Multinational drug companies a Third

A mixed blessing for poor nations

by Bhanu Kale

Travelling through seemingly unchangeable rural India, along a kachha road surrounded by rice fields and muddy shacks, one is often struck by a sign of modern times. One sees a smart young man sporting a nice tie despite sultry weather and carrying an elegant leather bag. The fingers of turbaned natives, all pointing in different directions, do not confuse him. Confidently he reaches his destination; the local chemist or a doctor. He is a medical representative of some pharmaceutical firm.

In many ways that medical representative symbolises the drug industry in today's India. With sophisticated marketing techniques he has penetrated even remote villages. Yet the vast majority of villagers are left untouched by him. He is selling what most people need but only a few can afford. His appearance suggests alienation. His efficient, dynamic way of working, ironically, confirms it. His nicely documented brochures do not inspire trust among those around. The desperate poverty of the latter is not of his making, yet an observer is tempted to wonder.

Growth: Enormous but Inadequate

If growth is a test of worthiness the drug industry comes out with flying colours. In 1948, according to a report of the Organisation of Pharmaceutical Producers of India, we were producing only two major or essential drugs. Today we produce 100. In 1952 the value of annual essential drug production was Rs 1 crore. Today it is 66 crores — a 66-fold increase.

And yet the scope for further growth is unlimited. The annual per capita drug consumption in India, according to World Health Organisation (WHO) statistics, is hardly Rs 8. Over 75 per cent of the population is beyond the reach of modern medicine.

"Common man today cannot afford medicines," claims S. K. R. Iyangar, who for the last 20 years has been a leader of the pharmaceutical workers and is the Deputy President of the Maharashtra Shramik Congress. "The drug firms have made even simple things like cotton or bandage or tincture of Iodine very expensive. The situation is so bad that if there is a train accident passengers hesitate to come out and buy the first-aid."

According to Mr Iyangar, "The drug prices are exorbitant solely because with the producers, the profit motive comes first. Take the case of Iodex. In several homes this ointment is used to cure simple pain, cuts or burns. It is made in the traditional Ayurvedic way using mostly inexpensive herbs. I feel it should not cost more than one rupee a bottle. Yet it is sold for around Rs 3.50."

In 1952 Prime Minister Nehru invited drug multinationals to India, sparking the growth of an Indian drug industry almost from scratch. Ever since it has been criticised, perhaps more so than any other industry. The Jaisukhlal Hathi Commission's report on the drug industry, tabled in Parliament this year, gave this criticism a new fervour. Is the accusation of profiteering right? Does the drug industry bribe doctors, buy politicians? Are drug prices unjustifiably high? Is that the reason for drugs being out of the reach of most Indians?

High Prices

"No," asserts B. V. Kapadia, since 1941 chief distributor for East India of CIBA, the renowned Swiss drug multinational. "Our drug prices are among the lowest in the world. For example nasal drops costing Rs 5 here would cost Rs 15 in Bangladesh, just across the border. This is because the profit margin for drug traders in India cannot be more than 12.5 per cent. Other governments allow it to be upto 33 per cent."

Reduction in drug prices in itself, says Mr Kapadia, may not help much to solve India's health problems. "At the moment our per person drug consumption is around Rs 8 per year. Even if the drug prices are slashed by as much as 25 per cent, which is hardly possible, the per capita consumption would go up to Rs 10 per year which by world standards is still miserably low.

"Drug prices are really a non-issue. What percentage of your medical bill is spent on medicines? That is a more pertinent question. Pathological investigation, X-rays, surgery, doctor's charges, hospitalisation etc. forms the largest part of one's medical expenses.

"The low consumption of drugs is a reflection of the general poverty of our people. People don't have enough money even to buy food. Is it surprising that they don't buy drugs?"

Comparative minimum monthy wages (in rupees)

	Peon	Clerk
State Government (Maharashtra)	268	340
Central Government (Railways)	337	445
Semi-Government (Port Trust & Docks)	446	561
Banks	350	550
Textiles	420	520
Engineering (Mukand Iron & Steel)	550	650
Pharmaceuticals (Pfizer)	753	923

per capita National Income : Rs 50 per month.

89-1

Multinational drug companies and the Third World

A mixed blessing for poor nations

by Bhanu Kale

Travelling through seemingly unchangeable rural India, along a kachha road surrounded by rice fields and muddy shacks, one is often struck by a sign of modern times. One sees a smart young man sporting a nice tie despite sultry weather and carrying an elegant leather bag. The fingers of turbaned natives, all pointing in different directions, do not confuse him. Confidently he reaches his destination; the local chemist or a doctor. He is a medical representative of some pharmaceutical firm.

In many ways that medical representative symbolises the drug industry in today's India. With sophisticated marketing techniques he has penetrated even remote villages. Yet the vast majority of villagers are left untouched by him. He is selling what most people need but only a few can afford. His appearance suggests alienation. His efficient, dynamic way of working, ironically, confirms it. His nicely documented brochures do not inspire trust among those around. The desperate poverty of the latter is not of his making, yet an observer is tempted to wonder.

Growth: Enormous but Inadequate

If growth is a test of worthiness the drug industry comes out with flying colours. In 1948, according to a report of the Organisation of Pharmaceutical Producers of India, we were producing only two major or essential drugs. Today we produce 100. In 1952 the value of annual essential drug production was Rs 1 crore. Today it is 66 crores — a 66-fold increase.

And yet the scope for further growth is unlimited. The annual per capita drug consumption in India, according to World Health Organisation (WHO) statistics, is hardly Rs 8. Over 75 per cent of the population is beyond the reach of modern medicine.

"Common man today cannot afford medicines," claims S. K. R. Iyangar, who for the last 20 years has been a leader of the pharmaceutical workers and is the Deputy President of the Maharashtra Shramik Congress. "The drug firms have made even simple things like cotton or bandage or tincture of Iodine very expensive. The situation is so bad that if there is a train accident passengers hesitate to come out and buy the first-aid."

According to Mr Iyangar, "The drug prices are exorbitant solely because with the producers, the profit motive comes first. Take the case of Iodex. In several homes this ointment is used to cure simple pain, cuts or burns. It is made in the traditional Ayurvedic way using mostly inexpensive herbs. I feel it should not cost more than one rupee a bottle. Yet it is sold for around Rs 3.50."

In 1952 Prime Minister Nehru invited drug multinationals to India, sparking the growth of an Indian drug industry almost from scratch. Ever since it has been criticised, perhaps more so than any other industry. The Jaisukhlal Hathi Commission's report on the drug industry, tabled in Parliament this year, gave this criticism a new fervour. Is the accusation of profiteering right? Does the drug industry bribe doctors, buy politicians? Are drug prices unjustifiably high? Is that the reason for drugs being out of the reach of most Indians?

High Prices

"No," asserts B. V. Kapadia, since 1941 chief distributor for East India of CIBA, the renowned Swiss drug multinational. "Our drug prices are among the lowest in the world. For example nasal drops costing Rs 5 here would cost Rs 15 in Bangladesh, just across the border. This is because the profit margin for drug traders in India cannot be more than 12.5 per cent. Other governments allow it to be upto 33 per cent."

Reduction in drug prices in itself, says Mr Kapadia, may not help much to solve India's health problems. "At the moment our per person drug consumption is around Rs 8 per year. Even if the drug prices are slashed by as much as 25 per cent, which is hardly possible, the per capita consumption would go up to Rs 10 per year which by world standards is still miserably low.

"Drug prices are really a non-issue. What percentage of your medical bill is spent on medicines? That is a more pertinent question. Pathological investigation, X-rays, surgery, doctor's charges, hospitalisation etc. forms the largest part of one's medical expenses.

"The low consumption of drugs is a reflection of the general poverty of our people. People don't have enough money even to buy food. Is it surprising that they don't buy drugs?"

Comparative minimum monthy wages (in rupees)

	Peon	Clerk
State Government (Maharashtra)	268	340
Central Government (Railways)	337	445
Semi-Government (Port Trust & Docks)	446	561
Banks	350	550
Textiles	420	520
Engineering (Mukand Iron & Steel)	550	650
Pharmaceuticals (Pfizer)	753	923

per capita National Income: Rs 50 per month.

DRUG INDUSTRY

In the minds of many people, high prices and high profits in the drug industry go together. The fact is that the drug industry in India operates under a straightjacket of price control. Since January 1, 1974 the fixation or revision of prices has been done by the Bureau of Industrial Costs and Prices which is directly under the Central Government.

A comparative study of commodity prices and drug prices over the last several years makes interesting revelations. The wholesale price index of essential commodities (food, cloth etc.) in 1957 was 105.3 (base: 1952=100), while that of drugs was only 88.7. In 1969 when the former rose to 211.6, the drug price index was only about 136.9. Thus while the prices of essential commodities rose by about 112 per cent, the rise in drug prices was only about 40 per cent. Again the commodity price index spiralled to 252 by August 1973; but the price index for drugs stood only at 148.7. It seems clear that the budget of an average consumer has been eroded more by the commodity price rise than by the drug price rise.

Free Samples

It is a common practice for all the drug companies to distribute freely some of their products to doctors. At least a few doctors sell these free samples, illegally, to the patients. This writer has personally come across one such case. Many feel that this free distribution amounts to bribing. Some feel that as much as 25 per cent of production goes into sampling, which, they claim, is largely responsible for "high prices" of drugs.

A. K. Bahl, now financial director of Cadbury, but who has held a similar position in a drug multinational, contradicts this opinion. "The distribution of samples is not as widespread as it is generally believed to be. And in any case sampling is natural in a competitive society. You have to let the doctors know about your product. Samples are given so that the doctors can make their own independent assessment of the medicine and its efficiency. I feel that this is a very healthy practice."

Disturbing Wage Differences

According to some, fat salaries paid by the drug firms also amount to bribing the employees. Drug companies certainly pay better than most (see box on page 14). An unskilled worker in Pfizer, for example, in his first month can draw a minimum wage of Rs 753 whereas a headmaster in a municipal school might retire after 35 years of service on a monthly wage of just Rs 650.

Certain drugs can be lethal. And 100 per cent quality control is impractical. So there is always a danger of sabotage. Even one defective bottle gone into the market, if detected by the public, can spoil the firm's name and the entire product may have to be abandoned. Therefore drug firms always have a policy of keeping their workers satisfied by paying handsome salaries. Perhaps they also reckon that it is better to pay their own employees than to let the Government take away the same money in taxes.

Whatever the justifications for high wages, Mr Iyangar feels "this has created bitterness among workers from different industries. In my union, for example, there are workers from pharmaceutical as well as from engineering industries and I have seen the tension among them. When the workers see that someone with the same or even less qualification gets more, they feel jealous. They too demand more, which their own industries cannot afford. The result is confrontation and bitterness. It also leads to vicious cycle of wage rise and price rise. The real sufferer is the average consumer."

Multinationals

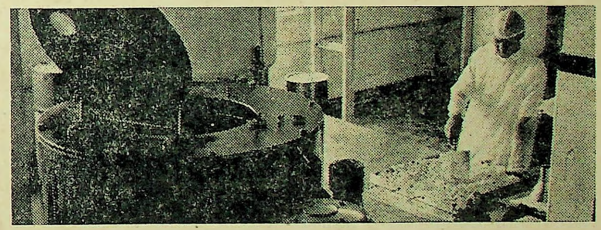
Facts do not support a widespread opinion that the multinationals have the monopoly over drug production in India. In a developing country like India, where the health service is largely contained in the private sector, the multinationals account for 56 per cent of basic drug production. In a developed country like Britain the same figure is 63 per cent, despite the fact that the health service there is nationalised (see box on page 17).

Moreover the share of the multinationals is decreasing. Many indigenous companies are coming up. For example, Alembic and Sarabhai, both indigenous, are today among the five biggest drug manufacturers in India.

Yet it is a fact that the multinational drug firms make high profits. In India 25 top drug multinationals made a profit of Rs 11.57 crores in 1973 on the investment of 32.5 crores. The Swiss multinational Roche quoted Sri Lanka a price for the tranquiliser valium which was 70 times higher than the price charged by an Indian company. Five United Nations agencies (WHO, UNCTAD, UNIDO, UNDP and UNICEF) are collaborating in an undeclared war on the multinational drug firms. This month they are meeting in Buenos Aires, Argentina, to plan their strategy. They are fighting what WHO's director-general calls "drug colonialism".

But there is another side to the coin. At least some people weigh the decision of the United Nations with cau-

CONTINUED ON NEXT PAGE



LARGE SCALE PENICILLIN MANUFACTURING: clean surroundings, strict quality control

DRUG INDUSTRY

MIXED BLESSING — from page 15

tion. They feel the UN has become an instrument of ideological warfare. The third world countries possess an overwhelming majority and the majority does not always spell the truth.

Mr Kapadia, for instance, strongly defends the drug multinationals.

"They pay Government taxes more honestly than the local firms. They pay their workers better. They pay their shareholders handsome dividends — that is why their shares are so high. And if after doing all this they make high profits then I think it is creditable to them. It shows their efficient management. What is wrong with making profit? It is true that like power profitability can be abused. But do you abolish power? Do you abolish the prime ministership because at times it is abused? Then why this hue and cry about the profits of drug multinationals? What is the point in complaining that these firms buy Indian officials and politicians? It is common sense that you can buy only that which is for sale. As long as a person is ready to be sold, he will be bought by someone, X or Y."

Research

The drug industry justifies its profits by saying that much of it is reinvested in research. The Western drug industry, which includes practically all the drug multinationals, spends about half its profits on research. Some successful innovators like Roche spend even more.

Multinationals have contributed greatly to the development of modern medicine. In the words of Sir Derrick Dunlop, former Chairman of the British Medicines Commission, "The revolution (of increase in life expectancy) has been very largely due to the pharmaceutical industry. Some years ago Sir Ernst Chain said that of the 66 most valuable drugs introduced since aspirin in 1899 only nine had been discovered in the Universities and research institutes. But all the other 57 had been discovered by the scientists working in the laboratories of an industry devoted to the profit motive." It is said that the multinationals spend only a fraction — less than four per cent — of their total research budget on tropical diseases. Over a billion people from the third world are exposed to tropical diseases still. Though one would wish multinationals to be more humanitarian in this matter it seems hardly likely that they would like to be dictated to about what they should do. Ultimately each country is responsible for meeting its own specific needs.

In the absence of the multinationals could Indian companies take on the research that is necessary? In the words of John S. Baker, Managing Director of Pfizer Limited, "on a worldwide basis Pfizer spends annually about Rs 20 crores on research and this has been found as a necessary sum for research with a substantial content. The company can afford to do this because it operates in a world market. The Indian operation alone, which constitutes a mere two per cent of Pfizer's worldwide total sales, could never contemplate a simi-lar research venture."

Again to quote from "The Economic Times": "The growth of the industry in the past decade was mainly due to the contribution of the private sector. Some of the bulk drugs which IDPL (Indian Drugs and Pharameceuticals Ltd., the public sector firm) manufactures now were introduced in the country by the private sector. The same is true about Hindustan Antibiotics Ltd, another public sector company. Judging from this experience, the country has to depend upon the expertise of Western European Nations to keep itself abreast of changing technology."

The present Indian Government, like past ones, is committed to encourage small scale industries. What

DRUG INDUSTRY

are the chances of small scale drug units taking over the larger share of the market? Fortunately remote. Most doctors hesitate to prescribe drugs made in the small scale units. They are often sub-standard and are produced without the necessary clinical conditions.

It is worth quoting, at some length, from the report of the Committee on Drug Control appointed by the Central Government. It states, "By and large, the smaller units, being housed in residential buildings, are not designed with the necessary layout for

PUBLIC SECTOR : growth due to private firms

pharmaceutical manufacture. Except in a few units attention was not paid to the hygienic conditions in the plants as well as in the surrounding areas...For example emulsions were being manufactured using a simple s[illegible]. Bottles were not properly washed and sterilised before filling. In one vaccine laboratory bottles were not cleaned at all but directly filled. In a number of units the raw materials were not tested before use while in others they were partially tested and the important tests for arsenic, lead, heavy metals etc. were not performed. In the course of visits to factories, the Committee came across many instances of fake records and cooked-up results....."

If this is the report of the official Government committee, is there much virtue in allowing these units to capture a larger share of the market by deliberately restricting multinationals? Should such a lifeline industry be entrusted into unclean hands just because they happen to be brown?

Perhaps the time has come when we need to decide clearly whether it is possible or right to refuse what the multinationals have to offer. As Mr Bahl puts it, "We cannot take the benefits of what they offer and still continue to abuse them." They are not running a charity and would certainly like to make maximum profit. But the profit they make is strictly within the limits set by the Government of India — which at most times has been left of centre. What they take out of the country as profits is much less than what they bring in by exports. In 1973-74 against a remittance of about Rs 5 crores made, the foreign exchange earnings of these companies were over Rs 12 crores; thus making a net gain of Rs 7 crores for the country.

The pharmaceutical industry, by its very nature, has to have a multinational outlook. Like diseases, medicines also do not know national boundaries.

The rhetoric of "exploitation by drug multinationals" is not likely to recede even if they distribute all their products free of charge. There are people who call outright charity as an instrument of "colonial, capitalistic exploitation". Those who accuse and those who defend the multinationals both have their own arguments. One is free to accept either side. One fact however deserves to be noted : Soviet Russia, which in theory should be most staunchly opposed to any multinational exploitation, has allowed, or rather welcomed, 200 out of top 400 multinationals to operate within its borders.

Structure of the drug industry in India

Name of sector	Production value in crores of rupees		Production value percentage-wise	
	Basic drugs	Formulations	Basic drugs	formulations
Public sector	18	28	27	7
Indian private sector	6	80	9	20
Small scale sector	5	80	8	20
Multinationals	37	220	56	53
Total	66	408	100	100

Government's Role

What should the Government do? The question is of particular relevance in India where many people almost expect the Government to be paternalistic. Z. F. Lashkari, who has worked in a pharmaceutical firm for nine years, has some suggestions.

"The Government can set up drug industries in basically rural areas. Certain drugs can be reserved for manufacture in these rural areas.

"Secondly, it can change the pricing policy so as to motivate companies to reduce costs. According to the present policy higher the costs, the higher is the mark-up, and hence the higher are the profits. This policy gives no incentives to reduce the costs.

"Thirdly, it can put restraints on expenditure for advertisements. Samples given can be restricted, too.

"Fourthly, a fairly good proportion of drugs produced are irrelevant — like cough-drops, cold remedies, etc. It is known that these drugs do not cure and to a certain extent are also addictives. They sell mainly because of good marketing techniques and do not require high technology. The Government should step in to cut down such false demands, and restrict the manufacture of these drugs to small scale sectors which can easily produce them."

Not everybody is content with Government playing such a moderate role. Mr Iyangar, for example, feels that "the Government should take over the production of essential drugs and make them available to people at cheap rates." Quite a few people genuinely believe that nationalisation

CONTINUED ON PAGE 23

DRUG INDUSTRY

'Drug prices must come down'

— says R. K. Anand

Dr. R. K. Anand, 44, is a child specialist from Bombay. He also works as a honorary Associate Paediatrician and Associate Professor at Nair Medical College Hospital, Bombay.

Q: The drug companies distribute a part of their production as free samples to the doctors. Do you think it is a healthy practice?

I personally feel it is not. They give three reasons to justify this sampling: to inform us about their products; to enable us to evaluate it; and to enable us to help poor patients.

All these are only partially valid. Firstly, they can inform us about their product by just giving literature about it. Secondly, most of the drugs they give have already been tried out and evaluated. Various papers have been published on them. We know their properties well. Thirdly, if a particular doctor genuinely wants to help poor patients there are many ways in which he can help. In most cases he has enough resources to help the needy ones.

Actually it is a subtle way of bribing a doctor. Right from student days these drug firms try to win over the doctors. When you accept their samples, almost unconsciously you feel obliged to prescribe their medicines. And samples are not all they give. They also give generous gifts.

Doctors too are to be blamed for this wrong practice. Some doctors actually demand samples. Unless the samples are given they don't prescribe medicines of that firm. Many doctors sell these samples, though it is illegal. Personally I have decided, nine months ago, not to accept these free samples from the drug firms.

Q: Do you support a recommendation made by the Hathi Commission that the brand names of various drugs should be abolished and that they should be sold only under their generic names?

Yes, I do. According to the world Health Organisation (WHO) we need only a little over 100 drugs. The large majority of the drugs in the market are not necessary. No doubt the same medicine manufactured by different companies can have different degrees of effectiveness, called bio-availability. In smaller units it can be less.

But I think this factor is often exaggerated by the drug firms. The difference that bio-availability makes in curing a patient is not all that significant. True, there is a danger of spurious drugs coming up in the market under the same generic names as those of reputed firms. But that danger exists even now.

The abolition of brand names would also help reduce the prices of drugs. No firm would then have a monopoly over a particular drug. There would be more competition and hence the consumer would benefit.

One factor which must be noted is quality control. If the existing regulations can be strictly enforced, drugs manufactured even by small scale units will gain credibility. This factor is important even if brand names are not abolished. Even for big firms strict enforcement of quality control regulations is necessary. And it is not too difficult to achieve. In Maharashtra, for example, the Food and Drug Control Authority is very efficient.

Q: Do you feel there are many drugs in the market which are sold not because of their necessity but because they make good money?

Yes, there are many. For example many tonics contain only some iron and vitamins which are also available in food. Ordinary people are taken in by effective advertising. But for much less money they could buy nutritious food which will give them all that the tonics promise.

Q: Would you say that the practices of the drug firms amount to profiteering?

Yes. Let me give a couple of examples. Tetracycline is not meant to be given to those less than seven years of age. It harms their bones. But now some firms are manufacturing tetracycline drops. Drops are manufactured mainly for children of a very young age who can take a medicine best in that form. Many parents nowadays have started in ignorance to give tetracycline to their children below seven. Is it not the fault of the drug firm which manufactures these drops?

In case of baby foods, which are now abundant in the market and which make great profit for the drug firms, the consumer is again made to suffer. Actually even if a mother is malnourished, for the first six months she can provide enough milk for her child. But because of the advertising by these drug firms, many poor mothers too are turning to milk powders and are neglecting breast-feeding. Finally the child comes to depend just on often-contaminated outside milk. It has been proved that bottle-feeding, especially in a country like ours where good hygiene is not maintained, can be harmful whereas breast-feeding is the ideal food for the child and costs nothing.

I would like to clarify one important point. When I say "drug firms" I do not just refer to multinationals which are regularly criticised for such practices. I also have in mind Indian drug firms who also adopt exactly the same practices.

Q: Some people believe that the real answer to the health problems of India is not to lower the prices of drugs but to reduce the costs of doctors, hospitals, X-Rays, pathological investigations etc. Do you agree?

There is no doubt that some doctors practise medicine as a business. A lot can be said on that. That is why Gandhiji has included doctors in the three enemies of people. He said that a doctor would give pills to a patient suffering from indigestion and cure him. But he will not try to cure the habit of overeating which is the root cause of indigestion.

We have to train people to remain healthy with the minimum of drugs. Most illnesses can be cured without any drugs. We need to get enough fresh air, clean water, nutritious food and exercise.

But all that does not go to say that the lowering of drug prices is an irrelevant issue. Drug prices have to be lowered and after having worked as a consultant to a drug firm I feel that the drug firms can afford to do so.

— B. K.

Calcutta
Oct-20, 1982

Dear Dr Phadke,

Enclosed is a cutting from the Statesman, Oct-17, 1982. I hope you will dash off a rejoinder right away. The address of The Statesman is:

Statesman House,
4 Chowringhee Square,
Calcutta 700001.

Regards & best wishes,

Yours sincerely,

Vimal Balasubrahmanyan

Statesman Calcutta edition
Oct-17, 1982 O 89-2

'Ban On Manufacture Of Drug Unjustified'

By a Staff Reporter

THE Union Health Ministry's decision in June banning the manufacture of all oestrogen-progestogen formulations (other than those used as oral contraceptives in low doses) from December 31 next and their sale from June 30, 1983, may come as a surprise to the pharmaceutical industry and many obstetricians and gynaecologists in West Bengal.

The Drugs and Appliances Standing Committee of the Indian Medical Association, Bengal State branch, at a recent meeting said that the Drugs Controller of India should consult appropriate scientific bodies and experts of specific discipline before imposing a ban. It felt that the withdrawal of such a "valuable" drug from the market would not be justified, as it was used gainfully in many gynaecological disorders.

The Union Health Ministry, in its circular dated June 25, said that medical experts in the country had noted that there had been misuse of these preparations. It also stated that many countries had banned these preparations and that their substitutes were available in India.

The IMA committee in its resolution made it clear that there was no difference of opinion over the fact that a combined oestrogen and progestogen preparation should not be used for diagnosis of pregnancy, because if it was used for this purpose there was the possibility of "congenital malformation".

This, it was pointed out, did not mean, that a fixed dose of the combination of these two drugs had no beneficial use in other gynaecological conditions. The committee recommended that the law should be enforced strictly to curb misuse of the drug and prohibit its sale without the prescription of registered doctors.

Dr S. S. Ghothoskar, Drugs Controller of India, in a recent Press statement in Delhi, reportedly admitted that the All India Association of Obstetricians and Gynaecologists was opposed to the ban as the drug was useful in managing secondary amenorrhoea (stoppage of bleeding among women for reasons other than pregnancy) and similar gynaecological disorders.

The association, the statement said, was of the view that misuse of drugs should be no cause for banning them outright. The Indian Council of Medical Research also was not in favour of banning the drugs, Dr Ghothoskar said.

The Drugs Controller said that the manufacturers were not at fault as the drugs prominently carried the warning label: "Not to be taken by pregnant woman". There would not have been a problem if women took it on a doctor's advice. When the stoppage of bleeding was not due to pregnancy, these combination drugs would help restore menstruation.

The Organization of Pharmaceutical Producers of India, representing the industry, in its memorandum to the Drugs Controller of India disputed his claim that similar drugs had been banned in many countries. It quoted some documents to show that these drugs were marketed all over Europe, Britain and the USA. Even if it was misused, the alleged problem could not be solved by banning them.

There was no drug which could not be misused by unqualified practitioners. The remedy lay not in banning the drugs but by taking appropriate action against the persons misusing them.

The OPPI said that the Drugs Controller had taken the decision against the advice of his own experts and that of the Federation of Obstetricians and Gynaecologists of India. The Union Health Ministry was not correct in claiming that there were non-hormonal substitutes available in India for the treatment of a host of menstrual disorders, a spokesman of the organization said in Calcutta on Friday.

Drugs: are we planning for shortages?

Are we in some danger of drug production falling short of demand? Let us examine the trends.

The Government estimates the country's requirement of bulk drugs in 1982-83 at Rs. 625 crores. This is to be met by production within the country (Rs. 475 crores) and imports (Rs. 150 crores).

The production of bulk drugs today is about Rs. 200 crores. Considerable expansion has to take place if the target of Rs. 475 crores is to be met.

The Government's present policy is likely to achieve the exact opposite. Several companies are to be asked to curtail output.

If this is persisted with, production targets will not be met. The gap between production and demand will widen. There will be more shortages.

Our import bill will then go up further. This is in spite of expertise and experience available to produce these bulk drugs within the country.

Cut in production when the need is to increase production:

When more production of drugs is the paramount need, we have the anomaly of drug companies being asked to curtail production. This stems from the Drug Policy announced in early 1978 under which companies whose production exceeded the licensed capacity are to peg their output at the highest level achieved in the three years prior to March 1977.

The Drug Policy is being implemented in 1980. The spirit of the policy demands that a production freeze, if still deemed necessary, should be at the highest level in the three years prior to 1980. This would take into account the normal growth in production brought about by improved processes and practices.

If several units in the industry have to go back to 1977 levels of production, a cut-back of up to 25 per cent in bulk drugs and drug formulations is likely. The current output of formulations is around Rs. 1000 crores. This may shrink to Rs. 750 crores. Which means that Rs. 250 crores of production will just not be available to consumers. There will be further shortages, necessitating more imports.

We can easily make the drugs we are now importing:

Imports are already showing an alarming trend upwards. They rose from Rs. 82 crores in 1976-77 to Rs. 147 crores in 1977-78 (landed cost). With better planning we can cut down our import bill.

The table alongside shows figures of some major bulk drugs imported in 1978-79. It is clear from the table that these drugs are already being produced here. The know-how, the experience and the capability are all available within the country. Yet we are importing these drugs because the existing units are not allowed to expand.

If the objection is to expansion by companies in India with foreign capital participation, how does one justify imports from totally foreign-owned companies abroad?

Today the position is that with all the licences issued put together the production targets set for 1982-83 cannot be met. It would seem that we are planning for shortages.

The issuing of a licence does not automatically ensure production. Monitoring of the progress of licensed units alone will reveal whether the licences are being "converted" into production.

The non-availability of imported raw materials is a major constraint on several units. Government allocations are not need-based and fall short of requirements. The question comes up again: are we planning for shortages?

The policy now being followed has to be viewed against the needs of the country. The Planning Commission has laid down production targets for the Sixth Plan. India is a signatory to the Alma-Ata declaration affirming the goal of primary health care for all by 2000 AD and medicines are a part, however small, of this long-term objective.

Our per capita availability of modern medicines was only Rs. 11 in 1976-77, compared to Rs. 79.2 in Venezuela, Rs. 54.9 in Brazil, Rs. 31.5 in Argentina, Rs. 27.6 in Egypt, Rs. 17.1 in the Philippines, Rs. 15.3 in Thailand and Rs. 12.6 in Pakistan.

Yet we are wasting a valuable national asset—production capability already existing within the country. A more forward-looking policy is urgently called for. We ought to plan for plenty, not for shortages.

Drugs we can easily make in our country are being imported

1978-79 import of major bulk drugs which are also indigenously manufactured

Bulk Drug	Unit	Production	Imports	
			Qty.	Value (Rs. lakhs)
1. ANTIBIOTICS				
Streptomycin	Tonnes	225.0	76.1	280.1
Chloramphenicol	"	95.0	38.5	117.5
Tetracycline	"	244.0	96.5	233.0
Ampicillin	"	10.3	92.0	584.6
				1215.2
2. SULPHAS				
Sulphamethoxazole	Tonnes	22.0	61.9	143.9
3. ANTI-MALARIAL				
Chloroquin	Tonnes	45.0	304.0	791.0
4. ANALGESICS				
Aspirin	Tonnes	1303.0	319.4	47.3
Oxyphenyl Butazone	"	25.0	14.1	42.9
Amidopyrin	"	16.0	95.6	39.6
				129.7
5. STEROIDS				
Prednisolone	kg	1070.0	869.0	69.2
6. VITAMINS				
Vitamin A	MMU	60.0	15.0	39.4
Vitamin B_1	Tonnes	29.0	78,710.0 (MU)	201.9
Vitamin B_2	Tonnes	7.0	28,338.0 (MU)	109.7
Vitamin B_{12}	kg	165.0	190.0	55.1
				406.1
			GRAND TOTAL	2755.1

SOURCE: *Production figures: Annual Report of the Ministry of Petroleum, Chemicals & Fertilizers, for 1978-79. Import: Data compiled by the Directorate General of Health Services, Ministry of Health.*

Issued in the public interest by
ORGANISATION OF PHARMACEUTICAL PRODUCERS OF INDIA
Cook's Building, Dr. D.N. Road, Bombay 400 001

DRUG INDUSTRY IN THE DOLDRUMS

89.4

The drugs and pharmaceutical industry in the country has yet to come of age. In 1948, the value of drugs and pharmaceuticals manufactured was only of the order of Rs. 4,200 million. In 1964, the number of units manufacturing drugs and pharmaceuticals was about 1,200; it is now over 2,500, comprising 119 units in the organized sector and the rest in the small scale sector. The value of bulk drugs produced in 1964 was Rs. 170 million; it has now risen to Rs. 4.2 billion. The capital investment in the industry has also increased from about Rs. 250 million in 1952 to about Rs. 2.5 billion in 1974–75.

Of the 119 units in the organized sector, 64 units produce formulations only and 7 have been recently issued industrial licences. There are 14 units manufacturing pharmaceutical auxiliaries, like gelatine capsules, sutures, etc. In the organized sector, of the 119 units, 24 units have foreign equity exceeding 50 per cent, 14 have foreign equity between 40 to 50 per cent and nine units have foreign equity between 26 and 40 per cent.

During the fifth plan, it is proposed to increase production of drugs from Rs. 3,700 million in 1973 to about Rs. 5,000 million at the end of 1978–79. This will require manufacture of bulk drugs of about Rs. 1,500 million per annum and investment of Rs. 1,500 million for bulk drugs and Rs. 1,000 million for formulations. Production of bulk drugs in the public sector, which is of the tune of Rs. 300–350 million at present is expected to be increased to Rs. 750 million, contributing about 50 per cent of the total bulk drugs production in the country. Similarly, in the field of formulations the public sector is expected to contribute about 20 per cent of the total requirements with only two more years left for the fifth plan to be over, the investment gap in the industry was about Rs. 1.8 billion.

Nearly 613 million people in India means as many cases for medical treatment. But only about 25 per cent of the country's population has access to modern medicines. Even within that percentage, the availability of drugs shows disturbing disparities in relation to levels of income and urban-rural distances. The rest of the population depends on native medicines and folk treatments.

It is in this context that the drug industry in India has to be viewed and its social obligations and business viability balanced. Government's current concern is medicine for the millions. A drug policy, which is on the anvil aims at providing at least a few essential medicines to the common people at reasonable prices. While implementing it, economic factors, management inadequacies, vested interest back-lashes and the sheer magnitude of numbers and distances are bound to counteract. The solutions,

Dr Madan is a senior scientific officer in the Indian Drugs and Pharmaceutical Limited, a public sector drug company. IDPL is the largest pharmaceutical complex of its kind in Asia and the middle east. Its share of India's bulk production of essential basic drugs and antibiotics is around 40 per cent. It has two plants, one each at Hyderabad and Rishikesh. They manufacture 48 products, including 38 drugs, vitamins, sulphas, analgesics, anti-pyretics, anthelmintics, anti-tuberculars, etc. IDPL has plans to double its output by 1978–79, adding 25 new products. Two new units are to come up in Bettiah, in Bihar, and Gurgaon, in Haryana.

According to Madan, the drug industry has seen a phenomenal growth in the last 25 years and the public sector has had an important role to play in this. It started from scratch. Now the private sector and foreign companies consider it a viable competitor.

The public sector works under several constraints. While foreign and private companies make the high-profit items known as formulations like multivitamins, cough syrups and compounds, the public sector makes low-profit bulk drugs. That explains why, Dr Madan says, profitability of the company is low. On top of it is the responsibility of making drugs in short supply. IDPL is making Chloroquin phosphate needed for malaria, which no private company is willing to manufacture since it is a cheap product. Similarly, when foreign companies refused to make Aldmat, we made it from imported raw materials from Hungary. Again, a company producing pethidine hydrochloride was shut down for three months and IDPL was asked to step in. We did, but then such things do cut down our efficiency and profits, Dr Madan bemoans.

At times, he continues, we come under pressure to discontinue manufacturing existing drugs. Sulpha Guanadine, a drug used in control of cholera, was almost banned because it was believed to be toxic. We make 1,000 tonnes of it. We approached the government saying that the number of people it saves are far more than the number it "harms" due to its toxicity.

The role of the public and private sectors and foreign companies is not yet complementary. The other two sectors concentrate on high profit and non-essential drugs like multivitamins, etc. It is not true that foreign companies bring in technology otherwise unavailable to India except in a few cases like insulin. Moreover, they can much more easily manipulate costs and prices. Our prices are strictly controlled. This inhibits the effort we should make in research and development.

"The public sector as yet has no preferential treatment with regard to licensing, pricing or anything else. In fact, because we have no lobbyists working for us, we often get step-motherly treatment from the government.

Yet the foreign companies cannot be nationalized or their operations stopped. They run about 40 units which cannot be shut down as there is no organization to take them over. If that comes to pass even IDPL will incur a loss of Rs. 40 million in the bulk drugs we supply to them. Also, some of the essential drugs they make would go off the market. But, we feel, that these companies should be made to manufacture raw materials, stopped from bringing doctors and prohibited from making slight changes in formulations with a view to charging higher prices.

We have been trying to help in the distribution of drugs to people in rural areas by designing a bit of household remedies. But essentially it is the job of the state governments to allocate more funds for drugs. Similarly we do not think it is our task to do research on tropical diseases. We do industrial research not basic research. The latter should be done by national laboratories.

According to Madan, the change-over to generic terms instead of brand names is impractical and is not likely to bring down prices of medicines in any way. Doctors do not have time to write long formulas. So they devise other ways. They specify the drug or the manufacturing company.

Dr S. S. Gothaskar is the Drug Controller of India. His job is to enforce the Indian drugs and cosmetics act and the drug and magic remedies (objectionable advertising) act. The first act is aimed at ensuring a high standard of drugs as well as for weeding out substandard drugs. The second act is meant to ensure that no claim for any drug for curing certain diseases such as cancer or sexual inadequacy can be advertised. Apart from this, Dr Gothaskar is charged with the task of ensuring the quality of imported raw materials for the drug industry. He also sees to it that the standards of drug quality are the same all over India. Besides, he is secretary to the committee on drug addiction.

Dr Gothaskar said that the law is comprehensive but enforcement is not effective. Some state governments like Maharashtra, Mysore and Madras are good at enforcing quality, others are far from it. Partly this is due to lack of money and manpower but largely owing to a lack of appreciation of the importance of this subject. Moreover, drug control is a state subject. The Centre can do little in the matter. The drug controller's office has only 24 inspectors to cover the whole country.

Spurious drugs are also checked by

the drug control office. They are made by unlicensed and unscrupulous operators in garages and in unhealthy surroundings. Such units, if they come to the notice of the drug controller, are raided, the culprits arrested and their goods seized. But the punishment meted out to manufacturers of such drugs is too light compared to the enormity of their crime. The jail term, according to him, should be a minimum of three years.

He, however, admits that spurious drugs are not very prevalent in cities. A survey of drugs, sold in Delhi, was made and about 200 samples were taken. None of them was found to be spurious. In another survey of some 60-65 mofussil towns in northern India some 300 samples were taken of which 40 per cent were spurious. This shows that the problem of spurious drugs exists much more in the rural areas than the cities because enforcement is not very effective there.

He said that sometimes strict enforcement of laws on drugs tend to keep medicines out of the reach of the rural population. So drug schedules are being revised every ten years. Some of the shorter acting sulphas like guanidine, analgin, antistamine will no longer require prescriptions. In the case of penicillin this cannot be done because its excessive intake will make the people immune to it and when they really require it, it will not be effective on them at all.

Dr Gothaskar said that there are no reliable statistics about drug addiction in the country. There have been random surveys but nothing comprehensive has been done so far in this regard. Opium, charas, etc. have been used in the country for centuries. What is perturbing the health ministry right now is the use of drugs by students. But according to him, the problem is restricted to the elite in the cities. So far the problem of abuse of psychotropic substances has not yet assumed an alarming proportion in the country at large except in some areas of Punjab. This is apparent from the fact that the import of materials for making barbiturates by amphetaminives and tranquillizers has not gone up significantly in the last four years. In India hallucinogens can be imported only under special licence from the government and hence are, not available easily for misuse.

But the problem with making too stringent laws for psychotropic substance distribution is that it will become extremely difficult for bonafide users to procure them. The chemists will stop stocking them because of the cumbersome rules and procedures. And the drug addict will be able to get them somehow or the other from other channels. Perhaps the solution to the ticklish problem is to put in a new schedule and to monitor their sales more carefully.

If the drug controller finds that the drug habit is miniscule it will be ignored. Otherwise they will have to arrange detoxification centres for treatment of drug addicts. Today, there are no such centres in the country. The addicts are treated in psychiatric wards and other such places.

"Nationalization of the foreign drug companies, the much maligned multinationals is not in the national interest," said soft-spoken 52-year-old Champak Zaveri, who heads the MAC Laboratories Pvt. Ltd. and also leads the Drugs and Pharmaceuticals Sections of the All India Manufacturers' Organization. "If we ever take the step of curbing the activities of the multinationals, we would be at a loss and disadvantage. No doubt the Indian sector has made tremendous progress in the last 10 to 20 years, but much remains to be done.

"Without the benefit of foreign technology we shall never be able to advance and make sizeable progress in the field of making sophisticated drugs. Mr Zaveri asserts that even countries like Switzerland, Germany and the U.S.A. have to import, acquire and adapt raw materials, know-how and technique. "In the interview of the Common Man's health, the so-called "Sector War", the jealousy between the multinationals and the Indian sector, must be forgotten and all should take up the task of nation building. Of course, the Indian sector is undertaking research; but, not basic research, which requires Government's collaboration, as it is too expensive.

"When the industry is in a position to mass-produce drugs, then alone will it be possible to reduce the prices of drugs—that will be the only guarantee of cheaper and quality drugs. Not a single Indian Company has adopted mass production technique of drugs. After all, that is our responsibility and ultimately we shall have to fulfil it, for the good of our countrymen, he added.

Talking of drug prices, he observed the general attitude is that a man will readily and willingly pay Rs. 1.25 for a bottle of coke; but when it would come to paying Rs. 1 for a glucose saline 25 ml. amp. he would demur and dither about the price of drugs.

Zaveri would not like to run down the Ayurvedic system. It, too, has a hoary lore and vast literature and some wonder cures. But, over the centuries the Ayurvedic Drug have had to be a "standardized".

Reverting to his pet theme with a quotation from Rigveda: "Let the wind of knowledge come freely from all directions," Mr. Zaveri said, the western countries have a vast storehouse of advanced medicinal and physio-chemistry, and we should not hesitate to drink at this fountain."

Formulation Production

	1974			1978-79	
	Rs. crores	%	Rs. crores	Growth contribution p.a. %	%
Public Sector	28	7	104	30	13
Organized Sector —wholly Indian	30	20	160	15	20
—with foreign participation*	220	53	352	10	44
Small-Scale Sector —wholly Indian	80	20	184	18	23
	408		800		

*Includes also small-scale units with foreign participation

therefore, will have to be based on pragmatic approaches, awakening of social consciousness and assertion of the political will.

The policy under review relates to licensing and expansion, technology transfer, pricing, supplies to hospitals and research and development. Several studies, including the now well-known Hathi Committee Report, offer the data and specify the parameters for the evolution of a workable policy. A commitment not to take a dogmatic stance has been evident both on the part of the government and the industry. However, there are differences of opinion.

The government's view is that foreign companies will be allowed expansion only in high-technology areas, and a list of drugs where expansion will be considered is being drawn up. Twenty-eight drugs for the public sector and 10 drugs for Indian-owned companies have been reserved. The residuary list, consisting of about 40 drugs—including items like chloramphenicol, vitamins A, B12, D-2, and D-3, insulin, steroids and hormones, aspirin, and chloroquin phosphate—is left to the others.

The organised sector, comprising foreign subsidiary companies and Indian firms with international collaboration, feel that in view of the large requirement, all those with technological and management competence should be allowed to expand and produce

the maximum to reach higher levels of economy of scale and socially relevant price levels. The organized sector now has to give 50 per cent of its bulk drug production to non-associated formulators. It feels that expansion of foreign companies, on the condition that all future liabilities in terms of profit remittance are fully covered by export earnings, is a reasonable proposition.

The small-scale sector, on the other hand, asks for a rather rigid stance in relation to the organized sector. The small-scalers say the foreign companies should be allowed to expand only in bulk drug production. They should not be allowed to formulate their enhanced bulk output, and their formulating capacities should be frozen at the present levels. While calling for a cut-back on production above licensed capacity by the organized sector, the small companies feel that products involving no major technology should be reserved for their own expansion.

The government's wish to avoid respective import of know-how is welcomed by one and all. That imported technology and know-how should not be for captive use by firms—both private and public—is also considered sound. However, unless the conditions are congenial for horizontal transfer of technology from company to company, including economic incentives for such transfer, the growth of the drug industry along healthy lines cannot be envisaged.

On pricing, the government's stance is that the industry should agree to produce on a large scale, non-profit basis a selected list of drugs required for mass consumption, whereas higher prices will be permitted for other products. The organized sector calls for realistic incentive pricing to encourage bulk drug production. It feels a 14 per cent post-tax return on net worth (equity plus reserves) as compared with 15 per cent on capital employed as allowed at present could induce productive enthusiasm, which has been sagging for some time in the industry. The small units say that those with a turnover of up to Rs. 10 million should be exempted from price control.

On the question of distribution, one and all agree that the drugs should reach the customer and the hospitals within the specified time of their potency and under hygienic conditions. The government wants industry to make drugs available in bulk packings at concessional prices to state hospitals for distribution in rural areas. The industry by and large is agreeable to such supplies, provided bulk purchases are made through centralized authorities. The small-scale sector, however, has expressed a preference that the government purchase from its members only.

It is a well-established fact that the advent of modern drugs and their application have been the result of constant research and development, much of which is confined to developed countries. In India, research and development in the field of drugs has

Bhai Mohan Singh is Managing Director of Ranbaxy Laboratories and President of the Indian Drug Manufacturers' Association. "The private sector of the pharmaceutical industry in India," he said, "has been growing satisfactorily in the past few years. Efforts on the part of both the Indian private and public sector have been very substantial."

"The public sector will play a dominant role in the manufacture of bulk drugs and will provide raw material to the private sector, both Indian and foreign. The government's decision to earmark areas for the public sector is indeed commendable. I do not agree, however, with the Hathi committee recommendations. Its implementation will hamper the growth of the pharmaceutical industry in India. Besides there are a number of hazards and pitfalls in its implementation. One simple result will be that chemists will sit on judgement over the doctor. Pakistan is a glaring example of the mess which followed the switching over to generic names. What is needed is a liberal licensing policy as far as the drug and pharmaceutical industry is concerned. The present system is a great impediment in the way of the Indian sector. Being a late-starter it had to face many difficulties because of the anomalies of the licensing system. As the sector has now come of age, it deserves better consideration. Recommendations of the Hathi committee in this regard need to be implemented at the earliest.

"Another hurdle in the way of the development of the Indian sector is the statutory price control on the industry. It is quite unnecessary and is not conducive to its development, particularly when we want to raise the per capita consumption of drugs. It is rather strange that, on the one hand, the government is anxious to increase the per capita of consumption of drugs and on the other it continues to impose new levies on the drug industry or raise he existing ones.

"Some extremist politicians are demanding that the foreign companies should be nationalized as recommended by the Hathi committee. This is a policy matter which can have wider international implications. However, it is known that a number of countries have nationalized foreign concerns for boosting their national industry and enterprise.

"As far as research and development efforts by the industry are concerned, I can take pride in the fact that we have a well-manned and well-equipped research laboratory which is recognized by National Council of Science and Technology. One of the reasons why Ranbaxy has moved ahead so fast is the emphasis that it places on R&D. Ranbaxy's research efforts are directed towards developing life saving drugs besides drugs relavent to tropical environments."

Sisir Mitra, President of the OPPI said:

"The Government's accent on health programmes, during the past four five-year plans, is to a large extent responsible for the remarkable improvement in health standards. The pharmaceutical industry has also played its part more than adequately by manufacturing and distributing a wide range of prophylactic and therapeutic medicines.

"In the fifth plan, an outlay of Rs. 796 crores has been proposed on health programmes. The plan envisages a minimum, uniform availability of public health facilities, covering preventive medicine, family planning and nutrition services, especially in the rural areas. The pharmaceutical industry's role in this challenging task is the important one of making available, in the quickest possible time, adequate supplies of essential drugs. Fortunately, the industry has the capability—technological, financial and managerial—to undertake this task.

"To appreciate the magnitude of the task let us look at the dimensions of growth required of the industry. Current production of drugs in the country is of the order of Rs. 4.5 billion a year, which works out to a per capita availability of drugs of Rs. 7.50 per annum. The demand for drugs at the end of the fifth plan is estimated to be around Rs. 8 billion or double the present output. In other words, if this demand is to be met, the industry would have to double its production by 1978-79. This is a formidable challenge which nevertheless has to be met if the country's growing requirements are to be fulfilled. Assuming that we succeed in this, the per capita availability of drugs in 1978-79 would still be less than a mere Rs. 15 per head per annum, for the country's population would by then have increased to 655 million.

