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This paper describes the experience of Sri Lanka in reforming the structure of production, importation, and distribution of pharmaceuticals in the period 1972-1976. It highlights the actions and reactions of transnational pharmaceutical corporations to these reforms, and traces the achievements and problems of the State Pharmaceuticals Corporation which was set up to implement the reforms. The roles of political leadership in regulating the power of drug transnationals, and of the medical profession in resisting reform, seem to be of crucial significance. Developing countries wishing to lower the present high cost of drug delivery must proceed with great care and immense caution, since complex problems of quality control, bioequivalence, medical acceptance, and consumer reeducation are involved.

This paper attempts to analyze the experience of Sri Lanka in reforming the structure of production, importation, and distribution of pharmaceuticals during the period 1972-1976. Since the pharmaceutical industry is of vital concern for every developing country, and since it is overwhelmingly dominated by transnational corporations (TNCs) that possess considerable market power as well as a proven ability to resist reform, such an analysis can serve two purposes.

First, it can help policy makers in less-developed countries (LDCs) who wish to reform the industry by illustrating the sorts of difficulties, resistance, and pressures they may expect to face, as well as the benefits they may expect to achieve.

The drug industry has aroused considerable controversy in both the home and host countries of the TNCs which dominate it.1 The U.S. Senate, during about 18 years of intermittent hearings in various subcommittees, has produced volumes of criticism, evaluation, and recommendation, on the basis of which the Food and Drug Administration (FDA) has set up a complex apparatus for controlling the introduction of new drugs, checking their efficacy, regulating advertising and labeling, and, most recently, reducing their cost to federally financed health schemes (although not to the public).

Other developed countries have also instituted controls of different degrees of intensity and comprehensiveness, though the dominant firms have, with the help of

1 Critiques of the international pharmaceutical industry are provided in references 1-5: for a defense, see reference 6.
various groups, managed to thwart substantial reform. Less-developed countries have not been able to institute successfully controls of the types used by advanced countries, and, with the exception of Sri Lanka, they have certainly not been able to achieve complete rationalization of the industry while retaining a basically capitalist system of production. A number of them have tried (Brazil, Pakistan, India, Turkey, and others have undertaken or are proposing to undertake partial reforms), but have not achieved the desired result of providing effective and inexpensive medicines to meet the basic needs of their populations. We believe that, with careful planning, this goal is achievable. The problem is why the effort is so rarely undertaken. The Sri Lanka case sheds light on this.

The second purpose served by our analysis of the Sri Lanka experience is that it can further our understanding of the TNC phenomenon, in particular of the interaction between these giant firms and the various groups in host LDCs that are concerned with them. While a great deal has been written about the problems raised by TNCs and the means that may be used to control them (7), much of the discussion by “conventional” economists has been conducted in a sociopolitical vacuum which abstracts from the conflict and compromise (or domination) between the interests involved. Many economists ignore the existence of excess profits arising from TNC operations that might be included in the bargaining process. Even when economists admit the existence of such profits, the game-theory approach (i.e. with an enlightened government embodying a clearly defined “national interest” on one side, confronting a politically powerless TNC on the other) generally used to analyze the process of how TNC earnings are distributed between the firms and host governments ignores crucial sociopolitical factors. It is mainly the political economists who have tried to integrate economic, class, social, and ideological factors in their analysis of the TNC-LDC interplay. Such attempts have not always been successful; the theoretical constructs still need considerable refinement, and there is an unfortunate tendency to overgeneralize from particular situations. Nevertheless, this approach reflects a much clearer grasp of the forces at work. The detailed analysis of one microcosm of the political economy of the TNC-host country conflict can certainly add to our limited knowledge of how such forces work.

A note of caution is necessary, however. One must be very careful in generalizing the experience of the drug industry in Sri Lanka to other countries or other TNC-dominated industries. The small scale of Sri Lanka’s economy and its relative industrial backwardness, coupled with relatively high degrees of literacy and political awareness, may limit its relevance to large countries such as Brazil, India, or Pakistan, or even small ones like Nepal. The peculiar nature of the drug industry, with its high technology and powerful promotional practices, its close relationship with the effective buyers (the medical profession), and public and official sensitivity to its products, may similarly render it different from industries whose products are of lesser social importance, whose merits are more objectively assessable, or whose market power is easier to dilute. Despite this, however, we believe that some interesting and important lessons do emerge from the Sri Lanka case which are of general validity, especially as far as the formulation of health and pharmaceutical policies in less-developed countries is concerned.
BACKGROUND TO THE REFORM

Prior to the reforms undertaken in 1972, Sri Lanka's health delivery structure was similar to that of most countries which do not have a national health service or a comprehensive insurance scheme (8). It consisted of a state sector, administered by the Department of Health, which ran hospitals and provided free medicines, and a private sector, where drugs were provided by relatively unregulated local producers and importers. Although there were 14 drug firms in the country, the bulk of their activity, which consisted of simple formulation and packaging of finished pharmaceuticals imported in bulk, was concentrated in over-the-counter (OTC) or "proprietary" drugs sold without prescription. The greatest share of "ethical" or prescription drugs was directly imported into the country in finished form.

Imports for some 800 institutions in the state sector were handled by the Civil Medical Stores (CMS), while those for the private sector were undertaken by 34 local agents of foreign suppliers. The state sector was, until the late 1950s, subjected to the same exuberant promotion and product-differentiation activity that the industry used in selling its products to the private sector, and still uses in most LDCs where official control of promotion is relatively lax. Several thousand brands were presented to doctors, with the accompaniment of heavy advertising, distribution of samples, and visits by detail men. So great was the influence of promotion on information flow that doctors in Sri Lanka hospitals were often unaware of the generic names of the drugs they were prescribing (and thus of which drugs were equivalent in their effects) and of the proper indications and contraindications for their use. Certainly their practice showed an appalling lack of awareness of drug prices and the possibilities for economizing on drug purchasing.

One of the present authors, then professor of pharmacology at the University in Colombo, was asked to help the CMS rationalize drug prescribing. He advised the government to reduce the drugs used to the 500 (in 1000 presentations) that were actually necessary, and to publish a Hospitals' Formulary listing medicines by their proper generic names only and giving full and objective information on their use. It was recommended that a Formulary Committee be appointed to prepare the report and to review it each month, deleting obsolete or unnecessarily toxic drugs and introducing new drugs that had been proven effective.

In 1959, the state sector was rationalized according to advice given in the face of

\[2\text{ In early years of excess, such promotional activities were used in the developed countries as well. Furthermore, various U.S. Senate hearings, most recently those under Senator Edward Kennedy, have shown that many of these excesses continue today. The U.K. situation was reviewed by the Sainsbury Committee (9) and Coleman (10), and the Canadian situation by Klass (3). The evidence suggests that the U.S. is subjected to the greatest amount of high-pressure promotion; the U.K. has recently experienced a fall in promotion expenditure, mainly as a result of official control.}

\[3\text{ This often led to situations where, when particular prescribed brands were not available, patients were deprived of that drug or had to engage in long searches, although the pharmacies and hospital dispensaries had stocks of identical medicines under different names. Bibble (8) also notes instances of doctors substituting one brand of a drug for another in the mistaken belief that they were changing the treatment.} \]
considerable opposition from drug companies and doctors, but nothing was done about the private sector. Drugs were purchased and dispensed by generic names in the state system, and the greatly reduced list proved over time not to have had any adverse effects on the hospitals' standards of medical care.

The 1960s witnessed a steady deterioration in Sri Lanka’s balance of payments position. The government was compelled to progressively cut allocations of foreign exchange to both the CMS and the private sector. The CMS found, under this pressure, that it could economize on the purchase of the generic drugs listed in the Formulary by “shopping around” on the world market and buying in bulk, rather than depending on its traditional TNC suppliers. The magnitude of savings was enormous, as we shall see later in our discussion of the rationalization of the private sector. Moreover, the experience gained by the CMS in this period was invaluable to the reforms that were to follow.

By 1963, the foreign exchange crisis had grown to such proportions that the government decided to economize on the purchase of drugs in the private sector. Its first step was to reduce the number of drugs imported, a step taken in the belief that this would reduce the total cost of drugs purchased abroad. The 4,000 drugs being used under a far larger number of brand names were cut, on the recommendation of a Drugs Subcommittee, to 2,100.4 No action was taken, however, to reduce the number of brands under which these could be sold, and the proliferation of differentiated products continued as before. Thus, 23 brands of tetracycline capsules, 12 of chloramphenicol, 12 of tetracycline syrup, and 12 of prednisolone were being imported, and in every case there was wide variation in the prices of generically identical medicines, with the more expensive and more heavily promoted branded products dominating the market.5 Advertising continued unabated and the prices of imports remained unregulated. Not surprisingly, savings on the total import of drugs turned out to be negligible.

From 1965 to 1970, the foreign exchange allocation for drugs was cut from a total of Rs. 33 million (Rs. 20 million for private and Rs. 13 million for CMS imports) to Rs. 24 million (Rs. 14 million and Rs. 10 million, respectively). As population and medical needs had increased steadily and prices had risen over this period, the per capita supply of pharmaceuticals declined drastically. The Prime Minister asked one of the present authors again to advise on the rationalization of the structure, this time to encompass the entire country. A report entitled The Management of Pharmaceuticals in Ceylon (13) was produced in collaboration with a member of Parliament. This report drew heavily on experience gained during the 12 years of operating a rationalized CMS list, and called on the expertise of a group of doctors, pharmacologists, and clinical pharmacologists at the University of Sri Lanka. This expertise,

4 There is no record of the number of brands then on the Sri Lanka market, but it probably ranged between 10,000-15,000. According to the Hashi Committee (11), India had some 15,000 drugs, and Brazil and Spain had between 20,000 and 30,000.

