<sup>45</sup>

Modern medical services in Sri Lanka are provided by a state sector whose administration is under the control of the Department of Health Services, and a private sector in which medical practitioners charge fees for their services. The change wrought in the supply of pharmaceuticals can be traced to 1959. Prior to that date both public and private sectors were plagued by the costly and dangerous practices described earlier in this study. Faced with the confusion and proliferation of medicines, the Ministry of Health published a Ceylon Hospitals Formulary containing a list of 500 essential drugs (in 1,000 dosage forms) *under their generic names*, along with instructions on the use of these drugs. From that point onward this list was the guide for all drugs to be used in hospitals.

A severe foreign exchange crisis in 1963 provoked import restrictions with private sector pharmaceutical imports limited to an approved list of drugs which

contained 2,100 items (in 3,000 dosage forms) as against double that before, 4,000 items (in 6,000 dosage forms). No limits were placed on the use of brand names within the approved list and the standard publicity machine was allowed to keep running untrammelled. A first step in rationalising private sector dealings had been taken, nevertheless, and this had been possible due to the parlous foreign exchange situation. Often situations of economic crisis, when the government as a whole is prepared to examine fresh ideas, may provide the opportunity to present schemes which would otherwise not be given such careful consideration.

By 1970 there were once more severe difficulties. Prices had risen by at least 50 per cent as compared to 1963 levels, annual foreign exchange allocations had decreased, and both public and private sectors complained of drug shortages. Given that the government could not make more foreign exchange available, drugs had to be obtained more cheaply. An investigation into sources of supply showed that, had the private sector purchased several of its major imports at prices paid by the public sector, *it would have paid only 30 per cent of the amount actually disbursed.* On the basis of these details, and of other proposals contained in the previously cited report of Wickremasinghe and Bibile, a State Pharmaceuticals Corporation was established in 1971 to rationalise management of pharmaceuticals in the private as well as the public sector.

To begin with, the number of drugs authorised for use by the private sector was reduced to 600 (in 1,000 dosage forms). To achieve this there was a sharp reduction in the number of imitative drugs, removal of an appreciable number of fixed-combination drugs which were not useful, and deletion of several drugs either not possessing proven therapeutic value or having high toxicity. The Corporation then organised a changeover from brand names to generic names. *The switch has been carefully phased to harmonise with the publication of cross-reference lists of brand and generic names.* Gradual change is important to ensure that doctors can again begin to identify the generic items (after so much bombardment with brand names), that reactions from the producers are successfully overcome, and that quality standards are satisfactory. For long-established drugs it has proved relatively easy to introduce generic labelling; for others the adjustment has been slower with labelling using both the generic and the brand names but the former being twice the size of the latter. In this way doctors can learn to identify the product by the generic name

and the brand can be dropped altogether. Sri Lanka being a rather small country, and the necessary quantities of some drugs being small, there remain some items for which it has not thus far been possible to use brand names since it is uneconomic for manufacturers to print special labels for Sri Lanka.

*An active policy has been adopted by the Corporation to ensure that information is distributed to doctors and pharmacists and this is reinforced by the crucial aspect of quality control.* Since the Corporation is engaging in *bulk buying*, with the substantial savings mentioned earlier (including major price reductions by the 'traditional' suppliers), it is vital to guarantee the quality of the products associated with different tenders. Ideally the Corporation would itself undertake inspection of the factories of suppliers and purchase only from those following Good Manufacturing Practices (as established by the World Health Organisation). This type of inspection is not possible on a systematic scale (it would be much easier if *several developing countries together arranged for inspection by one of their representatives*) so other procedures are used. In particular, the board which examines tenders can identify drugs where formulation and quality are critical and ensure that such purchases are made from suppliers whose quality standards are well known. Besides this, there are the simple procedures of requiring a certificate of quality from the manufacturer and, where necessary, arranging for an additional certificate of quality issued after inspection by an authorised and independent laboratory.

At present the Corporation has over 300 employees of whom only 15 are employed on sales and distribution (as compared to the much higher percentage devoted to these tasks in a company occupied with marketing as such).<sup>46</sup> Given the activities of the Corporation, the extensive promotion of products has of course collapsed (there being now but a single buyer, the State) and the paraphernalia of free samples and the rest has likewise ceased to be relevant.

