Editorial
The Rational Use of Drugs and WHO

On November 25–29, 1985, the World Health Organization held a 'Conference of Experts on the Rational Use of Drugs' in Nairobi. It was called in response to the mounting criticisms levelled against what is increasingly recognized as 'the irrational use of drugs' in both the industrialized countries and the Third World. The background to the Nairobi conference was the following.

In the early eighties, both the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) and Health Action International (HAI) had developed codes of pharmaceutical marketing practices in an attempt to come to grips with the malpractices in this field. It was, however, generally felt that a more comprehensive approach was needed, covering not only the marketing of drugs but the wider issue of the role of pharmaceuticals in health care seen in a global perspective with particular reference to the problems confronting the Third World. These considerations led the World Health Assembly, in 1984, to request the Director-General of the WHO to arrange in 1985 a meeting of experts of the concerned parties, 'including governments, pharmaceutical industries, and patients' and consumers' organizations', to discuss the means and methods of ensuring the rational use of drugs.

Since this subject is of a highly sensitive nature, involving enormous economic and professional vested interests and an increasingly critical and vocal public opinion, the Director-General decided to proceed with caution. A quote from his letter of invitation illustrates this: 'You will note that the final item on the agenda will be my summing-up of the findings of the meeting, which I hope will include recommendations for improving rationality in the use of drugs. I should add that this being a meeting of experts and not a meeting of governments, no resolutions will be adopted.'

This strategy was also followed at Nairobi, where the 92 participants were given an opportunity to make a long series of statements, but where little, in fact almost no time was provided for the participants to enter into a serious discussion of the different views advanced during the meeting. This is not, however, the impression one gets in reading the summing-up statement of the Director-General at the end of the conference or the short but carefully phrased report on the meeting published in the WHO *Essential Drugs Monitor* (No 2). What strikes one in these two documents is namely the surprising degree to which the experts seem to have been able to agree or reach unanimity in their recommendations on a series of issues that were never subjected to a true discussion in the light of what should be the central concern of the WHO, i.e. a health perspective on the role of pharmaceuticals in health development. But this should, on the other hand, not come as a surprise in view of the tense atmosphere between holders of opposing views leading up to the conference and the besieged position of the United Nations system, operating under the constant threat of attacks from pressure groups like the Heritage Foundation in the United States and other sinister bodies linked to the Reagan administration.

What emerged from the Nairobi conference was therefore more or less what could be expected under the prevailing circumstances: prime responsibility for rational drug use must rest with the member governments, operating through national regulatory authorities and assisted in their work by guidelines on minimum requirements for national drug regulation prepared by WHO, the application of ethical criteria in drug promotion etc.—but absolutely no international code of the kind approved in, for instance, the much discussed case of the marketing of breast-milk substitutes.

It was because this could be foreseen that the Dag Hammarskjöld Foundation decided to organize a seminar on 'Another Development in Pharmaceuticals' as an independent contribution to the international debate of this global issue. The seminar, which was directed by Professor Göran Sterky, was held at the Dag Hammarskjöld Centre in Uppsala, June 3–6, 1985. As is evident from the following introduction to the seminar work by Dr Sterky, the seminar was based

on the conception of development elaborated in the 1975 Dag Hammarskjöld Report (*What Now*), emphasizing that development should be need-oriented, self-reliant, endogenous, ecologically sound and based on structural transformations. Another Development in this sense is man-centred and the participants in the seminar were invited to examine the issue from a health perspective, beginning with an historical analysis of man's relationship to medicines and then concentrating on the crucial issue of 'the healthy use of pharmaceuticals', its implications for 'a healthy pharmaceutical industry by the year 2000' and the ways and means of achieving this goal. An essential element in this approach was not to lose sight of the fact that all societies and cultures have their own medical traditions and that the industrial 'pill culture' of the West is a recent and possibly partly transient phenomenon, which needs to be carefully examined and monitored in a cross-cultural health perspective.

In analysing the situation, the participants in the Uppsala seminar were asked to examine the crisis in pharmaceuticals from the points of view of 'all the concerned parties', which may be summarized as follows:

Governments view it mainly as one facet of the more general problem of spiralling health costs which put an intolerable burden on already overstretched welfare services. Even the richest countries, coping with economic recession, high levels of unemployment and a rapidly increasing proportion of elderly people to provide for, face severe difficulties;

The pharmaceutical industry sees the crisis largely in terms of excessively restrictive regulations which stifle innovation of products. The industry's life-blood is threatened: its very future is said to be at stake;

Health care workers and researchers see two sides of the problem. On the one hand, some doctors and pharmacists feel that increased regulatory measures will erode their 'rights' to prescribe and to control the supply and information to patients. On the other hand, some clinical pharmacologists and administrators express concern about excessive, irrational and uneconomic prescribing and its effects on public health in general and on the health of individual patients;

Consumer and other activist groups tend to define the problem in terms of an over-bearing and greedy business community, which outmanoeuvres governments and dupes or compromises health care workers, thereby foisting inappropriate and sometimes positively harmful products on an unwary public;

Ordinary people, against a background of proliferating drug sensations and scares in the mass media, often fail to understand what pharmaceuticals are doing to their bodies and fear the effects, rightly or wrongly.

A selection of the papers discussed in or arising from the seminar are published in this issue of *Development Dialogue* and a few comments should be made on the selection. Thus, the introductory contribution by Dr Sterky largely reproduces the substance of the memorandum he prepared in advance of the seminar to set the framework for the discussions. Hence it is not a report on the seminar discussions—for this the reader is referred to the Summary Conclusions (pp. 130–143), which reflect the conceptual space covered by the seminar and the general thrust of the meeting. It is regretted that space and other reasons did not allow for the publication of the papers on man's relationship to medicines as seen in an historical and cross-cultural perspective. It is, in fact, a subject which is little explored from a theoretical point of view and where the existing literature provides few, if any, clues to the urgent problems of today.

The central issue of the 'International Regulation of the Supply and Use of Pharmaceuticals' is dealt with at length by Charles Medawar in his contribution (previously made available in the

form of an 'advance offprint') and supplemented by Professor K. Jayasena's account of the 'Registration and Marketing Practices' of pharmaceuticals in the Third World.

The crucial issue of the 'Healthy Use of Pharmaceuticals' in both the industrialized countries and in the Third World is dealt with by Drs Joan-Ramon Laporte and Gianni Tognoni, Dr Claudio Sepulveda-Alvarez and Dr Mira Shiva on the basis of their research on and active involvement in the issue in Spain and Nicaragua, Thailand and India. Taken together as a cluster, their papers provide a fascinating insight into the extremely difficult tasks confronting those who are charged with the responsibility of developing appropriate drug policies in the highly complex political, economic, social and technological environment of the modern world.

The role of the pharmaceutical industry, 'that great Leviathan, whose blood is money' (to paraphrase Thomas Hobbes) is, of course, a crucial factor in view of its enormous financial importance as a growth industry and as such increasingly more responsive to its shareholders than to the health needs of the peoples of the world.* But these large profits may in the end turn out to be counterproductive even for the industry itself. In his searching and constructive analysis of its future prospects, Graham Dukes brings this into sharp focus, emphasizing that the industry in its own best interest should devote much more of its resources to innovative research and development, meeting the real medical needs of the world and particularly the Third World, and much less on promotion and the production of inessentials. Only then can it make its own distinct contribution to Health for All by the Year 2000 while at the same time ensuring its own economic and social health. Another aspect of this problem with special relevance for the Third World is dealt with in Andrew Chetley's account of how Dr Zafrullah Chowdhury has built up a pharmaceuticals factory within his grassroots primary health care project in Bangladesh. It shows that it can be done and that the products can compete in quality.

The main results of the seminar discussions in Uppsala are, however, to be found in the Summary Conclusions and a few comments should be made on how they differ from the outcome of the Nairobi conference.

As a consequence of the fact that the Nairobi conference was drug-centred rather than health-centred and only to a limited extent involved and addressed itself to the prescribers, the health perspective was partly lost and the responsibility for an improved rational use of drugs squarely placed on the national governments and their existant or non-existant drug regulatory bodies. This is, in fact, a curious outcome since no institution should know better than the WHO that the health ministries, especially in the Third World, are notoriously weak and that the state itself in most Third World countries is 'besieged, set apart and overloaded' and hence not in a good

*An illustrative example of the uneasy feeling that the pharmaceutical industry is unhealthy and needs a new image is provided by a short article in *Scrip*, the trade magazine, which deserves to be quoted *in extenso:*

'Serious consideration is to be given to the idea of renaming the pharmaceutical industry in Britain. Senior industry strategists believe that the word "pharmaceutical" has become synonymous with high profits, exploitation of the National Health Service and patients, and unsafe products.

The advantages that could be achieved by renaming the industry "the health care industry" or "the health care products industry" will be explored in the coming months by the Office of Health Economics and others. If the idea is accepted, companies will be urged to use the new term as widely as possible.

The industry strategists believe that the exercise is by no means trivial. They point to the switch in public attitudes towards the manufacturers of weapons when the industry changed its name from the armaments industry to the defence industry. The government also learned a similar lesson and called the relevant government department the Department of Defence.' (December 1985, No. 1062).

position to handle these increasingly complicated matters. In contrast to this, the Uppsala seminar concluded that the present crisis in pharmaceuticals is an international problem, which demands international action.* 'Nothing will really change in the absence of far greater determination by the international community to improve the present state of affairs. Here it is necessary that the first system, i.e. the governments, the second system, i.e. the corporations, and the third system, i.e. the citizens and their associations, cooperate in the interest of the overriding goal, Health for All by the Year 2000. It is now up to the international community to bring about two major shifts in current practice. The first is to restrict the supply of drugs for which there is no real medical need. The second is to supervise the ways and the extent to which drugs are promoted for use'. To this end, the participants in the Uppsala seminar recommended a series of measures ranging from an extension of WHO's essential drug concept to include a system of formal 'health impact evaluation' of all pharmaceutical products to the development by the WHO of an international code on pharmaceuticals (rather than a set of guidelines) and the setting up of an internationally recognized clearing house, which would not only communicate technical information but also information on progressive policies adopted in one country which other countries might be interested in using as a model.

The role of the code is essential and it would as envisaged define the rights and responsibilities of governments, industry, health care workers and consumers, and in addition provide a mechanism for adjudication in areas of dispute, and a carefully worked out monitoring system. Such a comprehensive and widely disseminated document would also serve as an unequalled educational instrument and meet the needs not only of the Third World but also the needs of the industrialized countries.

A code of this kind would then not primarily be a code for the regulation of industry but a code to regulate, motivate and inspire all the 'concerned parties', i.e. governments, industry, and consumers and last but not least the health care profession itself. And this last point is important since in a crisis situation like the present one, a special responsibility devolves on the health care profession, which in a deeper sense is the basic constituency of the WHO. Instead of working primarily with weak governments and weak health ministries, WHO should work more with its most fundamental resource, the health profession. And this should be done in close cooperation with the world's increasingly active Third System organizations, whose involvement in a global campaign to highlight and monitor Another Development in Pharmaceuticals, based on an international code, should be welcomed and given all the financial, technical and moral support it deserves. If this is not done in a farsighted way, WHO's proud goal Health for All by the Year 2000 may turn out to be just another slogan and its praiseworthy Essential Drugs Programme and other expanded activities in this field just another gimmick to push the supply of drugs at the expense of other elements in the Alma Ata primary health care programme and hence one more instrument in the service of what the Director-General of WHO once called 'drug colonialism'.

*That the WHO has an explicit mandate to act on these matters is clearly stated in Article 21 of its Constitution, which states that the World Health Assembly 'shall have the authority to adopt regulations' concerning, *inter alia*, 'standards with respect to the safety, purity and potency of biological, pharmaceutical and similar products moving in international commerce' and the 'advertising and labelling of biological, pharmaceutical and similar products moving in international commerce'. Article 22 does, however, restrict the regulatory power: 'Regulations adopted pursuant to Article 21 shall come into force for all Members after due notice has been given of their adoption by the Health Assembly except for such Members as may notify the Director-General of rejection or reservations within the period stated in the notice'.

Another Development in Pharmaceuticals
An Introduction

This introduction to the key-issues in Another Development in Pharmaceuticals provides a general framework for the contributions made to the 1985 Dag Hammarskjöld Seminar on the subject. It is largely based on the memorandum, prepared by the Seminar Director, Professor Göran Sterky, and sent to the participants in advance of the seminar. Only minor editorial changes have been made to allow for the passage of time.

Göran Sterky

It is generally thought, rightly or wrongly, that drugs play a major role in protecting, maintaining and restoring the health of people. It is, moreover, a fact that most people have no confidence in a health care system which cannot deliver medicines and that health authorities all over the world adhere to the same view. The provision of appropriate medicines of the right kind, quality and quantity, and at reasonable prices, is therefore a central concern for any government. At the same time, there is increasing recognition of the serious problems inherent in the existing systems of pharmaceutical development, promotion, marketing, distribution and use in all countries and particularly in the Third World. There is thus a general need for drug policies which, although changing in content from one environment to another, meet the health needs of the world's peoples.

The magnitude of this *problématique* is evident from a few figures. The global drug bill is now estimated at US $100 billion annually, out of which Third World countries, with three-quarters of the world's population, account for only US $15-20 billion. The situation is further complicated by the fact that while overuse and abuse of pharmaceuticals are common in some segments of the population in all countries, the vast majority of the people in most Third World countries, with their limited health budgets and health service coverage, have little or no access to effective and safe medicines. This is so despite the fact that many Third World countries spend 30-50 per cent of their health budgets, and sometimes more, on drugs compared to about 10 per cent in many industrialized countries. Moreover, in some Third World countries, up to 75 per cent of the drugs moving in the market may be outside the control of the health ministries. This situation contrasts sharply with the virtually universally held view that there must be some such official control to ensure that drugs are efficacious, safe, and of adequate quality, and that the information provided on them is reliable.

The acknowledgement of the many problems characterizing this situation is relatively recent. Only during the last few years has it begun to be understood just how difficult it is to develop and operate drug policies in the highly complex political, economic, social and technological environment of the modern world. National ministries of health have to cooperate with ministries of industry, trade, commerce and finance and international organizations in their attempts to deal with the growing dependence on a number of increasingly powerful transnational corporations based in the industrialized countries, monopolizing the global trade in pharmaceuticals.

Numerous intergovernmental meetings have therefore requested specific studies and actions from UN bodies such as the WHO, UNCTAD,

UNICEF, UNIDO and the UN Centre on Transnational Corporations. The problem of developing appropriate drug policies has been discussed in such fora as the Non-aligned Countries in 1979, UNCTAD in 1982 and repeatedly in the World Health Assembly since 1978. As a result of discussions in the Assembly, the technical concept of 'essential drugs' was introduced in the late 1970s and a WHO Action Programme on Essential Drugs and Vaccines was established in 1981. The current list comprises about 250 pharmaceutical products but it should be noted that in most countries the available number of products is 10 to 20 times as great and in some countries considerably higher. It should also be emphasized that while the Essential Drugs Programme marked an important step towards the improvement of health care in the public sector, it did not affect in any major way the situation in the private sector.

Acknowledging that the issues involved in the use and abuse as well as the production and marketing of pharmaceuticals are of a highly complex nature which needs further study, the World Health Assembly in May 1984 passed a resolution on the 'Rational Use of Drugs', requesting *inter alia* the Director General of the WHO to convene a meeting on this subject in 1985 'with all interested parties'. This meeting, 'a conference of experts', took place in Nairobi, November 25 to 29, 1985. The three main topics on the agenda were information, drug control and training. A summary of the meeting and the implications for WHO policies and actions will be presented by the Director General to the World Health Assembly in May 1986. The Assembly is mainly attended by representatives of ministries of health. As already stated, however, drug policies need an intersectoral approach and thus continuously also need other fora for discussion.

In addition to the debate carried on in different intergovernmental fora within the UN system and in the non-aligned movement, there has also developed an intensified national debate on these issues in many countries, both in the industrialized North and in some Third World countries—for instance, Mexico and Bangladesh—and in non-governmental or Third System organizations, such as Health Action International (HAI) and the International Organization of Consumers Unions (IOCU). In the pharmaceutical industry itself there is also an ongoing debate, which *inter alia* has resulted in a code of pharmaceutical marketing practices developed by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA). Important contributions to the debate have also been made by independent writers in books and articles in medical and other magazines.

Utilizing this material and on the basis of the concept of Another Develop-

ment outlined in the 1975 Dag Hammarskjöld Report *(What Now)* and other studies arising from the work of the Dag Hammarskjöld Foundation and its sister organizations, the Foundation organized a consultation on 'Another Development in Pharmaceuticals' in Uppsala in June 1985. It was based on a small number of papers commissioned for that occasion with a view to developing new approaches to some of the fundamental problems in this field and involving both national and international actors and institutions. The basic concern of these papers was to place the debate on pharmaceuticals in its proper historical, contemporary and future context by confronting the controversial aspects of the subject and bringing out a number of issues that had not as yet been dealt with in depth. The five major areas selected for discussion were grouped under the following headings: (a) Man and Medicines: A Historical Perspective; (b) Towards a Healthy Use of Pharmaceuticals; (c) Towards a Healthy Pharmaceutical Industry by the Year 2000; (d) First Principles for the Prescription, Promotion and Use of Pharmaceuticals: Towards a Code of Conduct; and (e) Monitoring Another Development in Pharmaceuticals.

Man and medicines: a historical perspective

All societies and cultures have their own pharmaceutical traditions and the present trend towards increased dependence on allopathic medical treatment (mainly through tablets and injections) can only be understood within its historical context. The 'pill culture' of the West, which is now invading or threatening to invade other cultures, emerged in Europe during the Middle Ages and was initially promoted by apothecaries and grocers and more recently by doctors and commercial companies, driving out other pharmaceutical traditons (herbs, fermented products, etc.), many of them rooted in self-reliant contexts and in unmedical (often magical) philosophies. Recent discoveries (e.g. sulfonamides and antibiotics) have, in addition to the many benefits they have brought, resulted in a massive growth of tablets and injections. This new material culture of the West has been little explored and even less related to its historical handmaidens, the industrial revolution (e.g. aspirin), colonial expansion in the tropics (e.g. antimalarials) and the ubiquity of modern war.

The recent post-colonial phase has been characterized by the rapid growth of the transnational pharmaceutical industries and the growing power of centralized governments, a development which has accelerated the medicalization of large parts of the Third World, as it has occurred in the context of the destruction of whole systems of traditional philosophies in the name of science and health. Present patterns of dependence are a product of this past evolution. The addictive nature of the new pill culture may as one of its unwanted consequences have played a role in creating or sustaining poverty

in the Third World. The price of foreign products is often out of proportion to their effectiveness and to the purchasing power of the poor, who thus may squander a large part of their income in the pursuit of what may be illusory hopes of benefit.

A systematic effort to provide these needy groups with essential drugs could have counteracted this development; the few attempts made have at best resulted in a decrease in mortality but not morbidity. Hence there is a tendency to keep people half-alive by supplying them with inappropriate pharmaceuticals without going to the heart of the matter and involving them as individuals and groups in the protection, maintenance and restoration of their own health.

Towards a healthy use of pharmaceuticals

Another major topic for discussion during the consultation, deriving from the historical overview and analysis, concerned 'the limits to the use of pharmaceuticals'. It was based on the assumption that pharmaceuticals are an inappropriate solution to many major health problems and that their consumption often does not meet the health needs of people. Plurality on the drug scene is not consistent with public demands for safety and efficacy. This is an issue that was examined in the light of the pressure exerted by various interest groups and professionals—transnational corporations, traders, government authorities, doctors and healers—as well as in the light of the psychological motivations of individual consumers. What one is confronting here is a complex of interlocking social, economic and political circles which are only dimly perceived—and their driving forces even less so. Despite the inherent diversity, an attempt was made to present, explain and evaluate the ideas and behaviour of those who make up these circles and to come to grips with their motivation.

It may be pointed out here that one of the disconcerting features of the contemporary pharmaceuticals debate is the limited extent to which it has become the object of grassroots self-reliant movements, or of Another Development processes generally. This curious situation is not well understood and needs more study, but a striking example relates to the large-scale use by women of oral contraceptives and tranquillizers, and the risks which this involves; it is noteworthy that even the women's interest groups are slow to take up their case. One may ask if the reason for this is that the use of pharmaceuticals is ultimately perceived as an individual decision which is not conducive to collective action. Such a view will counteract attempts to create independent channels of information addressed to those who are dependent on, and often overuse or abuse, pharmaceutical products.

But far more important in this context is the fact that the most dependent of the vulnerable groups, the women of the Third World, have little or no information about the drugs that could have a real impact on their health and that of their children. It is striking that in many cultures in the Third World people already want what they do not need, while lacking knowledge and understanding of the potential benefits of appropriate pharmaceuticals.

Any attempt to deal with this *problématique* has to be based on an assessment of the actual and potential sources of independent and objective information about the kind and quality of pharmaceuticals and drugs required in different situations and an analysis of how this information could be made available and communicated in a dialogue between all the interested parties, i.e. consumers, producers, governments, health professionals and international organizations.

Towards a healthy pharmaceutical industry by the year 2000

While some drugs are still being produced locally, notably by pharmacists, the pharmaceutical industry, be it transnational or domestic, is now the main producer of drugs in almost all countries. Ninety per cent of the world's production of pharmaceuticals originates in the industrialized countries, which also account for 80 per cent of the consumption. Projections of present consumption patterns, based on anticipated demand, indicate that the Third World's consumption is unlikely to rise to more than 25 per cent of the total by the year 2000. Both the *production* and *consumption* of pharmaceutical products are therefore likely to remain highly unequal for the foreseeable future. The prevailing economic situation in the Third World and technological developments in general are reinforcing this trend and making it more difficult to establish need-oriented and self-reliant pharmaceutical industries in the Third World; one of the few examples of a resolute attempt to break this trend is the establishment of Gonoshasthaya Pharmaceuticals Limited in Bangladesh.

Since the Second World War, pharmaceuticals have been one of the most attractive areas of investment. The pharmaceutical industry has ranked first or second in profitability among most industries since the mid-fifties. Worldwide sales of pharmaceuticals have furthermore been increasingly concentrated among a small number of corporations. There is mounting criticism of this concentration which is particularly striking in the production of bulk drugs and in certain therapeutic markets. The main sources of this monopoly power are the patent system, transfer pricing methods and brand name promotion, factors which have to be carefully examined in any attempt to remodel the industry.

The relation between transnational corporate investments in research and development, and expenditures on promotion and marketing have been given special attention. It has been estimated that while about 9 per cent of the income from the sales of pharmaceutical products by research-based companies is spent on research and development, more than twice this percentage is spent on advertising and promotion. Since there are many thousands of other companies engaged in promotion but not in research, the disproportion between world expenditure on drug advertising and that on research is far greater. Some governments have tried to set a limit to promotional expenditure and to negotiate to lower the promotion percentage to 11 per cent (UK), 14 per cent (USA) and 17 per cent (France). The magnitude of the problem, especially as related to the Third World, is illustrated by the fact that the Food and Drug Administration in the USA has estimated that each year US $6-8000 is spent on every single doctor in the USA in the promotion of different pharmaceutical products, while research and development expenditure directed by American pharmaceutical companies to Third World health problems amounts to a very small percentage of their overall research and development investments and this percentage is currently shrinking.

Another argument in support of these general criticisms is the contention that the pharmaceutical industries are making excessive profits because of the peculiar features of the market which shelter producers from price competition. Special, and favourable, agreements with governments are part of this. Also important is the fact that consumer sovereignty is absent in the prescription drug market, since it is not the consumer who makes the decision to purchase, but the prescribing physician.

Due to the fact that the world production of pharmaceuticals has been largely geared to consumers in industrialized countries, Third World countries have been supplied with a very inappropriate assortment of products by the pharmaceutical industry. What can be done to remedy this situation and why has the pharmaceutical industry failed to provide an adequate production capacity for the essential drugs needed at reasonable prices by the majority of people in the Third World? Is there an expanding market for such essential drugs or has the economic recession already put an end to such a scenario and to potential technological breakthroughs in this area? A complicating and relatively recent factor in this context is peculiar to the private market in the Third World, where traditional healers are now transcending their old areas of practice and beginning to use transnational pharmaceutical products in their concoctions without adequate knowledge

or understanding of their proper use, a situation which is further aggravated by the lack of any kind of effective control of these practices.

It has been argued in this context that it would be relatively easy to decentralize the production of drugs. Such local manufacturing would generate high indirect employment but would not necessarily produce cheap drugs of appropriate quality. What, under such circumstances, would be the prerequisites of a mutually rewarding system of cooperation in drug production?

It has recently been pointed out that there is at present no forum within the pharmaceutical industry which could be used for the preparation of such a cooperative effort and definitely no forum for carrying on a dialogue between the transnational corporations and the governments of the Third World. It is therefore, paradoxically, easier today to come to broad agreements as to what the transnational pharmaceutical industry should not be doing, than to agree on what it should do to make a major contribution to the health of three quarters of the world's population. One of the aims of the consultation was therefore to examine the structural and other means available to the pharmaceutical industry, governments, health workers, consumers and consumer organizations, when it comes to taking the necessary steps towards a developmental and reasonably profitable pharmaceutical industry geared to seeking solutions to global health problems.

Towards a code of conduct

In a situation where the existing systems of drug policies and control in most countries impose clear limitations, there is an obvious and growing demand for improved practices which will make them conducive to health development. An international harmonization of regulatory standards is needed. The fact that legal controls are ignored in many cases and in many countries is all the more reason to examine what law can and cannot achieve. The discrepancies between policies and legal requirements in the industrialized countries and most Third World countries place a special obligation on both governments and exporting companies, since the selling of pharmaceuticals cannot be considered an ordinary trade as it involves human health and well-being.

Over the last decade a number of specific requests have been made for the establishment of norms and standards regulating a whole set of issues reflecting relevant dimensions of drug utilization. Already in 1978, the WHO was requested to study the possibilities of reducing the prices of pharmaceutical products, 'including the development of a code of market-

ing practices'. No important results were, however, achieved. In 1981, the Council of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) approved its own code of pharmaceutical marketing practices. The recognition of the need for such a code by the producers themselves was an important event. But should such a code be limited only to marketing practices in view of the fact that other important issues such as trade, prices, transfer of technology, prescription and distribution are of vital concern? At an UNCTAD meeting in 1982, the International Organization of Consumers Unions (IOCU) also introduced a draft proposal for an international code on pharmaceuticals, prepared by Health Action International (HAI) while the Non-aligned Countries requested WHO and UNCTAD to develop a code.

While pharmaceuticals have a critical role to play in protecting, maintaining and restoring the health of people, an international code needs a health development perspective. Pharmaceutical needs in Third World countries can only partly be solved by supplying the countries concerned with sufficient quantities of essential drugs. The health infrastructure, prescribing physicians and dispensing outlets are crucial components. A comprehensive global code would be an important step towards a rational use of drugs in all countries, providing one of the few alternatives to the chaotic situation now prevailing in the pharmaceutical markets.

Another alternative might be to identify a set of 'first principles' relating to the promotion, prescription and use of medicines, and to recognize those practices which do not uphold the highest standards. These 'first principles' could be drawn together from current international efforts, and would embrace the necessity of establishing what the most essential drugs are for the public as well as possibly the private sector. They would recognize the rights and duties of the people themselves to participate in all aspects of health planning and policies; and the necessity for drug prescribing information to be 'objective', in 'good taste', and clearly stating indications, contra-indications, tolerance and toxicity etc. The main objective would be to put together a unified package of 'good' elements from all parties concerned, thereby providing a platform from which an eventual mutually acceptable code, based on a health perspective, could be developed.

Monitoring Another Development in Pharmaceuticals

The discussion of the above four areas selected for the consultation provided a number of entry points into the largely unexplored territory of possible monitoring and arbitration procedures with a view to promoting Another Development in Pharmaceuticals, a development which should be need-oriented, self-reliant, endogenous and ecologically sound and based

on the necessary structural transformations of the industry and the organization of health care. Some important measures have already been taken; laudable examples of this are the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, and the decision of the UN General Assembly to initiate and continue the publication of a Directory listing harmful pharmaceuticals and other products whose use has been banned or restricted in different countries. A system making it obligatory for governments to provide such information to an international body within the UN system might be considered an important objective. Another idea which has been advanced and could be further explored is the establishment of a UN Council on Pharmaceuticals by the UN General Assembly. Such a Council could, among other things, coordinate the activities of various international agencies and organizations involved in the development of the pharmaceutical sector: the WHO, UNCTAD, UNIDO, UNICEF, UNDP, WIPO and UNCTC.

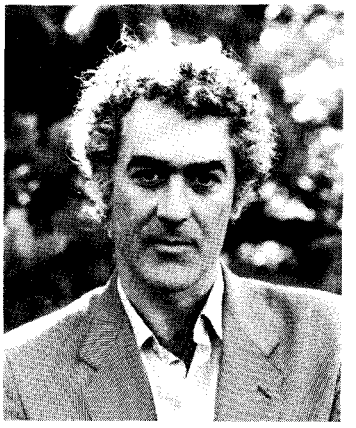
Outside the UN system, non-governmental organizations such as Health Action International (HAI), the International Organization of Consumers Unions (IOCU), Social Audit in the UK and Ralph Nader's Corporate Accountability Research Group in the US could play a decisive role by stimulating the establishment of national monitoring organizations in the Third World and developing techniques for bringing the information gathered to the attention of the world public. The proper fulfilment of this task would, however, require the development of a set of commonly agreed indicators which can be made operational in different environments. It may be that the methods and procedures used by organizations such as Amnesty International could to some degree be adapted and applied in this area, thus contributing to a situation where the health needs of the majority of the peoples in the world are met in a cooperative effort between 'all interested parties'.

A global non-governmental body concerned with the production and consumption of pharmaceuticals seems to be urgently needed at the present time. The establishment of such a 'pill ombudsman' could, in a longer time perspective, pave the way for Another Development in Pharmaceuticals by stimulating action on the part of governments, health professionals, industry and the general public towards the WHO's declared goal of Health for All by the Year 2000.

Göran Sterky

International Regulation of the Supply and Use of Pharmaceuticals

By Charles Medawar



For the many benefits they bring, modern medicines also fail humanity in two important ways. In the Third World, most people have little or no access to the medicines they need—yet where drugs are available, they tend to be excessively and unhealthily used. Under-medication and over-medication will continue to be major world health problems until there is general acceptance of the principle that drugs should be used exclusively in response to real medical need.

In the search for solutions, attention is increasingly focused on the World Health Organization (WHO) and on the collective efforts of the 160-odd member nations of the World Health Assembly (WHA). There are two very good reasons for this. One is that the Assembly has made a 'solemn commitment' to the global strategy of Health for All by the Year 2000—and because anything less than concerted action would achieve too little too late. Another is that WHO has developed a technically brilliant solution to the problems of under-and over-medication, in its proposals for the use of 'essential drugs'.

However, 1985 suggests that prospects for the year 2000 are grim: it is as if the WHO/WHA had the right key, but that the door was bolted or jammed. The underlying problem is that the WHO is largely financed and supported—and to that extent controlled—by the leading drug-producing countries. There are areas of serious conflict between therapeutic and commercial objectives, and world health suffers dreadfully as a result.

Against this background, Charles Medawar's paper reviews the need for better and more effective drug use, and the role of the WHO/WHA in achieving it. Specifically, this paper suggests some of the minimum standards and principles of drug use that will need to be adopted internationally—'forthwith and by acclamation'—if Health for All by the Year 2000 is not to appear a sham.

The author is not a doctor which, he says, 'is sometimes very inconvenient, but never a matter for regret'. He is director of a small, London-based, research unit, Social Audit Ltd., and involved also in a coalition of consumer/health/development action groups, Health Action International.

This paper discusses the principles involved in formulating international standards to regulate the appropriate use of drugs. It focuses particular attention on the role of the World Health Organization (WHO) in organizing this.

The WHO is focal because, to some extent, it represents the collective interest of the four parties most affected by regulation of drug use. These are: consumers, health care professionals, the pharmaceutical industry and individual nation states. Their interests sometimes conflict.

The paper is divided into four parts, each addressed to one main question. The case either for or against the adoption of international standards depends on the answer to each of them:

1. What is meant by 'the appropriate use of drugs'? What are the main determinants of appropriate drug use that all of the main actors seem to agree on?

2. How appropriately are drugs used today? To what extent are the standards agreed on in principle actually observed and upheld in practice?

3. Is regulation called for? Is further/better regulation likely to improve drug use; and what kind of regulation might work?

4. What might be achieved, and how? What standards would meet the needs of all countries; and how best might they attain them?

So far, such questions seem mainly to have generated bitter controversy —characterized both by vociferous comment and by deafening silence. However, the immediate purpose of this paper is not to advocate the international regulation of pharmaceuticals. It is to ask whether the debate on this question is over; or whether it is time it began.

The appropriate use of drugs

Medical need: the South

Appropriate drug use demands, above all, that pharmaceutical products meet real medical need. This implies providing drugs that people really do need; also restricting the supply of drugs to people who don't need them. This principle has been formally and universally accepted, as part of the global health strategy, abbreviated simply as 'Health-2000'.

In May 1981, the 158 member countries of the World Health Organization made a formal commitment to the global strategy of Health for All by the Year 2000. This means that, by the end of the century, 'people everywhere

should have access to health services which will enable them to lead socially and economically productive lives'.[1]

Health for All by the Year 2000 does not mean that in the year 2000 doctors and nurses will provide medical care to everybody in the world for all their existing ailments; nor does it mean that in the year 2000 nobody will be sick or disabled. But it *does* mean that there will be an even distribution among the population of whatever health resources are available. And it *does* mean that people will use much better approaches than they do now for preventing disease and alleviating unavoidable illness and disability, and that there will be better ways of growing up, growing old and dying gracefully. And it does mean that health begins at home and at the work place, because it is there, where people live and work, that health is made or broken. And it *does* mean that essential health care will be accessible to *all* individuals and families in an acceptable and affordable way and with their full participation.[2]

The global strategy of Health-2000 is addressed mainly to the most urgent world health problem: control over the disease(s) of poverty. For this reason, the Health-2000 strategy deals mainly with basic health needs, such as access to food and clean water. It does, however, emphasize the important contribution that drugs can make in protecting, maintaining and restoring health. This is underlined in the following recommendation, made at the 1978 Alma-Ata Conference on Primary Health Care.