5 This information is based on data collected by the State Pharmaceuticals Corporation on private sector purchasing for early 1972. In a study of the antibiotic markets in the U.S., Brooke (12) found that for well-established and out-of-patent drugs, the more expensive brands invariably dominate the market, with price variations on identical products of up to 1,000 percent being sustained over many years.
drawn from a milieu independent of the drug TNCs, proved to be of crucial significance in providing the complex of skills required to formulate and mount a comprehensive reform program.

Before discussing the implementation of the report, however, let us first describe its main recommendations:

- The channeling of all imports of processed pharmaceuticals and pharmaceutical chemicals through a state trading corporation. Prices of the 18 main categories of processed drugs (70 percent of the CIF (cost, insurance, and freight) value of private sector imports) were compared with those that were being paid by the CMS in 1969 for the same drugs. It was found that the annual actual import bill of Ceylon rupees 11.7 million would have been only Rs. 3.7 million (13. Table II), a savings of 68 percent, if the purchases had been made by a centralized agency taking advantage of the price differences in the international drug market and buying in bulk from economical sources. Prices of pharmaceutical chemicals were not compared since the CMS did not handle such imports, but it was assumed (rightly, as it turned out) that similar savings would be available here to a rational and informed buyer.

- Reduction of the number of drugs imported, and amendment of patent laws (Sri Lanka offers strong patent protection in the form of product patents) in order to obtain newer drugs from the least expensive possible sources. It was noted that the university departments of pharmacology were already preparing a rationalized list of drugs which would retain all the therapeutic properties of the previously imported drugs, as well as leaflets informing prescribers of the proper use of the reduced list and attempting to persuade them of the therapeutic efficacy and bioequivalence of generic named drugs. The rationalization and provision of objective information were to be extended to the category of over-the-counter drugs, where, it was noted, several ineffective, unnecessarily expensive, or "irrationally" combined drugs were in common use.

- The replacement of brand names by generic names in the sale and prescribing of medicines, and an end to the promotion of drugs by the manufacturers. The use of generic names would lead to better prescribing practices, while the provision of information on drugs from official sources would only remove the dangers and costs inherent in the extravagant promotional practices of the industry. As there was already an official quarterly publication of the Formulary Committee, the Formulary Notes, in existence for precisely this purpose, it was recommended that it be upgraded, better financed, and brought out more often.

6 Of the four most important categories of drugs examined, the cost of analgesics and anti-inflammatories would have been cut by 88 percent, antimicrobials by 52 percent, antidiabetics by 87 percent, and antihistamines by 79 percent.

7 Studies by the FDA, based on exhaustive reviews of the literature and clinical trials, have found that up to 60 percent of prescription drugs and, using a smaller sample, up to 75 percent of OTC drugs, lack evidence of effectiveness (14). Many of these drugs have been withdrawn from the U.S. market but continue to be sold in markets with more lax supervision, in developed as well as less-developed countries.

8 Such dangers and costs include overprescribing, inappropriate prescribing, lack of awareness of adverse reactions, and uneconomic prescribing. They are further discussed in references 2, 5, 14, and 15.
Future development of local manufacture of pharmaceuticals based on guidelines set by the government. Local manufacturers would produce according to the rationalized drug list, use materials imported by a state trading corporation, and leave promotion and distribution to the state. If they proved recalcitrant, the government would have the power to nationalize them under the provisions of the Sri Lanka State Trading Corporation (Drugs) Act.

The report also contained a number of specific suggestions on countries from which older, commonly used drugs should be imported (i.e. socialist countries of Eastern Europe), and on the training of pharmacists, improvement of quality-control procedures, and a restructuring of the CMS (which had suffered a drastic deterioration in its buying, storage, and distribution procedures).

The Wickremasinghe and Bibile report (13) set the stage for a complete overhaul of the system of drug provision in Sri Lanka. The government decided to establish the State Pharmaceuticals Corporation (SPC) of Sri Lanka (under the honorary chairmanship of one of the present authors), to enlarge the Formulary Committee and rename it the National Formulary Committee, and to hand over all drug importing and the bulk of distribution activities to the Corporation. Not all the recommendations noted above were implemented, and some proved more difficult to effect than has been envisaged. The industry protested strongly and made formal protests to the government but, by and large, the rationalization of the system was carried out. We shall discuss its achievement and limitations later.

MAJOR PARTICIPANTS IN THE REFORM

We can identify six broad groups which were directly or indirectly concerned with drug provision in Sri Lanka, and played a constructive or obstructive role in the implementation of the reform program.

The Government

Sri Lanka had at the time a coalition government made up of three left-wing parties. While certainly not unified in its objectives, the government had a strongly socialist ideology. It had implemented sweeping land reforms, started several public sector industries, promoted welfare services and equality of incomes, and was committed to a pattern of development of a primarily egalitarian nature. It was also a government in severe economic difficulty, which resulted in two opposing effects: (a) it made it far more willing to take measures to economize on pharmaceutical purchases along the lines described above; and (b) it made it more vulnerable to economic pressure from those opposed to the reform (i.e. the aid-donor countries whose TNCs were threatened).

The government was, of course, neither monolithic in its structure nor fully consistent in its strategy. The very fact that it was a coalition meant that its ideological positions shifted with the shifting fortunes of its constituent parties, thus affecting the political underpinnings of the entire policy. Since a clear and strong political direction is absolutely vital in any such policy, any change of direction clearly could weaken the
implementation of difficult portions of the reform, leaving the lower sections of the government (i.e. the SPC) at variance with the apex (the Prime Minister’s office). Until 1975, the Prime Minister fully supported her Minister of Industry and the SPC in their reform programs, but with growing political problems and food shortages, their paths diverged. The Lanka Sama Samaj Party (LSSP), the most radical party in the coalition, left the government. The Prime Minister, along with powerful sections of the government, moved distinctly to the right, accepted U.S. food aid, and backtracked slightly on her earlier strong stand on pharmaceutical reform. The Minister of Industry found it increasingly difficult to pursue his former strategy, and the SPC was obliged to compromise on some important elements of the program as originally conceived. Thus, the major achievements of the reform came in its early years; in later ones the momentum slowed perceptibly. The pace of reform had little to do with its objective merits or demerits; it was governed more by the power struggles at the apex.

Local Reformists Outside the Government

This category constituted the main intellectual, technical, and organizational force behind the reform, and comprised a group of highly trained, well-placed, radical-minded academics and doctors who could analyze the benefits of change, argue the case cogently, and provide the technical expertise necessary to implement it. The combination of ideology and expertise with a socialist-minded government was, as long as government support was given, crucial. Many less-developed countries have the expertise and ideology, but in disparate groups of people; others attempt reform at the wrong historical junctures. Then, depending upon who is in power (or close to it), reform tends to be hasty and misconceived, or stalled by the machinery which is to implement it, or simply not undertaken (or reversed).9

The Drug Industry

It was to be expected that the drug industry would be categorically opposed to reform. Not only would such rationalization reduce the profitability of expensive branded products, it would set a bad example to other poor countries which were trying to get more medicines from very limited resources. It would be misleading, however, to consider the entire industry in this manner. There are several contradictory forces at work, and it is crucial to differentiate between them.

Local Manufacturers. There are five large TNCs with subsidiaries operating formulation and packaging plants in Sri Lanka: Pfizer (U.S.), Glaxo (U.K.), Warner-

9There are examples for each of these possibilities. In Pakistan, the abolition of brand names in 1973 was initiated by a left-wing minister. It was introduced too suddenly, the requisite quality tests were not undertaken, doctors were not properly informed, the public was not reeducated, and the experiment failed. In the U.K., a Labour Minister of Health sought to implement the Sainsbury proposals, but the opposition of the industry and the civil service itself led to a weak compromise solution (16). In Brazil, a nationalistic military group abolished drug patents in 1969 and set up the Central de Medicamentos to provide cheap basic drugs to the poor; a change of government and an ideological reversal considerably diluted its original aims (4, 17).
Hudnut (U.S.), Unical (for Burroughs-Wellcome, U.K.), and Reckitt and Colman (U.K.). These account for about 75 percent of local drug production. Two local companies, producing under license for TNCs, account for another 22 percent. The remaining seven producers are small local companies, generally producing preparations for skin application. It is clear that the TNC subsidiaries would be hostile to the rationalization of drug production and promotion (since over half their production consisted of elegantly packaged and heavily advertised minor remedies and vitamins of little therapeutic value to the majority of the population, which could not afford them), and that they would oppose the channelling of imports of pharmaceutical chemicals (which they previously imported from their principals at arbitrary prices) through the SPC. Clearly also, their hostility would be more virulent and effective the greater the support they could expect from their home governments.