In this structure the removal of brand names has meshed with a total strategy whose objective throughout has been the rational management of the whole field of purchase and distribution of pharmaceuticals. Hitherto domestic production of pharmaceuticals remains on a small scale in Sri Lanka and there is anyway no entry into the more complex parts of the production network, for which a domestic basic chemicals industry is needed. What matters is that the trademark based system has been completely rationalised and the enormous social waste cut out.

(ii)

*India*

Three major reviews of the drug industry have been undertaken since Independence: 'The first one was the Pharmaceutical Enquiry Committee appointed in early 1953, the second was the Drugs and Equipment Standards Committee known as the Naskier Committee appointed in 1962 and the latest is the Committee on Drugs and Pharmaceutical Industry known as the Hathi Committee appointed in 1974.<sup>47</sup> When the first of these reported to government in 1954 it took pains to emphasise that 'only a few firms should be allowed to take up the development of the same product' and it presented a systematic argument for the phased move by India towards self-sufficiency in drug production. More than 20 years later the drug industry still has to import around 70 per cent of its requirements and even where the transnational firms import intermediates they do so focussed on those as near to the final product as possible rather than as close to the basic chemicals as is feasible.

The pharmaceutical industry, of which the lion's share within India belongs to the transnationals, has resisted proposals for change with impressive success. Fifty-five per cent of the business of the transnationals is in formulations and it has been stated that the foreign enterprises have

introduced many formulations in the market which this poor country could well do without...many irrational formulations particularly in the field of vitamins, corticosteroids and antihistamines, fetching high prices, are also marketed... The therapeutic field has been so much 'polluted' today that unless some drastic measures are taken the drug industry is bound to play on the gullibility of patients and physicians alike.<sup>48</sup>

According to recent comments the public sector policies have in practice resounded to the benefit of these companies.

A case in point is Hindustan Antibiotics (HAL), the public sector unit manufacturing penicillin and streptomycin. The eighteenth report of the Committee on Public Undertakings (Fifth Lok Sabha) brings out how the company has deliberately restricted its own production of formulations so as to sell a large proportion of its output in bulk form to private companies, even though it is more profitable for HAL to sell its output as formulations than in bulk form... The policy of selling a large part

of its output of antibiotics in bulk form was pursued by HAL even though this meant keeping idle much of its own vialling, capsuling and tableting capacity.<sup>49</sup>

The closing remarks of the report are revealing: The Committee are constrained to conclude that by showing excessive concern for the requirements of private viallers and by keeping HAL's formulation capacity underutilised all through this period, the administrative Ministry as well as HAL have not acted as the guardian and promoter of the interest of the public sector but have rather helped the private firms, particularly the foreign firms, to earn huge profits at the expense of the public sector and national interest.<sup>50</sup>

The purpose of these observations is to show that, at least in the Indian context, awareness of difficulties extends over a lengthy period and proposals have been offered at regular intervals. Thus far resistance has been strong, however, and it remains to be seen what will be the final fate of the Hathi Committee proposals. That Committee examined the brand name question in great detail and it is worth repeating in full the views of the Committee since they unite the issues raised in this study:

*Substitution of brand names of drugs by generic names*

The question of generic names and brand names was extensively discussed. All facets of the problem, such as impact on drug prices, bio-availability, quality of drugs, enforcement of drug control, multiple ingredient preparations, export of drugs, labelling difficulties, impact on small-scale industry, patent rights, distribution system, acceptance by the medical profession, role of distributions and pharmacists, effect on the growth of pharmaceutical industry, difficulties and inconvenience in the use of tongue-twisting generic names, etc, were discussed in detail. After taking into account all these very intricate problems, the Panel makes the following recommendations:

(a) Brand names should be abolished in a phased manner. This step is in the right direction for both the rational practice of medicine and general national interest. Drugs which are exported may be allowed to bear brand names.

(b) A beginning should be made for a changeover to



generic names for the drugs mentioned in Appendix II. These drugs are used very extensively and their generic names are as elegant as brand names. These drugs should, therefore, not be allowed to be marketed under brand names with immediate effect.

(c) The changeover from brand names to generic names may result in the increase of spurious and substandard drugs. It is, therefore, strongly recommended that steps should be taken to ensure more rigid and uniform quality control throughout the country.

(d) All supplies of single ingredient drugs and drugs included in *Indian Pharmacopoeia for General and State Government Institutions and Local Bodies* should be tendered and supplies made under generic names. At present, drugs, though tendered under generic names, are supplied under brand names, and this should be discouraged.

(e) All drugs other than those listed in Appendix II, should bear labels displaying prominently generic names. Brand names may be mentioned in brackets.