The Conference, *recognising* that primary health care requires a continuous supply of essential drugs; that the provision of drugs accounts for a significant proportion of expenditures in the health sector; and that the progressive extension of primary health care to ensure eventual national coverage entails a large increase in the provision of drugs, *recommends* that governments formulate national policies and regulations with respect to the important, local production, sale and distribution of drugs and biologicals so as to ensure that essential drugs are available at the various levels of primary health care at the lowest feasible cost; that specific measures be taken to prevent the over-utilisation of medicines; that proved traditional remedies be incorporated; and that effective administrative and supply systems be established'.[3]

This recommendation underlines the very important point that drugs on their own do not meet medical need. Drugs can be used appropriately only if there is an efficient health-care network, and adequate arrangements for administration and control.

Most of the Third World countries have none of these, hence the emphasis on provision of basic health services and limited numbers of essential drugs. The WHO lists some 250 'essential drugs', which are 'proven to be thera-

peutically effective, to have acceptable safety and to satisfy the health needs of the population'.[4] WHO has pointed out that these are not the only useful drugs, but they are the main ones.

Medical need: the North

The Alma-Ata recommendation on drugs applies to medical need in industrialized countries, as well as in the Third World. None of the richer countries has a really adequate regulatory and administrative system, though the standard varies from very good to very poor.

Certainly all industrialized countries now recognize the need 'to prevent the over-utilization of medicines'. The imperative is not only to control waste, but also to reduce an unhealthy over-dependence on drug and an appreciable amount of sickness caused by over-medication. For these reasons, the *British National Formulary* advises doctors that 'Medicines should be prescribed only when they are essential...'.[5]

It is increasingly recognized in the North that this must be achieved by reducing both the amount and numbers of drugs prescribed. There is evidence of this trend in many policies and practices, at every level in the health care system, and in the public and private sectors alike.[6] For example, in Western Europe and North America:

- Independent and authoritative drug prescribing guides often advise doctors how to distinguish between more and less essential drugs.
- Many major hospitals use drug formularies—'limited lists' which include only those drugs that doctors are encouraged to prescribe.
- In many public and private health care schemes, less useful drugs are made ineligible for reimbursement.

These policies have been clearly shown to reduce waste; and to reduce the burden on drug distribution and administrative systems. Restrictions on prescribing have been demonstrated also to promote more rational prescribing, and therefore to improve standards of patient care.

It is recognized that no doctor can become well enough informed to choose intelligently between many hundreds or thousands of drugs—indeed, invididual doctors usually prescribe from their own personal 'list' of perhaps 50–200 favourite preparations.[7] The case for limiting the numbers of prescribable drugs is further supported by evidence of the untoward effects of sales promotion, also of the extent of misuse of drugs.[8]

There is good evidence to suggest that more rational and effective drug use can be achieved when doctors prescribe from model lists, based on well

established and familiar preparations. This applies in institutions and at national level as well:

> Limitation of the number of drugs can be justified on the grounds of simplicity, safety and economy. It also has the advantage that the physician's armamentarium is of manageable size... Norwegian drug policy has demonstrated over a number of years that it is possible to restrict the number of drugs on the market quite appreciably without any adverse effects on patients.[9]

In Norway, doctors are discouraged from prescribing less desirable drugs, because the principle of medical need is recognized in law.[10] On a strict interpretation, the medical need provision means that a drug cannot be licensed for general use unless it has been convincingly demonstrated that it in some way improves on what is already available.

It is worth pointing out that, in Norway, there are about 1,000 brands of medicine available—probably one-tenth or less the number in most Third World countries. This graphically demonstrates that more drugs do not equal better health.

The Director-General of WHO and the Executive Director of UNICEF have acknowledged this and conclude in their report to the Alma-Ata Conference on Primary Health Care that, 'It is universally agreed that fewer drugs are necessary than the number at present on the market in most parts of the world'.[11]

Need for appropriate products

Indeed, fewer drugs mean better health. This is partly because, in most countries, there are too many drugs to be used effectively. It is also because there are significant numbers of drugs that are less effective than the alternatives that could be used.

> Combination drug products (i.e. with two ingredients or more) account largely both for the unwelcome proliferation of drugs, and for most of those considered less suitable for use. As a general rule—to which there are a few honourable exeptions—single-ingredient medicines are much to be preferred.[12]

Appropriate drugs include drugs of the greatest therapeutic value, which 'have full regard to the needs of public health'.[13] They are drugs which best meet local need, and which are most suited to local conditions of use.

The importance of local medical need is recognized in the Alma-Ata recommendation on drugs, partly in the provisions on local manufacture and use of indigenous remedies. In recommendations made by other

bodies,[14] attention has been drawn also to the relevance to local need of policies on pricing and on transfer of technology. Notwithstanding the advantages of regional cooperation, the claim to self-sufficiency in production, and to self-determination in drug policies, is a basic right of any nation state.

Beyond this, it is difficult to generalize about the appropriateness of a medicine without discussing individual types and examples of drugs, in specific conditions of use. The most that can be said is that the ideal medicine meets the most prevalent and serious health needs; and is safe, effective, simple and cheap. Oral rehydration salts are a shining but isolated example of this.

Though it is also difficult to generalize about how safe or effective a drug should be, the guiding principle is that 'in all cases the benefit of administering the medicine should be considered in relation to the risk involved'.[15] This principle does not apply only to the relationship between the health care provider and the individual patient. It must sometimes also define a relationship between the needs of the individual and of the community.

For example, in a poor country, a doctor may effectively have to choose between treating 20 people with a simple preparation or one person with an essentially similar, though perhaps slightly 'better' drug.[16] In situations like this, the appropriate drug is the cheapest one, unless a significant risk to the patient is involved.

Need for information

Information about drugs and pharmaceutical products is a prerequisite at all health care levels to ensure proper utilization and to promote rational prescribing.[17]

Consumers need information about how to use drugs safely and well; and tend to be more responsive to treatment when well informed.[18] Consumers also need basic information about how drugs work; and about what medicines can and cannot be expected to do. Informed consent to treatment (and to some extent the right to refuse it) depends upon this.

There is, therefore, substantial support in principle for the view that consumers should be informed about decisions made in their name. It is clearly also desirable that consumers, collectively, should approve the policies such decisions are based on.

It is realised today that science and technology can contribute to health standards *only* if the people themselves become full partners of the health care providers in safeguarding and promoting health...

> ... people have not only the *right* to participate individually and collectively in the planning and implementation of health care programmes, but also a *duty* to do so (original emphasis).[19]

Recognizing the prescriber's need to be informed, the international pharmaceutical industry has proposed that 'information on pharmaceutical products should be accurate, fair and objective' and 'should be based on an up to date evaluation of all the scientific evidence'. The industry has said it accepts the need 'to provide scientific information with objectivity and good taste, with scrupulous regard for truth, and with clear statements with respect to indications, contraindications, tolerance and toxicity'. It has acknowledged also that 'statements in promotional communications should be based upon substantial scientific evidence or other responsible medical opinion'.[20]

However, the need for information goes far beyond guidance on the use of drugs. The need is for a far greater and wider appreciation of community and world health priorities—and, according to WHO's Director-General, this is far from satisfied:

> Please don't misunderstand me; I have no quarrel with the medical profession as such. After all, I am part of it. But I am saddened that by and large the profession has not grasped the seriousness of the world health situation in spite of heroic medical efforts, nor has it realised how inappropriate society's response to this situation is, no matter at what level of social and economic development. I can only appeal to it again to assume its leadership role in health before that is taken away from it irretrievably'.[21]

How appropriately are drugs used?

There is extensive misuse of drugs, mainly because of serious deficiencies in each of the areas discussed above. Though the poorest are by far the worst affected by this, there are substantial problems in Third World and industrialized countries alike.

An important measure of this failure is the astonishing gulf between expressions of high purpose and practice on the one hand—and harsh reality on the other. This can be demonstrated by contrasting the main statements of commitment and principle (discussed above) with the evidence of some of what happens in practice.

1. *'The pharmaceutical industry, conscious of its special position arising from its involvement in public health, and justifiably eager to fulfil its obligations in a free and fully responsible manner, undertakes to ensure that all products it makes available for prescription purposes ... have full regard*

to the needs of public health' (IFPMA International Code of Pharmaceutical Marketing Practice).

However, as many as 70 per cent of the pharmaceuticals on the world market today are inessential and/or undesirable products;[22] and 'many pharmaceutical products are marketed with little concern for the differing health needs and priorities of individual countries'.[23] In Third World countries, inessential drugs outnumber essential drugs by upwards of 10 to 1.[24] Even in the richest countries, conspicuously inessential drugs are among the most widely prescribed.[25]

A survey by UK Department of Health officials of the drugs introduced into the UK in the 1970s concluded 'that an abundance of analogous drugs is offered, not rarely with exaggerated claims for efficacy'. These drugs were overwhelmingly for diseases which are 'common, largely chronic, and occur principally in the affluent Western societies'.[26] The international pharmaceutical industry is estimated to allocate about 1 per cent of its research and development expenditure on poor world diseases;[27] and there are said to be no good drug treatments for over half of the diseases specific to poor countries.[28]

In the Third World, in particular, there are well documented cases of the marketing of pharmaceuticals 'that are unsafe because of pharmacological dangers inherent in the medicine itself'; and/or 'in an environment where lack of adequate medical technologies, personnel or financial resources render the product unsafe'; and/or 'where the social context prevents proper use of the product'.[29]

2. *'Medicines should be prescribed only when they are essential'.* This is a cardinal principle of appropriate prescribing. It is the first point made in the 'Guidance on Prescribing' section in the *British National Formulary.*[30]

However, greatly excessive amounts of medicine are prescribed, including significant numbers of less desirable products. This is a serious problem in Britain and other industrialized countries;[31] and even greater elsewhere.[32]

The fact that many doctors in the UK prescribe for their patients up to about five times more often than some of their colleagues strongly suggests fairly generalized over-prescribing[33] while the prescribing of certain kinds of drugs (e.g. antibiotics, laxatives, tranquillisers) is well documented as profligate. Excessive prescribing 'constitutes a major cause of adverse

reactions', which account for about 10 per cent of all admissions to hospital of old people, and between 3 per cent and 5 per cent of the rest.[34]

Drugs which were officially 'not recommended' in 1984 comprised 20 per cent of all UK products; and were widely prescribed. Drug prescribing in the UK is also extravagant: the amount general practitioners could save by *not* prescribing the most expensive brand of ten popular medicines is equal to nearly three times the total annual drug budget in Tanzania.[35]

'Non-compliance' is a further indication of over-prescribing and waste. Up to 20 per cent of all patients are reported not to exchange their prescriptions for medicines;[36] while perhaps 50 per cent in all do not use their medicines as directed.[37] The evidence suggests waste of tens of millions of tablets each year.[38]

3. *'Science and technology can contribute to health standards only if the people themselves become full partners of the health care providers in safeguarding and promoting health'*. This principle was recognized as an important part of the 'Health-2000' strategy at the 1978 Alma-Ata Conference on primary health care; but the quote here is from the report of a 1983 WHO Expert Committee on health education.[39]

However, as a rule, decisions about medicine are almost completely dominated by professional and commercial interests; and are usually carried out in secret.[40] In most countries, consumers are given little or no information about using medicines—and in many are refused information even about what drugs have been prescribed.[41]

Even in some of the richest countries in the North, much remains to be done. Patients 'need to grasp a few very basic concepts relating to medicines... (for example) ... the notion of a benefit/risk relationship, and that this is affected by the nature and seriousness of illness; that the body gets rid of drugs, and that the speed with which this happens affects the frequency of doses; that a drug can have effects on the body that are not intended; and that medicines do not keep for ever. *We have to find ways of teaching patients these and other elementary ideas, but have hardly begun to do so'* (emphasis added).[42]

The doctrine of 'clinical freedom' still rules: this reduces the quality of prescribing;[43] and severely restricts the public accountability of health care providers. In most countries, consumers' rights of redress are either very limited or do not exist.

In spite of encouraging signs of progress in health education, medicine still seems 'basically concerned with "telling people" what is good for them'.[44]

4. *'Information on pharmaceutical products should be accurate, fair and objective' and 'statements in promotional communications should be based upon substantial scientific evidence or other responsible medical opinion'* (IFPMA International Code of Pharmaceutical Marketing Practice).

However, most prescribing information is partial, unreliable and incomplete. If this were not so, it would be impossible to sustain a world marketplace which included large numbers of unnecessary or undesirable drugs, most of them claiming significant and/or unique advantages over rival products.

Surveys have confirmed 'the marketing of pharmaceuticals without complete information essential for their safe use'.[45] Double standards are commonplace, especially in the provision of information between industrialized and Third World countries.[46] The benefits of drug use are routinely emphasized and over-emphasized; and the disadvantages are routinely played down.[47]

Information from tests and trials on drugs typically ranges from inadequate[48] to appalling.[49] In most clinical trials, the sample sizes are too small and the length of treatment too short to substantiate the claims made on the strength of them. This information is largely generated by the pharmaceutical industry, for use in promoting its products.

> There are now said to be over 20,000 biomedical journals worldwide, even though only 3,200 are indexed in a readily available format... Even more daunting is the exponential growth of biomedical literature which is doubling in volume every 10–15 years, i.e. 2–3 times faster than the worlds's population... Much of the volume of literature is of marginal use either because it is so academic that it is inapplicable, because it demonstrates incompetent techniques or because it produces trivial results. As many as half of all articles might never get cited even once by other authors. Only about one paper in eight provides what is said to be important new, useful information.[50]

Few countries systematically monitor drug prescribing standards and consumption patterns; and there is chronic and serious under-reporting of adverse reactions to drugs.[51]

The direct effects of drug promotion are, by and large, malign. Standards of promotion are higher in industrial countries than in the Third World, but work to the same general effect—because of the levels of expenditure allowed. In the UK, expenditure on promotion runs at about £5,000 per

GP, per year. Overlooking substantial evidence to the contrary, the medical profession tends to deny the profound influence of advertising and promotion on prescribing practice.[52]

Lavish hospitality is the least of many other inducements doctors are given to prescribe particular drugs. This is standard practice and hard to control. An important reason for this, according to a senior UK industry official, is that 'the recipients of lavish hospitality do not complain. The uninitiated do'.[53]

5. *Health for All by the Year 2000.* Member nations of the World Health Assembly have expressed 'a solemn commitment' to this objective; and the WHO's Director-General has repeatedly said that 'these are no idle words'.

However, the pharmaceutical industry is not party to this resolution and, with a number of richer nations, is strongly opposed to the notion of 'a new economic order'—which is an essential element in the global strategy proposed.[54] At the same time, support for this strategy from the world medical profession appears very inadequate.[55]

At the current rate of progress, there is in fact no prospect of achieving Health-2000 or anything like it. The World Bank's most optimistic forecasts suggest that 600 million will still be living in absolute poverty by the end of the millenium.[56] Oxfam estimates rather more.

In these circumstances, perhaps the most immediate concern of those who advocate further regulation of drug use is not the state of world health; but the evidence of a pretty comprehensive failure to face what needs to be done.

Everyone is *saying* the right things—but it seems mainly to disguise the fact that nothing like enough is being done.

Is regulation called for?

Why regulation?

The Health-2000 concept came into use in 1978: we should therefore by now have come about one-third of the way to health for all. But, for all the progress made, nothing like this has been achieved. There remains an urgent need to promote the more rational and economic use of drugs.

Two questions now arise. First, is it worth thinking about regulation (as opposed to, say, exhortation) as an instrument of the Health-2000 strategy? And, secondly, is it worth trying to regulate drug use? The following may be taken into account:

- Experience in the North has demonstrated beyond doubt that effective regulation is prerequisite to the effective use of drugs. If effective drug use is an important part of the Health-2000 strategy, then regulation must be too. The need for regulation is greatest in countries with the most serious health problems of all.
- Failure to regulate the supply and use of drugs undermines world health not only because it means that drugs won't be used well, but also because it leads to the diversion of essential resources. This means money is wasted on drugs—but, perhaps more important, it leads to the development of a health care system that is concentrated in wealthier, urban areas and which revolves around the prescribing and dispensing of drugs.[57]
- Acceptance of the greater discipline that regulation entails would signal a renewed and more realistic commitment to the challenge of Health-2000. The Health-2000 strategy makes no sense unless that commitment can be made.

The international dimension

The need for national regulation is already well established. The question now is whether international regulation is called for; and specifically whether or not to call on the WHO to organize it. As all of the member nations (the Assembly) of the WHO have expressed a solemn commitment to Health-2000, it seems logical to consider this.

A further reason for thinking about international regulation is that control over drug use would need to be specifically and largely directed at control over unwanted products. Many, if not most of these, move in international trade.

The need for provision of full information about the safety and effectiveness of drug treatments, and for effective control of drug promotion is well recognized—but, clearly, reducing the number of drugs must come first. There is no point in trying to control the promotion of, or provision of information about drugs that are not wanted in the first place. The first priority is to have these drugs removed.

Though the medical profession has a key role to play in achieving this, probably more could be accomplished through better training (including post-graduate education), than through policies based on enforcement. To this extent, regulation implies control over the activities of the main drug producers. This does require international initiatives, since an essentially transnational industry is involved.

Transnational corporations dominate the world market for drugs. The top 50 companies, all based in industrialized countries, control the supply and promotion of about half of all drugs sold.[58] The strength of these organizations is underlined by the fact that the 1980 world sales of each of the 15 largest companies (between US $1–2.4 billion) exceeded the Gross National Product of many Third World countries.

It has long been recognized, first that individual Third World countries are rarely in a position to control transnational corporations effectively; and secondly, that the priorities of transnationals may radically conflict with basic development needs. Thus, the United Nations Programme of Action on the Establishment of a New International Economic Order has recognized the need for an international code of conduct for transnationals:

> to regulate their activities in host countries, to eliminate restrictive business practices and to conform to the national development plans and objectives of developing countries...
>
> to bring about assistance, transfer of technology and management skills to developing countries on equitable and favourable terms;
>
> to regulate the repatriation of the profits accruing from their operations, taking into account the legitimate interests of all parties concerned; and
>
> to promote the reinvestment of their profits in developing countries.[59]

The purposes and limitations of international codes have been reviewed at length in a number of reports from the UN Center on Transnational Corporations.[60]

Regulation by WHO?

Though WHO has developed mainly as a forum for cooperation and as a major source of advice and technical expertise, it was set up also to develop and maintain standards for the international trade in medicinal drugs. Article 21 of the WHO's constitution specifically gives the Assembly authority 'to adopt regulations' relating to drug standards and promotion. This provision was adopted in 1948, but is believed never to have been used.

Following the Declaration of Alma-Ata in 1978, the WHO on a number of occasions broached, though never grappled with, the question of a Code on Pharmaceuticals. The following statement by the then Director of the WHO's medicines division (though considered within WHO to be extremely outspoken) illustrates the rather tentative nature of the commitment involved:

> Perhaps we should start to think now—or to dream—of a future regulatory system which would facilitate the discovery and introduction on a world-wide scale of drugs important, or essential, to meet real health needs and, at the same time, prevent the international trade of those proven to be harmful to health on the basis of scientific evidence.[61]

It is understood that, shortly after this, the Director-General of the WHO was warned that the US would withdraw from the Organization, if work on an international code went ahead. It stopped. The world's top drug producing nation, the USA, provides about one-quarter of the total WHO budget; and the top six drug-producing nations contribute over half.[62]

Not long after, a voluntary International Code of Pharmaceutical Marketing Practice, drafted by the US Pharmaceutical Manufacturers Association, was introduced by the International Federation of Pharmaceutical Manufactures Associations (IFPMA). In spite of its limitations,[63] and evidence from within the industry that the IFPMA had acted mainly to repel regulation from outside,[64] the WHO's Director-General welcomed this as a useful first step in raising standards. Since then 'WHO has reportedly decided to follow closely the implementation of the IFPMA Code, and refrain from pursuing vigorously the promotion of its own code during a trial, but unspecified period'.[65]

The IFPMA Code dates from 1981. Whatever has been achieved, the Code has not discernibly improved world health. Nevertheless, WHO still maintains that regulation of marketing practices ranks as a relatively low priority, considering what else needs to be done:

> As you know, there are many problems involved in getting essential drugs to the masses of people in these countries. Marketing practices are only one of them. I believe that it is most urgent at this stage to ensure the development and implementation of national policies based on the concept of essential drugs... it is the whole national managerial system relating to drugs that is crucial before any kind of international arrangements can be of use.[66]

In the meantime, proposals for the international regulation of transnationals, with particular reference to consumer protection, have been developed elsewhere in the UN system. The United Nations Code of Conduct on Transnational Corporations contains in draft specific provisions relating to product safety and to uniform standards for disclosure of information about possible hazards.[67] More recently (April 1985), the UN General Assembly unanimously adopted the UN Guidelines on Consumer Protection, with a view to the preparation of a model code.[68]

Strategy for regulation

Effective regulation implies the need for (a) carefully defined objectives and clear policies and standards; (b) machinery for monitoring and obtaining feedback on practice observed; (c) the ability to interpret defined standards, and to explain and justify enforcement decisions taken as a result; and (d) the power to impose effective sanctions.

Clearly, WHO is in no position to enforce standards along these lines. Equally, it has no wish for confrontation, either with the richer member governments, or with the industry. WHO is involved in cooperation and contractual relations with many pharmaceutical companies:[69] it would be very difficult to maintain a close working relationship with the industry and control it at the same time.

It therefore seems unrealistic to expect WHO to become involved in formal, full-scale international regulation. On the other hand, there is an urgent need for improved standards which individual countries cannot enforce without strong support; and there is also considerable pressure on WHO to provide leadership. Without it, Health for All by the Year 2000 must appear a sham.

In the circumstances, it seems reasonable to expect WHO to do at least three things:

- To monitor standard practices in drug promotion and use, and to clearly identify those which are acceptable and those which are not. At the same time, the WHO should be called on to draw up criteria for the approval and rejection of different types and classes of drugs—for example, as Expert Panels of the US Food and Drug Administration have done for years.[70]
- To help to develop and define basic appropriate standards relating to the supply, promotion and use of drugs—having regard to the overwhelming evidence there is of the insufficiency of some of the standards observed now. It is for the WHO to define now those standards and practices that are and are not conducive to Health-2000; and to emphasize their importance in achieving that goal.
- To promote vigorously the introduction and enforcement of appropriate standards—bearing in mind the need for general and co-ordinated acceptance of the principles on which those standards are based. In particular, the WHO might aim to catalyse the synchronized adoption of standards to ensure that all drugs really do 'have full regard to the needs of public health'. This is prerequisite to their proper use.

The WHO is already deeply involved in the application of appropriate

standards for drug use: it has now to communicate much more emphatically what those standards are and why they need to be upheld. If that need isn't defined, it doesn't officially exist.

None of this would need to distract the WHO from its other main objectives—since it would undertake no enforcement activity, other than to intervene at the specific request of a member state. WHO's main task would be to encourage member nations to adopt and enforce uniform standards on drug use—rather than to attempt any policing role itself.

This is essentially what was done when WHO drew up a Code of Practice on Breast Milk Substitutes, and saw it adopted by resolution of the World Health Assembly in 1981. It was up to the WHO to emphasize the general principle 'breast is best', and to identify promotion and sales practices which clearly conflicted with this—but it was left to the individual member states to define and interpret appropriate specific standards, and also to enforce them.

What principles of drug use might the WHO now be expected to uphold?

What might be achieved and how?

What standards should apply; and how should they be defined? The answer must be to define *now* those minimum standards which will have to be applied in all countries, within the next fifteen years. Such standards would need at least to be defined now to secure their general acceptance by then.

The following is a suggested outline of the main minimum standards relating to the supply and use of drugs that will have to be observed, if the strategy of Health-2000 is to work. So far as is practicable, the standards suggested here have been based on verbatim statements of the main principles of sound practice, recommended by the pharmaceutical industry and by professional bodies.

1. All pharmaceutical products must be approved and registered for use by the competent government authority.

2. All registered pharmaceutical products shall have full regard to the needs of public health. No drug may be registered for use in a country unless it has been convincingly demonstrated that:

- it meets real medical need; and that
- it is therapeutically effective; and that
- it is acceptably safe;

taking fully into account:

- the need for and availability and cost of alternative drugs and treatments for the same conditions;
- the circumstances of normal and normally forseeable use;
- the evidence of the therapeutic value of the drug in practice, in all places where that drug is used;
- the need to encourage more rational and economic drug use, by restricting the numbers and types of drugs available for prescribing to those that can be effectively used;
- the need to satisfy essential public health requirements.

Any manufacturer may export any pharmaceutical product which is designated by the World Health Organization as an essential or otherwise useful drug; or which fully satisfies the standards defined above for therapeutic effectiveness and safety in the exporting country; but pharmaceutical products shall not otherwise be exported.

As a condition of registration, the manufacturer shall provide such information as is needed to assure that the drug is properly used. All information provided by manufacturers shall be accurate, relevant, fair and factual and shall comply fully with legal standards.

In all contact with health care workers and the public, and in the quality and quantity of all promotional activity, manufactures and/or their agents shall at all times observe standards that are conducive to good medical practice.

The government in each country shall ensure that health care workers are sufficiently trained to be competent to prescribe and/or administer the pharmaceutical products they are permitted to use. The government shall ensure that prescribers have free and ready access to concise, up to date, relevant and balanced information about treatments, sufficient to inform them about the uses and limitations of registered pharmaceuticals; and about the likely benefits and costs of drug and alternative treatments.

Every government shall ensure that appropriate information about registered pharmaceuticals is made available to all consumers having regard to:

- the need to involve consumers as full partners in the health care system;
- the need to take medicines only when essential;
- the rights of the consumer to give informed consent to treatment, or to refuse it; and
- the therapeutic advantages obtained when people take greater responsibility for their own health and well-being.

The way in which information is communicated to consumers shall have due regard also to prevailing levels of functional literacy; to the circumstances in which drugs are likely to be used; and to evidence of actual or forseeable misuse.

Implementation

It is worth repeating that these general principles are based on an assessment of certain future need—and not on the expectation that they can be promised today and delivered tomorrow. It is obvious that many countries are not yet in a position to guarantee observance of these principles—however much they might support them.

This proposal envisages a period of vigorous debate and consultation, leading to the drafting of guidelines and basic standards for the appropriate use of medicines, for approval in the immediate future by the World Health Assembly.

A formal resolution of acceptance of these standards by the WHA might involve the following:

- An undertaking by all member states to prepare very shortly thereafter a detailed plan and timetable for the implementation of these provisions, and to report back to the WHA.
- Recognition of the need for all member states to implement these provisions as soon as practicable; but in any case no later than 1995.
- The setting up by WHO of panels of experts to assist and advise on the interpretation and implementation of the standards defined.

This timetable optimistically presupposes that a period of debate and consultation migh be ended by early 1987; but there has been no real debate so far.

It is high time it began.

Notes

1. *Health for All: One Common Goal,* WHO, Geneva, 1983.
2. Mahler, H., (Director-General of WHO); address to the 11th Assembly of the International Federation of Pharmaceutical Manufacturing Associations, Washington D.C., June, 1982.
3. *Primary Health Care,* report of the International Conference on Primary Health Care jointly organised by the WHO and UNICEF, at Alma-Ata, USSR, 6–12 September, 1978, published by the WHO, Geneva, 1978.
4. *The Selection of Essential Drugs,* Report of WHO Expert Committee, technical report series NO. 615, WHO, Geneva, 1977.
5. *British National Formulary,* No. 9, British Medical Association and the Pharmaceutical Society of Great Britain, London, 1985, p. 2.

6. Medawar, C./Social Audit; *Drugs and World Health,* IOCU, The Hague; 1984, pp. 34–37 and 47–50.
7. 'The average doctor has to repertoire of perhaps 30–40 drugs prescribed regularly and another 50 or so used occasionally. There is no evidence that the use of a large number of drugs improves health care. On the contrary, it is known to increase the incidence of unwanted effects' from *Guidelines on technology issues in the pharmaceutical sector in developing countries,* United Nations, New York, 1982, p. 11. A figure of 50–100 was suggested at the WHO informal meeting on introducing the essential drug concept [Geneva, 10–14 December, 1984]. The figure of 200–300 drugs for the average GP was suggested in: Greenfield, P. R., [Chairman]; *Report to the Secretary of State for Social Services of an informal working group on effective prescribing,* Department of Health and Social Security, London, 1983.
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9. Jøldal, B., 'Selecting drugs on the basis of need', *World Health Forum,* 1985, 6, pp. 67–9.
10. Though the law in Norway generally restricts the use of drugs for which there is no medical need, there is a small but significant amount of prescribing of unapproved drugs permitted for individual, named patients. See Hemminki, E., 'Noninvestigational use of unapproved drugs—experience from the Scandinavian countries' *Medical Care,* 1981, 19, 10, pp. 1056–60.
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13. *International Code of Pharmaceutical Marketing Practice,* International Federation of Pharmaceutical Manufacturing Associations, Zurich, 1981.
14. See, for example, 'Text of the draft United Nations Conduct on Transnational Corporations', *CTC Reporter* No. 12, Summer, 1982; also *Material Relevant to the Formulation of a Code of Conduct,* UN Centre on Transnational Corporations, United Nations, New York, 1977.
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59. Ibid. See also *Issues involved in the formulation of a code of conduct, United Nations, New York, 1976.*
60. See *Material Relevant to the Formulation of a Code of Conduct,* op. cit., and Text of the draft United Nations Conduct on Transnational Corporations, op, cit., and *Issues involved in the Formulation of a Code of Conduct,* op. cit.
61. Dr. V. Fattorusso was speaking at a symposium on 'The future of the European Community Procedures for the harmonization of drug registration', held in Rome, 31 May–1 June, 1979.
62. These countries are France, Germany, Italy, Japan, the UK and the USA. Their share of world production of pharmaceuticals, and the proportion of the WHO budget they provide [1986-7] are as follows:

Country	*Share of world production of pharmaceuticals* *	*Share of total budget of WHO* **
USA	25 per cent	25 per cent
Japan	20 " "	10.13 " "
West Germany	10 " "	8.38 " "
France	6 " "	6.39 " "
Italy	6 " "	3.67 " "
UK	5 " "	4.58 " "
TOTALS	72 per cent	58.15 per cent

* Tucker, D., *The World Health Market,* Euromonitor Publications, London, 1984, p. 42.

** 'Scale of Assessments for Financial Period 1986–1987', WHA document 38,7, agenda item 26.2, dated 13 May, 1985.

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Drugs—Registration and Marketing Practices in the Third World

By K. Jayasena

A Third World perspective on the regulation of the supply and use of pharmaceuticals—dealt with in a more general way by Charles Medawar in the foregoing contribution—is provided by Professor K. Jayasena in this paper. He emphasizes that the import of pharmaceuticals to the Third World or their local production is oriented more to profit-making than to the satisfaction of the health needs of the people. Among the problems in the field of marketing are the lack of qualified personnel in most Third World pharmacies, the common practise of many doctors to sell the drugs they themselves prescribe and the lack of adequate information concerning the different drugs available on the market. To counteract this, Professor Jayasena suggests that the manufacture and import of drugs should be restricted to the 250 or so essential drugs identified by the WHO, that quality control should be improved through a regionally organized system and that the whole range of health workers from medical doctors to traditional practitioners and primary health care workers should be mobilized in a broad educational effort to promote a better understanding of the role of pharmaceuticals in health work.

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Introduction

William Osler* is said to have observed that the desire to take medicine is the feature which most distinguishes man from his fellow creatures. Medicines are now dispensed in such attractive forms and new ones introduced to the medical profession with such promise and widespread media coverage that the general public not only expects miracles, but are also led to believe that life can be sustained only by the continuous ingestion of drugs. This has led to the consumption of drugs in large quantities and it is not surprising that an uninformed or uncritical person will resort to them even for the most trivial and self-limiting illness. This 'pill culture' which originated in the industrialized countries is now spreading to the Third World and having a serious impact, not only on the health of individuals but also on the economies of these countries. The inappropriate use of a multitude of drugs has led to the realization among certain individuals and organizations at both national and international levels that there is a need to promote the rational use of drugs, by legislation if need be.

* Sir William Osler, 1849-1919, was a renowned physician, born in Canada, who became Regius professor of medicine at Oxford University.

The need to regulate the use of drugs became even more urgent when the member nations of the World Health Organization (WHO) adopted the global strategy of Health for All by the Year 2000 (Health-2000). At the Alma Ata Conference held in 1978 when the strategy of Health-2000 was developed, it was recognized that the provision of primary health care (PHC) would entail a large increase in the supply of drugs.[1] It was also noted that the provision of drugs accounts for a significant proportion of expenditure in the health sector. The conference therefore recommended that member states should 'formulate national policies and regulations with respect to the import, local production, sale and distribution of drugs and biologicals so as to ensure that essential drugs are available at the various levels of primary health care at the lowest feasible cost; that specific measures be taken to prevent the over-utilization of medicines; that proven traditional remedies be incorporated; and that effective administrative and supply systems be established'.[2]

The formulation of an internationally acceptable code of conduct to improve the use of pharmaceuticals is a formidable task, given the world's varied and often conflicting socio-economic and political environments. The identification of the first principles on which such a code of conduct can be developed should be based on a realistic consideration of the conditions prevailing in different countries vis-à-vis drug promotion and development; marketing, distribution and management of drug supplies; prescription and utilization patterns; and patient expectation and compliance, etc. Whilst a consideration of these factors is necessary in all countries, it is even more important in Third World countries, where the health care delivery systems are quite different from those in industrialized countries. An account, therefore, of the practices prevalent in the Third World pertaining to health care delivery in general, and drug usage in particular, would assist the identification of new strategies for the promotion of appropriate use of drugs.

Provision of health care in Third World countries

The salient features regarding the provision of health care in the Third World could be summarized as follows:

- People often do not have easy access to the services of a qualified medical practitioner.
- Even where there is access to a doctor within a range of 4–6 miles, as in Sri Lanka, the doctor:patient ratio is so poor that it is hardly possible to provide proper medical care.
- Harsh economic realities preclude the provision of adequate health care in terms of medical personnel, and supply of basic equipment, essential drugs and hospital beds.

- Traditional practitioners are responsible for the provision of health care to a large sector of the population.

The provision of health care in the Third World, even within the context of Health-2000, does not envisage that by the year 2000, 'doctors and nurses will provide medical care to everybody in the world for all their existing ailments'.[3] Recourse will therefore have to be made to the services of primary health care workers and traditional practitioners. It is also an established practice that pharmacists, those with formal training as well as those who have 'learned by doing', provide health care to patients in the Third World. With respect to indigenous practitioners, who provide a traditionally acceptable form of inexpensive health care generally based on the use of plants, which are largely non-toxic, it is ironic that most governments in Third World countries pay only lip service to the development and utilization of this system. One reason for the propagation of the allopathic system of medicine with its attendant high costs is that the western-trained doctors form a powerful lobby in the Third World. Furthermore, politicians prefer the high profile they achieve by constructing large western-type hospitals for their electorate. That these large hospitals —which are expensive to run, and which soon become under-staffed and then under-utilized— contribute only marginally, if at all, to the improvement of the health status of the community is still not realized in most Third World countries. The people, too, reflecting the colonial past when traditional systems of medicine were poorly regarded, tend to seek allopathic treatment—which they can ill afford—often more as a status symbol than through genuine belief in its efficacy and safety.