The response of local firms would be more ambiguous. On the one hand, they (especially the large firms operating under foreign license) would resent the interference of the SPC in their production and marketing decisions. On the other hand, they would welcome the lowered costs of pharmaceutical chemical imports, the provision of technical expertise by the SPC, the protection given against foreign competition, and the aid provided by the state to promote local enterprise. They may also be more susceptible to local ideological currents, and have a weaker base from which to resist any reform.

**Foreign Suppliers.** Those TNCs which were previously selling high-priced patented and branded drugs would resent the reform, but would be unable to apply anything but indirect pressure unless they found patent infringements and decided to risk a court action in Sri Lanka against a public corporation. Some TNCs are also competitive suppliers in generic markets, and in this context they would not suffer from the change. (Some, like Roche, which sells extremely expensive tranquilizers and very cheap vitamins, are both.) Smaller foreign companies in capitalist countries which sell by generic names, especially those which do not observe patent laws, would welcome the reform, as would the large public sector companies in socialist and developing countries such as India and Egypt.

**Local Dealers.** Those who were dependent on the previous structure of the industry for a livelihood (e.g. detail men, importers, and firm representatives) would be bitterly opposed to reform, unless they could be absorbed into the new structure or persuaded of its wider social benefits.

**Local Opponents of Reform**

There are other interested groups, outside the industry itself, which would oppose reform. The most important of these would be members of the medical "establishment" (the Sri Lanka Medical Association) and the private medical profession, who received various direct (free samples and hospitality) and indirect (attractive advertising, easily digested information from detail men) benefits from the drug companies' promotion, and who were convinced of the superior quality, efficacy, and reliability of the branded products of the large manufacturers. There are two, relatively minor,
countervailing factors. First, a certain quantity of very common drugs is provided by doctors in Sri Lanka as part of the consultation fee, and doctors would welcome the lowering of cost for these drugs. Second, a few doctors could be expected to have a strong social conscience, or be aware of the criticisms of the industry voiced in the developed countries, to such an extent as to overcome the conditioning imposed by the industry's promotion.

Some opposition may also be expected from the consumers themselves, who are accustomed to brand names, have been persuaded by the advertising of OTC drugs, or are worried by the reduction in the number of medicines. Much of this opposition would tend to be concentrated in the ranks of the educated elite, who are conscious of branded and advertised drugs and are able to afford them, but its effectiveness would, at least in the Sri Lanka case, be limited by the strength of the dominant ideology and the socialist commitment of the ruling sections of that elite. As the political climate changes, however, this factor may well prove to be of great significance; the next year or two will show the strength of the elite's resistance.

Foreign Opponents of Reform

Since the TNCs as a group are likely to feel threatened by the reform, and since they wield far more power than small firms, it is to be expected that their representative organizations and home governments will do what they can to oppose it. The power that they wield will depend on a number of factors, including the extent of foreign investment (not just in the drug industry) already in the country, the expected inflow of direct investment and aid, and the involvement of the home country in the defense or support of the regime. The more the LDC is dependent upon the home country for aid, investment, or military support, the more pressure the drug industry is likely to bring against drastic reform.

Foreign Supporters of Reform

These are, by their very nature, unlikely to be as powerful in most LDCs as the opponents. Reformist doctors or pharmacologists, charity organizations, and even government bodies (like the FDA) in the developed capitalist countries may give moral support and advice, but are unlikely to be able to influence their own governments if a real threat to foreign investment is perceived. Those in developed socialist countries can, of course, be more helpful in terms of selling drugs and providing technology, but they do not possess either the capital or the advanced know-how of the TNCs. Thus, their support will be most valuable for countries in the first stages of pharmaceutical development and least valuable for those with advanced pharmaceutical industries. For Sri Lanka, with very little local production, the socialist countries may be quite useful; for India, they may be less so. Thus, the former would be freer to implement reform than the latter.

These, then, are the various groups which have an interest in the pharmaceutical industry, and the reactions that we may plausibly expect them to have to a major reform. The outcome is clearly far from determinate. On the contrary, it depends upon a complex interplay of social, political, and economic factors, as well as upon
how they exercise their influence by means of ideology, persuasion, bargaining, or straightforward domination. The following discussion can only scratch the surface of this complexity, but we do hope to elaborate upon the political economy of controlling transnationals in this area.

MAJOR ISSUES IN THE REFORM

Acting on the recommendations of the Wickremasinghe and Bibile report (13), the government set up the State Pharmaceuticals Corporation in 1971. It was initially empowered to import processed pharmaceuticals for the private sector, and later also for the CMS, but the patent law was not changed. The SPC was also permitted to import some pharmaceutical chemicals for local manufacturers on a negotiated basis. The principle of changing from brand to generic names was accepted. The promotion of drugs by manufacturers ceased, except for the relatively small proportion of the market for OTC drugs, which were manufactured locally and sold through the existing retail network.

The process of reform may be best examined in terms of four major issues: (a) the centralization of purchase from a rationalized list of finished drugs; (b) the purchase of pharmaceutical chemicals for local manufacture; (c) the non-observance of patents; and (d) the change from brand to generic names, with the accompanying problems of quality assurance, bioequivalence testing, and provision of independent information.

Centralized Purchase from a Rationalized List

The State Pharmaceuticals Corporation was faced with two immediate major tasks: to reduce the several thousand brands of the 2100 drugs being imported to a reasonable number without detriment to therapeutics, and to undertake the task of buying drugs of adequate quality economically on world markets, replacing the 134 private importers which had previously done this.

The National Formulary Committee was entrusted with the task of rationalizing the drug list for the private sector along the lines which had been used for the state sector in 1959. Three main criteria were used: (a) the deletion of imitative drugs which added nothing to the therapeutic value of particular drugs that were to be chosen on the basis of economy; (b) the deletion of a large number of "irrational" fixed combination drugs (similar to the FDA's action in the U.S.) where good practice required the flexible use of single drugs; and (c) the deletion of drugs without clear therapeutic value or with high toxicity (8). The number of drugs was reduced from 2100 to 600, and further reductions are being considered. Since brand names were almost entirely (but, as we shall see, not completely) abolished, the profusion of brands practically disappeared, drug prices were greatly reduced, and there is no evidence that health services were at all adversely affected.

The main initiators of the rationalization of the drug list were academic pharmacologists and clinicians. It was clear to them that such a reduced list was conducive to better prescribing and to economizing on purchase. The main opponents of the reduction were the medical establishment, the local drug companies and their dependents, private importers, and, in a few cases, consumers. Complaints were made
by some doctors of interference with their professional judgment, by drug companies and importers of the loss of therapeutically desirable drugs, and by consumers of the loss of familiar brands. The tactics of the opposition ranged from publishing adverse reports in the press and direct protests to the government, to organizing "symposia" of opponents and stirring up popular resentment through rumor and insinuation (powerful weapons on a small island). There was little attempt to produce scientific evidence for opposing particular deletions, and many went uncontested; but over the years a great deal of heat was generated by doctors and drug representatives about the restricted drug list and the activities of the SPC.

There were two ways of effecting a compromise on the rationalized list. The most important was to induct leading private practitioners into the National Formulary Committee and the tender board of the SPC, and make them a responsible party to the decision-making process. In the Committee they could be exposed to scientific evidence based on clinical trials and the findings of other countries; the conflict would then become localized and partly shorn of its emotional trappings, and the doctors outside would have a much weaker case to argue. The second way was simply to give in on drugs where feeling ran exceptionally high, in exchange for more acceptable deletions. As time passed and the doctors became accustomed to working with the reduced list, without obvious detriment to health care, the process of rationalization became somewhat easier. However, with the departure of the LSSP from the government in 1975 and the weakening of government support for the SPC's reforms, criticism grew more strident where vested interests were concerned. The local representatives of TNCs voiced more open protest in the newspapers, and doctors were able to force additional concessions from the Formulary Committee on the retention of particular branded drug imports. The progress of rationalization, while not reversed, was certainly slowed down in 1976. The battle is still being waged, and its final outcome will depend on political developments in 1977 and thereafter.

The second immediate task faced by the SPC was to replace the private import system for finished pharmaceuticals. This clearly required a great deal of careful planning, quality checks, inventory control, and so on before implementation. The SPC studied the pattern of private sector imports for 6 months in 1972, and started by taking over about one-third of these imports. This proportion was increased as the SPC gained experience, and by the end of 1973 it had taken over all imports.

Since the purpose of the exercise was to economize without compromising on quality or therapeutic benefits, the SPC had to take several factors into account. First, some drugs were so new that they were effectively monopolized by the innovator; on these, termed "monopoly quotations" (about 26 percent in terms of value in 1973 and 22 percent in 1975), the SPC could only bargain for better terms (but from a weak position) until a competitor (usually a non-patent observing firm) appeared and offered the drug more cheaply at satisfactory quality.

Second, price quotations on older drugs could be obtained from a number of

10 This was the case with soluble aspirin, which has no therapeutic advantage over ordinary aspirin but costs three times as much. The detail men for the local TNC subsidiaries concerned mounted an intensive campaign, via the doctors, to have the drug retained. So powerful was this campaign that the National Formulary Committee was forced to retain the drug, which continues to dominate the private aspirin market.
producers throughout the world. The maintenance of quality required that any small
generic drug producer seriously considered had to provide a certificate of quality plus
an independent certificate of quality from a reliable laboratory (e.g. the Haffkine
Institute in India), an agent (e.g. the General Superintendence Company of Geneva),
or an official body (e.g. the PARCOST program in Ontario, Canada). It was only after
such certification that a low-price bid would be accepted. The savings to the country
of “shopping around” and obtaining better information about market conditions were
usually substantial, as we shall see.