(f) The Drugs Controller (India) be requested not to give recognition to the brand names of new drugs when first introduced in this country.

(g) Multiple drug combinations often containing drugs, particularly vitamins in amount far in excess of what is required are presently marketed in India. The majority of such combinations are irrational. There is a colossal national wastage of drugs because of such combinations. The Panel therefore strongly recommends that the Drug Control Administration should immediately go into the various drug combinations and take prompt measures to eliminate irrational drug combinations. No firm should be allowed to import excessive quantities of any drug over and above what is required to go into the formulations for therapeutic and prophylactic purposes.

(h) The Indian Pharmacopoeia Committee be approached to devise simple, short and suitable non-proprietary names for drugs which have long and difficult generic names.

(i) Bio-availability studies are important in the case of a few drugs, although this factor has recently been overplayed, not always on a rational basis. The Panel recommends that facilities should be created in different parts of the country, so

that the industry, both large and small-scale, can take advantage of such facilities to plan and conduct bio-availability and pharmacokinetic studies.

(j) In order to keep the medical profession, particularly the general practitioners, well-informed about New Drugs and also to popularize the generic names, it is essential to take steps immediately to:

(i) revise the Indian National Formulary;

(ii) to publish journals on the lines of the Prescribers' Journals UK, Medical Letter USA, or Formulary Notes of Sri Lanka. Such publications will have to be under the control of an Editorial Board comprising leaders of the medical profession in the country constituted by the Ministry of Health, Government of India.<sup>51</sup>

Since these recommendations raise all of the relevant matters connected with a switch from brand names in this industry, some brief annotations on several of the points will serve to crystallise the arguments.

(1) *Quality*: Certainly every effort must be made to ensure that good quality products are the only ones sold. A large developing country, such as India, with a considerable industrial base and numerous highly skilled personnel, has at least as much a chance as most industrial countries to conduct quality controls - measures in smaller countries have already been mentioned with regard to Sri Lanka. Most important, however, *the question of quality should not be confused with that of brand names; whilst the protagonists of the system have continually propounded the inseparability of the two, the realities are otherwise.*

The study of antibiotics in the US market, mentioned earlier, 'notes that during the tetrocyclyne antitrust case, Lederle revealed that its quality-control costs on a hundred 250 mg capsules of Achromycin were 1.4 cents. At the time, it was selling the drug, its brand of tetrocyclyne, for \$3.60 for a hundred 250 mg capsules.'<sup>52</sup> *This means that the company's quality control costs accounted for less than 0.05 per cent of its selling price* - those who paid for the brand were certainly not paying for quality control costs. In terms of a direct comparison between brand name and generic drugs, there is similarly nothing to suggest that the former are better on quality: 'a review undertaken between 1966 and 1969 by the National Academy of Sciences - National Research Council [a private US organisation supported by industry]

on behalf of the US Food and Drug Administration found that 8.8 per cent of the 2,000 brand name drugs in the sample were ineffective while the comparable figure for generic drugs was 7.7 per cent.<sup>53</sup>

To summarise: good quality control is essential, generic drugs are at least as good on quality as the branded items, and the former are far cheaper.

(2) *Spurious and Substandard Drugs*: The argument that there will be more of these under a generic than under a brand name system is utterly false, unless of course there should be marketing of spurious items as a deliberate policy on the part of some manufacturers to undermine the generic name approach. Spurious or counterfeit drugs are marketed for reasons of profitability - and there are many more profit opportunities with brand names. Hence *the risks are higher in a brand name context*. The Hathi Committee itself stated: 'scrutiny of the total number of substandard, misbranded and spurious products reported...will reveal that there are more instances of branded products being misbranded or spurious. There have been no instances where a product marketed under generic name has ever been reported to be spurious.'<sup>54</sup> Similarly Illich, referring to work by Margaret Krieg in the US, says that she

reports and proves that an increasing percentage of articles sold by legitimate professional pharmacies are inert counterfeit drugs which are indistinguishable in packaging and presentation from the *trade-mark product*. Detection is increasingly difficult and prosecution of the Mafia behind this black market is beyond the control of current law-enforcement agencies.<sup>55</sup>

(3) *Bio-availability*: Drugs which are generically the same can differ somewhat in their clinical effects and thus in their therapeutic value. The rate of release of the therapeutic agent may be 'too much, too fast', in which case the recipient is exposed to the risk of adverse toxic effects, or 'too little, too slowly', when the plasma concentration fails to reach the levels at which therapy occurs and the drug is simply ineffective. A recent study<sup>56</sup> has argued that the plasma concentrations just mentioned can be affected considerably by the methods of formulation and manufacture of the substance, that the brand name identifies just what method is used for turning the drug (active ingredient) into that manufacturer's medicine, that the risks of switching from

one brand to another may be significant, and that these considerations are vital in accurate prescribing. A list of 43 drugs subject to bio-availability problems is given in the study.