Registration and manufacturing practices in the Third World.

In order to ensure that the public is provided with safe and effective drugs, a well developed regulatory system for the control of the manufacture and marketing of drugs is imperative. Whilst such systems are generally available in industrialized countries, they are either non-existent or ineffective in Third World countries.

Formulary Committees exist in several Third World countries but their ability to exert any real controlling influence on drug usage is often nullified by government policies on drug imports. The situation is perhaps worst in relation to the approval of new drugs, which are often minor modifications of existing drugs, usually inessential and invariably costly. Though provision has been made for doctors to seek the approval of the Formulary Committee to use a new drug which they consider essential, applications for approval of new drugs are more often than not made by the manufacturers. Clearly, any information supplied by the manufacturers in support of such

an application is likely to be highly biased. To compound matters, the rule of thumb applied by Formulary Committees in the Third World is that any drug approved for use in an industrialized country is suitable for use in their own countries. No attempt is made to determine whether the drug meets a real medical need, or whether identical or similar drugs are already available locally, or whether the cost of the drug is justifiable within the context of the economic status of the country. Local clinical trials are not a requirement for approval.*

With registration practices such as these, it is no wonder that Third World countries are flooded with thousands of branded drugs. A few years ago, in India, for example, a government committee estimated that the country's basic drug requirements could be met by 116 generic drugs, which is less than 1 per cent of the over 15,000 brand drugs available in the country. In Brazil, a government agency which provides drugs free or at very low cost to the poorer sections of the population manages with 108 generic drugs of which only 52 have been classified as essential. However, over 14,000 branded drugs are available on the open market. (In this respect, the situation in most of the industrialized countries is not better; the number of branded drugs available in England is about 20,000, in West Germany 24,000 and in Italy 21,000.[4] One exception is Norway which is able to provide good health care with only about 1,000 branded drugs). A WHO Report presented to the World Health Assembly in 1978 stated the situation clearly: 'In recent years many medical products have been marketed with little concern for the differing health needs and priorities of different countries. Promotional activities of drug manufacturers have created a demand greater than the actual needs'. The availability of this plethora of drugs also partially accounts for drug costs which constitute 40–60 per cent of the total health care bill in Third World countries but only 10–20 per cent in the industrialized world.

As in the industrialized countries, many of the drugs available in the Third World do not serve a real medical need. Many are ineffective and several constitute irrational combinations. Furthermore, notwithstanding the statement that 'the pharmaceutical industry will ensure that all products it makes available for prescription purposes will be with full regard to the needs of public health',[5] unsafe and obsolete drugs which are no longer approved for use in industrialized countries are sold to the Third World.[6]

* However, local clinical trials are often sponsored by the manufacturers after full approval has been obtained, the results of such trials being used in promotional efforts to boost sales.

Drug manufacturing practice in the Third World, often by transnationals, is oriented more to profit-making than to meeting a country's health needs.

Apart from their concentration on profitable products such as vitamins, cough syrups and tonics rather than essential drugs, the drug companies make no effort to promote technology transfer or to encourage research for developing drugs for diseases specific to the Third World. In fact, it has been estimated that the pharmaceutical companies spend only one per cent of their research and development funds on Third World diseases.[7] Transnationals operating in the Third World also often obtain raw materials from their own subsidiary companies at prices above the prevailing market rate. This serves as the *modus operandi* for transferring profits out of Third World countries. As Dr. Halfdan Mahler, the Director-General of the WHO has stated, the whole picture is one of 'drug colonialism'.

Drug supply and marketing in the Third World

Drug supply in the Third World has to be considered in relation to the public (state) sector and the private (market) sector. Drugs are usually freely available in the private sector. In the state sector, which comes within the ambit of ministries of health, the supply situation is characterized both by recurrent shortages, even of essential drugs, and spoilage of some drugs, with a corresponding exhortation to the doctors to accelerate the prescription of drugs such as antibiotics, nearing their expiry dates—the implication being this is to be done, regardless of whether there is medical need. Drug shortage does not necessarily occur due to lack of funds. Quite often it is due to erroneous estimates of drug requirements, insufficient monitoring of drug usage at the various levels of the health care system, and disruptions in distribution (which is sometimes due to something as simple as lack of a vehicle). The drug supply system in the Third World is in fact an area in which health services research is urgently needed.

A major problem in the poorest Third World countries is the entry of sub-standard drugs. This is partly due to economics: orders are placed with the cheapest supplier. Another reason, however, is the absence of adequate quality control laboratory facilities. Provision of fully equipped quality control facilities with trained staff is particularly difficult for the smaller Third World countries.

The practices adopted for the retailing of drugs in Third World countries is a matter of great concern. So called 'pharmacies' are often manned by unqualified persons. The general public has access to most drugs without a prescription. The urban poor, especially, hesitate to visit the crowded out patients' departments of state hospitals, where treatment may be free but

the patient receives less than two minutes of the doctor's time. To visit a general practitioner (GP) could cost the equivalent of a day's wages or more. Consequently, they go to the nearest pharmacy where, after a cursory inquiry, the patient is given two to three drugs. The only information the patient receives is on how the drugs should be taken. In Third World countries it is not uncommon for pharmacies to give patients drugs such as chloramphenicol, phenylbutazone and prednisolone—without a prescription. To the patient who is given only a one- or two- day supply of drugs, this form of treatment is still acceptable because it is affordable.

The drug retail men ('drug representatives') employed by the drug manufacturers play a dominant role in the marketing of drugs in the Third World. It is common practice, indeed the rule, in these countries for general practitioners not only to examine and prescribe for the patient, but also to sell the drugs to the patient. The income of the doctor is therefore more dependent on his earnings from the sale of drugs than on consultation fees. It follows, therefore, that in these Third World countries where the number of general practitioners is nearly as great as in the state sector, they account for the sale of a large volume of drugs. The drug representatives of all manufacturers are not surprisingly constant visitors to GPs. The latter are first supplied with free 'samples', together with other gifts. Once doctors are convinced that they have a profitable line of drugs, i.e. where the margin of profit is significant, they place their order directly with the drug representative. Obviously, this type of marketing practice does not protect consumer interests.

It is common knowledge that in Third World countries, drug representatives also visit traditional practitioners. The younger generation of traditional practitioners are now widely engaged in the practice of incorporating 'western' drugs in their medicaments without an adequate knowledge of the indications, adverse effects or contra-indications. Some common drugs that are used include aspirin, paracetamol, prednisolone and antibiotics such as chloramphenicol and tetracycline. Since the earnings of the drug representative are partly based on commissions earned for the volume of drugs sold, they have no hesitation in resorting to unauthorized sales. The senior managerial level staff of drug companies are fully aware of this practice.

Marketing is not accompanied by the transmission of adequate information on the drugs to either the physician or to the consumer in Third World countries. Since access to journals is limited, the physician relies heavily on the literature supplied by the drug firms. The promotional efforts of drug companies include the usual 'wining and dining' for the medical profession

as a whole, and sponsorship of trips abroad for the more influential. The ethical standards of drug promotion in the Third World are generally much lower than in the industrialized countries.[8]

Post-marketing surveillance of new drugs especially, to study their long term efficacy and to establish their usefulness in a setting more realistic than that of the controlled conditions of Phase III clinical trials are virtually non-existent in the Third World. Formal mechanisms for the monitoring of adverse effects on a country-wide basis is yet another need for most Third World countries.

The doctor and patient in relation to drug usage in the Third World

The axiom that, 'Medicines should be prescribed only when they are essential',[9] is often overlooked by doctors in the Third World (much as their counterparts in the industrialized countries). In countries such as Sri Lanka, where there are restricted drug lists for use at the various levels of health care (peripheral, district, base/provincial, and teaching hospital and specialist institutions), the drugs used are on the whole rational although there is still a tendency for over-prescription of certain agents. However, in the private sector there is no control. The result is gross over-prescribing. 'Sometimes the physician uses the prescription as a substitute for counselling or to satisfy the expectations of the patients. Usually it is a mixture of the two, where both doctor and patient have come to see a prescription as an essential outcome of the visit. The most common examples are antibiotics for the common cold, sedatives for mild insomnia and vitamins for nearly everything'.[10]

Often the choice of drugs by doctors in Third World countries is inappropriate, because they have no access to balanced and complete information. Doctors tend to accept uncritically the promotional claims of drug manufacturers, who usually emphasize the advantages and soft pedal on the disadvantages of their products.

Attempts to curtail the number of drugs available for prescription in a country tend to meet resistance from doctors under the guise of 'professional freedom'. Frequently such resistance really reflects the influence of the lobbying power of drug companies.

The strategy of Health-2000 envisages that the people will become full partners both in the decision-making process as well as in the provision of health care. However, in the matter of prescription of drugs, the decision-making is usually done solely by the doctor. The patient is given little or no information, even on such basic issues as the type of drug used, how it

could help the patients, possible adverse effects and precautions to be observed.

In the Third World doctors often defend themselves for such non-communication on the basis that the patient is illiterate. This overlooks the fact that they fail to give information even to literate patients, and that even illiterate patients are quite capable of comprehending basic facts if presented in simple language.*

Some recommendations with particular reference to the Third World countries

All member countries of the WHO are committed to the strategy of Health for All by the Year 2000 through the primary health care approach. In relation to drugs, this strategy envisages that national policies and regulations will be formulated to control the import, local production, sale and distribution of drugs and biological agents. However, the problem is too formidable to be tackled by individual nations. Clearly, an internationally acceptable harmonization of regulations to cover the major aspects of drug manufacture, distribution and usage is necessary.

In the field of drug manufacture many of the Third World countries are not in a position to regulate the activities of transnational drug corporations. They could, however, make such progress if a firm decision is taken—perhaps by a resolution at the World Health Assembly—to restrict the manufacture and import of drugs to 250 or so essential drugs identified by the WHO for the purpose of delivering primary health care. It is likely that the transnational drug companies would refuse to comply with a request that they restrict the manufacture of drugs in the Third World to those on the essential list. In such an event the Third World countries could, under the auspices of UN organizations such as UNCTAD, UNIDO and UNICEF, establish regional drug manufacturing organizations to cater to the needs of the member countries. For example, in the South-East Asian region, India could cater to both domestic and regional needs for a selected list of drugs. Sri Lanka, on the other hand, which does not have a large enough domestic market, could establish a viable drug manufacturing industry if it was to cater to the needs of the entire South-East Asian region for a few essential drugs. Apart from developing national industrial capacity, such a scheme would also promote Technical Cooperation among Developing Countries (TCDC).

* Though inserts are common in the unit-of-use packages used in the West, they are not always regarded as a means of conveying information to the patient. Furthermore, they are usually neither written in simple language nor comprehensive.

Quality control of drugs is another field in which regional cooperation could ensure that the drugs imported by Third Wourld countries meet appropriate standards. It was mentioned earlier that the establishment of national fully equipped and staffed Quality Control Laboratories is not always feasible, but they could be established on the basis that a national laboratory in one country serves as a regional laboratory for a limited specified number of drugs. A laboratory in another country in the same region could cater for another group of drugs. In this manner, quality control for all drugs would be ensured on a regional basis.

Recurrent shortages as well as spoilage of drugs is a common phenomenon in the Third World. This problem could be solved if the drug supply and distribution systems are re-organized. This re-organization should be based on the morbidity and drug utilization patterns in each country. Administrative solutions have not proved to be the answer to the problem. The WHO could play a major role if, with the concurrence of national governments, commissioned health services research projects were initiated to find the real solutions.

The expectations of Health-2000 will not be met in the Third World if the delivery of primary health care is assumed to come from fully qualified doctors. The services of assistant medical practitioners (or medical assistants), pharmacists, traditional practitioners and primary health care workers will have to be mobilized for this purpose. Handbooks or manuals containing balanced and complete information about the drugs they are permitted to use should be made available to all medical and para-medical personnel. A limit on the number of drugs permitted to be used by each level of worker would improve prescribing habits and also reduce costs. The latter could also be partially achieved by including the cost of the drugs in the drug manuals. Since the morbidity patterns of countries vary, these manuals could be prepared at the regional level. Here again, the Regional Offices of the WHO could play an active role.

Governments in the Third World should implement plans to utilize traditional practitioners for the delivery of primary health care. A specified number of activities in which these practitioners could play a useful role should be identified and additional training provided.

The sale of drugs should be strictly controlled by government legislation. This would necessitate the training of additional pharmacists in Third World countries. Training centres should be set up with the assistance of the WHO, UNESCO and UNICEF. On the basis that pharmacists have a role

to play in primary health care, their training should not be confined to the traditional curriculum but should include basic training in the treatment of minor illness and in patient counselling. The emphasis should be on clinical pharmacy rather than on pharmaceutics.

With regard to the consumer the important areas that need attention in the Third World are drug compliance, drug information and health education. The WHO, in consultation with its member states, should promote health services research on drug utilization and compliance. Governments should be encouraged by the WHO to pass legislation to ensure that drug inserts are made mandatory and that these give clear and complete information in the national languages.*

Health education on drugs should be intensified in a manner that would reduce drug usage, and improve patient compliance. The major target groups for health education in the Third World should be schoolchildren, youth and women. This would ensure that at least in the future, the people themselves could become full partners in the health care system.

Notes

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* Currently, drug inserts in many countries are in English and an assortment of other languages, but rarely in the national language.

Towards a Healthy Use of Pharmaceuticals

By Joan-Ramon Laporte

'Many medicines are useless; their therapeutic efficacy has never been demonstrated.' . . . 'Drugs are often used as substitute solutions to difficult problems, which have social roots and cannot be relieved or solved with medicines.' . . . 'The use of drugs is a field where manufacturers exert pressure to ensure a constant expansion of the market, rather than trying to fulfil a real need.' These are some of the provocative statements made by Joan-Ramon Laporte in this article, in which he concentrates on four important factors determining the kind and the quantity of medicines used in a community, namely drug promotion, the disease pattern, the pharmaceutical supply and the structure and priorities of the health system.

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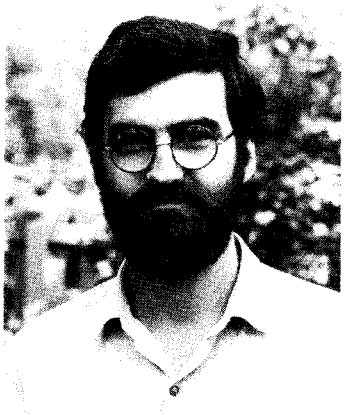

The prescription written by a doctor at the end of a patient's visit is, in a very general sense, the summary of his attitude and expectations with regard to the course of the disease and the role that drugs can play in its treatment. The prescription reflects the availability of drugs, the information that has been disseminated and, last but not least, the conditions—time, diagnostic facilities, prevalent pathologies—in which medical care is developed. As drugs are used almost everywhere in the various medical disciplines, they are the most direct point of contact between health structures and their users. In fact, the study of drug consumption—quantitative and qualitative—provides an insight into the nature of the health system itself.

The social history of a new drug passes through different stages, starting with it being designed, synthesized, and studied in simple laboratory models and in animals. It is studied in human beings under various circumstances: the clinical trials. The producers must then apply for the drug to be registered in the country or countries where it is to be marketed. If health authorities approve it (because of higher efficacy or lower risk, because it is less costly or causes less discomfort, or because of political and economic pressures) the drug is then produced or imported, and distributed.

Next, the drug is prescribed, generally by a doctor. This should be an iterative process, directly linked to diagnostic and prognostic considerations. Unfortunately, this is rarely the case, and it has been said that many

prescriptions are not 'rational drug prescriptions' but 'spinal reflex prescriptions'. Nevertheless, the better the working conditions are (time, training, diagnostic facilities, etc.), the more rational the prescription is likely to be. In addition, the prescriber will obviously be influenced by information received about the medicine.

Finally, the drug is used—in the great majority of cases—by non-hospitalized patients who themselves decide when, how and in what quantity to take them, and how to select from all the remedies offered by the doctor, by different non-coordinated health workers, or by their neighbours. The cultural perception of a drug by the user is therefore a critical determinant of its ultimate effect as a treatment. Needless to say, this cultural perception not only depends on the traditional indices of the 'culture' of a given country (percentage of illiteracy, proportion of children at school, etc.), but also on how health is planned and oriented, and on the participation of the community in health strategies.

The following questions should be asked (and answered) when a new drug is under consideration for registration or for inclusion in a drug list or a drug formulary:

- Is it potentially more/less effective than other drugs already on the market? Is it more/less safe? Is there a need for the new drug? What is the comparative cost?
- How will it be used?
- What information will be given to the prescriber?

In addressing these questions, a number of points should be taken into consideration:

1. Many medicines are useless: their therapeutic efficacy has never been demonstrated. Others—mostly combinations of two or more active ingredients—are unacceptable (i.e. their risks outweigh their benefits in any circumstances), and should be removed from the market. The drugs that are needed are often unavailable whereas useless and unacceptable drugs can be easily prescribed and dispensed. The proportion of 'useless' and 'unacceptable' drugs obviously varies considerably from one country to another. However, a recent study carried out in Spain, using the criteria suggested in Table 1, revealed that only 54.2 per cent of all drugs consumed in 1980 had an acceptable potential therapeutic value; 22 per cent of the consumed drugs had no value at all, and more than 20 per cent had an 'unacceptable' value. The figures may be even worse in some Third World countries where effective drug control has not been im-

Table 1 A possible qualitative classification of medicines, according to their potential therapeutic value.

'High value'	Products with no backing from controlled clinical trials, which are justified by their immediate and obvious effect (e.g. insulin for acute juvenile diabetes, vitamin B 12 for pernicious anaemia, penicillin for certain infections), and products for which controlled clinical trials exist, supporting their clinical efficacy; the estimation term 'high' does not depend on the therapeutic index of each product (that is, on the ratio between therapeutic and toxic doses, or on the incidence of side effects), and is based only upon published data on controlled clinical efficacy. Examples: ampicillin, 500 mg capsules; chloramphenicol, 250 mg capsules; ASA, 500 mg tablets.
'Relative value'	Pharmaceutical specialities that are irrational from a pharmacological and therapeutic point of view, because, together with a highly valid active principle, they contain one or more chemical entities with a rather doubtful therapeutic efficacy (vitamins, coenzymes, and so on), the addition of which is not supported by any published clinical data obtained by an adequately controlled clinical trial. Examples: diazepam + vitamin B6; ampicillin + 'mucolytic'; antacid + pancreatic enzymes.
'Doubtful value'	Drugs which are currently considered controversial and about whose long-term efficacy there is open discussion in international literature: this group includes chiefly drugs used in the treatment of chronic conditions, such as oral antidiabetics and antiplatelet drugs.
'No value'	Those products for which no adequate controlled clinical trials exist, supporting their clinical efficacy; this group also includes some products with 'high value' active ingredients formulated in an insufficient dose, even for paediatric use. Examples: coenzymes (ATP, acetyl-CoA, etc); 'cerebral vasodilators'.
'Unacceptable value'	Pharmaceutical specialities which, because of their composition, have a clearly unfavourable benefit/risk ratio under all circumstances. Examples: chloramphenicol + phenothiazine + corticosteroid + sulphonamide; cyproheptadine + isoniazid + corticosteroid.

Source: Laporte et al., *British Journal of Clinical Pharmacology*, 1983, No. 16, pp. 301-304.

plemented at the various levels of the health system (public and private, primary health care and hospitals, etc.).

2. Drugs are often used as substitute solutions to difficult problems, which have social roots and cannot be relieved or solved with medicines.

3. The more potent the drugs available are, the higher their iatrogenic potential. Thus, there is a risk of drugs being used in conditions that are not controlled: they may be given to the wrong patient, at a wrong (higher or lower) dose, for the wrong length of time, or prescribed as a way of avoiding tackling more complex sociological or psychological problems. A recent survey on the prescription of antibiotics carried out

in the outpatient clinics of the Social Security System in Barcelona showed that the prescribed dose was correct only in 64 per cent of the cases; the length of the recommended treatment was only correct in 24 per cent; only 37 out of 378 patients to whom antibiotics were prescribed received any oral or written information on the nature of the disease they had; and only 24 per cent of the patients were asked for any information concerning previous use of drugs for past diseases or for the disease they were presently suffering from.[1] This kind of data and the points made above suggest that a very low proportion (10–20 per cent) of all the drugs used in the Spanish health system are really needed.

4. The use of drugs is a field where manufacturers exert pressure to ensure a constant expansion of the market, rather than trying to fulfil a real need. A high proportion of the 'new drugs' are not real therapeutic innovations (the so-called 'me-too drugs'). In countries where governmental control is less stringent—either because of lack of trained personnel or political and economic circumstances, or both—information on drugs is lacking. The vacuum is filled by drug promotion, which is inevitably biased.

The kind and the quantity of medicines used in a community are determined by a variety of factors. Some of these factors have been clearly identified: the pharmaceutical supply, the structure and priorities of the health system, and the promotion of and information about drugs. Other factors are suggested as influencing drug consumption but have not been definitely proved to be determinants of drug consumption patterns within the community. These include: the provision or lack of pharmacology education for physicians and other health workers, the attitudes of the users and the pressures on them, and the extent of epidemiology within the community. I will refer to just four of these determinants: drug promotion, the disease pattern, the pharmaceutical supply, and the structure and priorities of the health system.

Drug promotion

Drug promotion is an obvious determinant of irrational and unhealthy use of drugs. The pharmaceutical industry spends between 15 and 25 per cent of its total budget in promotional activities. This proportion is certainly higher in Third World countries. I have seen certain drug firms' promotional materials for Third World countries which in my opinion were evidence of criminality. Far from having any educational value much of this professional 'information' material tends to present the firm's product as a miracle cure for any complaint, to exaggerate its benefits and play down the inherent risks. It is worth pointing out that the educational value and the

objectivity of drug promotion (i.e. of drug information from the manufacturers) varies widely from one country to another. It is not unusual that the promotional literature used in the drug's country of origin is much more objective than that used in foreign countries, and particularly in the Third World.

The disease pattern

It is generally assumed that the prescription of a medicine has some relationship with the disease the patient is suffering from, or at least with the identified symptoms. While this may be true for a proportion of the prescriptions, the evidence is less convincing when examined from an epidemiological viewpoint. The following examples may serve to illustrate this:

- International drug utilization studies carried out in certain European countries, dealing with hypertension and diabetes, suggest that the consumption of antihypertensive drugs and antidiabetics does not correlate with the prevalence of these diseases.[2]
- The wide international variation in *per capita* drug expenditure is particularly interesting if one looks at the sales of certain classes of drugs which are considered of unproven efficacy: for example, while 'cerebral vasodilators and reactivators' account for 4-6 per cent of the drug budget in Spain and in Italy, they are not even marketed in other European countries.[3]

The pharmaceutical supply

The number of marketed medicines in Western Europe varies widely from one country to another. According to a recent study by Dukes,[4] there are approximately 15,000 pharmaceutical specialities in the Federal Republic of Germany and in the United Kingdom; 14,750 in Spain; 13,700 in Italy; 7,900 in Belgium; 7,800 in France; 7,400 in Ireland; 3,700 in Finland; 3,400 in the Netherlands; 2,700 in Sweden; 1,870 in Norway; etc. It could be argued that these differences arise from the varying structures of the trademark markets, and that the number of active principles does not vary so much. However, a recent study carried out in the Division of Clinical Pharmacology, Universitat Autònoma de Barcelona, has shown that if a group of anxiolytic/hypnotic drugs, the benzodiazepines, is considered, while in Germany there were 22 such compounds in 1982 and in France 15, in Finland (1980) the number was 9, as it was in Norway (1980) and the USA (1982).[5] Differences of this kind have also been documented for other classes of drugs. There are therefore wide variations in the criteria applied to the registration of drugs.

'It has never been proven that an infinite number of drugs provides any greater benefits for public health than a more limited number of products.

On the contrary, the existence of a large number of drugs may result in confusion at all levels of the therapeutic chain, and represent a waste of manpower and money.' This concept, expressed by Lunde in 1979,[6] is still the cornerstone of any healthy drug policy.

Exceedingly high numbers of drugs can produce confusion at the registration level, causing insufficient control at the port of entry, more difficult quality control, and more difficult assessment of needs at each level of the health system. It also produces confusion at the distribution level: it aggravates the inequalities in distribution (i.e. between urban and rural areas), it reduces compliance with existing regulations regarding sale and distribution of prescription medicines, and it may favour more frequent periodic shortages at the central and peripheral stores. The prescriber is also confused: it has been repeatedly pointed out that it is better to use and to be knowledgeable about a limited number of drugs, than to use a greater number of medicines, with a more limited and diffuse knowledge about them. The use of a limited number of well known drugs can lead to improved follow-up of their potential benefits and adverse effects among those patients treated with them. In fact, in countries where there are no periodic shortages (i.e. industrialized countries) each doctor tends to use a limited number of drugs.

Last but not least, high numbers of drugs produce confusion among the users, particularly when the generic names are not used, and the same drug may have more than one trade name. In a community survey carried out some time ago in Barcelona, we identified an elderly man who was taking three different preparations of phenylbutazone (used to treat arthritis) every day, in the form of products bearing three different trade names; when we asked for the reasons he was taking each medicine, he told us that he was taking the third one because he had a stomach-ache!

The structure and priorities of the health system

In a broad sense, it seems clear that the economic and human resources allocated to health systems are the main determinants of drug consumption. It might be assumed that the greater the resources allocated, the greater the drug consumption. But this is not necessarily true. The Nordic countries spend between 7 and 9 per cent of their health budgets on drugs. This proportion is higher in other European countries: around 19 per cent in Spain and in Italy, and 23 per cent in Switzerland. In small African countries it can be as high as 60 per cent. In these countries drugs may be a (not very successful) substitute for other forms of health care and health promotion.

Other factors undoubtedly influence drug consumption. The ratio of public

to private sector spending and of primary health care to specialist, hospital-based care, and the existence or absence of specific disease-oriented programmes, are all important determinants of the consumption of medicines. The following is a summary of the major specific issues:

- Is there an essential drugs programme? Does it reach all sectors of society or only some? Is it only for primary care or is it more extended? Does it include the private sector? What experiences and obstacles are encountered in applying the programme?
- What exists in the way of drug legislation, drug registration rules, and product control?
- How is the drug supply organized?
- What is the general educational level of all the health workers? Are there specific training programmes in drug evaluation for health officers working at the central level? Is there any local university department participating in education, training and research activities carried out in accordance with the general drug policy?
- Are health workers provided with an annotated formulary or guide which helps them decide on appropriate therapeutic strategies and which gives advice on substitutes in the case of shortage?

The answers to these questions give a clue as to where the determinants of a healthy or an unhealthy use of drugs lie. They are also the main points to be considered if a healthy drug policy is to be developed.

The essential drug programme and the healthy use of drugs

Drug utilization, as defined by the WHO, involves three elements:

1. The drug supply, which includes lists of essential drugs, registration policy, importation and distribution.

2. The use of the drug in the health system: what is the regular pattern which leads to the prescription of a given medicine? How has the diagnosis been reached? On what grounds have the chosen drug and dosage and way of administering it been selected? Has the patient been informed about his or her disease and its treatment? Has any follow-up been done?

3. The use of the drug beyond the health system: how is the drug perceived by the patient, his or her family, and their community? What have been the adverse effects?

A healthy use of drugs is much more than an essential drug programme. A healthy drug supply does not necessarily guarantee a healthy use of drugs.

Not only should a list of essential drugs be compiled by each country, but also a *list of essential steps* which must be followed if a country is to finish with its 'drug dependence'. These should be training in clinical pharmacology and in drug evaluation, control of the pharmaceutical industry's promotional activities, education campaigns among health workers and among the people, provision of an annotated formulary, the development of a 'national' drug epidemiology and the setting up of networks for drug evaluation.[7]

Notes

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7. For some of the ideas presented in this paper, I am indebted to Drs P.K.M. Lunde and I. Baksaas (Oslo) and to Dr G. Tognoni (Milan).

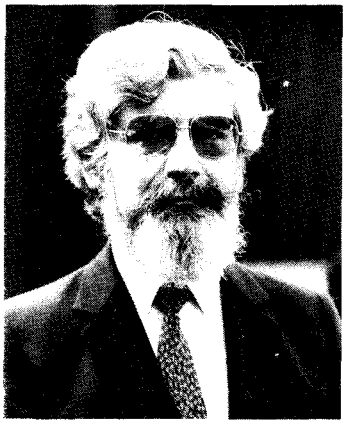
In Search of Pharmaceutical Health

The Case of Thailand

By Claudio Sepulveda-Alvarez

'Although this is a society which allocates the monetary resources required to offset, through drug therapy, all prevailing ailments in the country', writes Claudio Sepulveda-Alvarez in this case study from Thailand, 'the structure of the consumption is biased. Over-consumption of unnecessary products by urban elites leaves the poor majority underserved and bearing very high levels of morbidity for which no treatment is accessible, in spite of the availability of drugs in the country as a whole.' And while there has been a ten-fold increase of the pharmaceutical market during the period 1969-81, the prevalent pathology seems to go largely untreated. Claudio Sepulveda-Alvarez also draws attention to the exceedingly high 'mark-up' levels which are always more than 250 per cent over the estimated production costs. There is ample room for savings, he remarks, not least through more self-reliant production units.

Claudio Sepulveda-Alvarez, MD and MPH, taught epidemiology and health planning in Chile and Peru until 1974, when he joined the WHO and started to work in Asia and the Pacific. In January 1985 he took up the post of Senior Regional Planning Officer at the UNICEF Office in Bangkok. The views expressed in his paper are personal.



Pharmaceuticals and the restoration of health

The central question to be addressed when discussing the adequacy and relevance of pharmaceutical action in a country, or in the world generally, is what are the objectives of such pharmaceutical action. It is a premise of this paper that the central and overwhelmingly pre-eminent objective is to restore the health of suffering and sick people. Other objectives may be entertained, for example making national/individual profits, or developing the industrial sector, *provided* that they do not endanger the health restoration function or cause social problems by preventing other human needs being met because of the high drug costs involved.

In the restoration of health, pharmaceuticals are not the only alternative. Other forms of therapy and, above all, preventive measures should be utilized to the full. Drug therapy should not always be considered preferable to prevention or traditional therapies such as acupuncture or ayurveda. Whenever they are adequate, alternatives—including physiotherapy, psychotherapy or balneotherapy—may also be used.

The following case study draws on research in one Third World country, Thailand.

Pharmaceutical trends in Thailand

There is consensus among practitioners worldwide that health services in Third World countries have followed an urban-centred, hospital-based pattern. The consumption of pharmaceuticals has, therefore, followed a similar pattern. Thus, in 1979, the urban hospitals of Thailand,* both public and private, accounted for 30 per cent of the total drug consumption, or an estimated US $85 million. The urban population within reach was less than 15 per cent of the total population; the percentage of the population actually covered by the hospital services is unknown, although probably no more than 7-8 per cent. This asymmetry can also be seen in the consumption of drugs purchased from drugstores, which at the time represented 60 per cent of all self-medication, but which was heavily concentrated in Bangkok and other urban centres.

The primary health care (PHC) policies adopted at Alma Ata marked a change in this pattern and a greater awareness of the problems involved, which was expressed in the establishment of a special PHC unit in 1981 and in a number of pharmaceutical studies undertaken at the time. Thus, in 1982, the urban hospitals' share of drug consumption had slightly decreased (instead of continuing to rise), to about US $80 million. Instead, local level district hospitals, health centres and local offices of the Ministry of Public Health had increased their participation from 3.4 per cent of the 1979 total consumption to about 6.7 per cent of the total 1982 market. Manufacturers' prices in both years were roughly equivalent but had gone up from Baht 9,000 million in 1979 to about Baht 13,000 million in 1982 at retail level, representing more than US $600 million, or US $13 on a per capita basis.

The more relevant variables in this 'pharmaceutical explosion' are summarized in the following pages.

Pharmaceutical requirements

The monetary equivalent of these drugs, calculated on the basis of existing market prices in Thailand, would be sufficient to satisfy *all* or *nearly all* national pharmaceutical requirements.

* Thailand is a Buddhist country, ruled by a constitutional monarchy since 1932. The current Chakri Dynasty has been in power for over 200 years. As of 1982, the country had 48.5 million people, of which 78 per cent lived in rural areas, in roughly 60,000 villages. The per capita income that year was US $748, with 19 per cent of the GNP allotted to the Government (an exceptionally high proportion; usually it is below 15 per cent) of which about 1 per cent or US $7.3 p.c. was devoted to public expenditure in health. The population growth was estimated to be 2 per cent while economic growth stood above 6 per cent. The adjusted infant mortality rate (IMR) was about 56 per thousand while literacy was about 84 per cent for both males and females. Total enrolment in primary school was above 90 per cent.

Table 1 Prevalent pathology, estimated drug requirements and actual consumption (12 most frequent entries) Thailand, 1976-1981[1]

Diseases/symptoms	Million cases	Accumulated frequency (percentage)[2]	Drugs	Estimated requirements 1976 Weight ('000 kg)	Estimated requirements 1976 Value (US $m)	Estimates of actual consumption (US $m) 1976	Estimates of actual consumption (US $m) 1981[3]
1. Upper Respiratory Infections	29.4	25.8	Penicillin G	–[4]	113.0	*	*
2. Fever	9.0	34.5	Para-amino-salicylicacid (PAS)	6,565	109.4	0.3	*
3. Diarrhoea	6.7	41.0	Isoniacid (INH)	198	5.8	–	0.9
4. Headache	6.6	47.4	Aspirin	144	2.1	0.3	7.0
5. Intestinal infection	3.9	51.2	Streptomycin	110	17.3	0.7	2.0
6. Nutritional deficiency	3.8	54.9	Ampicillin	42	16.5	9.1	25.0
7. Dental diseases	2.7	57.5	Chloroquine	30	3.0	0.3	*
8. Immunizable diseases	2.6	60.0	Methyldopa	12	2.9	0.3	0.0
9. Backache	2.5	62.4	Paracetamol	9	0.2	7.2	68.0
10. Parasitosis	2.3	64.7	Ferrous sulfate	8	2.9	2.4	*
11. Neurological diseases	1.5	66.1	Ferrous gluconate	8	0.8		
12. Tuberculosis	1.3	67.3	Quinine	7	2.3	0.5	2.6

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2. of total morbidity
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4. Original figures calculated in millions of international units.
* unknown
Note: No correspondence of diseases/symptoms to drug requirements is intended on a line-to-line basis.