Third, in some cases, traditional TNC suppliers or other TNCs would themselves
quote the best price, substantially reducing their earlier price. There was, in other
words, a distinct benefit to be gained from bargaining apart from simply “shopping
around.” This benefit also applied to some traditional East European suppliers, and
not just TNCs. Recourse to public sector firms clearly does not obviate the necessity
of acting as a “rational” consumer.

By 1975, the market shares of various supplying countries had changed dramat-
ically as compared to pre-SPC days in early 1973: the U.K. supplied 16 percent of
imports in 1975 (47 percent in 1973), the U.S. 2 percent (16 percent); India 17
percent (7 percent); Hong Kong 6 percent (0.5 percent); Japan 7 percent (0.2
percent); and Poland, Hungary, and Czechoslovakia together 10 percent (0.4).
Switzerland and West Germany proved themselves to be competitive and maintained
their former shares of 7.9 percent, although some former TNC suppliers were replaced
by small generic manufacturers from these countries.

We shall not detail procedures for tendering, control of ordering and shipping,
storage, and so on, which are fascinating but not relevant to the present discussion.
Two points should be briefly noted, however. First, almost no drugs were purchased
from Italy, the best known source of inexpensive drugs (because it does not observe
patents on drugs), simply because the SPC lacked information on the manufacturing
practices of the cheaper generic producers who quoted on tender. Second, the
tendering system was far from ideal. Small manufacturers in the U.S., for instance,
ever submitted bids, partly because they were not aware of the tenders, and partly
because they prefer to bid anonymously for tenders channeled through their trade
association (quite separate from the U.S. Pharmaceutical Manufacturers’ Association,
which represents the TNCs) rather than openly under their own names, because of
fear of commercial retaliation by the big TNCs which are also important customers.

Resistance to the SPC buying procedures came from several sources. First, the
TNCs themselves, finding the very basis of their oligopolistic pricing and profitability
cut, mounted a campaign to persuade the government and the doctors to reject
low-price drugs. In a letter to the Prime Minister, Joseph Stetler, President of the U.S.
Pharmaceutical Manufacturers’ Association (representing the TNCs), argued forcefully
against various aspects of the reform program. The letter was delivered to the Sri
Lanka ambassador in Washington, D.C., and transmitted to the Prime Minister and

11 In his study of the U.S. antibiotic market, Brooke (12) notes that many large firms buy
finished drugs from small manufacturers and then sell them under their own brands at much
higher prices than generic equivalents sold by their suppliers. It is not surprising, therefore, that
these suppliers would not want to openly undercut their “big brothers” in the world market.
several Ministries concerned. In it, Stetler took the following position on buying drugs economically in the world market (18):

The restraints and prohibitions placed on the industry, and particularly affecting the world-wide, research-based major producers, would not only inhibit the growth of an indigenous pharmaceutical manufacturing base in Sri Lanka, but would also have a number of corollary consequences. Some that might be anticipated are:

1) World-wide tender purchasing by SPC does not guarantee availability of drugs or raw materials, their availability at the time or pricing desired by SPC, or assurance that they would be, in fact, less expensive than those available to companies.

2) Those companies having high investments in research and development and quality control would be discouraged from bidding; sources without such expenses or quality control standards would more likely submit low bids . .

3) Finally, the action calls in question the Government's position with respect to all foreign investment in Sri Lanka.

Stetler's arguments sound persuasive, and the veiled threat of point 6 is rather formidable. Yet events have proved the first two points completely wrong. Worldwide tendering was shown to be amenable to strict quality standards, inventory, and forecasting control, and far cheaper than the previous "free" system. Research-based TNCs showed no aversion to bidding; many of them continued to submit high-cost bids up to 1976, in spite of never winning a tender for commonly available drugs. When they were asked to quote prices for the new drugs on which they had effective monopoly, they were as willing to supply the SPC as they had been to supply private importers. Thus, one tends to question the veracity of Stetler's claim in his concluding paragraph (18, p. 6) to be concerned with the effects "not only on the pharmaceutical industry and on all private industry in Sri Lanka, but potentially for the health of all its citizens."

There was, of course, very little "muscle" to back up the Pharmaceutical Manufacturers' Association's threats, since the U.S. had relatively few investments in Sri Lanka and the TNCs themselves had no intention of boycotting the SPC. Other developed countries did not raise even an official murmur. However, the industry could wield more pressure within the country, through its importers and salesmen. A widespread and insidious campaign denigrating low-cost suppliers was launched. And a second source of opposition, the private practitioners, was drawn into the campaign. Drugs were reported to be ineffective, substandard, or toxic, but little empirical evidence was produced. The SPC always checked the quality of drugs reputed to be faulty, and in cases where such defects as unsatisfactory sugar coating, poor labeling, inappropriate ointment base, etc., were found, the products were immediately recalled and replaced. In some, relatively rare, cases, where the manufacturing firm was thought to be negligent, it was "blacklisted" and barred from tendering.

The important point to note is that there is always a risk of particular batches of drugs being defective, even with the strict controls exercised in the U.S., for example. The evidence from the U.S. does not support the claim that large manufacturers have a better record on drug recalls than small generic ones. Concerning its 1974-1975 recalls, the FDA points out (19):

The list [of 224 recalls] reveals the names of many large and small manufacturers, and the agency is unable to conclude from this list that there is any clear difference between these two groups based on recalls.
In Sri Lanka also, recalls involved large firms (e.g. Roche's tetracycline, Pfizer's penicillin tablets, and Burroughs-Wellcome's malt syrup) as well as small ones. The medical establishment, however, seized upon and publicized the latter, while keeping silent about the former. Physician distrust of lower-priced, unbranded drugs is a universal phenomenon and, indeed, is one of the main fruits of the expensive promotion undertaken by the big firms. This accounts for the latter's products continuing to command far higher prices than those of small firms, even when there is no scientific basis to differentiate between them, or when, as in some cases, they are identical products with different labels. The reaction in Sri Lanka was, therefore, entirely to be expected.

There is no easy way to counteract the opposition, and it still continues among sections of the medical profession. However, some progress has been achieved by two methods. First, doctors were sent literature based on clinical and recall evidence to persuade them that cheaper drugs are not necessarily bad. While such "re-education" was bound to be slow, it did show some success, especially among younger doctors. Second, a few high-priced drugs were permitted to be sold alongside much cheaper equivalents, and patients were found to switch to the latter in the course of a year or so. When the less expensive product was found equally effective, demand for the other gradually disappeared, and it could be removed without protest.

**Purchase of Pharmaceutical Chemicals for Local Manufacture**

The reform of finished drug imports proved far easier than that of buying pharmaceutical chemicals for local manufacture. One of the original purposes of setting up the SPC had been to economize on the cost of importing bulk chemicals as well as finished drugs. In April 1973, the SPC prepared a "34-drug program" in which a limited beginning would be made with 34 (of a total of 225) locally formulated drugs, whereby the chemicals would be imported on the basis of worldwide tenders by the Corporation. However, if the manufacturer was already buying materials at prices comparable to the best SPC tenders, it would be allowed to continue as before. For instance, when one local firm was buying vitamin raw materials from Roche, the cheapest supplier, and continued doing so, other producers were made to follow suit. The program aimed:

- to increase the local processing of drugs,
- to reduce the cost of imported chemicals, saving an estimated Rs. 3 million out of Rs. 9 million on the 34 drugs, and
- to work existing factories, which were running at well below capacity, at full capacity and in two shifts.

The SPC found that the installed capacity (at single-shift) of the seven large producers could manufacture 750 million tablets annually, but was only producing

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12 The cost of promotion per doctor in the U.S. came to about $5000 per annum in 1970, the bulk of it on detail men. There are about ten doctors per detail man in the U.S., as compared to five in Colombia and only three in Mexico, Guatemala, and Brazil (S, p. 122), a striking illustration of the relative intensity of promotion in developing countries.
the total tablet requirement of Sri Lanka was 1000 million. Similarly, installed capacity for capsules was 40 million, actual production was 6 million, and total requirement was 120 million. Thus, the entire requirement of tablets and capsules could have been met by increasing the number of shifts to two or three without adding further capacity; Sri Lanka would have saved considerable foreign exchange by formulating and packaging pharmaceuticals domestically.

The seven small local producers responded favorably; the five TNC subsidiaries, however, showed resistance. Initially, they simply refused to respond, until in December 1973 the Director of Regulation of Industries issued a stiff warning. Glaxo then accepted the program in principle, but the others did not. In May 1974, after further pressure and more warnings from the Ministries of Finance, Industries and Scientific Affairs, and Health, two other TNCs (Reckitt and Colman, and Unical) agreed to cooperate. Pfizer held out a little longer, but then followed the others in agreeing to the program in principle. Agreement in principle was, however, quite a different matter from cooperation in practice. Four TNCs started a further series of delaying maneuvers, asking for further discussion, clarification, and changes. An SPC official noted (20):

As a result, Unical tabletting capacity, which is 90 million a year in one shift, is lying idle; Reckitt and Colman, which has a 165 million tabletting capacity a year, is making only 45 million tablets, and not making the 90 million tablets of aspirin required in the SPC programme. Recently the SPC made an urgent appeal to Pfizer to make tetracycline capsules required in the cholera epidemic and offered quality tested raw materials and capsules. Pfizer delayed, raising one query after another, as is usual with them. The urgency of the situation has not concerned them in the least.