In assessing the weight of these arguments, the following points need to be borne in mind. First, absorptive response depends on the patient as well as the drug and there is nothing in the bio-availability argument to suppose that any drugs are going to reach the patient 'custom made'. Second, there may be variations as between different batches of the same brand name drug. Third, and most important, the empirical relevance of the phenomenon is not great. Thus, 'as evidence from the United Kingdom and the United States shows, there are only a few drugs [42] noted in the United Kingdom and 24 in the United States, where bio-availability presents a real medical problem.'<sup>57</sup> The principal cases of bio-availability are by now well-known and allowance for them can be easily made; given the other issues involved, it would be gravely misplaced policy for a developing country to maintain trademarks in pharmaceuticals on the grounds of bio-availability.<sup>58</sup>

(4) *Use of Generic and Brand Labels:* The printing of brand labels in brackets at the side of generic names may be insufficient to ensure that it is gradually the generic name which comes to be identified. Size of letters, colours used for the different words, type of print and even positioning of the letters are all devices by which the impact of one name can be enhanced relative to the other. These appear as small details, no doubt, yet they may influence the speed and precision by which doctors come to recognise the generic names.

(5) *Simplification of Generic names:* The introduction to this study emphasised that it was the pharmaceutical industry itself which had generated *both* the generic and brand names. There may be grounds, in some instances, for simplification of the generic name though great care should be taken with such a proposal lest it create opportunities for manufacturers to sow still further confusion.<sup>59</sup>

(6) *Identifiability of Manufacturer:* From the buyer's point of view the important consideration is to be able to have recourse to the seller in the event of either difficulties with the product or a desire to re-order the same item. Publication of the manufacturer's name on flasks, packets and other containers is not necessary

for these purposes since the normal transactions between buyer and seller offer sufficient indications, particularly at the wholesale level, or origin (especially where, as has been done in Sri Lanka, the supplier must give a certificate of quality). To retain the manufacturer's signet enhances the risk that purchasing patterns, especially by the private sector will not be amended.

(7) *Supply of Information:* The Hathi Committee mentioned some of the sources of reliable information, both from developed and developing countries; *there is no shortage of material based on scientific rather than commercial criteria and thus no reason why even a developing country unable to publish its own journal should lack up-to-date analyses.*

(8) *Exports:* In its comment on this subject the Committee maintained a flexible position. As a general rule, underlined by the moves towards co-operation among developing countries in this area, each country should refrain from exporting the problem to others, i.e. augmenting the severity of obstacles to control elsewhere by adding to the number of brands to be dealt with. If each country has a bulk buying scheme directed towards purchases of generic items, then retention of brands for exports is impossible (save to industrialised countries which may retain brands). In those cases where branded exports are allowed and are feasible (from a developing country which, like India, has production facilities located in its territory) the object should be to build up a reputation for genuinely domestic companies, not for affiliates of transnational corporations. The reputation will be accentuated not by trademarks but by the competitive performance of the products.

(9) *Effects on Growth:* To build up a pharmaceutical industry is not an aim which has any meaning unless clearly specified conditions are set out. What is wanted, wherever feasible, is access, in the right quantities, qualities, places and times, to those drugs which are the most useful, given prices and therapeutic effects, to the health needs of a country. Domestic production must be established on that criterion and growth, in the sense of greater output, is only helpful when it corresponds to those conditions.

(10) *Patent Life:* As noted earlier, whereas patents have a limited life, trademarks can be renewed indefinitely. The two combined give a perpetual legal protection which

must be removed; what has been said elsewhere in the study emphasises the importance of eliminating this source of market power.