"The task of doubling production is so enormous and so formidable that every sector of the industry—the public, the large, medium and small scale must work together, and complement each other to achieve the goal. There is enough scope and more for every sector because the country's requirements are so large and rapidly expanding."

remained a weak point when compared to the rapid expansion of the industry. Even among the largest companies, including the foreign subsidiaries, only a few do fundamental research which is basic to the discovery of new drugs. Most of the laboratories attached to production units do developmental research related to raw materials, quality control, process improvement and packaging. The excuse offered is that basic research is expensive and profits are not big enough to support it. There is a tendency to reap the technological spin-off from advanced research done elsewhere in the world. The performance of public sector companies, like the Indian Drugs and Pharmaceuticals Ltd (IDPL) and Hindustan Antibiotics in the field of research is far from satisfactory. The small scale sector units pass the responsibilities to government laboratories and the bigger units. Barring a few, the small outfits do not even have testing facilities or trained chemists to supervise production.

The government's stand is that the industry should spend more on R&D and undertake research in tropical diseases, nutrition and isolation of plant materials. The present investment of 1.5 per cent of the turnover on research is far too insignificant. The industry spends nearly six per cent of the turnover on sales promotion. The industry's argument, "the higher the profits, the higher the amount available for R&D", goes on indefinitely. What they forget is that some "mother companies" which started with insignificant investments have made fabulous fortunes by developing new medicines through dedicated research.

In the modern context, research involves large investments and an element of risk. A new chemical, even after identification for its pharmacological effects, takes nearly ten years to go through animal tests and clinical trials before being passed. The experience of the Central Drug Research Institute has established the cost and time involved in developing a drug. But research must go on and the companies which make profits by manufacturing and selling medicines cannot wash their hands off it. The government's plan to consider a cess on research has encouraged some large companies to set think of setting up R&D laboratories. It may be worthwhile for the government to encourage cooperative R&D efforts on drugs as it has done in the case of other industries.

The question whether drugs should have brand or generic names has been raised every now and then, and conclusive answers are yet to be reached. Studies conducted, in India and abroad, and the experience of some countries which adopted generic names for drugs have shown that it is impractical to give up brand names. Pharmaceutical manufacturers in Russia in the early sixties used generic names exclusively. But, following studies by the Central Pharmacological Research Institute to Moscow which showed that 50 to 75 per cent of drug specimens submitted were substandard, Soviet drug houses were allowed to identify their goods by brand names from the mid-sixties onwards. The Chinese similarly have returned to the practice of trade names after trying out generic or chemical names. Most drug products have three names—chemical, generic and brand. The first is far too complicated for any doctor to prescribe, and a chemist to dish out. The generic name is shorter but lacks the guarantee of exact therapeutic response, tested dosage, and quality control, all of which are offered by the branded product.

Another controversy arising in the public mind is over the multinational companies making and selling drugs in India. Some of them are here due to historical accident, others were invited to invest in the country because they brought with them technological know-how. It is now a well known fact that no nation is completely self-sufficient in the field of drug technology. The Hathi Committee acknowledged the role of foreign capital and technology as follows: "An important reason why the continued presence of multinational corporations under appropriate surveillance is desirable is because it provides the most effective and economical method for the transfer of technology in a field in which technological and product obsolescence is quite significant. Units in this industry can be—and indeed, should be—used for subserving national interests. In particular, the international character of operations can be utilized to increase exports of formulations to a much greater extent than at present". The accent, therefore, should be on surveillance for fair trade practices and subservience to national interest.

Whatever decision taken now as a national policy on the drug industry is bound to have long-term implications. The desired growth cannot be achieved with the present pattern of three-tier control on licensing, capacity and pricing. Incentives have to be built into policy directions towards producing medicine for the millions at reasonable prices.

The success of a drug policy inevitably also depends on expansion of medical services for barring a bunch of broad spectrum drugs, as modern medicines have to be administered under doctors' prescription. There cannot be relaxation on standards of manufacture and administration of highly potent modern drugs. Here, the drug control machinery will have to be expanded and streamlined to play the watch-dog function.

The magnitude of India's population offers vast opportunities and challenges to the drug industry. However, these challenges are common to both manufacturers of medicines and administrators of health services. In the ultimate analysis, the success of a drug policy will depend on the social purpose and dynamism of all concerned—the government, the industry and the medical profession. Medicine is a matter of ethics and trust. Trust may yet beget trust. Ethics presupposes discipline.

—W. S. Titus

For the last five years J. B. Mody has been actively associated with the Indian Drug Manufacturers' Association (IDMA) as a Joint Hon. Secretary and now as Hon. Secretary.

"We would not have grown to this stature without the confidence reposed in us by the medical profession and the public," he said.

The Hathi Committee has accepted most of the ideas he submitted to it. Apparently, he was able to convince the Hathi Committee, that the profits of the drugs and pharmaceuticals manufacturers are not very high, as they have to sink a large sum in research. For instance, Unique spends Rs. 300,000–40,000 annually in research over import substitution.

"This is a product-mix industry and it should be permitted a reasonable mark-up of 70 to 80 per cent on the prices. Some profitability for the firms must be essentially there." He was all praise for the role of the small scale sector. "We should develop more technocrafts," he explained, "if we want our industry to grow."

About the distribution of canalized items through government agencies, Mody said that the system was to provide the items on the best of the last two years' consumption plus 15 per cent (on more than Rs. 10 million turnover); or, 30 per cent on less than Rs. 10 million turnover, for all new-comers or for new items for existing units. An *ad hoc* quota of canalized items of 5 kg. to 150 kg. was not sufficient for production purposes.

Explaining this, he said: "The government should review and then revise the policy and give canalized items on the basis of production capacity, so that it will help all deserving units to grow faster."

He hoped that the government would soon implement the recommendations of the Hathi Committee, especially those pertaining to the growth of the Indian sector. "That would be a unique contribution of the government to this most vital of industries."

VIEW FROM THE TOP

P. C. Sethi, Minister for Chemicals and Fertilizers

India Today: What is the government's decision on the Hathi committee report?

P.C. Sethi: The Hathi committee report was submitted to the government in April 1975. Since then it has been examined in the Ministry and we have solicited the views of the planning commission, the Finance Ministry, the industries ministry, the health ministry and the concerned ministries. Now the matter has been referred to a cabinet sub-committee which is headed by Bansi Lal, the Defence Minister. We will be able to take a final decision when this committee meets.....

India Today: Does the government want to develop the indigenous drug industry? What is the priority in the government's thinking as far as dealing with the problem is concerned?

P.C. Sethi: Well, the Hathi committee recommendations are there. But even without that there are certain areas where the government's thinking is very clear. We want the drug industry to catch up with the research and development which has taken place all over the world. It is not only a question of producing life-saving drugs or important drugs today but also of keeping pace with research and development activities. At present our total production caters to no more than 20 per cent of the population. In terms of money, hardly six rupees are being spent per person per annum on medicines. So this is not an area where we have reached a stage where we can close our doors to the development that is taking place in other parts of the world.

India Today: Will the government or the drug industry have enough financial resources for research and development?

P. C. Sethi: The drug industry in India ought to spend more on research and development than it is. The minimum I would consider worthwhile is 20 per cent of the gross turnover. Apart from that we have several research institutions financing research work but they should upgrade the existing technology. But such vast technological developments are taking place in some parts of the world that where we are not able to catch up we will have to continue to import technology. But the main thing is that the technology which we import should not be a captive technology of a particular company but should be on the basis of national property and should be passed on horizontally to a private sector, public sector or joint sector unit.

India Today: How will you ensure that you will get enough scientific talent and that you can pay it enough and provide the requisite equipment to enable it to do proper research?

P. C. Sethi: The main thing is that the most advanced and developed countries are spending so much on R&D that in spite of the fact that we would be spending two to three per cent we can't match the total expenses that they put in. But at the same time we have got technical people and the equipment and we can certainly do some R & D work. For encouraging R & D work in the pesticide industry, we have imported a cess which will be pooled and used for R & D activity. So for the time being we will have to continue updating Indian technology in the field of drugs and manufacture of basic drugs and intermediaries.

India Today: Has there been any significant reorientation in the government's policy—towards manufacture of drugs and pharmaceuticals apart from recent thinking about change of foreign brand names and the monopoly of multinational companies?

P. C. Sethi: The broad principles which will govern the future drug policy of the government are: Firstly, to ensure that drugs are available in abundance in the country to meet the health needs of our people. Secondly, to achieve self-suffiency in the next few years and progressively reduce the quantum of imports and to develop self-reliance in drug technology. Thirdly, to make drugs available both to hospitals and to the common man at reasonable prices and for this purpose the system of price control may have to be continued; to ensure reasonable return on the capital employed by the industry. And lastly, to give a leadership role to the public sector in the drug industry.

India Today: Why is it that some life-saving drugs are not available or easily available in India?

P. C. Sethi: There is wide variety of life-saving drugs available in the country and by and large we are not receiving any complaints of shortages. But in working out our production strategy we propose to concentrate on the manufacture of 117 essential formulations identified by the Hathi committee.

India Today: Since it is primarily a question of importing intermediaries for manufacturing some essential drugs, why does not the government compel companies, especially multinationals, to manufacture life-saving drugs by drawing up a list of the essential ones? And, also, why does not the government force multinational companies to market at the earliest intermediaries of basic drugs which they have been either allowed to import or manufacture?

P. C. Sethi: I fully agree. It is our intention to achieve self-sufficiency in production of drugs within a few years time. For this purpose, we are encouraging all the three sectors of the industry to make investment for the manufacture of drugs. It is my hope that imports will progressively go down over the years.

As a part of our production policy, the public sector has been given the leading role to "Indianize" the manufacture of bulk drugs. So far as the multinationals are concerned, we are now insisting that they should not remain solely in the formulation business and that they must also manufacture bulk drugs. They are also expected to dilute their equity holding to 40 per cent in case they have not brought in the latest technology or are not export-oriented.

India Today: Has the government conducted any survey of the price structure of important antibiotics and broad spectrum drugs in relation to the purchasing capacity of patients? Who needs them?

P. C. Sethi: The prices of drugs in India are controlled under the Drugs (Prices Control) Order and companies are not allowed to charge what they like. While allowing price increase, we have to take into consideration the cost of production and give a reasonable margin to the producers. As things stand the retail prices of drugs in India are perhaps the cheapest in the world. It is, however, true that drugs are largely consumed in urban areas and it will be our duty to ensure availability and consumption of drugs in the poor rural regions. It must not be forgotten that large sections of society are, in fact, getting medical attention including drugs free of cost. These include government servants at all levels and industrial workers. You must also remember that medical attention is not merely a question of drugs, there is the cost of hospitalization and doctors' fees which are also beyond the capacity of the poorest sections.

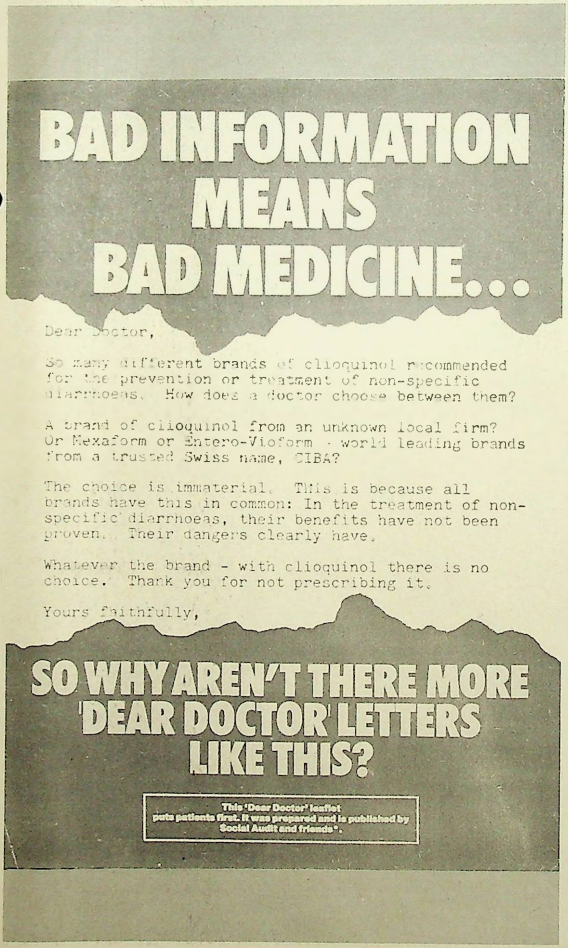
India Today: Some of the inexpensive drugs for relief in cases of common ailments are constantly being improved or fortified in the west. For instance, aspirin tablets have been available for the last three years in Europe with an admixture of Vitamin C. But even these simple improvements do not find their way into products marketed by our companies.

P. C. Sethi: You will widely appreciate that there is a wide diversity of drugs available in the country and almost every year new formulations are being produced. I do not think it would be correct to say that simple improvements do not find their way into the Indian market.

Uma Vasudev

Drugs ban

Awaiting the verdict



Ban harmful drugs or ban the ban? For far too long this three-cornered controversy, between concerned doctors, the government and drug companies has gone on, beyond the ken of ordinary mortals compelled to reside in a world where faith still heals. Anyway, as the saying goes, there are too many dangers to life and limb in the Third World to justify the import of "foreign" consumerist phobias. Even the government has not been above deploying this logic, which the drug industry itself has used to good effect to justify the marketing of questionable formulations.

The fate of the government's successive attempts to ban certain drugs is an eye-opener. Precious little has emerged by way of weeding out harmful or superfluous brands since 1975 when the government-appointed Hathi Committee delivered its report. Following in the footsteps of the World Health Organisation (WHO), the committee ruled that 116 essential drugs sold under their generic names were all that was needed to replace the 15,000 odd brands currently thriving in the market. But the government came a cropper by trying its hand at imposing generic names for just *five*! The Delhi High Court ruled in favour of patented brands - the cornerstones of free enterprise - and the matter inevitably landed at the doorstep of the Supreme Court, where it is currently *sub judice*.

In a fresh attempt, on October 19, 1981, the Drug Consultative Committee (DCC) recommended the ban of 23 fixed dose combinations (FDCs) on the basis of its sub-committee's findings. On December 31, 1981, this was pared down to a list of 18 by the Drug Technical Advisory Board (DTAB). Both the DCC and the DTAB are empowered - under Sections 7 and 5, respectively, of the Drugs and Cosmetics Act, 1940 - to advise the Drug Controller of India (DCI) on matters related to the production and sale of drugs.

Taking the cue, the DCI directed the state drug controllers to ban the manufacture of amidopyrine (either singly or in combination) by February 3, 1982;

and its sale by November 1, 1982; as well as the manufacture of phenacetin and hydroxyquinoline by April 30, 1982. But then, by an order dated August 3, 1982, following an appeal by the Indian Drug Manufacturers' Association (IDMA), he chose to extend the grace period before the ban on the sales of these to March 31, 1983.

Again, by an order dated June 26, 1982, the deputy drug controller banned the manufacture by December 12, 1982 of FDCs of oestrogen-progesterone (EP Forte contraceptive pills, whose use for pregnancy tests was known to lead to foetal abnormalities). In all, some 10 manufacturers and 19 brands were notified in this order and their sale was banned by June 30, 1983. The manufacture of all the remaining 15 on the list was banned by September 30, 1982 and their sale by March 31, 1983.

Unbelievable as it may seem, it took the Central Government close to one year to realise that it had no powers under the Act to act upon the advice of its committees and ban a drug that had been found injurious to the health or lives of its citizens. Since health is a state subject, Section 18 in Chapter IV of the Act empowered the state government to prohibit the sale and manufacture of only those drugs that were either not of standard quality or misbranded or adulterated, etc.

Beating the ban

Meanwhile, making hay while the sun still shone on their commercial fortunes, several companies got stay orders from the high courts. For instance, the Bombay-based Unichem Labs and Nicholas Labs; as well as Organon - now known as Infar (India) Ltd, Calcutta - all saved their rights to market brands of EP Forte drugs. Nicholas also saved its brand Mycropyrin-C (aspirin and vitamin C) which fell in the banned combination of vitamins and analgesics.

Only on November 15, 1982, in a late attempt to remedy this anomalous situation, was the Drugs and Cosmetics Act amended. With the newly incorporated sections 10A and 26A, the Central Government assumed the powers of banning the import, manufacture, sale or distribution of any drug which was likely to involve risk to human beings or animals; or which lacked its claimed therapeutic value; or contained ingredients in a quantity for which there was no therapeutic justification.

The Act came into effect on February 1, 1983, and on July 23, 1983, a gazette notification was issued by the Central Government banning 22 single drugs or FDCs of drugs. This list had many interesting features. For a list which was seeking to undo longstanding harm, it was surprisingly worded loosely enough to give scope to various interpretations. It did not contain all the combinations earmarked by the DCC; and yet it added some five others without providing the reasons for these (See *Misguided ban*). Other drugs such as Lomotil and EP Forte - which had been banned by earlier notifications but which were not part of the DCC's list - did not number here either.

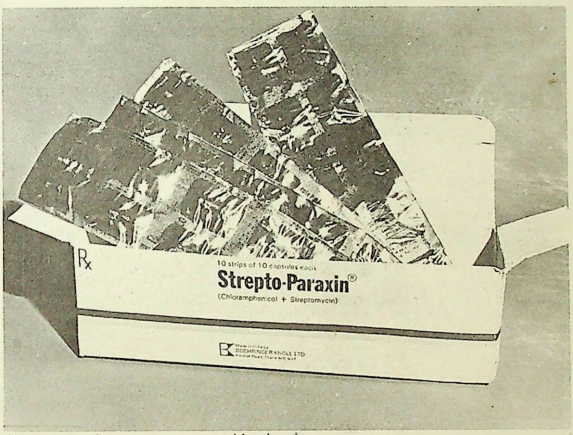
Quick off the mark, EP Forte manufacturers had managed another lease of life by filing writ petitions before the same high courts, challenging the new sections 26A and 10A on grounds of lack of objective criteria for the ban. The matter was again *sub judice*.

When the Voluntary Health Association of India (VHAI) offered to cooperate with the government on this case, DCI Dr Gothoskar refused to disclose either the contents of the petitions filed by the companies against the government or an outline of these or even the names of the government advocates handling the matter.

Vis-a-vis the ambiguities pervading the list, Deputy DCI Dr Das Gupta told VHAI, quite candidly, that since this was their first attempt at banning FDCs, they had not foreseen the lacunae. Further, that the sudden withdrawal of many drugs would have created much greater resentment than it already had; hence the decision to consciously withdraw only a few.

Lax controls

All this has meant that while some companies have adopted a brazen disregard for previous government orders, others have adopted shrewd dodges to exploit the laxity in governmental drug control and licensing agencies. For example, Lomotil - widely used in the treatment of diarrhoea for the paediatric age group - was banned earlier since "it could mask signs of dehydration and cause fatal toxic reactions"; manufacturer Searle reacted with stickers on each silver foil packing, warning against its use below the age of six. Last week, not only was it available over the counter in Bangalore but the sticker had vanished.



Strepto paraxin: unnecessary combination

Amidopyrine was banned since it retarded the production of infection-fighting white corpuscles in the blood; recently, in a low key reaction, manufacturers Ciba-Geigy quietly replaced it with propyphenazone in their formulation but mysteriously managed to retain the same licensed brand name: Cibalgin. The same thing happened to Roche's Saridon, where again the old formulation was deftly altered.

FDCs of steroids were also banned; but the May 1984 issue of the Current Index of Medical Specialities (CIMS) continues to list the brand Butacort, minus, however, the steroid prednisolone (1.5mg) which the producers PCI, in the most bizarre exchange, replaced with diazepam or Calmpose (2mg). How a steroid was allowed to yield place to a tranquilliser of the same potency, in the same branded formulation, is amazing.

The *modus operandi* has been replicated several times over. Pfizer currently markets the banned tetracycline paediatric syrup as oxytetracycline syrup. It is freely available without prescription; yet Dr Gothoskar believes that since it is banned, nobody buys it over the counter. Its overuse, according to the VHAI, has led to high incidence of mottling of teeth at the Rajghera mines in Durg district.

Even the public sector IDPL has not been above substituting atropine by homatropine in its banned combination with analgesics/antipyretics. All this has been made possible by the government ban order, which did not spell out that chemical equivalents of the banned generic categories were also prohibited. But how the licensing authorities have equally allowed the marketing of changed formulations under the same brand names is another matter.

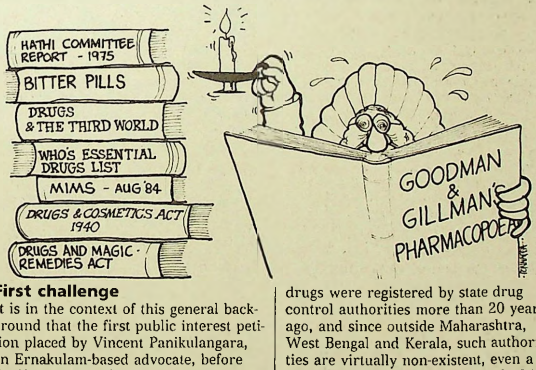
Some others, of course, continue to be marketed quite legitimately since they have been specifically exempted from the ban order. Among the EP Forte drugs, the most recent one to catch the public eye is a brand called Cyclenorm, which was administered by senior doctors in a government hospital in Cannanore to a housewife Shobna for delayed periods. Shobna died subsequently, but the reason for her death is not known; nor is it known whether the drug was intended for hormonal pregnancy testing or for inducing abortion. A damning confession was, however, made in the subsequent court hearing by Dr V. Sasikumar, secretary, Kerala State Health Services, Cannanore.

Said he: "The sad thing about the banned or banning of drugs is that doctors are left to understand about this decision from incomplete reports in newspapers. Who should inform the doctors in government and private hospitals about these drugs? Nobody has done it. As with other government decisions, initial decisions are widely published and then come amendments, court orders, stay orders, vacation of stay, etc. Ultimately leave everyone guessing."

In this guessing game being played with increasing dexterity, the companies argue glibly that misuse of a drug is no reason for banning it; they place the onus on the government. The Drug Controller has, in turn, thrown up his hands, saying "I cannot inform everyone" and shifted the responsibility onto "those involved in health education" and the voluntary health sector. The latter, in any case, are starved of information and floundering in the mire of technicalities.

Since this wheel continues to turn full circle several times over, its consequences are not difficult to illustrate. For example, Lut-Esteron Forte - a high dose EP drug manufactured by Mac Labs - continues to be listed for pregnancy testing in CIMS. This in turn influences the prescription practices of doctors who consult it. Again, diarrhoea continues to contribute to high infant mortality rates, while anti-diarrhoeal packs still go without consumer caution embossed on them.

In fact, in a recent development, medical literature specifying contraindications which earlier used to be inserted into packs of medicines has by and large been stopped altogether. Remarks Dr Ravi Narayan, convenor, Medico Friends Circle, a voluntary health action group: "Some companies are now claiming that this is being done to prevent self-medication! But nowadays, even their own medical representatives are often not taken into confidence and are caught unawares by sudden changes in formulations."



First challenge

It is in the context of this general background that the first public interest petition placed by Vincent Panikulangara, an Ernakulam-based advocate, before the Kerala High Court must be viewed. Since it came before the Drugs Act was amended, it challenged the DCI's provision of cut-off dates for the 18 drug combinations which had been found "injurious to health". It prayed that the court quash all such orders and demand a fresh notification banning their manufacture and sales forthwith.

However, given the peculiar circumstances in which the court found itself (*See Box*), it could only order that "the brand names corresponding to these 18 formulations must be made known to the public so that they are alerted to give a wide berth to such drugs even before the government comes up with any steps enforcing a ban on their manufacture and sale." It ordered the Union of India to give "due publicity" to this list "not later than two months" - from March 28, 1983.

How much heed the government paid to this order was clear in May 1983, when *The Eastern Pharmacist* reported that the Retail and Dispensing Chemists' Association had filed a writ petition in the Bombay High Court demanding the same information. This court also directed the government to notify by gazette, the list of generic combinations proposed to be banned under the amended Act, along with their formulations. Nevertheless, the July 23, 1983 ban notification does not contain this information. Till today, nobody - least of all the DCI - seems to know which brands are really involved.

One plausible explanation, provided by the VHAI, is that the drug companies got another stay order, this time prohibiting even the publicising of brands or the names of their manufacturers. Another is, of course, the sheer logistics involved. Since most of these drugs were registered by state drug control authorities more than 20 years ago, and since outside Maharashtra, West Bengal and Kerala, such authorities are virtually non-existent, even a willing government would have had its back to the wall. Despite this daunting task, Dr Das Gupta is reported to have told VHAI that a banned brand list will be available in approximately three months.

A little earlier, on April 7, 1983, Panikulangara filed another petition, this time before the Supreme Court. In view of the changed circumstances under the amended provisions of the Act, he prayed for:

- A writ of mandamus from the court, commanding the government to cancel all licences and ban forthwith the import, manufacture, sale and distribution of all 18 drugs recommended by the DTAB, as well as EP Forte.

Hollow defence

Delivered on March 28, 1983, the Kerala High Court's judgement was completely overtaken by events. Vincent Panikulangara's petition was filed before the Drug and Cosmetics Act was amended in November 1982. There was then, no provision under existing law whereby the court could order the government to enforce its drugs ban with immediate effect. By the time the judgement was delivered, however, the amended act had come into effect, leaving the court with no other option than to record the changed situation and advise the petitioner to await the renewed efforts of a government freshly armed with powers.

Nevertheless, the text of the judgement delivered by acting chief justice P. Subramonian Poti and justice K.S. Paripoornan, provides many illuminating insights into the hollowness of certain official actions and their justification in the government's counter affidavit. Especially because, since then, the government's arguments have been cited with approval in the counter affidavit currently placed by the Indian Drug Manufacturers' Association for consideration before the Supreme Court. Some highlights:

The main plank of the government's defence against the charge of lackadaisical enforcement of its own order banning 18 drugs was that these drugs had in fact been banned "not because they were injurious to health. But most of these formulations were banned on the consideration of therapeutic irrationality, benefit-risk considerations, consideration of local condition, toxic effect in animals". It added that merely because a preparation has side effects, it cannot be banned; and that "it may also be relevant to point out that all these 18 categories of combinations have not been banned throughout the world and continue to be marketed in some countries". It concluded that "unless the toxic effect is of a very serious nature, it has been the practice to allow a certain period" for stopping production and sale "to avoid hardships to the manufacturers, dealers as well as to patients who are taking these drugs".

Official bias

In a scathing comment, the judges said, "One fails to appreciate the hardship to the patients"; "As between the lives of the citizens of this country on the one hand and the loss that may result to the manufacturers and traders by the immediate ban on the manufacture and sale on the other, the government has chosen to view the latter as of more concern." Picking on amidopyrine as an example, they pointed out that "Even though Government of India had realised as early as in February 1981 of the danger of the use of this drug consequent on which its import and manufacture had been banned in India, the Government seems to have been powerless in effectively enforcing this ban...".

Despite official awareness - reflected in the DCI's correspondence with state drug controllers (SDC) - of continued sales of the drug and its formulations as late as February 3, 1982, the judges observed that "action taken by the SDCs had not been uniform". Even this had not restrained the government from entertaining the IDMA's plea for an extension of the cut-off date for FDCs of amidopyrine, phenacetin and hydroxyquinoline. "Nothing short of prohibiting manufacture as well as sale with immediate effect would be justified"; "There is no case that if they are withdrawn from the market, there would not be effective substitutes, assuming that again is a justifiable reason," they said.

Demolishing the difference between "injury to health" and "therapeutic irrationality", the judges held that, "A drug may be injurious by reason of side effects, by its adverse reaction on certain types of patients, by such reactions under certain conditions, by its irrational behaviour in relation to the consumer and even by its impotence in the matter of effecting a cure for the ailment for which the consumer is treated with it...Therefore, whatever may be the way in which the idea is expressed in the counter-affidavit the plea reduces itself to this that, drugs which ultimately are found injurious in the matter of treatment of patients are being banned...(then) the overriding consideration must be the lives and health of the consumer public."

They concluded that in a number of recent cases (such as People's Union for Democratic Rights v. Union of India, AIR 1982 SC 1473 and Maneka Gandhi v Union of India, AIR 1978 SC 597), the Supreme Court had read Article 21 of the Constitution in a wider and more meaningful perspective. "There can be very little doubt that a person is entitled to protection of his life and liberty and any serious encroachment upon the health of the citizen would call for protection by invoking Article 21 of the Constitution of India."

■ A writ of mandamus, commanding the government to set up a high-power authority to study the damages wrought by such drugs on the health and life of citizens; and to pay prompt compensation to such victims.

■ A writ of mandamus commanding the government and the DCI to frame and rigorously enforce rules pertaining to the quality and standard of drugs.

The grounds on which he based himself were two: Articles 21 and 47 of the Constitution of India. Article 21 assures that no citizen "shall be deprived of his life or personal liberty except according to procedure established by law". And Article 47 that, "The State shall regard the raising of the level of nutrition and standard of living of its people and the improvement of public health as among its primary duties and in particular, the State shall endeavour to bring about prohibition of the consumption, except for medical purposes, of intoxicating drinks and of drugs which are injurious to health."

Second assault

Inter alia, Panikulangara sought to highlight the general situation of the drug industry with a few very broad spectrum observations. For instance, he pointed out that the recommendations of the Hathi Committee had not been accepted by the government. The committee had highlighted the havoc played on the Indian drug industry by transnational corporations (TNCs) and pleaded for its nationalisation. Not only had the Drugs and Cosmetics Act, 1940 allowed profiteering by TNCs and their dumping of harmful drugs here, but the new drug policy, 1979, "had been repeatedly negated, violated and by-passed". Its goals of self-reliant technology, self-sufficiency in production and the leadership role of the public sector in the drug industry, had all proved elusive.

In fact, he felt that since there was "not yet a comprehensive legislation to prescribe the quality and standards of drugs", their reliability was "a matter of charity of the manufacturer and destiny of the patient". He alleged that a fifth of all samples tested were substandard; and three-fifths of all drugs in India were non-specific or pharmacologically irrational.

On November 7, 1983 - ie, after the final gazette notification - Panikulangara filed an amendment to this petition to bring it further up to date. In this he has prayed that the court:

■ Direct licensing authorities to neith-

er grant new licenses nor renew old ones, for the import, manufacture and sale of any drug except the 116 recommended by the Hathi Committee.

- Direct the government to streamline the licensing policy, administrative acts and statutory functions so that useless, injurious and harmful drugs are weeded out and essential and life-saving drugs are easily made available through the public sector undertakings.
- Ban the import, manufacture and sale of those drugs not yet covered by the recent order of the government.
- Direct the government to appoint an expert committee to report on the drug industry and the market after the period covered by the Hathi Committee.

Achilles heel

The Achilles heel of this petition lies in its appeal to fundamental rights and its reliance on Articles 14 and 47. As the petition itself admits, "a constitutional mandate to bring about prohibition of drugs that are injurious to health" cannot "be enforced by a directive of the court". But it has argued that since the import, manufacture and sale of such drugs casts a "backward" dimension to the Directive Principles of the Constitution, this "can and must be prevented by judicial action" - an argument that, in itself, could prove to be tenuous.

The second weakness of the petition lies in its largely rhetorical attack on TNCs' dominance of the Indian drug industry, which is, strictly speaking, no longer true and part of the older reality of the seventies when they controlled as much as 60 odd per cent of the total production. No doubt, the larger ones continue to figure prominently among the top 20 even today; but they have been eclipsed in overall terms by the growth of smaller local units. To illustrate, in 1982-83, the national sector (both private and public) produced formulations worth Rs930 crore; the foreign sector, Rs615 crore. In fact, other than their tussle for hegemony over local markets, the opposition of both together to any consumerist public interest litigation is equally trenchant. To fail to assess the significance of the one, is serious.

These points are borne out by the counter-affidavit filed by the Indian Drug Manufacturers' Association before the Supreme Court in July 1983. Although an amended version of this must certainly have been filed after the gazette notice banning 22 drugs, the original document is representative enough of the organisation's final stand. There are two major highpoints: firstly, it focuses very firmly on statute books - ie, the ex-

oxytetracycline: finding the loophole

tant laws which provide "sufficient" levers for official control of all aspects of the drug industry - and not on the applied reality of these laws. For any laxity or misuse in day to day practice, it thus blames the government's inability to extract the maximum potential out of available laws. Secondly, it focuses - with a great deal of medical obfuscation - on defending some of the banned FDCs.

Not only does the affidavit assert that the prices of Indian drugs are "effectively controlled by the government under the Drug Price Control Order, 1979", but that the various Drug Acts "contain sufficient and effective provisions for prescribing the quality and standards of drugs as well as for regulating their manufacture, distribution, stocking, sale and also the use of such drugs." The obverse is then used: "Prima facie, therefore, any drug which has been so approved or accepted cannot be regarded as harmful or injurious"; especially since, if all these drugs, which have been marketed and consumed over long periods, continue "to be administered within the parameters prescribed for each of them...". And again, that if these drugs have not already been, but "can be effectively regulated and controlled" under various statutory provisions and controls, then they should not be banned.

Manipulated prices

Three examples would suffice to inject a modicum of reality into these assertions. Firstly, in a paper on drug pricing circulated at the voluntary Drug Action Network meet at Wardha last week, Dr W.V. Rane and Dr A.R. Patwardhan cited the prices of two drugs with identical ingredients - the only with half the contents of the other cost almost the same. 100 tablets of Corbutyl (containing Dextropropoxyphene-65mg; Paracetamol-650mg) manufactured by Roussel, cost Rs35.83. But 100 tablets of Norgesic (with 32.5mg and 325mg respectively of the same ingredients) produced by Cipla cost Rs31.10. How does the DPCO, 1979, make this possible?

Then, the 64th report of the Estimates Committee, Ministry of Health and Family Welfare, tabled in the last session of Parliament, highlighted that from 1977-78 to 1981-82, the percentage of substandard drugs was between 14.5 to 21.6 per cent. In 1981-82, 18.3 per cent of drug samples were found to be substandard. In 1982-83, 60 out of 2,540 were again substandard. It further observed that no information regarding the percentage of locally produced drugs which were subjected to testing by either Central or state drug control authorities was available. No statistics related to the number of manufacturers whose licences were suspended or cancelled were available. No machinery existed to prevent the entry of spurious and substandard products into the market.

Further, a recent survey conducted by the National Institute of Nutrition in cooperation with the Directorate of Drug Control Administration and the Andhra Pradesh Chemists and Druggists Association, covering 33 retail pharmaceutical outlets in Hyderabad and Secunderabad, discovered two alarming trends. Not only was the self medication rate an alarming 46 per cent; but 58 per cent of the self medicated drugs were schedule 'L' and 'H' drugs, which are not normally meant to be sold or consumed because of associated major side effects and toxicity.

To return to the affidavit, annexure III deals with 'banned' FDCs. In the opening general comments, it is stated that FDCs are important "if two or more drugs are concurrently indicated for total patient care". According to Dr Ulhas Jajoo, the Wardha-based associate professor of medicine, this practice was definitely discouraged in modern therapeutics, especially "when the drugs were available individually or there was likelihood of the combination being misused". He cites the now banned category of steroids as a drug of last resort, whose doses also need to be individualised.

In support of the combination of chloramphenicol with vitamin C or B complex, it is urged that the misuse of such combinations is unlikely (probably

rope). It added that "an impression is gaining much clinical ground that the symptomatic improvement occurs much more readily in patients with enteric fever treated with this combination". But then no medical references are cited for this cleverly worded rumour.

Playing safe

The affidavit has many other interesting sidelights. It rigs up an impossibly elaborate structure of procedures, labs and tests, to be followed to prove that the known substitutes for the banned drugs are as cheap, have comparable availability and have fewer side effects, etc. However, it is easily forgotten that such tests were never conducted on many of the banned categories of drugs which were licensed decades ago. Indeed, the affidavit itself has been incapable of such rigour in its defence of FDCs.

In addition, a whole range of incredible assertions cover virtually every possibility. On the one hand the testimony of the Deputy Drug Controller before the Kerala High Court (*See box*) is bandied about, with some approval for his arguments against immediate ban, especially since, in his opinion, the drugs were not injurious to health but were therapeutically irrational. On the other hand, it is "denied that all these drugs are lacking in therapeutic rationale or justification...".

Simultaneously, it is urged that "merely because a drug of proven therapeutic utility, produces side reactions, or is harmful or injurious to health or involves any risk to human beings, it need not be prohibited under Sections 10A or 26A". Indeed, "Often, it may be necessary and in the interest of the country and consumers to permit continued use of a drug despite some harmful effects observed in some cases, and its ban abroad."

Descending from the perilous to the superfluous, it is argued elsewhere that drugs should not be banned "merely on the ground that such drug combinations do not offer any special advantages". In fact, drug control authorities "should intervene only if there are harmful effects, and leave the matter of usefulness of the drug to the discretion of doctors who are the best judges.

Finally, of course, in a direct rebuttal of Panikulangara's petition, it denies "that the Petitioner's fundamental rights under articles 14 and 21 are in any manner affected whether as alleged or otherwise. There is no question of any deprivation of the Petitioner's life or liberty, firstly because the drugs in question are not poisons as alleged by the Petitioner, and secondly because, there is no compulsion on the Petitioner or any other citizen to take any of these drugs." Is this to be taken to mean that the IDMA in its moment of triumph has unwittingly acknowledged widespread self medication, which is precisely what has made some of the banned combinations so dangerous? *Jugnu Ramaswamy*

HARMFUL DRUGS

Misguided logic

If in less than three years, 23 drugs officially recommended for banning are inexplicably transformed into 22 different drugs, after adding five new ones and subtracting 10, it proves two logical assertions. First, that the original list was not comprehensive; and second, that the final one isn't either.

On October 19, 1981 the Drug Consultative Committee (DCC) evaluated the therapeutic rationale, possible irrationality and harmful effects of 34 single or combination drugs. After specifying contraindications or simply the uselessness of some of these, it earmarked 16 of them for immediate ban, as well as seven for weeding out over a period of time.

But by December 31, 1981 this list had been truncated (with some qualifications and some entirely new names) into the Drug Technical Advisory Board's (DTAB) list of 18 undesirables. Yet again, on July 23, 1983 the list was incarnated anew with further changes in the gazette notification banning the manufacture and sale of 22 drugs issued by the Union Ministry of Health and Family Welfare.

The minutiae of detailed confabulations in the corridors of wisdom and power are not known; the gazette extraordinary mentions no medical reasons whatsoever for any of the drugs finally itemised in it. If "Health for All by 2000 AD" (India is a signatory to the WHO Alma Ata charter committed to this objective) was the general idea, then there could have been no more mysterious way of going about it. Ostensibly the government's efforts are directed towards guaranteeing the fundamental right to life and conservation of scant per capita earnings (by eliminating dangerous and superfluous drugs respectively). Especially since it is suggested that the use of the impugned drugs is likely to "involve risk to human beings or the said drugs do not have the therapeutic value claimed or purported to be claimed for them or contain ingredients and in such quantity for which there is no therapeutic justification".

Nevertheless, the wording of various combinations is loose enough to have more than one interpretation in court a lever the affected pharmaceutical companies are bound to exploit. In any case, since only generic categories (which have several chemical equivalents and hundreds of brand identities) are employed in the notification, the cause of consumer awareness could hardly have been furthered.

Loosely worded

The list is stricken by an unusual 'best-of-three, winners-lose-it-all' syndrome. For instance, it is not clear whether "combinations of strychnine and caffeine in tonic" indicts the presence of either or both in a given preparation. Other examples in the same genre are "combinations of yohimbine and strychnine with testosterone and vitamins"; and "combinations of iron with strychnine, arsenic and yohimbine

Then again, as the editorial in the September 1983 issue of the Monthly Index of Medical Specialities (MIMS) pointed out, "Ban on the combination of 'atropine with analgesics and antipyretics' does not legally bind a manufacturer to stop - or not to introduce - the combination products of other belladonna alkaloids or substitutes such as hematropine with analgesics and antipyretics." It added, "Ban on combinations of 'tetracycline with vitamin C' is meaningless if one can market a combination of doxycycline with vitamin C." And as the Low Cost Drugs and Rational Therapeutics Cell of the Voluntary Health Association of India is quick to expose, some preparations of the banned paediatric tetracycline are now being labelled and palmed off as oxytetracycline syrups.

Vanishing act

Equally damning is the list of seven 'also rans', recommended for immediate weeding out in the DCC's original list, which do not figure in the gazette notification. In the category of analgesics/antipyretics, while amidopyrine stands banned, it is puzzling why analgin (dipyrone) has been excluded. Dipyrone, which is the sodium sulphenate of amidopyrine, shares its propensity for causing fatal agranulocytosis (marked reduction or complete absence of white blood cells), stomach cancer and bone marrow suppression. Quite logically, the DCC's list had banned both simultaneously.

Medical Association pronounced: "There is evidence that dipyrone, a derivative of aminopyrine that shares its potential for toxicity, unfortunately is still being misused. That is probably because it is available in injectable form and because physicians probably do not recognise its similarity to aminopyrine since it is marketed under various trade marks. Its only justifiable use is as a last resort to reduce fever where safer measures have failed. Because dipyrone may produce fatal agranulocytosis and other blood dyscrasias, its use as a general analgesic, anti-arthritic or routine antipyretic cannot be condoned." By 1980, without any formal ban proceedings, these drugs had vanished from the drug list and the American therapeutic scene.

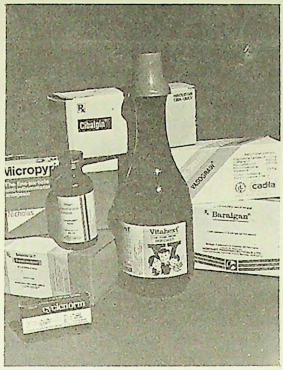
Currently, amidopyrine is banned in over 20 countries. Analgin sales are prohibited in Australia, Sweden, UK, Bangladesh; and severely restricted in Japan, Philippines, Denmark and Italy. Neither of them figure on the WHO's list of essential drugs. In India, leading brands of amidopyrine like Cibalgin continue to be marketed despite manufacturer Ciba Geigy's 1980 assurance of replacing it worldwide with propyphenazone. And analgin, without prescriptions or bills (in well known brands such as Hoechst's Novalgin and Baralgan), continues to gross Rs7 crore annual sales and ranks among the largest selling analgesics. Novalgin is sold as a "patent, non-salycilate, analgesic, antipyretic, antispasmodic, anti-inflammatory, anti-rheumatic agent for all kinds of pain, rheumatic fever, rheumatoid arthritis, relief of colics". Hoechst literature suggests that though the danger of agranulocytosis is remote, it should be borne in mind and a white cell count done if necessary.

What's the difference

If Dr S.S. Gothoskar, Drug Controller of India, and Arvind Nair, communications manager of the OPPI, are to be believed, the government is awaiting the outcome of individual toxicity studies of analgin being done by Hoechst, the University of Boston and West Germany. But if amidopyrine could be banned, why not dipyrone, especially when risks outweigh any benefits of their use and safe substitutes like aspirin are available.

Other notable omissions are:

■ Fixed dose combinations (FDC) of ayurvedic and allopathic drugs like stilboestrol, which the DCC felt could be very harmful since there is no adequate evidence of the safe interaction of these two systems of medicine.



Fresh lease of life

■ FDCs of chloramphenicol and penicillin with streptomycin, notable brands being Chlorostrep (Parke-Davis), Strepto-Paraxin (Boehringer-Knoll) etc. It is however known that quite unrelated to its dose, chloramphenicol can cause thrombocytopenia (drop in blood platelet count) and aplasia (retardation or lack of growth) of bone marrow which, in the DCC's opinion, can result in almost 100 per cent fatality if not carefully monitored. On the other hand, careless prescription of streptomycin, well known for its toxicity by itself, can cause vertigo and sometimes permanent blindness. Besides in 1969, a UK study had found it to be ineffective in such FDCs.

The indiscriminate use of these drugs in FDCs has been known to lead to drug resistance, making them useless in diseases where they are essential: streptomycin for TB and chloramphenicol for enteric fever (typhoid and paratyphoid). In Mexico, some 10,000 people died in a typhoid epidemic when the over-prescribed chloramphenicol failed to act. In fact, in India there could be no better argument for discriminate use than the fact that in 1980, 10 million were afflicted by lung TB and 0.3 million by enteric fever, while licensed production capacity remained underutilised. In 1980-81, the production of only 238 tonnes of streptomycin and 108 tonnes of chloramphenicol (Ministry of Petroleum, Chemicals and Fertilisers estimates) had necessitated imports of 44.1 tonnes and 165 tonnes respectively (Directorate-general of Health Services data). As things stand today, leading manufacturers Glaxo and Pfizer have virtually stopped streptomycin production which is far less refractory than tonics and vitamins.

■ FDCs of steroids, which, the DCC had stated, could lead to adrenal insufficiency. More specifically, according to the VHAI, in 1980, the DTAB had prohibited their combination with either bronchodilators or anti-histaminics or tranquillisers. Only by a sleight of hand could this have been transformed into Clause 14 of the gazette: "FDCs of steroids for internal use except...with other drugs for the treatment of asthma."

Says the September 1983 MIMS: "Since combinations of steroids with anti-histaminics can, at least technically, be used in the treatment of asthma...legally, the manufacturers can claim that in future they will indicate such products for asthma only, though in the past such products have been vigorously promoted for all types of allergies, food poisoning, insect bites and what not. Who will go to the nation's 206,000 doctors and tell them to forget all past detailings on, say a branded formulation of dexamethasone with cyproheptadine, and use it in future for asthma only? No one."

■ FDCs of both analgin and tetracycline with vitamin C had been banned by the DCC since such combinations lacked in rationale. For instance, vitamin C was supposed to help the absorption of tetracycline in the blood stream - an unproven suggestion. Analgin has been exempted from this category too.

■ FDCs of more than one antihistaminic were banned since the difference between their actions was marginal. But this was obviously not sufficient reason for the government to enforce this.

Other runners-up FDCs which the DCC had felt should be weeded out over a specified period are:

■ FDCs of anti-histaminics and tranquillizers, which the DCC felt might cause unwanted sedation and interfere with the patient's reflexes.

■ FDCs of anti-histaminics, tranquillizers and analgesics. Except for injectables which were "not likely to be misused", it was felt that these would also cause unnecessary sedation, especially since "there may not be many clinical situations which would need a FDC of these three categories".

■ FDCs of paracetamol, anti-histaminics and tranquillizers which, according to the DCC, were hardly justified by any clinical situation but may be allowed if the formula contains adequate doses of each ingredient.

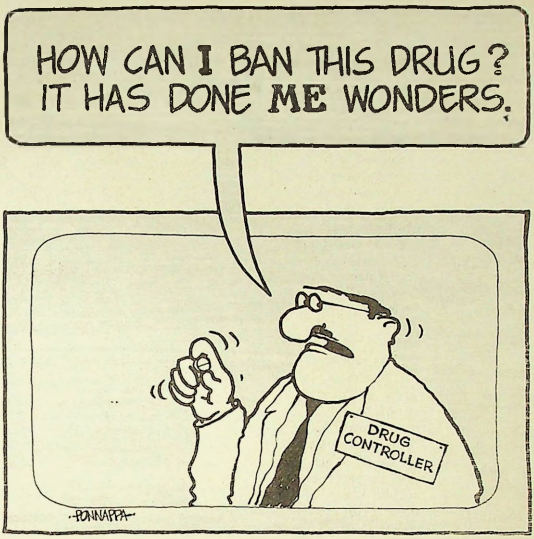
But the most serious distortion has occurred in FDCs of hydroxyquinoline, which had not featured in the DCC's

list as well. Although these are now included, the use of such preparations in diarrhoea and dysentery - where widely used market leaders such as Mexaform and Enterovioform have caused greatest harm - is exempted. Drug Controller Gothoskar clearly believes in setting a personal example. He is known to have told VHAI that "this is a safe drug. I take it myself". Reacting to Nepal's decision to ban it, he is reported to have said that we would have done the same had we also been an importing country. But since we manufacture it ourselves, we haven't.