'Requirements' of drugs are here defined as the physical weight/volume of active ingredients required to:

1. Complete a full course of disease treatment, utilizing a standard prescription determined by an essential drug, an appropriate dosage, a daily frequency, and a total duration of treatment adequate to ensure its efficacy.
2. Treat all cases of disease in a year, for all types of pathology, as revealed by crude morbidity rates calculated to adjust, usually upwards, the registered morbidity in the country.

However, an in-depth study carried out in 1979[1] showed that in spite of a monetary equivalent roughly sufficient to pay for most drugs' requirement, the actual physical consumption of anti-tuberculosis drugs, chloroquine, quinine, ampicillin, aspirin, chlorpheniramine, penicillin G, etc., were all below required levels, usually below 15 per cent of the requirement, although ampicillin and chlorpheniramine were consumed at 55 per cent and 38 per cent of their estimated respective requirements. Evidently, this meant that overconsumption, probably of more expensive items, was taking place elsewhere. This was found to be the case with substances such as paracetamol and other analgesics, diuretics, tranquillizers, hormones and antibiotics, which were widely—and possibly wildly—overconsumed.

Table 2 Drug consumption estimates: Thailand 1969 and 1976 ('000 US $ at wholesale value) and 1981 (retail prices)

Pharmacological class	1969[1]	1976[2]	Annual growth 1969-76[2] (percentage)	1981[3]
Analgesics	8,560	16,500	13	75,000[a]
Anesthetics	395	3,300	105	–
Psychotherapeutics	625	8,900	189	–
Sedatives, hypnotics	575	3,000	60	24,000[b]
Gastrointestinal drugs	4,625	6,900	7	–
Hormones	5,430	36,700	82	19,000[c]
Antihistamines	1,000	4,800	54	–
Respiratory drugs	4,550	2,800	-5	–
Topical drugs	4,900	4,300	-2	–
Antihemorroidals	425	2,500	70	–
Antimicrobials	18,580	75,000	43	–
Antiseptics	3,330	5,171	8	–
Antibiotics	10,025	59,421	70	32,000[d]
Sulfonamides	750	823	1	400[e]
Anti-tuberculosis	1,575	3,966	22	2,800[f]
Antimalaria	525	1,900	7	2,600[g]
Others	1,625	3,900	–	2,000[h]
Antihelmintics	750	5,000	81	–
Cardiovasculars	1,440	7,400	59	–
Diuretics	170	2,000	154	150[i]
Vitamins+nutrients	9,275	16,400	11	–
Others	2,250	40,300	–	–
Total (wholesale)	62,820	219,300	36	–
(retail)	–	373,200	–	600,000*

1. Stanford Research Institute, Country Report 12, Thailand, pp. 44-45, 1972
2. Hutangura P., Sepulveda C., 1979, op.cit.
3. Sepulveda C., Kaosard M., Dhanatrakul T., 1984, op cit. (unpublished) The information gathered in 1981 refers to only 18 drugs, at *retail* prices, as follows: a) Aspirin, Paracetamol only; b) Meprobamate Reserpine, Diazepam only; (c) Dexametasone only; (d) Ampicillin, Penicillin V, Metronidazole only; (e) Sulphadimidine only; (f) Isoniacid, streptomycin only; (g) Piperazine only; (h) Digoxin, Methyldopa only; and (i) Furosemide only.

**Note:* 1969 and 1976 are wholesale prices, that is ex-factory costs plus producers mark-up; 1981 is retail price, which includes distributors (middle men) and retailers mark-up. These have not been studied separately.

So although this is a society which allocates the monetary resources required to offset, through drug therapy, all prevailing ailments in the country, the *structure* of the consumption is biased. Overconsumption of unnecessary products by urban elites leaves the poor majority underserved and bearing very high levels of morbidity for which no treatment is accessible, in spite of the availability of drugs in the country as a whole.

The estimation of specific requirements is bound to change, according to changing treatment preferences and actual scientific progress in the assess-

Table 3 Estimated consumption[1] of selected pharmaceuticals, Thailand 1981

	Unit dose (mg.)	No. of market presentations	Intake (grs) per person and year	Total consumption Volume (kg.)	Total consumption Value ('000 US $)
Ampicillin	250	60	1.1	54,109	25,000
Aspirin	300	4	14.3	730,085	7,000
Dexamethasone	0.5	25	3.4 mg.	174	18,950
Diazepam	2.0	32	30.0 mg.	1,485	23,744
Isoniacid	100	5	0.4	19,300	830
Paracetamol	500	38	7.0	358,750	67,850
Quinine	300	6	0.15	7,295	2,600
Reserpine	0.25	4	0.05 mg.	2.2	39
Streptomycin	1,000	6	0.25	12,065	1,950
Sulfadimidine	500	1	0.35	16,800	403

1. On the basis of imports of active principles.
Source: Sepulveda, C., Kaosard, M., Dhanatrakul, T., 'Price Differentials of 18 Selected Pharmaceutical Products in Thailand', ESCAP, 1984, unpublished mimeograph.

ment of the drugs' efficacy. Nonetheless, the figures presented in Table 1 give an overview of the way in which requirements and actual consumption behave somewhat independently of each other. It is the duty of public health specialists to advocate the closing of the gap reflected by the wide asymmetry that currently exists.

Consumption and the health restoration function

The growth of drug therapy in Thailand has not been fully documented. Table 2 shows, however, that between 1969-76 the average annual growth in consumption at wholesale prices was 36 per cent; between 1976-81 the rate has been slightly higher. In other words, 1969-81, a period of 12 years, has seen a ten-fold increase of the pharmaceutical market. The highest increases seem to affect pharmaceutical classes such as psychotherapeutics, sedatives and hypnotics, diurectics, hormones and certain antibiotics. These results do not seem to tally with the prevalent pathology of the country, reinforcing the perception that the prevalent pathology goes largely untreated while consumption expands on the basis of mostly unwarranted demands by the elites of the country. A host of factors contribute to this situation, among which are poly-prescriptions by medical doctors, poly-formula products, lowering of the threshold to accept drug therapy, self-medication and unrestricted advertising.

Thailand still has more than 20,000 finished forms on the market, a much greater number than are available in European countries. A sample of selected per capita consumption figures can be seen in Table 3.

Table 4 Retail price differentials of selected pharmaceuticals, Thailand, 1981.

	Unit (mg.)	Price range (US cents)	Average yearly per capita expenditure (US cents)	Companies marketing the most expensive drug
Ampicillin	250	4 –70	50	Bristol
Aspirin	300	0.2– 1	14	Dumex
Dexamethasone	0.5	0.7– 1	37	Organon
Diazepam	2.0	0.2– 1	50	Roche
Isoniazid	100	0.2– 0.5	2	Daichii
Paracetamol	500	0.6– 4	140	Wellcome
Quinine	300	7 –18	5	Havis
Reserpine	0.25	0.2–55	0.1	Ciba
Streptomycin	1,000	10 –24	4	Dumex

Source: Sepulveda, C., Kaosard, M., Dhanatrakul, T., 'Price Differentials of 18 Selected Pharmaceutical Products in Thailand', ESCAP, 1984, unpublished mimeograph.

Marketing and retail prices

The multiplicity of brands and finished forms on the Thai market is also reflected in a wide price disparity. The share each product may have in the corresponding submarket is, however, unknown. The range of prices for standard equivalent dosages* for selected products is presented in Table 4.

It is clear from the above that advertising causes consumers to greatly prefer 'brand names' registered by transnational corporations. These are usually the more expensive options. In other words, brand names secure a psychologically 'captive' market, which leads to a costlier way of satisfying the need for drug therapy. Yet all brands on the market have been duly cleared by the relevant authorities.

It is also likely that the fragmented way in which the drug-specific submarkets function increases production costs.

The figures for yearly per capita expenditure for selected products show that the highest preferences are, apparently, for paracetamol, ampicillin, diazepam and dexamethasone. Collectively, they represent US $3 per

* It is necessary to introduce the concept of 'standard equivalent dosages' because the multiplicity of brands and presentations, and varying amounts of active ingredients, makes it impossible to compare products one-to-one. The rationale of this concept, is that, from a therapeutic point of view, what is important is a given blood concentration level of the drug.

Table 5 The value of formulation production at post-factory prices in Thailand

Year	Total value (Baht million)	GPO share (Baht million)	GPO share Percentage
1979	6,500	250	3.8
1980	7,800	300	3,9
1981	7,900	350	4,4
1982	6,600	406	6,2
1984	7,000	527	7.5

capita which, in turn, equates to 25-30 per cent of total pharmaceutical expenditure. Expenditure on these four drugs alone is also equivalent to 50 per cent of Thailand's total public health expenditure which, in 1981, was US $5.7 per capita.

Production of pharmaceuticals

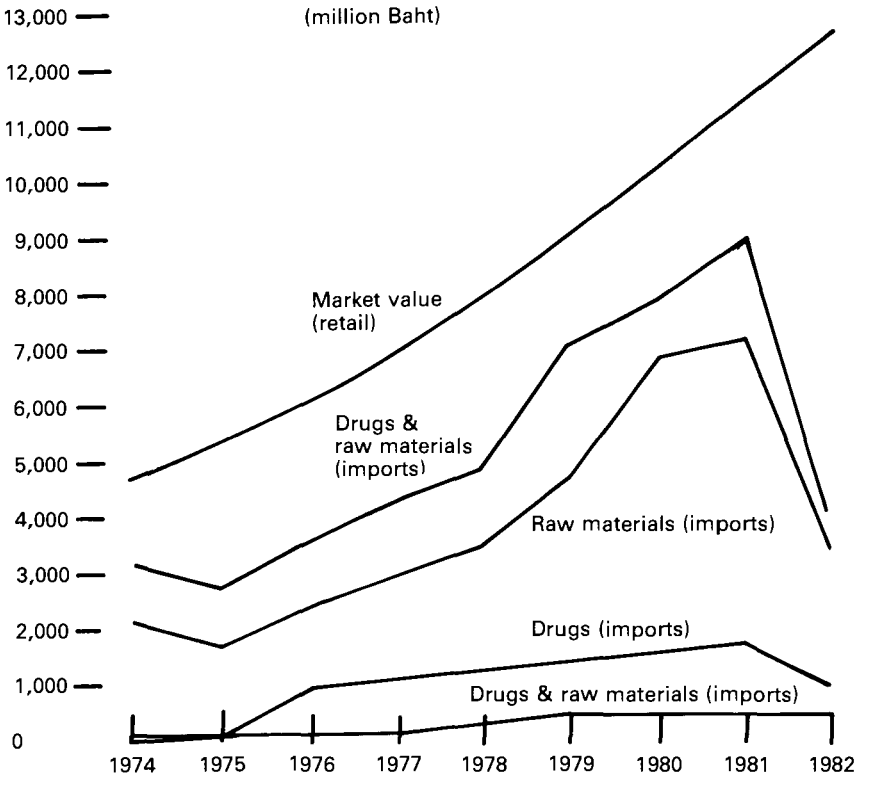
In drug production, a careful distinction should be made between formulation and manufacturing. *Formulation* refers to the production of finished forms and is a labour-intensive, relatively unsophisticated technology which, however, varies with the pharmaceutical form considered, e.g. tablets or ampoules. Many countries considered self-sufficient in pharmaceutical production are so in formulation terms only. We have called this type of situation 'market self-reliance'. In Thailand, this figure was 71 per cent in 1976, measured against the supply in the market.[2] However, if measured against drug requirements, as described above, the self-reliance (called 'technical') dropped to 55 per cent, that is, if all requirements—not just demand—are to be met, the formulation capability in existence is far lower.

Manufacturing drugs refers to the process of producing active principles; this industry is just being developed in Thailand, although some manufacturing of chloramphenicol may be more than ten years old. No analysis of this type of production has yet been made for the country.

The value of formulation production at post-factory prices in Thailand has been evolving as shown in Table 5, where the state production share is represented by the Government Pharmaceutical Organization (GPO).

These figures show a sharp reduction between 1981 and 1982 which was not however reflected in the retail value of sales for that year (see Figure 1), showing that through higher mark-ups, depletion of inventories, etc., the end-market was kept growing steadily to reach Baht 13,000 million in 1982, practically twice as much as the ex-factory prices.[3]

Figure 1 Consumption, imports and exports of pharmaceuticals, Thailand, 1974-1982



Source: Food and Drug Administration Office, Ministry of Public Health; quoted from 'The influence of the Multinationals on the Thai Pharmaceutical Industry', *Bangkok Bank Monthly Review,* April 1983, p. 148.

It is difficult to estimate what part of the mark-up actually represents profits, once overheads are deducted. Costs of production vary with the location, manpower policies, types of dosage forms, etc. Usually the industry is unwilling to share any data on these aspects of their operations. UNIDO has published some cost structures which, although inadequate, do shed some light on this crucial aspect of pharmaceutical transactions.[4] Applying these to selected products in Thailand for 1981, the estimates in Table 6 can be made.

It may well be that costs are higher than the averages used, especially considering that there are, in total, 183 formulation factories in the country and that, as shown earlier, ampicillin has 60 different forms on the market (*not* including combination products). It is also possible that the retail values may be too high, although by choosing estimates based on median prices this tendency is counteracted. Nonetheless, the fact remains that mark-up levels are exceedingly high (always above 250 per cent) and that

Table 6 Estimated retail market of selected drugs using UNIDO cost structure, Thailand, 1981

	Bulk import		Estimated prod. cost	Estimated retail value at median prices	Estimated mark-up
	Weight (kg)	US $'000	(US $'000)	(US $'000)	(percentage)
Ampicillin	54,109	5,077	8,900	25,000	280
Aspirin	730,085	1,789	2,820	7,000	248
Dexamethasone	174	714	1,050	18,950	1,800
Isoniasid	19,300	127	193	830	427
Paracetamol	358,750	1,800	2,635	67,850	2,575
Quinine	7,295	540	790	2,600	329
Streptomycin	12,065	500	732	1,950	266

Source: Sepulveda, C., Kaosard, M., and Dhanatrakul, T., 'Price Differentials of 18 Selected Pharmaceutical Products in Thailand', ESCAP, 1984, unpublished mimeograph.

there is scope for savings through a rationalization of the market. If savings thus generated could be redirected to increase people's accessibility to modern, sound and relevant pharmaceutical therapy, real coverage could be expanded and a meaningful contribution to Health for All could be made.

Imports: raw materials and finished products

For a country such as Thailand, with a fairly but not totally developed formulation industry and almost non-existent manufacturing of raw materials, the main dependency point is the import of active principles to support the local formulation. In addition, some 25-30 per cent of the finished forms also have to be imported.

The import of raw materials represented Baht 6,167 million in 1980 or approximately US $270 million, while finished forms represented about US $65 million, thus totalling about US $340 million. The corresponding figures in 1974 were US $105 million for raw materials and US $45 million for finished drugs, totalling about US $150 million. Thus, in a seven-year period, imports more than doubled, with a greater emphasis on raw material imports which went from 70 per cent of total imports in 1974 to 81 per cent in 1980. There is no compilation of figures available on the physical volume of products imported, although it is known to have increased sharply for ampicillin, aspirin, paracetamol, dexamethasone, diazepam, etc. Thus, it is not completely clear how much of this increase is related to *a greater number* of products and how much is attributable to *higher prices*.

Table 7 Bulk purchases of selected drugs, Thailand 1981

	Volume transacted (kg.)	Total expend. US $'000	Number of transactions	Price per transaction (US $) max.	min.	mode	Weighted average	Estimated savings (percentage)
Ampicillin	54,109	5,076	258	233.0	69.6	150	93.8	25
Aspirin	730,085	1,798	61	3.4	1.2	2	2.4	42
Dexamethasone	174	714	66	21,000.0	2,492.0	3,770	4,111.0	39
Isoniacid	19,300	127	12	8.3	4.9	6	6.6	25
Paracetamol	358,750	1,804	85	11.0	4.3	4.8	5.0	13
Quinine	7,295	540	42	400.0	65.6	125	73.7	11
Streptomycin	12,065	500	35	65.0	16.0	49.0	41.0	61

Source: Sepulveda C., Kaosard M. and Dhanatrakul T., 'Price Differentials of 18 Selected Pharmaceutical Products in Thailand', ESCAP 1984, *unpublished mimeograph.*

Nonetheless, recent work has demonstrated that here again there has been, and continues to be, a very wide variation in prices available, according to sources of supply (by company and country), relations between supplier and buyer (which implies the existence or absence of transfer pricing), the chemical form of the raw material, the period of the year when purchases are effected, and the size of purchases made.[5]

Table 7 shows the price variations existing for some selected products in Thailand in 1981, with hypothetical percentages of savings which could have been effected, if the purchases had been made at the cheapest price.

Apart from the wide price fluctuations and the multiplicity of transactions, Table 7 shows a great potential for savings which, given an accurate knowledge of the market, could lead to a substantial lowering of production costs, a reduction which could have a manifold multiplier effect at retail level. An analysis of the data compiled also showed that usually the maximum price was charged by a transnational corporation, although in other cases—sometimes even for the same drug but a different transaction—the same company also charged the minimum price.

In the case of the highest prices, an analysis of buyer-supplier relationships showed that these charges were very often made between an affiliate or a subsidiary in Thailand and a parent house abroad, a phenomenon already well documented as one of the forms of 'transfer pricing' by which higher profits are extracted to parent companies. Using a multi-classification analysis technique, the existence of transfer pricing was ascertained for ampicillin, aspirin and dexamethasone, as shown in Table 8. The upward

Table 8 Intra-firm trade of selected pharmaceuticals valued at different price assumptions, Thailand, 1981

	Ampicillin	Aspirin	Dexamethasone	Total
Total imports				
Volume (kgs.)	54,008	730,085	169	
Value (US $)	5,075,294	1,785,154	713,582	7,574,030
Actual intra-firm trade				
Volume (kgs)	6,625	260,000	4.65	
Value (US $)	845,439	923,200	77,276	1,845,915
Estimated intra-firm trade at				
mean price (US $)	665,742	574,600	26,865	
mode price (US $)	993,750	551,200	17,530	
minimum price (US $)	461,431	314,600	11,578	
Estimated excess import values resulting from intra-firm trade if valued at				
mean price (US $)	179,697	348,600	50,411	614,690
mode price (US $)	(148,311)	372,000	59,746	283,435
minimum price (US $)	348,008	608,600	65,698	1,058,306

Source: Sepulveda, C., Kaosard, M., Dhanatrakul, T., 'Price Differentials of 18 Selected Pharmaceutical Products in Thailand', ESCAP, 1984, unpublished mimeograph.

deviations of these three drugs, explainable by the transfer pricing mechanism, are about 23, 15 and 5 per cent respectively. Depending on what benchmarks (mean, mode and minimum prices) are used, they may represent between US $283,000 and US $1,058,000, that is between 3.7 and 14.1 per cent of the total value of these imported drugs in 1981.

The existence of these price variations and of the price transferring procedure demands urgent and essential action by Third World governments to increase their technical capacity, strengthen their controls and update their legislation in order to deal adequately with these problems.

Information, data and national pharmaceutical development

Perhaps the single most important factor hindering the development of national pharmaceutical capabilities is the commercial secrecy surrounding the operations of the industry. Such secrecy is hard to understand when the results affect the life and health of the majority of the world's population. However, even if the data presented in this article was sharper, the order of magnitude represented is unlikely to change. It would be easier to develop a negotiation process of 'pharmaceuticals in support of health for all' if the negotiating partners, governments and industries, were to make their

information publicly available. Governments generally do this but industries are often protected by legislation which keeps certain information away from public scrutiny.

While this situation remains, a positive contribution could be made by establishing a Documentation and Dissemination Centre to assemble, collate, further research and assess trends and local variations, at the global and national level, since the pharmaceutical industry is both a global and national phenomenon. This would be an important step towards Another Development in Pharmaceuticals.

Towards a pharmaceutical ethos: pharmaceutical health

The above presentation of the main factors, quantified and analysed within the limitations of the information currently available, clearly points a way to a new vision of the role of pharmaceuticals in the Third World in particular, but also for humanity in general.

Under the paradigm that money is the great equalizer, the world has been led to believe that every commodity is worth what its market price is, no matter what its effects or objectives in society may be. Thus, a nuclear submarine and its equivalent in produced pharmaceuticals are considered to have the same value in GNP accounting.

However, pharmaceuticals—next to food, maybe—are commodities with a difference. They are primarily intended to yield better health, and only secondarily, if at all, any kind of wealth. To preclude people's accessibility to drug therapy in their moment of need, be it directly or indirectly, constitutes a breach of human rights, as health has been unanimously proclaimed a fundamental human right by the governments of the world. Such a breach may produce untold suffering and unnecessary death.

Actions of the United Nations

World awareness of pharmaceuticals as a public health problem, and indeed as an ethical problem, is only too recent. The World Health Organization, through its Action Programme on Essential Drugs and Vaccines, has been a pioneer in advocating more rational utilization of pharmaceuticals. In addition to its purely industrial development activities, UNIDO has through two world consultations (in Lisbon, 1980, and Budapest, 1984) initiated a process of preliminary contacts between governments and the industry. In April 1985, UNICEF's Executive Board approved a US $23,000,000 'noted' sum to support the development of national essential drug programmes and provide capital for special procurement of essential drugs. With a pledge of US $100,000,000 over three years, made by the government of Italy in June 1985, UNICEF expects to accelerate immuni-

zations, a form of preventive bio-chemotherapy, in Africa and selected countries elsewhere.

In this context, Another Development in Pharmaceuticals—which caters for scientific requirements rather than demand induced by advertising, for moderate and informed consumption at reasonable levels of prices' mark-up and is based as far as possible on self-reliant production (formulation and manufacturing) and sound import policies—no longer appears utopian but can be seen as a long road on which the first steps have already been taken.

Notes

1. Hutangura, P., Sepulveda, C., *et al.*, 'The Pharmaceutical Industry in ASEAN Countries 1. Thailand', ESCAP-UNAPDI/UNIDO, 1979.
2. Sepulveda, C., and Menesses, E. (eds.), 'The Pharmaceutical Industry in ASEAN countries', (consolidated report). ESCAP-UNAPDI/UNIDO, 1980.
3. Food and Drug Administration, interview with the Director-General, *Bangkok Post,* March 21, 1983.
4. UNIDO, 'The Pricing and Availability of Intermediates and Bulk Drugs', Background Document, First Consultation on the Pharmaceutical Industry, Lisbon, December, 1980.
5. Sepulveda, C., Kaosard, M., and Dhanatrakul, T., 'Price Differentials of 18 Selected Pharmaceutical Products in Thailand', ESCAP, 1984, unpublished mimeograph.

Towards a Healthy Use of Pharmaceuticals

An Indian Perspective

By Mira Shiva

The 'modern scientific' system of medicine, which has expanded with little or no regard for the cultural diversity of the world, has reduced health care from being the balanced input of a good environment, healthy nutrition plus medicines to merely the provision of medicines in the form of refined or synthetic chemicals, argues Dr Mira Shiva in this article. Drawing on her experience as a medical doctor in India, she goes on to point out that 'while nursing homes, X-ray clinics, diagnostic labs, drug units, druggists and chemist shops have everywhere mushroomed, at rapidly escalating costs, there has been no significant and substantial change *in the health status of the people ... For such a situation to thrive, it requires the nurturing and perpetuation of myths like "Health is Medicine" and "Doctors + Drugs = Health".' But 'questions regarding the role of drugs and of medical care in health are beginning to be asked ... The refusal by a large number of aware and conscious citizens to swallow anything and everything in the name of "health", "development" and "progress" is just the beginning of an important process—a process that is directed towards Another Development.'*

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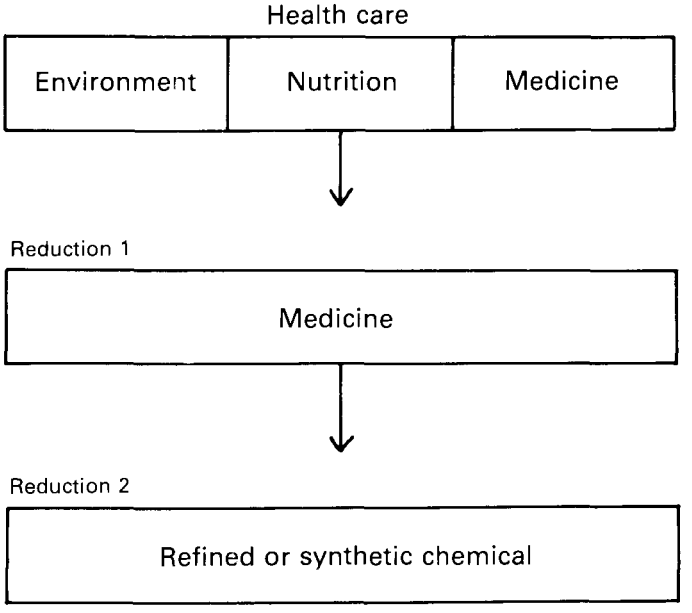
Pharmaceuticalization of health care

Throughout human history, societies have had particular perceptions of health and disease. Related to these perceptions has been a plurality of practices for disease prevention and cure. In the Ayurvedic system of medicine, remedies are a combined action of medicine *(ausadha)*, diet *(ahara)* and hygienic living *(vihara)* which bring about the cure by counteracting either the disease's causes or symptoms. In India, China, Africa and many other parts of the world, medical systems have viewed drugs and medicines only as a partial treatment for disease, with complementary treatment being at the nutritional and environmental levels. Further, most drugs throughout history's different civilizations have been plant based. In India's indigenous medical systems, over 1,500 drugs are plant derived. In China one billion people still depend on traditional medicine, most of which involves plant drugs. With the increasing attack on these ancient, time-tested systems as unscientific, it is worth asking, 'Can such a medical system have survived for 3,000 years if the entire populace was being served placebo medication'?[1]

Figure 1: The process of pharmaceuticalization of health care



The 'modern scientific' system of medicine, which is eroding the cultural diversity in health care, has reduced 'remedy' to 'drugs' and has redefined a drug as a refined or synthetic chemical, concentrated and identified (see Fig. 1).[2] These reinterpretations of fundamental concepts in therapeutics have created large, centralized, standardized medical-industrial complexes which are indifferent to cultural diversity and economic inequality, and insensitive to health needs.

Health care is first reduced from being the balanced input of a good environment, healthy nutrition plus medicine, to being merely the provision of medicines. A second reduction takes place because medicine is reduced to refined or synthetic chemicals, to the exclusion of natural, plant-based remedies on which ancient systems of medicine have been based.

Towards a healthy use of pharmaceuticals

Low cost, self-reliant, indigenous, locally available health care alternatives, such as Ayurveda, Siddha and Unani, have been marginalized with the rapid growth of the medical-industrial complex. Yet while nursing homes, X-ray clinics, diagnostic labs, drug units, druggists and chemist shops have everywhere mushroomed, at rapidly escalating costs, there has been *no significant and substantial change* in the health status of the people.

With commercialization of health care, the pharmaceuticalization has increased and so has drug dependence. This has led to an erosion of the age-old health care concepts, which saw the inner balance between body

and mind, between self and others and between self and nature, as fundamental to good health. In Ayurveda, health is described as the achievement of *dhatusamya*—the equilibrium of sustaining and nourishing factors.[3] Simple health care solutions, for example changes in diet, simple massages, home remedies and herbal medicines, which are as relevant today as in the past for the majority of trivial problems, have been gradually excluded from the health care scene, because of an assumed superiority of modern drugs for all kinds of health problems. This assumed 'scientificity' has not been demonstrated by comparing the existing and new pharmaceuticals with alternative therapies in terms of efficacy, side effects, drug interaction, costs, acceptability and availability. Thus studies undertaken for hypertension therapy have never compared antihypertensives with non-drug modes of hypertension management, taking into account all the costs, side effects etc. Allopathic antidiarrhoeals are not compared with oral rehydration therapy and plant-based antidiarrhoeals but are instead compared with other similar useless and hazardous antidiarrhoeal drugs. Antidiarrhoeals are seen as 'bug killers' or 'stool stoppers', with a total negation of the holistic approach to diarrhoea cure. Hence, in spite of our markets being flooded with antidiarrhoeals of every kind—including hazardous ones like hydroxyquinoline and lomotil for children[4]—1.5 million children still die of dehydration due to diarrhoea.

Recently, however, in affluent countries themselves the relevance and rationality of the present medical models is being seriously questioned. For Third World countries, to base their health care services entirely on such a model, which will ensure an unhealthy and almost total dependence on pharmaceuticals in the name of 'science' and 'progress', is even more irrational because it is neither ecologically nor economically viable for the poor.

Yet today, in spite of Third World countries' existing cultural socio-economic differences, and the presence or absence of alternative systems of medicine, present health care solutions have become imitative, standardized, universalized, dependency-creating and alienating.

For such a situation to thrive, it requires the nurturing and perpetuation of myths like 'Health is Medicine' and 'Doctors + Drugs = Health'. Such myths benefit the medical-industrial complex the most. Not merely do they encourage the proliferation of an exploitative drug-dependence-creating medical system, but they eclipse, marginalize and distort the existing alternatives and destroy any possible future emergence of meaningful alternatives.

The warped development of pharmaceuticals

Not only has the process of commercial pharmaceuticalization been marginalizing other existing health care systems, it has failed to address itself even to the 'curative' care needs of the people. It therefore blocks the healthy use of pharmaceuticals in two ways: firstly by failing to recognize the limits to the use of pharmaceuticals; and secondly by allowing drug production to be dictated by profit rather than need. The drug production pattern has very little to do with the drug needs of the majority.

It is a tragic fact that the drug industry controls: (a) the kind of drugs in the market today; (b) most of the information available about these drugs; (c) the kind of drugs to come on the market tomorrow because of its control of research and development. Even national drug policies and policies of international bodies are strongly influenced by the industry or its spokespersons. This occurs in industrialized as well as Third World countries, indeed, particularly in the latter.

While, in the name of fulfilling the health needs of the people, pharmaceutical units and their brand names proliferate unhealthily, other dimensions of this 'development' or 'growth' fail to keep pace, namely '*drug control*' and *drug information* systems.

The concept of the universalization of the pharmaceutical medical solution and of dosage recommendations, irrespective of the nutritional and health status of patients in deprived areas, is irrational.[5] Moreover, the fixation with language and terminology, again in areas suffering from illiteracy, ignorance and grossly inadequate drug controls, indicates a total disregard for social reality. It also indicates an unhealthy First World bias on the part of drug exporters, transferers of technology and propounders of myths.

The shortages of essential drugs on one hand and the paradoxical flooding of the market with non-essential, irrational and hazardous drugs on the other, indicates the warped priorities in drug production, distribution and availability. The growth of the pharmaceutical industry has not been commensurate with better drug use. Rational drug use is more a function of social concern, and of a good understanding of health needs and people's needs, than of technical knowledge about drugs.

Ensuring the healthy use of drugs

To ensure the healthy use of pharmaceuticals, action has to be taken at international, national, regional and local levels. It can be ensured only by the continued efforts of socially conscious policy makers, concerned health professionals, a responsible drug industry and an informed public. The role

of these different agents and actors in perpetuating the present maldevelopment in pharmaceuticals or in contributing to Another Development in Pharmaceuticals will be analysed in the following sections.

The government role: the psychology of colonialism

One aspect of cultural colonialism is that Third World countries have adopted and strengthened pharmaceuticalization trends. On the assumption that western medicine is superior and that to change is the same as to improve, the state makes every attempt to introduce pharmaceuticalization—from encouraging pharmaceutical manufacture to emphasizing dependence on drugs throughout the national health service infrastructure, including medical training. This is often done at the cost of more viable, effective and long-lasting alternatives in health care.[6] The psychology of colonialism on the part of governments is matched with the psychology of profit maximization on the part of the transnational company and the rest of the drug industry, which pushes everyone deeper into the pharmaceuticalization process. Half-hearted attempts to break out of this situation never succeed, for however worthy the words of a national health policy may sound, they are impossible to implement in a system which runs according to priorities detrimental to the health of the poor majority. As far as drug policies are concerned the motivating force is the belief that pharmaceuticalization equals 'progress' and 'development', rather than a desire for large profits, as is the case when governments promote the tobacco or alcohol industries. However, for the drug industry itself the driving force is profit maximization, not the health and drug needs of the people. Given the leadership role of the pharmaceutical industry, this principle of profit maximization generates dangerous trends which become the models for health care in general. These models are unwittingly adopted by actors and agencies who might, in fact, not be committed to maximizing their profits. Government attempts to remedy the distortions inherent in the pharmaceuticalization process consist of creating public sector companies—which continue to replicate trends set by the transnationals.

The strong influence of the powerful drug bodies and their corrupting effect on Third World politicians, policy-makers and bureaucrats, is as dangerous for a nation as are the health hazards due to some of their drugs. This internal infiltration and influencing of the policy-making process has to be looked upon with as much anxiety and caution as infiltration across borders by so-called 'enemies of the state', since in a very fundamental way they undermine national security and people's security. I will give a few specific examples to highlight the maldevelopment in pharmaceuticals that arises from concern for profits rather than for people's health.

Table 1 The production of anti-TB and other drugs and the estimated requirement.

	Estimated demand 1979-80	Production in tons			Estimated production 1982-83
		1979-80	1980-81	1981-82	
Anti-malarial					
Chloroquin	250	35.16	34.62	58.96	70.00
Amodiaquin	40	38.49	23.15	26.02	33.00
Anti-tubercular					
PAS & Salts	600	481.78	405.46	261.97	290.00
Isoniacid (INH)	200	112.43	129.20	110.40	128.00
Thiacetazone	40	12.55	8.44	13.98	25.00
Streptomycin	300	220.16	227.33	255.45	266.00
Anti-filarial					
DEC	30	21.57	18.99	16.43	13.00
Anti-leprosy					
DDS	28	16.20	21.05	25.61	30.00

Source: Rane, W.V., 'Why don't our drugs match our diseases'?, *Science Today*, October, 1982. (Updated, Chemicals and Fertilizers, Annual Report, 1983).

Essential drug shortages

In spite of a large pharmaceutical industry, countries like India continue to have severe shortages of essential drugs for major diseases. For example, India has 10 million TB patients: 2.5 million are actively infectious and 50,000 die each year because of TB. It is a national health priority and we have a National TB Control Programme to ensure this (it was part of Indira Gandhi's 20 point Programme). *Yet* we produce half of the minimum requirement of anti-TB drugs (and one third of the anti-leprosy drugs) according to the Indian Council of Medical Research (ICMR) and the Indian Council of Social Science Research (ICSSR) Report on 'Alternative Strategies: Health for All'.

Another example is the production of Vitamin A: around 40,000 children become blind each year due to Vitamin A deficiency. In real terms this means the non-availability of nutritious food in adequate quantities to supply Vitamin A in the diet. Not only are there shortages of Vitamin A but production is going down rather than up.