The Indian policy experience is a valuable one, coming as it does from the largest developing country producer of pharmaceuticals in which a major part of production is in the hands of transnational companies. Thorough investigations of the industry have combined to give all the recommendations which, if implemented, would dramatically alter the face of the industry. Numerous problems remain, however, and the stakes are so big that one can depend on the resources available with the multinationals to resist any attempt to touch brand names. '60

(iii)

*Brazil*

In 1971 a government body called the Central de Medicamentos (CEME) was established with the objective of providing medicines to the poorer parts of the population at very low or zero cost. A basic list of 400 medications was drawn up on the basis of which most of the country's chemically treatable health problems could be met. The list formed part of a Master Plan which included tight controls on the sale and promotion of drugs, regulations on the content of package inserts (the leaflets supposed to describe what the drug does or does not do) and restrictions on the distribution of free samples. By end 1973 CEME was dealing with 108 pharmaceutical products of which 52 were classified as essential.<sup>61</sup> Items were purchased through public bids with CEME specifying type, quantity and delivery dates. 'All purchases must carry the CEME signet or seal, with the name of the medicine incorporating the name CEME. The name of the actual manufacturer does not appear on the package, contrary to original expectations of the industry which had anticipated some publicity fallout from the arrangement.'<sup>62</sup>

In Brazil, as in the vast majority of developing countries, wholesale purchasing by the government could not be effective without a major effort to alter the prescribing practices of physicians. Those connected with government health services were expected to prescribe to low-income patients whilst those in private practice were urged to prescribe to their low-income clients. As an aid to this CEME has engaged in promotion of products, albeit on a modest scale, through radio announcements in the north-east of the country, and has

sought to conduct promotional campaigns vis-à-vis the medical profession itself. The reaction of the companies to these initiatives has been predictable enough. As the President of Pfizer's Brazilian subsidiary indicated: 'We are prepared to co-operate with CEME, to provide the drugs at a 50 per cent discount - in fact, we have some room for an increase in production - but we are only prepared to do it as long as the government does not distribute the medicines to those who can buy them.'<sup>63</sup>

The division between the market for the poor, seen as an appendage by the companies, and the market for the middle classes and above was stated in a report by *Business Latin America* at the end of 1973: 'Some executives feel that Brazil's rapidly growing middle class can afford to pay for more specialised and sophisticated remedies than those marketed by CEME. In other words, they are content to leave to CEME the job of developing a future market among Brazil's poor.'<sup>64</sup>

A series of administrative shifts reflecting re-evaluations of the Master Plan have taken place since it was announced and their effect has been to reduce drastically the scope of action for CEME. Insofar as the purchasing decisions are concerned, the list of drugs, originally 400, was cut to 293 in July 1975 when the Minister of Welfare (under whose wing part of CEME's functions were now to be exercised after their removal from the Office of the Presidency) published a fresh list of medicines on which CEME was supposed to focus attention. 'Certain essential drugs were no longer on the list, and, more importantly, the list had been reduced to a mere guideline. CEME, and other government institutions which might distribute drugs to the poor, could substitute for the drugs named on the list any similar drug on the market.'<sup>65</sup>

Brazil is the second largest developing country producer of pharmaceuticals and likewise has a dominant share of its market in the hands of transnationals. The proposals and initiatives taken there have also, thus far, failed to make a decisive breach in the pattern of production, marketing and distribution. The general pattern of government action is clear yet successful radical moves have still to be made.

#### CONCLUDING REMARKS

Whatever is done with regard to trademarks in the pharmaceutical sector must be part of a total strategy. The

prime requirement, as is being increasingly recognised, is the establishment and implementation of a basic drug list drawn up in accordance with each country's health needs. Given such a list, purchasing procedures which ensure that imports are obtained as cheaply as possible subject to quality considerations are required for many if not most developing countries - for those where domestic production can fill the requirements, so much the better. Yet the existence of the right drugs is not by itself enough. Doctors must be informed about them and intensive information diffusion must be undertaken by the public authorities; only then will prescribing habits be altered. In this process the professional skills, currently idle, of the pharmacists should be mobilised to the full.

In this setting, and in view of the evidence set out in this article, there is a powerful case for the elimination, or at least restrictions of the grant of trademarks in the pharmaceutical sector in developing countries. This would represent a departure from the hitherto standard practice of accepting trademarks in all sectors without exception. Yet the pernicious effects of the brand name plague are abundantly clear; unless steps are taken rapidly, it is hard to see how the limitations on patents in the sector, now fairly common in developing countries, can hope to bear fruit. For the export market, particularly to developed countries, some countries may wish to permit the trademarks to continue, irrespective of whether the exporting is done by a foreign or national enterprise. In the context of co-operative arrangements among developing countries, where there was jointly organised production to meet the needs of the participants, the use of a brand name would not serve any purpose for intra-group supplies; if the co-operative wanted to export to third markets, a labelling device of some sort could then be used.