The outcome of Pfizer's refusal to encapsulate SPC-imported material (from Hoechst of West Germany) during the epidemic was that the tetracycline lay unused in SPC stores and Pfizer equipment lay idle, while tetracycline capsules had to be airlifted to the country at enormous expense.

By 1975, only 14 of the 34 drugs were being produced according to the program. The situation had improved slightly by the end of 1976, but Pfizer was still refusing to use material imported by the SPC, Glaxo had just agreed to start producing 7 drugs, and the other TNCs had not yet launched into actual manufacture with SPC materials. The final outcome of the battle, especially with Pfizer, is still unclear, but that company's refusal and stalling have enabled it to hold out for over 3½ years against a host government's clear intent and policy.

Two questions then arise: Why did Pfizer hold out? And how did it manage to get away with it?

The "why" is easily answered. Pfizer was buying tetracycline from its parent firm at a CIF price of $99 per kilo, when raw material of equivalent quality was being offered to the SPC by Hoechst (an even bigger transnational) at $20 per kilo. This is a classic example of transfer-pricing behavior, where the usual defense used by TNCs, in terms of quality (Hoechst could hardly be accused of poor quality products) or of reaping a return on research and development (the drug has long been out of patent and is technologically well diffused) could not possibly be justified. Glaxo was engaged in identical practice: its chlorpheniramine imports cost $411 per kilo from the parent firm and $53 from Halewood (a small British firm).
The “how” is more complicated. The initial stalling and resistance of the transnationals was to be expected. It may also have been expected that the U.K. firms would, in the absence of outside support, ultimately accede to the demands of the host government. The fact that the one large U.S. TNC held out may be traced to two factors. The first, and apparently determining one was pressure brought by the U.S. government to protect Pfizer. By the end of 1974, the SPC, with the strong support of the Minister of Industries, was recommending nationalization of Pfizer to ensure its compliance. The reaction of the U.S. was swift and, as it turned out, decisive in preventing such a measure. The U.S. Ambassador personally intervened with the Prime Minister in the matter, and, while we can only speculate as to the nature of his intervention, the dependence of Sri Lanka on U.S. aid (food aid had just become crucial) may have figured largely. The chairman of the SPC was ordered to “continue negotiating” with Pfizer; no further disciplinary action was taken. Pfizer is still holding out in the hope that the forthcoming elections (mid-1977) will bring a government which is more “reasonable” in its pricing arrangements with its parent company. In the interim, of course, the government’s move to the right has strengthened the TNC’s resolve to minimize their compliance with the 34-drug program, and there is a real danger that the whole plan may be jeopardized by a leadership unwilling to take the necessary political measures to discipline TNCs.

The second factor, perhaps a minor one, affecting Pfizer’s attitude may have been the hard line taken by the Pharmaceutical Manufacturers’ Association. In his letter to the Prime Minister, Stetler argued strongly against channeling raw materials through a state agency:

> We submit that it is entirely inconsistent with the drug manufacturer’s responsibility [for quality] to withhold from it the right to select its source of supply for raw and partially finished materials. . . . Inconsistency in source of raw material for any given drug would produce a wide range of medical and therapeutic problems, as well as production, sampling and testing difficulties.

While the second point is valid if the raw materials were indeed of poor or variable quality, the stress laid on bioavailability (which we will discuss later) is almost certainly misleading. The familiar “bogeyman” of the drug TNCs’ promotion, i.e. the small supplier of poor quality, cheap merchandise, keeps reappearing in different guises, and no amount of evidence to the contrary makes him go away. The Pfizer tetracycline episode provides a perfect example; the quality of materials was in fact one of the main delaying devices used by the firm in its refusal to use the Hoechst chemicals.

Stetler goes on to argue, “With companies reduced to a service operation [i.e. not choosing their own raw materials], the flow of information concerning new technology and scientific development through the private sector would be impaired or cut off” (18). This charge deserves to be taken more seriously. While various TNCs have quoted for raw material tenders, and this represents the sale of “embodied” technology produced by pharmaceutical research and development, there may exist a distinct problem concerning the transfer of new technology to set up new plants for drug production. The problem is not very pressing, however, for Sri Lanka. The SPC is considering setting up a plant for formulating several products, and has received...
various offers for the supply of technology. Of these, one of the most attractive seems to be from Indian Drugs and Pharmaceuticals Limited, an enormous and highly sophisticated public sector manufacturer. No equity participation is demanded; the turn-key job will be done on a cost-and-commission basis. Whatever the merits of this offer, it certainly does not seem that the reform program has set back the country's industrialization process in the slightest.

A note of caution is necessary, however. Sri Lanka is just starting to manufacture drugs, and technology is relatively easily available at this stage. The cooperation of TNCs may be more of a constraint to countries at the level of India or Mexico, for example. These countries should consider Steller's warning seriously, and explore alternative sources of technology from developed capitalist countries, socialist countries, and other LDCs before launching on a program which antagonizes TNCs. The solution to aim at would be not to accede to the TNCs' desire for a "free" market, but to create conditions in which suitably regulated local enterprises could buy technology from TNCs at appropriate fees.

Patents

In spite of the recommendations of Wickremasinghe and Bibile (13), the government did nothing to amend the strong patent protection that it offers to drug processes and products. The SPC decided, however, to buy patented drugs from non-patent-observing sources. Propranolol, patented by Imperial Chemical Industries, was available from Polfa (Poland) at U.S. $7.6 thousand instead of the $27.3 thousand charged by the patent holder for the quantity needed by Sri Lanka, a savings of 72 percent. Diazepam, patented by Roche, was available from Ranbaxy (India) for less than $200, while the TNC quoted $7760, a savings of 97 percent (this was an extreme case, but savings were always substantial).

The patent holders (e.g. ICI and Roche) realized, of course, that patent laws were not being observed and sent warning letters to the SPC which were forwarded to the Minister of Industries, but none of them has yet taken the SPC to court. TNCs generally are aggressive litigants when patents are threatened; however, the prospect of fighting a state corporation in a socialist-minded regime clearly did not appeal to them. If the regime changes, there may well be a spate of infringement cases. However, Argentina provides an interesting parallel. In 1970, the Supreme Court of Argentina ruled that a local firm which imported an American Cyanamid-patented chemical from Italy was acting in the public interest (4, pp. 63-64). The law in Argentina was not changed, but the precedent set allowed several other local firms to break the legal monopoly and import drugs at a fraction of the previous cost. The TNCs involved are dragging their feet about suing; a similar outcome is possible in Sri Lanka.

The patent issue is a highly sensitive one for the pharmaceutical industry. It is one of the few major industries which depends on patents for effectively guarding its technological innovations and which is in the forefront of all battles to strengthen and extend patent monopolies. However, while it is clear that the TNCs need patents to reap an overall reward from their expensive and risky research and development, the benefit a small developing country receives from offering patent protection is
far from clear. It certainly pays much higher prices than it needs to; every new drug
has effective competitors from non-patent-observing bases within 3-4 years, and a
worldwide buying service can save enormous sums by shopping around. What, then,
does it gain? Stetler (18, p. 4) answers forcefully:

Such protections [on patents and trademarks] provide a major incentive for
producers to make new medicines available to smaller markets, such as Sri Lanka,
where product exclusivity is a compensation for low per capita income and a variety
of business risks which otherwise would make the market unattractive. Patent
protection is a strong inducement, not only for direct investment, but for the transfer
of technology and know-how licenses. . . . The major international trend is to
strengthen rather than weaken patents and industrial property protection.

As with Stetler's other arguments, this is a mixture of half-truths and exaggerations.
First, there is no evidence that Sri Lanka would be unable to obtain the latest medi-
cines if it did not offer patent protection. Second, there is no evidence that non-
observance of pharmaceutical patents inhibits the inflow of capital or technology:
neither Brazil nor Italy has patents on drugs, yet in both cases the TNCs have been
investing heavily, buying up local firms, and selling their latest products. Third, there
are several exceptions to the "major international trend" Stetler describes: India has
considerably weakened drug patents, as has Argentina; Brazil has abolished them;
the United Nations Conference on Trade and Development is negotiating major
revisions to the Paris Convention.

Stetler does not mention the main reason for retaining drug patents: to promote
innovation. But he clearly realizes the futility of making this point to a country which
constitutes a minuscule portion of the world drug market. It is doubtful, in fact,
whether this argument would even apply to all LDCs taken together for a large part
of drug innovation which is aimed at "rich man's diseases" (e.g. cancer, heart and
psychotropic illnesses), and for which LDCs constitute less than 10-15 percent of
world sales. For innovation specifically directed at tropical diseases, some form of
guaranteed returns would of course be needed, but a system of universal patents for
drugs does not seem to be the most advantageous from the LDCs' point of view (21).

The increasing tendency in LDCs to weaken the application of patent laws on drugs
has worried TNCs (even the Canadian government has relaxed the laws somewhat).
But, in contrast to a threat to direct investments, it is not an issue on which their
home governments can act directly. Moreover, even TNCs are prepared to accept a
few aberrations as long as they are allowed to operate freely in other ways, and thus
retain their market dominance and profitability. In the longer run, therefore, the
counterattack will probably concentrate on marketing elements of the reform rather
than on the patent issue.