There are 60 million people with iodine-deficient goitre in India's goitre endemic areas. A recent study conducted by the Nutrition Foundation of India indicated that, while the requirement of iodized salts was 700,000 tons, only 100,000 tons were produced. Failure to distribute it effectively has allowed the birth of a large number of deaf mutes, and/or caused other subnormalities. Iodized salt would be cheapest of essential drugs under the circumstances.

Table 2 The role of transnationals in the production of essential drugs in a national priority programme, India.

Name of firm	INH	PAS	Thiacitazone	Ethambutol	Rifampicin	Streptomycin
Abbott	Nil	Nil	Nil	Nil	Nil	Nil
ACCI	Nil	Nil	Nil	Nil	Nil	Nil
Hoechst	Nil	Nil	Nil	Nil	Nil	Nil
S.K. & F.	Nil	Nil	Nil	Nil	Nil	Nil
Searle	Nil	Nil	Nil	Nil	Nil	Nil
Sandoz	Nil	Nil	Nil	Nil	Nil	Nil
Roche	Nil	Nil	Nil	Nil	Nil	Nil
Parke-Davis	Nil	Nil	Nil	Nil	Nil	Nil
Sarabhai	*Yes*	Nil	*Yes*	*Yes*	Nil	*Yes*
Boehringer Knoll	Nil	Nil	Nil	Nil	Nil	Nil
Glaxo	Nil	Nil	Nil	Nil	Nil	*Yes*
E. Merck	Nil	Nil	Nil	Nil	Nil	Nil
Ciba-Giegy	Nil	Nil	Nil	Nil	Nil	Nil
Pfizer	*Yes*	*Yes*	*Yes*	Nil	Nil	*Yes*
Warner	*Yes*	Nil	Nil	Nil	Nil	Nil
Burrough Wellcome	Nil	Nil	Nil	Nil	Nil	Nil
German Remedies	Nil	Nil	Nil	Nil	Nil	Nil
Cynamid	Nil	Nil	Nil	*Yes*	Nil	Nil
Ethnor	Nil	Nil	Nil	Nil	Nil	Nil

Source: Majumdar, J.S., 'A Study on Preventive Disease in India',(paper prepared for the drug workshop in Jaipur organised by VHAI), August, 1982.

It is well known that malaria has staged a comeback and—in many areas—with a vengeance. Resistant malaria and cerebral malaria have been taking their toll. The following table on chloroquin imports in 1980, 1981 and 1982 shows that it has not been possible for governments to enforce production of essential drugs as a priority when the production of non-essentials is more lucrative.

Table 3 Chloroquin imports in tons

Production	Imports	Production	Imports	Production	Imports
1979-80		1980-81		1981-82	
35.2	52.8	34.6	71.8	35	166.3

Source: Narayana, P.L., The Indian Pharmaceutical Industry: Problems and Prospects, National Council of Applied Economic Research, New Delhi, 1985.

Research and development and priority health problems

A 1984 study by the National Institute of Science, Technology and Development Sciences (NISTADS) indicated that most of the research being undertaken by the leading drug companies studied was not directed at our major health priorities. Industry's alleged 'great' contribution to research and development was exposed as not totally valid.

The concept of 'essential drugs' has to guide the selection, production, distribution and utilization of drugs. The non-availability of the fruits of 'medical science' and 'medical technology', when the need for them is apparent, is an insult to medical science, the drug industry and medical professionals and an indictment of governments that fail their people. An attempt to diffuse the potential of the essential drug concept by saying that it is only appropriate for the Third World has already been made, but it is essential for industrialized countries too.

India's pharmaceutical industry is one of the best developed in the Third World. According to UNIDO at the Lisbon Conference 1980, it belonged to Category V, i.e. with the capacity for total self-reliance in drug production. Shortages of essential and life-saving drugs in such a country are unacceptable. Yet, it also proves that the mere presence of a drug manufacturing capacity, without a commitment to the concept or principles of 'rational drug use', will result in shortages of essential drugs while the market is flooded with non-esential ones.

The concept of essential drugs is extremely important for the Third World as it can help (a) ensure adequate production, distribution, and storage of the selected drugs; (b) ensure provision of relevant information on the selected drugs; (c) make quality control easier by limiting drugs; and (d) assist the subsidizing of essential drugs and the removal or lowering of taxes in countries where people have low purchasing power.

Numerous discussions on what we meant by essential drugs brought us to the following conclusions:[8]

- Medico-scientific justification should act as a primary criterion.
- Priority for production has to be given to the prevailing disease pattern and incidence of disease, which, in India for example, are mainly communicable as well as nutritional.
- Drugs required for community medicine, and for diseases causing greater mortality, and greater morbidity, are essential drugs.
- Treatment of severe sequelae (after effects) should get greater priority.
- Drugs used in national programmes, e.g. on TB, leprosy, malaria, blindness, goitre control, and immunization, should get priority.

- Efficacy, safety, cost, ease of administration, availability and potential for misuse, are all important factors in any evaluation.

Evaluation of the drugs on the market, and revision of lists, should be done periodically.

The flood of hazardous drugs
The drug ban in India—a story without end

That essential drugs are unavailable to the majority of people, who are often deprived of their other basic human rights, is tragic. And to inflict hazardous and irrational drugs on unsuspecting people is, as the late Dr Olle Hansson of Sweden put it, criminal. It involves not only forcing people to waste their scarce resources on such drugs, but making them pay a further price in terms of their health. A large number of government officials involved in importing drugs, or in issuing licences for the production of drugs, are not fully conversant with the potential hazards of some of these drugs when available in other countries and under different conditions.

The compilation of the 'Consolidated list of products whose consumption and/or sale have been banned, withdrawn, severely restricted or not approved by governments', which has been prepared by the UN Secretariat in accordance with General Assembly Resolution 37/137, is a valuable contribution towards rational drug use. The problem, as always, will be in the implementation. The drug industry systematically frustrates or sabotages all governmental attempts at rationalization, as the following example illustrates:

In 1980, the Drug Consultative Committee reviewed 34 categories of fixed dose combinations and recommended withdrawal of 23 categories (16 of them immediately). In 1981, the Drug Technical Advisory Board met and a certain dilution of the list took place. On July 23, 1983 the Drug Controller of India issued an official Gazette Notification banning certain drugs. Certain drug companies went to court, questioning the rationale of the drug ban. Some attempted to reformulate their products, while ensuring that all previous stocks continued to be sold, prescribed and consumed.

The worst example of blatant disregard of medical opinion and government action related to drug control is the story of high dose Estrogen Progesterone Combination (EP drugs).

In 1982, on Women's Day (March 8th), a national campaign was launched against these products, spearheaded by the Voluntary Health Association of India (VHAI). It was joined by several other health groups, consumer groups, women's groups, the peoples' science movement, etc.

The press and the public applied sustained pressure, backed up by medical facts and information about action in other parts of the world. The high dose combination, used for hormonal pregnancy testing and inducing abortion and allegedly other gynaecological disorders, was known to be associated with foetal malformation as well as false positive and negative tests.

The Drug Controller of India banned the manufacture of the product from 31 March, 1983 and the sale from 30 June, 1983.[9] It could be considered a success story illustrating the strength of informed people, combining their power with appropriate official action.[10]

Yet Organon, Nicholas Unichem, the manufacturers of the products, went to court and obtained a stay order against the ban. It should be noted that one of the reasons why this was given pertained to the denial of the Indian woman's right to these desperately needed products. Strangely enough, Organon, so concerned about the health of Indian women, does not produce these drugs in its home country, the Netherlands, thereby depriving Dutch women of their 'right' to them. On the basis of this legal verdict an extension of license for another two years has been obtained and high dose EP drugs continue to be produced and sold.

Since national legislation has tended to fail to ensure withdrawal of hazardous drugs, international efforts are needed to protect the people. International codes, marketing policies and legislation have to ensure that countries with the least developed drug production capabilities and drug enforcement machinery are not exploited by the dumping of hazardous and irrational drugs.

International community concern about the health of everyone in this one world has to stall government legislation like the Hatch Amendment Bill in the US, which would allow exports of toxic drugs not marketed in America. Attempts to ensure the healthy use of drugs at micro level is possible only when decisions at national and international levels make it so.

Chemists and druggists: the psychology of middlemen

Traditional healers prepared their potions and medicines based on an individual assessment of patients. Today, the main role of the majority of chemists and druggists is to count the tablets and then count the coins.

In this medical-industrial complex, the gap between healers and drug producers is being bridged by this new cadre of professionals called chem-

ists and druggists, and by stockists, retailers and distributors. A study conducted by the National Institute of Nutrition, Hyderabad, in 1984 indicated that 46 per cent of drugs consumed by the people are bought over the counter without prescription.[11] Sometimes these drugs have been specifically asked for by the patient, but often it is the patient who comes directly to the chemist with the complaint, for which the chemist or druggist prescribes and dispenses medicine.

Since a large proportion of the thousands of druggists and chemists are 'untrained' and unaware not merely of the specific indication, contra-indication and dosages of the drugs they sell, but also of their hazards, they further aggravate the problem of pharmaceuticalization as disease rather than cure. In addition, the drugs are selected for stocking in the shops largely on the basis of the 'trade commission' received from the company. Ironically, a greater commission is paid on category III and IV drugs in India, i.e. the less essential and non-essential drugs. Several drug companies, who by-pass quality control and flout the regulations set for good manufacturing practice, often provide greater commission. Thus, one of the reasons for shortages of essential and life-saving drugs, besides inadequate production, is the inadequate and inefficient distribution system. Again, the distribution, stocking, promotion and dispensing mechanism is not based on the drug needs of the people but on profitability.

While the role of the medical establishment, the drug industry and national governments in ensuring or sabotaging a rational drug policy is well known, the role of pharmacists and chemists is not so well understood. The Organization of the Chemists and Pharmacists has acquired a lot of bargaining power in many Third World countries. A few examples from India illustrate the response of chemists and druggists to certain policy decisions.

Response to restriction of sales of psychotropic drugs

The government's attempts at restricting sales of psychotropic drugs was to put them on prescription and to demand the keeping of adequate records. This was met with a boycott. The drugs ceased to be stocked, creating massive problems for epileptics and psychiatric patients on these drugs.

Response to pharmacy amendment act

The government's decision to ensure that drugs were sold *only* by 'trained', 'qualified' pharmacists resulted in a three-day total national strike.[12]

Response to Drug Ban Order

As a response to the Gazette notification ordering a drug ban by the Drug Controller of India, the chemists and druggists obtained a stay order from the court, stating that unless a banned brand drug list was published, they

could not be held responsible for sales of such drugs. Yet the drug companies had already obtained a stay order against publication of a banned brand drug list, giving a list of drugs and drug houses involved. According to the drug companies this would effect their image and they were planning to reformulate the banned products anyway.

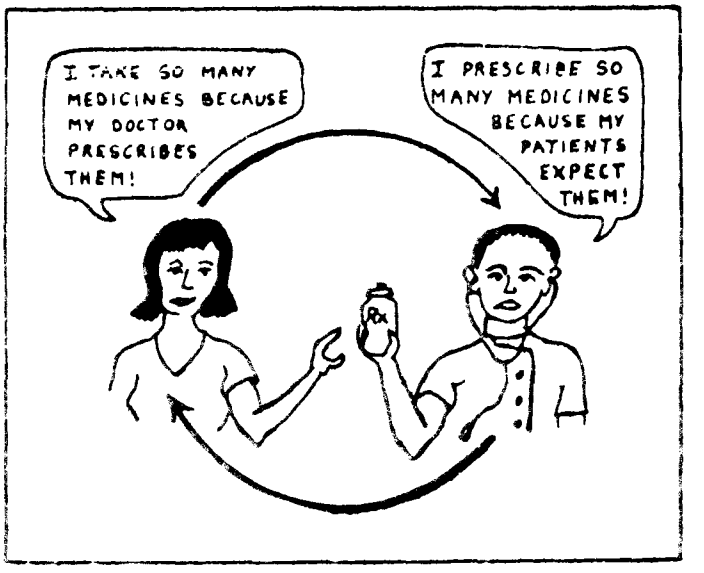
Response to new drug policy recommendations

The chief demand of druggists and chemists regarding the New Drug Policy is greater trade commission for themselves. They are the drug distributors—and they are mainly from the private sector, as are the majority of the drug sales. Alternative methods of drug distribution have to be evolved, whether these be the strengthening of the public sector, or allowing sales of essential drugs at subsidized rates from the different outlets forming the health care infrastructure.

Drug control and drug legislation in Third World countries never seems to keep pace with the proliferation of drug units and brands. Even in a country like India, 20 per cent of the drugs on the market are substandard. Unless the quality control mechanism, drug legislation and the qualified personnel who monitor drug use, adverse drug reaction, etc., keep pace with the growth of the drug industry—drugs will start posing a major health hazard themselves.

Health professionals

The psychology of doctors in Third World countries is not always the same as that of their counterparts in the West. Indian doctors largely come from the privileged sector of society, and their class backgrounds and the process of medical education (based on western models) ensures their alienation from the majority, and from poverty and the people's health and drug needs. Moreover, the only ongoing education for the majority of doctors comes from the ever obliging drug industry through its advertising. Added to the unquestioning style of their education in medical school and the constant input from the pharmaceutical industry, is the need to prescribe 'scientific solutions' and 'modern advances'. While the UK drug industry has one medical representative to 'enlighten' seven doctors about their product, in the Third World the ratio is one to three or four doctors. The psychology of compliance with the words of the medical representatives reinforces the psychology of control and mystification of information when dealing with patients. It is unrealistic to expect the majority of such doctors to give an unbiased critical analysis of the pharmaceutical situation. Moreover, false values, such as the longer the prescription the more up-to-date the doctor, create a vicious circle in which doctors prescribe what consumers allegedly demand.



The vicious circle that leads to the overuse of medicine: The prescribing of a medicine becomes both the symbol and the substitute for human caring.
Source: Wener, David, & Bower, Bill, 'Helping Health Workers Learn', Hesperian Foundation, USA, 1983.

Modern healers, like witch doctors, too often use their medicines to gain power and create dependency.

In the past, most medical professionals have not felt the need to communicate information about diseases and their treatment to patients. This arises partly from the feeling that it is not necessary for the patient to know and worry, and partly from the belief that illiterate and 'ignorant' patients will not understand the treatment anyway. Deeply ingrained in the mind of the medical professional is their *unquestionable right to prescribe.* In the absence of accountability, medical knowledge and technology can be a tool for exploitation. Prescribing for profits can take place, especially when the consumer is unaware and their psychology permits the doctor to be all-powerful and all-knowing. Controls such as medical audit systems can be counter-productive.

Consumers: psychology of modernization

It was the elite and those close to the ruling colonial masters who had access to modern medicine when it was first introduced to countries like India. Upon independence we adopted it universally for our people, ignoring indigenous systems. Our health services are based on the western model, and the drugs which are prescribed by government hospitals, by private practitioners, by registered medical practitioners and by chemists, as well as those available over the counter, are all western. Alternatives are not being sustained by the government, which gives neither adequate training nor resource allocation nor psychological support.

The doctor's implicit faith in western medicine is passed on to the consumer. This is reinforced by the widespread fascination with all that is western. A high value is put on injections as they have become symbolic of western medical technology. Consumers want them just as much as doctors want to cash in on their magical and dramatic value. Exotic packaging of medical technology increases its status and makes matters worse.

In the Third World, doctors are held in high esteem by the illiterate masses. The fact that they have had higher education and are therefore assumed to be more learned, lends a credibility to them and their actions which embraces their prescriptions, practices, and drugs. In the past, the traditional healer's non-commercial approach and the tradition of community service earned them high esteem. This respect for the traditional healer has now been transferred to the modern profit-oriented professional. At the same time there has been a negation of the traditional healer, who is today considered 'out of date', 'orthodox', 'unscientific', 'sectarian', 'rustic', 'superstitious', etc.

Moreover, unfortunately, the role of the drug industry, druggists and doctors in the issues related to the pharmaceutical industry, cannot be fully comprehended by the vast majority of consumers. Most people, who are totally unfamiliar with the function of transnationals and of the motives of the drug industry, have no reason to doubt the sincerity of doctors and the goodness of drugs. It is unrealistic to expect people who have no access to newspapers, radios, etc., and who have rarely moved out of their villages, to have even a basic awareness of issues related to modern health care and drugs. They are fed half-truths, the risk element of drugs being either totally denied or minimized, so that they never doubt the relevance of the most irrelevant drugs.

To ensure compliance, some of the currently prevailing myths are actively promoted; for example, allopathic medicines are claimed to be 'quick acting' and to lead to fast alleviation of pain and symptoms. The validity of this statement is rarely queried, nor is the question of the cost of this fast action and potency ever posed. Is 'quick action' at a heavy cost in terms of both money and health hazards really justified?

In Third World countries myths and half-truths about modern medicine are sold along with drugs. And it is a fact that worse than the shortages of essential drugs is the shortage of essential and relevant information pertaining to drugs.

The need for counter-information

Technical information from the WHO and other agencies becomes very valuable when the social implications of it are seen and understood. Health Action International (HAI), the International Organization of Consumers Unions (IOCU), Social Audit and other such organizations and networks which are committed to the concept of rational drug use, have systematically made an effort to demystify information and communicate it in such a way that it becomes part of the ordinary person's knowledge and is not merely the property of professionals.

Unless policy makers of the Third World, health professionals and the general public become aware of what is happening in the drug scene and assess the implications of various policy decisions on their lives, the health situation will continue in its currently chaotic fashion. There is an urgent need for resource centres where relevant information can be easily obtained from a centralized source. The inclusion of matters relating to rational drug policy in medical and pharmaceutical education is crucial. Today, all over the world, a new awareness about health issues is growing. The drugs issue is bringing together medical professionals, pharmacologists, social scientists, journalists, lawyers, women's groups, and health and consumer groups. Efforts to link 'centres of learning' with 'grassroot movements' and other like-minded groups and individuals are occurring spontaneously alongside continuing conscious efforts to do so.

Questions regarding the role of drugs and of medical care in health are beginning to be asked. Experience shows that more and more individuals are coming to the conclusion that 'enough is enough'. The Bhopal tragedy made a large number of ordinary people, and scientists in their sterile labs, sit up. A clear realization that people have to be put before profits is beginning to dawn. The refusal by a large number of aware and conscious citizens to swallow anything and everything in the name of 'health', 'development' and 'progress' is just the beginning of an important process—a process that is directed towards Another Development.

Reactions to pharmaceuticalization among grassroot groups

In a country like India, the demand for the basic needs of food, water, shelter and employment are a much greater priority for grassroot organizations than is the question of health care. Even in areas where health problems abound they remain a low priority, since it is here that the needs for food, water and shelter are most acutely and painfully experienced.

Unfortunately health care has tended to mean medical care, and curative

care has obviously depended on increasing use of pharmaceuticals. A large number of grassroot groups, like most other sections of society, continue to strongly believe that the fruits of development, namely medical care, should be equitably shared with the people. The overdependence on drugs is not recognized, nor is the exploitative nature of the pharmaceutical business widely known. Hence, well-meaning efforts towards social justice in health care unfortunately leave the already vulnerable even more vulnerable to exploitation. As people are unaware of alternatives, pharmaceuticalization is welcomed. Some groups feel that any kind of medical care is better than none at all. To them the quantitative aspect of medical care is more important than the qualitative one.

Several other groups, aware of the issues related to pharmaceuticals, are deeply concerned about the increasing commercialization of health care, and about the letting loose on the public of medicines known to be hazardous, especially when safer alternatives are available. The concern is born out of recognition of the disparities existing between health and drug needs and the purchasing power of the people on the one hand, and the kind of drugs available and their costs on the other.

A large number of grassroot groups are involved in survival issues related to human rights: fighting for freedom on behalf of bonded labour; fighting for minimum wages; fighting for due compensation for displaced tribals when their homes, land and villages are submerged for building dams; and fighting for the implementation of various schemes, legislation and policies for the benefit of the poor. These issues require urgent attention and long-term action. In addition, voluntary relief work has been called for when disasters like drought or floods occur, and when there is violence such as took place in Delhi, Bhiwandi, Assam, and Gujarat. The groups who responded to the Bhopal gas tragedy were those who were already deeply involved in the issues of survival and basic needs.

Indeed, unlike the general situation in the West, most of these grassroot groups are involved in several issues at the same time. Those fighting against industrial pollution will also be fighting for minimum wages, employment and basic education, for example. It is often those same groups who work against violation of human rights and for social justice, and who rise to the occasion when disasters strike. Scarce resources and multiple tasks compound their difficulties, and their deep commitment to independent action precludes outside funding, so they face continual manpower and financial constraints.

In such a situation, the fight for a rational use of drugs takes on a low priority—a fact which many of us recognize and, under the existing circumstances, have to accept. After all, groups and organizations that are deeply concerned about the pharmaceutical issues do exist and are doing something about it.

There would have been many more, had it not been for further constraints. India's size makes travelling, meetings, and discussions with like-minded groups expensive. In addition, the diversity of language, the cultural differences, the differences in state law, and in state allocation for health and drug budgets (health is a state responsibility, except for a few nationally controlled programmes) and the existence of several medical systems, makes any approach to the pharmaceutical issue a complicated one. This is compounded by the painful lack of unbiased information about pharmaceutical issues from government authorities and the drug industry. Even the information which does exist is hard for outsiders to get hold of. The reaction of grassroot groups to the issue has been influenced strongly by the above factors, as well as by their own different ideologies, i.e. Gandhian, Sarvodaya, Marxist, Marxist-Leninist or plain anti-neocolonialist.

A few illustrations of the work which is being done are given below. The list is far from exhaustive, but it does indicate that, in spite of all these constraints, the problems related to pharmaceuticals have been recognized as a cause for deep concern, and that action on several fronts has been attempted and an effort at coordination initiated.

The groups whose contributions are described include health groups; consumer groups; the People's Science Movement; legal activists; and coordinating organizations.

Health Groups

Deenbandhu Medical Mission, RK Pet, Tamil Nadu. In a Tamilian village bordering Andhra Pradesh there exists a health programme that has evolved over the past decade from a curative care centre, to a health extension programme, and finally to a training programme for village health workers. Deenbandhu has responded to the pharmaceuticalization process by not merely carefully selecting the drugs used in the programme, but by propagating the use of traditional medicines and home remedies. Each village health worker (VHW) at Deenbandhu takes care of her herbal garden, and her medical and health education work includes sharing her knowledge of self-reliant alternatives, ensuring back-up referral services if required. Not merely has the use of other non-drug therapies been ad-

vocated but efforts at prevention of disease and ill health, and for the liberation of the people from poverty and social bondage, have been made.

Comprehensive Rural Health Programme, Jamkhed. Jamkhed has responded to increased commercialization of medical care by organizing a very comprehensive rural health programme. While proliferation of medicines and medicine shops has occurred in the vicinity, the challenge has been met with rational use of carefully selected drugs at all levels, with health education and increased dependence on preventive measures, and with socio-economic programmes backed up with the help of trained village health workers.

Padhar Hospital, Madhya Pradesh. Based in a tribal area in Betul District, Padhar offers specialist medical services and acts as a referral centre for thousands of people in the surrounding villages and neighbouring towns. Even though paediatric, obstetric, gynaecological, surgical, orthopedic, eye, ear, nose and throat services, dentistry, cancer treatment and radio therapy are provided, a diagnostic study of the hospital undertaken by VHAI in 1983 showed that on an average only 50–60 drugs are used. The hospital pharmacy stocks around 150 drugs. The Padhar hospital is known for its good medical care, showing that numbers of drugs and length of prescriptions cannot compensate for concern and compassion. If the giving of drugs can be legitimized by its placebo value, humanized medical care is more than legitimized by its positively therapeutic value, along with rational use of essential drugs.

In today's medical context, with its increasing pressure on doctors to prescribe more medicines and on hospitals to stock more medicines, the positive example provided by referral hospitals like Padhar becomes all the more important.

Khurji Holy Family Patna, Bihar. In one of the poorest states in India, which paradoxically has one of the highest drug consumption rates, this hospital took a policy decision against great odds to restrict its drug list and provide therapeutic guidelines for its medical staff. A hospital formulary was developed which is being used as a guideline by other voluntary health institutions.[13]

While several health groups have attempted to streamline their own rational purchase and use of drugs, others have contributed by facilitating this process. These are some very specific responses to the warped pharmaceuticalization that is taking place in India.

LOCOST, Baroda, Gujarat. Initiated by the Voluntary Health Association in Gujarat, Locost attempts to make reasonably priced essential drugs available under generic names to NGOs. Efforts at bulk purchase and distribution do not merely cut costs but make essential drugs available to those in need.

WBVHA Central Marketing Unit, Calcutta, West Bengal. The West Bengal Voluntary Health Association (WBVHA) is attempting the same thing as Locost for NGOs in the eastern part of India. Efforts to make unbiased drug information available are very much part of the overall activity.[14]

Medico Friends Circle. A network of socially conscious medicos (and also non-medicos) has been critically analysing health related policies and, as part of the drug action network, has been demanding a rational drug policy. Some of the groups have focused specifically on drug education of consumers, seeing this as the priority intervention area.

Drug Action Forum, West Bengal. Even though it is only one year old, it has been actively campaigning against continued sales of hazardous drugs.

Arogya Dakshata Mandal (ADM), Pune. For several years Maharashtra has been bringing out the *Pune Journal of Continuing Medical Education* which attempts to provide unbiased drug information to its readers. ADM has been actively campaigning against antidiarrhoeals, the use of anti-inflammatory drugs, EP drugs and high dose EP drugs and has actively propagated the concept of oral rehydration solution (ORS) from the ORS centres in Poona slums. Their material for ordinary people, in regional languages, has attempted to raise the local health and ecological consciousness.

People's Science Movement, Lok Vigyan Sangatna, Bombay, has been attempting to build in the people a critical analytic capability on issues related to science. They have chosen to focus on the drugs most commonly consumed by the people in their area, mainly over-the-counter drugs, e.g. analgesic anti-inflammatory agents, cough syrups, etc. Meetings, circulation of pamphlets in the regional language, exhibitions, talks, street theatre, in different parts of Maharashtra, have helped a great deal in increasing people's awareness about pharmaceuticals.

Kerala Sastha Sahitya Parishad (KSSP), Trivandrum, Kerala. This is a Kerala based People's Science Movement. Their chief concern has been the negative impact of so-called development on people's lives and the use of

science and technology for exploitation rather than liberation. Having focused on the 'silent valley' product, where a several thousand-year-old tropical forest would be submerged as part of a hydro-electric project, and on pollution of the Chalyar river by industry, KSSP now also concentrates on pharmaceuticals. Street theatre, magazines and journals in the regional language, and talks and discussions during their annual 'jathas' when they travel from one city to another, have helped raise awareness about the role of the transnational pharmaceutical industry in the area.

Consumer Groups

The consumer movement is fairly new in India, and in the past few years an effort to bring drugs into consumer issues has been made. While the issues taken up by consumer groups remain largely related to consumer goods, a few are beginning to see the need to deal with consumer neglect.

Consumer Education Research Centre, Ahmedabad, Gujarat. This has been concerned about the hazards of drugs and pesticides and the double standards employed in their advertising. They have attempted to focus the attention of the public on the patent laws concerning transnationals and have brought out a comprehensive report on the subject, based on a study of analgesics. Their legal expertise means their contribution will be most valuable.

Consumer Guidance Society, Bombay. This has been actively involved with baby food issues and also the use of unsafe drugs. In the past few years several other consumer groups have become involved with the pharmaceutical issue, including the Consumer Association of Karnataka, the Consumer Association Kottayam, the Delhi Consumer Association, and Gyan Pandit. 'Consumer Columns' in several national dailies have been focusing on drugs issues and a new drug and health consciousness is building up with these efforts at counter-advocacy.

Women's Groups

In India crucial issues related to dowry, bride burning, reforms in divorce legislation, rape, compensation, and maternity benefits, have required greater priority from women's groups, than health issues have done. For rural women, issues related to availability of food, water and fuel are more urgent.

In the absence of basic health care, problems related to the non-availability of drugs would take precedence over the issues related to the existence of rational and hazardous drugs.

Unfortunately, the thinking of the health service and the health profes-

sionals has tended to revolve around the care of women in terms of pregnancy and family planning.

The majority of women—largely illiterate, denied equal rights and even basic rights by society, and further marginalized within the family itself—cannot be expected to organize themselves around pharmaceutical issues, even if they have first-hand painful experience of the denial of essential drugs. In spite of these constraints, the women's movement today is no doubt taking cognizance of health issues very seriously. Issues related to the medicalization of child birth, contraception, and the dumping of hazardous and irrational drugs are being taken up by women. The active participation of Saheli, a Delhi based Women's Group, and others in the EP drug campaign was extremely commendable.

Recently, women's groups have protested against attempts to include injectable contraceptives as part of the national Family Planning Programme without public debate and without completion of adequate trials.

Role of legal activists

The increasing use of legal loopholes by the drug industry has forced some of the legal action groups to react and public litigation suits have been filed in the High Courts and Supreme Court. Notable amongst these have been that by the Cochin Legal Aid Society against continued sales of banned drugs,[15] and the litigation against the state for non-availability of iodized salt for the 60 million goitre cases, and of chloroquin in some Rajasthan villages where several malaria deaths took place.[16] Changes in legislation related to advertising and in the Drugs and Cosmetics Act are being increasingly demanded.

Coordination efforts

VHAI, a federation of over 3,500 non-profit and non-governmental health institutions, began its existence as a coordinating agency for health planning. VHAI's Low Cost Drugs and Rational Therapeutics Cell has been actively involved in the drug issues.

For the past five years it has been actively involved in trying to get health groups, consumer groups, women's groups and development agencies involved in research and action related to a healthy use of pharmaceuticals.

VHAI and drugs

The drug culture and modern myths

The April-June 1981 special issue of *Health for the Millions* (VHAI's bimonthly magazine), was called 'Medicines as if people mattered'.[17] Long before its publication, some of us had begun to realize the negative impact of the 'drug culture' and its pollution of the minds of an increasing number

of literate, illiterate, urban and rural health personnel and consumers alike. We felt that this unshakable faith and implicit trust in drugs was being skillfully created and taken advantage of by the medical-industrial complex. The myth that there was a 'pill for every ill' was a modern day superstition, a medical myth which was being created, fed and propagated by vested interest. There was just no reason why irrational, useless, costly and often hazardous drugs should have been flooding the market, finding places even on the shelves of our service-oriented voluntary health institutions, and being prescribed and dispensed without anyone questioning the rationality of their very existence.

Our initial efforts were geared towards our own VHAI members. In the various training programmes—whether they were clinical assessment workshops, community health training programmes, seminars, school health or holistic health workshops—misuse of drugs and the issues involved, as well as the existing alternatives, were increasingly discussed.

By the end of 1981, we realized that in a society where the giving of long prescriptions with the latest 'wonder drugs' had such value, it was difficult for health personnel to have a different perception of health care and rational drug use. Even though many health institutions and health personnel accepted the concept of essential drugs and of rational drug therapy, it was hard to put it into practice in isolation and under current market pressures.

Many of our concerned and aware participants have contributed significantly through their conviction that something needed to be done, and by their initiative and willingness to alter some of the practices in their own institutions and programmes.

By this time we were beginning to recognize the shortages of essential and life-saving drugs. We also realized that most of our health institutions were not very well informed about drug and health policies. Had they been informed they would never have allowed some of the decisions, which were totally against the public interest, to be passed so easily. We felt an increasing need for health personnel and the people to participate and indeed to force their participation in decision-making which affected them, their work and their health.

The first drug workshop

On 8–10th January, 1982, in Pune, VHAI organized a workshop entitled 'Drug issues—seeking feasible alternatives', which was attended by representatives of consumer and health organizations, socially conscious doc-

tors, pharmacologists and journalists. The objective was to take stock of the existing drug situation, identify the trends it reveals and our own roles and responsibilities, and coordinate our efforts. This first workshop is a milestone in VHAI's work as well as in drug work.[18]

It was the first time VHAI had taken a decision to work in a coordinated way with other organizations and individuals from various backgrounds. This meeting and its regular follow-ups led to the formation of Drug Action Network, which was later joined by several others to form the All India Drug Action Network (AIDAN).

EP campaign

It was here that the decision to take on the issue of EP drugs and their misuse for Women's Day, i.e. 8th March, was taken. EP drugs were being prescribed for pregnancy testing in spite of the fact that they had not been recommended for such a purpose since 1976 by the WHO because of foetal malformation. In the case of the EP campaign, women groups, journalists, and other peoples' organizations started coming together. A network spontaneously started to grow.

The second drug workshop

In August 1982, at Jaipur, many of the drug enthusiasts met again for Drug Workshop II. The focus this time was 'Hazardous Drugs'. Handouts providing unbiased information about amidopyrines, paediatric tetracyclines, hormonal preparations, clioquinols, anabolic steroids and an EP update were specially prepared and circulated. Most of the background work again was done by VHAI.

Preparation of drug material

The Low Cost Drugs and Rational Therapeutics Cell of VHAI has functioned as a clearing house for relevant drug related information. The *Drug Action Network Newsletter* and various handouts have kept the networkers informed about drug policy and issues of local, regional, national and international relevance.[19] We have compiled and prepared original and relevant material, and identified areas requiring more information. We have taken open stands regarding drugs after investigating and informing ourselves. Our material has been prepared for health personnel and groups in the field. We have tried to meet the flood of requests for material from action groups, legal aid cells, community health programmes, hospitals, documentation centres, state VHAs and VHAI members. VHAI's activities were strengthened by visits of the late Dr Olle Hansson from Sweden, Mr Etsuro Totsuka from Tokyo and Dr Zafarullah Chowdhury from Bangladesh.

VHAI realizes that the fight for humanized health care has got to take place

at all levels: local, regional, national and global. VHAI's links with other member organizations of the informal network of HAI has contributed to the mutual strengthening of everyone's efforts. For the first time, efforts bringing together individuals, groups, organizations from different backgrounds and different political ideologies have been made over an issue which concerns us all. While working strategies differ, we share a common goal. We increasingly realize the extent of ignorance existing regarding health and drug matters.

Our involvement in drugs is not merely to improve the drug scene, but to ensure that our policies, health care policies and the current concept of the so-called development is seriously questioned. It is an attempt to help people realize the impact of all this on their health and their lives. These efforts are being made so as to ensure that soon people will begin to refuse to swallow anything that is harmful to their health but profitable to vested interest. Such a refusal, by large numbers of aware and conscious citizens, would be the beginning of an important process: a process which believes in putting people before profits and which respects the right of the people to health care and to democratic decision-making, especially in issues concerning their health and their lives.