Like the Hathi Committee before him, he is known to have justified this argument on two grounds. First, lack of equally cheap substitutes (a genuine problem); and second, absence of documented evidence of victims. (Unfortunately, since meticulous case histories are virtually non-existent in India, such proxy assessments of benefit-risk ratios can be - and indeed are - used to justify anything at all.) The WHO obviously disagrees, since in 1977 it felt that the risks of treatment outweighed potential benefits and excluded it from the essential drugs list. But because an Indian Council of Medical Research expert committee had seconded these opinions in 1978, and since Gothoskar has stated that he would not re-evaluate this product but was willing to consider alternative expert opinions, the government is clearly content to put the onus on concerned voluntary health agencies.

It is well known that leading manufacturer Ciba Geigy was held liable by Japanese courts for failing to pass on information about the dangers of the drug which caused sub-acute myelo optic neuropathy (SMON), resulting in pain, paralysis, blindness and some deaths for 10,000-30,000 Japanese in the seventies. In 1977, the organised boycott of Ciba products by Swedish doctors protesting against the continued promotion of this drug in the Third World had lost the company 25 per cent of its Swedish market share, a total loss of some 75 million kroner.

According to Dr Ole Hansen, who spearheaded this campaign, in 1935 itself, when Ciba of Switzerland started marketing this drug, the company had received a report from Argentinian doctors describing exactly the same side effects as the Japanese cases; and in 1939, experiments with dogs and cats had proved fatal. In 1977, a Ciba-funded study in Bombay emphasised that "it would be imprudent totally to ignore the Japanese experience", since it cannot be proved that SMON in its



epidemic form is genetically localised to Japan.

While the company has consistently managed to "hide facts, deny facts" (Dr Hansen's words), hydroxyquinolines continue to be marketed in more than 100 countries. Yet in 1972, the Journal of the American Medical Association stated that clioquinol was "no more effective than a placebo" in preventing travellers' diarrhoea; and in 1977, the UK Committee on the Safety of Medicines held that there was "inadequate evidence" to support its claimed efficacy in the treatment of diarrhoea.

Limited efficacy

More specifically, the WHO Drug Information Bulletin, January-March, 1978, stated: "Hydroxyquinolines are active only on organisms present within the intestinal lumen. Used alone, therefore, they are active only in the absence of significant tissue invasion - a development that cannot be excluded with certainty even in patients with asymptomatic amoebiasis." According to Dr P.G. Pandiya, one-time president of the Pharmacy Council of India, the dramatic relief associated with Mexaform was in fact due to "oxyphenonuim which reduces the spasm of the intestines and bowel movements and thus markedly reduces abdominal pain and discomfort".

Understandably, it has been placed on restricted prescription in Australia, Denmark, Venezeula, Norway, West Germany, Finland, France. In the US, the maximum dose of clioquinol for amoebic dysentery is restricted to 22.5 gms for 10 days. In UK, although available on prescription, it has vanished from the market. It is actively banned in Japan, Sweden, Bangladesh. In India, although theoretically these are prescription drugs, they continue to be freely sold over the counter as cure-all remedies for all kinds of stomach disorders.

In the absence of a ban, appeals by voluntary health activists for warnings on anti-diarrhoeal packs have been in vain. They had proposed that each pack should state: "These drugs are known to cause blindness, paralysis of the legs, burning and pain in the limbs and loss of bladder control"; and again, in keeping with WHO recommendations, that "Anti-diarrhoeals are not enough; oral rehydration is the main treatment for diarrhoea". But Dr Gothoskar has perceptively observed that he cannot imagine drug companies doing this. Since he is also known to have professed helplessness in the face of unrestricted sales, what is the alternative to ban?

Jugnu Ramaswamy

T of I 28/3/82

Unrealistic pricing hits drug production and investment

Drug prices are under Government control for the past two decades. And since the last 10 years they are fixed according to a clearly defined, rigid pricing formula. Not only the prices of all bulk drugs but also the price and profit margins of each and every finished formulation are controlled. On top of this, there is a ceiling on the overall profit a company can make. This three-tier control ensures that no company can overcharge or make exorbitant profit or increase prices without the prior approval of the Government.

While drug prices are rigidly controlled there is no control whatsoever on costs of raw materials and packing materials. Their costs have increased phenomenally. Costs of other inputs and services have escalated too — electricity, water, freight, wages and salaries..

There are inordinate delays in dealing with applications for price revision. As input prices are continuously escalating, by the time prices are approved they become uneconomic.

The approved prices are inadequate and, in several cases, even below cost of production. This is because actual costs are not taken into account; several legitimate costs are arbitrarily disallowed.

Unprecedented cost escalation without timely price adjustments has sharply eroded margins to levels well below those prescribed by the Government. Very few companies are able to get even a modest return. Some established units are already in the red; others are moving rapidly in that direction.

New investment and production have slowed down while demand is rising. Result: shortages of several medicines.

The drug policy does not encourage investment and production. Nor does it permit optimum utilisation of productive capacity. It has pushed up the country's import bill for drugs to a record Rs. 113 crores last year.

This policy is crippling a vital industry. Another look at it is imperative and long overdue.

No control on cost

Although prices are controlled, there is no control on the costs of inputs which have escalated sharply (see table). The price control order provides for periodic revision in drug prices on the basis of increases in cost of production, but there is no adequate administrative machinery to deal expeditiously with hundreds of price revision applications. And by the time prices are revised, costs have increased further, rendering the approved prices uneconomic.

COST ESCALATION OF INPUTS

	Unit	Price in 1976 (Rs.)	Price in 1981 (Rs.)	Percentage increase (%)
Raw materials				
Lactose	kg	7.15	14.75	106.29
Gelatine	kg	31.09	55.59	80.09
Sugar D30	kg	2.15	7.49	248.37
Salicylic acid	kg	15.78	32.96	108.87
Alcohol (isopropanol)	kg	8.86	18.54	109.26
Packing materials				
Vial 5 ml white	1000	107.07	204.24	90.75
Glass bottle (amber) 50 ml	1000	233.60	378.47	62.02
PP caps	1000	140.40	185.76	32.31
Tubes 5 gm	1000	326.27	656.29	101.15
Aluminium foil (printed)	kg	45.73	69.55	52.09
Utilities				
Electricity	KWPH	0.24	0.45	87.50
Furnace oil	Litre	0.96	2.57	167.71

Inordinate delay

Inordinate delay in price revision is not the only problem. What is even worse is that when prices are finally approved they are inadequate and far below what is warranted by the cost of production and even the Government's own pricing norms. This is because actual costs are not taken into account; several legitimate costs are arbitrarily disallowed.

Furthermore, the mark-up allowed is inadequate and unrealistic. Under the pricing formula the consumer price of a drug is arrived at by adding a percentage mark-up to its factory cost. Mark-up is not profit; it is to cover costs not included in factory cost, such as freight, distribution charges, trade discount, selling expenses and manufacturers' margin.

Under the old formula mark-up was a maximum of 75% of factory cost for certain drugs and 150% for others. This has now been reduced to 40% for some drugs, 55% for a second category and 60%-100% for a third, although in no area have costs gone down. The break-even mark-up for most companies is around 75%. When costs are going up and prices all round are rising, drug prices cannot remain the same without adversely affecting investment, production and availability of drugs and medicines.

Sharp decline in profitability

The drug industry, like any other industry, must have a fair return to enable it to pay a reasonable dividend and to plough back for new investment and increased production. But cost escalation without timely price adjustments has sharply eroded margins to levels well below those prescribed by the Government. The position today is that very few companies are able to get even a modest return. Obviously, there is something basically wrong with the policy itself.

The impact of cost escalation on the profitability is clearly demonstrated by a study of the balance sheets of 20 leading companies by the Economic Times Research Bureau. These 20 companies together account for a total drug sales of Rs. 474 crores in 1980-81 or about 50% of the entire production of the organised sector of the industry. The study showed that although sales increased by 9.5% in 1980-81 over 1979-80, profit before tax dropped as much as 25.2%. Retained profits for the year recorded a sharp decline of 22.5%.

The financial viability of several companies has been severely hit. Some established units are already in the red; others are rapidly moving in that direction.

Shortage

Naturally, this has adversely affected investment and production. New investment has slowed down. Shortages of several essential medicines, which were occasional in the past, have now become frequent and wide-ranging. Other factors have aggravated the situation: scarcity of critical raw materials and packing materials; inadequate and irregular supply of canalised drugs; power cuts and labour unrest.

HOW DRUG PRICES COMPARE WITH OTHER PRICES

	Wholesale price index	
	All commodities	Drugs & medicines
1970-71 (base)	100.0	100.0
1975-76	172.9	118.7
1978-79	186.4	136.1
1979-80	212.3	135.2
1980-81	256.9	137.6

A policy for growth, not stagnation

The aim of the policy-makers was to encourage investment and production. But the policy has produced the opposite effect. Our Prime Minister has recently called for removal of all policy constraints and procedural handicaps that prevent optimum utilisation of the country's productive potential. But the drug policy does not encourage more production to prevent shortages.

Another look at the policy is long overdue. It is crippling a vital industry. It has caused shortages and hardships to the consumer. It has also pushed up the country's import bill.

In the year of productivity we need a drug policy that encourages growth, more production and greater availability of drugs and medicines to the consumer

MARK-UP IS NOT PROFIT

Mark-up is meant to cover costs **not** included in factory cost: namely, freight, marketing and distribution costs, trade discount and manufacturers' margin. The mark-up which was 75% for some drugs and 150% for others in 1970 has been slashed to 40%, 55% and 60%-100% under the DPCO 1979, although in no area have costs come down.

ORGANISATION OF PHARMACEUTICAL PRODUCERS OF INDIA
Cook's Building, Dr. D.N. Road, Bombay 400 001

"Unintended profits" on formulations at a time of falling prices of imported bulk drugs.

Is drug policy weak-kneed?

Aug - Sep - 17

MR. VASANT SATHE, Union Minister for Chemicals and Fertilizers, was grilled in Parliament again for his Ministry's helplessness over the profiteering from the sales of essential medicines by their manufacturers. It was again Dr. Joseph Leon D'Souza, Rajya Sabha member of the ruling party, who caused acute embarrassment to Mr. Sathe and the issue this time was the "unintended profits" made from the sales of formulations.

The charge against the Government is that it has permitted drug companies to appropriate for themselves instead of mopping up the "unintended profits" from the sales of medicines made from bulk drugs like rifampicin given for treatment of both leprosy and tuberculosis.

While the drug companies have take a different view of this matter, it is true that the fall in the international prices in recent months of rifampicin and other drugs imported for the manufacture of furmulations have led to the companies making profits which have not been mopped up by the Government under procedures laid down in the Drug Prices Control Order (DPCO) 1979.

Similar charges have been made of unintended profits having been made in formulations from the bulk drugs, metronidazole for treatment of dysentery and dapsone and lamprene for treatment of leprosy.

Though the Government has granted licences for the manufacture of rifampicin to seven companies including the State-owned Indian Drugs and Pharmaceuticals Ltd., indigenous production has not commenced. The country's needs, therefore, are being met only by imports, which went up from 8.95 tonnes in 1980-81 to 16.07 tonnes in 1981-82 and 36.90 tonnes in 1982-83.

Downward trend

For reasons which will be explained here the international prices of rifampicin which the drug companies in India had been importing from different countries had been showing a downward trend, the prices hovering between Rs. 1,800 and Rs. 1,675 a kg. The Government, however, allowed the companies to charge the prices for formulations made from rifampicin on the basis of a price of Rs. 2,404 a kg. for the bulk drug. As many as 17 drug companies including the IDPL have been making "unintended profits" on the sale of these formulations.

The same situation prevails in respect of a number of other drugs. The most glaring case seems to be that of the formulations made from metronidazole, the major producer of which in India is Metronl Drugs Private Ltd., licensed to manufacture 120 tonnes of metronidazole a year. It commenced production in October 1981 and the total production in 1982 and 1983 amounted respectively to 34.42 tonnes and 45.67 tonnes. The price fixed by the Government for metronidazole is Rs. 497.98 a kg. and Rs. 600 for metronidazole benzoxylate.

And yet it has been brought to the notice of the Government that these two drugs are available in the market at prices ranging between Rs. 290 and Rs. 325 a kg for metronidazole and Rs. 310 and Rs. 347 for metronidazole benzoxylate. As a result of the Government having allowed the formulators to use the higher prices as the base, buyers of these formulations have been paying as much as Rs. 14 for a 60 millilitre bottle while it should not be more than Rs. 4, according to Dr. D'Souza.

Price formula

The DPCO lays down a formula for arriving at the prices of formulations made from the bulk drugs providing for appropriate mark-ups for packaging, transport and marketing. Formulators who make the medicines from imported bulk drugs which are cheaper than those produced indigenously are required to deposit the profits worked out on the basis of pooled and retention prices into the Drug Prices Equalisation Fund account. The Chemicals and Fertilizers Ministry seems to lack the will to defend itself effectively. It has pleaded that it has issued notices to the companies to provide details about the unintended profits to help the Government mop them up.

Apart from the 17 companies which have been issued notices relating to rifampicin formulations, notices have also been issued to as many as 113 companies for a number of other drugs from the sales of which unintended profits have resulted. These drugs include, apart from metronidazole, doxycycline, ampicillin trihydrate, salbutamol, dapsone and chioroquin phosphate.

The Government should blame only itself if the spiritlessness of its defence has spread suspicions about it being hand in glove with what is called by its strident critics as the mafia of the drug industry.

Why the declining trend?

Since the Government has assumed major regulatory functions for ensuring that the drug industry does not overcharge the buyers, particularly those belonging to the poorest in the community vulnerable to disease, it has undoubtedly the duty to see that the benefits of a fall in the international prices of bulk drugs are promptly passed on to them. At the same time there has to be some understanding of why the international prices of bulk drugs like rifampicin have shown a significantly declining trend. This did suggest that there had been some efforts at dumping but lately the international prices of refampicin are reported to be climbing.

Rifampicin has been known as an effective drug for treatment of leprosy. But only during the last five or six years has it become widely known as effective for treatment of tuberculosis as well. The result of this discovery has been that the overseas manufacturers of the drug have stepped up production because of the increase in the demand, particularly from the developing countries.

While this did effect a downward pressure on price, the overseas suppliers have a vested interest in seeing to it that the efforts of countries like India to produce the drugindigenously are either frustrated or delayed to preserve their own market. This is best done by making the drug available at ever cheaper prices since this could rob them of the incentive to make expensive investments on indigenous production. However present indications of a rising trend show that international suppliers could not indefinitely persist with their efforts to sell the drug cheap to India.

Selectivity given up

The case of the drug companies is that the charges of their having made unintended profits arise from those who have focussed their attention on one or two formulations made for imported drugs available at lower prices and not on their whole range of production and profitability. This merits some attention.

The Government does indeed keep track of the movements in international prices of imported bulk drugs but by the very nature of things the machinery cannot move as fast as it should. The Bureau of Industrial Costs and Prices (BICP) has to call for data relating to prices and determine what should be the selling price and there is inevitably a time-lag before the benefits of a fall in international prices can materialise for the buyer.

The situation in which the Government finds itself is in fact far more difficult than what has just been indicated. This is because of its own earlier draconian but unimaginative efforts to overregulate the drug industry without a proper awareness of the magnitude of the task.

When the Government announced the drug policy in 1978, it did take a practical view of what could be attempted by way of regulation. It was decided that a watch should be kept over the prices of some selected imported drugs and the Government should ensure that the benefits of any fall in their prices should be passed on to the buyers by the formulators.

However when the Drug Prices Control Order was issued in 1979, this policy of selectivity was given up and the order provided for a watch being kept over the imports of all raw materials and for the regulation of prices on the basis of the recommendations by the BICP. The result of this has been to push matters relating to drug prices into the stickiest mess one could have thought of.

Wide ranging

It will be interesting to find out whether there is an entity like the BICP anywhere in the world being asked to recommend selling prices for such a large number of items on the basis of price movements influenced by a variety of factors. The BICP is being put on an endless run on the trail of prices of raw materials and bulk drugs to recommend what should be fair selling prices and how much unintended profits should be mopped up. If the prices rise — as they do very often — it will have to compute the new selling prices to save the producers from the unintended losses too. How much efficiency and speed can an official agency bring to a job of such dimensions to ensure a fair deal both to producers and buyers?

This brings one to the case put forward by the drug companies. There are not many producers making only a few formulations from the bulk drugs. The range of production of most of them covers quite a large number and the mix is generally such that while there may be unintended profits in the case of one or two formulations, they may be making losses or just breaking even in the case of the others.

Though the Government has a responsibility to see that there is no unconscionable profiteering in the case of essential and life-saving drugs and formulations, its task would be a lot easier if it focusses its attention on the overall profits being made by the drug companies to ensure that they are not enriching themselves by fleecing those who are ill and who can least afford to pay the prices demanded.

C. V. Gopalakrishnan

89-G

Replacing the multinationals

ENDING "DRUG COLONIALISM"

by Anil Agarwal

Under the political leadership of the Third World, five UN agencies (WHO, UNCTAD, UNIDO, UNDP and UNICEF) are collaborating in an undeclared war on the multinational drug companies. They are fighting what WHO's director-general calls "drug colonialism".

A basic drugs list, bulk buying, new patents laws, small-scale manufacture and traditional herbs are the weapons they have chosen.

Taken separately, the policy of each UN agency is a powerful lever for change. Taken together they build up into an integrated strategy which could transform the world pharmaceutical scene. This is the first coherent step taken by the UN towards translating the New International Economic Order from rhetoric into reality.

THE UN agencies seem finally to have found an answer for Asian pharmaceutical problems. Nearly 90 per cent of the world's drug output comes from the developed countries, and within these countries, most of it comes from the giant multinationals. These firms exploit Asian countries in every possible way. According to the UN agencies, they indulge in excessive profiteering and tax-evasion; they sometimes sell harmful products; when their position is challenged by a budding local industry, they often try to force it out of business or to buy it.

At first sight, the monopoly of the giant multinational drug industry looks virtually indestructible. Yet the UN agencies have made some remarkable progress — without any of the huge and lavishly-funded international projects and conferences for which the United Nations is now infamous. The UN has a workable strategy to help Asian countries boost their bargaining power against the drug multinationals, and move towards the establishment of their own drug industries.

The UN strategy is still unofficial and unwritten. This is because it is composed of varying strands of thinking in the different UN agencies. The opportunity for them to cooperate came not from within the UN system itself, but the Government of the South American state of Guyana. Acting on behalf of the non-aligned nations, Guyana set up a task force on pharmaceuticals, consisting of experts from the World Health Organisation (WHO), UN Industrial Development Organisation (UNIDO), and the UN Conference on Trade and Development (UNCTAD).

This task force is a unique arrangement within the UN system. A number of UN agencies are working towards a single objective, under the political leadership of the developing countries themselves.

This task force is currently visiting Afghanistan, Indonesia, Pakistan and the Philippines, as well as nine other countries in Africa and Latin America to advise them on an integrated national policy for drugs. If funds permit, the task force will also visit India and Vietnam. Later, the UN will try to identify concrete programmes to increase regional cooperation within Asia and the rest of the Third World. The underlying theme of the UN strategy is simple: drug use within a country must reflect the real health needs of the majority of its population.

There are five main reasons for this theme. First, the number of essential drugs needed to meet the health needs of the majority within a country is amazingly small — one or two per cent of the thousands of different branded drugs at present marketed in most Asian countries. WHO has prepared a list of essential drugs for the Third World, which consists of only 220 items.

Second, the sources of supply for most of these essential drugs range from large multinationals to small, local manufacturers. By centralising a country's purchases and making all these companies compete for orders, many essential drugs can be obtained at much cheaper prices. Sri Lanka, which pioneered many of these ideas, bought the tranquiliser diazepam in 1973 at one-seventieth the price charged by its previous multinational supplier.

Third, the technology needed to manufacture many essential drugs is within the reach of even relatively small developing countries. UNIDO now looks upon pharmaceutical manufacture as a key area for technical cooperation among developing countries.

India has a large number of small-scale multipurpose plants, each of which produces several chemically related drugs in successive batches. Through UNIDO, India recently supplied Cuba with a single plant to manufacture 15 drugs (including paracetamol, aspirin, diazepam and vitamin B base), for a mere $ 500,000.

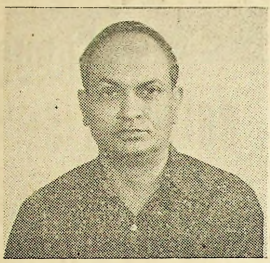
Fourth, the Third World can produce drugs for many essential health needs from local medicinal plants. The experiences of China and Vietnam shows that herbal drugs can be prepared in the villages themselves, using local labour and resources, and substantially reducing the demand for imported synthetic drugs. A recent meeting in Lucknow, India brought together experts from Burma, India, Nepal, Pakistan, Thailand and eight other countries to discuss the Third World production of herbal drugs.

Fifth, as the essential drug lists of neighbouring countries should be quite similar, regional cooperation should become easy.. Countries could collaborate in joint drug purchasing, joint market intelligence, joint quality control, joint research and development, and possibly even joint production of drugs and vaccine which cannot be produced economically by small countries.

Many of these ideas are already being adopted by various Third World countries. Sri Lanka, for instance, now restricts its purchases to a basic drugs list, and Afghanistan is also taking an interest in centralised drug purchasing. The Caribbean Community

CONTINUED ON NEXT PAGE

;ouraging



GENERAL MANAGER KINI :
"some achievements to our credit"

has to be supervised by senior officials. There are umpteen people involved down the line. A number of actions have to be taken like cable pair allotments etc and records are made of each action. Anything done out of the way is easily found. One problem is probably there. After the equipment is available and when a release is made, a man who has this information can go to the people concerned (who he knew are already sanctioned a phone) and say, I can get you a connection. The subscriber doesn't know this. To plug this possibility, whenever we decide on a release, we send an advertisement immediately to the press, and a small card to the party concerned.

Q: Shortages of telephones and equipment encourage corruption How can funds be made more readily available to avoid this?

For production to increase, it will take time. A factor which will change the situation is our present process of supplementing indigenous production with import. Telecommunications was not given core priority in the past, both for funds and for the plant. For cable or equipment we depend on our own production or surpluses. We largely reinvest what we earn from our revenue. On the equipment side we depend on what our own factories in the country can produce. Very little was imported except against World Bank loans because of foreign exchange difficulties. In the case of telex, we had to design our own. Which developing country has done this? This is the major constraint that has limited production. Because of the improvement of the foreign exchange situation, larger imports are planned so we can aim at larger expansion than in the past.

Q: Why has the Department not taken action against the so-called "telephone consultants" who advertise with complete details, assuring phones within 15 days? There is not even a verbal public dissociation from them.

We have issued press notices in the past and we will issue them again if it is of any use. We cannot take steps against anyone from publishing such notes. What action can we take? He is not a subscriber. We do not have police powers. What offence is disclosed? Many of these problems arise from shortages.

Secondly there is a lack of information for the public. I have studied this problem and made comprehensive proposals for a public relations office. It is not in my capacity to sanction this. It has gone to Delhi and will have to be favourably considered by the P & T Department. Something may happen soon.

Q: What are your proposals?

I would like to do the following :

1. Have some place where the subscribers can come and get routine information at a counter and not waste the time of senior officers.

2. I would like to have the counters and the staff specially selected.

3. I would like to have printed leaflets — with certain points that people commonly ask. These can be used at the counters and for answering correspondence.

All this is something novel for the Department. It requires organisation.

Q: Perhaps then complaints and other correspondence will be acknowledged?

It is not enough to merely acknowledge correspondence. It has to be handled. You must not underestimate the effort involved in keeping things up to date. There is a big difficulty about handling correspondence. It fills a volume. When people are waiting, they keep on writing. My officers do not have stenographers. We have 50 posts vacant. At the salary we offer, we cannot get the necessary speed. The officers cannot handle their own letters.

Q: Is the corruption within the Department so rampant because of low salary scales?

This may be partly true. But the question of corruption does not depend on a salary alone. Our salary scales are the standard Central Government scales. It is certainly lower than public sector undertakings, banks, etc. As I said before, the public has a great deal to do with it. You can go on feeding people with money to keep your line going and naturally, the man will keep on demanding more.

Q: What are the steps that you, as General Manager have taken to improve efficiency?

I am the last person to say that Bombay Telephones are in perfect working order. But I think that we have some achievements to our credit. The service has improved. The complaints on 198 services has shown a steady downward trend. The written complaints per 100 telephones has gone down — from 8.12% in 1976 to 7.19% in 1977 and 2.91% till June this year. The rate of provisions of new telephone connections have been very sharply stepped up. In the last 2 years — 1976 to 1977 — the annual increase was more than double the average rate in the previous five years. The International Subscribers' Dialling service was introduced to London for the first time. After considerable preparation major steps were taken in 1977-78 for decentralisation of the organisation and setting up area telephone offices. Five of the six area telephone offices which were planned are now functioning in different parts of the city and suburbs. Earlier people from Ghatkopar had to come here (to Colaba).

Q: According to the rules of the contract signed between the Department and the subscriber, it is illegal to charge rental on dead phones. Why does the Department do so?

I cannot find any such rules. We have sent a reply in a letter to the press to those who say they exist.

Q: Why are lines cut without warning? According to the contract, you must serve at least seven days' notice.

This notice does not apply to cutting off the lines for non-payment of dues, within the prescribed dates. About 45% of the subscribers do not pay within the due date. The accounts' office start ringing up the people who have not paid and make a record of the conversation. Of course errors can occur. We issue about 1.2 lakhs

CONTINUED ON PAGE 20

A strategy for Third World nations

by Anil Agarwal

In an article "Replacing the multinationals" (Himmat, September 1), Anil Agarwal outlined a combined move by five United Nations bodies — WHO, UNCTAD, UNIDO, UNDP and UNICEF — in an as yet unofficial strategy to combat what WHO's director general calls "drug colonialism".

The following article comprises extracts from a pamphlet "Drugs and the Third World", written by Anil Agarwal and published by Earthscan, which deals in detail with the situation as it is and the remedy proposed by the UN.

THE UN drugs strategy forms part of a new approach to development within the UN agencies. This aims at increasing production within developing countries through a process of self-reliance. Wherever possible this self-reliance should be achieved on a national basis, by the use of appropriate technologies and rational utilisation of local resources. Where this is not possible, effort should be made to become self-reliant on a collective Third World level, through cooperative action among the developing countries themselves.

The Third World drug industry

Large-scale commercial drug production is restricted to a very small number of developing countries. Brazil, India and Mexico account for about 50 per cent of the Third World's drug production outside China.

But even within these countries, drug production is largely controlled by Western multinationals, through licensing arrangements or local subsidiaries.

Forty-five developing countries have no drug manufacturing facilities whatsoever, and drug production in 43 others is restricted to packaging and formulation of imported drugs into tablets and capsules.

Developing nations which do have their own drug industry increasingly complain that foreign-controlled subsidiaries indulge in a variety of improper trade practices. They are alleged to charge excessive prices for their products; to be least interested in producing those drugs which are most needed by the bulk of the population; and generally to impose conditions on the transfer of technological know-how which restrict the growth of locally-owned industry.

High drug prices

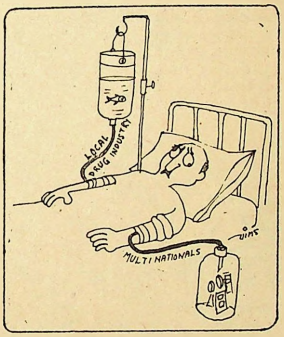
Thirty years after the formation of the World Health Organisation, and after massive investments by developing countries in hospitals, medical colleges and drug factories, modern health services are still beyond the reach of the great majority of Third World people. The use of modern drugs in the Third World remains confined to a small urban elite. In India, for instance, the consumption of modern drugs in 1973 was only Rs 6 per person, and only 20 per cent of the population used them, despite the fact that India has the most sophisticated drug industry in the Third World.

There are enormous differences in drugs expenditure between developing and developed nations. For instance in 1967 per capita consumption of pharmaceuticals in the US was over $20, in Japan $15 and in Europe $14, while in Latin America it was $4 and in Asia and Black Africa only $1. Drug costs often represent 40-60 per cent of the total health care expenditure in developing countries, compared with only 10-20 per cent in the developed ones.

The prices of many drugs sold by western drug companies to the developing countries are often higher than the prices at which they are sold at home. For example whereas Britain paid US firms $2.40 per kg of Vitamin C in 1973, India had to pay nearly $10. Tetracycline antibiotics which cost $24-30 in Europe were being sold to India, Pakistan and Colombia for $100-270.

DRUG INDUSTRY

Around 1000 million people, mostly the world's poorest, are exposed to mainly infectious and communicable tropical diseases. Until the mid-1970s the total global annual research expenditure on these tropical diseases amounted to about $30 million — less than one fiftieth of the annual expenditure on cancer research, and the equivalent of the cost of building a few miles of motorway.



With the end of the colonial era, interest in the developed world in communicable diseases has declined, with the result that very few new drugs or vaccines against tropical diseases have been developed in recent years. Also the global demand for tropical disease drugs is not thought sufficiently large to make their production and research economic. Those who suffer from these diseases are poor, and the drug companies say they find it hard to market tropical drugs profitably.

A basic drugs list

The markets of both developed and developing nations are flooded with a wide variety of brand medicines. Most of these are merely different combinations of a small number of drugs, presented in different dosage forms.

The contrast between branded drugs (eg Aspro) and generic drugs (eg aspirin) is central to the concept of a basic drugs list.

CONTINUED ON NEXT PAGE

DRUG INDUSTRY

Several countries have tried to identify those drugs which are essential for the needs of the majority of their patients. They have found that only a very small number is required — in the case of the developing countries often just 1-2 per cent of all those on the market.

Even developed countries like Sweden and Norway, which provide the most advanced forms of therapy to their populations, deal with a restricted list of about 2000 drugs in their state-run drug distribution systems. In West Germany, by contrast, there are 24,000 drugs on the market.

The total drug purchases of individual developing countries are usually small compared to the worldwide sales of the large drug companies. The bargaining power of most Third World countries is therefore also inevitably small. It is further reduced if a country has several importers. Bulk purchasing usually substantially reduces the cost of drugs. This is one reason why a developed country is able to buy drugs cheaper from the same firm than a developing country.

UNCTAD therefore strongly recommends that developing countries should centralise their purchases via a single state buying agency to the maximum extent politically possible. Essential prerequisites for centralised drug buying are the preparation of a basic drugs list and the prescription of generic drugs only.

Traditional herbs

Both UNIDO and WHO see the use of traditional herbal remedies as an important part of the Third World strategy for drugs self-reliance, coming as they do into the category of "remedies used on the basis of long experience". All over the world people have used locally available natural drugs for centuries. These products are trusted by the consumer, and can be assumed safe since no toxic effects have been recorded during widespread use. In any case many modern medicines come from plants which have been used in traditional medicine through the ages. Today more than half the prescriptions written by American physicians are estimated to contain a plant-derived drug — one either extracted directly from plant, or one synthesised to duplicate (or improve on) a plant substance.

In India the ancient medical system of Ayurveda has a materia medica containing over 8000 herbal recipes. The plant Rauwolfia serpentina, from which most modern tranquilisers were developed, came from Ayurveda.

The Centre for Scientific research into Plant Medicine in Ghana has found excellent herbal preparations against guinea worm and shingles for which western medicine has no effective remedy. Herbs under investigation for diabetes mellitus and broncial asthma appear to be far more effective and less risky than modern drugs.

Towards the end of 1978, WHO will organise a meeting to identify and most widely used medicinal plants and then establish a network of collaborative research centres to study their effectiveness.

Quality control

The multinational pharmaceutical industry has always claimed that the local manufacture of drugs and the abolition of brand names will lead to a deterioration in quality. Developing nations must set up their own quality control systems if they wish to undertake generic prescribing and local manufacture. This is necessary not only to ensure quality control but also to set at rest the doubts of the medical establishment.

Small-scale manufacturing can lead to problems, where lack of adequate instrumentation and control can lead to substandard products.

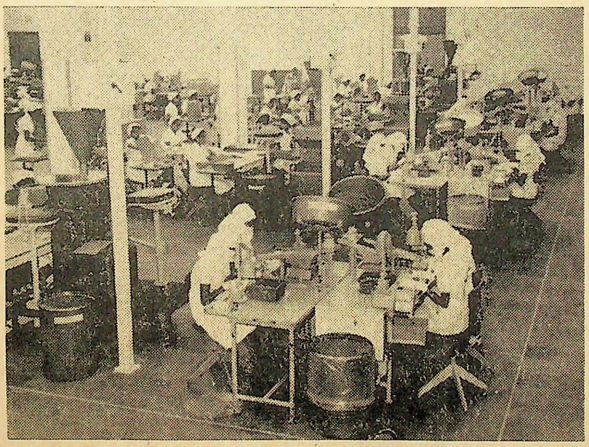
Few Third World countries possess adequate drug testing facilities at the moment. But the central problem of quality control in developing countries is usually the lack of skilled personnel.

Political will

For the UN policies on drugs to work, developing nations will above all need a strong political will.

They will need this political will at the national level, to develop and enforce their national drug policies despite local professional and commercial opposition, and to reform their existing health services to serve the primary health care needs of their peoples. Without a relevant health policy based firmly in primary health care, there can never be a proper drug policy.

Developing countries will also need a strong political will on the international level, to cooperate among themselves.



LARGE SCALE DRUG MAKING IN INDIA:
but 45 Third World lands have no facilities at all.

to the politicians. We have no executive powers."

What alternative plan, if any, has this association to offer for rural health problems? An ex-President of the IMA had put forward a comprehensive health scheme not dissimilar in principle to the present one. This was not accepted by the Government. Nor was it accepted by the IMA who thought it was a "personal scheme" and so refused to endorse it.

"If doctors had any idea of the basic problems of rural health care, they could campaign effectively in various fields," stressed one IMA member. "They can campaign for better roads in certain areas which are quite inaccessible to health services. Naturally, no doctor will want to go to an area where he has to splash through knee deep mud. Doctors can also campaign for better agricultural incomes. Poverty is the root of ill health. Here it is not the question of the right kind of diet, but lack of any. We can influence the agricultural crop pattern of the villages by pointing out the crops that can improve nutrition. Doctors can also think of ways in which intermediate technology can be developed so that specific care can be taken to the village. At present health camps cannot be held in areas where there is no clean, tiled floor to lay patients on."

This doctor takes a band of young doctors twice every month to an area in the Uran Taluka in Maharashtra. They have just released a batch of fish into the village pond. Every villager suffers from guinea worm and the fish will feed on and destroy these worms. "Doctors do go into the backward areas and treat people. But we need more doctors concerned with preventive and not just curative measure in the rural areas."

Are there enough concerned with either?

CHWs — from page 15

cines — now even chloromycines are to be found in the villages along with aspirins — and more often than not prescribe them have come to the primary health centres and demanded certificates for CHWs. "We have anyway been doing this work, so now you can give us the certificate," is their argument.

In effect the CHWs are meant to complement and supplement the services of intermediate health workers operating at the tehsil and district level. Even for services like immunisation, child and maternity care, they need supervision of the public health nurse and the health supervisor.

The nursing staff has to play a vital role in their supervision and training because there are too few doctors and those who are there spend 95 per cent of their time treating illnesses. They are not in a position to handle the whole gamut from training dais to coronary specialisation. That is one reason why health care has been given secondary importance. The responsibility of prevention and promotion of health care should be shifted to the next cadre of health workers, that is the nurses. This aspect of the programme needs thought.

Though there has been little feedback on how the programme is doing after a year, reports of those working in the field point to areas where there is room for improvement. For a start more imagination could be shown regarding the scheduling of programmes according to the convenience of the villages rather than of the functionaries. There could also be greater flexibility about teaching techniques and adopting a more non-formal approach. "There is no point taking a poster to villages showing a milk bottle when they don't get bottled milk. The techniques have to be based on their ethos", commented one worker.

Over the distribution of the kit promised to the CHWs there have been difficulties. Not all of them have received them. Moreover replenishing of supplies requires an effective machine which does not exist. Consequently medicines have been in short supply.

The programme of CHWs is dovetailed into the Government's earlier scheme of multipurpose workers, initiated in 1974, under which there is a female and a male health worker looking after each subcentre.

The community health worker scheme is a move in the right direction. It envisages an infrastructure where health care is made accessible to people through their own efforts. What requires the thought of the medical community as well as of nutritionists, social workers and private agencies is how to improve its implementation. Certainly doctors who are not prepared to go to rural areas themselves should not block the efforts of those trying to provide a semblance of health care to people long forgotten — imperfect though the plan may be.

BOOKS

Hope and realism do mix

RICH WORLD, POOR WORLD by Geoffrey Lean: Georage Allen and Unwin; 352 pp; £ 7.95, paper back £ 4.50.

AT first reading, you may be tempted to feel that the title of this book is not comprehensive enough for the range of subjects covered. The broad scenario includes the growing economic imbalance, the dangers of nuclear energy, alternative to oil, food, preventing cancer, population, slum resettlement and changing philosophies necessary to meet the crisis and challenge of the second half of the 20th century. Geoffrey Lean argues that all these are vitally linked to the rich world-poor world struggle and that indeed solutions to most of these problems will only be found through a new attitude towards the imbalance of the rich and poor worlds and a world embracing outlook.

From experience

Lean brings to his research knowledge gained from experience. He was environment specialist on the "Yorkshire Post" for eight years. He is credited with initiating changes in attitudes and the law which brought radical solutions to that area of industrial England. He now works for "The Observer"

The book under review is the product of nearly three years intensive research, 24.000 miles of travel and interviews with hundreds of people — authorities and the man in the street. It is a mine of statistics for the researcher but readable for the layman. The issues discussed have normally been regarded as technical ones, the province of experts, but more and more they must become the concern of everyone. Lean's approach is refreshing in that he discusses solutions rather than merely outlining crises and proclaiming disaster. He is realistic but gives us a book of hope.

The author opens with a world survey of the food situation. Although 15 million children die before they are five each year, caused mostly through malnutrition and 3/5 of all developing countries do not get enough food to give each person a minimum subsistence diet, Lean asserts that there is enough food for all or the potential within easy reach.

At the beginnnig of the 1970s the people of Western Europe, Australia, and Japan were consuming 23 per cent more calories than they required, North America was ahead with an excess of 26 per cent, and the Soviet Union was in the lead with 27 per cent. Each citizen in the rich world consumes up to about a tonne of grain every year — the equivalent of more than six loaves of bread each day. This, of course, is not literally true. What happens is that 90 per cent is fed to live stock to produce meat, milk, cheese and eggs when a great deal of this could be avoided through more intensive grazing on grassland, otherwise unproductive for agriculture. Animals in the rich world eat about 1/3 of the world's crop of food.

More serious still is the fact that a good deal of some of these products are imported from poor countries, many of whose people need the food themselves.

In the Far East alone some 100,000 children lose their sight every year through lack of vitamin A — blindness which could be prevented at a cost of about seven paise per child per year.

These and other facts vividly underline the gross imbalance in the world. Aid can go part way to meet the need but in the long term, all are agreed, more radical answers are required. We have to create a new pattern of food production and consumption which will include the ability of developing countries to grow more of their needs, and an economy whereby their people can buy the food that is produced.

The potential for increasing food production in the poor world is enormous. Of the world's total land surface, less than 11 per cent is cultivated out of a possible 24 per cent arable land. It is estimated, for instance, that India could produce at least 230 million tonnes of grain a year in place of her present 105 million tonnes.

Bridging the gap

The staggering imbalances and the growing economic gap between the rich and poor nations calls for a new economic order. Lean examines on a basis of world cooperation, trade agreements, stabilising of raw material prices, the present pro and con practices of multinationals and the fascinating possibilities of exploiting the resources of the sea bed. It is not generally known that at least ¼ of the world's recoverable oil is thought to be beneath the sea bed besides large quantities of "nodules" containing manganese, nickel, cobalt, copper, molybdeum, aluminium and iron.

In the realm of economic power, Lean points out that the dice is no longer completely loaded in favour of the rich nations. He instances the vulnerability of rich country economies by the fact that the oil price hike of 1973 set in motion deep troubles when in actual fact the hike only represented a transfer of two per cent of the income of developed nations to OPEC countries. An overlooked significance of the OPEC countries' action is that it challenged the seemingly impregnable old economic order and showed that change could come and come rapidly.

Similarly he argues that there may be other areas in which the poor countries can improve their bargaining position. He cites the possibility that the African countries could, for instance, decide to buy only Volvo cars and trucks because of Sweden's record of support for a new economic order.

Lean also advances the idea that poor countries could reduce their dependence on rich ones by increasing trade and cooperation among themselves. However he issues a warning. "The gap between the rich and poor in the poor world itself is as great as it is between nations. Until this is changed increased wealth

High cost of a doctor's cure for illness

India

WARDHA

by Dr Ulhas Jajoo

EVERY time a patient goes to a doctor, he goes with an element of faith. He expects two things from the doctor: one, diagnosis of his problems; two, prescription of medicine for treatment.

But do doctors always prescribe right? Do they sometimes overprescribe?

Trials have been conducted in US in which the prescriber was informed that the prescription would be screened for inappropriateness of drug prescribed or the doctor would be asked to fill in a form justifying the use of antibiotics. These trials revealed a reduction in antibiotic use of as much as a quarter.

Another study published in a leading US journal reports that in a case where doctors were asked to write the diagnosis along with their prescription, it was found that antibiotics had been prescribed without any evidence of infection in 62 per cent of prescriptions. No such studies are available in India or from other developing countries, but many doctors would not be surprised if overprescribing was true in 80 to 90 per cent of cases.

In a country like India with an extremely low per capita drug consumption — about Rs15 a year — it is only reasonable to expect that doctors will prescribe more carefully and rationally. This will not only benefit the society as a whole by diverting drug expenditure away from unnecessary medicines toward life-saving preparations but will also help to cut down side-effects and thus benefit the individual patient.

In a country where per capita drug consumption is just Rs15 a year, it is obvious that prescribing should be biased toward life-saving drugs and not unnecessary drugs like tonics. Let us study a few prescriptions usually given by qualified doctors. The following are actual prescriptions for two common problems for which we often visit doctors.

Case 1. The disease is acute diarrhoea. The history of illness is loose motions three or four times a day from first day; no fever, no abdominal pain and no vomiting; and, passed urine five times in first 12 hours.

The treatment given is Lomomycin syrup, two teaspoons six-hourly; Lomotil tablet, one with each stool; Pecto-Kab, two teaspoons six-hourly; Baralgan, twice a day; Flagyl syrup, two teaspoons three times a day; and Pentalmine, one tablet twice a day for three days.

Let us analyse this prescription. First, most acute diarrhoeas are self-limiting. They do not require antibiotics (Lomomycin).

Secondly, Lomotil is a drug of the morphine group which may reduce the frequency of motions but hides the fluid loss which continues within the gut. In the false security of diarrhoea being controlled, a child might land up with severe dehydration.

Thirdly, colloidal kaolin (Pecto-Kab) has no role in treatment of diarrhoea. It creates a false impression of diarrhoea being controlled as it solidifies stool.

Fourth, unless pain is severe, Baralgan-like drugs do not have any use. They should never be given in twice-a-day doses but only as a single dose, when required, to relieve pain.

Fifth, Flagyl is a drug used for amoebiasis and giardiasis. Unless stool examination reveals these organisms, addition of this drug to a prescription for bacterial diarrhoea (antibiotics are being given already) is not ethically justified.

Sixth, Pentalmine is a drug used against worms. It is the costliest wormicide available in the market here. The rationale of adding this drug to the prescription cannot be explained without carrying out a stool examination.

The conclusion is that this is "shotgun" therapy. All the drugs against the common causes of diarrhoea have been prescribed. Some drugs are not ethically justified. The most important part of the treatment of diarrhoea is oral rehydration, which is totally missing. One glass of water with a pinch of salt, sodium bicarbonate and two teaspoons of sugar is all that is required. And it is available to everybody at home. Most diarrhoeas of this type are self-limiting and get cured by the third day. The cost of such a minor ailment has been alarmingly raised by visiting a doctor.

Case 2. The complaint is common cold. The history of illness is running nose for two days; cough for one day; throat pain, one day; and mild fever, one day.

The treatment given is tablet Septran twice a day for seven days; Otrivin nasal drops three times a day for seven days; tablet Cosavil, one tablet three times a day for seven days; tablet Crocin, one tablet twice a day for seven days; Benedryl cough syrup, one teaspoon three times a day; injection B-complex; throat lozenges; and syrup B-complex, one teaspoon twice a day.

Common cold is a self-limiting viral infection which responds within a week if treated and takes a full week if not treated. The use of a potent antibiotic like Septran which can sometimes harm the patient cannot be justified. Otrivin contains ephedrine nasal drops to dry the nose. It is the costliest such preparation in the market here.

Cosavil contains aspirin and an antihistaminic drug which also helps in drying the nose. Prescribing Crocin — a pain and fever relieving drug — when aspirin is already being given is not justified. To suppress the irritating cough of common cold, one does not need a Benadryl syrup (which has antihistaminic drug as an ingredient). Adding Benadryl syrup to the drug list only helps in increasing the cost of the prescription.

Use of injection B-complex and syrup B-complex is unwarranted except to help pharmaceutical firms or the doctor to earn money out of an injection. Throat lozenges are costly. They help only to suppress the cough by their local action. Throat paint application is better.

The simple conclusion is that the prescription is mainly to provide "bread and butter" to the prescriber and to the drug industry. The real therapy — repeated saline gargles or steam inhalation — is totally forgotten. The repetition of the same drug in different forms has increased the cost of treatment.

There are innumerable such examples. The observations from the prescription can be summarised as follows:

1. Unscientific prescribing. Many prescriptions reveal combinations of incompatible drugs. Many times the doses of the drugs prescribed are inadequate. This reflects the poverty of the knowledge of the prescriber.

2. The prescription is aimed at early relief of symptoms even if it is likely to harm the patient in the long run. Doctors have a shotgun therapy. Their prescription covers all possible causes for a particular clinical symptom so as to avoid efforts required for a careful diagnosis. This tendency exposes a patient unnecessarily to many drugs and their side-effects. It reflects the failure of a doctor to diagnose properly the cause of illness.

3. Potent drugs have been used when they should normally be preserved for desperate situations. For example: use of broad-spectrum potent antibiotics even for an illness which does not require them, exposes the population to the problem of developing resistance against these drugs. With drug companies overselling and doctors overprescribing antibiotics, disease-causing bacteria are already resistant to antibiotics. This poses a serious public health problem to developing countries.

Corticosteroid preparations like Betnelan and Wymisone, though good drugs, can be double-edged swords. If not used at a proper time and in proper conditions, they can harm the patient in the long run.

4. Many prescriptions are aimed at earning money. Most illnesses that a private practitioner deals with are self-limiting. Once a patient has come to a doctor, he feels obliged to prescribe some drugs even if not necessary.

Most doctors do not charge consulting fees separately. They dispense drugs from their dispensary at an exorbitant cost, which includes their consulting charge. The charge depends on the paying capacity of the person. The name of the drug dispensed is never told to the patient because if the patient knows it, he may try to compare the cost with the market rate.

The more drugs prescribed, the bigger the profit. The long list of drugs, thus, is a mechanism to earn money without the patient being aware.

Doctors have conditioned the minds of the people to drugs so much that now if a doctor does not prescribe, the patient starts demanding it.

The pressure is on the pocket of the patient — in India, usually a poor person — who spends all that he has in blind faith.

It is not the doctor alone who earns in this business, but also the pharmaceutical industry. A doctor's knowledge is enriched from time to time by pharmaceutical agents, who try to convince him that his company's product is the best available.

A heap of physician's samples is usually enough to convince those who are hesitant. The free samples are then sold. It is unusual to see a doctor who refuses this bribe.