Brand versus Generic Names, Quality,
Bioequivalence, and Promotion

The mechanism of promotion and marketing in the drug industry is at the heart
of the market power exercised by the large firms, and thus must be the core of a
program to lower their prices. The profitability of the TNCs depends on their ability
to introduce “new” drugs (i.e. genuine innovations, duplicates, or combinations), impress brand names upon the consciousness of doctors, and persuade them of the superior performance and quality of their products. So rapid has been the introduction of “new” drugs, so powerful the promotion system of the large companies, and so close the relationship built up with the medical profession that doctors in most countries are virtually dependent on the firms themselves for information about new therapies, are unaware of the economics of prescribing, and are convinced of the superiority of branded products. The situation is rather worse in LDCs than in developed countries. In the latter, “consumerism,” the growth of official concern, and a better awareness on the part of doctors have provided a weak but growing countervailing force. In LDCs, belief in international brand names is stronger, official attempts to provide objective information weaker, and consumerism still nascent.

Reform of the marketing system requires tackling two distinct problems: first, ensuring that the cheaper generic products are of adequate quality and are biologically equivalent with the branded products of the TNCs; and, second, ensuring that the change from brand to generic names is accepted by prescribers, who are provided information on the proper use of drugs by means other than private brand promotion.

Let us now briefly return to the issue of bioequivalence and illustrate how it was used to hamper the SPC’s program. While the SPC took every feasible means to ensure that the drug imports were of adequate quality, the industry tried to prevent the acceptance of these drugs by claiming that inexpensive generic drugs were not bioequivalent with expensive branded products. It insisted that the generic producers’ alleged lack of stringent quality control rendered their products therapeutically less effective or ineffective, even if they met the chemical requirements laid down for the relevant drugs (12, 22). Doctors are, as we have noted, predisposed to accept this on the basis of the scantiest evidence, and the TNCs did their best to strengthen that belief. Two examples will further illustrate the problem.

The first example concerns tetracycline. In late 1976, Bibile (23) noted:

The prevailing impression among many doctors in Sri Lanka is that tetracycline supplied by the SPC is either ineffective or not as effective as it used to be when this drug was imported by the private sector. As a result some doctors even administer double the usual dose of this drug in an attempt to control bacterial infections. . . . [Locally capsulated tetracycline imported from Hoechst] was tested before it was capsulated and tested again after capsulating (by the Drugs Quality Control Laboratory of the Ministry of Health) before it was released on the market. Even so the SPC received complaints of clinical inefficacy of tetracycline although none of the complaints was accompanied by any evidence.

Detailed examination by a bacteriologist at the General Hospital in Colombo found that the problem lay not with the quality of the drug, but with its serious overuse for minor ailments which had led to resistance to the drug. The bacteriologist commented (24), “The problem of drug resistant strains of staphylococci is a worldwide problem and develops because of the widespread use of antibiotics and the abuse of antibiotics. Our figures may be higher than in other countries since tetracycline is freely prescribed by all Government Medical Officers, by General Practitioners and Ayurvedic Practitioners.” Doctors were placing the blame for their predilection to prescribe antibiotics freely, even for the common cold, on the buying policies of the
SPC, despite the fact that in most developed countries such overuse had become widely recognized as a cause of the reduced effectiveness of drugs.

The second example involves the industry's move to more overt attacks on the SPC. In September 1973, Mr. C. Ponnalagan, a local representative of one of the drug TNCs, published a letter in the Ceylon Daily News (25) arguing that since the FDA in the United States had recalled a certain batch of generic oxytetracycline for not producing the desired blood levels, branded products of "reputed manufacturers" were more reliable and should be purchased even if they were more expensive. He also asserted that "most of the drugs imported [by the SPC] are not even tested for their chemical equivalency."

The argument was misleading, and the assertion was simply wrong. As the chairman of the SPC pointed out in the same paper the next day, U.S. drug recall data did not support the claim that small generic producers were more prone to recalls than large brand-name producers. The SPC did not import any drugs that did not carry quality certificates from abroad, and also tested imports locally in the Ministry of Health's Quality Control Laboratory. Bioequivalence was a problem, but only for 25 drugs on the rationalized import list. These were imported from traditional sources until bioequivalence testing could establish the equivalence of cheaper suppliers. Despite these assurances and scientific evidence, however, criticism and distrust of generic drugs continue to this day.

Bioequivalence is a problem that plagues reform programs everywhere, and TNCs constantly seize upon it to prevent major changes from taking place. Stetler (18, p. 3) argued that "It is now widely accepted, on the basis of chemical and other analytical tests, that the assumption of therapeutic equivalency in medicines is unsupportable. ... The conclusion, we submit, is that 'generic equivalency' in medicines is a misconception which has now been refuted." If this were indeed so, a buyer would have no option but to continue to depend on large TNCs with products of proven efficacy. But is it? As with his other arguments, Stetler stretches the evidence to defend the status quo.

Where very careful and detailed tests are not utilized, it is true that for certain drugs chemically identical products may produce different bioavailability. Different bioavailability may or may not indicate therapeutic inequivalence; only trials can establish this. Moreover, the number of drugs where nonequivalence constitutes a therapeutic problem is small. The most recent tests of the FDA, which can hardly be faulted for a lack of exhaustive study (in fact, Stetler quotes a former FDA authority), have narrowed the list to 24, and a report of the U.S. Office of Technology Assessment (22) notes that the methodology and experimental procedures required for bioequivalence studies are available from that Office. This report (22) also notes that "drug products meeting the standards and falling into categories for which evidence of equivalent bioavailability is not essential can be considered as interchangeable and listed as such..."

Stetler and the industry are attempting to confuse the government (and the medical profession) with half-truths, conveyed in scientific jargon, which no one but a trained pharmacologist could evaluate. Drug TNCs try very hard to establish generic inequivalence, and are on occasion not above manufacturing the evidence. To quote one example (12, p. 42).
Thus, an editorial critical of generic products. That same issue contained an article on the
generic formulation of the anti-diabetic drug tolbutamide. The generic product was
compounded with less than the standard amount of agent and the article claimed that
the generic formulation was far less effective than the tolbutamide marketed by Upjohn under the name Orinase. The paper, entitled "The Generic Inequivalence
of Drugs," was written by a member of the Upjohn staff. The inferior product had
never been marketed, had never been proposed for clinical use, and had been develop-
ed for this article by the Upjohn laboratory.

Bioavailability is a problem requiring expert understanding and exhaustive scientific
testing, but it does not raise fundamental barriers to a rationalization program: what
better evidence of this than the fact that the FDA is launching (naturally, in the face
of fierce opposition from big drug firms) its Maximum Allowable Cost program to
promote generic purchasing by government-financed health programs in the U.S.? In
the Sri Lanka context, however, it is clear that the reform program would have
encountered insuperable difficulties had it not been directed by experts having the
knowledge necessary to counter the propaganda of the TNCs and the entrenched
prejudice of the doctors. If bioavailability had not been checked and the results not
made known, even on a few drugs, the whole program could have been jeopardized.
Doctors, being generally suspicious of the reform, would have raised much stronger
protest than they did. Consumers would have joined them, and the TNCs would have
been back in business.

The efforts of the FDA to establish drug interchangeability and reduce the cost of
its own health programs proved crucial in providing the example, techniques, and
findings necessary to the rationalization in Sri Lanka. The "openness" of the American
system, with its detailed published accounts of the operations of the drug industry and
of the results of the FDA's exhaustive clinical and scientific tests, thus bore (unlikely)
fruit in Sri Lanka. The FDA is instinctively sympathetic to the needs of consumers,
and potential reformers would do well to draw upon its experience. It would be
interesting, however, to see whether the FDA would be willing, and able, to provide
positive and explicit support for reform in the face of opposition from U.S.-based
TNCs.

The change from brand to generic names faces other problems. Patients from the
affluent minority have a strong belief in well-known brand names, not just for OTC
drugs but also for prescription drugs with which they have become familiar. In a few
cases, the demand for particular brands was so entrenched in Sri Lanka that the SPC	had to give in, even when much cheaper generic substitutes were available. The
strategy of the SPC was then, as noted previously, to sell both products at their
respective prices and let economic rationality win out over a period of time. This
strategy seems to have been fairly successful.

A greater problem was posed by the doctors, who had become so accustomed to

13The SPC managed, by means of the gradual pace of change and some compromise, to avoid
an all-out battle with local firms. In Pakistan, however, local subsidiaries of TNCs opposed the
generic scheme bitterly; Ciba-Geigy even sold out its local operations in 1973 in protest, and
"pressure from other firms led to extended permission for the use of brand-named products for
18 months after the implementation of the Act [Drug (Generic Names) Act, 1973]" (26, p. 59).
Thus, hasty and inadequate planning was compounded by poor political strategy.
prescribing by brand name that they were unaware of the generic names of several drugs. The change in their habits thus had to be gradual and had to be accompanied by a minor process of reeducation. The SPC provided cross-reference lists of brand and generic names to doctors. For old drugs, the changeover was relatively easy since generic names had become more familiar as a number of competing brands had emerged; for new drugs, it took longer. In the interim the SPC permitted brand names on packages, but they had to be displayed less prominently (in half the size) than the generic names. As the traditional sources of supply were replaced and prescribing habits changed, the majority of brand names were dropped. Some brand-name products are still sold, mainly those which are new and still under the effective monopoly of a TNC.