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15. Writ Petition No. 5047 of 1982 in the Supreme Court of India Residents of this well defined Goitre Endemic areas of the State of Jammu and Kashmir, etc. Filed by Ms Kipla Hingorani.
16. Civil Writ Petition No. 3492 of 1983, Under Article 32 of the Constitution of India in the Supreme Court of India (for banned drugs being sold in the market). Filed by Dr Vincent Panikulangara, Public Litigation Centre, Cochin, Kerala.
17. Shiva, Mira, 'Drugs As if People mattered', Special issue of *Health for the Millions,* VHAI, 1982.
18. Shiva, Mira, *Workshop on Drugs Issues—Seeking Feasible Alternatives,* Pune, 8-10th January 1982, VHAI, 1982.
19. Several meetings and workshops have been held since 1982. The Drug Action Network has met in Calcutta, Bangalore, Wardha and Delhi. On 31st August, 1984, the All India Drug Action Network was formalized with representatives of 10 organizations forming the AIDAN Coordinating Committee. The author of this article was asked to serve as the coordinator. The organizations are: Arogya Dakshata Mandal, Catholic Hospital Association of India, Consumer Guidance Society of India, Drug Action Forum West Bengal, Delhi Science Forum, Kerala Sashtra Sahitya Parishad (K.S.S.P.), Lokvigyan Sanghatna, Locost, Medico Friends Circle, and Voluntary Health Association of India.

Drug Production with a Social Conscience

The Experience of Gonoshasthaya Pharmaceuticals

By Andrew Chetley

In many Third World countries, people face shortages of the most essential drugs for primary health care and an excess of drugs which are inappropriate to their basic needs. In Bangladesh, a grassroots primary health care project has established its own pharmaceuticals factory—Gonoshasthaya Pharmaceuticals Limited (GPL)—to challenge this situation. Freelance journalist Andrew Chetley visited GPL for DEVELOPMENT DIALOGUE *and found that the technology to produce drugs was accessible to a poor, rural workforce with little or no formal education. Because the factory grew out of the health care project, it has been integrated into the surrounding community, accepted and supported by the local people. Its very existence and the example it provides of being able to produce low-cost, high-quality essential drugs, has challenged the dependence of a country like Bangladesh on the transnational pharmaceutical industry. That challenge has led to political controversy and conflict both within the country and internationally. GPL has played a prominent role in transforming the drug production and supply system in Bangladesh, and its example could have future impact in other Third World countries.*

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Early one February morning, the drug factory of Gonoshasthaya Pharmaceuticals Limited (GPL) near Savar in Bangladesh contained more doctors than production staff. A group of 150 Indian and Bangladeshi doctors arrived unannounced to tour the factory.

Why should this factory, some 30 miles north of Dhaka, be of such interest? Because here a unique experiment in the local production of medicines was underway. GPL, in business since 1980, was playing a major role in transforming the drug supply system in Bangladesh.

GPL is the eighth largest national pharmaceutical company in Bangladesh according to the sales value of drugs produced and the sixth largest in volume terms. Those figures by themselves tell part of the story—GPL produces low-cost drugs.

And it only produces *essential* drugs. GPL makes 7 of the 12 drugs most essential for primary health care, plus 10 of the 33 drugs necessary for the secondary level of health care. In all, the factory produces some 40 different dosage forms.

It may seem remarkable that in one of the world's poorest countries, it was possible to introduce the technology necessary to produce drugs. Yet the experience of this factory shows that learning how to use the technology is not the real difficulty. Many more problems result from the political pressures which occur when such a development becomes successful.

Even before the factory was built, it faced strong opposition. The idea for the factory came about as an organic development of the Gonoshasthaya Kendra (GK) project—the People's Health Centre described in an earlier issue of *Development Dialogue*.[1] GK's project director, Dr Zafrullah Chowdhury, who is also chairman of the board of directors of GPL, explained that although every effort was being made to encourage primary health care in order to *prevent* illness, people who were already sick needed some medicines, particularly the types of drugs recommended as essential by the World Health Organization in 1977.[2] Yet often those medicines were not available in a country like Bangladesh, or were priced beyond the reach of the poor.

Dr Chowdhury cited the example of tuberculosis where 'a poor man would even sell his land, sell his cows, sell himself out' to get the necessary drug treatment.

The success of the paramedics at GK, with only the most basic education and minimal medical training, in reducing deaths from diarrhoea, improving nutrition through encouraging better eating habits and increasing immunization against several infectious diseases, showed that ordinary people could take the lead in disease control. Why could they not also produce the simple drugs needed for primary health care? As Dr Chowdhury put it, this was only a simple formulation process, 'little more than cooking, and Bangladesh has plenty of good cooks'.

GK had several options. Some European donors said they would supply low-cost generic drugs as part of their contribution to the health care project. Dr Chowdhury described this as 'typical of the European attitude —to keep control of the technology and the supply process'. Another suggestion made by donors was that one or two tablet machines could be supplied for installation at the small hospital at GK which would be ample

to meet the immediate drug needs of the project. This too was unacceptable. The decision was made to establish a medium-sized factory—one that would have impact at the national level as well as serving local demands.

The potential benefits were clear: improved drug supply; lower costs for drugs; less dependence on overseas companies or institutions; local employment opportunities *and* a chance to demonstrate that the near-monopoly held by many of the transnational drug companies operating in Bangladesh could be broken.

It was that last point which began to trigger the controversy and difficulties which still surround GPL.

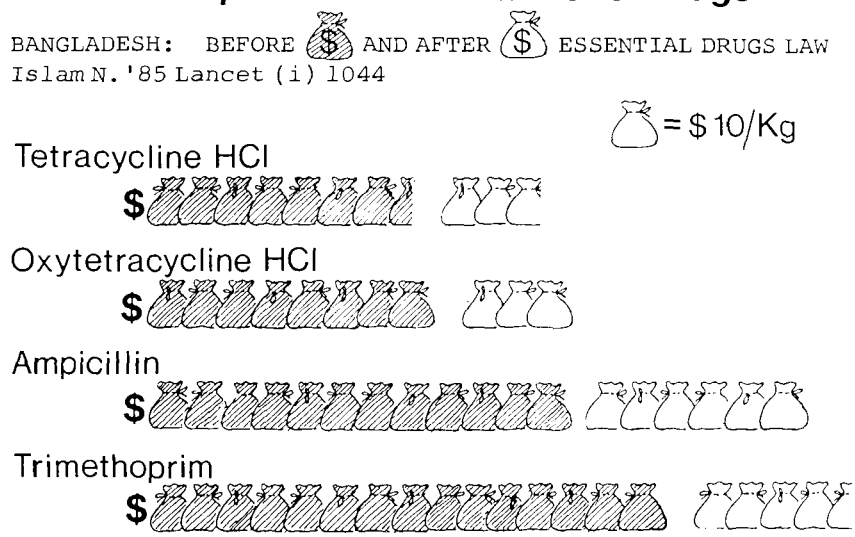
A donor was found to put up the initial capital to start the factory. However, first, permission was required from the Bangladesh government. It seemed a simple procedure, but took three years because of opposition to the idea. According to Dr Chowdhury, the opposition came from transnational and local companies who were afraid GPL would disrupt their business and force the prices of drugs down. One of the major supporters of this point of view was the chairman of the nine-member National Investment Board, who also served on the boards of several large companies in the country. After getting clearance from several ministries, the National Investment Board was the final hurdle. GK canvassed the support of the eight ordinary members of the Board and was convinced approval would be granted. However, after a lively discussion, the chairman simply took the item off the agenda of the meeting and said he would make the final decision in due course.

'What could we do?' said Dr Chowdhury. 'We gave the chairman an ultimatum. We gave him 72 hours to make a decision and said we would go to the newpapers about his connections with other companies and seek a writ in the high court. It worked like a miracle. The approval was given.'

However, by then, the original donor had lost interest in the project and the work had to start all over again to raise the necessary funds.

A leader in quality

That first set-back sharpened the awareness of the management team at GPL to some of the problems they would be facing. They recognized that at all costs, the drugs produced by GPL would have to be of the very highest quality. Any lapse of quality, even if it was not harmful to users of the drugs, would be ammunition to discredit the company. An extensive quality control laboratory was set up within the factory, equipped with precision



instruments. It is currently staffed by 17 highly-trained personnel who perform a never-ending series of tests on each batch of drugs produced.

But the key to good quality is the right 'attitude', according to Dr Jiben Roy, Deputy Manager of GPL's Research, Development and Quality Assurance Department. 'Quality control is an integral part of the whole manufacturing process. At every stage of production, we have a quality inspector supervising the process.' All the staff are trained in the basics of Good Manufacturing Practice (GMP) and understand that it is their performance, not the laboratory tests, which assures high quality.

GPL's Managing Director, Golam Mohiuddin is proud of the company's standards. 'We can claim that our quality is one of the best in the country. It can even be compared with anyone in Europe.'

That claim is reinforced by an investigation carried out by the Danish and Swedish international development agencies (DANIDA and SIDA) in late 1983. After examining a number of companies in Bangladesh, they found that only GPL and Glaxo had a 'recognized high standard' of quality control and an 'understanding of GMP'.[3]

The starting point for quality is the raw materials. Although high quality raw materials could be purchased from China or countries in Eastern Europe at a reasonable price, GPL made a conscious decision to buy its raw materials at good prices in *Western* Europe to begin with. This was to avoid any possible claims by competitors that GPL was using raw materials from socialist countries which might have lower standards and lower quality. Some years previously, similar claims disrupted government plans to en-

courage the import of low-cost raw materials by all companies. Today, now that GPL is firmly established and is able to run its own tests on the quality of raw materials, it purchases worldwide.

The initial purchase of raw materials in Western Europe had another motive. GPL was able to demonstrate that the high transfer prices some transnational companies were charging their Bangladeshi subsidiaries for raw materials from Europe were totally unnecessary. The materials could be obtained from reputable companies at much lower prices, representing a considerable saving for both the consumer and for the foreign exchange balances of the country.

The struggle against unethical competitors

In June 1980, when the first ampicillin capsules were produced, GPL thought it was on the way to making a large dent in the market for this essential antibiotic. The product had everything—proven effectiveness, assured quality and low price. GPL's G-Ampicillin sold for 1 Taka (then approximately US $0.05) per capsule. The nearest competing product was 2 Taka.

GPL put advertisements in the newspapers for doctors and also received good media coverage on the opening of the factory. However, the transnational companies were selling more ampicillin than ever. For some time, GPL was puzzled, until it was discovered that the medical representatives of the other companies were spreading rumours to doctors about GPL's ampicillin. Dr Chowdhury explained that he found out from a senior marketing manager of a British transnational drug company that several of the transnational and national companies had met and agreed on a strategy to combat the GPL threat to their business.

'He told me he was made responsible for the whole campaign', said Dr Chowdhury. 'He gave a briefing to the sales representatives and told them not to promote their own drugs, but to talk about GPL drugs. Go to a doctor and say, "Doctor, did you hear? It causes diarrhoea!" Some doctors will not know this and say "Oh, really?" Others will say, "Well, all ampicillin causes diarrhoea". Then say, "No sir, this has been very serious. But as soon as you stop G-Ampicillin, the diarrhoea stopped." And then you name some doctor in a different area and say "He is very keen on the GPL drug, but he needs two". So even with the doctors who were writing prescriptions for G-Ampicillin, it convinced them to write two instead of one capsule. So if you write two, the price becomes the same. They were tremendously successful in that respect. The same thing also happened with our paracetamol.'

GPL initially had no medical representatives. Today, partly as a result of the ampicillin incident, it has a marketing staff of 65. Dr Chowdhury said, 'looking back, we realize that we really should have gone for the medical profession like any other drug company. We were paying all the taxes, had the sophisticated machines and highly qualified managers and left out the marketing, which was a terrible mistake. While you are playing cricket, you have to follow the rules of the game. Some people now tell us that if we had started in that way we could now occupy a bigger share of the market. But it also has a danger. Our people might be changed. We would become like a transnational company and lose all our idealism. So, I don't know.'

GPL and the Bangladesh drug policy

GPL is unlike most other drug companies engaged in the *production* of drugs. Of course, it is important for the company to maintain sales and run at a profit. (Half of all profits goes directly back into the company for its continued development, and the other half is transferred to GK to help support the general health programme.) But perhaps its most important contribution is the example it sets by focusing drug production on basic health and development needs. Managing Director Mohiuddin pointed out that to examine GPL's achievements only in terms of market share or sales of drugs would be incorrect. 'One should evaluate GPL's achievements in other respects. We are the first company to make high quality essential drugs. Secondly, we've shown that it is possible to establish a pharmaceutical company with local help and expertise. Thirdly, we have had an effect on the price stability of drugs in Bangladesh. Our price is given as the reference in the price control meetings.'

The best indicator of the decrease in prices occurs in the rates paid for imported raw materials. In 1981, the average price for ampicillin was US $120 per kilogram. By 1984, it was down to only $60. Bangladesh's Drug Administration has recorded similar reductions in many other raw materials, although it noted that the full effect of these reduced prices has not filtered through completely at the retail level. Nonetheless, one observer notes that 'there is an overall trend towards lowering of retail prices of drugs in spite of general inflationary pressures'.[4]

Another important achievement was the role which GPL played in the development of Bangladesh's Drug Policy in 1982. At that time, there were 4,340 registered products on the market, of which 2,600 were local and 1,740 were foreign brands. Nearly 50 per cent of the local capacity was taken up in the manufacture of non-essential products. The government set up an eight-member expert committee to review the situation. The committee worked rapidly, and in total secrecy, to produce a report which called

for the removal of some 1,700 drugs from the market—most of them produced by local companies—and established guidelines for the future evaluation of whether a drug should be allowed on to the market. On 12 June 1982, the Drugs (Control) Ordinance was issued, incorporating the main elements of their report.

According to Dr Chowdhury, 'without GPL, there would have been no drug policy for Bangladesh'. He explained that the existence of GPL gave the government confidence that, even if all the transnational companies withdrew from the country as a result of the policy, local firms could meet high standards of quality and produce at least the essential drugs. Furthermore, if the workers at GPL could run the machines, the workers at other factories could also function, even if the companies withdrew their managers.

Dr Chowdhury, who was one of the members of the eight-person expert committee, said GLP 'had a very positive role in the policy formulation. We had the knowledge and information about the costing and profits of drugs as well as up-to-date information on their effectiveness. Even more interesting, no one else in the eight-member committee could guarantee the security of the document. The other seven knew that the document was going to be leaked. The Drug Controller said he could not guarantee the security of it. In the Drug Administration, the companies had one man who had been on their payroll for 12 years. You don't need to buy the boss. You can buy the second or third man and it will be all right. You'll get a copy of everything. So ultimately the responsibility came to us for guaranteeing the security of it. And here, I think, we played a very vital role. Nobody knew what was happening. The drug companies could not know what was coming. Only in the last day before it was released did they find out. They made a guess, really, that it had to be typed somewhere, because they were not getting a copy. So their anger was turned on GPL.'

That anger exploded with a massive campaign to discredit the drug policy in the media and among doctors. Both GPL and Dr Chowdhury himself were attacked. Rumours abounded. One suggestion was that GPL had engineered the entire policy so that the other companies would be forced out of business and GPL would have a complete monopoly in Bangladesh.

Four years later, it seems that most companies have found that they can live with the drug policy. According to the managing director of one of the largest national companies, the transnationals, who had been particularly vocal when the policy came into effect, 'are quiet now'. He said the policy

had been hardest on the local companies, but agreed that 'some of the drugs should have been removed'. His main concern was over the 'short amount of time' manufacturers were given to deplete their stocks and their raw materials for drugs that were removed.

One clear result of the policy has been an increase in both local production of drugs and local production of *essential* drugs. In 1981, local production was valued at 1,734 million Taka, with 30.3 per cent of that figure relating to the production of the 45 most essential drugs. By 1984, local production had risen to 2,830 million Taka, of which 64.7 per cent represented the production of the essential drugs.[4]

Tricks of the TNCs?

The drug policy did not leave GPL untouched. One of its products had to be reformulated to meet new specifications laid down in the policy. It was a relatively minor inconvenience. However, later on, another government decision cut deeply into one of GPL's major production items—oral rehydration salts (ORS). GPL was the first company in Bangladesh to produce ORS and at one time had some 90 per cent of the market.

Even though it was inexpensive to produce, and therefore inexpensive for people to purchase, Dr Chowdhury said he wished that more people would make a simple solution from ingredients they had at home. 'But this is the reality of life. People are lazy or don't believe a home-produced solution will work or something like that, so they like to have a packet. That is the gimmick of promotion.'

GPL began producing ORS in a foil pack to make up a one-litre solution. Then some American researchers suggested that a half-litre pack was better and this message began to be given prominence in Bangladesh. Dr Chowdhury said, 'Funnily enough, right at the same time, a few million packs of Ciba-Geigy ORS in a half-litre quantity arrived in Bangladesh. I just do not take this as a sheer coincidence. It is the same old conspiracy. The government, at one stage, ordered that within four weeks everybody had to produce a half-litre pack. We had 10 million sachets of foil for our one-litre pack. Most of the Third World machines, like in India and other places, were designed for a one-litre pack. However, now we have switched over to the half-litre pack.'

But further problems loom. Plans are underway to establish a factory in Bangladesh with the capacity to produce 15 million sachets of ORS, subsidized by the US Agency for International Development (AID). This version of ORS will also benefit from a plan to launch a 'social marketing'

campaign in the country, telling people what a life-saver ORS can be. Meanwhile, GPL is debating whether it should risk the installation of two more machines to manufacture ORS. Their future sales may not justify the investment.

In 1984, another incident occurred which threatened to undermine GPL's security. Apparent labour troubles at the factory flared into an angry confrontation. There is a provision in the contract with the workforce for regular meetings to settle grievances. In the approach to one of these meetings, a small number of workers, less than 10 per cent of the total workforce, felt they needed outside help and union organizers from Dhaka became involved. Several times they held small meetings outside the factory, calling on the management to meet their demands. However, no demands were submitted. One of the managers explained to the workers, 'You might have demands. We really have to consider them. And you also have to really see that it's a new factory. If you think there is something unfair, then it must be corrected. But tell us what your demands are.' Ultimately, demands were submitted and a meeting was set up to discuss them, even though they were felt by the management team to have been designed not to be accepted, but to stir up confusion.

Two days before the meeting, one of the maintenance crew was discovered in the administrative area of the factory early in the morning, carrying a spanner (wrench). When asked what he was doing, he explained that he was supposed to attack the manager and then turn off the electricity supply to create chaos. He said that he was not going to do it and that he had come to warn the manager. A few minutes later, union officials outside the factory called on the workers to come out on strike. A few did, but most continued working.

The management explained to the workforce that the laws on strikes were not in favour of the workers—demands have to be submitted and a negotiation process set up; if negotiation fails, then tripartite negotiations are established; if they fail, workers are free to hold independent meetings and decide about a strike; if they decide on a strike as a course of action, there has to be a secret ballot with three-quarters of the workers in favour; the strike can then only take place after a three-week cooling-off period. Failure to follow that procedure means the strike can be declared illegal and the workers could lose their jobs or even be arrested. Most of the workers opted for negotiations on the following Saturday morning.

Dr Chowdhury said that 'on the Saturday morning, while we were all happy

that everything would soon be resolved, we found that there were 2,000 people surrounding the compound, armed with sticks and rocks'. They broke into the GK compound and in the confrontation that followed, 84 GK workers and 30-40 of the mob were injured, including 60 women.

According to Dr Chowdhury, the crowd beat the manager's wife. 'Who ever heard of a trade union beating the manager's wife? People know that workers sometimes, being angry, beat the manager, stop their food and other things, but never their wives and children.'

During the fight, leaflets from the union were found which identified the weakest gate to attack and which singled out Dr Chowdhury as someone who should be physically attacked. While this was going on, cars from one of the major transnational companies and a local company were spotted outside the factory. Dr Chowdhury said, 'It can't be sheer coincidence. How can it be sheer coincidence that on the next day the papers are full of the story, yet not a single journalist was seen? They put out the story that we attacked the mob. Why would Gonoshasthaya workers attack the mob? And if they attacked the mob, then the fight should have been on the street. Nobody came to see that the fight was within the Gonoshasthaya Kendra compound.'

At the same time, pickets were set up at GPL's distribution centre in Dhaka. The pickets were not GPL workers, but were hired. Most were later identified as garment workers. Dr Chowdhury said, 'Everybody believed that they were GPL workers. Everybody believed that GPL was closed, with the placards in Dhaka but not here in Savar. And the medical representatives from the transnational and national companies were telling all the doctors that the factory was closed for good. But the factory was open. Not for a single day was the factory closed. But sales dropped.'

The incident also damaged GPL's image in the West, because it was presented as a union dispute. 'People do not realize', said Dr Chowdhury, 'that in Third World countries unions can be purchased. They can be fictitious. They can be created. This union never had a full meeting of the workers. It created the impression that we were paying low salaries to our workers. But even before the government introduced a general wage agreement, our salaries were even higher than that.'

GPL has weathered that storm. But new clouds are forming on the horizon. Recently, two of its major products—an antibiotic and an anti-worm tablet —have come under stiff price competition. One national company has

undercut the GPL antibiotic, while a transnational has undercut the other drug significantly. Dr Chowdhury expects that in the near future, the rest of their leading drugs will suffer the same fate. He admits that 'this is the first time we are feeling the pinch. For the other companies, if they cut the price of only one of their products, it doesn't affect them. But if any one of our products is undercut, it affects us.'

For the consumer, in the short-term, a price war such as this may have some benefits. After all, lowering drug prices was one of GPL's initial objectives. But what happens if GPL is forced out of business? Is it likely that prices would remain low? Experience with other products in other countries suggests that if the independent producer who holds down prices is forced out of business, prices quickly rise. The short-term benefits are rapidly eroded.

Local participation

The fact that GPL has survived so far is, to a large degree, because of its relationship with the local community. During the trouble in 1984, local villagers spontaneously came to the factory every night to act as guards. They wanted to defend *their* factory. That loyalty and support stems from the benefits that both GPL and GK have provided to the local community.

With the exception of some of the senior positions and the skilled people dealing with quality control, the workforce at GPL is from the local area. Most are women. It was a deliberate policy to employ women. According to Managing Director Mohiuddin, the policy is not to employ a man when a woman can do the job. He said he would not be surprised if one of the local women became managing director within ten years.

The reasons for this policy rested in the realization that in agriculture, health care and the general maintenance of society, women did the majority of the work—even though their contribution was rarely recognized or valued officially. The major function of GK was to provide health care and education to the poor and the oppressed, to assist them in their struggles to end their oppression. 'When you talk about the poor and oppressed, who is the more poor? The women,' said Dr Chowdhury. At the same time, there were benefits for the factory. 'They are good workers. They are the spirited workers. Because they know they have to change their society. They are more keen for change than men are.'

While most of these women were not educated, GPL soon found that it was relatively easy to train them quickly. As long as a woman could read an article from a Bengali newspaper, she could be trained. One of the roles of

the quality control department is to run regular training sessions after each day's work.

Those sessions deal with both the training necessary for production within the factory and general education in literacy and numeracy. The impact of such training reaches beyond the walls of the factory. After learning that hygiene and cleanliness is important to avoid contamination of the chemicals in drug production, it is a small step to realize that cleanliness and good hygiene at home and in the village can bring better health.

The children of the workers attend the school at GK, where they receive a free meal at lunch time. Recently, a daughter of one of the workers reached the ninth year at the school, and will become the first female graduate of the school. Next year, she could go to high school, if the money could be found. The other workers at the factory have encouraged her to go on with her education, and have promised to help with the cost. Everyone will pay a little bit. And everyone will share a little bit of the pride and the success.

From the very beginning, that spirit and determination was present—a result of the earlier positive achievements of GK. The factory itself was built by local labour in only two years. There were none of the strikes, thefts or bribery that occur on many other construction sites in the country. The building went up quickly and at less cost.

Business with a social conscience

GPL is clear proof that business can operate with a social conscience. It can interact with the community around it and play a major role in fulfilling the community's needs—both material and non-material. GPL provides essential drugs—a material need for better health care. At the same time, it provides employment, education, and that intangible sense of pride and achievement for many of its workforce and for the people in the surrounding villages.

Many of the women working at GPL have found a new independence and a new determination. They are asserting themselves in the factory, in their daily lives and in the community. With a better income and a sense of purpose outside the traditional roles of marriage and child-rearing has come a reduction in pregnancies—a vital consideration in a country with a population growth of 2.4 per cent per year. Those women employees who do have children can take six months paid leave and up to one year unpaid, with a guaranteed job. Now, some of them are asking, 'Why is there no child care facility at GPL?' The question is being answered. The facility is under construction.

GPL has also demystified the technology of drug production. Dr Chowdhury claims that within six months GPL could train anyone from anywhere in the world to use the machines in the factory. The use of the technology is certainly within the scope of rural, uneducated people within Bangladesh. There is little doubt that similar people in other Third World countries could handle it. A bastion of power currently held by corporations in Europe, North America and Japan has been breached.

Yet there is conflict and there are difficult decisions still to come. The questions facing GPL are not easy ones to answer. How can it maintain its original integrity and idealism if the rules of the game in which it plays are potentially corrupting? GPL believes in avoiding the waste of scarce resources in a country like Bangladesh and encourages its employees to choose a bicycle rather than a car. But a sales representative on a bicycle is not as effective (nor does she/he command as much status) as one in a car.

If doctors have come to expect gifts, samples, entertainment and expensive equipment from drug companies in return for a few prescriptions, can a company like GPL survive without doing likewise?

How big or how small should GPL be? If it grows too fast or too large, will its employees simply become cogs in a production machine, losing the participation and the feeling of community? If it fails to grow, will GPL lose its ability to influence other companies on prices, quality and the selection of drugs to manufacture?

The questions were always there, latent in the genesis of the company. Today, they are becoming more tangible, more necessary to deal with, because GPL has assumed more responsibilities and more roles. It is not only a factory producing essential drugs. It has become a symbol of a struggle for a rational approach to drugs and health care. It has the livelihood of 320 employees in production, quality control, distribution and marketing to consider. At the same time, it carries the hopes of many and the ill-will of some. It is no easy burden. But, in the words of Dr Chowdhury, 'The struggle is not over. We still have a long way to go. It is a very tortuous road. But we know that.'

Another Development in pharmaceuticals

The experience of GPL fits solidly into the framework of Another Development. It is *need-oriented,* and arose primarily to meet some basic human needs. It emerged *from within* the society and the community, an outgrowth of natural development. It is essentially *self-reliant,* depending for its strength on the people and their resources. The support and the contribu-

tions of the local population far outweigh the loans and grants which led to its initial establishment. Even those were accepted with care. The control over the development of the factory has remained firmly rooted in the decisions of the workers and the managers, not in outside donors. It is based on the principles of *sound ecological management* and the recognition that resources are scarce and must be appropriately used. And, it is *based on structural transformations* both in terms of its daily functioning such as the choice of the workforce, and in its relationship to the larger power structure of the global manufacture of drugs.

These are liberating forces. GK itself grew out of the struggle for liberation in Bangladesh and has maintained the tradition of liberation in its activities. GPL was born in that tradition, and offers the prospect of a liberation with universal implications. Other organizations in other countries could establish similar factories with similar objectives.

Pharmaceutical manufacture *is* a form of industrialization that is possible even for very poor countries. However, building a factory in isolation from the social and political conditions is unlikely to succeed. Using pharmaceutical firms as a vehicle for industrialization is likely to prove to be unsuccessful. Integrating a pharmaceutical firm into the whole approach to health and development, so that it functions in the context of the needs, resources and aspirations of the society and is prepared to challenge values and power structures in a constructive manner, can result in benefits for the majority.

It is possible. But no one can claim that it will be easy.

Notes

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Towards a Healthy Pharmaceutical Industry by the Year 2000

By M.N.G. Dukes

'If we want the pharmaceutical industry to be not only physically healthy but also socially healthy by the year 2000 a lot has to change. Part of that process of change has started; part has as yet hardly been contemplated. It is in the interest of everyone that this should happen. The pharmaceutical industry cannot please all the people all the time, but at least sections of the industry should be seen to be trying harder than they have done so far. At the very least, people working in the industry should be as open as possible about their motives, activities and faults. This is a high-risk industry which must deliver a high rate of return on investment if that investment is to continue to be attracted and not directed into other fields of industrial endeavour; the return is currently, however, often higher and sometimes much higher than it need to be. We have to find a balance. If such a balance can be assured by the year 2000, we shall have come a long way', concludes Graham Dukes in this assessment of the role the pharmaceutical industry should play in health care development during the next 15 years.

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The title accorded by the organizers of the Uppsala seminar to this paper is 'Towards a Healthy Pharmaceutical Industry by the Year 2000'. From the moment that it was suggested, the title has raised a lot of questions in my own mind, and I am probably not alone. The questions relate primarily to what one considers to be the criteria of health in a particular field of industry, both in an economic and a social sense, and also to how one can take positive steps to ensure that industry enjoys a healthy future.

The title is clearly derived from the declared objective of the World Health Organization—'Health for All by the Year 2000'—which is perhaps a good place to start. That slogan has always caused some amazement, but only among those who have not properly considered its meaning. 'Health for All' has never meant that all will be healthy, and that the peoples of the world should merely wait until health descends upon them as a universal gift. What it does mean is that the means to secure optimal health should be available to all, and that no-one should suffer ill-health because he/she lacks access to those means. What we have a right to expect is that within that period of time, quite apart from acquiring new knowledge, the world will have found ways of putting all existing knowledge and experience relating

to the maintenance and restoration of health at the disposal of every human being. We have therefore given ourselves some fifteen years—a convenient and reviewable period—in which to find ways of developing and mobilizing our resources better than we do at present. It is in the spirit of that interpretation of the WHO's crusade slogan that I think one can fairly look at the future of the pharmaceutical industry.

I will take it as a basic and unquestionable assumption on behalf of all, that we *want* a healthy drug industry. We need it because such an industry will, one hopes, continue to develop, manufacture and make available innovative drugs of high quality at least as well as it has done in the past (and perhaps better), and because it can and should remain a valuable bastion of the economy, even in countries at a relatively early phase of economic development. But above all, because a healthy industry is one way to ensure healthy people.

To define what we mean by a healthy industry let me again take a leaf out of the WHO's album, and look at the opening passage in the Constitution of the organization. It defines the health of an individual and reminds us that health is much more than the mere absence of disease; it is a complete state of well-being—both physical and spiritual. It is a criterion which applies well to our search for the health of an industry.

To start with the present: how healthy is that industry today? There is no simple answer, because this is an extraordinarily heterogeneous industry, although this is not a description it likes.

The material well-being of an industry is most commonly measured in terms such as turnover, profit and growth. These are matters which have been very much the focus of attention in Europe recently because of the intention expressed by a number of member states in this region to reduce their public expenditure on drugs. That was one reason which led the WHO's Regional Office for Europe to produce its draft report, *Drugs and Money*[1], based on some of the advice given individually to member states which come to the WHO with such plans. In that report, one major cause for concern is expressed quite clearly: hasty and ill-advised attempts at cost reduction in the pharmaceuticals sector can do more harm than good, and there are situations where they soon backlash on public health itself. But that report did give a general view of the financial state of the drug industry in 1985 and in that respect there was clearly no cause for despondency; as it currently exists the pharmaceutical industry is a great deal more profitable and wealthy than most other large manufacturing industries.Thus, in those

terms, it is quite simply very healthy, though again it does not always find it convenient to admit the fact. Exactly the same picture is emerging from the parallel European Studies of Drug Regulation, again undertaken by the WHO in Copenhagen. The drug industry became enormously profitable during the 1950's and 1960's and, unlike many other industries, it succeeded in maintaining that state of financial health during the recession which followed.

The best evidence that the pharmaceutical industry worldwide is doing very well for itself comes from the industry itself—not from its policy spokespersons (who are excellent at playing the Jeremiah when cost reductions are in the air) but from the Annual Reports of its chairpersons and presidents. Addressed as they are to shareholders rather than to economy-minded health ministers, they are almost uniformly optimistic. And those statements find ample confirmation in the detailed figures which are available. Naturally, there are isolated cases of pharmaceutical companies which find themselves in financial difficulties or go bankrupt, but that is part of the cut and thrust of normal commercial life. This industry is, after all, highly competitive and it is merciless on the weakest within its ranks.

So much for the pharmaceutical industry's physical health, which—while I would stress the need to care for it in purely financial terms—is not my main concern in this paper. Other aspects of its health are much more important to its future.

Some basic social criteria

One could say that an industry like this is spiritually and socially healthy only if it fulfils a number of basic social criteria. These could be formulated under seven headings:

- to provide the goods which the community has a right to expect of it;
- to provide these goods at a fair price;
- to avoid exerting an undue or unwanted influence on society;
- to be honest about itself;
- to be honest about its products;
- to build a solid future for itself with new products and services;
- to maintain a healthy self-confidence and a clear conscience.

Using those criteria, how is the industry doing?

To provide the goods which the community has a right to expect of it

In terms of research, it is to the credit of the pharmaceutical industry that a lot of useful drugs have been developed, a point to which I shall return below. In terms of making these drugs available to the people who need them, the drug industry obviously does so in profitable and uncomplex

markets. It does not take much trouble to serve the less attractive markets, preferring to sell in wealthy countries and to the wealthy elite of poor countries. It puts little effort into providing its services in the backwaters where the great majority of people live, or to providing them in a manner which these people can afford. It is an astonishing fact that a proportion of the world's population is oversupplied with drugs and subjected to much pressure to swallow them, while the rest is undersupplied or without drugs at all. Whatever one thinks of western synthetic drugs, there is clearly a minimum list of 40 or 50 substances, old or new, which everyone would agree now represents a basic right for the people of this earth; yet even those are at present still out of reach for a great many people. It is greatly to the credit of the WHO that its 'Action Programme on Essential Drugs' is now doing something about it. But what it can do is limited. The attitude of the drug industry towards the programme has been variable. At first, the concept of limited drug lists for essential needs met violent opposition from some industrial quarters; a period of hesitation followed, then one of grudging acceptance; finally, the industry has become an active supporter of the concept but largely in a small number of spectacular 'shop-window' areas where it can demonstrate its goodwill. In too many other areas, nothing is yet being done. Does that show an entirely healthy state of mind?