The sufferer is the patient. The doctor hardly ever knows anything about the ingredients in the brand drug that he is prescribing, nor does he have knowledge of other similar brand drugs which may be cheaper.

Why is all this happening in a profession that is concerned with human suffering?

The root of the malady lies in our value system. The medical profession has unfortunately been commercialised. If this goes on too long, the faith in the healer may cease to exist. — Centre for Science and Environment

The dangers of anti-diarrhoeals

Calcutta: The visual shows a traveller armed with suitcases rushing to catch a train or plane. The copy, in large letters, reads: "Got the runs? Don't forget your Enterovioform." This high visibility street hoarding has been reproduced in the August issue of *South*, the Third World magazine, to illustrate a feature on unscrupulous drugs promotion in developing nations. Enterovioform is an anti-diarrhoeal, banned in the West.

The *South* article is by Charles Medawar of Social Audit, a very ...cal and effective British pressure ...oup, who says: "One important Third World concern is supply and promotion of inappropriate and sometimes positively undesirable products." He goes on to add that three-fourths of all anti-diarrhoeal drugs sold in developing countries could be classified "as undesirable preparations."

The April 1982 issue of *World Health* (the WHO journal) has the theme 'Travel and Health.' An article on 'Travellers' Diarrhoea' says: "The best way of preventing diarrhoea is to avoid exposure to the infective agent (i.e. in food and drink). If you do contract diarrhoea, the mainstay of the treatment is the use of oral rehydration fluids." The message of the article is: if you are travelling and eating out, keep oral rehydration salts handy; not Enterovioform or any other anti-diarrhoeal. In fact, the article goes on to add, "There is no evidence that drugs ...y much part in curing travellers' ...rrhoea except under specific conditions... A vast number of commercially available anti-diarrhoeals are on the market. It is doubtful whether any of these really cure diarrhoea although they may temporarily reduce its severity and relieve symptoms."

Because of self prescription of anti-diarrhoeals, in addition to unnecessary prescription of these products by doctors, the Medico Friends Circle (MFC—a group of activist doctors) has launched an educative campaign to inform the public about the principles of modern 'diarrhoea management.' This was decided upon after the successful protest movement (by various groups including MFC) against the hormone pregnancy test (SUNDAY 11 April 1982) which resulted in its being banned this June.

MFC's background paper, 'Operation Anti-Diarrhoea' aims at dispelling current diarrhoea myths in medical practice and promoting the use of oral rehydration therapy which is often all that is needed in the treatment of common diarrhoea. Here are some facts documented in the paper which has been prepared by a team of MFC doctors with support from Dr Raj Anand of the Consumer Guidance Society:

"It is now scientifically established that in the majority of cases of acute diarrhoea, antibiotics have no role to play. About half of such episodes are caused by virus, against which no antibiotic can help. Out of bacterial diarrhoeas only some are cut short by antibiotics. Antibiotics should be prescribed only in the following cases along with rehydration therapy: bloody stools with high fever; suspected cholera in endemic areas; when lab investigations are positive for bacterial infections."

Besides being expensive and ineffective against common diarrhoeas, antibiotics unnecessarily taken can result in drug resistance, undesirable changes in bowel flora as well as toxic side effects. Much misuse of anti-diarrhoeals stems from their ready over-the-counter availability, even though many are Schedule L drugs. The MFC paper stresses a number of hazards which self-prescribers are largely unaware of: Anti-diarrhoeals containing neomycin not only cause renal damage but make dehydration worse and interfere with absorption of oral salts. Binding mixtures containing kaolin or pectin, merely solidify stools without fighting infection.

Lomotil: inadequate warning

They give nothing beyond a "false sense of security" but do not control fluid lost. In cases where antibiotic therapy is indicated, these preparations interfere with drug absorption.

The paper comes down heavily on anti-motility agents which are widely self prescribed. "These drugs have no role to play in acute diarrhoea." The body gets rid of the organisms that cause diarrhoea by ejecting them through stools. Anti-motility agents, by reducing the frequency of stools, ironically cause the organisms to remain longer in the gut without, in anyway, fighting them. One of these, Lomotil (G. D. Searle) has come in for severe criticism the world over. Since the margin between the therapeutic and the toxic dose is small, this product could be very dangerous for children.

Again, the MFC paper says that there is no evidence that the clioquinol drugs (Enterovioform and Mexaform by Ciba-Geigy as well as other brands) are effective against diarrhoea. Because some of these brands also contain an anti-motility agent, they give the impression that clioquinol controls diarrhoea. Despite being banned in the west for causing optic nerve damage, these drugs continue to be promoted in the Third World as a preventive for 'travellers' diarrhoea. Though the manufacturers argue that the drug is harmful only if consumed in large quantities, since it is widely self-prescribed there is really no way of keeping its consumption down at a 'safe' level.

Sales promotion of both anti-motility agents and clioquinol drugs has attracted sustained protests from doctors and pressure groups in the West. In 1977 Swedish doctors began a boycott of all Ciba-Geigy products because of their continued sale of Enterovioform and Mexaform in Third World countries. With veterinary doctors also joining the boycott, an effective dent was made in this firm's sales in Sweden. Yet, both products continue to be sold and even promoted to the lay public, as the Lagos hoarding shows.

Last June, Social Audit published a leaflet listing various kinds of misuse of Lomotil in children. Since 1973 the product has been contra-indicated in the USA for children below two. *The Lancet* reports that in Thailand and the Philippines prescribing information recommends the product for infants over three months. Even in the UK it was being recommended for children below one until strong protests from the Social Audit compelled the firm to revise its label. The firm has agreed under pressure even to contra-indicate the product for children below two years in all countries "where the regulating authority permits such limitation."

This means, however, that if the regulating authority is not vigilant

enough, the onus is not on the drug firm. Tablets of this Schedule L product, easily available without prescription in Calcutta, have the dosage indicated for children from one to three. Lomotil drops have no adequate warning except "keep out the reach of children." Nowhere is it stated that the medicine should not be given to children below two. Literature accompanying the drops is in complicated medical language and the jargon about dosage according to body weight is unintelligible to the lay person and is a poor substitute for a clear warning which ought to be on the outer label. Interestingly, last December a question on Lomotil was raised in the Lok Sabha but no action has been taken.

Health Action International has been particularly active in raising public awareness about the clioquinol drugs and Lomotil. Such efforts are important, considering the extent to which the multinationals go in sales promotion. The Lagos warding is innocuous compared to this tailpiece from a back issue of the *MFC Bulletin*: "Lomotil, the powerful anti-motility drug is sold only by prescription in the US as it is fatal in amounts slightly over the recommended doses. But it is sold across the counter in Sudan by advertising that it was used by the astronauts during Gemini and Apollo space flights."

In order to educate self-prescribers, the MFC has listed the brand names of commonly sold and misused anti-diarrhoeals: Those which contain neomycin are: Kaltin, Renokab and Combactin. Products containing chloramphenicol which should be reserved for typhoid and should never be used for ordinary diarrohea are: Chlorostrep, Ifistrep and Enterostrep. Common brands of binding mixtures are: Pectokab, Pecklin, Linopec and Chlorambin suspension. Anti-motility agents besides Lomotil are Imodium, Imosec, Lomofen and Loperamide. While these are the commonly consumed brands of anti-diarrhoeals a number of other brands also are sold and prescribed. Intrestingly nearly all these are listed in the popular prescribers' guide, *Monthly Index of Medical Specialities*, without all contra-indications adequately described. Which explains why doctors continue to prescribe them.

Vimal Balasubrahmanyan

MARRIAGE RACKETS

Another gang is busted

Calcutta: Close on the heels of the busting of a marriage racket in Srinagar (SUNDAY, 25 July) the West Bengal police has rounded up another gang which specialised in abducting girls and selling them in other parts of north India and also to Shiekhs from the Gulf. With this, two of the biggest girlrunning rackets in North India have been busted.

The police first started tracking down the gangsters when they received a complaint from Abdul Sekh Karim of Sikandarpur village, Hooghly, that two of his daughters had been taken away by a man from Aligarh who called himself Osman. His eldest daughter, Jahanara (16), was married to Osman while his younger daughter Farida (12) was taken away by him on the pretext that Jahanara was longing to see her. Another complainant was Sekh Ainaluddin of Kantagarh, Dadpur, who said that his wife's sister was taken away by the same "Osman from Aligarh."

Police officer interrogating the culprits

Goutam Kaul

Osman and six other members of his gang were arrested on 15 July from Dadpur, where they had gone to arrange a 'marriage' for one of the gang members. Kalyan Mali alias Kallu. The police raided Osman's house in Borotha village, Aligarh to rescue Jahanara and Farida but neither of them was there. However, the police did learn that Farida had been sold to a man called Sushal Khan in Haryana for Rs 1,500. Soon afterwards, the West Bengal and Haryana police jointly raided Khan's house in Faridabad district and Farida was rescued from there. The 12-year-old girl, who was terror-stricken after the experience she had been through, told the police that Sushal Khan was planning to sell her to yet another man for Rs 5,000. The Haryana police have been requested to continue the search for Jahanara.

Farida, now in custody, told SUNDAY that during her stay with Osman, she would get only one *chapati* in the morning and night and that both Osman and Sushal Khan used to torture her as she refused to sleep with them. Asked how she was sold to Sushal Khan she said: "Osman took me out on the road, put me into a bus and jumped out of it. I felt someone in the bus holding me from behind—it was Sushal Khan."Osman, the principal convict, states however, that Farida was never sold to Sushal Khan but to another man called Noor Mohammed of Langloi near Agra. He has confessed that he had married many girls with a view to selling them afterwards. When this correspondent asked him whether he, a Muslim, had organised Hindu weddings, he replied in the affirmative.

A confidential police report says that in West Bengal also, 126 adult and 161 minor girls were missing in 1981. During the first six months of 1982, 76 adult and 66 minor girls were missing. Another 59 girls have been 'married' to unscrupulous gangsters, who later traded them. Clients—according to Osman who has made big money by trading girls—are no problem. He comes to West Bengal because there are not many girls 'available' in UP. Normally, poor parents are delighted when they hear that there are boys willing to marry without asking for dowry. What is more, these 'grooms' bear all the wedding expenses too. From the marriage *pandal* the girls are taken away and sold in the flesh markets of north India.

Hopefully, with the arrest of Osman, the situation can be expected to improve. Intelligence sources have said that a large number of girls were sold in and around Bankunia village of UP alone. With the busting of two major rackets in girl running, perhaps the exploitation of innocent women will be reduced.

Devaprosad Purokayastha

Fri Aug - 24

Flood relief work stepped up

MIDNAPORE, Aug. 23.

Relief and rescue operations were stepped up in West Bengal's flood-ravaged Midnapore district even as all major rivers — the Silabati, the Kangsabati and the Keleghai — were receding last night.

The flood water which had entered 85 villages under Moyna sub-division, was being drained out by cutting the embankment near Dheubhanga. The 60 feet-wide breach near Ejmalichak was also being repaired.

Thousands of people have been rescued by speed boats. Army boats are also standing by. The district authorities have so far spent Rs. 50 lakhs to combat the floods.

Police said two people died of snake bites yesterday. Meanwhile, two more persons succumbed to gastro-enteritis in the district hospital sources added. — PTI.

Editorial on page 8

Communicating with subs

NEW DELHI, Aug. 23.

An underwater grenade to be dropped in by helicopter to communicate with submerged submarines has been developed by scientists at the Armament Research and Development Establishment (ARDE), Pune. The grenade replaces a similar device now being imported.

When dropped into the sea the grenade gets energised by a sea water battery. Electronic relays make the device explode under water giving a loud sound which can be heard by the submerged submarine.

User trials have been successfully carried out and it is likely to be introduced into service.

Mrs. Gandhi must take a moral decision: CS

MADRAS, Aug. 23.

Whether Mr. N. Bhaskara Rao be allowed to continue as Chief Minister of Andhra Pradesh even for a single day should immediately be decided by the Prime Minister on the basis of the moral, ethical and legal issues involved in the dismissal of the N. T. Rama Rao Government and the installation of the new Ministry, Mr. C. Subramaniam, former Union Minister, said today.

Delivering the K. Santhanam memorial lecture here, he said even assuming Mrs. Gandhi had not been aware of the happenings in Hyderabad and that she had come to know of them only from a news agency, it was her bounden duty to go into the moral, ethical and legal aspects of the episode, now that she had with her all facts.

Impersonation had occurred in Hyderabad. So, apart from the issue of majority or otherwise, it was a case of allowing a person who was prepared to commit impersonation and forgery to continue as Chief Minister and take decisions not only on matters of day-to-day administration but policy.

Mr. Subramaniam strongly pleaded for immediate investigation of the charges of impersonation and forgery which had been *prima facie* established against Mr. Bhaskara Rao.

Mr. Subramaniam also charged that the Governor, Mr. Ramlal "had observed double standards first in dismissing the Chief Minister and secondly by bringing the new incumbent". It was claimed on behalf of the Governor that on August 15 he was satisfied Mr. Rama Rao had lost his majority in the Assembly as Mr. Bhaskara Rao had presented to Mr. Ramlal a list of 91 MLAs who were supporting him. It was also claimed that he took these 91 MLAs to the Raj Bhavan. While the Governor was very particular about the Chief Minister enjoying majority and, on that basis, dismissed the Rama Rao Government, it was incumbent on him to be sure, while swearing in Mr. Bhaskara Rao, that he commanded the majority support.When Mr. Rama Rao was called upon to resign, he was conferring with 163 MLAs (out of the total strength 195 in the Assembly). But without going through the legitimate procedure, the Governor hurriedly swore in a Chief Minister, whose majority was doubtful, to say the least.

It was alleged there was impersonation of MLAs when Mr. Bhaskara Rao claimed to have produced 91 supporters at the Raj Bhavan. Not only that, charges were made that the names of many MLAs had been forged in the list submitted to the Governor. When such serious criminal allegations were made against Mr. Bhaskara Rao, the Governor, instead of ascertaining whether there was no basis for them, entrusted the governance of the State to him.

At the time when Mr. Rama Rao presented in Delhi 162 MLAs with identification cards from the Speaker, Mr. Bhaskara Rao claimed to have paraded before the Governor 95 Telugu Desam MLAs, 36 of whom were produced before the President. How could 36 MLAs have been present in both Hyderabad at the same time? It was had been impersonation in Hyderaba

Could the President and the Pri allow a person facing charges of im and forgery to continue in off criminal and immoral acts disqu Bhaskara Rao for the rest of hi occupying any public office, leave Ministership, observed Mr. Subrama

Even as Congress-I president, M would have to take a moral decis her party should support such a dubious character. Without Congre ing, Mr. Bhaskara Rao could not even for a day. The Prime Minist pected to rise above party and politi rations and ensure that the politics was not polluted by such immoral a conduct of public men.

Newspapers to get ad newsprint for elections

NEW DELH

The Government has decided t newspapers additional newsprint connection with the next general ele

The decision was taken at between the Information and B Minister, Mr. H. K. L. Bhagat, Finar Mr. Pranab Mukherjee and the Minister Mr. V. P. Singh.

The meeting, held at the initia Bhagat, reviewed the indigenous a newsprint situation. It has also be that newsprint import will be i ensure there is no shortage.—UNI.

Growing drug abuse

—Lack of focus on prevention and control

THE Union Deputy Minister for Health, Miss Kumudben Joshi said in the Rajya Sabha recently that the question whether the subject of drug abuse should be dealt with by the Ministry of Education and Social Welfare or by the Ministry of Health was under consideration. It may seem an innocuous statement but behind it lies a story which not only does not redound to the credit of the Government but also exposes its skin-deep interest in problems of social welfare.

The growing use of intoxicating drugs, particularly among students, has been a cause for concern for quite some years and in 1976 the Health Ministry set up a committee of experts under the chairmanship of Dr. C. Gopalan, then Director General of the ICMR, to go into the extent of drug abuse and suggest remedial measures. The committee presented its report in 1977 and its recommendations were broadly in three categories: legal and penal measures, educational programmes and social action.

The recommendations under the first category included the setting up of a national advisory board of drug control, enactment of a single central law to deal with the abuse of all intoxicating drugs except alcohol, evolution of a national policy on alcohol, removing inadequacies and plugging loopholes in existing laws, more stringent punishment for drug pedlars, establishment of a registration service for drug addicts and enabling those who register to get the needed supplies of drugs.

Deaddiction centres

The educational programmes contemplated creation of awareness of the drug problem among all social groups and inclusion of the subject in health education. This social action envisaged involving youth in challenging programmes and a social transformation that will reduce the need for using drugs. It was also recommended that as part of the general health services, deaddiction centres should be set up in different institutions with Central financial support and ultimately there should be one such centre in each State.

The committee noted that though drug abuse among the general population was limited, there was a shift from abstinence to non-abstinence among students particularly in the use of alcohol and tobacco and that the situation was likely to deteriorate and get out of hand if adequate measures were not adopted to curb addiction.

The Janata Government which was then in office lost no time in accepting the recommendations and formulating a scheme. But before the scheme could be enforced, the Government fell and the successor Congress (I) regime took it up in earnest in 1980.

A scheme for inclusion in the Sixth Plan was drawn up which envisaged the setting up of a national advisory board comprising representatives of all the interests and the Ministries concerned and the starting of one deaddiction centre as a pilot project at the All India Institute of Medical Sciences in Delhi. It was approved by the Planning Commission and a financial provision of Rs. 85 lakhs was made for it.

Nodal ministry

The choice of the nodal ministry for the implementation of the scheme came up even at that time and it was decided that the Health Ministry should be entrusted with the responsibility, at a joint meeting of the then Health Secretary, the Social Welfare Secretary and the Chairman of the Drug Abuse Committee, Dr. Gopalan.

The Health Minister, Mr. B. Shankaranand not only gave his approval but also got a resolution passed by the Central Council of Health seeking effective implementation of the control scheme. Following this, the All India Institute of Medical Sciences was advised by the Health Ministry to go ahead with the establishment of the deaddiction centre. But till now neither the national board has been set up nor the deaddiction centre come up.

Enquiries show that the scheme suffered a setback in 1983 when the Health Secretary, Dr. S. S. Sidhu was posted as Adviser to the Punjab Government. The issue of who should function as the nodal agency was reopened by his successor in the Health Ministry and it was felt that the Ministry of Social Welfare should handle it. This was endorsed by Mr. Shankaranand. Evidently, he forgot— or was it not brought to his notice—that he himself had given approval in 1980 for the subject being under the charge of the Health Ministry. The Health Ministry's revised stand was not received favourably by the Social Welfare Ministry which was ready to play the role assigned to it under the scheme but not shoulder the full responsibility.

Delay in implementation

It contended that all along the Health Ministry which had set up the committee to go into the problem of drug abuse had dealt with it. Its officials participate in the meetings of the WHO concerned with drug abuse and go on WIO fellowships to study the problem in other countries.

The Social Welfare Ministry finds no justification for the Health Ministry declining to function as the nodal agency for implementing the drug abuse control programme. It has conveyed its stand to the Health Ministry and the issue is now before a coordination committee comprising the Health Secretary, the Education Secretary and the Social Welfare Secretary.

It is anybody's guess how soon the issue will be settled. But the resultant delay in giving effect to the recommendations of the Gopalan Committee is viewed with concern by all those who have been associated with the problem. The Health Ministry's claim that action has been initiated to implement the recommendations has not cut any ice with them.

One of the measures claimed is that the attention of the Ministries of Education and Social Welfare, Finance, Home Affairs and Information and Broadcasting, has been drawn to specific paragraphs in the report for necessary action. Where is the need for this when representatives of these ministries were on the committee and as such had a hand in making these recommendations? If the national advisory board had been set up comprising representatives of these ministries, action programmes to control drug abuse could have been taken by now.

Multiplicity of laws

The addition of a new schedule to the Drugs and Cosmetics Rules to exercise stricter control over import, manufacture and sale of psychotropic substances is another action claimed to have been taken by the Health Ministry. This has been welcomed to the extent it controls the use of one type of drugs but this is not the main recommendation of the committee which wants a single law to be enacted to deal with the prevention and control of abuse of both narcotic and psychotropic drugs.

At present there are several laws dealing with one aspect or the other of drug abuse. These include the Opium Acts of 1857 and 1878, the Dangerous Drugs Act of 1930, the Drugs and Cosmetics Act of 1940, the Medicinal and Toilet Preparations Act of 1953 and the Customs Act of 1962. In addition there are State laws. The multiplicity, according to the committee, results in lack of focus on prevention and control of drug abuse. But the drafting of a single law is yet to be done.

A disturbing aspect is that as the Government is dragging its feet in enforcing the control scheme, the incidence of drug abuse is on the rise. Prior to 1980, the Psychiatry Department of the All India Institute of Medical Sciences had not received any case of heroin addiction but in 1982 there were at least a dozen patients, according to Prof. Devendra Mohan.

Easy heroin availability

In the first six months of this year, 46 patients have been admitted and 180 are being treated as outpatients. Prof. Mohan noted that in 1982, the addicts were mostly students but now most of the addicts are autorickshaw drivers, businessmen and those working in hotels in the age group of 20-30. He attributes this to easy availability of heroin at a low price. According to him, the price has dropped from Rs. 250 a gram in 1982 to Rs. 20 a gram at present. He does not think that the trend will be any different in other metropolitan centres.

Another distressing feature is that the delay in deciding which Ministry should handle the subject has hampered the formulation of the control scheme for the Seventh Plan.

B. S. Padmanabhan

29.11

DECCAN HERALD
Bangalore, Monday, July 23, 1984

Medicines for masses

WITH AN ELEMENT of gimmickry, Chemicals and Fertilisers Minister Vasant Sathe announced a 10 to 15 per cent reduction in the prices of seven essential drugs last week. The announcement was made at a function at the Indian Drugs and Pharmaceuticals Limited, Hyderabad, in an apparently spontaneous response to President Zail Singh's plea to make available drugs at cheap prices to the poor. Mr. Sathe, who has been swearing by the slogan "Medicines for Masses" went on to add that the Government was considering a further price cut of 15 to 20 per cent. The fact is that the prices of several drugs have been reduced on a piecemeal basis during the past year, the cumulative cut being as high as 70 per cent in one or two cases. Yet, the index numbers of wholesale prices of bulk drugs and formulations in May this year show an increase of 11 per cent and 5.5 per cent respectively over the figures for the corresponding month of 1983.

Mr. Sathe said a new drug policy would be introduced in two months with a view to realising the twin objectives of good-quality drugs and "medicines for masses." It remains to be seen whether he can make good this promise. for there is a good deal of confused thinking in his Ministry and powerful elements in the drug industry are seeking to impose their own views. A 14-member steering committee set up by the National Drugs and Pharmaceuticals Development Council in March this year is still grappling with the problem of "synthesising" the reports of its three working groups which dealt with planning and development, industrial approval, and pricing policy and procedure. There is a fear, by no means unfounded, that the recommendation of the working group on pricing to decontrol 75 per cent of the drugs may open the door for the big units to manipulate the markets to the detriment of the interests of both the small units and the general public. While decontrol is a desirable objective, it should be done in such a way that the consumers are not left to the tender mercies of the captains of industry. The way official members of the working group agreed to the recommendation and have been trying since to mitigate its effects indicates that they are not clear how best to go about the task of achieving the Government's objectives. The efforts to formulate a new drug policy are taking place against a complex background. On the one hand, there is over-production of non-essential drugs and on the other production of bulk drugs and formulations has fallen short of targets. The major lesson which emerges from the working of the previous policy, laid down in 1978, is that a policy is good only to the extent it is implemented effectively.

IE 19/7/84

Bandh will hit vital drug supply

By I CHANDRAMOULI
Express News Service

BANGALORE, July 17

Life-saving drugs will be 'choked off' at the private outlets for three days following the decision of the Karnataka Chemists' and Druggists' Association to go ahead with the bandh beginning July 27 as part of the nation-wide closure of retail shops.

An imminent spectre will haunt the accident victims and emergency patients being rushed to hospitals where they might not receive timely supply of life-saving drugs with only a miniscule government outlets selling them during the three consecutive days.

The State Drug Control Department is hopeful of meeting the contingency by dispensing the drugs through the government shops in janatha bazars, cooperative stores and medicine counters in the hospitals. Besides, doctors are being requested to keep extra stocks of medicines for emergencies.

How far the tiny official network would manage to handle the near-crisis situation during who have spotted the bandh notibogglie the minds of the people es prominently hung in all the the 3 day closure has begun to retail medical stores in the city.

State Drug Controller S S Kattishettar said the Directorate of Health Services was also being requested to instruct the primary health centres and units in towns and rural areas to keep enough stocks in view of the bandh. Efforts were being made to persuade the retailers to adopt other forms of protest other than the closure.

The Central Drug Controller at Delhi, Dr S S Gothoskar, who is in the city on a visit said that it would be for the state governments to arrange similar measures to meet the situation prompted by the elosure notice. In Delhi he said drugs would be dispensed through the super bazars.

The nation wide strike call was given by the All-India Organisation of Chemists and Druggists to protest against the alleged apathy of the government to settle their demands.

Two of the demands common to all the states relate to the postponement of implementation of Sec 42 of the Pharmacy Act and removal of the life-saving drug 'phenobarbitone' from Schedule 'X' which strictly regulated its sale through special laws and licences.

The Act which was passed in 1964 and amended in 1976, stipu-

(Continued on page 9 Col 3)

Tax on tax; main grouse

Turn to page 1

lates that only a registered pharmacist will be allowed to dispense drugs. Sec 42 of the Act, enforcement of which has been kept in abeyance and now come into force from Sept 1 this year, has given rise to apprehensions that it will lead to large-scale closure of medical shops run by unqualified pharmacists all over the country.

The proposed bandh demanding further postponement of the enforcement of Sec 42 will not affect the pharmacists in the state since there is no dearth of qualified pharmacists here, according to Karnataka Chemists and Druggists Association Secretary D.A. Gundu Rao.

The Drug Controller also agreed that this would not pose any problem to Karnataka as the state turned out 2,000 pharmacists a year from its 33 colleges and with another 17 colleges coming up this year there would be a surplus of qualified pharmacists. As far as the unqualified pharmacists running the shops, the government held special coaching camps and conducted an examination certifying those with four years of experience in running the shops as qualified. This would protect the existing unqualified pharmacists from losing their business he said.

Dr Gothoskar on the other hand contended that it was high time that an element of professionalism was infused into the drugs sale involving human lives unlike other business Especially, in the wake of widespread reports about malpractices and negligence in the sale of dangerous medicines by unqualified pharmacists eht enforcement of Sec 42 was inevitable to professionalise the trade.

Dr. Gothoskar said eight years was a long time for the State government to set up an adequate number of colleges to train enough pharmacists. If some states faced dearth of qualified pharmacists, they could get them from other states which had a surplus.

Mr. Kattisbettar, who is also the vice-president of the Pharmacy Council of India, said that there were 4-lakh registered pharmacists in the country and 1.25 drug dealers and as such there was no shortage of qualified persons to handle the drug business.

Association sources however contend that in states like Gujarat Uttar Pradesh Orissa and Maharashtra there is an acute shortage of pharmacists and colleges and these states will be worst affected when the Act comes in to force. They fear that several hundred shops in these states will be closed and hence Karnataka Association is extending its support to the demand, though it is not affected as such.

Yet another demand common to all the states is the removal from schedule 'X the drug phenobarbitone, which is extensively used in treating epilepsy for long-drawn periods. At the moment only the government drug stores doctors and a few shops are allowed to sell the drug and the laws governing its sale are "stringent and cumbersome".

Dr. Gothoskar said phenobarbitone though an essential drug and widely needed. was also prone to potential abuse by youth and addicts. Hence it was included in the Schedul 'X along with 17 other habit forming drugs marketed in the country. Besides, India being a signatory to the Geneva Convention stimulating the trade of such barbiturates could not contravene the international agreement by removnig it from the Schedule.

Dr Gothoskar contended that stringent laws dealing with the sale and manufacture of barbiturates were inevitable in view of the country's name figuring in smuggling of such drugs. Phenobarbitone was accessible to patients and the doctors themselves could administer it without any restriction. Besides some shops were given licence to market the drug.

This being so, the demands of Karnataka pharmacists boils down to other issues—abolition of turnover tax on retailers and abolition of rural development cess on medicines. Association Secretary Gundu Rao said in addition to the 4 per cent Central sales tax and 8 per cent surcharge sales tax there was another 10 per cent rural development cess (RDC) on the sales tax all amounting to 13.6 per cent tax in total. This would be a burden on the consumers who would have to pay 48 paise as taxes and other invisible cost factors on each rupee they spent on drugs. These taxes, did not affect the seller in any way since they were allowed to be passed on to the consumer.

What affected the retailer was the .5 per cent tax over the total turnover of the shops which was not allowed to be passed on. Mr Gundu Rao said the tax had been in force since 1981 and despite representations, the government did not concede to scrap it.

He argued that a medical shop owner with an average annual turnover of Rs 2 lakhs would have to pay Rs 1,000 as TOT. In view of the low profit margin (about 10 per cent), he lamented that this further eroded their earnings. The profit margin, he claimed, was not revised since 1982. According to estimates, the net revenue to the government in the form of TOT stood at Rs 2.78 crores. The wholesale dealers, however, were not subject to the tax.

The other demand of the bandh is abolition of sales tax on life-saving drugs as was done by West Bengal, Orissa and Maharashtra. This is one of the demands being projected by the pharmacists as a humanitarian one for the public good.

Zafrullah Chowdhury
photo: Someswar

Our medicare system creating

WEALTHY DOCTORS, UNHEALTHY PEOPLE

THE REALISATION that public health policies of developing countries like India had been — wittingly or unwittingly — *mortgaged to the giant multinational companies which control the pharmaceutical industry and the national companies following their techniques is not new.*

What is new is the feeling that doctors in India and countries like it have become pawns in the game — at the cost of the health of the millions.

That the multinationals have been making astounding profits (some times more than 2000 per cent) has been known for decades. Several feeble attempts at controlling the "mark up" of prices by them have been made. When Dr. Triguna Sen became the Minister for Petroleum and Chemicals in 1967, he initiated the move for abolishing brand names for some popular formulations and make drug companies sell them under generic names. Could it be just a coincidence that ministry (which controls the pharmaceutical industry) was taken away from him and the proposal scuttled?

Could it be the normal red tapism and official lethargy that prevented the Government from considering the recommendations of the Jaisukhlal Hathi Committee which, among other things, sought the banning of at least 23 of the many irrational drug combinations?

These are disturbing questions. The answers are obvious to anyone with some social consciousness. Why did not doctors, who should be most concerned with these issues, ask these questions so far — or answer them?

"Doctors are tremendously ignorant people," says Dr. Zafrullah Chowdhury of Bangladesh, a medical doctor himself by training. The young project coordinator and co-founder of Gonoshasthya Kendra (people's health centre) at Savarthana in Bangladesh, says: "Doctors and money are, for most part, safely ensconed in institutes designed to serve the rich. From there they produce their scholarly papers saying that the poor also have problems, but not problems for which treatment is available to them."

Several seminars have been held in the last one decade in the country. Lengthy, academic papers have been read by the doctors calling for a medicare system that is more suited to the needs of the majority. From time to time there is talk of evolving a system of "barefoot doctors" and creating "paramedical cadres". Frequently impassioned appeals are issued asking doctors to go to rural areas. There are occasional threats to make rural service compulsory for.

And yet a vast majority of the doctors produced at the expense of the tax-payers' money (the Government spends on training a doctor many times more than the amount paid by a medical student as fees) prefer to stay in cities even if they have to live on a meagre practice or take to teaching physiology in schools. But they would not go to villages where they would be treated as demi-gods, where they can have a thriving practice and also job-satisfaction.

The result is that even today thousands of quacks and half-baked doctors have a roaring practice in villages. Even today various unscientific "systems of medicine" and "witch doctors" have a field day in villages. Even today thousands of doctors trained at the expense of poor Indians are allowed to man the public health services of England and Arab countries just because the country gets some foreign exchange.

Says Dr Chowdhury, who recently visited Bangalore: Colonialism has left much of the developing world with health systems largely irrelevant to their conditions." The functions of medicine are social — fulfilling the social needs to promote good health prevent diseases, treat those affected when the preventive measures fail and rehabilitate them. And yet the whole approach of medical education is not that of a social science It is presumed that the body is machine. Most of the treatment is symptomatic and not prophylactic.

Medical education is open only to the rich, who mostly have their values based on money. A student who pays a capitation fee of Rs 1.5 lakh to 2.5 lakh to undergo the costly and prolonged course of studies is not going to spend all that money without deciding in advance who quickly it could be recovered and how the investment could be multiplied over the years.

One need not expect the medical practitioners to do social work sacrificing their self interests. All one would expect from them is not to be racketeers, not to sacrifice the interests of public health to make a fast buck, not to become willing tools of companies trying to make money on the sufferings of the masses. Racketeer may be a very strong word to use, but what else would you call "general practitioners" who would send their patients to half a dozen specialists unnecessarily to get a commission from them, who would prescribe costly new brand names just because the medical representative of the company had given a good gift? How many doctors really keep abreast of the recent developments in medicine

other than what the drug firms' literature tells them? How many question those claims or verify them?

"Doctors need continuing education. Nowhere in India have I come across arrangements made by the State for providing refresher courses for the doctors. Most doctors are too busy earning money to read anything" Dr Chowdhury says.

"The only books most doctors read today are the bank (pass) book and the cheque book," says a wag. The way some of the modern general practitioners function now, all that they need to know is a list of broad spectrum antibiotics. Even before you complete telling the symptoms, a prescription will be scribbled and the palm extended —

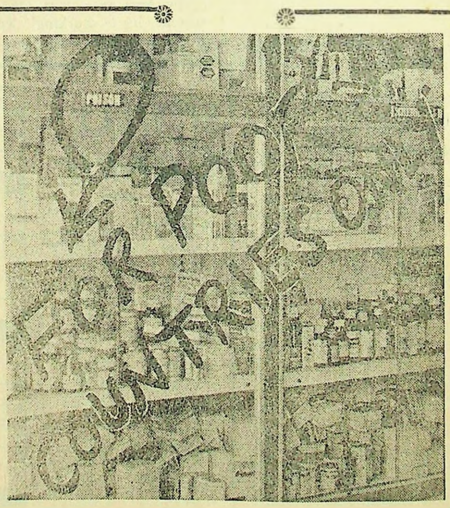
By Someswar

for money. Anything a little complicated will always be referred to specialists. Most of the knowledge a private practitioner now acquires after passing out of the medical college is what the medical representatives dole out—along with free samples and gifts.

It is very easy to condemn doctors, but it is to be realised that they only reflect the rot in the society itself. It would also be an exaggeration to say that all doctors fall into this category. There are exceptions which prove the rule.

The movement against this decadence has come from the younger and more socially conscious doctors themselves. There are today nearly a dozen organisations of doctors and scientists, which are trying to evolve a new ethos for the medical profession and give it a new direction. Some of the organisations are: Medico Friend Circle, Pune; Voluntary Health Association of India, New Delhi; Low Cost Drugs and Therapeutics Cell of VHAI at Dehradun; Arogya Dakshata Mandal, Pune; Del-

O... 11, col 4



Does increased life expectancy in the Third World mean — at least for the poor — more years of pain and suffering? With poverty itself the main cause for ill-health, most developing countries have, with their mixed-up priorities , not been able to evolve health policies that meet the conditions and needs of their own communities.

There has been a growing suspicion for long that these policies are influenced to a large extent by the multinational companies or their national counterparts which have a vested interest in continued ill-health of a majority of the people. Another doubt that has been gaining ground in recent times is whether modern — by which is meant Western — drugs offer a solution at all to the health problems of the poor countries.

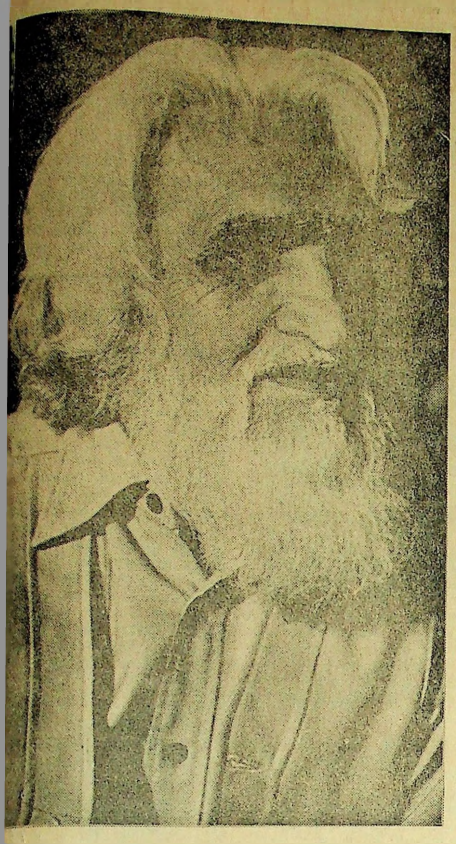
Oxfam, which has been doing commendable work as a British Voluntary agency promoting health — as a positive concept of higher quality of the life rather than absence of disease — has brought out this book by Mrs. Dianna Melrose, based on field experiences of Oxfam activists.

The book has a fund of useful information on health problems and services available in developing countries. It pinpoints the main problem: the medicare system is so drug-based and doctor-oriented that poor people often buy unnecessary Western medicines they cannot afford, believing that they hold the key to good health. 'Bitter Pills' explodes this myth carefully nurtured. It highlights the work of organisations like Gonoshasthya Kendra in Bangladesh crusading against false claims of multinationals.

The book comes at a time when there is a growing awareness of the need to evolve a broader strategy for better health in the poor countries, based more on preventive measures and inexpensive, easily accessible remedies and systems. This book will go a long way towards coordinating the efforts of several groups in different countries to evolve this alternative strategy. It makes valuable reading for everyone who feels concerned and wants to bring about the socio-economic changes necessary for such a policy.

BITTER PILLS: Medicines and the Third World Poor by Dianna Melrose, Oxfarm publication pp. 277 4.95 sterling Can be had from Oxfarm, 59, Miller Road, Benson Town Bangalore-560046 For payment in rupee equivalent.

icasso of India



Maqbul Fida Husain

Photo: G. Narayanaswamy

By Aban R. A. Lal

AS DAWN breaks over old Delhi, a tall, boyishly slim, white-haired figure, quietly brings his Fiat car to halt at one of the Dhabas Nizamuddin. With quick ng strides he slips inside is crowded, noisy, place d sips his strong morning ha", listening to the talk those who struggle from awn to dusk for sheer exisnce.

In this milieu of the hume, his bare feet and long wing white beard raise curiosity. In fact, he ems to be so well accept, that a fellow stranger estions, "Do they pay you ell?" to which the old man olitely answers: "Yes, my ss is good to me". He is istaken as some Sahib's river, since he always mes driving a car.

This is Maqbul Fida Huain narrating to you a ase of his mistaken identy. India's Piccasso, the an who might well be desribed as the Number One odern artist of this country, Husain has a piquant ense of humour and thorughly enjoys the lighter oments of life. He was mazed when a young coule spotted him at Connaught Place and he overheard hem say: "He looks like Iusain! Husain is well aware that his bizarre looks may sometimes earn him the label of a 'tramp'. If the price of fame is instant recognition, in his case it has lead to some very funny experiences and he likes to have a good laugh talking about it. A few years back, on a visit to New York city, he went into a 24-hour restaurant after a late night movie. He found himself a corner seat and as he waited to place the order, he moved aside a box of cigarettes he found lying on the table top. His movement was noticed by the manager who was quick to confront Husain with a rude yell: "Out, get out of this place." They thought him to be a tramp out to steal the cigarettes!

Getting this celebrity painter to talk about himself wasn't easy. Husain promised to be interviewed on a Sunday morning during his recent visit to Bangalore where he had been specially invited to display a selection of his works by a five-star hotel. When I tapped on the door of his suite at the appointed hour, a young lady informed me that Husain was out and would return an hour later. Much later. I located him at the hotel's coffee shop and reminded him of my interview. He cracks the boiled egg he has ordered for breakfast and tells me that he "is not in a good mood to talk." The interview is then fixed for next morning. I find him at the gallery giving some finishing touches to his paintings.

Greetings over, I ask if we can now sit down and talk, but to my utter surprise, even with out an "excuse me", Husain walks away from the gallery. I wait another 45 minutes wondering where he has gone. Someone in his room informs me he is at the gallery — another helpful hotel stuff member tells me he saw Husain going out of the hotel! Puzzled by this strange behaviour I decide to leave the hotel, only to find Husain coming in a car up the drive. I ask him if he is interested in the Interview. He renders no apology for his absence but effusively leads me to the poolside and orders coffee as a prelude to the interview.

Close friends tell me that he is "very forgetful" and I let that be an explanation for his odd, if not rude, behaviour.

If Husain canvases are large, so is his story. He punctuates his talk with colourful imagery and emerges as an ageless figure with amazing vitality. Two hours quickly slip by as he talks of imporant landmarks in his 50-year-old career as painter extraordinary'.

Born into a relatively poor family living in Gujarat, Husain was one of eight children. His father was an accountant. His mother, a Gujarati woman, died when Husain was a mere baby of one and a half years.

Husain's childhood was spent at Baroda and Indore He learnt Persian in school and dreamt of being a poet like his maternal uncle. "I thought I might one day become a poet or an art director for films, but I never thought of becoming a painter." He claims however, that he started painting as a child and was eleated when two of his landscapes were sold for Rs 10 each, way back in 1932. "I felt very confident about painting when I found that someone was prepared to pay twenty rupees for them. In those days a whole family could live on twenty five rupees a month. It was a big sum". When asked what was price range of Husain paintings today, he parried the question by saying that the paintings he sold for in 1952 for about Rs 500 would today fetch over Rs 40,000.

On page 11, col 1

For a people-based drug policy

From page 9

hi Science Forum; Society of Young Scientists, New Delhi; Concern for Correct Medicine, New Delhi; Consumer Education & Research Centre, Ahmedabad; Centre for Education and Documentation, Bombay; LOCOST, Baroda; Federation of Medical Representatives Associations of India, Patna and popular science movements like Maharashtra Lok Vignyan Sanghatan, Shastra Sahitya Parishad of Kerala and Science Circle of I.I.Sc.

It is at the invitation of some of these groups that Dr. Chowdhury, the one-man crusade against exploitation by multinational companies, which has grown into a movement now, came to India recently.

The Gonoshasthya Kendra founded by Dr. Chowdhury and his associates in 1972 created history last year and gave the lead to organisations in the developing countries including India, by successfully campaigning for a ban on hazardous and irrational drugs. A eight-member expert committee of which Dr. Chowdhury was a member, recommended a ban on 1707 products of medical and pharmaceutical companies in three categories. The first included 265 locally made and 40 imported drugs regarded as positively hazardous which were recommended for immediate ban and destruction. The second category included 134 drugs which required reformulation and were to be banned in six months and the third 742 locally manufactured and 526 imported drugs. The last category either had little or no proven therapeutic value or could easily be manufactured by local companies, instead of the multinationals, at much lower costs. The report of the committee, submitted on May 12, 1982, was approved by the Chief Martial Law Administrator on May 29 — perhaps a speed record in governmental action. On June 12, the Drug Control Ordinance was promulgated.

America exterted maximum pressure on behalf of the US companies and was joined in by the British, French, German and Dutch governments. The US administration in Washington did its best to have the ban lifted. It succeeded in getting some changes made.

Says Dr. Chowdhury: "Seventy per cent of the annual drug sales in my country are of drugs described as useless or therapeutically insignificant by the British National Formulary, the National Research Council, USA and the Federal Drug Administration, USA". He said out of the 51 products of Glaxo sold in his country, only 17 were marketed in UK and just one-third of them listed as 'essential' drugs by the WHO.

Sri Lanka, which also adopted a similar drug policy buckled under the American pressure. Pakistan was too preoccupied with Islamic fundamentalism to bother about such progressive measures. The 'failure' of these two countries to ban these drugs and the fact that India, considered more advanced, had not bothered to ban any of these drugs including the acknowledged harmful enteriovioform and maxaform are held out by the pro-American lobby and the multinationals as proof that the Bangladesh policy was wrong.

"What is probably the most humiliating comment on the social consciousness of India health personel is that the Indian drug policy is quoted by the multinationals to condemn the Bangladesh ban. Drugs which have been banned in England in the 30s and even in Nepal in recent years are freely available across the counter in India. This makes banning them in Bangladesh more difficult as they enter our country from India." Dr. Chowdhury says.

The social consciousness of the Indian medical community has finally been aroused, Dr. Ravi Narayan of St. John's Medical College, who is actively associated by Medico Friends Circle, VHAI and another similar organisation 'search' is working with groups like the Science Circle to first mobilise the science community and then generate public opinion in favour of cheap alternatives to the modern drug-based health system.

In an article in the forthcoming issue of the *Bulletin of Sciences* published by the Popular Science Movement and the Science Circle, Dr Narayan says that practices which needed to be checked in India are:

i. Sale of drugs banned in other countries, ed. Lomotiland cliquinol preparations.

ii. Sale of irrational combinations and formulations.

iii. Sale of drugs without adequate precautionary product information.

iv. Sale of drugs as highly inflated costs. For example, Analgin is being sold at 20 to 30 times the cost of production.

v. Promotion of drugs for indications that are not clinically proved and are often potentially dangerous. or example, pregnancy testing drugs which induced abortions were freely sold, till a campaign was launched against them, despite well - documented scientific evidence that the risk of foetal deformity is increased by the use of these harmonal preparations.

vi. Sale of spurious, adulterated or poor quality drugs Eg. turmeric powder is sold as tetracycline in capsules.

vii. Sale of old, expired and unused drugs

viii. Over - prescription and misuse of tonics, high-protein foods, harmonal preparations and baby foods.

ix. Sale of drugs without prescriptions and

x. Production of drugs for profits rather than health needs.

Quoting the Indian Council of Medical Research (ICMR) and Indian Council of Social Science Research (ICSSR), Dr. Narayan says that while drugs for diseases like leprosy and tuberculosis are produced at one-third or one-forth of actual requirements, tonics vitamins and high protein substitutes are being produced in wasteful abundance.

A joint report by ICMR and ICSSR has warned against the emergence of a "doctor-drug producer axis" to exploit the people.

Can India not do what even Bangladesh could do?

king

By P. S. Sharma

ill
he
ul-
els
er-
e.
ice
our
nd
ply
ing
Pra-
de-
the
tion
tion
me-
de-
e to
tres,
pani-
the
go

Pra-
1977,
5 dis-
ering
mine.
e of
sts in
d dis-
ears.
iachal
econo-
orests,
f for-
icidal,
reckl-

dimen-
energy
aste a
n this
illages,
is to
hours
nce of
gather
become
elpless

victims of this energy crunch: as adults are busy earning a living or doing household work, the children come in handy to be assigned the fuel-gathering work. Their education, and mental development suffer irretrievably.

The position is much worse in villages, especially in the desert and in the hilly areas where long distances have to be traversed and long hours to be spent on getting drinking water too. Farmers with large herds of cattle have set up biogas plants and big landlords have started using crop residues as fuel. But the problems of those who own no land have grown manifold. When they hardly have enough money to buy food, where is the question of their buying firewood? It seems that millions of rural men and women have got entangled in a vicious energy crisis. They eat food, to produce energy and then spend this human energy — all of it — in producing food and gathering fuel to cook it. And so on and on in a circle like the proverbial bullock going round a 'kolhu'.

The firewood crisis has hit the city dwellers too. According to reliable statistics, nearly three quarters of fire wood and about half of the dung used in urban India is purchased. A substantial part of it is brought from the villages on head, in bullock carts or in trucks. Most wood stoves or chulhas have an efficiency of only five to ten per cent. So it may just be that this firewood gives us less energy than is spent by trucks in transporting it. Ultimately, it comes down to so much energy wasted.