While promotion was still allowed for OTC drugs made by local manufacturers, it virtually disappeared for drugs imported by the SPC. With the disappearance of promotion, the distribution of free samples, hospitality, and visits by representatives also practically stopped. According to Stetler (18, p. 5) this led to the problem that "the information function on drug research and applicability now performed by companies through their medical and marketing representatives [was] eliminated. Doctors and pharmacists in remote locations, and even in urban areas, may be hard put to fill this information gap."

Stetler was certainly right that an "information gap" was created. The SPC has attempted to fill the gap by publishing and distributing two quarterly journals: one edited by the National Formulary Committee, called The Prescriber, and the other edited by the Independent Medical Practitioners' Association (private practitioners), called Sri Lanka Practitioner. These publications carry the latest information on the rational use of drugs, drawing upon the state of the art and science internationally, and contain scientific findings on the indications, contraindications, and adverse reactions to drugs. While these publications are not as glossy or seductive as the TNCs' promotional literature, the following points favor their continued use as a means of disseminating information:

- First, with the reduced list of drugs and the use of generic names, the need for information was also greatly reduced. The flow of "new" drugs is far less than under the free market system. The removal of the profusion of brand names makes the informational task much easier.
- Second, the information provided by TNCs is not renowned for its objectivity. It is intended to persuade as well as inform, and often contains exaggerated claims, suppression of adverse reactions, incorrect indications, and the implicit denigration of competitors' products. The potential for misinformation is much greater in LDCs, where authorities are relatively lax. Silverman (5) has collected a horrifying compendium of data on the misinformation practiced by U.S. drug companies in Latin America, greatly extending and strengthening earlier findings by Ledogar (4). Focusing on seven major categories of pharmaceuticals, Silverman describes the variety of labeling and promotional practices used in different Latin American countries as compared to the U.S., and he concludes (5, p. 106):
It is abundantly clear that there are glaring differences in the ways in which the same multinational pharmaceutical companies describe essentially the same drug products to physicians in the United States and to their medical colleagues in Latin America. This holds not only for global corporations headquartered in the United States. It is true also for such companies based in Switzerland, France, West Germany and other nations. . . . With few exceptions, the indications included [in Latin America] in the reference books are far more extensive, but the listing of hazards are curtailed, glossed over, or totally omitted. In some cases, only trivial side effects are described, while serious or possibly fatal reactions are not mentioned.

A strong case can therefore be made for official control of this "information function," even in the absence of broader reform. In the context of a broad reform, of course, the case is overwhelming.

- Third, provision of official information is far less expensive than TNC promotion. As it is the consumer who pays in either case, there are certainly grounds for economizing on this score. The SPC has decided to provide, in partnership with the Ministry of Health, the two "official" publications free of charge to all medical practitioners.

The people in Sri Lanka who are most unhappy about the abolition of private drug promotion have been the local detail men and importers, for whom it had provided a comfortable livelihood. Many private practitioners regret the loss of free samples and glossy, easily digestible literature on new drugs. However, because this is not an issue that can be publicly aired, their annoyance is diverted into channels such as complaints about drug quality. A number of physicians do, however, accept the social desirability of channeling information through neutral publications. In fact, the SPC publishes such a journal on behalf of private practitioners, undercutting those who would argue for a return to the old system.

ACHIEVEMENTS OF THE REFORM

We have already described the achievements of the reform in terms of reducing the number of drugs and abolishing brand names. This section will deal with some of the more tangible benefits.

Table I shows the savings achieved on selected drugs by the centralized purchase of finished pharmaceuticals. It gives the number of private sector suppliers before the SPC takeover and the number of tenders received for the drug afterwards, the average weighted price paid before and the ensuing tender price, and the value of SPC purchases for the second half of 1972 and the percentage of savings achieved over what the same purchases would have cost under the old system. In 1972, the SPC took over the import of 52 drugs, and achieved an overall saving of more than 40 percent; some of the drugs shown in the table have been selected to illustrate the more dramatic savings.

It should be noted that the number of tenders received has always been higher than the number of actual suppliers before the takeover. The SPC was able to introduce a much stronger competitive element into the market than had existed previously.
Table 1

Savings in Ceylon rupees achieved by the SPC takeover of finished drug imports in Sri Lanka, 1972a

<table>
<thead>
<tr>
<th>Drug</th>
<th>Private Sector, January-June 1972</th>
<th>State Pharmaceuticals Corporation, July-December 1972</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. of Suppliers</td>
<td>Average Weighted Price per 1000</td>
</tr>
<tr>
<td>Tetracycline caps. (250 mg)</td>
<td>23</td>
<td>74.26</td>
</tr>
<tr>
<td>Chloramphenicol caps. (250 mg)</td>
<td>12</td>
<td>64.88</td>
</tr>
<tr>
<td>Sulfadimidine tabs.</td>
<td>7</td>
<td>22.62</td>
</tr>
<tr>
<td>Neomycin tabs.</td>
<td>2</td>
<td>791.80</td>
</tr>
<tr>
<td>Phenylbutazone tabs. (100 mg)</td>
<td>5</td>
<td>43.09</td>
</tr>
<tr>
<td>Phenylbutazone tabs. (200 mg)</td>
<td>8</td>
<td>79.88</td>
</tr>
<tr>
<td>Chloroquine tabs.</td>
<td>6</td>
<td>41.68</td>
</tr>
<tr>
<td>Metronidazole tabs.</td>
<td>5</td>
<td>170.02</td>
</tr>
<tr>
<td>Aspirin tabs.</td>
<td>7</td>
<td>8.50</td>
</tr>
<tr>
<td>Chlorpromazine tabs. (25 mg)</td>
<td>2</td>
<td>48.86</td>
</tr>
<tr>
<td>Hydrochlorothiazide tabs.</td>
<td>1</td>
<td>139.40</td>
</tr>
<tr>
<td>Tolbutamide tabs.</td>
<td>1</td>
<td>55.80</td>
</tr>
</tbody>
</table>

a The 1972 rate of exchange was U.S. $1 = Ceylon Rs. 6.18.
The bulk of its savings resulted, however, simply from "shopping around" and disregarding brand names and, where relevant, patent protection. In most cases, moreover, the lowest tender was not accepted. Suppliers of the very cheapest drugs tended to be of dubious quality and manufacturing practice, and the SPC always obtained independent certification of quality before awarding a tender. Even so, the savings were considerable.

The benefit to the consumer showed up directly in price reductions. As distribution and retail margins have been determined for some time by the government, a reduction in CIF prices led to a proportionate reduction in the final price to the patient.

A glance at Table 2 shows that similar savings were achieved in the import of pharmaceutical chemicals for local formulation. We noted earlier that some of these imports were previously from the parent companies of the subsidiaries (Pfizer and Glaxo), and high prices simply represented the clandestine transfer of profits abroad. However, it should be apparent that high prices reflect not so much the existence of transnational investments and intrafirm operations as that of a strong element of monopoly power in the final product market, based on the technological and marketing practices of the large firms. Thus, Beecham was able to charge an independent local firm extremely high prices for cloxacillin and ampicillin. Yet, when faced with the prospect of competition in a market where its brand name did not matter and where the buyer had information on alternatives, Beecham was prepared to cut its prices by about 80 percent in each case.

If bids submitted by traditional TNC suppliers are any indication of what the suppliers would have continued to charge Sri Lanka, it appears that the SPC has continued to save considerable sums of foreign exchange year after year. In fact,

**Table 2**

<table>
<thead>
<tr>
<th>Intermediate Chemical</th>
<th>Private Sector, 1972</th>
<th>SPC, 1973</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Supplier</td>
<td>CIF Cost per Kilo</td>
</tr>
<tr>
<td>Tolbutamide</td>
<td>Hoechst</td>
<td>40.62</td>
</tr>
<tr>
<td></td>
<td>Polfa</td>
<td>9.25</td>
</tr>
<tr>
<td>Paracetamol</td>
<td>Sterling</td>
<td>3.24</td>
</tr>
<tr>
<td></td>
<td>Glaxo</td>
<td>1.16</td>
</tr>
<tr>
<td>Chlorpropamide</td>
<td>Pfizer</td>
<td>126.21</td>
</tr>
<tr>
<td>Aspirin</td>
<td>Glaxo</td>
<td>1.16</td>
</tr>
<tr>
<td>Magnesium hydroxide</td>
<td>Sterling</td>
<td>5.18</td>
</tr>
<tr>
<td>Prednisolone</td>
<td>Organon</td>
<td>63.268</td>
</tr>
<tr>
<td>Chloramphenicol</td>
<td>Boehringer</td>
<td>25.24</td>
</tr>
<tr>
<td>Cloxacillin</td>
<td>Beecham</td>
<td>606.47</td>
</tr>
<tr>
<td>Ampicillin</td>
<td>Beecham</td>
<td>569.90</td>
</tr>
<tr>
<td>Tetracycline</td>
<td>Pfizer</td>
<td>98.87</td>
</tr>
<tr>
<td>Chlorpheniramine</td>
<td>Glaxo</td>
<td>411.00</td>
</tr>
</tbody>
</table>
as its tendering procedures have become more efficient and broad-based, the market it faces has become more competitive. Furthermore, as the SPC organization has grown (e.g. employment rose from 103 in 1973 to 330 in 1976), it has become financially self-reliant. It pays market rates of interest, a "contribution" to the government as well as taxes, and has made a healthy profit every period since the second year of its operation.