A final observation is needed. The benefits from liquidating the brand name difficulties will not be realised unless the resources saved are genuinely put to work improving the totality of health services and thus the health of the population. This must remain the central objective not merely of trademark policy in the sector but of policies towards pharmaceuticals as a whole.



NOTES

- 1 'Registered or registrable trademark is a term applicable only to those trademarks which have been or will be accepted for registration by the Registrar of Trade Marks under the provisions of the Trade Marks Act. A brand name is only a popular term used to mean one or another of the specific legal terms.' Economic Council of Canada, *Report on Intellectual and Industrial Property* (January 1971), 181. In this paper I shall use the terms trademark and brand name interchangeably to refer to those marks which are registered.
- 2 Figures taken and derived from Sanjaya Lall, *Major Issues in the Transfer of Technology to Developing Countries: A Case Study of the Pharmaceutical Industry* (UNCTAD document TD/B/C.6/4, Geneva 1975).
- 3 *Eastern Economist* (22 August 1975), 370.
- 4 *Report of the Committee on Drugs and Pharmaceutical Industry* (New Delhi, Ministry of Petroleum and Chemicals, April 1975), 194. This Committee is usually referred to as the Hathi Committee.
- 5 Figures taken from DAFSA, *The Pharmaceutical Industry in Europe*, 40 and 41; Hathi Committee; *Business Latin America*, (5 December 1973); Constantine Vaitos, *Intercountry Income Distribution and Transnational Enterprises* (London 1974), 38; and Ivan Illich, *Medical Nemesis* (Calder and Boyars, 1975), 41, for the reference to Mexico.
- 6 Jorge Katz, *Oligopolio, Firmas nacionales y empresas multinacionales* (Buenos Aires, Siglo Veintiuno, 1974), gives comparative data.
- 7 See Peter O'Brien and Ruman Foruqi, 'Industrial Property in Ethiopia', *Journal of World Trade Law* (November-December 1976).
- 8 Instituto Nacional de Tecnología Industrial, *Aspectos Económicos de la Importación de Tecnología en la Argentina en 1972* (Buenos Aires, 1974).
- 9 Jaime Alvarez Soberanis, 'Justificación de Una Política que Restrinja el Uso de Marcas Extranjeras en México' (Comercio Exterior, August 1976), especially 948 and 949.

- 10 Kevin Goggin, 'The Irish Trademark System' (mimeographed, Dublin 1975), 71, 72 and 74.
- 11 A Special Correspondent, 'In Defence of a National Drug Industry', *Economic and Political Weekly* (27 March 1976), 498.
- 12 Ibidem, 498 and 499. An article entitled 'Switch from Branded Medicines would save only 2%!', *Financial Times* (22 September 1976) reports on a document just published by the Office of Health Economics in London and entitled *Brand Names in prescribing*. According to the report 'The Office, a research body sponsored by the UK drug industry, has drawn up the report in a bid to counter the frequently advanced arguments that the use of brand names in prescribing adds excessively to pharmaceutical costs and can lead to confusion among the prescribers... The Office would like to see the term "branded" replaced on the grounds that it no longer sufficiently describes the role played by manufacturers' own preparations. It suggests instead the term "pharmaspecific name" describes a specific medicine having a particular action in individual patients or groups of patients' (emphasis added). As will be shown later in this study, these reactions form part of an emerging strategy by which pharmaceutical companies are trying to use the bio-availability arguments as a justification for retaining the present apparatus. Though it is not the subject of this study, it is worth emphasising that the corporations are also doing what would be expected given growing awareness of the problems of the industry, namely *diversifying* into other fields.
- 13 DAFSA, *The Pharmaceutical Industry*, 29.
- 14 The argument has been developed at greater length in Peter O'Brien, 'Foreign Technology and Industrialisation: The Case of Spain', *Journal of World Trade Law* (September-October 1975), reprinted in Spanish in *Información Comercial Española* (mayo de 1976).
- 15 *The Pharmacist's Journal* (London, 25 September 1976), 260.
- 16 Put in a different terminology, pharmaceuticals and the functions connected with their production, distribution and use exhibit in stark form what happens when exchange-value dominates use-value of a commodity.