Sensibly, firewood is meant for local consumption. Its transportation to the cities is both uneconomical and wasteful, and it should, therefore, be completely banned. The alternative sources of liquid petroleum gas available to the urban population is highly restricted so that the vast majority has still to depend on coal or kerosene. But supplies of coal and kerosene are also limited, and we have to find out newer and newer sources of energy for industrial, agricultural and transportation purposes. Hydro-electricity is one source; biogas is another. Then there are the ocean and tidal waves, the nuclear energy and the inexhaustible source of solar energy. The potential is vast, but we do not have as yet the requisite technology to exploit it.

Even then, the most essential requirement of energy will still be for cooking purposes. We may close down the air-conditioners, but not put off cooking ranges. We must therefore increase our firewood supply to at least four-fold of its present quantity. That is the crux of the matter. The forests, as suppliers of firewood, are the lifeline of the rural poor. If the indiscriminate denudation of forests is not checked, it will spell doom on our agricultural and industrial economy.

Tractor run by the sun

Soviet engineers have designed a prototype of a solar powered tractor. On the outside it differs from a conventional tractor by a broad visor above the cabin. This visor is actually a solar cell assembled of flat-shaped direct solar energy converters. The maximum capacity of the cell is 400-600 watts. This is too little to activate the tractor but sufficient for recharging storage batteries. Tractors never operate non-stop. Some time they idle, while energy accumulation is a continuous process, which does not stop even on a cloudy day. The cells are sensitive enough to operate by scattered light.

The development of this prototype does not mean that tomorrow it will go into serial production. Solar cell production is a very costly business. This tractor, however, can be effectively used for improving the design and systems of the machine. As soon as the cost of solar cell production comes down to an acceptable level, the tractor will immediately go into massive production.

Dog bails master out

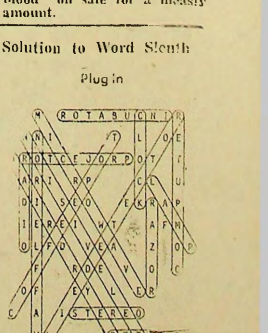
A persistent dog won the hearts of the police in Madurai and got his master, a 28-year-old hawker, released on bail. T. Jeevanandam, hawker, was arrested for his involvement in fight and placed in lock-up at the Tallakulam police station. His dog's fidelity the Inspector annot leave till touched by the dog's fidelity the Inspector approached the legal aid cell to get Jeevanandam released on bail.

Sold blood 800 times

Madan Lal, 40, father of a five-year-old boy, is one of the estimated 60,000 people who live on selling their blood. Over the last 20 years Madan Lal has donated blood about 800 times — at times thrice a day and his rare 'O' group with negative Rh factor fetches him customers from far off areas. These people haunt blood banks at New Delhi and put their blood on sale for a measly amount.

Solution to Word Sleuth

Plug in



[illegible] of the uterine cavity begins.

SECRETION

Should the ovum get fertilised, however, the secretion of progesterone is maintained and there will therefore be no shedding. But the disappearance of bleeding may not indicate pregnancy absolutely. Normally, the urine sample taken early morning can provide a good test. In its place, MNCs have begun to push EP pills. Given orally, or by injection, these substances raise the level of the two hormones in the blood. Within a week, however, both are expelled rapidly through the bladder. The sudden decline induces "withdrawal" bleeding as in the normal cycle and the woman may, according to the prevailing popular wisdom, not be pregnant. If she is pregnant, the secretion of progesterone will be maintained naturally, and she will not bleed.

The International Journal of Gynaecology and Obstetrics categorically states that "hormonal tests for pregnancy are not reliable. The test is false positive in one out of five women. There is also an increased risk of foetal abnormalities."

The possible teratogenic action of the hormones has also convinced the scientific group of the WHO that these tests should no longer be done and they have made this recommendation in their report on 'The Effect of Female Sex Hormones on Foetal Development and Infant Health."

The Physicians Desk Reference, which is the official text of pharmaceutical companies in America for American doctors, observes strictly: "The use of progestational agents during the first four months of pregnancy is not recommended....there is evidence of potential harm to the foetus when such drugs are given during the first four months of pregnancy." It also observes: "Several reports suggest an association between intrauterine exposure to female sex hormones and congenital anomalies, including congenital heart defects and limb reduction defects.... If the patient is exposed to progesterone during the first four months of pregnancy or if she becomes pregnant, while taking these drugs, she should be apprised of the potential risk to the foetus." About estrogens, it says: "Estrogens should not be used during pregnancy. The use of female sex hormones, both estrogens and progesterones during early pregnancy may seriously damage the offspring."

A cursory look at the latest issues of MIMS India (December, 1981) and CIMS (September, 1981) would confirm that certain multinational drug companies continue to advocate their use for pregnancy testing without mentioning that this involves a much greater risk of congenital birth defects to the baby in the mother's womb. Certain firms recommend its use in the "diagnosis of pregnancy", while others who had till very recently advocated its use as a pregnancy test mention its use in "secondary ammenorrhoea". That these agents are contraindicated in pregnancy is still not mentioned. The drugs publicised in this category are Lut-Estron Forte (Mac), E.P. Forte (Unichem), Gestapion (Khandelwal), Secrodyl (Allenburys), Cyclenorm (MPI) and Lynoral (Organon).

Some firms have cleverly put under "indications", "see literature'. Examples: Duoluton (German Remedies) and Oestrone (Lyka).

Preparations such as Dieseron Forte (Nicholas), Menstrogen (Organon), Norlestrin (Parke-Davis), Graseeron Forte (Nicholas), Orgaluten (Organon), Primolut-N (German Remedies), Voldys 21 (Glaxo) have in their list of contraindications included pregnancy. Firms like Parke-Davis in their contraindications have also included the phrase, "there is some evidence to show that hormonal preparation when used during pregnancy may lead to foetal [illegible]normalities."

A[illegible] disturbing phenomenon [illegible] to these drugs is the[illegible] [illegible]olitions use for inducing [illegible] abortions. Pregnant women [illegible] to doctors and ask for [illegible]

[illegible] the thalidomide syndrome but presented a somewhat different pattern. One may speculate that a number of factors may influence whether or not an anomaly will occur as a discrete malformation or in association with other anomalies - among these are hereditary predispositions, dose response and precise timing of the insult."

One would think that the catastrophe of children so severely maimed and handicapped due to the administration of a drug like thalidomide would have brought about an appreciation and awareness of the dangers of administering drugs to pregnant women, but this has happened only in the West, where MNCs are liable to be sued for millions of dollars for negative impacts. Our own drug controllers, in fact, [illegible] to think that we should not be unduly alarmed about reports of drugs being withdrawn for unmanageable side effects from Western markets.

In medicine, the relevance of a principle such as the one that obtains in law — the benefit of the doubt — becomes inoperative. In no circumstances can any drug today be given the benefit of the doubt. Drug companies are the worst guides in the matter. The Distillers' Company in Britain that marketed thalidomide, for example, continued to emphasise in its advertisements that the drug was safe, even after negative reports began pouring in, and the *British Medical Journal* supported the company in its editorials for some time.

OPINION

What have all our authorities been doing in the meantime and what is the prevailing medical opinion here about these drugs? Most enlightened medical practitioners are aware of some of these problems, but those in charge of the politics of drugs and medicine in our society have already chosen to look the other way. A task force of the ICMR recently recommended that Government permit the distribution of oral contraceptives through "non-clinical channels", which in ordinary English would mean, without prescriptions from doctors. Contraceptive pills are hormone pills too, and should one continue to take them after one has become pregnant by accident, then the risks are the same.

From the circumstances it seems obvious that the task of fighting the deadly ignorance surrounding hormonal EP drugs is one for women's groups alone. The day is not far away when women, like Ralph Nader's "raiders" will have to militantly confront chemists, MNC offices and drug companies over the issue, to get back some measure of control and guaranteed safety in matters of their health and that of the children they will bear. Everyone else has been found seriously wanting or ineffective.

89.13

DECCAN HERALD
MARCH 8, 1982

Hormonal drugs: shades of thalidomide

By Claude Alvares

CONCERNED medical groups in the country including the Medical Friends Circle, Health Action India, and the Arogya Dakshata Mandal from Pune, have started a campaign on the occasion of International Women's Day (8th March) to educate women to stop the indiscriminate use of hormone drug combinations if they are pregnant.

There is growing evidence that such drugs containing large doses of female sex hormones, estrogen and progesterone, are teratogenic, that is, are liable to cause foetal abnormalities. While the use of these drugs has been discontinued abroad and medical opinion is ranged against their exploitation particularly in early pregnancy, multi-national companies, chemists and quacks continue to dispense them in this country as "over the counter" (OTC) pills or injections and some women are being advised and enabled to use them for attempting to induce abortions.

Despite being totally unreliable, hormonal drugs are usually prescribed for diagnosing pregnancy. One out of five women who undergo such a test may bleed after a few days and yet still be pregnant. In the meantime, the exposure of the foetus to the hormones will possibly have harmed its development in a manner similar to what thalidomide did in Europe in the sixties to more than seven children before it was eventually banned.

Estrogen and progesterone are the two female sex hormones secreted in rhythmically fluctuating amounts by the ovary in adult menstruating women. In the first half of the cycle, estrogen levels are high. In the second, progesterone dominates. Just before menstruation, progesterone secretion rapidly declines and since in its absence the growth of the mucous membranes in the uterus cannot be maintained, menstrual shedding of the lining of the uterine cavity begins.

SECRETION

Should the ovum get fertilised, however, the secretion of progesterone is maintained and there will therefore be no shedding. But the disappearance of bleeding may not indicate pregnancy absolutely. Normally, the urine sample taken early morning can provide a good test. In its place, MNCs have begun to push EP pills. Given orally, or by injection, these substances raise the level of the two hormones in the blood. Within a week, however, both are expelled rapidly through the bladder. The sudden decline induces "withdrawal" bleeding as in the normal cycle and the woman may, according to the prevailing popular wisdom, not be pregnant. If she is pregnant, the secretion of progesterone will be maintained naturally, and she will not bleed.

The International Journal of ... an injection of this drug, and quacks have a roaring business from this angle. No one knows when this particular rumour or whisper campaign was started. In fact, hormone drugs were once used to prevent threatened or habitual abortions, thou h even this practice has now been discontinued. Pregnant women who therefore receive this injection run the risk of giving birth to a malformed baby, since the foetus rarely aborts.

A better option for such women is to resort to "menstrual regulation" as soon as they miss their periods. This is a very simple, out - patient procedure. The thin tube of the "M. R. Syringe" is introduced into the uterine cavity and the piston is withdrawn. The uterine lining is sucked into the syringe. This starts off the menstruation whether the woman is pregnant or not. "Menstrual regulation" is a very simple and safe procedure, not requiring any anaesthetic, and which any doctor can perform. Yet for most doctors in India, doling out prescriptions for the hormone pills seems to be the easy way out.

CHEMICALS

How do the abnormalities occur? Most drugs are simple chemicals which when introduced into the mother will pass from her circulation to that of the foetus because of a lower concentration on the foetal side of the placenta. Tetracyclines, for example, taken by a pregnant woman, will cross the placenta and be stored in the teeth and bones of the unborn baby and result in yellow discolouration of the teeth. In the thalidomide case, more severe birth deformities were induced.

..*The New England Journal of Medicine* recently editorialised: "The unique feature that first attracted our attention to the potential teratogenicity of progestogen [estrogen" were "the associated anomalies now covered by the acronym VACTU ... These anomalies of simultaneously developing and simultaneously vulnerable structures ... stimulated the systems involved in the thalidomide syndrome but presented a somewhat different pattern. One may speculate that a number of factors may influence whether or not an anomaly will occur as a discrete malformation or in association with other anomalies - among these are hereditary predispositions, dose response and precise timing of the insult."

One would think that the catastrophe of children so severely maimed and handicapped due to the administration of a drug like thalidomide would have brought about an appreciation and awareness of the dangers of administering drugs to pregnant women, but this has happened only in the West, where MNCs are liable to be sued for millions of dollars for negative impacts. Our own drug controllers, in fact, continue to think that we should not be unduly alarmed about reports of drugs being withdrawn for unmanageable side effects

To, Mira

FRIDAY JUNE 21 1985

Bhopal's deformed children

Plea For Euthanasia

By D. C. Jain

THE environmental pollution caused by MIC gas leakage in Bhopal last year has resulted in the birth of about 100 deformed and birth-defective infants till April this year to the gas victims. About 1,500 such women are pregnant and there is every possibility of their children also being birth-defective or deformed.

I am not a prophet of doom but with the rapid industrial growth and the scant regard for the law controlling environmental pollution, we are destined to suffer recurrences of the Bhopal tragedy and the number of deformed children will multiply. I wish to suggest how to deal with such a problem legally.

When a severely birth defective infant enters a family, its parents are faced with an excruciating dilemma — should they provide medical treatment for the child or terminate treatment when it is unfeasible, medically or economically. There are moral and ethical problems associated with the agonizing decision of life and death. Some of these infants have been born without the cognitive part of the brain, some have mental and physical handicaps that although not necessarily fatal will severely impair even minimal functioning. It will make life miserable for them and their poor parents. The parents may sacrifice everything they possess and keep the infants marginally alive without curing the underlying defects. But to what gain?

If these infants die, their death may result from the decision for non-treatment. Non-treatment decisions challenge fundamental attitudes towards life and death. The right to life is the basis of all other rights. The United States Supreme Court has held that, within limits, both abortion and contraception decisions should be made according to one's own moral views (Roe V. Wade (1973) 410 U.S. 113). The decision to terminate treatment for a birth-defective new-born presents a parallel moral dilemma.

Medical decisions concerning severely birth-defective infants involve three primary parties — the child, the parents and the State.

An infant's needs and interests are important to any decision concerning its well-being, because the infant is the focus of the decision. Yet defining those needs and interests is difficult. They are unable to express their desires or interests. Inevitably, parents will make the final determination. Medical care will not always serve the child's interest. An infant with a severe birth defect will never have an awareness of the outside world. The defect may be incurable and he may never leave the hospital. When a child with severe birth defects is born, the parents may decide that the family should avoid the financial and psychological disruption that the infant will create. Parents of the deformed children, who are themselves victims of the Bhopal tragedy, acting as individuals will face similar conflicts.

The potential satisfaction to be derived from raising a birth-defective child must be juxtaposed against the necessary sacrifices in the parents' lives. Parents with deformed child will often disregard friendship, forgo job opportunities and spend their life savings in an extra-ordinarily short time and for nothing in return. Some parents will believe that these actions will run directly counter to their personal welfare, others will gladly make the sacrifice. But still a large number of parents will feel torn by so many conflicting interests that they will find any decision difficult to make.

The State is the guardian of society's basic values. One of the basic values protected by it is the sanctity of human life. For this reason the state has an interest in protecting the lives and welfare of its citizens. When the citizen in question is an infant, the state interest may be specially strong, because an infant is unable to care for and protect itself. But the state has limited resources. A birth-defective new-born may drain the state's resources and yet never become a productive citizen. In such a case, the state's interest in protecting a birth-defective infant's life would be minimal or perhaps nonexistent.

The 14th Amendment to the US Constitution indicates that life is a fundamental interest which economic interests are not strong enough to override. Nevertheless, there are decisions which recognize that continued medical care may not always serve the best interests of every patient. The New Jersey Supreme Court has held that even individuals who are incapable of exercising the right to die have such a right. In re Quinlan (1976) the Court allowed Quinlan's parents to exercise by proxy her right not to have her life extended by artificial means. Extending the Quinlan analysis it could be said that an incompetent infant has a right to die that also could be exercised by proxy. Karen Quinlan was irreversibly comatose and in a persistent vegetative state. In many ways her condition could be characterized as unfeasible. The Court held that the constitutional right to privacy is broad enough to encompass a patient's decision to decline treatment under certain circumstances.

The courts in India could also articulate a right to privacy that inheres in certain aspects of the family relationship, ranging from the decision to conceive children to the right to raise children according to the parents' values. It is reasonably expected that our courts will protect parental decisions concerning children's religious and educational upbringing. If the non-treatment decision can be characterised as one that concerns an infant's upbringing, it, too, may be protected under the Indian Constitution.

If the parents were without the economic resources to treat the child, or if the available medical treatment could not benefit the child, the medical care could be characterized as an impossible duty. A standard for non-treatment decisions should satisfy three criteria: (1) The standard should project the best interest of the child and accommodate the interests of the other participants in so far as they are compatible with those of the child. (2) The system should provide certainty and consistency of application in line with present legal doctrine, yet retain enough flexibility to handle an unforeseeable situation. (3) The standard should not undermine widely held moral values of our society: the sanctity of life, the equal right of all citizens to life and medical treatment, and the duty of society to protect the weak and the helpless.

On these premises, the standard assumes that (a) whenever the infant's potential quality of life is extremely poor, death is preferable to continued existence. (b) A treatment is unfeasible if it cannot benefit the infant, i.e., if the treatment inevitably will prove futile. Medical treatment is unfeasible if the child will die within a brief period, regardless of any attempt to save the life. When an infant is irreversibly unconscious, as when the cognitive part of the brain is non-existent, the medical feasibility standard would apply. In such a situation, the physician can restore breathing through a respirator but can never restore brain functioning. The infant at best will be able to breathe and perhaps to blink and swallow, it never will be able to see, feel, think, or otherwise relate to the outside world. Under such circumstances, few would argue that the available treatment actually benefits the child. As soon as the physician can determine that the child has no chance to regain consciousness, treatment can be withdrawn.

On the basis of the above discussion it is suggested that the non-treatment decision should be legalised in certain carefully limited circumstances by legislative enactment. As a first step, the physician must determine that the child's condition is medically infeasible. Next, the parents must decide whether they wish to continue or withdraw treatment. If the parents decide to terminate treatment, a court will review the decision. Procedural review by a Court will safeguard the State's interest in the integrity of the decision-making process.

All this may sound like a chimera to many readers, but at the advent of 21st century, India will need such a legislation, to make the lives of unfortunate persons like Bhopal gas victims and their progeny, less miserable. What Victor Hugo said has relevance in this context: "There is one thing stronger than all the armies in the world: and that is an idea whose time has come."

The author owes gratitude to Elizabeth S. MacMillan for her article "Birth Defective Infants" Stanford Law Review Feb. 1973.

Better rural health: Paramedics' role cited

By Our Staff Reporter

Bangalore, Dec. 1 — The most practical way to improve rural health service is to integrate preventive programmes with other areas of health care such as nutrition, agriculture and family planning.

This can be enforced with the help of para-medical workers as envisaged by Dr. Zafarullah Chowdhury.

Chowdhury, reknowned for engineering the ban of 1,707 hazardous and irrational drugs in Bangladesh, told medical students at St John's Medical College, here today that a doctor's role in a rural health could be fulfilled with the help of trained paramedics. In most third world countries, threee-fourths of the health budget is urban-oriented, resulting in adverse health conditions in rural areas where the masses live.

In India and other developing countries, only 16 per cent of the population can afford modern medicine, Chowdhury said. In such adverse conditions, doctors alone cannot deliver health care to all. The concept of paramedics could evolve to bridge this gap. Most community health problems like diarrhoea, skin diseases, chest infections and malnutrition can be tended by a trained paramedic, he said.

Paramedics should be drawn from among the community so that they can communicate at that level acceptable to that community.

"Doctors", he said, "fail to reach most patients because they stick to textbooks." Paramedical workers, on the other hand, are able to communicate in more acceptable and traditional ways, and with proper training, can handle 60 per cent of the ailments in rural areas without undermining the role of doctors.

Regarding the drugs situation in India, Chowdhury said it was sad that despite so many drug manufacturers in the country, they are unable to supply even one third of the leprosy and tuberculosis drugs. On the contrary, many useless and dangerous formulations are being manufactured and marketed.

Education would be the most effective means of bringing about a reversal in the deteriorating situation, he added.

The Times of Deccan, Dec. 2, 1983

Newstime 13.5.35

89-20

Study for ban on pain killers

Press Trust of India

Hyderabad: A majority of the analgesic preparation or pain killers being used as medicine in the country have been found scientifically not justified, according to a study done by the rational drug policy cell of the Pune based voluntary medical group – Medico Friend Circle.

Analgesic is a substance used in medicine to relieve pain and is commonly referred to as a pain killer. The 50 analgesic preparations were listed in the monthly index of medical specialities (MIMS) that gives standard preparations currently promoted by the pharmaceutical industry, the authors of the study, Dr Jamie Uhrig and Dr Penny Dawson said in their report.

The group using a rigorous procedure graded the 59 pain killers into four categories – A, B, C, D. It recommended the immediate withdrawal of the preparations falling into the B, C, and D categories. Use of preparations found good and justified according to the study are plain paracetamol, aspirin, crocin, dispirin, mazetol, paracin, calpol, fortwin, curepar, molin, parvon, predimol, pyrigesic, sosegon, tylenol and tapal junior numbering 14 in group 'A'.

The group listed apidin, avamol, beserol, betaflam, bral, cariaspirin, corbutyl, dolopar plus, equagesic, fortagesic cyclopan, norgesic, malidens, parvon-N, proxyvon, ralcidin, spasmo proxyvon, tysyne, sudhinol, tapal, treupel, veganin, walagesic be withdrawn.

The group wanted the following analgesics and antipiratics to be immediately banned for they contained analgin. Anadex, avaforton, baralgan, codolsic, dolopar, neogene, novalgin, novalgine quinine, pamagin, promalgin, sedyn-a-forte, spasmizol, ultragin, ultragin syrup, ultragin injection, simalgin-A. Analgin, a minor analgesic, enjoyed widespread popularity in India. It was an unnecessary and dangerous drug that had safe and inexpensive substitutes. The doctors group said it should be banned. A World Health Organisation expert committee had established a list of essential drugs for all countries that include a list of analgesics and antipyretics like aspirin, paracetamol, codeine, pethidine and morphine injection.

Pain is a universal phenomenon and the development of drugs to relieve pain is one of the few remarkable achievements of modern medicine. It is necessary to make a judicious decision on the relevant drugs to relieve pain, the doctors said. The Medico Friend Circle with doctors and socially conscious members from all parts of the country urged for a government policy with provision of all essential analgesics and antipyretics at low cost and the banning of ineffective preparations as a first healthy step in forming a rational drug policy in the country.

Minister to open meeting

Newstoday

Hyderabad. The Minister for Small Scale Industries, Mr S Ramachander Reddy, will inaugurate the 31st Regional Purchase Advisory Council meeting of the Director-General of Supplies and Disposals, Government of India, on Monday. In the meeting, issues relating to the problems of small scale industries located in southern zone will be discussed. Central Government officials and officials from Tamil Nadu, Karnataka, Kerala, Pondicherry, and Lakshwadeep will participate in the meeting.

Mill's policy condemned

Newstoday

Hyderabad: The policy of the management of Vijay Spinning Mills, Vijayawada, in asking women workers seeking regularisation of job to submit divorce certificates or bonds promising that they would not marry has been vehemently condemned by the general secretary of the state Textile Workers Federation, Mr Amolak Ram. He urged the Labour and the Social Welfare Departments to take appropriate steps to stop such practices.

Television

12.45 Higher education programme
4.00 Higher education programme

i) will put PTI chap on mailing list
ii) No Ed article
iii) will send Bhopal report pc soon.
Replied RN 4/6

Secunderabad
May 19, 1985

Dear Thelma,

Enclosed is a PTI item in the local Hyderabad newspaper, Newstime, on the pain-killers. I understand it also appeared in the Deccan Chronicle of Hyderabad & The Statesman. Can you put on your mailing list for press-release, perhaps also MFC bulletin, the PTI reporter here? He is: Mr M. Somashekhar
Press Trust of India
Hydergurda, Hyderabad-29.
500029.

23/5/85

He's a young chap, very

receptive to MFC type information and also has a Science background. I had given him the material you sent and requested him to do a news item since PTI news will reach all newspapers. If he gets the press releases directly the time gap & my contacting him and both of us finding the time to meet etc will be avoided. By the way, Sunday March 31 published my item on MFC study on Bhopal. It's right at the end of the issue, after the News section, so you might have overlooked it.

Best wishes,

Vinod

Health-for-all needs eight-fold rise in outlay

From Our Special Correspondent

NEW DELHI, Nov. 21.

The launching of a "universal immunisation programme" to protect all children against six specific diseases before the age of one, introduction of continuing financial benefits for acceptors of terminal methods of birth control and 100 per cent achievement in the establishment of primary health centres and sub-centres are some of the targets the Union Health Ministry has set for the Seventh Plan to reach the goals of "health-for-all" and "net reproduction of one" by the turn of the century.

The Ministry's proposals, recommended by the steering group of the Planning Commission, will require Rs. 10,329 crores to implement—Rs. 8,138 crores for family welfare, including maternal and child health programmes, and Rs. 2,191 crores for health schemes—in the Central sector, and Rs. 3,337 crores on health schemes in the State sector.

This is an eight-fold increase on the Sixth Plan outlay of around Rs. 1,400 crores but health planners and administrators feel that unless resources of this order are provided, the goal of health for all by 2000 cannot be achieved.

Should not be grudged: It is contended that an increase in productivity—one of the three main aims of the Seventh Plan—is not possible unless people are healthy, both physically and mentally. Hence, these inputs are necessary and should not be grudged. The outlay sought is a little over five per cent of the proposed total Plan outlay of Rs. 180,000 crores, compared to 3.3 per cent in the Sixth Plan.

Though no new strategy is envisaged, the thrust will be shifted to prevention and the strengthening of the rural health infrastructure.

The "universal immunisation programme" seeks to immunise babies against diphtheria, whooping cough, tetanus, polio, tuberculosis (part of the present programme) and measles.

To achieve this, the existing capacity for vaccine production will have to be increased. Already, production facilities have been created for DPT and BCG vaccines, and a unit to produce measles vaccine is proposed to be set up. The Health Ministry expects to get technology from abroad and set up the unit by 1988.

Stronger 'cold chain': Another important requirement is an effective 'cold chain' (centres to store vaccine under refrigeration). International assistance is expected for this. Recently, there was a meeting in Italy of international donors interested in strengthening the 'cold chain'. They felt Columbia, Senegal and India could be helped. If the assistance comes through, facilities for transport of vaccine in refrigerated containers from the manufacturer to the district headquarters, and for cold storage at the district and PHC level, will be created.

For effective implementation of this and other programmes, the rural health infrastructure will be strengthened at an estimated cost of Rs. 1,665 crores. The idea is to have one PHC for every 30,000 of population—in hilly and tribal regions one for every 20,000—and one sub-centre for every 5,000 of population (3,000 in hilly and tribal areas). So far, targets in this regard have not been achieved. The Seventh Plan will also try to ensure that the numbers of 'auxiliary nurse midwives' (ANM) (multi-purpose workers) are in accordance with targets.

100 per cent Central funding: It has been noticed that States have not appointed male ANMs as this expenditure has to be borne by them. The female ANM is fully funded by the Centre. It is proposed to make the sub-centres scheme 100 per cent Centrally sponsored. About 500,000 are expected to be set up with the full complement of two ANMs.

'Continuing benefit' for terminal acceptors: As regards population stabilisation, acceptors of terminal methods will be provided attractive incentives under the "continuing benefit" schemes. One envisages a monthly allowance of Rs. 50 for five years to every such acceptor after two children.

Another scheme envisages presentation of a cash certificate, not less than Rs. 50,000, encashable after 20 years, only for acceptors of terminal methods after two female children. It has been found that such couples disfavour terminal methods as they want a male child to provide for old age. This cash certificate will provide an assurance of financial support. About Rs. 3,800 crores are proposed to be spent on these schemes, from the proposed outlay of Rs. 8,138 crores for family welfare.

Can be attained: Official sources are confident that if resources are provided the demographic goals set for 1990 can be achieved. These aim at reducing the crude death rate from the present 12.5 per thousand to 10.7 per thousand, the birth rate from 33.3 per thousand to 27 per thousand, increasing life expectancy at birth from 55 to 57.5 years and reducing the infant mortality rate from 114 per thousand live births to 87.

This will call for an increase in the couple protection rate, from the present 29.3 per cent to 42 per cent.

Assassination fiasco may not deter Qadhafi

From Sashi Kumar

BAHRAIN, Nov. 21.

The Libyan leader, Colonel Muammar Qadhafi's resentment at Cairo's public expose of the foiled bid to assassinate the former Libyan Premier, Mr. Abdel Bakoush, and the forms it could take have become a major ponderable in diplomatic circles here. The whole affair—in which Egyptian undercover agents posing as mercenaries undertook to do the Libyan-commissioned hit squad's (two Britons and two Maltenese) work for them, then faked a photograph showing the intended victim lying dead with blood gushing out of a bullet wound on the forehead and fooled Tripoli into announcing a successful execution—was more illustrative than illuminating, because it was already a wellknown and acccepted fact that terrorism is a centrepiece of the Libyan leader's foreign policy.

When the cover on the operation was blown Libya, far from being abashed or embarrassed, poured vitriol on the Egyptian leadership for aborting its mission to eliminate "stray dogs" (the stock phrase for opponents of the Qadhafi regime) and ridiculed the Egyptian President, Mr. Hosni Mubarak, for doubling as a sleuth. From the interrogation of the four would-be assassins now in Egyptian custody it appears, moreover, that the death net cast by Tripoli included several other world leaders, among them the West German Chancellor, Mr. Helmut Kohl, the French President, Mr. Francois Mitterrand, the Saudi King Fahd and—although it is not yet clear whether Libya had anything to do with it after all—the late Prime Minister, Mrs. Indira Gandhi.

Overtures suspect: While it may be necessary to make some allowance for the pro- (on which Libya is seen as taking a more extreme posture than the other radical State in the area, Syria), his ambition to be acknowledged as the ideological and political leader of the Islamic world had only succeeded in isolating him from most moderate States.

Union with Arab States: Union with one or more of the Arab States (he made unsuccessful attempts to enter into union pacts with Syria, Sudan, Tunisia, besides Egypt) has been his constant theme and bugbear. After starting out as a passionate follower of Nasser he fell out with Egypt when Sadat sidestepped his long, nurtured plans of bringing the two States under a common political banner. The rupture deepened when Egypt signed the Camp David peace accord with Israel and ever since there have been frequent allegations by Cairo of Libyan-sponsored subversion in its territory.

The former Egyptian President had branded Qadhaffi "one hundred per cent mad" and his successor, Mr. Mubarak, held him responsible for the Red Sea mining scare that led to an international scouring of those waters, a plot to blow up the Aswan dam and plans to hijack a U.S.-built war plane to Libya. Mr. Mubarak has also accused him of an air raid on Omdurman in Sudan this year, while the Sudanese President, Mr. Jaafer Nimieri, has been crying wolf against a Qadhafi scheme to overthrow him.

Israeli colony: Jordan's resumption of relations with Egypt made it an "Israeli colony" in Col. Qadhafi's eyes and when his latest shot at Maghreb unity (of northern African States) under his leadership was challenged by Algeria, he promptly shook hands and sealed an accord with Morocco over and across and against that country. He had then put out feelers to Saudi Arabia that was seen as the

544 killed

MEXICO CITY: Army troops dug on Tuesday through the remains of a working class neighbourhood flattened by a series of gas explosions that authorities say killed at least 544 people and left 10,000 homeless. Some 1,500 people were injured in the fire that raged through the northern suburb of San Juan Ixhuatepec when a gas tanker exploded on Monday near a distribution centre, sparking at least 12 other earth-shaking blasts. The blast levelled houses and factories nearby. The fire, which survivors said fried birds in the air, began before dawn when 80,000 barrels of liquefied gas exploded at the distribution centre. Many houses made from petrol barrels in the poor suburb simply melted in the immense heat of the fire, killing their occupants in seconds—UPI.

Limits on loan

WASHINGTON: The IMF has announced a reduction of "enlarged access" borrowing options for its member countries next year. The "enlarged access" borrowing, designed to aid countries with balance of payments problems, was reduced to 95-115 per cent from 102-125 per cent of each country's quota in the IMF. The limit on borrowing over a three-year period was also reduced to 280-345 per cent from 306-375 per cent of each country's quota. The IMF also stipulated that a member's total foreign debt must not surpass 408-450 per cent of its quota, down from 500 per cent at present. The limit on loans to compensate for reduced export earnings Stays at 83 per cent of the quotas.—AFP.

Boat tragedy

DHAKA: More than 100 people were feared drowned when a boat capsized in a river on Tuesday in southern Bangladesh. The "Sihangal" turned upside down with more than 500 passengers on board in midstream on the Sirston Hola river near the town of Barisal. Many passengers swam to safety but more than 100 [illegible] women and children, were

89.18

units are not interested in producing bulk drugs in countries like India. In Europe and USA, the multinational units produce bulk drugs in a spirit of collaborative relationship. In the developing countries such production is avoided by them and where it is done, the host country pays dearly for such drugs...The multinational units operating in India produce only a small fraction of bulk drugs. The main thrust of multinational units continues to be towards capitalising on drug formulations and non-drug items like cosmetics and luxury goods where technology and capital inputs are much lower and which permits promotion of aggressive salesmanship and brings in much higher returns on investments." Even when there is a reduction in production costs, there is no reduction in prices. For example, the price of Betnelan, manufactured by M/s Glaxo Laboratories, was fixed taking into account the cost of production at a particular time. Thereafter, though the cost of production came down, the price was not proportionately reduced. This was brought to the notice of the government by the workers of the company in 1977. Ultimately, the company was forced to reduce the price of the product by Rs seven per 100 tablets in February 1979. Again, despite the increase in sales, the number of workers employed by these companies has not increased. (Refer table)

Again, to simply earn profits, some multinationals are marketing drugs, which are totally or partially banned in their parent countries. Some of these drugs are Penicillin and Sulfa combinations, Penicillin and Streptomycin combinations, combinations with Chloramphenicol and drugs belonging to the Esgapyrin group. These are the drugs which have been totally banned in the parent countries.

In addition to these, some drugs which have been partially banned in other countries are being marketed in our country. These are Estroprogyn, Estrois Forte, Lynoral, Menstrogen, Orasecron Forte, Norlestrain, Secrodyl, Premarin, Disecron, Disteron, Duogynon Forte, Duogynon Oral and Amenoron, known as pregnancy test drugs which cause deformation in unborn children. These drugs have already been either banned or withdrawn in at least six countries during the last nine years following the reports that they can damage babies in pregnancy. Sweden was first to ban them in 1970, followed by Finland ('71) USA and Singapore ('75), Belgium ('77) and the United Kingdom ('78).

Some multinational drug companies even reintroduce banned drugs under different labels. Duogynon, manufactured by M/s German Schering, though banned in India was marketed as Cumorit.

'Drive out harmful drugs'

SYED KAMALUDDIN reports on the Dacca government's new drug policy which bans the manufacture of a number of drugs produced by multinational corporations

The new drug policy recently announced by the Bangladesh government, banning the manufacture and import of 237 pharmaceutical products with immediate effect and restricting the activities of the multinational drug manufacturers in the country has prompted immediate and angry reaction from them. The policy has also outlined that another about 1,500 pharmaceutical products would have to be withdrawn in the next nine months.

What particularly annoyed them was that the new restrictive drug policy has followed the most liberal New Industrial Policy (NIP) which virtually denationalised all industries and provided all possible facilities to the private sector, to play an increasingly important role in national economy. The NIP has reduced the reserved list for industries in the public sector to six: armament and defence related industries, atomic energy, air transport, telecommunication, generation and distribution of electricity and mechanised forest extraction. All other industries, including jute and textiles, can now be owned by both the public and private sectors either separately or jointly.

While the industrial policy aims at "a new dimension and greater thrust to industrialisation of the country," the drug policy's objective is to ensure the supply of life-saving drugs and medicines at a reasonable price to the people. Multinationals based in Dacca and Western observers here feel that prospects for the promotion of foreign investment in Bangladesh which brightened up with the new industrial policy have largely been diminished due to the drug policy.

The local pharmaceutical industries would be particularly affected as the new policy stated that "no foreign proprietary medicines will be allowed to be manufactured under licence in any factory in Bangladesh if the same or similar products are available manufactured in Bangladesh as this leads to unnecessary high prices and payment of royalties. In the light of this policy, all existing licensing agreements should be reviewed."

The drug policy, announced by the health and population minister Maj-Gen M. Shamsul Haq, said that a total of 4,140 brands of drugs are available in the country now as against only 182 drugs that the government had earlier selected as essential. Only about 90 of these essential listed drugs and medicines are locally manufactured. "All pharmaceutical companies," the policy said, "are mainly engaged in formulation. And they procure their raw materials by import, involving an annual expenditure of more than Taka 60 crores in foreign exchange." While these raw materials produce finished drugs worth three times, an additional quantity of finished products worth Taka 30 crores are also being imported annually.

According to the policy statement, the Drugs Act of 1940 which is the basic drug legislation, is outdated and grossly inadequate. The outdated legal procedure hinders rather than helps prompt prosecution and penalties. Much of the unethical practices in manufacture and trade has been possible because of the weakness of the existing legislation. Further, the concept of drugs and medicines as an essential component of healthcare is missing.

The statement said: "In the present drug laws, there is no provision for regulation technology transfer and/or licensing agreement with foreign collaborators. Similarly, there is neither provision for protecting consumers against drug hazards nor is there any protection of national interest in respect of patent rights for pharmaceutical substances. The present government is committed to health and welfare of the people. As a member of the World Health Organisation (WHO) we are committed to health for all by the year 2000. Being conscious of this responsibility the government was anxious to discover the pitfalls in the national health policy as a whole and the drug policy in particular. As the two were inseparably linked, the government was pleased to constitute an eight-member experts committee to evaluate all the registered licensed pharmaceutical products presently available in the country and to formulate a national drug policy consistent with the health needs of the country," it added.

Production or importation of nearly 2,000 brand names has been banned under the drug policy.

The Chief Martial Law Administrator (CMLA) has already promulgated the new "Drug Control Ordinance of 1982" to administer the new drug policy and monitor the functioning of the pharmaceutical manufacturers as well as others involved in the field of healthcare. The ordinance, promulgated on 12 June came into immediate effect. The government has also prepared a list of 150 essential drugs considered "adequate for most therapeutic purposes."

A forum for readers on topics, ideas, developments of current interest

89.17

Wanted a national drug policy for positive health care

DRUGS and the related chemical industry form an integral part of the infrastructure of any National Health Service. To have a proper and effective "people's drug policy" we must have a "people's health policy". Without knowing the common or major diseases prevalent in our country, we cannot plan what must be produced and how much of that to be produced.

Even after 36 years of independence India could not formulate an effective 'national health policy' and medicare programme. The formulation of a national health policy depends on something more than building hospitals and blaming the medical profession for not going to the villages where 80 per cent of the population live. Proper health care for the entire population could not be achieved even in developed countries like the U.S. and the U.K. But the socialist countries like U.S.S.R. and G.D.R. could achieve total health care while the health care of the people is nearing completion in other developing countries like China, Cuba and North Vietnam. The social structure of the countries and the class character of its ruling section on every sphere of life are the reasons for this achievement.

Proper health of our population could be achieved if we can eradicate 'communicable diseases' and for that the Government has set apart Rs. 36 crores a year. Hardly the cost of a warplane it is planning to buy.

Common diseases and essential drugs

We know the common diseases and the drugs to be produced to treat them. But if you study the production pattern during the last few years you will learn that the Government administrative machinery is not at all serious to implement its own decisions nor has the drug industry taken the Planning Commission reports seriously. There are about seven common diseases and 10 drugs termed as essential drugs. The production of these drugs has suffered due to the manipulation by the drug manufacturers and the total negligence on the part of administration.

The diseases are malaria, filariasis, T.B., leprosy, typhoid, dysentery, hepatitis, hookworm and rabies. These diseases account for 22 per cent mortality and 18 per cent morbidity and 80 per cent of the population is at risk. The people of the Third World countries who are suffering from these tropical parasitic diseases were compelled by the drug industry to purchase vitamins and tonics marketed in very attractive bottles and cartons. The share of tonics in Indian market is 12 per cent while in the developed countries it is just three per cent.

Obsolete formulations

In India we have 5,000 pharmaceutical firms producing about 60,000 formulations. Seventy per cent, that is 42,000 of these formulations are obsolete and useless. 5,000 are useful and another 2,500 are of marginal use. The rest may be included in the harmful group. The Hathi Committee identified 117 as essential drugs. The World Health Organisation says 200 of these are enough to take care of 90 per cent of the existing health problems. Finally to save the 80 per cent of the population at risk in India, we need only 10 drugs, termed the essential drugs. They are chloroquine, diethyl carbamazine, streptomycin, INH, PAS, thiacetazone, dapsone, chloramphenicol, metronidazol and piperazine.

This year the drug industry will sell about Rs. 3,115 crores worth of formulations, of course, mainly tonics and vitamins. The Government itself admits that five per cent of that will be spurious. While there are millions of sepoys and policemen, and thousands of officials, MLAs and MPs, the whole of India has hardly 500 or so drug inspectors to monitor the affairs of 5,000 registered pharmaceuticals and double that number of unregistered firms and thousands of chemists and druggists. To test 60,000 formulations we have hardly five or so drug testing laboratories.

Out of 5,000 registered firms, 45 are multinational companies, 118 are in the organised Indian private sector and six are the chronically losing public sector firms. Of these 1,500 firms are based on loan licence and 3,500 are the so-called manufacturing units. Hardly 200 are actually engaged in production and the rest are tablet-making, capsule-filling and tonic bottling plants. Fifteen big concerns produce 80 per cent of the drugs and five among them are Indian and the rest multinationals. Even after 36 years of freedom, we still import 50 per cent of the raw materials at stupendous prices. The 45 multinationals market 78 per cent of the formulations, while the Indian private sector has a 16 per cent share and the public sector six per cent.

"We are businessmen and not bishops," said an executive of a pharmaceutical firm, to Mr. Hathi. So to be in the drug business profession profitably, they produce more and more; much more than their rated production capacity. The firms have so conveniently and mystically tuned the medical profession to go in for the completely imported and costly third generation rifampicin and ethambutol replacing all the other cheaper group of drugs for TB. I am sure that no medical man has heard of streptomycin, INH, PAS or Thiacetazone during the last five years or so and thus they have lost complete faith in these drugs. The firms have so conveniently made these as useless and old fashioned first line of drugs, thereby creating a lack of demand for this cheaper group and to project it as an excuse to cut down drastically the production and to increase the import of the costly rifampicin and ethambutol, and the multinationals have christened these as the 'Third Generation' drugs, yes for the Third World.

Likewise, I may warn you that 'Phenobarbitone' a cheap life-saving drug required by millions here to save them from epileptic and febrile fits will soon disappear from the Indian market to be replaced by costly imported substitutes. Please don't conclude that all the drugs included in the First generation by the Americans are harmful. Most of them became first generation because of the manipulation by the multinationals, and just because they are cheap. That is the case with the drugs mentioned above.

With these details just outlined I may say that national drug policy is the part and parcel of national health policy, which is comprehensive positive health care and that is promotion of health, prevention of diseases, prompt diagnosis with treatment and proper rehabilitation in all stages of life from womb to tomb. In the sphere of drug policy we must see that no person dies of any illness for want of medicines, irrespective of social and economic conditions and remoteness of his habitation. Medicines, chemicals and equipment required for the protection of health, prevention of diseases, restoration of health and rehabilitation should be freely made available to each and every individual of the society without any social, political, economic or geographical constraints.

The import monopoly of the State Trading Corporation with its top heavy, and unhealthy bureaucratic set-up have made things worse. The irony is that while it—the STC—could reduce the price of 15 per cent of the imported bulk drugs, it helped to increase the cost of 75 per cent.

Hathi Committee's recommendation

The Hathi Committee recommended nationalisation of the drug industry and out of 15 members in the committee nine gave it in writing, to nationalise all the foreign-owned drug companies without paying compensation. But our rulers joined hands with the four bureaucrats in it who differed. The report as such vanished totally right from the Government printing press without a trace. The one presented before Parliament is there for you and the nation to express profound sorrow and the deep sense of shock and to weep at times and offer homage.

Each patient was found to have received an average of 10 to 14 drugs for simple ailments. We generally have a temptation to treat each new symptom as it emerges with a new drug, something avoidable. Osler a great physician—you may not agree his greatness—stated in 1901, "One of the first duties of a physician is to educate the patient not to take drugs." This may be true a century back, during his stone age. Now nothing prevents us from choosing a dozen or so for every patient, from 60,000 formulations at our disposal, at a reasonable profit. Most of us have first hand information about the length of prescriptions. It is polypharmacy that we practice now and it is the physician who needs to be blamed and censured and not the pharmaceutical firms.

More than 50 per cent of the patients after the first visit to a doctor are treated on hunch, intuition, experience, etc. rather than on established certainty. The evils and dangers of practising habits by us is very difficult to estimate and there is no method to determine it in India. There is no secrecy in modern medicine and if the people are educated to take some more care in their health problems and if they are willing to carry a notebook whenever they visit a doctor and demand a true copy of the case sheet every time from their doctor, I am sure that most of the evils can be prevented amongst the allopathic practitioners. Let the patient keep his health record. If the poorest man can safely maintain a ration card, what prevents him from keeping his own health card?

Dr. K. Kishore Kumar,
Secretary, IMA, Mavelikarabranch, Kayankulam (Kerala).

89-16

Fight against HPT Still On

VIMAL BALASUBRAHMANYAN

THE campaign against the hormone pregnancy test (*Mainstream*, April 10, May 8, July 24), which seemed to have yielded results, is not yet over. The fight is still on. Although the Health Ministry note on June 30 announced a ban with a deferred cut-off date, less than a fortnight later, Deputy Minister of Health Kumud Joshi told the Lok Sabha that the products have not been banned. She merely repeated that the manufacturers had already been told to include warnings on the lables. How these warnings are worded, their low visibility, ambiguity, the continued availability of these drugs over the counter, and their continued prescription by doctors for pregnancy testing have all been outlined in the previous *Mainstream* articles.

The campaign against HPT misuse, initiated — in March by the Voluntary Health Association of India, the Medico Friend Circle, Arogya Dakshita Mandal and the People's Science Movement, and subsequently joined by women's groups and journalists all over the country, is the first such mass protest aimed at combating the pernicious influence of the drug industry on the Government and on a large section of the medical profession. Whether or not the Government is willing to admit it, it was this mass movement that resulted in the ban announced in June. Obviously the drug industry's machinery has not been idle meanwhile. How else does one explain Kumud Joshi's unabashed announcement barely two weeks later on July 15?

One is tempted to suspect that even the deferment of the ban (to come into effect only from June 30, 1983) was motivated, probably with the idea of again citing new 'experts' on the indispensability of the drugs and thus pave the way for lifting the ban. However, despite Kumud Joshi's announcement, the whole thing seems ambiguous and the drug industry itself seems unsure of the Government's attitude: will it yield to people's pressure or will it bow to pressure from the drug industry? So the next step from the industry is understandable: woo the press.

Business Standard (August 27, 1982) published a report, quoting drug industry sources who have urged the Government "to appoint a statutory body to examine the propriety of the ban". The sources criticised the June 30 directive and said "the misuse of these drugs by a few uninformed or ill-motivated persons for pregnancy testing ... did not warrant a total ban on their use for any other purposes." Does that not sound vaguely familiar?

When pressure was put on the baby food manufacturers, their argument was on similar lines. Unhygienically prepared, overdiluted, and fed in insanitary bottles, baby food could cause infection. Not if the manufacturers' instructions were properly carried out. So, if the illiterate and the ill-informed don't know how to bottlefeed, why blame the innocent manufacturers? Big business philosophy is the same, be the product baby food or combination-hormone drugs.

Anyway, let's examine the drug industry's point of view. First of all, a large number of women (and their unborn babies) affected by HPT are affluent and literate. A large number of prescriptions for these drugs come from doctors who have no excuse whatsoever beyond ignorance and indifference. A large number of chemists who 'prescribe' these drugs do so because they know that doctors themselves recommend their use for pregnancy testing, despite the minuscule warning on some of the packets and despite all the latest medical findings.