To provide these goods at a fair price

On the issue of pricing, the WHO/EURO draft report *Drugs and Money* also provides some answers. Again, there are credits and debits. On the credit side I see no reason to criticize in principle the fact that drug prices vary from one country to another. The commercial principle of asking as high a price as the market will bear runs reasonably parallel to the theoretical ideal that poor countries should pay proportionately less for their drugs and that wealthy countries should pay higher prices, thereby carrying the bulk of the overhead costs of administration, research, and returns on investment. But on the debit side one has to say that the process is only half carried through. It may be splendid to charge eight times as much for a drug in Germany as in Italy, if you can get the Germans to pay that much, but the whole morality of doing that stands or falls with your willingness to go off and sell the same substance at one tenth of the Italian price to people who will otherwise not get the drug at all. Alas, that does not often happen, despite the fact that one tenth of the Italian price is still probably enough to cover the basic manufacturing costs. Many of the companies engaged in this juggling act do not operate outside Europe at all; the money which could be doing good elsewhere remains in the rich corner of the world.

One reason why this does not happen often enough is that, if a drug industry virtually gives away its drugs to a very poor population, some unscrupulous

middleman will soon start buying them up and reselling them at inflated prices elsewhere. That is where governments and international organizations need to step in. 'Parallel import' of this nature can do a great deal to undermine healthy initiatives taken by the drug industry, or to discourage their being undertaken at all.

To avoid existing undue or unwanted influences on society

Regarding the influence which the drug industry exerts, the situation is not always a happy one. A health industry should be able to live, by and large, by meeting expressed needs and to some extent by meeting latent needs which it discovers and exploits, to the good of all parties. It should not need to engage in want-creation, a process which in a field like this is entirely reprehensible. But it exists. There is much evidence that the pharmaceutical industry is responsible to a significant extent for the overconsumption of medicines, though it is not the only causal element. Its representatives and its literature will not usually say in so many words that you must swallow more drugs or do so more often, but the highly emphatic character of drug advertising and the one-sided nature of some health research conducted by industry create an imbalance. There is no comparable advertising pressure in favour of non-drug therapy, even where reasonable alternatives are available; economic and social analyses produced by industry-sponsored institutes are generally reliable but they are directed almost exclusively to matters which are of industrial concern and which throw light on factors favouring drug use.

One must again add, however, that these things are not necessarily industry's fault. There are examples where the drug industry has actually found itself prohibited by the authorities from giving balanced health advice in package inserts for its drugs, regulatory agencies taking the view that drug companies should write about drugs and nothing else. I find it hard to agree. And as far as economic and social studies are concerned, one can hardly blame the industry for studying intensively those things that are likely to help its case; the trouble is that the community has not been sufficiently wide awake to do the complementary work which is needed in order to provide a complete picture.

On this point then, I conclude that there is an imbalance, that the pressure in favour of drug treatment is far heavier than that favouring the alternatives, and that this is something for society to put right. It would provide a healthy challenge, and public health would benefit.

To be honest about itself

How honest really is the drug industry about its economy, its achievements, and its effects? It is certainly not as open as it might be. I have already

mentioned its astonishing ability to proclaim impending bankruptcy when it wishes, and then to turn around and coddle its shareholders with promises of a golden future. This technique, and others like it, is wearing a little thin. Events in Great Britain late in 1984 illustrate this. In an attempt to reduce the effects of government proposals to limit the list of drugs allowed for prescription at National Health Service expense, some quite remarkable liberties were taken both with pharmacological and economic facts in order to prove that the measures envisaged would be therapeutically and economically disastrous. The physicians, seeing in the 'limited list' a threat to their freedom of prescribing, which might, if tolerated in principle, lead to further shackles on their freedom, were willing allies in this process. No outsider taking a calm look at the issues could believe very much of what was said or written; nor did the astute ministers involved; but the pharmaceutical industry played to the gallery on the grand scale and, of course, it produced results. This is often the way that policy is made in the short term, but it is not a sound way to develop long-term policies. Any community hoping to play its own part in ensuring a healthy industry will need a much more objective picture of the facts—both economic and scientific—than the industry has sometimes given.

One of the problems has been that industry has become so adept at getting other people, in a position of apparent independence, to promote its views. There are numerous bodies around the world which express views on drugs and which profess independence but which are in fact acting entirely as agents of the pharmaceutical industry. That was the situation which we encountered at WHO/EURO when we set out some years ago to analyse the effects of drug regulation. Various institutions had done something of the sort before, curiously all concluding, with one exception, that regulation was a disaster for the drug industry, for public health and for society. Not one of those research institutes whose conclusions we analysed was independent. Most were puppets of the pharmaceutical industry, and were not free to conclude anything else. The one exception was sponsored by a political party which had decided in advance that the transnational industry was wicked, and the conclusions of that particular study were as valueless as those which they contradicted. This sort of activity is unhealthy and unhelpful. It creates smokescreens where we need data. A really healthy industry does not need to engage in this sort of practice.

To be honest about its products

Various aspects of product information are worrying. In the first place, the honesty and reliability of drug promotion leaves something to be desired. At a guess, 90-95 per cent of drug promotion is honest and accurate. The trouble is that the other 5-10 per cent can gain a lot of attention and do much

harm. Doctors, throughout the world, do not really know a lot about drugs; a weakness which will be with us for a long time. It follows that very high standards have to be expected of anyone engaging in drug promotion; even a relatively small percentage of deception can do a disproportionate amount of harm.

Secondly, the maintenance of old and discredited products is an unhealthy element in the present situation. Long after a drug has become outdated, its manufacturer will continue to milk it for the profits which it can still produce. Many such products do disappear when a regulatory body merely leans on them, but it should not be necessary to wait for that.

To build a solid future for itself with new products and services

Is the pharmaceutical industry building a solid future for itself? To an extent, it is. Over a period of ten years one can point quite distinctly to a number of new compounds, perhaps 5 or 10 per cent of those entering the market, which have contributed something new to medicine. Antifungal preparations, to take a single example, are far better than they were a decade ago. The number of companies contributing to that small group of real innovations is, however, very small indeed. Even among the research-based companies there are many which just do not seem to have found a way to produce the innovations which society need, though there is plenty of less useful innovation in the form of 'me-too' molecules. This is a source of real concern inside those companies, although they commonly maintain their well-being by intensive promotion of these half-wanted or unwanted novelties. I do not pretend to suggest in this brief paper why things can go so wrong, but the fact remains that the total expenditure on research in this industry is still ludicrously small for a sector which is so dependent on building a solid future. It is particularly small if one compares it with the vast amount being spent on advertising and promotion by all the companies combined (including those which do no research). It may also be that the total amount spent is scattered over too many different companies, research units and projects.

It is sometimes said that regulation has siphoned off a great deal of money from productive research into costly safety studies of dubious relevance. Certainly this is true and it needs correcting, but regulation is not, I think, the main villain. To a large extent regulation has merely confirmed the standards which decent companies would have imposed upon themselves; and again the total expenditure on such safety research is small as compared with the advertising budget.

Time and again I return to the question of advertising expenditure, because

it may be one of the things which is most fundamentally wrong. There are countries where the number of detailmen selling drug messages is about the same as the number of doctors; there are a great many countries where they exceed by far the number of researchers. Is the much vaunted promotional approach to drug marketing efficient? If a doctor wishes to decide on the best beta-blocker, is the best way to go about it to send him eight detailmen selling eight different products, each claiming to be best? Will he end up prescribing that which is truly the best or that which is the best advertised? In a healthy situation, drug companies would compete with each other on the basis of the therapeutic and safety qualities of their drugs; the best drugs would win and the finest innovations would produce the greatest rewards. At present, all too often, funds flow most rapidly to those who sell most astutely rather than to those who innovate most brilliantly; the field of non-steroidal anti-inflammatory drugs provides some sad examples of this. Is that a basis for a healthy future?

To maintain a clear conscience and a healthy self-confidence

I am not sure that the pharmaceutical industry does have a clear enough conscience; an industry which should be adult enough to admit its errors and resilient enough to correct them has instead spent much effort in hiding and denying them. Recently, I was smuggled into a pep-talk for senior staff in the drug industry. It revolved around the theme that the thalidomide disaster was really no-one's fault, and that in any case, since then there had been no other disasters of comparable severity. Diethylstilbestrol? I wondered. Clioquinol in Japan? One can name too many more. Do people need to be so brainwashed to be proud of themselves? Is there not a risk that perspective will be lost if they are?

As far as self-confidence is concerned, I do not know that much of the pharmaceutical industry sees clearly where it is going or where it wants to go. There are some brilliant exceptions, fortunately, but the solid central core of industry has developed a strong tendency to adhere as rigidly as possible to its social *status quo,* fearing that any alternative situation might be less favourable to it. The criticism which industry has experienced has engendered much mistrust and even paranoia as regards the outside world. I get invited periodically to congresses at which companies or their staff members meet. There is a worrying entirely self-congratulatory tone about these meetings. The speaker who tells the participants what they want to hear is cheered; those who come with criticism, however constructive, may find themselves greeted with silence or worse. But it should be added that congresses of physicians and pharmacists are just as bad in this respect, with people *en masse* closing their ears and eyes to an outside world which they regard, rightly or wrongly, as hostile.

The future: ensuring industrial health

What can be done to ensure a healthy industry tomorrow? Where must the initiative for change come from? To find the answers calls for careful analysis and a broad debate, but I would like to suggest a few elements that must play a role in that debate.

I believe, in the light of the available evidence, that as regards its physical state, and in particular its financial balance, the drug industry is quite capable of taking good care of itself for the foreseeable future, provided it is protected from unjust and unreasonable complications, such as massive litigation or entirely unreasonable legislation. On both issues a lot of work is being done. It also needs consistent long-term approaches to expenditure and pricing, and not the haphazard national policies which we have sometimes seen. The approach to 'integrated drug policies' which is being developed at the University of Groningen may prove helpful. Particularly by consulting and working together, national governments could do more to develop these soundly integrated approaches to drugs policies and the transnational drug industry. Those policies should provide the industry as a whole with a secure future, seeking to provide a generous rate of return on high-risk investment, but demanding a great deal in the way of openness and maintenance of standards in return.

But creating a healthy situation may involve pushing for some more fundamental changes as well. It is essential to find a way of redistributing the money spent within the drug industry. Of the 10-20 per cent of its health budget that an industrialized western country spends on drugs, a third goes to the retailer, and if one adds the wholesale margin then nearly half the total sum paid never reaches the original supplier. Of the money which the latter does receive, far too much—probably between 15 and 20 per cent in many cases—goes on sales promotion in order to maintain its place among vicious competitors. That has to change if more money is to go into research. I have no objection to paying pharmacists well but to justify those payments, the profession of pharmacy must reform itself drastically as a scientific profession, handling, for example, the major task of disseminating objective information on drugs. The pharmacist does not deserve this sort of income merely for handling packaged drugs, which is too often the case at present. If pharmacy can take on this new task, that of itself will improve prescribing, directing the physician towards the best drugs rather than those with the best advertising.

That brings me to the physicians, who have to be better educated about therapy—and I deliberately avoid the word drugs—than they have been up to now. No codes, no laws, and no amount of imposed regulation will

protect the doctor from nonsense and persuasion if he/she is not better informed, irrespective of whether he/she works in an industrialized or Third World country. The medical profession has the industry it deserves; if doctors are gullible, why should detailmen make any effort to present them with material of a high standard?

Finally, in this list of desiderata, there has to be an open social dialogue on the pattern of therapeutic research which society needs. More money should be going into drugs of entirely new types—into releasers, specific enzyme inhibitors, lysozyme-bound active agents, and the exploitation and mobilization of traditional knowledge—rather than unadventurous and wasteful excursions into 'me-tooism'.

It is much more difficult to suggest how to straighten out the unhappy mental and social condition in which part of the industry finds itself. The industry is not coherent enough to undertake the task jointly, for some of the most miserable sinners are companies outside any form of association or federation. Individual companies which become too puritanical may find themselves paralyzed in their competitiveness with the less scrupulous. I think things will improve if we can achieve a more honest and open debate, both inside and outside industry, where people are better informed and more honest with themselves than hitherto. All the pressures exerted on industry, even if they sometimes engender paranoia within its ranks, are also clearly doing some good; they are at least stimulating rethinking.

One major question is whether international or regional organizations can do anything to help. In recent years a lot of people have begun to feel regional bodies have greater authority and power to bring about change than global organizations. In this particular field, I would disagree. Bodies such as the European Economic Community have indeed been endowed with greater powers but also with a great measure of conservatism and inertia when it comes to planning ahead or fundamentally changing society's deficiencies. The EEC is very much an economic community, with a vast industrial influence and only a very secondary interest in health matters; bearing in mind its activities to date, it is highly debatable whether it is capable of sparking off fundamental change.

I still believe that the WHO can achieve more. From time to time there is criticism of the WHO's hesitance on the drugs issue, but it is not uncommon for the world community to blame the organs of the United Nations for faults which are the community's own and for a degree of inertia which it has itself imposed. An international agency of the UN is no stronger than the

community which it represents. Having somewhat hesitantly established the United Nations in 1945, the countries of the world have subsequently spent much time and effort in preventing it from attaining the goals which were set for it. The world is certainly not ripe for any supranational, global, forceful approach to correcting its ills, either in the drug field or any other. What an organ like the WHO can do on issues like this is to provide a forum for broad social debate, to suggest approaches, to carry out experiments and to show where successes emerge. Quite apart from that, it can create impressive and concrete programmes—like those on Essential Drugs, Tropical Disease Research and Human Fertility—which can affect the situation in a very important manner indeed. Finally, it can marshall facts and, quietly, with its enormous moral and scientific reputation, help and advise individual countries in their policies. It is happening already, and in what seems to be the right direction. It may be the best means we have of marshalling and coordinating all the influences which we need to bring to bear to improve things.

The industry in the year 2000

I would like to sketch something of the picture which the pharmaceutical industry should present by the year 2000. It is a status which it can attain partly under the influence of all the forces which are currently working on it, and partly by self-discipline and careful planning. The following points are conceived mainly with a view to what is likely to happen in those countries with a competitive economy; I entirely appreciate that in a planned economy different influences will operate.

1. The greater part of the prescription pharmaceutical industry will be organized in sufficiently large units to be able to undertake sophisticated basic and applied research in order to develop truly innovative products, large enough to survive comfortably between innovations without the need to introduce the third-rate or maintain the outdated, and large enough to provide its goods and services worldwide and not merely to the most lucrative sectors of the market.

2. The research which it does will be aimed at developing new prophylactic and therapeutic techniques which can be exploited commercially but will often not entail administering chemical substances. In part, therefore, it will become a medical industry rather than a purely pharmaceutical one.

3. The prescription pharmaceutical business will continue to be an important provider of information using up-to-date techniques, but the standards of that information, provided to a much better educated and more critical medical profession, will greatly improve.

4. Finally, alongside this transnational macro-industry there will be room for a new ethically based industry, studying and exploiting traditional knowledge, much of which may well prove to be unsuitable to standardized mass production approaches.

In conclusion: if we want the pharmaceutical industry to be not only physically healthy but also socially healthy by the year 2000 a lot has to change. Part of that process of change has started; part has as yet hardly been contemplated. It is in the interests of everyone that this should happen. It is a field where the commercial rewards can be high, but there is also a price to be paid for this: if profits are excessive, the industry is likely to be increasingly exposed to both reasonable and unreasonable criticism. The pharmaceutical industry cannot please all the people all the time, but at least sections of the industry should be seen to be trying harder than they have been so far. At the very least, people working in this industry should be as open as possible about their motives, activities and faults. This is a high-risk industry which must deliver a high rate of return on investment if that investment is to continue to be attracted and not diverted into other fields of industrial endeavour; the return is currently, however, often higher and sometimes much higher than it need be. We have to find a balance. If such a balance can be assured by the year 2000, we shall have come a long way.

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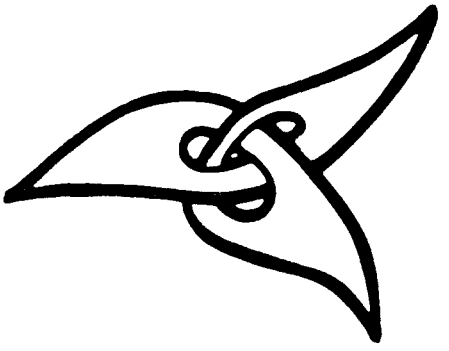
FROM THE OUTSIDE LOOKING IN
Experiences in 'Barefoot Economics'



Manfred A Max-Neef

In this volume, Manfred Max-Neef relates two of his experiences in 'barefoot economics'. In his own words: 'The first is about the miseries of Indian and black peasants in the Sierra and coastal jungle of Ecuador. The second is about the miseries of craftsmen and artisans in a small region of Brazil. The former is, in a way, the story of a success that failed. The latter is, in a way, the story of a failure that succeeded. Both refer to a people's quest for self-reliance. Both are lessons in economics as practised at the human scale.'

The book emerged out of the author's personal crisis as an economist. He points out that economics has become *the* magic science of our time: the one to provide the answers to most of the problems affecting humanity.

As a consequence its practitioners, newly endowed with unexpected power to exercise their influence over enterprises, interest groups and governments, have swiftly and proudly taken for granted their new role as inaccessible and powerful sorcerers.

Hence, he concludes, economists have become dangerous people and economics—originally the offspring of moral philosophy—has lost a good deal of its human dimension, which has been replaced by fancy theories and technical trivialities that are incomprehensible to most and useful to none, except to their authors who sometimes win prizes with them.

In Max-Neef's own words: 'The fact that I was living in a world in which, despite all kinds of transcendental conferences, accumulated knowledge and information, grand economic and social plans and "development decades", increasing poverty—in relative as well as in absolute terms—is as indisputable a statistical trend as it is an obvious and conspicuous fact to anyone just willing to look around and *see,* induced me to re-evaluate my role as an economist.'

Manfred Max-Neef is a Chilean economist, founder and Managing Director of the Centre for Study and Promotion of the Urban, Rural and Development Alternatives—CEPAUR.

FROM THE OUTSIDE LOOKING IN: Experiences in 'Barefoot Economics'. By Manfred A. Max-Neef, With a Foreword by Leopold Kohr.

Part One: The ECU-28 Project: Horizontal Communication for Peasants' Participation and Self-reliance.

Part Two: The 'Tiradentes Project': Revitalization of Small Cities for Self-reliance.

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Drug Policy in Nicaragua

Between Need-oriented Activities and Aggression

By Joan-Ramon Laporte and Gianni Tognoni

One important instrument in the struggle for Another Development in Pharmaceuticals is the WHO Action Programme on Essential Drugs and Vaccines. Although the Programme can only be said to form part of a comprehensive national drug policy, it has certainly inspired some Third World countries to take new initiatives towards more suitable policies in a field which for a long time has been open to all kinds of manoeuvres. In this case study from Nicaragua, an account is given of how the Essential Drugs Programme developed 'in a context which certainly reflects exceptional external political, economic and military pressures'. The overall picture is, however, 'by no means exceptional and could offer a useful guide to the issues behind such an apparently simple concept as the essential drugs list'.

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Introduction

The list of essential drugs published eight years ago by the WHO rapidly became one of the most successful and, at the same time, controversial documents to emanate from a United Nations agency. Its novel approach and the sensitivity of the issues at stake could be seen as ample justification for the reactions, which continued through the second edition. For the first time there was a proposal for a clearly formulated, immediately workable means of putting general recommendations, and inevitably often generic recommendations, into practice. The proposal was formulated by a panel of well-known experts from both Third World and industrialized countries and was the result of a very extensive consultation of health and academic authorities. It was able to claim technical credibility (no substantial criticisms have ever been made of it), while at the same time carrying an attractive and easily intelligible message, namely that with fewer than 200 cheap drugs the great majority of health problems can be dealt with very satisfactorily. The intensity of the opposition was in direct proportion to the sensitivity of the issue: the drug field is a traditional area of conflicting interests in medicine. The fact that the WHO appeared to become the leading force of a tendency thought to be the exclusive realm of minority radical or 'leftist' groups in industrialized countries, and of very poor and powerless Third World countries, could be seen as an ominous sign of a dangerous trend which might spread to other health areas. As is so often the case, the hot controversies simmered down to become mutually acceptable

Table 1 Some features of the Nicaraguan Unified National Health System (SNUS)

Principles	Health is a right of all people and the responsibility of the state and organized people.
	Health services will be accessible to all the population and will cover all their needs.
	Health activities must be planned and multidisciplinary.
	The community must participate in all the activities which are related to the management of the SNUS.
	Research must be directed to the optimum use of available resources, so as to guarantee the efficiency needed in a situation of prolonged austerity, and at the same time it must allow training and scientific development.
Organization	The Ministry of Health, with vice ministries specifically devoted to preventive medicine, primary health care, people's education, and training.
	Health regions, with directorships with decentralized executive capacity and responsibility for the regional health structures.
	Health areas, defined by geographic and accessibility criteria, of 15-80 000 inhabitants, with people's councils which guarantee and verify coherent functioning.
	Three-level coordinated structures: hospitals, health centres with beds, primary health centres.
	Close integration between health technicians (physicians, nurses, auxiliary personnel) and other 'non technical' operators with continuously problem-oriented up-to-date training: 'brigadistas' (health volunteers) and 'parteras empiricas' (traditional midwives).

formal agreements and promises of cooperation between the WHO and the drug industry. The real question remained how to implement the challenge raised by the document in the daily life of countries where even the idea, let alone the practice, of meeting the needs of the majority with 'essential' tools was far from being clear or practicable. The cultural background of medicine tends to the opposite: the coincidence of technical and administrative intelligence and openness is far from being a normal occurrence, yet it is an absolute prerequisite if the idea is to succeed and economic and commercial pressures are obviously unlikely to disappear as the result of publishing a well-designed document.

A fully implemented global drugs policy is a success story which still has to be written, and no doubt it would tell us much about the potential and the problems of the wider issue of Health for All by the Year 2000 (Health-2000). A model case, however, could be the drugs policy of Nicaragua after

Table 2 Some achievements of the Nicaraguan Unified National Health System (SNUS)*

- The percentage of the working population covered by social security has doubled, from 16 per cent to 32 per cent. Most of the newly covered groups work in the formerly neglected agricultural sectors in outlying parts of the country.
- More than 80 per cent of the population now has some regular access to medical care.
- Since 1977, hospitalizations and surgical procedures have risen more than 50 per cent, outpatient medical visits have nearly tripled, and the number of vaccinations administered has more than quadrupled.
- There are two and a half times more primary health units, while the number of hospital beds has risen only slightly.
- Equitable distribution: in 1980 there was a 4:1 ratio between areas with the highest and lowest rates of outpatients visits per capita; by 1982 this was reduced to a 3:1 spread. In the same period, the variation in hospitalization rates was reduced from 2.5:1 to 2:1. In 1980 the variation in doctors per capita between the best and worst served areas was 16:1, while for nurses it was 5:1; by 1982 these had been reduced to 3:1 and 2.5:1 respectively.
- Health campaigns: immunization, malaria prophylaxis, and sanitation campaigns. Up to 10 per cent of the people in the country were mobilized as health volunteers ('brigadistas'); there are now 25,000 permanent 'brigadistas'.
- It is estimated that between 1978 and 1983 infant mortality decreased from 121 to 80.2 per 1000 live births; life expectancy at birth rose from 52 to 59 years.
- The number of reported malaria cases has decreased by 50 per cent; polio cases have not been reported for two years; no measles cases were reported in the first half of 1984.
- Diarrhoea has fallen from the first to the fourth most common cause of hospital mortality.

* Data from Garfield, R.M., and Taboada, E., *American Journal of Public Health*, 1984, 1138-1144.

the Sandinista revolution, the topic of this article. Its achievements and failures are framed in a context which certainly reflects exceptional external political, economic and military pressures. The overall picture, however, is by no means exceptional and could offer a useful guide to the issues behind such an apparently simple concept as the essential drugs list.

Terms of reference

The health policy adopted by the Nicaraguan authorities, after the Sandinistas overthrew the 40-year-old Somoza dictatorship and gave this small country of three million people the first chance of a life in freedom, is universally recognized as an example of what should be done towards 'Health for All by the Year 2000'.

The few descriptive data which are presented in Tables 1 and 2 summarize some of the main features and achievements which justify such a favourable judgement. The performance is all the more impressive as it has been

pursued and is being maintained against highly unfavourable 'external' conditions which are a continuous threat to any rational planning and consolidation. A health system in which the interests of the majority and the adoption of a decentralized distribution of resources are the rule, is the 'natural' framework for a policy based on the concept of essential drugs. This policy should include the following items:

1. *Planning:* definition of needs and priorities; legislative and organizational measures.

2. *Drug selection:* definition of a national formulary and its experimental application.

3. *Drug supply:* evaluation of quantities; definition of supply conditions (importation, local production); quality control.

4. *Distribution:* management of central warehouse; distribution to rural areas; qualitative and quantitative evaluation of drug consumption.

5. *Prescription and use:* up-to-date drug information for health workers; information to patients.

6. *Routine follow-up:* coordination of the whole system; evaluation of its efficiency and quality, and introduction of adequate improvements.

The need for specific training programmes of selected health workers (at central as well as at peripheral levels) must be stressed in connection with the first five items.

From principles to practice

From the position of someone who has lived inside the country and followed the development of Nicaragua's drugs policy from the very beginning, it is interesting to look at it now from two different points of view, which could be seen as either opposed or complementary. The first view is to see it as a mainly straight path, which proceeds rapidly enough from the initial revision of a drug registry—which reflected the infamously low quality of the drugs scene in Central American countries—to the annotated version of a carefully selected National Formulary which serves as a bridge between the national health service and the teaching of clinical pharmacology (see Table 3). The second view sees it as a more crooked path, beset with the difficulties, delays and contradictions which have accompanied and still threaten the implementation of a satisfactory drug policy, and which obviously comprise both medical and managerial aspects (see Table 4). The

Table 3 Promoting a healthy use of drugs in Nicaragua

1981	First revision of the almost 4,500 registered pharmaceutical specialities and discussion of a hypothetical National Drug Formulary (*Formulario Terapéutico Nacional,* FTN) according to the essential drugs principles.
	Proposals for a reorganization of the supply and distribution system.
	Revision of the Drug Law for drug registration.
1982	Formal proposal and presentation of a FTN to be discussed with GPs and consultants.
1983	First discussion of the FTN with groups of consultants.
	Evaluation of needs for the training of pharmacists.
	Proposals for mechanisms for consumption control at central and peripheral levels.
	Approval and financing of the pharmaceutical programme by the WHO.
1984	Preparation of the FTN: lists of drugs for each 'level' of health care and definitive general list.
	Preparation of the annotated formulary.
1985	Publication and distribution of the annotated formulary.
	Adoption of the annotated formulary as the main reference textbook at the University training programmes started at the Universitat Autónoma, Barcelona (drug information, drug evaluation, drug selection, drug monitoring), PAHO and Instituto de Cooperación Iberoamericana.

lack of integration between the two paths appears to be a constant critical feature of the drug scene, as it seems both to belong to the sphere of competence of the ministries of industry and of economic planning, and to obey priorities established by the health ministries. The coexistence of the two paths is an unavoidable consequence of the fact that drugs must be bought, and they therefore represent a problem of financial viability over and above a question of scientific medical decision. This constraint, which is at the forefront in Third World countries, mirrors the situation in most industrialized countries, where a market dominated by the pharmaceutical industry is the key determinant of drug registration and prescription. Recently, the inevitability of the situation has been questioned through various initiatives in the field of clinical pharmacology and drug policy. It is tempting to imagine that the same perspective could be employed in Third World countries.

For a need- and science-oriented drug policy

The criteria for including drugs in the National Formulary were those of the WHO report on essential drugs, i.e. proven efficacy, acceptable risks associated with their use, favourable cost, and need. Drugs were classified

Table 4 The 'confounding' variables: underdevelopment and aggression

• Total absence of medical or pharmaceutical staff with competence in clinical pharmacology at the Health Ministry.	
• Initially, difficult relationships with the representatives of the consultants, problems in gaining their support.	
• Economic blockade hampers the supply of essential drugs in certain markets.	
• Delays in the supply are complicated by attacks on the ports.	
• Some indications of the military aggression:	
Total material damage (1983):	128.1 million US$ (equal to 31 per cent of exports, 3 per cent of GNP, 20 per cent of investments, 6 per cent of consumption)
Direct damage by submarine mines to ships:	9.1 million US$
Decrease of foreign financial support from multilateral organizations:	1980 = 32.3 per cent; 1983 = 15.6 per cent
Government military budget:	1982 = 18 per cent; 1983 = 20 per cent; 1984 = 25 per cent; 1985 = 40 per cent
Population necessarily reallocated from war zones:	114,000 people
Damage to health structures:	US$ 1,000,000: destruction of at least 19 health centres plus 16 health workers killed, 27 others seriously wounded, and 30 kidnapped and tortured. 3 health educators, 7 medical students, and at least 40 health volunteers have been killed by the contras.

in therapeutic groups following the general classification of the WHO Technical Report, and they were divided according to certain criteria into three priority groups:

1. Sixty-five priority drugs, of general use, which can be used by physicians and nurses, since they are associated with small risks. They are used at all levels of health care, and they can help to solve almost all pathology not needing the support of special diagnostic techniques.

2. Three hundred and forty-three drugs whose use requires clinical pharmacological knowledge, the support of diagnostic tools or, in the absence of these the clinical skill of a consultant. With these, and those in group 1, 100 per cent of primary health care and almost all secondary health care can be guaranteed. The supply of some of them has top priority.

3. Seventy-six drugs whose use is associated with substantial risks, and therefore require the keeping of adequate records. It is considered top priority to have certain but not all of these drugs available.

Drugs were also classified according to the level of the health system where they are to be used, with the aim of better planning their supply and distribution.

The proposal of the basic list of drugs, classified in therapeutic groups and according to their priority and level of use, was prepared by a central Committee for the National Drug Formulary. This included a majority of representatives from different medical specialities, and representatives from the central Ministry of Health organization. The list was circulated among committees and health centres, together with a form where health workers could propose the inclusion or exclusion of particular drugs and give the reasons for their proposals. These were examined at central level and decisions were taken by the National Formulary Committee regarding inclusion and exclusion proposals, and classifications according to priority and health system levels.

An annotated Formulary was prepared by two coordinated groups of WHO/PAHO* (Division of Clinical Pharmacology, Universitat Autónoma de Barcelona, and Mario Negri Institute for Pharmacological Research, Milan), and 3,000 copies were published with the financial support of the Spanish Ministry of Health and the Spanish 'Instituto de Cooperación Iberoamericana'. This annotated text aims to ensure consistency with rigorous scientific standards, to meet the needs of daily practice and to use straightforward language. Drugs which were already part of a national or regional preventive or disease-oriented programme were included with the same indications as in the programme (i.e. malaria, tuberculosis, leishmaniasis, etc.).

The annotated therapeutic formulary has been distributed to all physicians, other health workers responsible for peripheral health centres, pharmacists, and students in the School of Medicine. It has been adopted as the main reference textbook for teaching clinical pharmacology and therapeutics to medical students. This is particularly important, as almost 500 new doctors graduate each year, in a country with little more than 2,500 doctors.

* Pan-American Health Organization

A training programme in clinical pharmacology has been started at the Universitat Autónoma de Barcelona. This pays particular attention to drug evaluation, drug epidemiology methods (clinical trials, epidemiological methods for the detection and risk evaluation of adverse drug reactions, and estimation of comparative benefit/risk ratios), and retrieval and preparation of drug information for health workers.

This brief description is not an artificial attempt to claim a perfect correspondence between theory and practice. Nor is it a eulogy of the favourable context offered by the Nicaraguan Unified Health Service (SNUS) for a healthy drug policy, nor a saga of the unfavourable conditions which have been created by the aggression. Rather, it is an attempt to investigate how the essential drugs theory can be developed in practice, in a context where a people is looking for its own route to freedom.

The effect upon public health of this dramatic yet well-planned change in drug policies in Nicaragua deserves to be carefully monitored in the years to come.

An International Society of Drug Bulletins

Prescribers in all countries need reliable comparative information about alternative treatments that are available for a given health problem. In many countries one or more bulletins exist which publish such critical assessments of drugs. Since drugs are international, and the problems of choosing between them have much in common in different countries, bulletins in different countries share many concerns in detail, not only the same general approach to drug evaluation. Those who produce bulletins therefore help one another and use their skills more effectively and efficiently. Relatively few people have the skills required for the critical assessment of drugs. Such assessment needs not only a knowledge of medicine, but also of clinical and experimental pharmacology. Even fewer people are able to express balanced critical appraisals in a way which prescribers find easy to read and understand. These are the reasons for establishing an International Society of Drug Bulletins. Its aims are to help its members to work together, and to encourage and support the development of bulletins in countries where they are needed but do not yet exist. The Society will be formally established at a meeting in Stockholm on August 1 and 2, 1986.

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Summary Conclusions

These Summary Conclusions give an account of the main points made during the discussions at the Dag Hammarskjöld Seminar on Another Development in Pharmaceuticals, organized by the Dag Hammarskjöld Foundation in Uppsala, June 3-6, 1985.

Introduction

All the parties concerned—governments, the pharmaceutical industry, health care workers, consumer groups and ordinary people—agree that an international state of crisis exists which affects the development, production, distribution and use of pharmaceuticals. The main elements of the crisis identified during the discussions at the Dag Hammarskjöld Centre in Uppsala were:

- *Under-medication* of the poor, particularly in the Third World, who cannot afford or obtain access to essential pharmaceuticals—the result: death and suffering which could be prevented.
- *Over-medication* of large segments of the population, particularly in the industrialized countries, who could be better treated by more selective drug therapy or by non-drug therapies—the result: an increase of drug-induced diseases and profligate waste of scarce health care resources.
- *Excessive and irresponsible promotion* which creates false demands for pharmaceuticals among physicians and consumers.
- *Misdirected innovation* which sees much too low a proportion of industry resources dedicated to developing genuine therapeutic breakthroughs and almost none devoted to tropical diseases.
- *Inadequate training of health care workers,* be they doctors or medical assistants, who often are insufficiently schooled in drug matters and often do not give the right drugs in right amounts at the right time. Even if the health care worker gets it right, the patient often gets it wrong by failing to comply with treatment instructions or—as is frequently the case in the Third World—by running out of money before a course of treatment is completed. Thus, potentially good drugs may turn out to be useless or even harmful in practice.
- *Alienation of consumers* from control of their own health in overly professionalized and commercialized health care systems leaving them with little personal understanding of or control over their own health situation.

The fundamental solution to these problems is to have a clear perception of the goal. The goal is health, not pharmaceuticals. There will be less confusion and better understanding if these problems are analysed by applying the principles of Another Development. Thus, policies in the phar-

The views incorporated in the Summary Conclusions do not necessarily represent a consensus of all participants on every issue. They reflect rather the conceptual space covered by the discussion. It should furthermore be noted that the participants were expressing themselves in their personal capacities, that is, without committing the organizations or governments to which they belong. A list of participants is attached.

maceutical field must be problem-centred and people-centred rather than drug-centred.