- 17 Lall, *Major Issues*, 27.
- 18 Quotation from *The New York Times*. (6 January 1975), 35. The study from which the figures are drawn is Council on Economic Priorities, *Resistant Prices: A Study of Competitive Strains in the Antibiotic Market*. The seven antibiotics included were (by generic name): Penicillin VK, Penicillin G, Oxytetracycline, Ampicillin, Erythromycin, Chloramphenicol, Tetracycline, Hydrochloride. It was estimated that consumers were overpaying by at least \$180 million a year.
- 19 Senaka Bibile, 'State Pharmaceuticals Corporation of Sri Lanka (document presented to the Non-aligned Summit Conference, Colombo, August 1976), 4.
- 20 Lall, *Major Issues*, 26.
- 21 DAFSA, *The Pharmaceutical Industry*, 30.
- 22 Robert Ledogar, *Hungry for Profits* (New York, 1975), 27. Frequently, as part of the verbal obfuscation which shrouds the pharmaceutical industry, the toxic effects are called 'side-effects'. The usage of this misleading term has been effectively destroyed by Sacks in his discussion of the drug L-DOPA, which was introduced by some as a 'miracle drug' in 1967. Sacks states: 'The term "side-effects" is objectionable and to my mind untenable, on three sets of grounds: practical, physiological, philosophical. First, the vast majority of what are now called "side-effects" had long ago been observed as characteristic responses of "normal" animals given L-DOPA; in this situation, where there were no therapeutic assumptions, intentions or insistences, there was no thought of introducing such categorical distinctions. Secondly, the use of such a term hides the actual structure and interrelation of "side-effects", and therefore prevents any study of this. The enormous number and complexity of "side-effects" from L-DOPA, though an affliction to patients, is uniquely instructive if we wish to learn more of the nature of disease, and of being; but the possibility of such learning is foreclosed if we take the term "side-effects" to be the end of the matter. Thirdly, to speak of "side-effects" here (or in the context of technology, economics or anything whatever) is to divide the world into arbitrary bits, and deny the reality of an organised plenum.' See Oliver Sacks, *Awakenings* (Pelican Books 1976), 287.

- 23 Ledogar, *Hungry for Profits*, 39.
- 24 Cited in Oscar Caballero, *Las multinacionales del dolor* (Madrid 1974), 10 (my translation).
- 25 There are two additional problems of identification which can create plenty of headaches. The first is that, contrary to the repeated assertions about each company's painstaking elaboration of its own version of a generic product, the company selling the drug might not be the producer. Thus in *The New York Times* article cited earlier (see 18) it is stated that 'because a drug company's name is on a pill does not mean that the company actually produced it. Bristol Laboratories, for example, which controls 24 per cent of the market for ampicillin, actually produces 70 per cent of all the ampicillin certified for sale in this country. Smith Kline, Upjohn and Parke Davis all buy their ampicillin from Bristol, put their own names on it, and then sell it for less than Bristol.' I have also been told that at least one prominent trans-national company buys its supplies of penicillin from Eastern Europe and then sells under its own brand label. A developing country in that market could certainly buy direct and save the premium on the brand - provided, of course, as will be emphasised later, that it had collected information on alternatives.
- The second identification obstacle exists when a potentially dangerous substance has been mixed into so many preparations that it may be difficult to find all of them quickly enough. 'One of the reasons it took so long to withdraw the tranquiliser Thalidomide /which was responsible for the birth of thousands of deformed babies in Europe in the early 1960s/ from the market is that it was sold in preparations combining aspirin, phenocetin, quinine, aninopyrine, bacitrocin, dihydrostreptomycin, or secobarbital for the treatment of such varied conditions as colds, coughs, flu, nervousness, neuralgia, migraine and other headaches, and asthma. In all, 37 thalidomide-containing drugs were sold and the original producer, Chenia Grünenthal of Germany, granted licences in 11 European, 7 African, 17 Asian, 2 North American and 9 Latin American countries.' See Meredith Turshen, 'An Analysis of the Medical Supply Industries', *International Journal of Health Services*, 6, 2 (1976), 283.