A senior Calcutta gynaecologist, who strongly condemns HPT misuse, told me a few months ago that just the previous week a woman patient had come to him very agitated, saying she had taken HPT on a general practitioner's advice and now what should she do? What had made her suddenly aware of the danger? Probably the articles in the press, said the specialist. If the first doctor had been up-to-date with medical knowledge, and if the brand she bought had a large, bold warning printed on the outer label, she need not have exposed her baby to danger. The industry's argument about the 'uninformed' doesn't say how this situation is going to be prevented. And the industry also implies by using the word' uninformed' that only the illiterate are at a disadvantage. Not a word about the doctors and chemists whom they are directly in contact with.

As for the illiterate: if the reality in this country is that the mass of the women are illiterate and ill-informed, should not Government health policy be specially formulated to protect this majority? The small print ambiguities which pass for 'warnings' do not even protect the literate. Even in literate UK and USA it was not action by the Government or the medical profession that brought HPT misuse to a halt but organised people's action. What is the logic in hiding behind the 'warning' excuse in a country where illiteracy reigns and when the ranks of the 'uninformed' include qualified doctors?

I had earlier mentioned that the Government has a clear duty to inform and educate the mass of women on HPT misuse through posters and films. Only recently big prizes have been awarded for TV and radio scripts on family planning. But it is left to a women's group in Delhi, Saheli, and VHAI to design a poster, with text in Hindi that

aims at warning the semi-literate never to take any tablet or injection to confirm pregnancy, and informing them what kind of deformed babies could be born if they took any such drug. But how many women can two voluntary groups with slender resources reach? Our cynical Government's priorities are reflected in its attitude not only in the case of HPT. It can be seen in its non-action on the baby food front, and its token response to the question of female foeticide only after women's groups had made enough noise.

What is significant is that in each of these instances of Government cynicism it is the female section of the population that is vulnerable. It is women who are illiterate but who have a touching faith in what doctors, quacks and chemists tell them. Why does a woman take a drug to confirm pregnancy except because it is she who suffers the greatest anxiety over it? Why does a woman give baby food to her child except because she more than anyone else wants to give her baby 'the best', believing that tinned food is indeed the best? Or if not for that reason, isn't it because her working conditions compel her to leave the baby with a bottle in the care of others? And why does a woman need to be so desperate to get rid of a female foetus except because it is her own position as a woman that tells her that female babies are best not born?

All these are related themes. The HPT ban is the issue at the moment, but it is not just a drug issue. In each of the instances cited, where women are vulnerable, they are the target of an unholy combine of big business and medical science. Add to it the policies of an insensitive Government and it becomes obvious that mass action alone can protect the interests of this vulnerable section.

One heartening feature about the anti-HPT campaign is the involvement of a number of socially conscious doctors. This is necessary because scientific and medical expertise is needed to counter the pseudo-scientific arguments of the drug industry, which the Government seems to be pathetically willing to accept at face value. *The Hindu* in the past few months has published many letters from doctors, condemning HPT misuse, calling for a ban, and welcoming the ban announced in June. One of the letters, by N.P. Bhanumathy of Madras, who has been a vocal protester on a number of drug issues, clearly shows that the 'other uses' argument, for which the drug companies claim their product is 'needed', is bogus. She points out that if the products were really needed for 'other uses' then a number of advanced countries would not have banned them. She also quotes the findings of Dr Palaniappan whose controlled studies at Kilpauk showed beyond doubt not only that HPT is dangerous to unborn babies but that it use to bring on a delayed period would only further delay the menses. He had demonstrated that often the apparent effect of the drug in bringing on a delayed period was psychological. "A majority of women who were given dummy injections had bleeding much earlier than those treated with costly hormones." She also quotes

DRUGS : DACCA's BOLD MOVE

Health Action International (HAI) has released a briefing paper, *The Rational and Economic Use of Drugs in the Third World*, which supports the Bangladesh Government's bold move to rationalise national drug policies and eliminate more than 1,700 drugs from the Bangladesh market by the end of 1982. The Government's action was prompted by the report of the Expert Committee for Drugs that an estimated one-third of all money spent on medicines in Bangladesh went into 'useless, unnecessary and at times harmful drugs'.

HAI feels strongly that the Bangladesh Government's important initiative demands widespread international support. The new National Drug Policy is a substantial commitment to public health in one of the world's poorest countries. The Expert Committee has stressed the pressing need for change: "At present, not more than 20 per cent of the population have access to even the most essential drugs for their health needs and yet the market is flooded with hundreds of useless or non-essential medicinal products". The policy is designed to concentrate provision on some 250 drugs considered essential for health care. By doing so it follows both the letter and the spirit of WHO's Action Progamme on Essential Drugs, which was unanimously endorsed by the May 1982 World Health Assembly.

International support for the National Drug Policy is urgently needed. The policy has come under heavy attack by pharmaceutical industry interests since its establishment on June 12. Industry's protests have led to the appointment of a committee of militaty doctors to review the policy. The review committee and health ministers are being lobbied by representatives of the major US companies affected by the drugs ban — including Wyeth, Squibb and Smith Kline — at meetings arranged by the US ambassador to Bangladesh, Jane Coon.

A number of HAI's members — Oxfam (UK), War on Want (UK), and the International Organisation of Consumers Unions — have congratulated the Bangladesh Government on its efforts to establish rational and economic drug use. HAI's new briefing paper gives the reasons behind these endorsements and calls on WHO to publicly support the new policy. In addition, it stresses the need for the Organisation to establish authoritative criteria which other Third World governments could use to determine inessential drugs.

WHO has yet to respond officially to the Bangladesh Government's initiative. HAI's attempts to determine the Organisation's position on this move to eliminate wasteful and harmful pharmaceuticals from Bangladesh have so far met with silence. A series of direct questions to WHO's Director-General, Dr Halfdan Mahler—have gone unanswered. HAI urges the WHO to dispel the doubts this silence creates about its commitment to rational, economic Third World drug policies by unequivocal endorsement of the Bangladesh Government's New Drugs Policy.

Health Action International is a network of more than fifty research, consumer and development action groups worldwide who are interested in questions of pharmaceutical policy and their effect on the Third World. An international clearing house for HAI is operated from the International Organisation of Consumers Unions' Regional Office for Asia and the Pacific, PO Box 1045, Penang, Malaysia.

the *WHO Technical Series No. 657* which says: "Women who are not pregnant will have their delayed menses further delayed if hormones are administered."

Bhanumathy then asserts, rightly, that the drugs, being useless for 'other uses', should be totally banned — "the point is no more a technical issue deserving expert view" — and that the Government should take a really 'conscious' decision based on therapeutic rationale. It will be recalled that in March this year Health minister B. Shankaranand had said the Government had taken a 'conscious' decision not to ban HPT on the basis of 'expert' advice.

The above arguments have been echoed in the August issue of the *MFC Bulletin*, quoting recent editions of gynaecology text-books which do not recommend the combination hormone drug for *any case* of amenorrhoea. The bulletin editorial says: "There is no indication for the use of this high-dose combination and the patient will not lose anything if these preparations are banned."

Commenting on the Government's ambiguous stand on HPT, the MFC has urged all those concerned about the birth of babies with needless cogenital defects to join in the campaign against HPT drugs by rousing public opinion and by writing to the Drug Controller of India, Ministry of Health, Nirman Bhavan, New Delhi 16, and urging him not to go back on the earlier announced deferred ban but instead to ban this dangerous drug *now*. □

WOMEN'S WORLD

The Price of Courage

ANJALI DESHPANDE

MADHU is being made to pay the price for having challenged existing social mores. The police is deeply interested in humiliating her into inaction for her own sake and as an ominous lesson to future women activists. If the rich colonisers of Agra are to acquire land occupied by the poor through some quirk of law, if the prostitution at Sikandra is be maintained in peace without raising hopes of rescue among its wretched, if the downtrodden are to be kept at bay, the voices of Madhu, Anal and their like have to be muffled. For males, the new anti-dacoity measures come handy. For women, their sex is the source of innumerable forms of outrage that the police does not mind resorting to.

Twentyfour-year-old sprightly Madhu and her young friends have become an eyesore to the Agra police for various reasons. These members of Chhatra Yuva Sangharsh Vahini insist on staying in the Harijan basti Bapu Nagar. They have struck roots among the 250 families there and the 450 Harijan settlers at J.P. Nagar. They rescued Gita, an unwilling prostitute, from the infamous flesh market at Sikandra. And with their support the dalits lay claim to a little piece of land legally owned by Lajjaram Gupta, a rich coloniser.

What must irk the police most of all is the rescuing of Gita. Forced into prostitution at the tender age of eight, she had managed to convey to the Vahini her desire to be free. It was not an easy job. Five police officers had to be transferred before Gita safely reached the Nari Ashram. Even in choosing the women's home where Gita was to be placed, Vahini had had its say. They did not allow the police to take her to a home of their choice. The very fact that five police officers had to be put out of the way to deliver Gita from the Sikandra brothel, is proof enough of the powerful hand of the police in maintaining the place. It was also a firm pointer to the growing force and strength of the Vahini in Agra which could not be ignored. Most important of all, it gave hope to other prostitutes by making it clear that those who want to be free cannot be confined against their will.

In the whole case Madhu had emerged as a very determined and efficient worker. In fact she was against admiting Gita to the Nari Ashram, and was preparing to take her away to Vinoba Bhave's Ashram at Paunar where she had hereself had a year-long stint. On the eve of her intended departure she was taken into custody.

Meanwhile Lajjaram had managed to obtain a court decree on 2.5 acres of land at Bapu Nagar which he had bought years before. Despite Agra falling in C category of the Urban Ceiling Act which says no person can hold over 1500 square metres of land. Probably in dread of local resentment, Lajjaram, instead of sending notice to the 20 families settled on his land to vacate it, engineered the destruction of the statues of Mahatma Gandhi and Babasaheb Ambedkar. In what reverence the two leaders are held by the Vahini and the Harijans needs no mention. There could have been violent outburst and then it would have been possible to stow away quite a few "trouble-makers" behind bars. But wise counsel of the non-violent Vahini prevailed. Nothing untoward happened. On July 23, Anal was shot at by Parikh, a known thug of Agra. The bullet missed the target, but soon Anal was surrounded and beaten up. Anal's FIR was not registered by the police, who preferred to act

on Parikh's FIR that Anal had robbed him of Rs 3.50, a watch, etc. Warrants against Anal were issued.

The ordeal for Madhu began on the night of July 25-26, when the police descended upon the Vahini office at Bapu Nagar. She had been charged under Sections 307 (attempt to murder) and 395 (dacoity) on the basis of an FIR lodged by Parikh, the man who had taken a pot shot at Anal and missed. Anal was not there. Madhu was. She would not allow the policemen inside the room where a number of women from the colony had taken shelter from the leaking roofs of their homes in the pouring rain. A policeman brought up his knee to kick her in the lower abdomen. After she fell down the police switched off the lights and lathi-charged the women inside the room. Finally they took away Madhu to the police station.

At the police station she was beaten up and tortured. Her ankle bone was broken, she was burnt with cigarettes, she was asked to urinate in front of a row of policemen. Even in the face of such humiliation she would not reveal the whereabouts of Anal. The police told her they would make a 'Gita' out of her, that her mother would be brought to the police station and tortured in her presence, if she did not tell them where Anal was. The courageous Madhu did not yield.

On July 26 a procession of five hundred proceeded towards the police station to demand Madhu's release. The brave UP police, who had protected Chabiram when he held his durbar and let the Deoli murderers escape initially, made the mounted police charge into the crowd of unarmed men and women with kids in their arms. Horses ran amuck. One hundred and fifty people were injured. An infant was flung away from its mother's arm and died in the diabolic lathi charge. A bayonet pierced the knee of a 12-year-old. The police was holding Madhu to ransom, and they were determined to get Anal as the price of her release. Section 144 was clamped on Agra. The terror is so much that private doctors refuse to examine and treat the injured, for fear of repercussions.

Tormented by thoughts of what the police would do to Madhu, Anal went and surrendered. When Madhu told the ADM that the police had dishonoured her by taking away her dupatta, the ADM is reported to have asked the ASI to take away her dupatta once again to give her *prasad* which consisted to twisting her arm bghind her back.

She is now recuperating in Tundla. Her bladder is ruptured, the ankle shows a fracture. Her body is full of bruishes. The blisters on her mind, the trauma of those held in custody must be even deeper. If rape is taken in a literal technical sense Madhu was not raped. But what she underwent, was it less than rape, mental and emotional?

All Opposition parties in Agra including the CPI, CPI-M, Janata Party and the Sarvodayis have lent support to the movement against repression and police torture of activists. On their persuasion Anal broke his indefinite fast in jail. He was not being permitted to see visitors as a punitive measure. Despite the impressive number of parties and groups that have joined hands with Vahini on the immediate issue of police atrocities, quite a few express reservations regarding the basic issue of land-grabbing by the rich; not many from outside the stronghold of the Vahini have either courted arrest or made their presence felt in large numbers, barring one member from the Rashtriya Seva Dal and three women leaders. The vicious slander campaign by the police and the administration against Madhu is taking its toll. She is being declared an "unchaste" girl. And the so-called educated middle classes do not pause to consider why an 'unchaste' woman should have taken the risk of rescuing Gita in the teeth of opposition from the police.

Despite the mounted police and all, a large number of women joined a 1000-strong dharna in front of the Collector's office. Fortytwo persons were arrested including 12 women. On August 23 five hundred women defied Section 144 to demonstrate against police atrocities and 51 women were arrested that day. Among them two were minors and eight women were carrying infants. The struggle was echoed in Delhi on August 9. Twelve Vahini and Samajwadi Yuvajan Sabha members courted arrest in support of the fight in Agra. A joined committee of various groups including Indian People's Front, SYS, PUCL and PUDR, was set up on August 31. The newly-formed Agra Jan Sangharsh Sahyog Samiti will carry on supportive actions like signature campaign, postering, processions and dharna to highlight the role of the police in repressing political and social workers and to fight the character assassination of women workers in particular.

A woman living away from her family and mixing freely with men, does not automatically become unchaste. And even if her ideas on sex are not as orthodox as many would wish them to be, chastity is not the whole of virtue. There is compassion, courage, intelligence and the will to live not only for one's own narrow self but for better causes that concern society. On this count Madhu stands far above those orthodox women who are scoffing at her. The Harijans she lives with realise this and stand by her. This is no small achievement. □

CORRECTION

In *Mainstream* (August 21, 1982), page 25, column 2, line 11, in place of "prevent", please read "prepare for". The sentence as corrected will read thus: "With the policy of the Trilateral Commission of President Carter (which is still alive despite Carter's defeat) which witnessed Americans, Europeans, and Japanese united in an economic front, there was a bilateral accord in Italy between the reactionary Masons, financiers and Jewish bankers to invite the Vatican block to collaborate with them in order to anticipate and prepare for the efforts of the Trilateral Commission".

The error is regretted. —*Editor*

WHEN Judith Mogid, a legal aid attorney, learned in 1976 that pharmaceutical companies were testing new drugs on inmates at the State Prison of Southern Michigan, USA, she considered representing the prisoners in a class-action lawsuit against what she felt was dangerous exploitation.

She had to drop her plans in the face of vociferous opposition. The resistance came not from the drug companies, but from the prisoners.

Now, five years later, it is the federal US Food and Drug Administration that wants to stop the medical research. This time the prisoners have filed a lawsuit — against the FDA, not the drug companies.

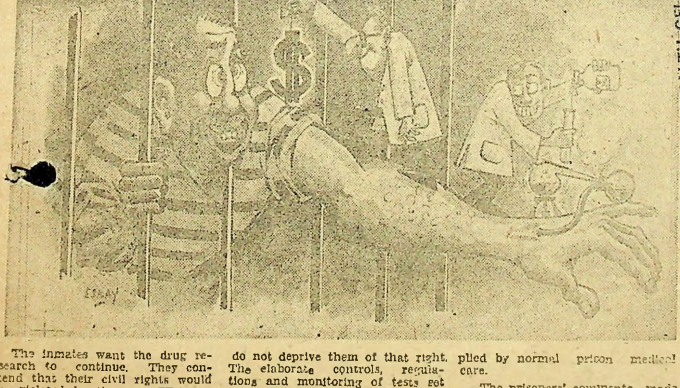
Inmates of the State Prison of Southern Michigan, USA, staunchly defend their dangerous role as human guinea pigs for drug research. The money incentive and the relative comfort of the research lab are a welcome chance to escape the hostile and unpleasant prison environment, they contend.

con in 1975, 93 found prisoners nearly unanimous in support of the research programme, with money the clear incentive.

A major problem for an inmate at Jackson is finding a salaried job of any sort. With 5,000 prisoners, this is the largest walled prison in the world, and many inmates end up with no work. Asked what would happen if drug testing stopped, Cone answered simply, "I'd be out of a job."

The four prisoners listed other attractions of the research programme: it provides escape from prison tension, crowding, silence, chow hall food and boredom; it provides a chance to see and talk with outsiders who treat them better than the guards; it offers an education of sorts in medicine, diseases and treatment; it gives them a full medical exam far more elaborate than what is sup-

Painkillers for the prisoner



The inmates want the drug research to continue. They contend that their civil rights would be violated by the very FDA regulations designed to protect them. They are asking for injunctions against the scheduled shutdown of the testing as of June 1.

The lawsuit has focussed attention on two intriguing questions. Do prisoners have the right to volunteer for the possibly dangerous role of human guinea pig? And are they volunteering freely?

The prisoners say yes. They like the money they earn from the drug companies and the chance to trade hostile and unpleasant prison environment for the relative comfort of the research lab.

"It's more dangerous out there (in the prison) than the worst experiment they could ever think up in here (the lab)," one inmate

do not deprive them of that right. The elaborate controls, regulations and monitoring of tests set up in recent years have eliminated past abuses. A contained prison population is much better suited for the tests than non-prisoner groups, because the environment and activities of prisoners can be controlled. There is a greater danger from inadequate testing than there is risk to prisoners; unsafe medicine might be marketed to the general population.

But the National Commission for the Protection of Subjects of Biomedical and Behavioural Research, after listening to hours of testimony and visiting four prisons in 1976, finally took a position against the tests. It concluded that "although prisoners who participate in research affirm that they do so freely, the conditions of social and economic deplied by normal prison medical care.

The prisoners' comments made it clear that being selected for medical research in jail is considered a great privilege.

The half-million dollar research lab built by Parke-Davis and Upjohn offers clean, quiet cells, 12-man wards, colour TV, table tennis and pool tables. And those of infection disqualifies a prisoner from drug tests for six months, so a high proportion of those chosen come from the prison's two honour blocks.

The National Commission found that test subjects are disproportionately white. The prison population is 68 per cent black but the pool of volunteer subjects is only 31 per cent black. Volunteers tend to be older, in prison much longer than average and better educated.

Shiv Shankar, subsequently revoked the suspensions and the CMOA withdrew its strike notice.

Meanwhile, as part of its campaign to give itself a better image, the CMOA has come out with a list of collieries it considers unsafe. Any such move by the CMOA opposing the government's ruthless policy of slaughter mining — however fitful and partial, and from whatever partisan angle it may be intended — can only help the workers' movement for greater safety in mines. This would be a change from the usual situation when members of the CMOA, with their ruthless implementation of government policy towards the workers besides their own oppression of them, are the immediate targets of the workers' movement.

HEALTH

Cheap but Dangerous

Vimal Balasubrahmanyan

LATE in August newspapers had a prominent item on why India had asked Ciba-Geigy to continue marketing of Enterovioform, an anti-diarrhoeal recently banned by Bangladesh. The news, based on a *New York Times* story, seems to be part of a strategy with the objective partly of discrediting the new Bangladesh drugs policy but more substantially of building an image for Enterovioform as an 'essential drug for Third World countries'. This latter motive seems particularly likely, considering the growing strength of the attack on this drug in both developed and developing countries.

The Ciba-Geigy spokesman is reported to have cited Enterovioform as an example where 'benefits outweigh risks'. He admitted that it is "possible" that "not all patients in developing countries are informed of the risks or of the fact that safer, alternative drugs may be obtained". The justification cited for marketing it is that "it costs barely one-fifth of what some of the other anti-amoebic drugs cost and is known to be effective as long as taken under a doctor's prescription". The spokesman made no mention of the fact that the drug is not only widely sold without prescription but is actively promoted by the firm itself to the lay public in some Third World countries.

Enterovioform is one of the clioquinol drugs that has attracted sharp criticism because it is known to cause neurological damage. Last year Social Audit of UK brought out a leaflet on the dangers and misinformation of clioquinol drugs entitled "Bad Information Means Bad Medicine". Commenting of its harmful effects a *Lancet* editorial in 1976 had said it was still being sold over the counter in 100 countries. At a Penang meeting last October, noted Swedish neurologist Dr Olle Hansson had said that in serious cases victims could become completely blind and their legs could get paralysed. Dr Hansson is active in the campaign against Enterovioform which he says is irresponsibly being sold in the Third World, the accompanying 'cautionary' literature containing scientific jargon unintelligible to the layman.

A very legitimate question is: if Enterovioform is widely sold without prescription, whose responsibility is it to inform the public of its risks? Also, when doctors prescribe it unless patients are told of its risks and the fact that safer, alternative drugs exist, how can they make an informed choice?

It is claimed that Enterovioform is a cheap and effective anti-amoebic, necessary in a country where amoebiasis is rampant. The fact is that the drug of choice against this disease is metronidazole, and if the country's health needs demand it, the drug of choice ought to be made cheaply available. It is a strange kind of health policy that justifies the foisting of a harmful drug for a widespread disease, simply because it is cheaper than the safe one.

However, one suspects that the amoebiasis argument is an elaborate multinational double-speak. This drug is actively promoted to the lay public in Third World countries not as an anti-amoebic but as a cure and preventive for "travellers' diarrhoea" for which it has shown no evidence of being effective. An outsize boarding in Lagos, reproduced in the August issue of *South*, depicts this product as a 'must' in every traveller's kit. Would the Ciba-Geigy spokesman care to elaborate on the risks and benefits of Enterovioform in Nigeria? In fact both Enterovioform and Mexaform (also by Ciba-Geigy and with the same active principle) are listed in the popular prescribers' guide, MIMS, not under anti-amoebics but under anti-diarrhoeals. In any case it is now known that most of the anti-diarrhoeals, especially the clioquinol drugs are useless against common viral diarrhoeas.

Clearly Ciba-Geigy is trying to create the image of an 'essential drug for amoebiasis' while actually continuing to promote it to the lay public as an ordinary anti-diarrhoeal — it has long been self-prescribed thus and will continue to be thus consumed by the uninformed. Bangladesh, a country where endemic diarrhoeal disease is probably a much more serious problem than in India, has chosen to ban Enterovioform. So has Malaysia. A campaign against it has begun in Indonesia. The boycott by Swedish doctors of Ciba-Geigy products because of the firm's continued sale of Enterovioform and Mexaform in the Third World has resulted in Ciba-Geigy losing 25 per cent of its share of the Swedish market. The new 'image' sought to be created for Enterovioform must be understood against this background.

The case of SMON victims in Japan where the side-effects (abbreviated as SMON) were first observed is well known. In Sweden a number of Enterovioform victims were paid massive damages by Ciba-Geigy in an out-of-court settlement. And last February the *Sunday Times* reported that a British woman won huge damages from another firm whose similar product had caused her to go blind and partly paralysed.

Facts quoted in the latest issue of *HAI News* (newsletter of Health Action International) place Ciba-Geigy's new tactics in perspective. On August 7 the Malaysian government banned import, supply and sale of clioquinol. The move came after pressure groups and consumer unions gathered mounting evidence against the drug. On August 12 the Social Audit leaflet was launched in Jakarta soon after the Indonesian Health Minister announced that the drug was still 'needed' in that country.

It will be observed that in countries

Doctors urged not to overprescribe

Indian Express 29/11/84

Express News Service

Bangalore, Nov. 24: Health Minister H. L. Thimme Gowda has appaled to the doctors in the State to desist from overprescribing drugs as it could prove to be dangerous for the patients in the long run.

Inaugurating on Friday the 41st national convention and workshop organised by the Catholic Hospitals Association of India on "Towards a People-Oriented Drug Policy", the Minister lamented that overprescribing had become a fashion for most doctors, as was the prescription of 'glamorous' and expensive drugs. Mr Thimme Gowda said that in Karnataka, Rs. 10 crore was being spent for the purchase of drugs which was more than adequate if spent judiciously. He cited the instance of a district hospital, which had used drugs worth Rs. 40,000 in the first three months of the year itself.

Mr Thimme Gowda said that at present the State had 1,300 primary health units and 300 primary health centres. In another two years the Government hoped to set up 300 more primary health units. Recruitment of 570 doctors was also to be completed very soon, he said.

The Minister lauded the nursing care provided in the Catholic hospitals which was far superior to that in other hospitals.

Earlier, Father Ferdinand Kayavil, President of the CHAI, said in his welcome address that the manufacture of only expensive drugs, meant for the rich, had to stop. Drugs should be brought within the reach of the poor. The drug production in the country had increased hundred-fold, with nearly 25,000 drug formulations and nearly 5000 manufacturing units. Despite this, drugs remained largely a luxury item affordable only by the well-to-do. He felt that consumer awareness programmes and public opinion mobilisation would help people know the evils of overconsumption.

Father Kayavil said that "Health for all by 2000" was an ambitious plan, as the health problems in the country were too big to be tackled so soon. However, he felt that collective tenacity of the people and the right health policies framed by the Government could help achieve the goal. The CHAI had set up 499 hospitals and 1,274 dispensaries all over the country to provide health care to the masses.

Bishop Gilbert Rego, Ecclesiastical Advisor of CHAI, presided. Father John Vattamattom, Executive Director, CHAI also spoke. Dean of St John's Medical College, Dr G. M. Mascarenhas welcomed. Later Excise Commissioner J. Alexander inaugurated the exhibition.

Myopic policy on drugs bemoaned

BANGALORE, November 28: The 41st annual convention organised by the Catholic Hospital Association of India (CHAI) on the theme "Towards a people oriented drug policy", has expressed deep concern over the increasing scarcity of essential and life saving drugs as against wasteful abundance of non-essential drugs and formulations.

The association said that the convention, which concluded here recently, also discussed the continuous availability of banned drugs and the spiralling cost of pharmaceuticals.

The convention has resolved to appoint an expert body to formulate a rational drug policy, which is people oriented, within the context of a health care strategy and policy.

Nearly 500 delegates including doctors, nurses, hospital administrators and pharmacists attended the convention.

THE TIMES 29/11/84

Concern over increasing scarcity of life saving drugs

From Our Special Correspondent

BANGALORE, Nov. 27.

Over 500 delegates to the four-day 41st annual convention of the Catholic Hospital Association of India (CHAI) on the theme "towards a people-oriented drug policy", consisting of doctors, nurses, pharmacists, hospital administrators and health activists representing around 1,900 member hospitals and health care institutions, which concluded here, has expressed concern over the increasing scarcity of essential and life saving drugs, as against wasteful abundance of non-essential drugs and formulations.

The excessive number of over 30,000 drug formulations, as against the Hathi committee and WHO expert committee recommendations of 116 and 200 respectively, the continued availability of banned drugs despite the Government bans, the continued availability of bannable and hazardous drugs in spite of the mounting scientific evidence and directives of various courts, the spiralling cost of drugs as against the decreasing purchasing power of the people and the continuing domination by the multi-national drug industry as against the national policy of self-reliance were the other areas of concern.

Govt. list endorsed: The convention fully endorsed the Union Government's list of banned drugs and agreed to implement it in its organisations and urged all sister institutions to do likewwise.

It asked the member institutions to prepare a list of essential drugs along the lines of the Hathi/WHO committees for immediate adoption in all institutions, urgently take steps to reduce the present unhealthy and unethical influences of the drug industry on the medical and allied professions and mobilise public opinion against the apparent lack of concern of State Governments and professional and expert bodies on this vital issue.

The convention resolved to appoint an expert body to formulate a rational drug policy, which is people oriented within the context of a health care strategy and policy benefiting the national commitment to health for all by 2000 A.D.

At the 41st annual general body meeting, Fr. Ferdinand Kayavil of Benzigar Hospital, Quilon, Kerala, Sr. (Dr.) M. Fernandes, Marianpur Hospital, Kanpur, U.P., and Fr. Antonyswamy of the Diocese of Ooty, Tamil Nadu, were electd President, Secretary and Treasurer respectively of the CHAI, for a term of three years.

28/11/84 — The HINDU

Study for ban on pain killers

Press Trust of India

Hyderabad: A majority of the analgesic preparation or pain killers being used as medicine in the country have been found scientifically not justified, according to a study done by the rational drug policy cell of the Pune based voluntary medical group – Medico Friend Circle.

Analgesic is a substance used in medicine to relieve pain and is commonly referred to as a pain killer. The 50 analgesic preparations were listed in the monthly index of medical specialities (MIMS) that gives standard preparations currently promoted by the pharmaceutical industry. the authors of the study, Dr Jamie Uhrig and Dr Penny Dawson said in their report.

The group using a rigorous procedure graded the 59 pain killers into four categories – A, B, C, D. It recommended the immediate withdrawal of the preparations falling into the B, C, and D categories. Use of preparations found good and justified according to the study are plain paracetamol, aspirin, crocin, dispirin, mazetol, paracin, calpol, fortwin, curepar, molin, parvon, predimol, pyrigesic, sosegon, tylenol and tapal junior numbering 14 in group 'A'.

The group listed apidin, avamol, beserol, betaflam, bral, cariaspirin, corbutyl, dolopar plus, equagesic, fortagesic cyclopan, norgesic, malidens, parvon-N, proxyvon, ralcidin, spasmo proxyvon, tysyne, sudhinol, tapal, treupel, veganin, walagesic be withdrawn.

The group wanted the following analgesics and antipiratics to be immediately banned for they contained analgin. Anadex, avaforton, baralgan, codolsic, dolopar, neogene, novalgin, novalgine quinine, pamagin, promalgin, sedyn-a-forte, spasmizol, ultragin, ultragin syrup, ultragin injection, simalgin-A. Analgin, a minor analgesic, enjoyed widespread popularity in India. It was an unnecessary and dangerous drug that had safe and inexpensive substitutes. The doctors group said it should be banned. A World Health Organisation expert committee had established a list of essential drugs for all countries that include a list of analgesics and antipyretics like aspirin, paracetamol, codeine, pethidine and morphine injection.

Pain is a universal phenomenon and the development of drugs to relieve pain is one of the few remarkable achievements of modern medicine. It is necessary to make a judicious decision on the relevant drugs to relieve pain, the doctors said. The Medico Friend Circle with doctors and socially conscious members from all parts of the country urged for a government policy with provision of all essential analgesics and antipyretics at low cost and the banning of ineffective preparations as a first healthy step in forming a rational drug policy in the country.

89.20

Most analgesics dangerous: MFC

FREE PRESS JOURNAL, Indore
Monday, May 13, 1985

HYDERABAD, May 12 (PTI): A majority of pain killers used in India are either dangerous or do not produce the desired results and need to be withdrawn, says a study by a voluntary medical group.

About 50 of these analgesic preparations were listed in the monthly index of medical specialities, (which gives standard preparations currently promoted by the pharmaceutical industry), according to a study conducted by the rational drug policy cell of the Pune-based Medico Friends Circle.

The group, grading the 59 pain killer into four groups A,B,C and D, recommended the withdrawal of the B,C, and D categories.

Paracetamol, Aspirin, Crocin, Dispirin, Mazetol, Paracin, Calpol, Fortwin, Curepar, Molin, Paracin, Parvon, Predimol, Pyrigesic, Sosegon, Tylenol and Tapal Junior fall in group 'A'.

It listed Apidin, Avamol, Beserol, Betaflam, Bral, Cariaspirin, Corbutyl, Dolopar Plus, Equagesic, Fortagesic, Cyclopan, Norgesic, Malidens, Parvon-N, Proxyvon, Ralcidin, Spasmo Proxyvon, Tysyne, Sudhinol, Tapal, Treupel, Veganin and Walagesic to be withdrawn.

analgesics and antipyretics like Aspirin, Paracetamol, Codeine, Pethadine and Morphine injection.

The study was conducted on a report by Dr Jamie Uhrig and Dr Penny Dawson.

Other analgesics and antipyretics to be banned were Anadex, Avaforton, Baralgan, Codolsic, Dolopar, Neogene, Novalgin, Novalgine Quinine, Pamagin, Promalgin, Sedyn-A-Forte, Spasmizol, Ultragin, Ultragin syrup, Ultragin injection and Zimalgin-A.

Analgin, a minor analgesic enjoying widespread popularity in the country, was unnecessary and dangerous and had inexpensive substitutes, the study said.

A world health organisation expert committee had established a list of essential drugs for all countries which included

'Most pain-killers useless and harmful'

HYDERABAD, May 12.—A majority of pain-killers used in India are either dangerous or do not produce the desired results and need to be withdrawn, says a study by a voluntary medical group, reports PTI.

About 50 of these analgesic preparations were listed in the monthly index of medical specialities, (which gives standard preparations currently promoted by the pharmaceutical industry), according to a study conducted by the rational drug policy cell of the Pune-based Medico Friends Circle.

The group, grading the 59 pain-killers into four groups, A, B, C, and D, recommended the withdrawal of the B, C, and D categories.

Paracetamol, Aspirin, Crocin, Dispirin, Mazetol, Paracin, Calpol, Fortwin, Curepar, Molin, Paracil, Parvon, Predimol, Pyrigesic, Sosegon, Tylenol and Tapal Junior fall in group 'A'.

It listed Apidin, Avamol, Beserol, Betaflam, Bral, Cariaspirin, Corbutyl, Dolopar Plus, Equagesic, Fortagesic, Cyclopan, Norgesic, Malidens, Parvon-N, Proxyvon, Ralcidin, Spasmo-Proxyvon, Tysyne, Sudhinol, Tapal, Treupel, Veganin and Walagesic among those to be withdrawn.

Other analgesics and anti-pyretics it said should be banned were: Anadex, Avaforton, Baralgan, Codolsic, Dolopar, Neogene, Novalgin, Quinine, Pamagin, Promalgin, Sedyn-A-Forte, Spasmizol, Ultragin, Ultragin syrup, Ultragin injection and Zimalgin-A.

Analgin, a minor analgesic enjoying widespread popularity in the country, was unnecessary and dangerous and had inexpensive substitutes, the study said.

A World Health Organiaztion expert committee had established a list of essential drugs for all countries which included analgesics and antipyretics like Aspirin, Paracetamol, Codeine, Pethidine and Morphine injections.

The study was conducted on a report by Dr Jamie Uhrig and Dr Penny Dawson.

Statesman 13.5.85

Asian seminar calls for 'rational' drug policies

By Our Staff Reporter

A four-day Asian seminar on "Pharmaceuticals and the Poor", which concluded in the City on Tuesday noted with concern "the deterioration in the drug supply situation" in most Asian countries where governments have adopted "counterfeit substitutes in the name of pharmaceutical industry policies" instead of formulating comprehensive and rational drug policies based on the health needs of the people.

In a 'Madras declaration', outlining its conclusions, the seminar urged the governments to totally ban irrational and dangerous drugs, as a first step. This was "an urgent need which cannot be postponed except at the cost of the nation's health".

Organised by the International Organisation of Consumers Unions, the Voluntary Health Association of India and Asian Community Health Action Network, the seminar was attended by over 30 delegates from different health workers' groups in Asia who prepared a 11 point model national drug policy draft.

Asian countries which have adopted rational policies, banning the unnecessary and harmful formulations, witnessed "a remarkable improvement in the drug supply situation", the declaration noted.

Briefing newsmen, Co-ordinator of the All India Drug Action Network, Dr. Mira Shiva, said the proliferation of harmful or unnecessary "drugs" was the worst in India and Brazil. At least two-thirds of the 40,000 formulations manufactured in India fell into these categories.

Dr. Zafrullah Chowdhury from Bangladesh said the medical community in most Asian countries had become totally dependent on the pharmaceutical industry. For prescribing medicines, doctors relied on the literature supplied by the drug companies themselves.

The governments also were recalcitrant in informing the people and the doctors on which of the formulations were harmful or useless, said Dr. Mira.

The seminar also noted "with distress the alarming decrease in recent years in the production and supply of vital drugs needed to combat diseases such as Malaria, TB, other infectious diseases and nutritional blindness". There was no inbuilt mechanism in our drug policy to check the decline in the production of essential drugs, Dr. Mira added.

A fall-out of the proliferation of formulations was the lack of reliability and quality of "a large proportion of medical preparations on the market".

It urged governments to make laws for ensuring strict quality control and promptly punish those who violated such laws.

Supporting the public's right to "complete information on drugs and public accountability of the drug industry and health professionals including doctors", the declaration called for concerted action to regulate the drug industry, change laws relating to registration, supply of complete, unbiased information on drugs to doctors and consumers, and for a scheme to monitor adverse drug reactions.

Lack of deterrent action by the governments had encouraged the multinationals to aggressively sell harmful formulations which were banned in the West and several other countries in the world, Dr Chowdhury said.

This affected the neighbouring countries; for instance, drugs banned in Bangladesh were being smuggled into the country from India.

The declaration urged the governments to take action on the resolutions adopted by the non-aligned countries in Colombo and Havana in 1976 and 1979 by formulating drug policies based on the concept of essential drugs being made available at reasonable prices to the people.

Indian Express 11 Dec

17

'No access to reliable and basic essential drugs still'

The Hindu 7 Dec 85

MADRAS, Dec. 6.

Participants at a seminar on "pharmaceuticals and the poor" today stressed that consumer organisations should actively involve themselves in law suits filed by the Government to protect public interest.

They pointed out that several socially relevant measures initiated by the Government were thwarted by a few individuals and some manufacturers taking the issues to court. "Even well-meaning litigation had gone against the interests of consumers simply because people's views had not been adequately presented," they said.

More than 50 delegates from 10 countries are participating in the four-day seminar organised jointly by the Asian Community Health Action Network, Hong Kong, the Voluntary Health Association of India, New Delhi and the International Organisation of Consumers Unions, Penang.

Charge against multinational companies: Despite a mushroom growth of pharmaceutical firms in India and the Third World, a vast majority of people still had no access to reliable and basic essential drugs. The participants said and regretted some multinational companies continued to dump in India and other developing countries several harmful drugs banned elsewhere.

Dr. Badal Sen Gupta from Bonn said health programmes and drug policies of various countries in the Third World were greatly influenced by a few developed countries. He was sorry development strategies had not brought any appreciable benefit to most people.

Some participants said there was an urgent need to look at the question of non-availability of essential drugs to the poor and the general non-accessibility of the health care system which resulted in increased mortality of the poor, depite high technology.

Drug policy irrational: Dr. Mira Shiva, Co-ordinator, All-India Drug Action Network, said India's drug policy and practice today were irrational. The manufacture of a host of essential generic drugs should be taken up in a big way instead of going in for more formulations.

Dr. Kumariah Balasubramaniam, Pharmaceutical Advisor to the Carribbean Community Secretariat in Guyana, said redistributing health care among all sections of society would require innovative policy measures. Restricting the national formulary to a limited number of essential drugs, adoption of generic names, elimination of the multiplicity of brand name products removing from the market unnecessary and expensive tonics and vitamins and replacing these with a few essential vitamins and mineral preparations would meet with considerable resistance from the medical profession and the urban elites, he warned.

Dangerous drugs—with no warning

Hindustan Times 15/3/82.

LAST Monday was International Women's Day. A handful women gathered at various in the city to pass resolutions to underline various demands for the betterment of the status of women.

At the end of the ritual, they hurried back home to look after the day's meal and their children. Not that there is anything wrong with cooking one's meal and looking after children but in a city where the Beat Club witnesses more speakers than even London's Hyde Park and where, you can collect crowds according to your pocket, public meetings are of little significance except to those who manage to get an 'honourable mention' in the newspapers.

A voluntary body which calls itself Health Action India did attempt in its way to draw into focus something which should be of interest to all women. In a letter, it has pointed out the indiscriminate use of Oestrogen-Progestrone combination of drugs in women. What is vital is the need to educate women about the dangers that the use of these drugs might entail. If cigarette packs across the length and breadth of country can be sold with the warning that smoking is injurious to health how is it that in the Capital city, right under the nose of the Drug Controller, these drugs continue to be sold without their dangers being spelt out. Look at the enormity of effects—possible foetal abnormalities in the pregnant mother, foetal abnormalities in the child being breast fed, if the mother uses these drugs.

Of the 13 companies selling these drugs under different brand names, only one has listed amongst the "contraindications", saying that "there is some evidence to show that hormonal preparation when used during pregnancy may lead to foetal abnormalities."

The drugs are a hormone preparation used largely as a diagnostic test for pregnancy. Not only is it not reliable as a diagnostic test — for one out of five women who undergo the test, it leads to the wrong conclusion—but many women believe that this is an injection for abortion. On the contrary, the woman who receives the injection runs the risk of giving birth to a malformed baby.

The literature available with the World Health Organisation (WHO) on the subject points out that studies suggest "an association between cardiovascular defects and sex steroid hormones exposures during the first trimester. Again "there exists a suspicion that the hormones used in pregnancy tests may cause birth defects especially congenital heart and limb reduction anomalies."

With the availability of immunological tests which enable early detection of pregnancy, the use of these drugs, in any case for pregnancy detection, needs to be discouraged.

There are doctors who recommend that pregnant mothers who take this injection should be advised to have medical termination of pregnancy.

In any event one would tend to agree with the Health Action India that labels of these drugs should carry a warning in bold letters 'Not to be used for pregnancy diagnosis "May cause foetal abnormalities."

One may argue that when there is such callou disregard for the present generation, how can one expect that the future generations would be taken care of. It is in the knowledge of the Delhi Administration that within the city's elf there is a flourishing cottage industry of substandard and spurious drug makers.

The lowest tender still continues to be the sword for all city hospitals for purchase of drugs. A more rigorous drug control, thorough examination and analysis to ensure the efficacy of drugs is definitely required.

Follow Me Around

By Rahul Dua

PPST NEWSLETTER

Vol.1 No.9 October 1983

Modern medicine, in terms of its spread and consequences, has - in a perverse sense - possibly helped to create as much disruption as the sum total of all the military aid the third-world has received. The decay and collapse of traditional systems of medicine which depended wholly on locally available materials, the consequent dependence on non-local skills, materials, alien concepts and methods are good indicators of the lack of correspondence between modern medicine and the social realities of the third world. It is, perhaps, because of this that the baby food, supposed to help children obtain nutrients, causes disease due to secondary effects; fancy programmes to reduce malnutrition cause further suffering; new forms of disease grow alongwith claimed 'cures', in the single-minded mad-race in search for the elimination of human suffering through thoughtless drugging of the human body. Perhaps, Gandhi's identification of modern medicine with the essence of witch-craft comes close to a proper characterization of the problem.

This issue of Newsletter contains some glimpses of the problem of disease causation. 'Man and His Environment' is abridged from Britannica Perspectives (Vol.1), 'Cleaning up Third World Disease's from the Economist (Sept.1983) and the last two pieces are from the New Scientist (June 30, 1983).

-----XXXXX-----

Man and His Environment

Everywhere in nature life is a collective enterprise. All organisms, primitive or complex, naturally spend much of their lives in the company of their own kind; but in addition, and more interestingly, they always occur in intimate and lasting associations with other forms of life not genetically related to them. Any measure that grossly alters natural conditions is likely also to have direct or indirect unfavourable effects because all components of nature are interrelated and interdependent. Man is dependent not only on other human beings and on the physical world but also on the other creatures - animals, plants and microbes - that have evolved together with him. Man will endanger his own survival if he thoughtlessly eliminates the organisms that constitute essential links in the complex and delicate web of life of which he is a part.

Please address all correspondence to: J.K. Suresh, 62/2, Shop-street, Basavanagudi, BANGALORE-560 004.

All natural phenomena are the result of complex interrelationships; all manifestations of human disease are the consequences of the interplay between body, mind and environment. Overwhelming evidence indicates that many forms of disease have emerged or have been disseminated in the modern world because our ways of life have created new and complex constellations of circumstances favourable for their spread.

The outbreak of Manchurian plague at the turn of this century constitutes a well-documented example of role of living patterns in disease causation. The plague bacillus is widely distributed among the wild rodents in many parts of Asia. Manchurian marmots normally harbour this microbe, but they do not suffer from this infection under usual circumstances. Around 1910, a change in women's fashions in Europe suddenly created a large demand for the fur of Manchurian marmots, and a number of inexperienced Chinese hunters began to hunt this wild rodent. Until then it had been hunted only by Manchurians who had a taboo forbidding them to hunt sick animals. In contrast, the inexperienced Chinese trapped every animal within reach, especially the sickest who were slower and easier to catch. As it turned out, the sick marmots were suffering from plague, and many Chinese hunters contracted the infection from them. When the hunters met in the crowded, illventilated Manchurian inns, those who had caught the microbe spread it to their neighbors, thereby initiating a widespread epidemic of pneumonic plague. A change in women's fashions in Europe thus indirectly caused an epidemic of pneumonic plague in Manchuria.

Porphyria, an affliction which changes the red blood cells, illustrates how modern innovations can result in new forms of disease. This hereditary disorder, originated with a Dutch woman who migrated to South Africa in 1686. As far as is known, the gene for porphyria has been transmitted ever since to all her descendents; although these are now numerous, the disease itself has become a problem only during recent years. Under ordinary conditions, the porphyria gene manifests itself only by the production of mild neurological symptoms and minor skin blemishes usually overlooked. However, violent reactions often culminating in death are likely to occur if porphyric person takes certain drugs such as sulfas and barbiturates. The normally mild signs and symptoms of the genetic disorder are converted suddenly into a severe and often fatal response by modern drugs otherwise considered life saving.

While man's nature will remain fundamentally the same as it has been since Paleolithic times, the patterns of his disease continue to change because his physiological responses to changing environmental situations do not adapt him rapidly enough to the new conditions. Change itself may constitute a cause of disease. Once man is adapted to certain kinds of food, weather, housing, microbes, and social habits, he commonly finds it unpleasant and traumatic to be uprooted suddenly and forced to live under new conditions even though these appear more favourable to outsiders. As Hippocrates, the father of modern biology and medicine, wrote 2,500 years

ago, "It is changes that are chiefly responsible for diseases, especially the greatest changes, the violent alterations both in seasons and other things".

Man is trying to eliminate the unpleasant effects of environmental forces, by controlling them instead of making the greater effort required to cope with them through his own adaptive physiological responses. The environmental control decreases the need for physiological adaptation. Man finds it more convenient to air-condition his dwellings than to adapt physiologically to heat or cold; wherever possible, he tries to use mechanical devices instead of depending on his muscles; he invents learning aids to decrease mental effort; he takes drugs as substitutes for mental discipline in resisting pain and overcoming fatigue.

Man's control of environment has gone further than his biological adaptabilities towards eliminating many forms of suffering; it has thus constituted one of the most influential determinants of modern civilization. Yet, it is dangerous error to believe that disease and suffering can be wiped out altogether by raising still further the standards of living, increasing our mastery of environment, and developing new therapeutic procedures. The less pleasant reality is that, since the world is ever changing, each period and each type of civilization will continue to have its burden of diseases created by the unavoidable failure of biological and social adaptation to counter new environmental threats.

Environmental pollution illustrates how many of the adjustments that facilitate life in a hostile environment commonly express themselves later in disease and misery. The inhabitants of industrial areas of northern Europe behave as if they had made a successful adjustment to massive air pollution. For more than a century they have functioned effectively and successfully despite irritating substances in the air they breathe. However, their adaptation is less satisfactory than might be supposed. The lining of their respiratory tracts registers the insult of air pollution. The cumulative effects of years of constant exposure to various pollutants have resulted in widespread chronic bronchitis and other forms of irreversible respiratory disease. Chronic respiratory disease is now the leading cause of disability among adults in all the industrialized parts of northern Europe and is becoming increasingly prevalent in United States.