Another benefit of the reform was achieved by banning or restricting the use of particular drugs. In his study of drug TNCs in Latin America, Ledogar (4) names some drugs which were exceptionally toxic but which were being promoted and sold without proper warning. In contrast, let us look at a few examples to see how the reform helped Sri Lanka:

- **Dithiazanine Iodide.** By the mid-1960s, this drug had been banned in the U.S. and France. Yet, according to Ledogar, "In the areas outside the jurisdiction of the FDA, Pfizer's marketing tactics have not been interfered with in the same way. Under brand names like Netocyd and Dilbrin, the drug was being promoted in many countries of Latin America as late as 1974 as a broad-spectrum antiparasitic agent" (4, pp. 30-31). Pfizer was also promoting its extensive use in Sri Lanka until 1972, when the National Formulary Committee banned it on the basis of the U.S. evidence.

- **Dipyrone.** A pain-killer with toxic side effects, dipyrone is severely restricted in its use in the U.S. and banned in Australia (4, pp. 31-32). Yet it is sold by several TNCs in Latin America as a completely safe analgesic. In 1972, Winthrop's Conmel was the 20th most popular ethical drug in Colombia. It has been banned in Sri Lanka, except in the rarely used injectable form necessary for bringing down high fever in patients who cannot take oral medication.

- **Long-Acting Sulfonamides.** These drugs have also been banned or severely restricted in the U.S. and many European countries because of the associated fatal Stevens-Johnson syndrome and other severe allergic reactions, but they have been heavily promoted and sold without adequate warning in Latin America. They were removed from the market in Sri Lanka, but only after a long battle with the drug companies in which the doctors, armed with literature provided by the detail men, sided with the firms.

Other examples could be given, but our point has been made. Let us now conclude our discussion on the political economy of TNC reform.

CONCLUSIONS

What has been learned from the Sri Lanka experience? And are the lessons valuable for other less-developed countries? We shall attempt to answer these questions in the concluding remarks which follow:

1. Sri Lanka has benefited in several significant ways from its reform of the international drug industry. Drugs are now much less expensive, undesirable and ineffective drugs have been excluded, and prescribing practices should show more rationality once the effects of the cumulative promotion of the firms have been counteracted.
2. The process of reform is extremely complex and difficult. Nonetheless, it can be successfully implemented given the appropriate combination of technical skills, a strong and socialist-minded government, gradual, carefully planned and well-propagated change, and insistence on quality assurance.

3. It can be concluded that reform is much easier in terms of controlling imports of finished drugs than those of pharmaceutical chemicals, not because of the nature of the product but because of the attitudes of the TNCs concerned. They are willing to bid in worldwide tenders and occasionally sell inexpensive drugs, but they resent any attempt to channel their intrafirm trade through the state. It follows that the larger the direct investment of TNCs in a particular country, the more difficult it will be to implement reform of local production. Sri Lanka found it relatively easy to change the status quo simply because the structure was small and undeveloped.

4. TNCs can bring several forms of pressure to bear upon the most committed government. They can use threats and persuasion from abroad; they can get their home governments to support them in cases where nationalization is threatened; they can restrict their future investments; and, most important, they can use their powerful alliance with doctors.

5. Even without pressure from TNCs, doctors are reluctant to accept a reformed drug delivery system. There are real problems posed by the quality of inexpensive drugs and bioequivalence which governments must face and overcome. Doctors must be persuaded that the new system is trustworthy, and their conversion requires time, education, and determination. Furthermore, since they are used to a powerful promotion system, which has to be replaced by a less attractive (but cheaper and more objective) information-provision system, the change has to be gradual.

6. Locally owned industry has been proven amenable to reform in Sri Lanka, but this is no indication of how it would react in countries where it is larger, better established, and able to promote its own drugs effectively. It is likely that in a country where such industry is profitable and successful (e.g. Argentina), it would fight reform, especially of the marketing system, just as hard as TNCs do. This does not rule out the likelihood of local firms asking partial reforms which strengthen their position vis-à-vis foreign competitors. (The proposed Indian reforms clearly have this sort of flavor.)

7. The local elite and the doctors accepted radical reforms on drugs and in other matters in Sri Lanka largely due to the mass pressure which had installed a socialist government in a landslide electoral victory in 1970. The importance of political direction cannot be overemphasized: the SPC made its major achievements before 1975, when the government had a unified socialist ideology. From 1975 onward, the government shifted its course, succumbed to local and foreign-vested interests, and enabled the critics to slow down or halt the pace of reform, especially as far as local production was concerned. With the reemergence of right-wing forces, it is to be expected that the elite, and especially the medical establishment, will try to revert to the old system of TNC-dominated drug provision. The lessons of this are of vital significance: it is difficult to imagine a government in a developing country undertaking or implementing a genuine reform of drug TNCs in the absence of a long-term and powerful socialist base and ideology. The internal and external constellation of opposing forces would otherwise be too strong.
8. It has been noted that the development of domestic industry is not adversely affected by reform in the early stages of development since a great deal of technology is available and there are few economies of scale (meaning capital requirements are low). At later stages, however, a reduction of TNC investment and technology may be more of a real threat, and has to be carefully considered. Economies of scale do become important in the production of intermediate chemicals, and the technology is often held monopolistically.

Lessons for Other LDCs

The list of conditions under which a comprehensive reform of the pharmaceutical industry is likely to succeed is, therefore, long and restrictive. There are not many developing countries which at present have the ability, the willingness, or the patience to launch and carry through such a program. Attempts at reform are, of course, widespread, but their achievements are often piecemeal and lopsided because one or the other ingredient for success is lacking. India, for instance, may take a tough line with TNCs and force them to accept local ownership and sell technology to domestic firms; given the strength of private firms as a whole and the lack of political direction, however, it is unlikely to achieve much by way of reducing the number of drugs on the market or abolishing brand names. Pakistan is even less likely to undertake reform because of the disastrous results of its ill-planned generic drug program. Brazil and Mexico both have a very powerful TNC presence and a strong influence on policy from the home countries of the TNCs; thus, no major reform policy is likely to get sufficient political support. Countries like Argentina have a strong indigenous sector which relies heavily on brand name promotion, and which will resist any encroachment on this source of profitability.

In sum, we do not expect any major changes to take place in the developing world in the system of drug delivery. The main changes are, in fact, occurring in the rich countries like the U.S., France, Sweden, Germany, and the U.K. It is they who may first achieve some real reform, and it is they who will probably set the pace for change in the Third World. Certainly the emerging political-economic climate of the Third World does not bode well for comprehensive independent reform there.

POSTSCRIPT: DEVELOPMENTS IN 1977

Unfortunately, the trends which became evident in late 1976 seem to have been strengthened in the first four months of this year. After the Sri Lanka Communist Party left the coalition government in protest over its handling of a general strike at the end of 1976, the swing to the right became even more pronounced. By the end of February, some Parliamentarians of the Sri Lanka Freedom Party had resigned from the government. More significantly, the Minister of Industries, a stalwart supporter of the SPC, also resigned in protest of the right-wing policies of the Prime Minister; he specifically stated that, among other things, he had recommended the takeover of drug TNCs but the proposal had been shelved. One of the present authors has resigned from the chairmanship of the SPC, protesting the lack of government support for SPC policies and the growing bitterness of the opposition from vested interests. He also
noted the increasing disenchanted among the staff of the Corporation, and the
danger that this may lead to a deterioration in its former levels of efficiency, honesty,
and dedication. The coming months will determine whether or not Sri Lanka retains
the valuable gains of the reform, and whether or not the TNCs and their supporters
can reestablish their former hegemony.

Acknowledgments—We are grateful to the State Pharmaceuticals Corporation, Sri
Lanka, for permission to publish the findings of our research concerning its operations
and to T. Attapattu for collecting the statistical material. We also wish to thank Ajit
Singh for his comments on an earlier draft. The authors retain full responsibility
for the content of this paper, a version of which first appeared in World Development.

REFERENCES

1. Lall, S. The international pharmaceutical industry and less developed countries, with special
2. Lall, S. Major Issues in Transfer of Technology to Developing Countries: A Case Study of
the Pharmaceutical Industry (TD/B/C.6/4). U.N. Conference on Trade and Development,
4. Ledogar, R. J. Hungry for Profits: The U.S. Food and Drug Multinationals in Latin America.
7. Lall, S., and Streten, P. P. Foreign Investment, Transnationals and Developing Countries.
1967.
Petroleum and Chemicals, New Delhi, 1975.
16. Lang, R. W. The Politics of Drugs: A Comparative Study of the British and Canadian Pharma-
17. Evans, P. B. Foreign investment and industrial transformation: A Brazilian case study. Journal of
20. Edirimansinghe, S. M. 34 Drug Programme: A Summary of Negotiations with Local Manu-
21. Lall, S. The Development of the Pharmaceutical Industry in Developing Countries: Problems

Manuscript submitted for publication, June 7, 1977

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