- 26 In the article in *Financial Times*, op cit, it is stated that 'The report points to a growing preference among doctors for the use of branded products in prescribing. It says the proportion of medicines dispensed as branded preparations grew from 16 per cent in 1949 to 82 per cent in 1973.'
- 27 The Monopolies Commission, *Chlordiazepoxide and Diazepam* (London 1973), 58 and 59.
- 28 S A Wickremasinghe and Senaka Bibile, *The Management of Pharmaceuticals in Ceylon* (Colombo, March 1971), 6 and 7.
- 29 H A Handoussa, *The Pharmaceutical Industry in Egypt* (PhD Thesis, University of London 1974), 141.
- 30 Robert Aries, *The Pharmaceutical in Europe* (Paris 1975), 25.
- 31 Lall, *Major Issues*, 37.
- 32 DAFSA, *The Pharmaceutical Industry*, 31.
- 33 Ledogar, *Hungry for Profits*, 22.
- 34 *New Scientist* (23 May 1974), 491.
- 35 Monopolies Commission, *Chlordiazepoxide and Diazepam*, 52 and 53. Further comments on the hospital supply system, this time in the Indian context, have been made in a recent note 'No Drugs for the Poor', *Economic and Political Weekly* (11 September 1976.) There it is shown that 'it is not a fact even that the pharmaceutical industry supplies medicines in the required quantities to government hospitals at specially low prices', (p 1482). In 1974-75, three hospitals studied had to make, taken together, 64 per cent of their purchases on the open market paying prices on average 80 per cent in excess of the rates at which the companies were supposed to supply certain drugs.
- 36 Ledogar, *Hungry for Profits*, 17.
- 37 *Economic and Political Weekly* (27 March 1976), op cit, 499.

- 38 R W Lang, *The Politics of Drugs* (Lexington 1974), 298.
- 39 B M, 'Scuttling the Hathi Report', *Economic and Political Weekly* (31 May 1975), 818.
- 40 'New medicines are not always more efficacious than older ones, though they are usually more expensive. An interesting example is the introduction of Rifampicin in the treatment of tuberculosis: clinical trials showed that the drug was not more effective than older ones such as isoniazid, but a daily dose of Rifampicin (0.6 grain) cost \$1.63 as compared with that of isoniazid (0.45 grain) at \$0.02 [prices are for Algeria in 1973]. Pressure from pharmaceutical companies to buy Rifampicin was so strong that participants in the Third African Regional Conference of the International Union against Tuberculosis in 1972 adopted a resolution calling upon all doctors in African public health services to resist and refuse to allow the drug into their countries.' Turshen, 'An Analysis of the Medical Supply Industries', 276, 277.
- 41 Wickremasinghe and Bibile, *The Management of Pharmaceuticals*, 6.
- 42 Goggin, 'The Irish Trademark System', 76.
- 43 *Action Programme for Co-operation among Non-Aligned and Other Developing Countries on Pharmaceuticals* (Document HAC/CONF. 5/11, Colombo, August 1976). The present writer was one of the authors of this document.
- 44 Resolution NAC/CONF.5/S/RES-25, adopted on 19 August 1976.
- 45 This sub-section relies heavily on the paper by Bibile, 'State Pharmaceutical Corporation', and on discussions with him.
- 46 Some of the more highly qualified of these private sector employees could be brought into the State sector.
- 47 *Economic and Political Weekly* (27 March 1976), *op cit*, 496.
- 48 *Ibidem*, 498.

- 49 'Pharmaceutical Industry: Public Sector at Private Sector's Service', *Economic and Political Weekly* (8 May 1976), 678.
- 50 Ibidem.
- 51 Hathi Committee, *Report*, 260-261.
- 52 *The New York Times*, *op cit*.
- 53 Turshen, 'An Analysis', 277.
- 54 Hathi Committee, *Report*, 245.
- 55 Illich, *Medical Nemesis*, 22.
- 56 Office of Health Economics, *Brand Names in Prescribing* (London, September 1976).
- 57 Lall, *Major Issues*, 55. Note also the following statement from the Final Report of the Task Force of the Department of Health, Education and Welfare (Washington, February 1969): 'The Task Force finds, however, that on the basis of available evidence lack of clinical equivalence among chemical equivalents meeting all official standards has been grossly exaggerated as a major hazard to the public health.' Quoted Ross A Chapman and George A Boyd, 'A Preliminary Study of Drug Costs in the Commonwealth Caribbean' (February 1974), 45 and 46.
- 58 A 1975 expert mission to the People's Republic of China encountered only one reference to bio-availability during a 26-day trip. See Norman R Farnsworth, 'Pharmacy Practice and Pharmacy Education in the People's Republic of China' *American Journal of Pharmaceutical Education* (May 1976).
- 59 Witness the proposals mentioned in the *Financial Times* article cited earlier.
- 60 *Economic and Political Weekly* (27 March 1976), *op cit*, 499.
- 61 *Business Latin America* (5 December 1973), 390.
- 62 Ibidem.

63 Ledogar, *Hungry for profits*, 69.

64 *Business Latin America*, *op cit*, 391.

65 Ledogar, *Hungry for Profits*, 70.