As in the case of environmental pollution, apparently successful adjustments to emotional stresses caused by competitive behaviour and crowding can result in delayed organic and mental disease or at least in behavorial disturbances. Through, the experience of social intercourse, man learns to control the outward manifestations of his emotional responses. He usually manages to conceal his impatience, irritations and hostile feelings behind a mask of civil behaviour. Inwardly however, he still responds to emotional stimuli by means of

physiological mechanisms inherited from Paleolithic ancestry and from his animal past. The ancient fight and flight responses still operate in him, calling into play through autonomic nervous system various hormonal mechanisms that generate useless and potentially dangerous physiological reactions.

The most disturbing aspect of human adaptation to various situations is paradoxically that human beings are so adaptable. They can become adjusted to conditions and habits that will eventually destroy the values most characteristic of human life.

In the final analysis, not physical fitness to environmental conditions nor comfort of the body, nor even survival of the human species, suffice to encompass the richness of man's nature. Medical problems posed by the environmental stimuli and insults of modern civilization have acquired a critical urgency; most technological and social changes now achieve their full effects in very short time and affect simultaneously all parts of the world and all economic classes. Until recently, the rate of change was generally so slow as to allow time to make proper conscious and unconscious adjustments. Many individuals suffered when conditions changed for the worse but bulk of mankind slowly and almost unconsciously adapted. The genetic endowment of population became progressively altered; phenotypic modifications helped each person to function in his particular niche, and especially most human beings slowly learned to achieve better fitness to their milieu through technological and social innovations without entirely sacrificing or jeopardizing the future. Now the rate of change is so rapid that there may not be time for orderly and successful operation of these conscious and unconscious adaptive processes. For the first time in the history of mankind, the biological and social experiences of the father is almost useless to his son.

- Excerpts from

'Man and His Environment'
by Rene Dubos
in Britannica Perspectives, Vol.1.

-----XXXXX-----

Cleaning up Third World Diseases

Disease is a part of the land scape in the Third Word. In Asia, Africa and South America, one person in ten is in some way disabled. Most of the poor suffer diseases such as acute diarrhoea and pneumonia during their lifetimes. Because they are undernourished and therefore vulnerable, many die of these diseases. During the 1960's and'70s endemic diseases were tackled with pills, vaccines and pesticides. Scientists now recognize that providing drugs to cure diseases is no solution in countries where almost everyone lacks basic resources like food, clean water and

sanitation. Some third world countries, too, are coming round to the view that money spent on glamorous drug programmes could be better utilized on improving living conditions.

Since improving life-style costs money, concentration on improvements that directly reflect on health - like water supplies and sanitation, is necessary (around 80% of infections in the third world are spread through water). Developed countries have generally been able to eradicate infectious disease through sanitation rather than chemical remedies that have been pumped into the third world.

Vaccinations, although effective in the case of smallpox and measles, are not very successful because: 1) it is difficult and costly to set up distribution systems, especially in rural areas; 2) some vaccines are too specific; 3) animal host must also be treated. The failure of malaria compaign in India and elsewhere has been attributed to these causes.

Water plays an important role as a carrier of micro-organisms and as a breeding ground for vectors. Some water related infections could be eradicated solely by improving community's water supply. Other parasites could be eradicated through provision of an adequate excreta disposal systems.

WHO's goal is to provide safe water and sanitation to all by 1990. Its Director General, Dr. Halfdon Mahler, said, "I am utterly convinced that the number of taps per 1000 population will be an infinitely more meaningful indicator of health than the number of hospital beds for 1000 population".

With less money, careful well thought out action needs to be taken to improve health standards. It should be borne in mind that improper methods of improving health standards have serious side effects. Unless there is a general availability of clean water, unless there is sanitation and hygeine education, diseases will continue to spread and well-intentioned efforts will come to nothing.

(Summarized from the Economist,
Sept.10, 1983).

-------xxxxxx-------

Tree Chopping releases Virus

Forest cleaning is causing a deadly virus that normally infects monkeys and other small mammals to attack humans. The latest outbreak of Kyasanur Forest Disease, better known as monkey disease, came in January in the Western Ghat mountains of Karnataka. So far it has affected more than 1000 people and killed 96.

The link between tree felling and the spread of the disease stems from the virus's transmitters - 16 different species of tick that live on a wide variety of mammals. As clearing began in Nidle State Forest last September, the animals and their ticks migrated to nearby forests next to villages in the Belthangadi area of South Kanara district.

The Indian National Institute of Virology says the disease is the result of clearing up 400 hectares of forest to make way for cashew plantations. So far, six villages have been affected but there are fears that it could spread to others in the area.

Most mammals are unaffected by the virus, but monkeys fall severely ill and die. Humans experience high fever, pains, headaches, blood vomitting and nose bleeding. The human mortality rate is over 10 percent. The Institute first noticed the virus in 1957 in the Kyasanur State Forest, and so gave it its name. However, locals call it 'monkey disease' because monkey deaths often preceed a human epidemic.

In the last 27 years, the virus has spread to more than 400 square kilometers of forest in four districts, and the Institute suspects these earlier outbreaks were also the result of forest clearing.

(New Scientist 30 June, 1983)

-----xxxxx-----

Strange case of the Disappearance of Morning Sickness

The decision to end the manufacture of Debendox, the best selling morning sickness pill, marks the end of one of the more startling cases of a "boom" in a particular illness tied to drug marketing.

Morning sickness usually begins in the first three months of pregnancy. In 1978, doctors in Britain were dishing out as many prescriptions for morning sickness as there were pregnancies. They gave a prescription to almost every pregnant woman who complained of morning sickness. Half the prescriptions issued during this period were for Debendox. There were 400,000 prescriptions for Debendox in 1978, and another 400,000 for other morning sickness drugs, like Ancoloxin and Avomine. The recipients were most of the 350,000 pregnant women suffering from varying degrees of morning sickness who consulted their doctors. The British National Formulary, published jointly by the British Medical Association and the Pharmaceutical Society and distributed to all doctors by the Department of Health, states that nausea and vomiting in the first three months of pregnancy does not generally need drug therapy. And yet three-quarter of all prescriptions were handed out in the first three months.

Merrel, the manufacturer of Debendox, decided to stop making it after losing a court case in the US alleging that Debendox caused deformity in a new-born baby.

Since then the number of women complaining of morning sickness has dropped; the number of consultations has fallen by 35 percent since 1979. Patients, as well as doctors, have become aware of the danger of using, and asking for, drug therapy during pregnancy.

(New Scientist, 30 June, 1983).

-----xxxxx-----

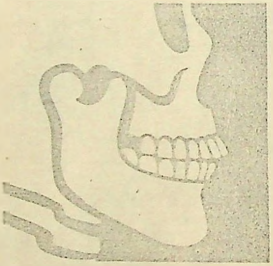
Controversy

DEATH TO ADMINISTER

Essentially life-saving, the widely prescribed IV (intravenous) fluids have, in recent months, been achieving just the reverse; taking rather than saving lives. The manufacturer's callous disregard of safety measures sadly, however, has found no visible critics in the Drug Control Department, and it becomes clearer by the day why this is so: accused now of colluding with the 'merchants of death', its officials appear more than ever on the defensive. Here are the latest developments in this regard, and how it all began.

The fourteen people who died are fourteen people who are known. There could be many who are not — Justice S. Lentin who led the enquiry into the deaths reported in Bombay's JJ Hospital from IV fluid contamination in an interview with Newstrack

The message contained in the verdict could not have been lost on anyone familiar with the deadly events. The issue had made headlines in February this year. After seven people, including a doctor, died in the Capital on being administered a drip—observe the irony of it — life-saving fluid. And it's even now reportedly around, this killer fluid - in these apparently harmless looking bottles which, we were warned, contained not glucose, but death.



The malaise is intimately related to our low health priorities. Health being a state subject, the Central authorities totally wash their hands off the pharmaceutical licensing policies followed in the states, which continue to subscribe to widely differing guidelines. Their non-observance alone unites them, and those such as Maharashtra follow them not at all. The drug controllers in many of these states function more as beaurocratic scarecrows than as effective counters to these latest merchants of death. The recent Lentin Commission report which enquired into the IV fluid deaths in Bombay's JJ hospital had exposed the dubious role played by the Maharashtra government in the tragic episode equally at the official/ministerial levels.

What now reportedly is unfolding is a sordid tale of gross corruption and apathy involving the erring firms and those in the drug control administration to whom these shady people have access. The one currently in the news concerns the complaint lodged by Mr.S.S.Kataria, a Delhi based pharmaceutical distributor to the Drug Controller of India and the Drug Controller, Delhi that some 30,000 bottles of contaminated IV (intravenous) fluids were supplied to him by Oslers Pharma, a Coimbatore-based firm. Its products were subsequently alleged to have figured in several deaths in Delhi at the time, leading to their withdrawal. The complaint lodged on February 3 this year was taken note of following the publication of a newspaper report on the matter three days later. A team of officials from the office of the Drug Controller of Delhi seized 12 samples on February 10 from the godown which significantly, was left unsealed despite the distributor's entreaties.

An even bigger surprise followed two months later, in April, when the Drug Controller's Office cleared the samples. The five questions raised on the issue in Parliament thus far have failed to shake the office out of its apparent slumber; and in his interview with *Newstrack* the Drug Controller of Delhi, by stating that the presence of fungus in bottles containing IV fluids need not be all due to the manufacturers' negligence, had strangely given the impression of being merely an uninterested passerby.

The five questions raised on the issue in Parliament thus far have failed to shake the Drug Controller's office out of its apparent slumber

That may not so easily be accomplished now with the arrest by the CBI of Mr PK Jaggi, a drug inspector in the Drugs Control Department, who is alleged to have 'shielded' Oslers Pharma Ltd, the suppliers of the contaminated bottles to Mr Kataria. Several senior drug officials are reportedly still to be traced by the CBI. Mr Jaggi has meanwhile been remanded in judicial custody following the rejection of the bail application submitted to the Additional Sessions Judge by his defence counsel.

As we were about to go to press it was learnt that Mr. Jaggi has been released on bail. He reportedly had to furnish a surity of Rs. 50,000.

The acute understaffing in the Drugs Control cell was brought sharply to the fore at a high-powered meeting last April. The higher figures in the break-up that follows indicate the number of drug inspectors required, and the lower the existing position. Overall — 2689 : 669; Delhi — 55 : 19; Karnataka — 105 : 36; Gujarat — 317 : 65; Maharastra — 477 : 81. (This was the position as on April 1 of this year). In contrast the drug industry itself has rapidly grown,the revenue recorded by it having shot up from Rs. 10 crore in 1947 to the current Rs. 3000 crore.

But let us now take a peek at the fluids' constituents before resuming the history of the controversy that has dogged it since the last few months. The IV (intravenous) fluids are frequently resorted to in all hospitals and nursing homes for meeting the basic nutritional requirements of seriously ailing or injured patients. It is essential in the treatment of dehydration victims when normal intake becomes difficult — such as in accident cases, infections, nausea and gastroenteritis. The elements intravenously introduced into the body through the ad ministering of IV fluids include glucose, dextrose, normal saline, mannitol, and gastric replacement fluids.

Messrs Osler Pharma Ltd., a cooperative venture of 350 Coimbatore doctors, were quick to deny Press reports blaming certain deaths on intravenous fluids (glucose) manufactured by them. Dr. S.G. Rajarathnam, the company's chairman and a medical practitioner, stated that the drug controller of Tamil Nadu who had visited the factory premises on February 10 had not given any adverse comments so far. The chairman pointed out that the pharmaceutical company was floated by about 350 doctors from Coimbatore and Kerala for meeting their own requirements. The 50,000 bottles of intravenous fluids manufactured by them were tested over a period of nine days prior to their marketing, he claimed.

Mr. O.V. Subramaniam, the firm's fulltime director, said its products were marketed chiefly

in Kerala and Tamil Nadu. Mr Kataria of Eskay Pharmaceuticals, New Delhi, had sought and was given dealership for the Delhi region. In August 1988 Mr. Kataria, who is also a shareholder, sent feelers, according to him, suggesting he be made the company's 'vice-chairman', marketing, with a fat takehome packet. This, he said, the board rejected. He then indented for one lakh bottles more and sold only 70,000 — says this version — and procured a dubious test report from a private laboratory on the unsold 30,000. These reportedly carried no particulars, batch numbers, the dates of manufacture and expiry etc.

The tests carried out by Central India Pharmacopeia, Ghaziabad, had earlier declared the 'seized' samples as being 'of standard quality'. An agitated and disturbed Mr Kataria in Delhi alleged that "the drug controller and his department, as also the government analyst, were pressured by Oslers Pharma to manipulate the analysis report and give a clean chit to the erring company". The tardily conducted tests on the samples, which normally take only a few seconds to complete suggested, Mr Kataria said, that 'political pressure' was exerted by the Oslers to formally obtain a clean chit.

Then, in September, a bottle of a life-saving intravenous drug, Mannitol, which was about to be administered to a patient at the All India Institute of Medical Sciences (AIIMS) was found to be contaminated with fungus. The AIIMS Resident Doctors Association said that an identical incident had been reported some months before. In May a doctor in the medical department had found a bottle of saline produced by Tablets (India) Limited, to be contaminated with fungus. The association subsequently demanded that the company be blacklisted and no bottles of the batch no 9RB 767, (manufacturing date June'89, expiry date May'93 and manufacturing licence No-4) be issued. The association warned that failing such measures the residents would boycott the company and ask their patients to bring with them their own bottles.

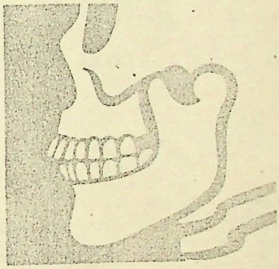
Two people recently died on being injected with contaminated intravenous fluids in Safdarjung hospital. Five others developed severe complications during the same period after they were administered the fluids. All seven of them betrayed identical symptoms — violent shivering, swelling of the face and sometimes acute respiratory problems — from administering of the fluid, doctors said. All, except one, had been given a dextrose solution manufactured by the Faridabad-based Dhavsons Pharmaceuticals. The exception was Shanti (50) from Sekhpur Khurza who died within a half hour of being given ringer lactate manufactured by Prem Pharmaceuticals.

Shanti was admitted to the hospital's ward B on September 3 with a superficial stab injury in the chest. She developed violent rigors and swelling immediately on being administered the ringer lactate of batch 89532C. The second case related to 22-year old Mohammed Izhar who died on September 3 after being put on a 5 per cent dextrose solution of batch no. 318059. Izhar registered in the hospital under No. 207938 and was a patient of abdominal peritonitis. Izhar too reportedly started shivering, his face swelling up abnormally on being injected with 200 ccs. of the fluid. The two deaths were immediately linked to the fluid as it was the only drug that had been administered. "We can't be one hundred per cent sure in the other five cases, but the circumstantial evidence certainly points to it. They were quite all right till the moment the fluid was injected and they all had exactly the same symptoms," the doctors added.

In all, eight adverse reactions stemming from the use of contaminated IV fluids were reported early last month

In all, eight adverse reactions stemming from the use of contaminated IV fluids were reported early last month. The hospital authorities took official notice of four of these although doctors had earlier, around September-end, been told to discard the faulty batch. Another mishap was averted when doctors at Safdarjung hospital seized on October 12 a bottle containing contaminated IV fluid. The bottle of normal saline base bore once more the label of Dhavsons Pharmaceuticals.

The IV fluid bottles manufactured by the Government - owned Hindustan Antibiotics Limited also came in for widespread criticism last month-end after Bhopal's Hamidia hospital reported observing 'black spots' and fungal growth in some of them. Two persons who were administered their contents developed rigors, one of whom, a patient of gastro-enteritis, died the same evening. The hospital authorities said it was not possible to ascribe the death to the administering of contaminated saline in the absence of a post-mortem, nonetheless, the state government had felt immediately obliged to order an inquiry in the matter and the hospital to freeze the HAL stocks in its possession. Significantly the fluids were manufactured by the HAL using the imported CORE technology and supposed to be of the highest standard so far available in the country.



Storage lapses need to be seriously looked into. According to *Martindale's Extra Pharmacopeia*, a pharmaceutical guidebook famed for its accurate information, Anhydrous Glucose (BAN) needs to be stored in airtight containers. Glucose solutions for intravenous use should be stored at 2° to 25° and must be carefully examined for the presence of foreign bodies. The instructions, one is informed, are seldom, if ever closely followed — not even, according to experts in the field, in some of our reputed hospitals. Dextrose being a sugar-based solution, even very tiny cracks suffered by the bottles during transportation can result in the development of fungus. The guidelines laid down in this regard, reportedly, continue to be flouted.

— RAJEEV P.I.
WITH BRAJENDRA SINGH

WHAT AIIMS COULD DO

Enquiries reveal that a good number of IV fluid manufacturers reuse empty bottles. This is a very hazardous practice. IV fluid bottles have a natural inner coating which ensures the fluid's separation from the glass walls. Before the bottles are reused they are sterilised once more in the autoclave causing this coating of natural chemicals to peel off. The fluid, as a result, suffers silica contamination.

The sets used for administering IV fluids produced by small units, have aroused doctors' apprehensions regarding the manufacturers' claim that they are sterilised. These sets are packed in thin, unreliable plastic bags vulnerable to punctures.

Most such hazards could be eliminated if hospitals developed captive IV fluid plants. This applies, in particular, to medium and large sized public hospitals where their daily consumption runs daily into hundreds of bottles.

The casualties reported in the AIIMS from IV fluid contamination have given considerable fillip to this demand. The hospital enjoys the status of being the premier institution for medical sciences in the country and possesses the basic facilities required for the manufacture of IV fluids. It had, in fact, been manufacturing these for its own use since 1977 till production was abruptly brought to a halt in 1981.

It is learnt that (a) the daily consumption of IV fluid in the hospital averages about 3,000 bottles (b) the purchases are effected through annual tenders, cleared by a purchasing committee headed by the Medical Superintendent. (c) the hospital's tender regulations have built-in clauses seeking to ensure the quality of the drugs purchased. Sources reveal, however, that these regulations are not always observed. To cite just one instance, tender regulations do not allow a new unit to bid and the purchase committee can reject any tender without assigning reasons. It is said that even these two clauses are being used arbitrarily to victimise suppliers who do not curry the committee's favour. (d) despite numerous complaints regarding the quality of IV fluids and the recent reported deaths in the hospitals on their account the hospital authorities have shown no inclination as yet to initiate any action against the erring firms. All the AIIMS is known to do is to remove the offending bottles, or at most have the Drug Controller's office take the bottles away for analysis. (e) the AIIMS Inspection Control Unit, although well equipped, is understood to have conducted hardly any tests on IV fluids in the past couple of years. (f) the hospital used to manufacture its own IV fluids from 1977 to 1981. No complaints relating to IV fluid contamination were heard at the time. The hospital still has the facilities to manufacture IV fluids in quantities sufficient enough for its own needs. According to experts within the AIIMS costs could be cut down by 30 to 35% if the fluids were not to be procured from private firms. During talks with AIIMS officials, the following points were raised:

The autoclave used for IV fluid manufacture has been in disrepair for years. All things considered the AIIMS has no reason to continue buying IV fluids from private manufacturers, in public interest. If this cannot be done immediately, the least it can do is to review its tender regulations and remove such loopholes from them as are likely to promote corrupt practises. The Defence hospitals usually send their own quality control officers to the IV fluid suppliers' premises to ensure the fluids quality at the time of delivery. It should not be difficult for an institution like the AIIMS to evolve a system of quality control on similar lines.

MURDEROUS LACUNAE

Dr. Mira Shiva, winner of the first international Olle Hansson award for her outstanding contribution in the field of health activism, exposes some of the disturbing half-truths spawned by the IV fluids controversy in this interview with RAJEEV P.I.

The Drug Controller of Delhi recently told Newstrack that if the government analyst found the samples safe there wasn't very much more to be done in the matter. How did that strike you?

Well if he was talking on the basis of those eleven samples on which the analysis was reportedly based, without bothering to look at the rest of the stocks, and this with the hospitals continuing to churn out adverse reports, such a remark comes across as being highly irresponsible. But to say that 50 per cent of the stocks would have to be found substandard before he, as the Drug Controller, could have them withdrawn —that most certainly was the limit.

The Drug Controller had further observed that fungus-hit IV fluids couldn't cause death.

All right, then what did all those people die of? The clinical reports clearly say that death followed shortly after the IV fluids were administered ... and so many others reacted to the fluids. When you put all that together, it becomes clear that these were not isolated incidents — just consider the number of hospitals who have returned the stocks and blacklisted their suppliers. One would further like to know why, if these were not unnatural deaths, the doctors in these hospitals were so perturbed? So, obviously, those deaths had some connection with the IV fluids that were administered. The deaths need not, though, have been due to fungal contamination alone, there might well have been other contaminants: bacterial or viral or chemical in the fluids.

So how does one sort out this mess?

It's a nationwide malaise and much more serious than some people would have you imagine. The manufacture of IV fluids requires technology much less complicated as compared with that required in the manufacture of most other drugs and injectable vaccines. Fungal contamination on such a large scale as reported in IV fluids is unpardonable. Keeping a check on the latter is comparatively much easier as the fungus can be spotted with the naked eye and the side effects are both more immediate in their occurrence and easier to report. This is indicated by the experience of several hospitals. When a gross thing like fungus escapes the notice of the people who handle the fluids at various levels — stockists, pharmacists, nurses, doctors etc., — it means the responsibility must needs be shared by them all, including the fluids' manufacturers and distributors. It also speaks volumes on the sort of drug control system we have and its total failure in ensuring quality control and the immediate withdrawal of substandard stuff. These lacunae were equally obvious when the AIDS sero positive Anti D Vaccine and other blood products continued to be used long after AIDS sero positiveness had been recognized, albeit fairly late. There is practically no follow-up of these patients.

Which is the more striking in your view — the negligence of the hospital staff or the apathetic response to the all-round concern over these reported quality lapses?

They both deserve equal attention. The manufacturers' apathy is for all to see, not merely in the present case but in most other areas of drug manufacture as well. However, in the issue here under scrutiny, I think the hospitals have displayed a matching disregard in the observance of basic precautions like checking of expiry dates and looking for suspended particles in the bottles. These together might have helped save several lives. Moreover, quite often deaths from IV fluid infections are blamed on other factors, for very obvious reasons. It is only when some responsible public spirited individual decides to take up the issue that the truth gets to be known. This happened last year too during the cholera epidemic.

But on whom ultimately does the onus lie ?

There are a great many people who could be blamed, but it's the manufacturers and the drug control authorities who must chiefly be held responsible in cases such as these. Further, one thing has become very, very clear, especially after the Lentin Commission report on the JJ Hospital deaths from contaminated glycerol. Drug manufacture in the states being the responsibility of the respective drug controllers posted there, there remains no control whatsoever on what happens after the drug is transported elsewhere. This has particularly frightening implications for states such as Bihar, M P etc., where the drug control mechanism is so abysmally weak that even basic manufacturing norms are often not followed.

POINTS TO PONDER

Mr H.D. Shourie, a retired ICS officer and former Director-General of the Indian Institute of Foreign Trade, has filed a petition before the National Consumers Disputes Redressal Commission urging it to look into the IV fluids controversy. The petition was filed on behalf of *Common Cause*, a voluntary organisation of which Mr Shourie is director. Subsequently, on October 20, the Supreme Court asked the Drug Controller of India and drug controllers in the states to inform it about the steps being taken by their respective offices to arrest the inflow of spurious IV fluids in the market. A month's time has been given to them to depatch their replies. The following are some of the important points raised in the petition:

- In the Delhi Doordarshan newscast on October 3 and in *Newstrack's* presentation of this problem, the Drug Controller of Delhi had stated that the fungal development appeared to be linked to its transport and storage, and that the contamination need not necessarily be harmful if administered intravenously. This opinion was subsequently contradicted by doctors who maintain that IV fluids contamination can cause serious complications, convulsions and even death.
- It is understood that the latter are often not reported by the doctors and nurses concerned out of fear for themselves, and to protect the reputation of the institutions that employ them. There have been reports that attempts were made in Delhi's Safdarjang hospital to tamper with the history sheets of some of those who were administered contaminated IV fluids.
- The Central and state authorities should re-examine the licences issued to manufacturers of IV fluids, survey facilities and equipment in the licensed units, and cancel the licences of those failing to measure up to the standards laid down with regard to their safety. These need to be very stringent and should under no circumstances be relaxed regardless of whether the unit concerned is big or small.
- The guidelines and conditions laid down for the manufacturers should be strictly adhered to while licensing new units.
- The particulars relating to the licences issued should always be available at the offices of the drug controllers in the states and Union Territories, and in the office of the Drug Controller of India. The latter should arrange for periodic inspection of the licensed units by the licencing authorities concerned.
- The possibility of contamination during manufacture should be studied in detail. These studies should include *inter alia* the safety requirements.
- The suppliers of IV fluids need to be thoroughly screened.
- The Drug Controller of the Government of India and the drug controllers of the states and Union Territories need to be held personally responsible for anything going wrong in the manufacture and supply of IV fluids to the hospitals. Representatives of consumer organisations should, wherever possible, be associated with the prescription and observance of the guidelines relating to the manufacture, stocking and purchase of the fluids.

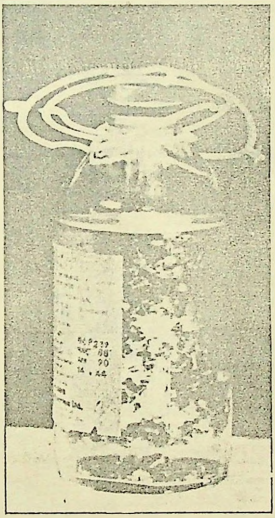
But putting the onus on the state governments doesn't help. Unless the drug administration at the centre is made to ensure drug safety measures in the states things are not going to improve at all. The trouble, you see, is that in states like Bihar the budget allocated for drug control activity in the overall health package is so inadequate that they are unable to ensure even basic safeguards through the setting up quality control labs, and recruitment of efficiently monitored drug inspectors. The result is that when such an issue surfaces there is a general tendency to pass on the buck. Unless the Health Ministry decides to become more responsible, rather than just shift blame onto others, incidents like these cannot be checked. It is our system that at various levels needs to be streamlined. It's indeed a shame that it should have been Delhi, with its somewhat better facilities, to first report deaths from the administering of IV fluids. A gross shame!

Any comments on the Lentin Commission report ...

It is very important, this being the first time in the country's history that a commission was set up to conduct an in-depth probe into drug-related deaths. The report, thorough and unbiased, had implicated several people and urged the importance of strengthening our drug control set up. Its message was that one couldn't rely on private drug testing labs and it exposed the politician bureaucrat nexus in the process. Among other pertinent questions raised by it was the one concerning the lives lost through the administering of substandard drugs. Do the victims' families ever get any compensation? In the case of the Bombay deaths, the government had ordered Rs. 10,000 to be paid to each of them.Did anyone check if the amount actually reached those for whom it was intended? And what about those who survive after being administered spurious drugs but whose lifespan is shortened all the same — do they get any compensation? And yet,when such things continue to occur, one can't help but conclude that the present drug control system in the country is inherently, gravely defective — that if the Industry Ministry continues to be the architect of the nation's drug policy, our people's health is bound to be marginalised

What would you say has been the Indian government's role in the matter of drug manufacture and distribution?

This is one area in which I would say the government has shown absolutely no seriousness. It's shameful. Numerous organisations and groups have been at pains to emphasise that so long as you don't regulate the drug flow all sorts of people (even those who have no intention of following the GMP) are likely to venture into the business. There is absolutely no way that drug safety can be ensured by the existing overloaded, inadequate drug control mechanism. On account of the abundance of trash on sale here, doctors often are unable to decide on the drugs they can safely prescribe and those they can't. And to top



it all licences are being distributed without as much as considering what is being produced or how. When life-saving drugs like IV fluids start doing the opposite ...

What are the immediate steps in the case of IV fluid deaths that you would have the parties concerned follow?

They could probably set up an inquiry commission to go into the issue — but then whoever knows how long they will be at it or what will ultimately come out of the exercise. Most deaths having been reported from government hospitals, there is a feeling there's something very wrong with the purchasing practices followed by these government institutions — such as going in for the lowest tenders regardless of the product's quality. There have been cases when known substandard drugs were allowed to be purchased. What is required is an efficient mechanism which will test drug samples for their safety, especially in our government hospitals and health centres.

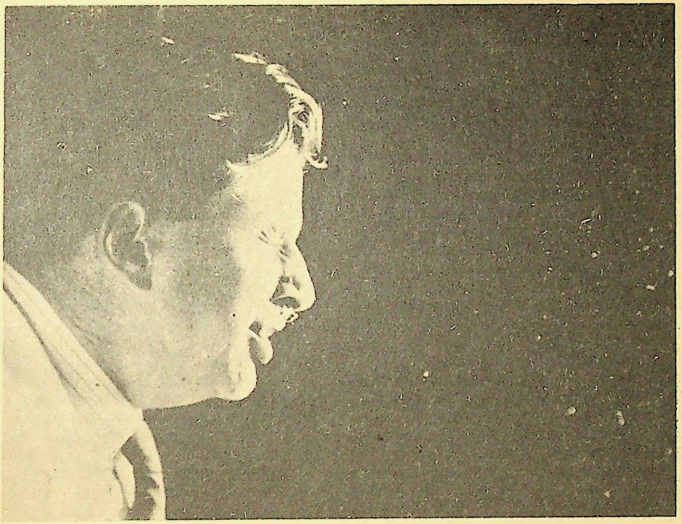
It still strikes one as odd that the majority of IV fluid-related deaths should have been reported from government hospitals rather than private institutions. It can't all be coincidence ...

No, it can't. You see there is no system in these places to monitor adverse drug reactions. As a result in the case of all those who die of iatrogenesis (drug & doctor induced death) none ever gets to know the cause of death.

How efficient are the death review committees in our hospitals, and do all hospitals have them?

Most hospitals are expected to have them though I'm not informed on their functioning. But then, as we all by now know, the IV deaths came to light because some junior doctors in the AIIMS and Safdarjung hospital raised the issue, and not through death review committees or post-mortems. It is also a fact that most deaths of this nature are reported simply as "cardio respiratory arrests", because that way they are able to safely cover up the incident. Starvation deaths for instance. It isn't written on the victim's forehead that he/or she died of starvation. Starvation causes the body's resistance to break down making it vulnerable to a host of ailments,sometimes even trivial infections which, in the normal course, he would have survived. But here too they almost never tell you what precisely the victim died of — diarrhoea, pneumonia or whatever .... It happened in Rajasthan during the drought and in Kalahandi in Orissa. Drug reactions from IV fluids are unlike those induced by, say, penicillin, as the former require close monitoring — but then who should be interested in monitoring it? I should think no doctor or nurse would be particularly keen on reporting their own negligence.

89-23



THE UNCOMMON COLD

By Our Medical Correspondent

WHAT EXACTLY is the common cold? And how has it come to be so named? As Sir Christopher Andrewes puts it, "That it is common admits of no dispute. But why cold? Is it because we feel chilly when we have a cold, or because chilling brings it on (or is supposed to), or because the infection is commoner during the cold time of the year? Perhaps all three ideas play a part in conveying the image

Modern medical texts however refuse to call it the 'common cold'—they prefer to shroud the ailment under more impressive terms like 'acute rhinitis' and 'the coryzal syndrome'. But for our purpose, Andrewes' definition will be more than adequate: "The common cold is one of a number of virus infections which affect, often repeatedly, the lining of the nose and other passages leading to the lungs."

they expecting the boy?" she asked. "Yes," he said looking at me again. "But they said he would be arriving tomorrow."

"They'd forgotten the date," said Grandmother in a huff. "Anyway, you can unpack and have a wash and change your clothes."

Turning to the servant, she asked, "Is there any lunch?"

"I will make lunch," he said. He was staring at me again, and I felt uneasy with his eyes on me. He was tall and swarthy, with oily, jet-black hair and a thick moustache. A heavy scar ran down his left cheek, giving him a rather sinister appearance. He wore a torn shirt and dirty pyjamas. His broad heavy feet were wet. They left marks on the uncarpeted floor.

A baby was crying in the next room, and presently a woman (who turned out to be the cook's wife) appeared in the doorway, jogging the child in her arms.

"They've left the baby behind, too," said grandmother, becoming more and more irate. "He is your young brother. Only six months old." I hadn't been told anything about a young brother. The discovery that I had one came as something of a shock. I wasn't prepared for a baby brother, least of all a baby half-brother. I examined the child without much enthusiasm. He looked healthy enough and he cried with gusto.

"He's a beautiful baby," said grandmother. "Well, I've got work to do. The servants will look after you. You can come and see me in a day or two. You've grown since I last saw you. And you're getting pimples."

This reference to my appearance did not displease me as Grandmother never indulged in praise. For her to have observed my pimples indicated that she was fond of me.

The tonga-driver was waiting for her. "I suppose I'll have to use the same tonga," she said. "Whenever I need a tonga, they disappear, except for the ones with white ponies. . . When your mother gets back, tell her I want to see her. Shikar, indeed. An infant to look after, and they've gone shooting."

Grandmother settled herself in the tonga, nodded in response to the cook's salaam, and took a tight grip of the armrests of her seat. The driver flourished his whip and the pony set off at the same listless, unhurried trot, while my grandmother, feeling quite certain that she was going to be hurtled to her doom by a wild white pony, set her teeth and clung tenaciously to the tonga-seat. I was sorry to see her go.

* * *

MY MOTHER and stepfather returned in the evening from their hunting-trip with a pheasant which was duly handed over to the cook, whose name was Mangal Singh. My mother gave me a perfunctory kiss. I think she was pleased to see me, but I was accustomed to a more intimate caress from my father, and the strange reception I had received made me realise the extent of my loss. Boarding-school life had been routine. Going home was something that I had always looked forward to. But going home had meant my father, and now he had vanished and I was left quite desolate.

I suppose if one is present when a loved one dies, or sees him dead and laid out and later buried, one is convinced of the finality of the thing and finds it easier to adapt to the changed circumstances. But when you hear of a death, a father's death, and have only the faintest idea of the manner of his dying, it is rather a lot for the imagination to cope with—especially when the imagination is a small boy's. There being no tangible evidence of my father's death, it was, for me, not a death but a vanishing. And although this enabled me to remember him as a living, smiling, breathing person, it meant that I was not wholly reconciled to his death, and subconsciously expected him to turn up (as he often did, when I most needed him) and deliver me from an unpleasant situation.

My stepfather barely noticed me. The first thing he did on coming into the house was to pour himself a whisky and soda. My mother, after inspecting the baby, did likewise. I was left to unpack and settle in my room.

I was fortunate in having my own room. I was as desirous of my own privacy as much as my mother and stepfather were desirous of theirs. My stepfather was ready to put up with me provided I did not get in the way. And, in a different way, I was ready to put up with him, provided he left me alone. I was even willing that my mother should leave me alone.

There was a big window to my room, and I opened it to the evening breeze, and gazed out on the garden, a rather unkempt place where marigolds and a sort of wild blue everlasting grew rampant among the lichi trees.

Lichi trees! As long as there were trees to climb and lichis to eat, I felt I could cope with life.

THE END

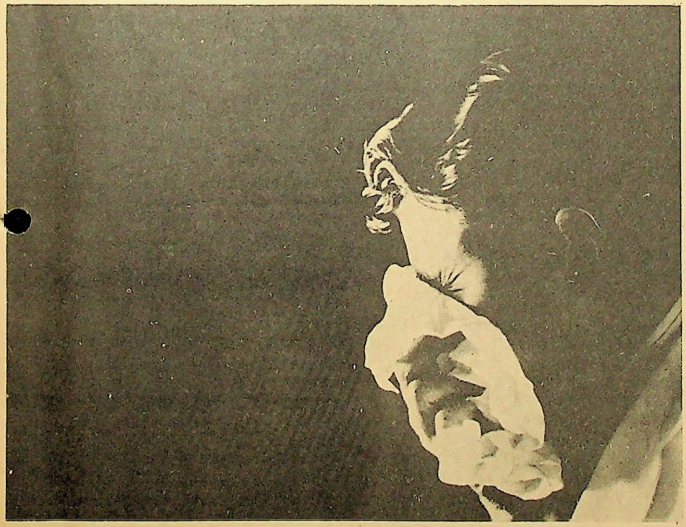
Any honest doctor will tell you that for all the misery that it inflicts on you, there is really nothing like a remedy for the common cold. But built around this common cold is a multi-million dollar drug industry which offers a colourful range of syrups, capsules, tablets and rubs backed up by an advertising campaign that makes them irresistible for the man with a running nose. Our Correspondent analyses these drugs and shows how the drug industry takes the common man for a ride.

Cold Causes

HOW IS the common cold caused? First, the viruses responsible have to gain an entry into the upper parts of the respiratory tract, and they usually do so through the nose, transmitted from another infected person. Viruses are fascinating creatures; each is just a bit of nucleic acid wrapped in a protein coat, so tiny that electron microscopes, which magnify some hundreds of thousands of times, are required to see them clearly. Disease-causing viruses each have a specific organ or 'target tissue' which they attack. With 'rhinoviruses' (from the Greek, 'rhino' meaning 'nose'), the target tissue is the mucous membrane of the upper respiratory tract. As soon as the rhinovirus invades the membrane, penetrating into its cells, it sets into motion a number of changes that ultimately culminate in a full-blown common cold.

The virus makes a beeline for the nucleus of the mucus-producing cell, and virtually 'captures' the DNA (Deoxyribose nucleic acid) molecule that makes it tick. Normally the DNA directs the metabolism and functioning of the cell, but the virus stops all that, and instead, forces it to turn out exact replicas of itself. The virus thus reproduces itself at the expense of the cell: the cell ultimately dies and hundreds of viruses are liberated. These again attack other cells, and the cycle is repeated.

As a result of viral invasion, the blood supply



to the parts concerned increases tremendously and the mucous membrane begins to swell. This is responsible for the first symptom—a stuffiness or tightness in the nose. Those cells of the membrane not affected by the virus produce more and more mucus because of the increased blood supply. The death of virus-affected cells and their rupture releases still more mucus. Therefore, there occurs a discharge—a running of the nose—which is initially thin and watery. Soon, as the dead cells are shed off, the secretions become more viscous, straining the propelling capacity of the cilia. Therefore, they tend to accumulate, giving rise to that 'blocked' sensation in the nose. Further down the respiratory tract, the accumulation irritates the mucous membrane, eliciting a reflex called the 'cough reflex' which permits a forceful expulsion of the secretions. Simultaneously, there is a huskiness of the voice, a feeling of weakness, a chilling sensation and rarely, a slight fever.

Cold Is Big Business!

WITH any ailment, the pharmaceutical industry has always had a penchant for churning out 'remedies' in inverse proportion to the actual number of effective or curative drugs available. The gimmicks employed are many and varied, ranging from the ridiculously simple to the cunningly devious—juggling with a few standard drugs, altering the dosage of one, adding some harmless ingredient here, putting in an 'attractive' colour or flavour there, changing the shape, the size, the colour of the container and the packaging, and so on and so forth. . . . The sky's the limit as far as pharmaceutical legerdemain is concerned. Actually, if brand names alone were to be eliminated, our pharmocoepias would shrink to unrecognisable, slender versions of their present tome-like selves!

Now, with the common cold, the pharmaceutical industry began with three distinct advantages—one, the universal nature of the illness, two, the failure of medical science to come up with any specific drug so far, and three, the resulting willingness of the victims to try 'anything' to get some sort of relief, however transient or imaginary. No wonder it has spawned such an infinite range of tablets, capsules, drops, lozenges, syrups, ointments and what-have-you!. .

It is also no surprise that in an industry like this, where large funds are essential for the gigantic scale on which advertising and marketing campaigns are conducted, multinationals are doing a roaring trade. The two hundreds or so rhinoviruses may be the bane of millions all over the world, but to pharmaceutical companies exploiting this 'insignificant' ailment, they are an endless bonanza of cold, hard cash. Not only has a multimillion dollar industry mushroomed around the common cold, but it is even said that some firms exist more or less solely because of their 'cold' products!

The 'cold' industry initially found it difficult to get a toehold in India becuase of the impregnable position held by "grandmother's remedies". With time however, the trend is changing and today, the average Indian is slowly but surely approaching his American counterpart who pops in a pill for everything ranging from boredom to Bornholm disease.

Endless Market

IN A RANDOM survey conducted among some Bombay stores, this writer discovered to his surprise that the average druggist sold about Rs.800 worth of just a handful of the most popular cold remedies *in a month.* Considering that Bombay has more than a thousand drugstores, this means that Bombayman spends at least *half to three fourths of a million rupees* a month on the common cold!

Pharmaceutical sources estimate that the Indian cold market, as of now, is worth anything from five to 10 crore rupees a year—closer to 10 if analgesics proper are included, and closer to five if these are excluded. A large chunk of the market—between three and four crores—belongs to the 'cold tablet' range of products. The [illegible] market—ointments, balms, etc—accounts for nearly an equal fraction.

How has this market evolved? How are people manipulated into buying larger and larger quantities of cold remedies?

Says a media source, "Years ago, before the 'cold' concept came into the picture, consumers were sold on the 'analgesic' treatment of the common cold. Then, the pharmaceutical industry decided to devise its treatment along three or four different lines, according to the different stages of the common cold. For stage one, where all one had was a mild sore throat, 'drops' and 'lozenges' were promoted. For stage two, where a stuffy nose had to be treated, 'rubs' were promoted. It was after stage two, for a 'full-

fledged' cold, that 'cold tablets' came to be advertised. In fact, the concept of the cold tablet is not even a decade old in India. Stage four, of course, is when the infection goes much beyond a cold and an antibiotic becomes necessary.

"Promoters of 'cold remedies' have been unwittingly helped by doctors. After all, who wants to go to a doctor for a 'mere' cold? Think of the waiting, the cost involved when all one has to do is pop in a pill or rub something soothing on oneself, or better still, get someone you love to rub it on you? These feelings have been assiduously fanned by an efficiently-organised advertisement campaign.

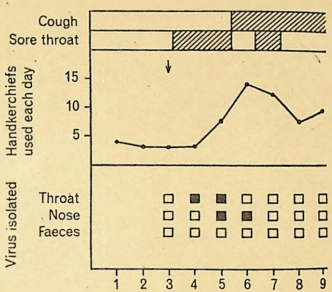
"Vicks manufacturers were, I believe, the first to set into motion a campaign of this sort. They started a series of ads for the promotion of two categories of products—one of lozenges and drops and another of 'rubs'. For the first category, they had a series of ads depicting various professionals—singers, actors, politicians —suddenly developing a hoarse voice in the midst of their work. . . . and a helpful guy would give them Vicks drops and presto! they would be instantly cured.

"As for the 'rubs' products, the personal factor has always been stressed in advertising media. For instance, the Vicks Vaporub ad shows those kids getting wet in the rains, their mother rubbing in Vicks—and they're hale and hearty the next morning!

"In recent years, some of the bigger companies have decided to shift the emphasis from the urban to rural centres. They've realised that the urban market is getting saturated with products, while the rural market is still largely untapped. In cities like Bombay, competition is fierce and advertising is expensive. Therefore they're conducting ad campaigns in less urbanised areas— showing popular films, with their own ads in between, and with an accompanying trailer containing their products. Such mobile campaigns have proved very effective in the rural market.

"The latest trend in advertising is to get the consumer to associate a certain product with a certain kind of person. For instance, the Vicks Action 500 ad shows an 'executive' complete with attache case, suit, foreign car, sumptuous office, secretary, etc. This kind of 'status-symbolisation' of a cold remedy was never attempted before."

The advertising outlay on cold remedies is



The course of a typical cold showing (shaded) occurrence of symptoms on different days after inoculation (arrow), number of handkerchiefs used, and presence (black square) or absence (white square) of virus in specimen tested.

estimated to be over two crore rupees, annually. At present, nearly three fourths, that is about one and a half crore is expended for the promotion of 'rubs'—Vicks Vaporub apparently with a lion's share of about one crore rupees. A 'mere' half crore rupees is spent on promoting cold tablets. "But," says a pharmaceutical source, "the scope for tablets is gradually increasing, with a consequent shrinkage of the 'rubs' market."

Pharmaceutical companies follow a more or less standard procedure when they decide to market a cold 'remedy'. First, it is sold as an 'Ethical' medication, that is, on doctor's prescription only. Corps of medical representatives (and multinationals have particularly well-organised and huge ones) 'sell' the product to general practitioners and the like. How this 'selling' is accomplished need not bother us here. After a few years, the product gets established in the patients' minds. Or the introduction of new products by their own firms, or other firms, shortens the 'Ethical' life-span. After this, the product is withdrawn from the ethical list and sold as an "Over-The-Counter" (OTC) medication. Simultaneously, a massive ad campaign is launched to establish the product on a firm footing. The product's subsequent fate is also largely determined by the advertising media.

The Cold Pharmacopoeia

OVER the years, 'remedies' for colds have gone through a number of stages. First,

antihistamines were claimed as a panacea but were later proved to be useless. After this a group of chemicals called biflavonoids (collectively termed *Vitamin P*) came to be advocated, and similarly passed into limbo, when their true worth was discovered. Later still, the 'shotgun' approach—using multiple ingredients—was initiated by an ingenious pharmaceutical industry out to make a quick buck from the common cold.

As for analgesics, the 'traditional' remedy for headache and colds, the chart carried with the article lists some of the vast range of brands, each generically more or less the same, but with differing prices. (One single drug—Analgin—alone has *90* different brands!) Another disconcerting fact is the addition of phenacetin (known to have certain toxic effects on the blood and kidneys after prolonged use in high doses), and caffeine (in too low doses to be of any use)

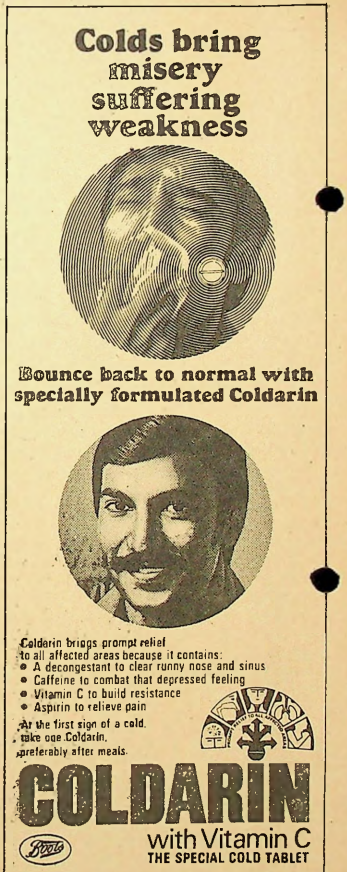
Incidentally, a recent study carried out by the Abraham Lincoln School of Medicine, University of Illinois, pointed out that aspirin does nothing to reduce infection or illness from colds. On the other hand, aspirin relieves the discomfort of colds and allows persons who would have otherwise stayed at home, to go to work. Thus aspirin treatment indirectly increases 'virus shedding' by the patient, making him a greater epidemiological hazard in the transmission of the disease.

Let us now take a close look at each category of the cold pharmacopoeia.

Coldarin

WE SHALL first consider 'Coldarin', apparently the most popular OTC cold tablet on the market. It has been on the OTC market now for the last five years or so, before which it was an Ethical product. Its phenomenal popularity is no doubt due to an enthusiastic advertising campaign, said to cost the manufacturers (Boots, a multinational firm) some 20 odd lakh rupees every year.

A typical Coldarin ad goes this way: "Colds bring misery, suffering, weakness"—interposed is a blurred image of an individual very obviously undergoing the torment so familiar to many of us—then: "Bounce back to normal with specially formulated Coldarin"—below is the sufferer all smiles. In tinier print follows the message—Coldarin brings prompt relief to all affected areas because it contains one, "a decongestant to clear runny nose and sinus", two, "caffeine to combat that depressed feeling", three, "vitamin C to build resistance" and four, "aspirin to relieve pain". The customer is exhorted to take one Coldarin, preferably after meals,



at the first sign of a cold. The punchline of the ad, so to speak, is in bold black letters–Coldarin, with Vitamin C, The Special Cold Tablet.

So much for the ad. Now let's see what each tablet of Coldarin actually contains: Phenylephrine 10 mg, Caffeine 30 mg, Vitamin C 20 mg, Aspirin 600 mg, Calcium carbonate 200 mg and Terpene hydrate 30 mg.