Another Development and pharmaceuticals

A problem-centred and people-centred policy in pharmaceuticals should be *need-oriented* in accordance with the first principle of Another Development. Under-medication and over-medication are equally unacceptable, but the co-existence of the two is especially damaging. Fewer but better and more appropriate drugs will better meet human needs at lower social cost; this can be achieved, *inter alia,* by reallocating resources from expenditure on promotion to investment in research and by redistribution of capacity within the research sector from development of inessential drugs to truly innovative ventures.

Second, Another Development in Pharmaceuticals should be *endogenous,* that is, drawing in the first instance on the cultural and material resources available to each society. Pharmaceutical development policies, while benefiting from what has been done elsewhere in the world, must grow from each society's vision of its future—Third World drug policies cannot continue to be bankrupted by a diet of 'rich man's drugs'.

Third, pharmaceutical policies must be *self-reliant.* The mystique of professional monopolies of expertise which deny consumers information, and transnational corporation monopolies of technology which deny industrial development to the South, must be shattered. Third World governments in particular must exercise greater control over the whole drug supply chain to ensure that it better serves the needs of its citizens.

Fourth, pharmaceutical policies must be *ecologically sound.* In a sense, Another Development in Pharmaceuticals is about avoiding unnecessary pollution of patients' bodies with toxic chemicals. The challenge of manufacturing pharmaceuticals without serious pollution of the environment or exposure of workers to chemical hazards is not a great one, yet not all pharmaceutical manufacturers have met this challenge.

Fifth, Another Development in Pharmaceuticals must be *based on structural transformations.* The pharmaceuticals market should be replaced by programmes and therapies for better health, some of which will involve pharmaceuticals, others which will involve getting people off unnecessary or unhelpful drugs, often by offering more satisfactory ways of alleviating symptoms or avoiding illness. The crisis in pharmaceuticals will be solved only by a profound change in the structure of the market, the nature of the industry, the training of health workers and in the thinking of a community

which has been seduced into believing that every ill can be solved by a little pill.

Man and medicines: the historical perspective

The recent history of pharmaceuticals is characterized by a period of remarkable faith in the ability of modern medicines to improve health dramatically. In industrialized countries this faith has been attributed to such phenomena as a growing secularization, rejecting the older view that illness was punishment for sin, and the empirical observation that immunization and antibiotics saved lives. These perceptions led some people to sit back passively taking pills, in the comfortable belief that in this way health could be had with a minimum of effort.

In Third World countries too, the eradication of smallpox, the dramatic benefits from yaws campaigns and other appropriate uses of antibiotics created a faith in drugs as offering deliverance from misery. In all types of societies, the role of doctors who commanded the mysteries of powerful drugs tended to shift from that of humble servants to custodians of the new salvation.

However, the foundations of this euphoria are also rooted in a long history and tradition of utilizing herbs, plants and other therapies to deal with illness. Perhaps more important, however, than the actual nature of the remedies used in the past was the whole perception of the nature of illness and the healing process as well as a different and slower concept of time. This led, in many cases, to the selection of therapies which enhanced the healing process and were concerned with treating the *whole being* rather than simply targeting a specific symptom or cause of ill health, an approach which stands in stark contrast to the modern perception that there is or should be an instant cure in the form of a pill for every ill. Unquestionably, however, some of the remedies used were either ineffective or even dangerous. Over the centuries, too, there are many examples of exploitative individuals who have misused both older beliefs and newer knowledge to profit from the ignorance and fears of people who were suffering from disease.

There has been too much of a tendency to dismiss traditional medicine as unscientific, magic and superstitious, while accepting unquestioningly all that is new. The current market in mass-produced traditional remedies unfortunately includes too many products which are only marginally effective or safe, and too many which can be used only for treating superficial and self-limiting conditions; some parts of the market owe more to the

charlatans of the past than to either older or newer knowledge. These shortcomings should not lead to a rejection of all that is good in traditional knowledge and experience.

The traditional approach to health care is most readily visible in Third World societies, particularly those in which the high cost of modern pharmaceuticals prohibits their extensive use. However, in industrialized settings too, some people are now beginning to concentrate more on diet, exercise, and meditation as a means of relieving stress, in preference to the consumption of tablets.

It thus becomes evident that pharmaceutical therapy is rarely the sole alternative in the restoration of health. Other forms of therapy, especially preventive measures, should be utilized to their fullest extent. Traditional forms of medicine may sometimes yield better results than those which can be obtained by the use of modern pharmaceuticals. But one must, in this context, beware of the tendency towards exploitation of the 'back to nature' movement by people who do not understand (and are not interested in) the traditional concept of herbs as a part of total health care and instead deal with them just as they deal with synthetic drugs and, in the more extreme cases, prescribe scientifically indefensible concoctions of both.

Towards a healthy use of pharmaceuticals

Discussion of the healthy use of pharmaceuticals focused on five main issues, which, if properly resolved, would be conducive to Another Development: (i) the extent of useful innovation; (ii) the usefulness of information; (iii) the integrity of promotional activity; (iv) the extent of drug distribution; and (v) the effectiveness of drug regulation.

Drug innovation geared specifically to Third World needs accounts for an estimated one per cent of the international industry's research and development expenditure. There is still no prophylaxis or effective treatment for many of the tropical diseases of the Third World. A far higher priority also needs to be given to drug delivery systems suitable for use in primary health care programmes: for example, drugs given in a single dose, for administration other than by injection, not requiring refrigeration and so forth.

Useful drug innovation should be strongly encouraged. However, it must be recognized that, in most countries, probably less than one 'new' drug in 20 entering the market offers any worthwhile gain on what is already available. Research and development efforts which lead to the introduction of 'me-too' drugs and/or indefensible fixed combinations of drugs are unwelcome. They lead to a confusing proliferation of products, too many to

be evaluated properly by a government registration authority and/or to be used effectively by prescribers. The number of drug products that are either needed or worth having represent, in most countries, a very small proportion of the total numbers currently available.

Drug selection and use tend to be greatly complicated also because of vast quantities of less-than-useful information about drugs, notably that provided in advertisements in journals and, via company representatives, by word of mouth. Among the information given—often at a cost of thousands of dollars per prescriber per year—may be found useful information on the properties and uses of individual products, but the ratio of 'lean' information to 'fat' tends to be very low indeed. In particular, comparative data enabling the doctor to choose the right drug for the individual patient, are usually lacking. The overwhelming effect of the information available is to impress upon health care workers the value of drug treatments over alternatives and to endorse particular brands. The lack of any analogous influence on doctors to use nutritional, physiotherapeutic or other non-drug approaches results in a considerable distortion of medical practice. The quality of treatment suffers measurably as a result—as it also does as a result of the usually negligible amounts of drug information that are made available to patients.

Very little of the industry's promotional effort can honestly be said to improve the quality of patient care—and much of it has the opposite effect, in part by helping to sustain a market that is over-burdened with duplicative, indifferent and poor products. The effects of drug promotion may be particularly pernicious in situations in which doctors supplement their basic income by dispensing the drugs they prescribe—as is particularly the case in many Third World countries. Both the quality and the amount of promotional activity need to be tightly controlled. What is needed is more independently produced information and far less commercial propaganda about drugs.

In the Third World, particular emphasis must also be placed on improving the distribution of essential drugs to the rural periphery. Effective distribution is more difficult to organize with a multiplicity of drugs in use. Improved distribution systems might be expected to encourage a shift in commercial strategies—away from high mark-up drugs sold to a relatively small urban elite, towards a high-volume, low mark-up strategy. This would benefit consumers in the Third World and would not necessarily impair valid commercial interests.

However, few of the necessary major reforms can be expected to take place either on a piecemeal basis or through self-regulation by drug producing interests themselves. Short-term commercial ambitions—which affect business enterprises and the major drug producing nations alike—have proved to a considerable extent to prevent and/or obstruct the proper use of medicines. In the absence of tight supervision and careful monitoring, this situation cannot be expected to improve.

We have concluded that the present crisis is an international problem, and demands international action. Nothing will really change in the absence of far greater determination by the international community to improve the present state of affairs. Here it is necessary that the first system, i.e. governments, the second system, i.e. the corporations, and the third system, i.e. the citizens and their associations, cooperate in the interest of the overriding goal, Health for All by the Year 2000.

It is now up to the international community to bring about two major shifts in current practice. The first is to restrict (or at least render less commercially attractive) the supply of drugs for which there is no real medical need. The second is to supervise the ways in which and the extent to which drugs are promoted for use.

To this end, we propose, *inter alia*, an extension of the WHO's 'essential drug' concept and a system whereby all pharmaceutical products and all means used to promote their use should be subject to a formal 'health impact evaluation'. The objective would be to encourage all countries to set their own standards for the use of drugs, but to ensure that these standards are based on clearly established local need.

More specifically, we envisage a system in which approvals for human and animal pharmaceuticals and human medical technologies would be based in all countries on 'health impact statements'—similar to the 'environmental impact statements', now widely used throughout the USA. The public information in these impact statements should include complete data on:

1. Drug uses and efficacy in relation to both drug and non-drug alternatives.

2. The relationship—both qualitative and quantitative—between the therapeutic benefits and likely adverse effects of a drug, considering how it is likely to be used.

3. The need for the product—taking into account also its cost—in relation to alternatives.

4. How, when and for whom the drug should and should not normally be used, and the situations in which it should not be used.

The impact of the methods used to promote particular drugs should be similarly evaluated and checked in practice—and in both cases, the content of these health impact statements should be regularly reviewed and revised.

Health impact statements of this type would represent only a modest extension of existing regulatory requirements, e.g. many countries already require cost/benefit calculations from producers before approving a new drug for health insurance reimbursement.

Analogous health impact statements might well be instituted for new animal pharmaceuticals and for human medical technologies as well, in view of the possible effects of these on public health.

Towards a healthy pharmaceutical industry by the year 2000

A pharmaceutical industry which contributes to Health for All by the Year 2000 deserves general support. The world is indebted to the pharmaceutical industry for many of the life-saving chemical solutions made available to existing, pressing health problems. These solutions have, however, as pointed out above, been directed largely towards the health needs of the industrialized countries and only to a limited extent to those of the Third World. In addition, the industry has attained and maintained its high-level turnover, partly by encouraging the vision of health problems as solvable only by technological means. A contrived pill-popping culture may be in the short-term economic interest of the pharmaceutical industry. It is not, however, in the interest of long-term, endogenous, self-reliant health development—and is almost certainly not in the long-term interest of the industry itself.

Ultimately, the pharmaceutical industry runs the risk of suffering from a massive consumer backlash against its products, unless it recognizes that people want and will increasingly demand to be treated as intelligent human beings with a right to understand and select the treatments they are undergoing and not as mindless pill receptacles. Paradoxically, the pharmaceutical industry's health depends in the long run on its willingness to state when consumption of its products is a bad idea.

Another Development in Pharmaceuticals means a proposal to the industry to ponder whether higher profits in the short-term from the marketing of drugs to meet imaginary needs of the wealthy is a wise policy or if it means building a future on a foundation of sand. It may be that the companies which cultivate the growth markets of the Third World with research and development on pathologies which exist in massive numbers among the poor will be the companies more likely to be around 20 years from now.

Under a 'new world therapeutic order' some companies will be winners and some will be losers. The winners will be those which satisfy real needs with genuine therapeutic breakthroughs and those which recognize that the industry is uniquely one which depends for success on its reputation. This, in turn, depends on substance, not image—on the reality of useful products and effective cures. The losers will be those that scoff at their critics, or even attempt to suppress honest criticism or render it suspect.

The companies most likely to fit into a 'new world therapeutic order' may also be those which negotiate with their critics in the consumer movements and in the health care professions. This is because it is the companies who listen and respond to the increasing assaults on their reputations who will find the capacity to build a new industrial base out of their responsiveness.That new base may involve more than simply producing drugs; the pharmaceutical industry could become a genuine health care industry by promoting non-drug approaches to the maintenance of health and the treatment of illness.

The critics of the present situation should not aspire to convert the entire pharmaceutical industry to their cause. They will accelerate change by concentrating their energies on dialogue with the new managers of the health-centred companies whom they would like to see grow while bringing increased public pressure on the drug-centred companies.

Life-saving therapies are not like any other commodity. They are a right of every citizen in the world. The pharmaceutical industry has been and remains a highly profitable one. This profitability will be threatened unless the industry is willing to negotiate on policies to guarantee all citizens their right to safe, effective, affordable and socially contextualized therapy. There can be no single grand forum for this negotiation. It should occur on many fronts—international (e.g. WHO, UNIDO, UNCTAD, UNICEF, UNCTC, IFPMA, IOCU, HAI, etc.), regional (e.g. ECA, ESCAP, ECLA, ASEAN, OAU, CARICOM), and national (e.g. national governments, national firms, NGOs). The willingness to engage in conversation as

an alternative to confrontation will, however, require a new state of mind of some of the parties which will manifest itself in new fora of dialogue being opened up at many levels.

While the industry will gain from entering into the total process of negotiation, it will obviously suffer some specific losses from concessions it gives as a result of the process. These concessions might include reduced expenditure on promotion, increased expenditure on information (including information on when *not* to use drug therapies), increased research on the health problems of the poor, a reduction in the number of drugs on the market, generic prescribing, transfer of technology to the Third World, a tightening of publicly accountable self-audit in areas like quality control as an alternative to government interventions, and so on. On the positive side, industry might win higher prices for products with real therapeutic advantages and a freer market in circumstances where both producers and consumers benefit from resulting efficiencies in distribution. It is, of course, impossible to specify in advance of the process of negotiation just what the industry would end up losing and winning. The point to be made is simply that negotiation is never a costless process for any of the parties involved. But nor is negotiation a zero-sum game. Conflicting parties can come out of negotiations both having suffered losses, yet both being better off than if the process of negotiation had never occurred.

The pharmaceuticals conflict as it has developed in the last two decades has often been one between powerful industry uncomfortable with public dialogue and impatient social movements demanding immediate improvement in world health. Many of the adversaries simply did not exist in the first half of this century, and this is why they have not yet developed a mature relationship. It is time for both sides of the debate to show greater sophistication. That does not mean an end to conflict and confrontation, but it does mean a beginning to give and take.

Towards an international code on pharmaceuticals

Although discussion of the crisis in pharmaceuticals has often concentrated on the practices of the pharmaceutical industry, it must be recognized that there are faults on all sides. Governments, physicians, pharmacists and drug users have often fallen into serious error in their policies. An international code for all the parties concerned is urgently needed to improve the use of pharmaceuticals.

The code envisaged would define the rights and responsibilities of governments, industry, health care workers and consumers with a view to receiving the widest possible support for a new approach. Since the goal is health

and not drugs, the code should be developed by WHO, which is the lead agency in this sector of the UN system.

Two possible approaches were considered—one involving a broad statement of principles, the other involving more detailed provisions for performance in areas like labelling, patient information, advertising and promotion, product registration, pricing and medical training and education. Neither of these is ideal: a statement of general principles runs the risk of being vague, even platitudinous. On the other hand, too detailed a schedule of requirements may make impossible or inappropriate demands on some countries, because of the sometimes very different styles and states of development of different health care systems. At the present stage of development it would also be likely to arouse formidable opposition from the international pharmaceutical industry—and from the principal drug producing nations which have become economically dependent upon the *status quo* and need time to accommodate to change. The best approach would be to compile a code which enunciates broad principles but which in selected crucial areas provides more detailed guidance. Such a comprehensive and easily accessible code would have the advantage over, for instance, a mere 'set of guidelines' that it can be systematically monitored and hence serve as a better instrument for the promotion of Another Development in Pharmaceuticals and can develop progressively as the situation improves.

The development of an international code would, *inter alia,* have the following objectives:

- equitable supply and access to appropriate drugs, globally and nationally;
- a drastic reduction in the number of brand-name drugs and mixtures, available for prescription. An adequate choice must remain, but the available drugs must not be superfluous to real medical need;
- the provision and control of information of all kinds—including information to consumers—to encourage the appropriate use of drugs, and to curb over-medication and other abuse.

Such a code would, however, be of little value without a mechanism for adjudication in areas of dispute. To this end, one should consider the setting-up of an international panel, with members nominated by government, industry, health care workers and consumers, to hear serious complaints of non-compliance with the code.

Natural justice and principles of openness and accountability would require that these should be, in general, public hearings. Clearly the panel would

need to be empowered to decline to hear frivolous or vexatious complaints. The panel would have no power to impose any formal sanctions on an actor found to have violated the code, but would simply make its determination public. It would then be up to governments and other concerned parties to take any further action. Provision should also be made for offering advisory opinions without public hearings; this could encourage hitherto adversarial parties to enter before the panel into a dialogue that they do not engage in today.

The international code itself would be totally oriented to uplifting corporate and professional responsibility through moral suasion. It would exercise its moral influence directly on the health profession, the pharmaceutical industry and consumers, and not only through governments.

Governments would, however, be requested under Article 62 of the Constitution of the World Health Organization to report annually on what actions they had taken to foster compliance with the code. National governments would for example be encouraged to change or set up their own regulatory system as appropriate in order to promote compliance with the international code.

Over time, the development of a 'case law' under the code would give it greater specificity. This development could be further promoted through the setting up of WHO Expert Committees to interpret and elaborate on specific items under the code as the need arises.

Failure to adopt a code along the lines proposed is likely to result in greater pressure for more comprehensive regulation and control. Moreover, the present adversarial climate would increase and lead to loss of confidence in medicine and further aggravate the crisis in pharmaceuticals.

Monitoring Another Development in Pharmaceuticals

Moving from the identification of the global crisis in pharmaceuticals and an outline of means to solve the crisis requires communication with those who can use the knowledge to change policies. Knowledge is power in the struggle for rational drug policies. And, because it is a global crisis, it requires a global campaign of information dissemination, action and accountability to ensure its resolution. Key actors in such a campaign include:

1. Pharmaceutical industry managers in the Third World who, even when their head offices adopt socially responsible promotional policies, themselves often yield to economic temptations to behave irresponsibly.

2. Government policy makers in the Third World who can implement a rational drug policy.

3. A network of NGOs (consumer groups, church groups, the kind of community organizations which were crucial in the breast milk substitutes campaign) who can in turn put pressure for reform on industry, the health professions and government.

4. Perhaps most importantly of all, doctors, pharmacists and other health care workers in the Third World. This group comprises both the 'doers' of drug policies and the most important large group of opinion leaders who can change attitudes.

5. The general public in all countries who must be encouraged to take responsibility for their own health care and to reject the view that all they need to do is wait for something to go wrong and then seek out pills for passive ingestion to restore health.

The information, which needs to be disseminated to these target audiences does in fact, as this seminar has concluded, already exist. It comprises both general information on problems, policies and solutions and technical information on individual drugs. However, the problems are:

- Reducing the mountains of paper to short, comprehensible messages on key issues.
- Presenting the information imaginatively in ways which will attract and hold the attention of people who are bombarded by many other messages, particularly competing messages from advertising professionals employed by the pharmaceutical industry.
- Tailoring the information in ways that are different for different audiences. Messages appropriate for doctors will not be suitable for lay audiences (community groups, politicians).
- Getting the appropriately packaged information out cheaply and in a timely fashion as new developments occur.

To facilitate this exchange of data a clearing house is needed, working, perhaps, as a collaborating centre of the WHO. The existence of a single respected, internationally recognized clearing house would mean that much important information which is presently being lost would be stored, and that the information which is collected together would be summarized, imaginatively presented and disseminated. Such a clearing house should be independent of any political or commercial influence, but it should maintain broad worldwide contacts with the many bodies involved in the field of

pharmaceuticals. It would itself collect, store and disseminate general information, including information on progressive policies being adopted in one country which other countries might be interested in using as a model. Technical information is already the province of the WHO itself, but the clearing house could handle the effective presentation and dissemination of these data as well.

An urgent challenge, therefore, is the identification of resources to enable the development of such a clearing house and the more general communication which is needed if the death and suffering caused by irrational drug use are to be tackled.

Monitoring Another Development in Pharmaceuticals means not only getting the information out, but also reporting back on whether the information is being acted upon. The eyes and ears in the Third World are already moving into place to do this—networks such as Health Action International, IOCU, professional associations, churches, universities, and the aid networks. The problem is coupling them to a central locus of feedback. Again the clearing house is the answer.

The role of such a technical clearing house must, however, not be exaggerated since it is only one of the instruments needed to come to grips with the present crisis situation. Of great importance in this context are the mass media; newspapers, journals and radio can play a major role in highlighting these increasingly complex global problems. An important contribution in the area of information and communication about the appropriate use of pharmaceuticals both in the Third World and the industrialized countries could be made by Inter Press Service Third World News Agency (IPS) through its regular news service and through its development feature service and specialized weekly bulletins covering science and technology, environmental matters and women's issues in Africa, Asia and Latin America. In addition, it should be possible to utilize the IPS Technological Information Pilot System (TIPS), funded basically by the UN Financial System for Science and Technology for Development and UNDP, when it begins to come into operation in mid-1986.

Using these instruments, it may be possible to create the conditions for an open debate on the pharmaceutical issues which have up to now been the almost exclusive preserve of comparatively small groups active in the health sector. The time has come for a comprehensive global discussion of and a global campaign for Another Development in Pharmaceuticals, involving

actors not only from the voluntary health organizations in the Third System but also other Third System organizations as well as representatives of the First and Second Systems, governments and industry.

Participants

John Braithwaite *(Australia);* Graham Dukes *(The Netherlands);* Mersie Ejigu *(Ethiopia);* Ann-Christin Filipsson *(Sweden);* Harris Gleckman *(USA);* Sven Hamrell *(Sweden);* Elina Hemminki *(Finland);* K. Jayasena *(Sri Lanka);* Joan-Ramon Laporte *(Spain);* Carol MacCormack *(United Kingdom);* Charles Medawar *(United Kingdom);* Leonard Ngcongco *(Botswana);* Olle Nordberg *(Sweden);* David Pitt *(Switzerland);* Ahmed Rhazaoui *(Morocco);* Claudio Sepulveda-Alvarez *(Thailand);* Mira Shiva *(India);* Hank Schut *(The Netherlands):* Bo Stenson *(Sweden);* Göran Sterky *(Sweden);* Göran Tomson *(Sweden).*

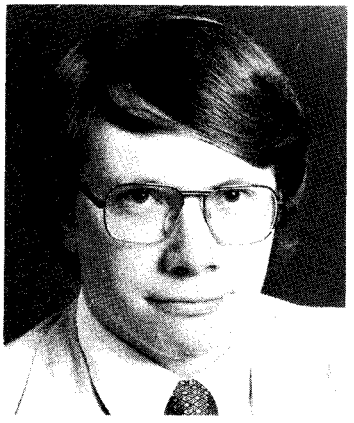
Book Review

Criminal Organizations

By Nils Christie

In this 400-page book John Braithwaite makes a thorough and critical study of the criminal behaviour of the pharmaceutical industry, drawing examples mainly from the United States and Australia. After reading this book few will be able to trust that industry as much as they did before, argues Nils Christie, Professor of Criminology at the University of Oslo, in this review and goes on: 'The description of criminal behaviour in this book is interesting and well organized but hardly new. Much of the material was known before. But the second part of the book is extremely stimulating, even for those well acquainted with the subject. Braithwaite raises some rather fundamental questions on how we can control this type of criminal behaviour. His final chapter, 100 pages on strategies for controlling corporate crime, is bound to become a classic within the theory of crime control.'

John Braithwaite is a Fellow of the Research School of Social Sciences at the Australian National University in Canberra.



John Braithwaite

John Braithwaite, *Corporate Crime in the Pharmaceutical Industry*, Routledge and Kegan Paul, 1984.

Many would see the pharmaceutical industry as one of the main pillars of people's health and well-being. Modern medical services were inconceivable without such an industry. Our trust in doctors extends into a trust in the medicine-makers.

Few will be able to feel that trust to the same extent after reading John Braithwaite's book. The topic is crime in the pharmaceutical industry. And crime it is, to an extent that shakes even one relatively accustomed to it.

The major cases are from USA, but the author has also made detailed studies in Australia, which is his home country, as well as in several Latin American countries. He has interviewed representatives from the drug industry and the various control agencies, and in particular investigated the files of these and other state or federal agencies. So well informed was he that it proved impossible for top management within the industry to brush him off. He was acquainted with so many of their secrets that they preferred to talk and to try to explain.

Seven types of criminal behaviour are predominant within the industry. The table of contents reveals them: bribery; negligence and fraud in safety testing of drugs; unsafe manufacturing practices; antitrust behaviour; the

Table 1 Summary of questionable payments disclosed to the SEC in the 1970s by US pharmaceutical companies

Company	US rank in pharmaceutical sales, 1977 (Gereffi, 1979)	Amount of questionable payments disclosed	Years of payments
Merck & Co	1	$3,603,635	1968-75
American Home Products	2	$3,442,000	1971-5
Warner-Lambert	3	$2,256,200	1971-5
Pfizer	4	$307,000	—
Upjohn	6	$4,245,949	1971-5
Squibb	7	$1,919,000	1971-6
Bristol-Myers	8	$3,034,570	1971-6
Schering-Plough	9	$1,094,702	1971-6
Abbot Laboratories	10	$774,000	1973-6
Johnson & Johnson	11	$990,000	1971-5
Cyanamid	12	$1,225,000	1971-5
SmithKline	13	$712,700	1971-6
G.D. Searle	14	$1,303,000	1973-5
Baxter-Travenol	15	$2,160,220	1970-6
Revlon	16	$189,600	1971-6
Dow	17	$197,000	1970-6
3M	18	$3,127,341	1970-5
Richardson-Merrell	19	$1,243,000	1971-5
Sterling Drug	20	$1,806,000	1970-5
Syntex	22	$225,000	1972-6
A.H. Robins	23	$228,000	1972-5
Miles	24	$400,000	1971-5
American Hospital Supply	Unranked	$5,800,000	1971-6
Rorer-Amchen	Unranked	over $837,000	1971-6
Morton-Norwich	Unranked	$245,000	1971-6
Carter-Wallace	Unranked	$631,150	—
Becton-Dickinson	Unranked	$182,000	—
Alcon	Unranked	$359,933	1971-6
Allergan	Unranked	$51,899	1971-5
Medtronic	—	$323,563	1973-7

corporation as pusher; dumping of medicine in the Third World; and fiddling with state money.

Bribery. Braithwaite has gone through the files of the US Securities and Exchange Commission (SEC). Due to lack of control capacity, the commission has allowed major American firms to submit reports on the type and volume of bribery in which they have taken part, but on the understanding that the would not be prosecuted if they registered it all with honesty. It is the sort of arrangement where a firm says: 'I did not do it, but I won't do it

again'. Table 1 reproduces some of the major findings. The figures involved are not small. Nor are the firms of minor importance. Braithwaite exposes and destroys the popular myth that criminal behaviour by and large is concentrated among small firms; those which poverty forces to attempt survival through criminal short-cuts. Again and again, he proves that big crimes are committed by big firms. Merck and Co. is the biggest pharmaceutical firm in the US and number two in the world. The other firms cited in Table 1 are not small fry either.

Fraud in safety testing. This is perhaps the most shocking practice, viewed with the perspective of the ordinary citizen in the western world. There is an endless variety of criminal acts, particularly related to fraudulent scientific behaviour. A classic case goes as follows: A laboratory was testing out a supposedly safe anticholesterol drug, but one monkey did not act according to the hypothesis. It stopped jumping, could not see properly, showed weight loss, etc., etc. A girl worker, who had grown fond of the animal was told not to report the findings, and the monkey was replaced in the experiment by one that had not received the drug. Reports were also changed on several other monkeys. The cover-up on animal testing was followed by a cover-up on human testing. Doctors took part in biased reporting, or lent their names to 'scientific' articles advocating the anti-cholesterol drug.

Unsafe manufacturing practice. Braithwaite documents an abundance of malpractices here as well. Sterile intravenous solutions ought to be sterile. Sometimes they are not, due to criminal negligence. To call back non-sterile solutions is an expensive procedure, involving loss of face. Better to take the risk that nothing goes wrong. Often it does go wrong. Pacemakers ought to be reliable. Often they are not, and certain firms know so. Again, there is no end to the examples.

Dumping in the Third World. This provides us with a sample of all that is most unpleasant in company behaviour. What is controlled and—slowly—diverted away from our drugstores, is on open sale here, supported by aggressive sales campaigns. As a general rule drugs in the Third World are credited with a *wider* area of possible efficacy and are generally claimed to be useful for many more ailments than within the industrialized world. And they are said to have a more *limited* range of possible bad side-effects.

For connoisseurs, the description of criminal behaviour in this book is interesting and well organized but hardly new. Much of the material was known before. But the second part of the book is extremely stimulating, even for those well acquainted with the subject. Braithwaite raises some

rather fundamental questions on how we can control this type of criminal behaviour. His final chapter, 100 pages on strategies for controlling corporate crime, is bound to become a classic within the theory of crime control.

His essential idea is that there is a fundamental difference between the control of individuals and the control of social systems. What you cannot do to individuals, you can do to firms, and vice versa.

First and foremost, it is generally accepted within criminology that *rehabilitation* of offenders is a discredited idea. It does not work, and attempts to make it work also raise several ethical problems. But on both counts corporations are in quite a different situation. As Braithwaite states: 'Rehabilitation is a more workable goal for corporate criminal law than for individual criminal law because organization charts can more easily be rearranged than human personalities'.

Secondly, while belief in *general prevention* or deterrence is not overwhelming, corporations are again in a different situation. Braithwaite points out that they have more (money) to lose, and are therefore more easily influenced by observing losses within other firms. I would like to add a further point and that is that the ethical considerations are of less importance vis à vis a business undertaking. To my mind, deterrence is based on a rather dubious morality. A is hurt in order to teach B, C and D a lesson. Human beings are *used*, pain is intentionally applied, not for the benefit of the person that is suffering, but for the benefit of other people and for other purposes. It offends several important ethical norms to use people as pedagogical examples, at least when they are caused to suffer for such a purpose. But corporations, as social systems, are quite another game. They are involved in clearly demarcated exchange relations: I give you something, and you give me something in return, with my contribution and your repayment both clearly accounted for. The relationship has, in theory, only one purpose: profit. The exchange of goods in such a relationship need not alter us as human beings, or affect us personally. Trade systems have to do with money, and *things*. Thus the same strong objections towards treating firms as pedagogical examples, as things cannot be raised. Punishment of firms is thus more acceptable than punishment of individuals.

Thirdly, *restitution to victims* and reparation to the community is a more feasible solution for firms than for individuals. These corporations have the capacity to pay, and a pool of expertise which makes possible reparatory acts of community service.

Fourthly, *questions of equal justice* also differ when it comes to crimes committed by corporations, compared with crimes committed by individuals. The system of control will never be able to prosecute all crimes within the area, not even all crimes clearly seen by the control agency. But since this goes on in the area of commerce, it can be argued that ideas of "just deserts" and punishment to all that deserve it, is of somewhat limited importance. In Braithwaite's words: '. . . giving regulators discretion to do deals with guilty corporations, to selectively forget "just deserts" in order to get corporations to cooperate with, for example, schemes to rapidly recall dangerous products, is in the public interest. The uniform and just treatment of offenders should never take precedence over protection of human life as the primary responsibility of pharmaceutical industry regulators.'

A fifth point is related to this: in theories of punishment it is seen as objectionable to punish people for *what they are*, rather than for *what they do*. We do not like to punish people for being a vagrant, recidivist, hooligan, etc. But the same objections cannot be raised against treating firms in that way. Legal sanctions against individuals ought to be reserved for specific harmful acts which occur at a particular point in time, but the pharmaceutical industry ought to—and can be—corrected for a harmful pattern of conduct. Again, in Braithwaite's words: 'Criminal law fixed at the level of specific harms can certainly suppress, one at a time, symptoms of the underlying malaise. But without reforms of the faulty compliance systems, new symptoms will be forever surfacing. Perhaps the solution, then, is to make it an offence for a company to have a slipshod system for ensuring compliance with the law?'

I fail to see any reason for a presumption that public companies should enjoy the same rights and privileges as private individuals. Attempts to control corporate crime will never succeed if they remain constrained by principles developed to deal with individual crime. There will never be effective control until the two become regarded as qualitatively different. Legally enforced rehabilitation of a publicly traded company is not the same invasion of privacy as the enforced rehabilitation of an individual. Attempting to rearrange an organization chart is not so oppressive as rearranging a psyche, especially when the latter involves enforced incarceration.'

The goals of control can, according to Braithwaite, be achieved without resort to the repressive measures (imprisonment, corporal punishment, capital punishment) which have been so unsuccessful in attempts to control traditional individual crime. Instead he suggests fines, restitution orders, community service orders, intervention on the corporation's management

system, licence revocation, injunction, seizure and remedial advertising. In general, his view is that most control of corporate crime is through negotiation between regulators and corporations. Criminal law is, in his view, important in this process as the ultimate sanction to back up the threats of regulators. In this connection he also considers the possibility of punishment of individuals, responsible within the corporations.

On this very last point, the question of the need for any application of formal punishment directed towards individuals, I have some reservations. When we enter the arena of delivering intended pain to individuals in the form of formal punishment, then we will again be confronted with the usual need for protection of the individual against the state. When that happens, we are back to point zero—where powerful individuals will use and abuse these protective devices in a way that makes prosecution impossible. The powerful will never be effectively controlled within the penal institution. Negotiation is here probably the only alternative to nothing.

This is an important book; and one which greatly rewards the reader.

Index to Development Dialogue 1972-1984

Compiled by Nina Bergström, Librarian, Dag Hammarskjöld Library, Uppsala, Sweden.

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Pharmaceuticals: A Layman's Glossary

Name of drug	Common use
Ampicillin	Bacterial infections
Clioquinol	Diarrhoea
Chloramphenicol	Bacterial infections
Chloroquine	Malaria
Chlorpheniramine	Allergy
Dapsone	Leprosy
Dexamethasone	Severe asthma
Diazepam	Minor nervous disorders
Diethylcarbamazide citrate	Filaria, parasites
Digoxin	Heart insufficiency
Ferrous gluconate	Anaemia
Ferrous sulphate	Anaemia
Furosemide	Cardiovascular, oedema
Isoniacid (INH)	Tuberculosis
Meprobamate	Minor nervous disorders
Methyldopa	High blood pressure
Metronidazole	Enteric disorders
Para-aminosalicylic acid (PAS)	Tuberculosis
Paracetamol	Fever, pain
Phenylbutazone	Rheumatic pains
Piperazine	Worms
Prednisolone	Asthma, rheumatic pains
Reserpine	High blood pressure
Streptomycin	Tuberculosis
Sulfadimidine	Bacterial infections
Tetracycline	Bacterial infections
Thalidomide	Sleeping problems

development dialogue
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