Phenylephrine theoretically causes nasal decongestion by constricting the blood vessels in the nose. But no pharmacological authority advocates phenylephrine as an *oral* decongestant because it is not well absorbed from the gut and it does not selectively act on the blood vessels of the nasal mucous membrane. Even if it were to be so advised, Coldarin's 10 mg would be too little.

Consider the next claim "caffeine to combat that depressed feeling". Caffeine is a central nervous system stimulant, and even an ordinary cup of coffee contains 50-100 mg of caffeine. We all know how effectively this combats 'that depressed feeling'–Coldarin contains only 30 mg of caffeine.

Consider now the third claim–"Vitamin C to build resistance"–a wonderfully vague statement indeed. The content is 50 mg of vitamin C, which oddly enough happens to be the daily minimal requirement of a healthy adult. And since not many of us suffer from scurvy, which is a sure indication that we're getting more than our daily requirement of vitamin C, one can't see how a miniscule amount like 50 mg extra will help. In fact, it will only be washed out of the body within 24 hours of so. Probably the promoters are trying to capitalise on the "Vitamin C for Cold" controversy. They are, perhaps, not aware that Dr Pauling advocates large doses (and by large he means a dosage in the region of several hundreds to several thousand milligrams per day) to fight the common cold. . . but more of this later. The Coldarin ad again stresses the Vitamin C angle: "Coldarin–with vitamin C–The Special Cold Tablet" There's nothing 'special' about the 50 mg of vitamin C added–it merely provides yet another excuse to further hike up the tablet's price.

At long last, we come to "aspirin to relieve pain", and since aspirin is an established analgesic, to be administered orally in the adult dose of 300-1000 mg, one cannot quibble about it. It is indeed ironical that the one legitimate claim the tablet boasts of–that too of an analgesic–is mentioned last in the ad.

Thus, a careful analysis of this sort proves that Coldarin is only a glorified analgesic tablet (which was traditionally used to treat colds anyway) with a few extra ingredients thrown in to be sold at a price three-four times that of ordinary analgesic tablets. The extra ingredients may be theoretically all that the promoters claim (or imply) to be–but in the quantities present, they are more or less ineffective, as any pharmacologist will tell you.

Vicks Action 500

LET US GO on to "Vicks Action 500", another OTC product believed to be the 'arch-competitor' of Coldarin. The manufacturers very courageously put it straightaway on the OTC market, without the usual span of years as an 'Ethical' medication. Though a bare couple of years or so on the market, Action 500 is said to be doing extremely well–again largely due to an intensive ad campaign costing its manufacturers (Richard Hindustan, another multinational) around 25 lakh rupees a year. Action 500 is also marketed in an attractive 'capsule'-like form, which helps the manufacturers in two ways. Since the average consumer, for some unfathomable reason, always thinks a capsule is more 'potent' than a tablet, it is bound to evoke a better response from him, and secondly, it provides the manufacturers one more reason to justify their price.

An analysis of Action 500's formulation reveals that each tablet contains–Salicylamide 390 mg, phenacetin 242 mg, Caffeine 32 mg, Sodium Citrate 32 mg and Ephedrine 8 mg.

Salicylamide is a weak, aspirin-like drug and therefore its dosage should be greater than aspirin's for the same effect. This is supposedly counterbalanced by the addition of phenacetin, which has a painkilling action of its own. However, as mentioned before, pharmacologists no longer recommend its inclusion because of its high toxicity. The next ingredient is Caffeine 32 mg and we have just seen, in the case of Coldarin, how effective 30 mg were. Sodium citrate has been added as a 'filler'. At long last, we come to Ephedrine, which falls in the same 'decongestant' category as Coldarin's phenylephrine. Unfortunately, even if Ephedrine did work as an effective nasal decongestant when given orally (a very big if, because usually it has been administered locally, in the form of nasal drops, for this effect), Action 500's dose of eight mg is just too small.

Ethical Market

AS AN EXAMPLE of a cold tablet from the 'Ethical' market, we shall consider 'Vikoryl' (which for a change, is the product of an Indian company, Alembic). Each Vikoryl tablet contains Aspirin 200 mg, Paracetamol 120 mg, Phenylephrine five mg and Chlorpheniramine maleate two mg. Paracetamol has been added presumably due to its anti-pyretic and analgesic action, to add to aspirin's. We have seen above that 10 mg of oral Phenylephrine is not effective as a nasal decongestant, so that the efficacy of Vikoryl's five mg can well be imagined.

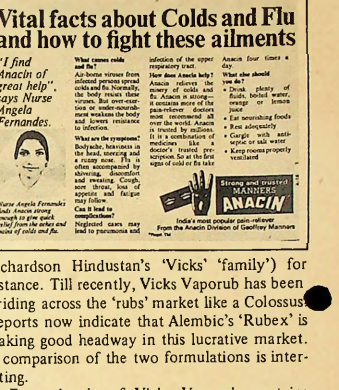
That leaves Chlorpheniramine maleate. This is an antihistamine, which can hardly be recommended for a viral disease like the common cold. As 'Drugs of choice, 1978-79", an internationally acknowledged pharmacological authority, says *"Despite clinical evidence that antihistamines do not cure or abort the common cold, and are indicated only in a few rare instances of cough, occurring as a manifestation of allergy, many of these compounds have been incorporated into popular cough preparations."*

Sir Christopher Andrewes also deplores this in 'Assessing Cold Cures' ("The Common Cold", Chapter 16, p.151) "The sad thing is that years after the antihistamines were debunked as cold cures in scientific journals, they are still being sold in quantity for this purpose and bringing in large profits. A new cold-cure is headline news: debunking a cold-cure does not deserve a line of even the smallest print."

We have, in all, considered in detail just three cold tablets. But it has become obvious that each is a sort of prototype on which every other is based. The recipe is very simple: Take an analgesic or two, a decongestant, an antihistamine, Vitamin C and any other harmless ingredient you can lay your hands on easily. Make a combination after your heart's fancy, add an enticing colour and flavour, arm yourself with the finances necessary for a hectic ad campaign, and presto! you will have automatically joined the long line of pharmaceutical companies eager to alleviate the torture of the teeming millions suffering from the common cold—at a price of course!

Ointments

WHAT does the 'cold' industry have in store for us in the shape of Ointments? Take "Vicks Vaporub" (another member of



Richardson Hindustan's 'Vicks' 'family') for instance. Till recently, Vicks Vaporub has been striding across the 'rubs' market like a Colossus. Reports now indicate that Alembic's 'Rubex' is making good headway in this lucrative market. A comparison of the two formulations is interesting.

Every bottle of Vicks Vaporub contains Menthol 2.82%, Camphor 5.25%, Thymol 0.1%, Turpentine oil 5.57% and Paraffin oils and essential oils to make the rest.

Every bottle of Rubex, on the other hand, contains Mentisol 2.82%, Camphor 5.25%. Thymol 0.1%, Turpentine oil 5.6%, and Eucalyptus and nutmeg oils.

60 grams of Vicks Vaporub costs about Rs.6.50.

65 grams of Rubex costs about Rs.6.20.

Can the discerning reader perceive any significant difference in the composition (even the % composition!!) of the two brands?

Of the various constituents of the 'rubs' products, Camphor is what pharmacologists call a 'counter-irritant'—a drug, that when rubbed in, increases blood supply and warms the part. So are menthol and turpentine oils. Thymol is an anti-bacterial and anti-fungal substance, used primarily in certain skin creams, lotions etc. Cold is caused by viral infection; it is not a skin disease. Paraffin oil is an 'emollient'—a spreading lubricating substance that facilitates application over the skin. Eucalyptus oil is a volatile odorous oil obtained from Eucalypta plants, also added as an counter-irritant. Nutmeg oil is another volatile oil got by distilling nutmeg. It is a flavouring agent and a mild rubifacient—a drug that resembles a counter-irritant in effects.

Thus it is obvious that not a single constituent of the 'rubs' range has any direct connection

with the common cold–notwithstanding the claims of products like Rubex, which has an ad, prominently displayed in many drugstores, depicting a happy mother holding aloft her child, both bursting with health, and the slogan reading "Ah-choo. . . .Rubex. . .choo!" (which could be roughly translated as "Colds? Gone with Rubex!") Rubbing these ointments on the chest, back, etc–even by the most loving of touches can have little effect on the common cold.

Syrup Solutions

NEXT, LET us go on to the myriad multi-hued, multi-flavoured 'syrups' the cold industry has put out on the market. Take, for instance, Waterbury's Red Label. Its ad runs as follows–"Recurring Coughs and Colds? Take Waterbury's Red Label!" It is claimed to be 'The Best Remedy for Coughs and Colds' and it 'Builds resistance while it gives relief'. A harassed-looking housewife is shown in her kitchen, and under this, the theme continues–"Colds and coughs come when your body's resistance is low. When they go, they leave you weaker still. So you get coughs and colds more easily again. And again. But the work of the house must be done. A housewife can't really fall sick; can she?–The thing to do is to build up your body's resistance while you fight your coughs and colds. Only Waterbury's Red Label does both. It has two groups of ingredients–First it has Creosote and Guaiaicol which relieve coughs and colds. Secondly, it has ingredients that tone up your system, restore energy and build up resistance.

Every 15 ml (about three teaspoonful) of elixir contains–Creosote 0.0075 ml, Iron 3 mg, Manganese 0.7 mg, Guaiaicol 0.00035 ml, sodium salicylate 0.135 gm, sodium benzoate 18 mg, sodium iodide 1.8 mg, potassium phosphate 22 mg, sodium hypophosphate 18 mg, malt extract 1.05 mg, and aqueous extract of cherry, eucalyptus, yerba santa, gentian, etc.

Now Creosote and Guiaiaicol are *expectorants* (drugs that increase the output of fluid, facilitate expectoration or promote the discharge of mucus, from the respiratory tract). But, according to 'Drugs of choice, 1978-1979" *there is considerable controversy regarding their efficacy. One experimenter has shown significant expectorant activity in anaesthetised animals*

only when given in toxic doses at certain seasons of the year. Another has shown that sputum 'stickiness' does decrease but only with doses of 300-600 mg four times a day. Therefore the amounts of Guaiaicol and Creosote in Waterbury's Red Label are too microscopic to be effective.

Second Group

CONSIDER now the second group of ingredients 'that tone up your system, restore energy and build up resistance'.

Sodium salicylate is the sodium salt of salicyclic acid, just as aspirin is the acetylated compound of the same. Its uses (Satoskar, Kale, Bhandarkar–Pharmacology and Pharmacotherapeutics Vol I, p.126) are in the oral doses of 0.6 to two gm for muscle-pain, joint-pain, etc and five to 10 gms in acute rheumatic fever. So much so Waterbury's 135 mg per every 15 ml cannot even cure these ailments, leave alone coughs and colds. In fact, one would require about 10 whole bottles (470 ml each) for the first use, and about 100 bottles for the second use.

Sodium benzoate is the sodium salt of benzoic acid, and has been added merely as a preservative.

Sodium iodide is a compound of sodium and iodine. Iodides are used in therapy as expectorants, but the minimum effective dose of sodium iodide for this purpose (Satoskar et al, p.805, Appendix B) is 250 to 500 mg. A little rough calculation again reveals that one would need at least four to five bottles of Waterbury's to make up this dose!

This writer could not trace sodium hypophosphate and potassium phosphate in any of the pharmacoepias he consulted, which leads him to suspect that they have been added as mere 'fillers'.

Malt extract is got from barley and contains a number of sweetening and enzymatic substances, while the aqueous extract of cherry, eucalyptus, yerba santa, gentian, etc are flavouring agents. All these have been possibly thrown in only to impart that characteristic 'sweet' taste to the syrup.

Coming now to the variegated mineral content of the syrup, we must admit that iron, manganese, sodium and potassium *are* minerals we need for normal health. We require at least 10 mg of iron in our diet, of which only one mg is actually absorbed, while the rest is excreted. The daily requirement of manganese is about 350 mg. Sodium comes to us in the form of common salt, which is mainly sodium chloride. To quote Orten Neuhaus ("Human Biochemistry") "The usual daily intake of sodium chloride is about 10-15 gms. This is far greater than what is required (about 4-6 gms daily) but the amount is used chiefly because of its flavour. About 98% is eliminated by way of urine and 2% by faeces. The usual amount of potassium in the diet is 2.4 grams (about 1.5-4.5 is needed daily)"

A deficiency of any of these minerals causes certain disease processes to develop. A deficiency of iron for instance causes anaemia. That of sodium leads to what doctors call 'hyponatremia'. Similarly a potassium deficit is called 'hypokalemia'. Medical science has still to record a single case of pure manganese deficiency.

Now each of these deficiency states produces definite signs and symptoms. Normally all of us get our required quota of minerals from our diets–in fact, we get more than is required most of the time, and the extra is just excreted. Waterbury's minerals will also suffer from this fate. At least, this writer has yet to see Waterbury's Red Label prescribed for iron-deficiency anaemia or hyponatremia or hypokalemia!

Therefore, in concluding this discussion of Waterbury's 'second group of ingredients that tone up your system, restore energy and build resistance', one can only ask, "Resistance?" To What? The cold viruses!?" (Medical science would indeed hail it as a magnificent breakthrough in cold research if the assorted minerals the syrup contains 'built up' resistance to the cold viruses!) and "How?" (for, as we have seen, in a healthy individual getting his required mineral quota from his daily diet, Waterbury's minerals will only be taken in from one end and discarded through the other end of the gastro-intestinal tract!) In the case of a weak person, it may be good for general deficiency. But that is as far as it goes.

All in all, Waterbury's Red Label is a pleasant-tasting mixture. It is largely ineffective as far as its claim–"the best remedy for coughs and colds"–is concerned. It is therefore a pleasant surprise to discover that other syrups on the market, like Glycodin and Vicks Formula 44, at least contain an anti-tussive (cough-depressing) drug in effective doses.

Drops and Lozenges

WE NOW come to the variety of cough drops, lozenges, etc marketed by the cold industry.

Take for instance Vicks 44 cough discs. Each contains–Dextromethorphan 3.65 mg, Ephedrine 3.76 mg, Benzocaine 1 mg, Cetylpyridinium chloride 0.4 mg and Menthol 4.8 mg.

Dextromethorphan is an anti-tussive (cough-depressant) while ephedrine acts as a bronchodilator (widening the bronchial tubes to facilitate 'bringing up' and coughing out the secretions) but their doses for these uses are 15-30 and 15-60 mg respectively (Satoskar et al). Therefore Vicks' 3.65 and 3.76 mg respectively are going to be effective unless you take at least five or six at a time!

Benzocaine is a local anaesthetic, and 'sensitisation' is a dangerous effect of its use in such local medications. After repeated use, an allergy can develop and a fatal swelling of the glottis can occur (a few such cases have been reported).

Cetylpyridinium chloride is what pharmacologists call a 'cationic surfactant'–a drug with detergent, emulsifying, anti-bacterial and anti-fungal effects. But its concentration and contact time in the 'cough drop' formulation have not been proved to be adequate to achieve this purpose.

Menthol is a substance got from plants of the 'Mentha' variety. As Drill's 'Pharmacology in Medicine' puts it, "menthol when applied locally causes a pleasant tingling sensation and a feeling of coolness. These changes which are probably due to the result of an effect on the sensory nerve or nerve endings have led to the use of menthol in a variety of proprietory nose drops, liniments and cigarettes." Menthol too has obviously got nothing to do with the common cold–the cold industry has merely capitalised on its 'soothing' action.

"HALLS", another heavily-advertised product, contains two main constituents–menthol and eucalptus. Menthol has just been considered. Eucalyptus is a substance got from a plant of the Eucalypta variety. It has an aromatic camphoraceous odour and a pungent cooling taste–neither of which is going to help the common cold any.

Much has been made of the 'soothing' effect of this class of product–the fact remains that

all they actually do is increase the flow of saliva, and as "Drugs of choice, 1978-1979" says "Although the use of gargles, lozenges, troches and cough drops is helpful in stimulating the flow of saliva and thus preventing the 'drying out' of the pharyngeal (throat) mucous membranes, *most of the stimuli that give rise to cough originate in the lower respiratory tract, which is not reached by demulcent saliva.*" (emphasis mine) Therefore it can be inferred that these products are not of much use even in the relief of cough (not all cases of cough anyway), leave alone the other symptoms of the common cold.

Mouth Wash

LET US NEXT take a look at 'Listerine', the antiseptic solution, which contains–Menthol 0.04%, thymol 0.06%, eucalyptol 0.09%, methyl salicylate 0.06%, benzoic acid 0.03%, boric acid 2.35% and alcohol 27%.

We have seen what menthol is. Thymol is classified in a group of chemicals called 'miscellaneous phenols' and to quote from Goodman Gillman's "The Pharmacological Basis of Therapeutics" (p 992) "Thymol is both antibacterial and antifungal. It is promoted for the treatment of acne, haemorrhoids and tinea pedis. It is also *present in some mouth washes but in the concentrations used, it is not effective within any practical contact time.*" (emphasis mine)

Have you a cough coming on? Eat sugar candy!

DR U K SHETH, former Professor-Director of the Department of Pharmacology, KEM Hospital and Seth G S Medical College, Bombay was asked his opinion on the plethora of cold remedies sold on the market "Most of them are as good as simple aspirin in adequate dosage. Colds usually take their own time to disappear and the 'remedies' marketed only give symptomatic relief."

As for the shotgun, multi-ingredient cold tablets, Dr Sheth said, "These sell because people believe that aspirin is meant only for headaches, so that if you prescribe it for colds, there is an element of resistance on the part of the patient. There are a lot of misconceptions prevalent–like cold tablets must contain one drug for drying the secretions, one drug for cutting down the duration of colds and so on. Advertising campaigns are partly responsible for these misconceptions.

No multi-drug combination has yet proved effective in controlled trials. Most of them contain aspirin, an anti-histamine, a decongestant and vitamin C. No one has proved that the secretions in colds are histamine-induced, so that anti-histamines can be of no possible use. The decongestant dose is too small to be effective–but if it is increased it can lead to adverse effects like prolonged wakefulness. Vitamin C as advocated by Dr Linus Carl Pauling has to be in doses of 1 gm, and more per day–most tablets contain just 25 to 50 mg."

With respect to ointments, Dr Sheth says "They're a good gimmick. People fall for the warmth, tingling and vapour that the volatile oils contained in them generate when rubbed it–after all, when you take a tablet you don't feel anything! Again no controlled trials have ever been undertaken to prove the efficacy of these ointments."

Finally, coming to cough drops, lozenges, etc, Dr Sheth said, "A bit of Khadi Shakhar–which our mothers used to give us–is as good. The object is to prevent drying of the throat mucous membrances which brings on coughing. This purpose can be served easily by a piece of sugar candy, lemon drops, etc."

How were pharmaceutical companies allowed to make and get away with their grandiose claims? "Well, the fact is that even in the USA it is only now that pharmaceutical companies are being asked to prove each and every claim they make. But here, so long as a combination preparation is not harmful, permission is granted by the authorities."

Asked if he agreed with this writer's belief, that the cold industry was taking the consumer for a ride, Dr. Sheth smiled and said "Yes, of course it is!"

Methyl salicylate, benzoic and boric acid are the constituents that justify the name 'antiseptic'. Alcohol acts as an antiseptic only in concentrations of 70% by weight (Satoskar et al, p. 53, Vol I) so that 'Listerine's 27% of alcohol will only produce a sensation of warmth and increase salivary secretion (This factor no doubt accounts partly for the popularity of 'antiseptics' and 'tonics,' to name but two types of products that cash in on alcohol)

Listerine throat lozenges are also sold on the market, and are thought to be very popular.

I can only close this section on lozenges by quoting Drill's "Pharmacology in Medicine", p 1881," Lozenges and troches are flat, variously shaped medicated candies. Besides the active ingredients which are mostly antiseptics or antibiotics, menthol and local anaesthetics, they contain sugar and mucilage. They are designed to soothe a sore throat or similar oral infection.

GENERIC FORMULATIONS OF SOME COLD REMEDIES (TABLETS)
CONSTITUENTS (IN MILLIGRAMS/TABLETS)

		ASPIRIN	PHENACETIN (may be toxic)	CAFFEINE (dose too small)	DECONGESTANT (not effective)	ANTIHISTAMINE (not effective)	VITAMIN C (dosage too small)	OTHERS	Approx Price (In Paise)
1.	ASPRO	350		20					8
2.	AVEDAN PLUS	350		30				Acetyl amino Phenol - 125	8
3.	ANACIN	389		16.2				Quinine 8.1	7
4.	ANALGIN		90 Brands (Believed unsafe)						
5.	APISTIN	225	150	30		2			6
6.	CODOPYRIN	250	250					Codeine 8	13
7.	CAFIASPRIN	300		30					6
8.	COLITHEN CPA	230	150	30		4			15
9.	CODALGIN	260	260					Atropine 0.3 Phenobarb 20 Codeine 8	17
10.	COLDARIN	600		30	10		50	$CaCo_3$ 200	
								Terpene 30	25
11.	COSAVIL			15		11.25		Phenazone Salicylate 250	14
12.	DISPRIN	Soluble							12
13.	DRISTAN	230	97	16	5	10	20		17
14	DAPRISAL	160	160		5			Amylobarbitone 32	18
15.	HALLS							Menthol, Eucalyptus	12
16.	MICROPYRIN	350		20					7
17.	MICROPYRIN C	350					25		14
18.	CECON 500						100	Sodium Ascorbate 450	
19.	REDOXON (Chewable)						200		12
20.	REDOXON (Tablet)						50		3
21.	VIKORYL	200 (Salicylamide)			5	2		Paracetamol 120	15
22.	VICKS (Action 500)	390 (Salicylamide)	242	32				Sodium Citrate 32 Ephedrine 8	32
23.	VEGANIN	250	250	32				Codeine	24
24.	VERINDON	250	[illegible]	1.5				Phenobarbitone 16	10
25.	ZEET					4			4

They are generally conceded to be of dubious value and the US Pharmacoepia does not contain any such preparation" (emphasis mine). This is the nearest that that august tome comes to debunking this class of products!

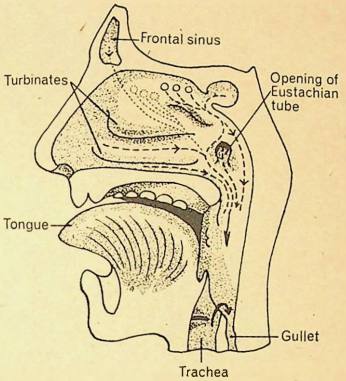
IV—Vitamin C For The Common Cold?

VITAMIN C or ascorbic acid is a chemical commonly found in citrus fruits, green vegetables, tomatoes, etc. It is essential for a number of biochemical reactions at the cellular and subcellular levels in the body. It is needed for the synthesis of a vital protein called collagen, which is responsible for the integrity of blood vessels, bones, cartilage and teeth. Man seems to be the only animal whose liver cannot synthesise ascorbic acid—most other animals can produce it from glucose. In man, deficiency of this vitamin causes a disease called scurvy, characterised by bleeding in the skin and subcutaneous tissues, muscles, joints, gums, etc.

Vitamin C, as a cure for the common cold, first came into the news when a paper by Dr Linus Carl Pauling was published by 'Nutrition Review' in 1967. Dr Pauling's paper, coming as it did from a controversial figure like him, created a sensation in medical circles.

In the late 1960s, Dr Pauling opened the Pandora's box of yet another controversy. Working in close association with two other biochemists, Dr Fred Klenner and Dr Irwin Stone, Dr Pauling became fully convinced of the beneficial effects of large doses of Vitamins ('mega-vitamin therapy') on ailments ranging from cancer to the common cold. Dr Klenner had observed the 'curative' effects of Vitamin C in a number of viral diseases. Dr Irwin Stone too has worked on Vitamin C for the least forty years. Dr Pauling's advocation of large doses of Vitamin C for the common cold was actually based on Dr Stone's work, which he admitted as much in "Vitamin C and the common cold", a book published in December 1970.

Shorn of all controversy, what exactly does Dr Pauling prescribe for the common cold? I can only quote from his book—"Take about one-half level teaspoonful of the powder form of ascorbic acid each day. At the first sign of a cold, take about a gram of ascorbic acid each hour till the symptoms disappear. This usually occurs within a few hours. For a few days thereafter, take a slightly higher doses than normal, since cold symptoms have a tendency to reappear if the dose is dropped to maintenance level all too soon. You must not be disappointed if your physician at first expresses opposition to your use of ascorbic acid."



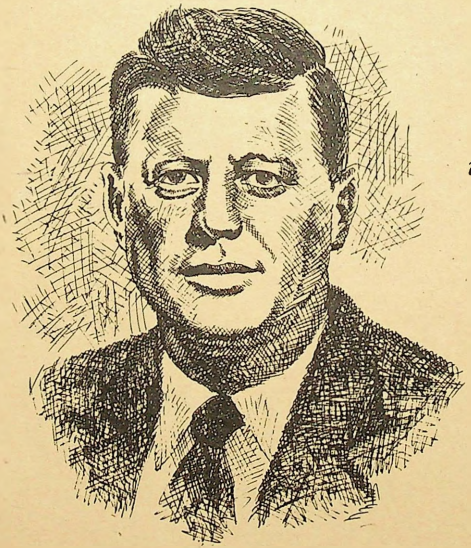
Longitudinal section through a human head showing the direction flow of mucus backwards through the nose, downwards from the sinuses, and up and over-the-top from trachen to oesophagus.

Unfortunately, there is still no conclusive proof, one way or the other, about the exact role of Vitamin C in the treatment of the common cold. No one has yet clearly demonstrated how exactly Vitamin C prevents, aborts or cures colds. Its reported beneficial effects in other diseases like atherosclerosis and cancer have also to be confirmed.

The author would like to acknowledge the following sources, on which certain sections of the 'Uncommon Cold' are based:

1) *"The Common Cold"* By Sir Christopher Andrewes.
2) *"Pharmacology and Pharmacotherapeutics"* Vols I and II By Drs Satoskar, Kale and Bhandarkar
3) *"Drugs Of Choice,* 1978-1979" Ed by Dr Walter Modell
4) Drill's *"Pharmacology In Medicine"*
5) Goodman Gillman's *"The Pharmacological Basis of Therapeutics"*
6) Martindale's *"Extra Pharmacoepia"*
7) *"Current Therapy 1978"*
8) *"The Indian Pharmaceutical Guide, 1978"*
9) Orten and Neuhaus—*"Human Biochemistry"*

THE END



"The discipline of
the world market place
is an excellent measure of efficiency
and a force to stability."

John F. Kennedy 1917-1963

Even the world
is getting to be too small
a market for us
at Teksons, Thana
and at Singapore.

Teksons Ltd. Kolshet Road, Thana.

Leading manufacturers of heat exchanger components and hydraulic flexibles.

everest/78/TL/321

Brief Note on 'Antispasmodics - I (Spasmolytics)

Compiled by
Dr.Sagun Desai

Introduction

In the strict sense, all those drugs which can relax the smooth muscles in the body and thereby abolish the spasm and associated effects should be defined as spasmolytics. A large number of agents can be put in this category. But from the view of clinical application, antimuscarinic drugs like atropine and a scoporamine and their synthetic and semisynthetic derivatives are conventionally called as antispasmodic or spasmolytic drugs. These drugs have actions on the smooth muscles of Gastro-intestinal system, biliary system, genitourinary tract etc, and therefore are widely used in treatment of disorders of these systems. Besides relaxation of smooth muscles of these systems, may also have various other pharmacological actions which can be used therapeutically or are responsible for producing undesirable effects.

We shall briefly consider these agents here.

Atropine and Scopolamine

Both atropine and scopolamine are alkaloids of belladona plants. Atropine is chiefly found in Atropa Belladona and Datura Stramonium. Atropine is also known as hyoscyamine. Scopolamine (hyescine) is chiefly hielded from Hyoscyamus Niger and Scopolia Carniolica. Both these alkaloids competitively block the muscarinic actions of exogenous and endogenous acetylcholine by blocking muscarinic receptors in various organ systems.

Pharmacological actions

a) Gastro Intestinal Tract :

Atropine and scopolamine reduce both the tone and mobility of all parts of the gastro intestinal tract. This has led to their use as antispasmodic agents for gastro intestinal disorders and in the treatment of peptic ulcer. Atropine only partially blocks the effects of vagus nerve stimulation and does not interfere significantly with normal.

b) Other smooth muscles

Atropine decreases the normal tone and amplitude of contractions of the ureter and bladder, and often eliminates drug induced enhancement of ureteral peristalsis. Therapeutic doses tend to reduce the tone of the fundus of the bladder and enhance the tone of the trigenal sphincter and hence, tend to produce urinary retention.

Atropine exerts a mild antispasmodic action on the gall bladder and bile ducts in man. Atropine alone is not effective as a biliary antispasmodic.

Atropine has negligible effects on the human uterus. Scopolamine when used to cause amnesia during labour does not alter or interfere with uterine contractions or increase the duration of labour. Both cross the placental barrier, but the foetus is not adversely affected.

c) Other actions

(1) Belladona alkaloids reduce the secretions of the exocrine glands except production of milk. They reduce salivary secretion causing dryness of mouth. Volume and total acidity of gastric secretions are decreased. All phases of gastric secretions are partially reduced. Pancreatic, bile and intestinal secretions are not significantly affected. They reduce the secretions of nose, mouth, pharynx and bronchi. Following atropine, bronchial secretions become viscoid . Even in small doses, sweat secretion is reduced xxx raising the body temperature.

(2) Atropine produces mydriasis and cycloplegia resulting into blurring of vision, photophobia, diplopia etc. It may precipitate glaucoma in susceptible people.

(3) Conventional doses of atropine produce tachycardia but blood pressure is not changed significantly.

(4) Atropine in routine doses produces insignificant stimulation of CNS but in toxic doses it may produce excitation, restlessness, irritability, hallucinations, delusions convulsions, etc.

In therapeutic doses Scopolamine produces drowsiness, euphoria, amnesia and dreamless sleep. Both Atropine and Scopolamine are effective orally and are rapidly absorbed from the gastro intestinal tract.

Adverse Reactions

Adverse reactions to belladona alkaloids are mainly due to extension of their pharmacological actions. They include dryness of mouth, difficulty in swallowing, fever, constipation, blurring of vision, retention of urine in elderly and palpitation. xxxxx Occasionally they may produce allergic manifestations. Large doses may produce acute poisoning.

Use of Belladona Alkaloids as Antispasmodics

(1) Gastro intestinal colics : Both Atropine and Scopolamine are used to control hypermobility and pain associated with diarrhoea and dysenteries. Drug induced diarrhoea (guanetridine, reserpine) and constipation due to spastic state of intestine (morphine) are relieved by Atropine. Occasionally they may be useful in treating conditions like pyloropspasm, cardiospasm or hypertrophic pyloric stenosis, diverticulitis, etc.

(2) Other smooth muscle colics : Though atropine has a weak relaxant action on smooth muscles of genito - urinary and biliary tracts, it used in combination with morphine/pethidine to relieve ureteric and biliary colics. Occasionally Atropine may be useful in dysmenorrhoea. It is also used to allay the frequency and urgency of accompanying cystitia. It is frequently employed to control nocturnal xxxx eneuresis in children.

Preparations and dosage

1. Tablets of Atropine Sulphate : 0.5 mg tabs.
   Dose 0.25 - 2.00 mg

2. Atropine sulphate Injection : 0.5 mg. in 1 ml
   Dose 0.25 - 2.0 mg by subcutaneous or intramuscular injection

3. Hyoscine (Scopolamine) Injection : 0.4 mg in 1 ml.
   Dose : 0.3 - 0.6 mg. by subcutaneous injection.

Synthetic and Semisynthetic Substitutes for Belladona Alkaloids

Atropine substitutes are developed because of the lack of selectivity in action of belladonna alkaloids. Thus, the dose of Atropine required to produce the therapeutic effects on gastro intestinal tract, invariably produces numerous adverse effects. Therefore, drugs have been synthesized to produce more therapeutic selectivity. Unfortunately, there is no such ideal substitute for Atropine.

The spasmolytic atropine substitutes are mainly used in the treatment of peptic ulcer and colics. The quarternary ammonium compounds are relatively free from the central effects of belladoma alkaloids due to poor crossing of blood-brain-barrier. They are poorly and unreliably absorbed from the gut after oral administration but usually have a somewhat more prolonged action. Because of their ganglion blocking property, over and above actions like Atropine, they produce impotence, urinary retention, postural hypotention and curarimimetic action (neuromuscular blockade) leading to respiratory paralysis.

There are many antispasmodic Atropine substitutes available. Commonly used are :

(1) Atropine Methonitrate : Mainly used in opthalmic practice. But also used orally in the dose of 0.2 - 0.4 mg. orally. 4-6 times daily in the treatment of congenital hypertrophic pyloric stenosis.

(2) Methacopolamine Bromide : Quarternary ammonium compound. No CNS effects of Scopolamine. Used in peptic ulcer, renal colic, frequency of micturition associated with cystitis. Dose 2-5 mg. x 3 times a day orally or 0.25 - 1.0 mg. by injection. Less potent than atropine.

(3) Methantheline : (Banthine) Synthetic quarternary ammonium compound with a high ratio of ganglion blocking to antimuscarinic activity. More potent than atropine and comparatively longer duration of action (6 hrs.) Dose 50-100 mgs orally x 6 hrly or 15-25 mg i.m. inj.

(4) Propantheline (Pro-banthine) : Closely related chemically to methantheline with similar properties but two to five times more potent than it. One of the most widely used antimuscarinic drugs. Used in peptic ulcer, for relieving pain of diverticultitis and in treatment of diarrhoea. Available as 15 mg tabs. Dose 30-45 mg. x 6 hrly orally or 10-20 mg i.m. inj.

(5) Oxyphenonium (Antrenyl) : Quarternary ammonium compound with a high ganglionic blocking action. Dose 10 mg. orally.

(6) Adephedrine Hydrochloride (Trasentine) : Has a weak muscarinic blocking and a prominent direct relaxant effect on smooth muscle, used for spastic colon, biliary colic and dyamenorrhoea. Less potent than atropine. Dose 75-100 mg x 3-4 times a day orally or 50 mg i.m. inj.

(7) Dicyclomine Hydrochloride (Bentyl) : A tertiary amine with antispasmodic action. Decreases spasm of the GIT, billary tract, ureter and uterus, without producing characteristic atropinic effects on the salivery, sweat or gastro intestinal glands, the eye, or the cardiovascular system, except in large doses. It appears to be a direct non-specific relaxant of smooth muscle and not a competitive blocker of acetylchloline.

Thipenamil is similar to dicyclomine and is closely related to local anaesthetics, with local anaesthetic activity. However, clinical use of these drugs has been disappointing.

Other drugs :

(i) Homatropine methylbrumide
(ii) Hyoscine - N - Butylbromide (Buscopan)
(iii) Diphemanil
(iv) Pipenzolate (Piptal)
(v) Poldine
(vi) Clidinium (Quarzan)
(vii) Procyclidine
(viii) Glycopyrronium
(ix) Pavatrine
(x) Isopropamide Iodide
(xi) Emepronium (Cetiprin)
(xii) Flavoxate (Urispas)
(xiii) Oxyphencyclimine
(xiv) Tricyclamol

Many of these drugs in tolerated doses are claimed to be superior to atropine. None, however, can be considered as highly effective in action and clinically a effective doses will evoke some adverse effects.

Certain of the synthetic belladonna substitutes are used much more extensively than are the natural alkaloids in a number of clinical conditions. However there are few situations in which this preference is supported by evidence.

Sources

1. Goodman and Gilman
The Pharmacological Basis of Therapeutics
Sixth Edition 1980

2. Satoskar, Kale and Bhandarkar
Pharmacology and Pharmacotherapeutics
Seventh Edition 1980

3. Dr. R. Laurence
Clinical Pharmacology
Fifth Edition 1980

....

Annexure

Inventory on use of Antispasmodics

LOCOST

Name

Qualifications

Profession

Professional standing (in years)

Address Tel.No.

---

1. How often do you prescribe/use antispasmodics ?
   Quite often / Frequently / Occasionally.

2. For which clinical conditions do you prescribe/use them ?
   (1) (2) (3)
   (4) (5) (6)
   (7) (8) (9)

3. Preparations/formulations commonly prescribed/use by you. (You may use brand names if you wish so). Please write in order of preference.
   (1) (2) (3)
   (4) (5) (6)

4. Route of administration commonly adopted by you :
   Oral / Intramuscular / Intravenous

5. Average duration of treatment with antispasmodics
   _____ days.

6. Reasons for using the drug of first choice:
   (1) (2) (3)
   (4) (5) (6)

7. Commonly encountered adverse reactions/toxicity in your practice while using drug of first choice.
   (1) (2) (3)
   (4) (5) (6)

8. While prescribing/using the antispasmodics do you consider the 'cost factor' ?
   Yes / No / Not relevant.

9. Any other information/comments which you wish to share :

(signature)

THANK YOU

Antispasmodics - III

Inventory on use of Antispasmodics

- Dr.Sagun Desai
- Dr.(Mrs.)Rajul Desai

Introduction

Pharmacologically speaking belladonna alkaloids like atropine and scopolamine are very effective and reasonably safe antispasmodics. However a large number of synthetic and semisynthetic atropine substitutes have been developed with claims of increased safety, less toxicity, more specificity and prolonged duration of action. This has resulted in mushrooming of a large number of marketed antispasmodic preparations, often in combination with analgesics and anxiolytics. Obviously this results in increased cost. Their superiority over atropine and/or spopolamine is not unequivocally proved. Still they are widely prescribed and used by medical profession. The aim of this small study was to find out various aspects of use of antispasmodics by doctors in Baroda City.

Method

A small questionnaire (Annexure) was evolved incorporating various aspects of antispasmodics. This was sent to 70 doctors in various categories, doctors working in general teaching hospitals, charitable hospitals and privately practicing, with an appeal letter to fill it up and send back. The questionnaire was sent 5-7 days in advance. A careful thinking and filling up should not have taken more than 15-20 minutes from the individual. Active personal follow up was done to collect the questionnaire. The results are briefly summarised and discussed.

Results

TABLE 1 : Response of Doctors

Category	No.of doctors to whom questionnaire was sent	No. of doctors who responded	%
Surgeons	15	8	53.33
Physicians	13	6	46.16
Gynaecologists	10	6	60.00
Paediatricians	10	2	20.00
Resident doctors	12	6	50.00
General Practitioners	10	5	50.00
	70	33	47.14

TABLE 2 : Qualifications of respondents

M.S. (Gen. Surgery)	..	7
M.S., M.Ch. (Urology)	..	1
M.D. (Medicine)	..	7
M.D. (Ob. & Gy.)	..	6
M.D. (Paediatrics)	..	2
M.B.B.S.	..	10
		33

TABLE 3 : Professional standing (experience) in yrs.

Yrs.	Nos.	Yrs.	Nos.
0 - 3	4	13 - 15	0
4 - 6	13	16 - 18	1
7 - 9	3	19 - 21	3
10 - 12	5	- 21	3
		Not answered	1

Of the respondents, seven prescribe/use antispasmodics quite often, 18 using frequently and 8 only occasionally. The clinical conditions for which these antispasmodics are used are varied.

TABLE 4 : Frequency distribution of use of antispasmodics in various clinical conditions

Ureteric colic	22	Infantile colic	1 to 3
Intestinal colic	18	Intestinal parasites	-do-
Nonspecific colic	13	Labour	-do-
Dysentery	12	Post MTP cramps	-do-
Biliary colic	9	Pelvic inflammatary disease	-do-
Dysmenorrhoea	8	Salpingitis, post	-do-
Peptic ulcer	5	operative, post-I.U.D.	
Gastritis	4	insertion, Episiotomy Backache, Diffuse Oesophageal spasm	

TABLE 5 : Choice of drugs (Frequency distribution)

Drug	First choice	Alternative
Baralgan	12	14
Belladonna (atropine)	6	4
Buscopan	2	9
Dicyclamine	4	2
Spasmindon	2	10
Spasmoproxyvon) Avafortan, Trigan) Colinol, Stelabid) Colimox, Cydropam)	1 each	varying from 1 to 6
Probanthine	0	7
Antrenyl	0	4
Maxigan) Epidosin)	0	3 each

P.S.

(1) Brand names are mentioned without comments. One can refer to composition of several of above in part II and arrive at own comments.

(2) Several preparations have figured as alternatives only occasionally (one or twice) and are not mentioned.

(3) Curiously 2 doctors mentioned paracetamol and 1 pethidine.

Of the 33 respondents, 32 resort to oral route of administration while using antispasmodics. 11 of them use them intravenously and 10 resort to intramuscular injection.

TABLE 6 : Average duration of treatment with antispasmodics

Days	Respondents	Days	Respondents
1	3	5 - 7	5
1 - 2	4	7 - 10	2
2 - 3	3	10 - 20	1
3 - 4	3	S.O.S.	1
4 - 5	10	Few	2
		varying according to condition	1

TABLE 7 : Reasons for using drug of first choice

1. Efficacy	15	10. Orally effective	1
2. Less side effects	14	11. Only drug	1
3. Cheap	9	12. No combination of drugs	1
4. Easy availability	9	13. Experience	1
5. Reputation of company	4	14. Because of first exposure information	1
6. Additional analgesic + antiemetic action	4	15. Easy to remember brand name	1
7. Absence of sedative	1	16. No specific reason	1
8. Available oral + parenteral route	1	17. Preferred combination	1
9. Specificity	1	18. Quick relief	1

TABLE 8 : Commonly encountered adverse reactions to the drug of first choice

1. No adverse reaction	12
2. Dryness of mouth	7
3. Constipation	5
4. Not replied (? No reaction)	4
5. Retention of urine and gastro-intestinal upsets	3 each
6. Abdominal distension, vomiting allergic reactions	2 each
7. Sedation, leucopenia, decreased appetite, thrombophlebitis perspiration(?), pain in abdomen(?) failure of therapy.	1 each

15 respondents consider the factor of cost before using/ prescribing antispasmodics. 14 think that factor of cost is irrelevant. 2 do not think about cost and 2 have kept mum on the matter. A few interesting comments received have been reproduced :

(1) In suspected inflammatory pathology of abdomen use of intravenous baralgan should be restricted since it decreases guarding and pain making reassessment difficult.

(2) I do not prefer combination of analgin and diazepam with antispasmodics.

(3) The addition of sedative should be deprecated.

(4) Rationale of combinations with dosages be explored.

(5) Antispasmodics are meant only for symptomatic relief and therefore, efforts should continue to arrive at a definite diagnosis

(6) In our experience, isopropamide has highest incidence of constipation and urinary retention and dicyclomine has highest incidence of allergic reactions.

(7) For dysmenorrhoea, antiprostaglandin drugs like aspirin are superior. Reassurance of course is needed every time especially for post MTP cramps.

(8) We need to use cheap and effective drugs.

(9) Antispasmodics should not interfere with bleeding and clothing mechanisms directly or indirectly in obstetrics and gynaecology practice-

(10) Antiapasmodics producing paralytic ileus should not be used in paediacric practice.

(11) High cost of medicines of brand names from well known companies unnecessarily put the burden on poor patients for better treatment. Medicines of other compannies with the same formula cost less. Why there should be vast difference between the cost of same medicines of different companies ?

Discussion

No discussion is offered.

The study is open for your own interpretations, comments, criticism, etc.

...

A N T I - S P A S M O D I C S - II

Compiled by:

Dr. Nayan D. Swadia
MS
(Gen. Surgery)

Sr. No.	Trade Name (Company)	Composition	Available as	Market rate	Rate at Sheth Khushalchand Charitable Medical Centre (S.S.G.Hospital)
1	2	3	4	5	6
1.	Antrenyl (Ciba Gegy)	Tablet Oxyphenomide 5 mg	For 10 tablets	2-40	1-25
		Duplex Oxyphenonium Bromide 10 mg	"	3-90	3-30
		Drops Oxyphenonium bromide 10mg/ml	10 ml. tablets	3-10	N.A.
2.	Avafortan (Khandelwal)	Injection Avapyrazone 24 mg + Metamizol 240 mg	Ampule 3 ml Vial 30 ml	2-85 14-70	N.A. N.A.
		Tablet Avapyrazone 60 mg + Metamizol 210 mg	For 10 tablets	6-00	N.A.
3.	Baralgan (Hoechst	Injection Analgin 500 mg + (a) P-Piperidinoe thoxy - o-Carb-methoxy Benzo-phenone hcl-2mg + (b) diphenyl pipe-riclno-clthy-lacetamidebrom-o-methylate - 0.02 mg	Ampules 2 ml 5 ml Vial - 30 ml	1-40 2-20 13-25	1-30 2-10 12-50
		Tablet Analgin - 500 mg +(a)5 mg(b)0.1 mg	10 tablets	3-90	3-20
4.	Bellaphen (INGA)	Belladona dry extract (containing 0.25 mg) active alkaloids of bello-donal 25 mg + Phenbarb 50 mg.	10 tablets	1-75	N.A.

...2.

1	2	3	4	5	6
5.	Belladenal – IN.(Sandoz)	Tablet Hyoscine -0.0.208mg + Hyosayamine 0.2292" + Phenobarb 50 mg	10 tablets retard	1-45	N.A.
6.	Bral (Micro Labs.)	Same as Baralgan Tablets	10 tablets	3-75	N.A.
7	Duscopan (German Remedies)	Tablets Hyoscine-N butyl bromide 10 mg	10 tablets	5-35	4-90
		Injection Hyoscine N butyl bromide 20 mg	Ampul 1 ml	1-60	N.A.
8.	Buscopan Compositum (German Remedies)	Tablets (a)Hyoscine N butyl bromide 10 mg + (b)Analgin 0.25mg	10 tablets	7-10	N.A.
		Injection in 5 ml (a) = 20 mg + (b) = 2.5mg	Ampule 5 ml	3-90	N.A.
9.	Colimex (Carter Wallace)	Suspension per ml Dicyclomine hcl 10 mg + dimethyl-polysiloxane 40 mg	10 ml. bottle	3-85	3-70
10.	Cyclopam (Indoco)	Dicyclomine hcl 20 mg + Paracetamol 500 mg + Diazepam 2.5 mg.	Tablets 10	2-85	N.A.
11.	Maxigan (Unichem)				
12.	Prydonnal (Eskay lab)	Paracetamol 500 mg + Hyosayamine Sulph 0.22 mg + Scopolamine hydrochloride 0.02 mg + atropine sulph 0.02 mg + Pherobarb 30 mg	Capsule pack of 6	3-90	3-70.

...3.

1	2	3	4	5	6
13.	Pyrispam (Biddle Sawyer)	Capsule Dicyclomine hcl 10 mg + Paracetamol 500 mg + Chlordiagepoxid 5 mg	10 Capsules	7-55	N.A.
		Syrup per 5 ml. Dicyclomine hcl mg + Paracetamol 125 mg	60 ml bottle	7-05	N.A.
14.	Spalcin (Martel Hammer)	Analgin - 500 mg Dihydroethaverine Chloride 40 mg	Tablets	4-90	N.A.
15.	Spasmolysin (Standard)	Analgin 500 mg + atropine methanitrate + 0.32 mg + Paraverine hcl 15 mg + Diazepam 2.5 mg	Tablet 10	3-35	N.A.
16.	Spasmo-Proxyvon (Wockhardt)	Capsules Dicyclomine 10 mg + dextropropoxyphene hcl 65 mg + acetaminophen 400 mg + chlordiazepoxide 5 mg	6 cops.	5-50	5-50
17.	Synalgesix (Geoffery manners)	Papaverine hcl 15 mg + bellandona dry extract 5 mg + analgin 500 mg + phenobarb 25 mg + caffeine 25 mg mag.trisilicate 75 mg	Tablets 10	3-20	N.A.
18.	Trigan	Injection Same as Baralgan	Ampule 2 ml 5 ml		
		Tablet Same as Baralgan	Vial 30 ml x 10 tab.		