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ISSUES IN PHARMACEUTICALS

Pharmaceuticals: Limitations of Left Perspective

WHAT are the issues that arise when we are discussing the relationship between pharmaceuticals and health? There are three types of issues. First, the issue of the general relationship between pharmaceuticals and health. Second the role of pharmaceuticals in capitalism, and especially monopoly capitalism, as well as that in state socialism and revolutionary socialism. Third, the objective and the standpoint of the Left movement in India as regards this issue of pharmaceuticals and health. Let us take a brief overview of the various sub-issues involved in these three aspects of this problem.

Contrary to what the drug industry or the technocratic ideology would like us to believe, drugs have played a marginal role in improving or maintaining the health of the people. In a way this is obvious because it is clear that health-status basically depends upon food, water, sanitation, environment, working-conditions and cultural atmosphere. Moreover, until recently, therapeutic efficacy of medicines was very low. In ayurveda, the ancient Indian approach to health and disease, what is notable, (given the primitive tools of enquiry available in those days and given the dominance of idealist tradition), is its materialist outlook—not much scope for spirits and the like. It is however a controversial issue as to what extent ayurvedic medicines have been effective and safe. That they have been used for hundreds of years does not necessarily mean that they have been effective and safe. In the west things were probably worse. Medical professionals had very few useful medicines to offer to the patients (less than the folk-people had) till as late as late 19th century. Many of the remedies were of the nature of blood-letting, branding and the like or use of corrossives or other drastic and harmful substances as medicines.

The era of safe and effective antimicrobials, anti-biotics, started from 1930s and most of the antibiotics and other 'wonder drugs' came after the second world war as a part of the third industrial revolution and post-war restructuring of the imperialist system and its boom. By this time, however, most of the major infectious diseases in the west had already declined substantially. Now it is well-known in informed circles that modern drugs have thus not played an important role in the improvement of the health-status in the west. It is basically the improvement in the general living standards (food, sanitation, housing, work, education, etc.) which did the job. In the developing capitalist societies, these powerful catalytic agents—the modern pharmaceuticals including most importantly the vaccines—have hardly realised their potential because the socio-economic conditions are inimical. This can be seen from the case of megapolis like Bombay. Here we have drugs and doctors (including specialists) available in every lane, but tuberculosis, leprosy, venereal diseases and even polio show to sign of the respite. China, which is a quite comparable out of the capitalist straight-jacket has shown how modern drugs can be a powerful aide in the rapid control over the scourge of infectious diseases when social conditions are favourable for such a control.

The so-called 'diseases of industrialisation' (which are the diseases of monopoly capitalism and the culture it breeds—cardiovascular diseases, injuries due to accidents, cancers, diseases due to obesity and psychiatric problems—cannot be cured with drugs. On the contrary, the overuse of drugs in such disorders lead to a number of iatrogenic health problems.

It may be argued that the above is a rather simplistic statement. Yes, indeed, it is; it being a brief statement of a standpoint about a historical phenomenon or trend. There are some phenomenon which do not quite fit into this scheme. But that does not alter the overall picture. Secondly, to point out the marginal role of medicines in improving health status of population is not a criticism of modern medicines but of technocratic, self-servicing ideologues who overplay the role of medicines. There is no doubt that modern medicines have a tremendous catalytic potential and even in absence of favourable social conditions, they have made human life more tolerable that what it could otherwise be. But its wrong to attribute more than this to medicines.

The question of the role of non-allopathic medicines is a perplexing one. Homeopathic and allopathic medicines have entirely different presuppositions, are of entirely different nature, both qualitatively and quantitatively; yet both help in different degrees and instances the human body in its recovery from illness. It is a theoretical puzzle as to how this can happen. This discussion cannot, however, be separated from the one about different disciplines of medical care—homeopathy, ayurveda, unani and others. Secondly, this question is also related to the question of the very method of science. Statistical criteria are used to decide the efficacy of medicines in allopathy. How can this be done in homeopathy and ayuveda when their basis is that of individualisation? Is there a way out? Is the very notion of scientific criteria as used in allopathic science open to question? Is there any alternative scientific method? Can there be? There are a long list of such questions which do not seem to lead us anywhere.

One thing is, however, definite. Research into these systems needs to be given more resources—financial and otherwise. At the same time, unless the efficacy and safety of the non-allopathic medicines have been proved through research, by some intelligible criteria proposed by the authorities in these systems, these drugs should not be allowed to be commercially produced.

Capitalism and Pharmaceuticals

Drug technology was one of the branches of technology, which stagnated for quite sometime even after the advent of the industrial revolution in Europe. The knowledge of human body in health and disease and the development of chemistry was too meagre for quite some time. It is only in monopoly capitalism—the advanced stage of capitalism—that enough resources could be pumped into research in these complicated sciences and it is only then that diagnosis and treatment of diseases could flower into a discipline solidly based on modern science. Modern pharmaceuticals is essentially a product of monopoly capitalism. This same monopoly capitalism has, however, at the same time, become an

obstacle in the path of the full and proper use of modern pharmaceuticals. Monopoly drug companies restrict production and jack-up prices to ensure monopoly profits by using methods characteristic of monopoly capitalism, a lot of irrational and even harmful drugs are pushed onto the consumers. In India and other peripheral countries, this occurs in a very crude manner wherein the market abounds in useless, irrational, harmful products which fetch higher rates of profits. This is at the expense of essential drugs which are at least under some price-control. In the rest, this phenomenon takes place in a more subtle form through a technocratic consumerist ideology of 'pill for every ill'.

The full flowering of the science of pharmaco-therapeutics is also adversely affected by monopoly capitalism. A lot of resources are wasted in inventing 'me-too' drugs which have no significant advantage over the existing ones, but which can be marketed as 'new and better' through aggressive monopolistic marketing techniques. Social resources are also wasted in attempts to prove through 'scientific research', really harmful drugs as safe, or useless drugs as very effective.

Monopoly multinational drug companies represent a classic case of how modern imperialism operates. These monopoly MNCs have on the one hand introduced the fruits of the development of modern science of pharmaco-therapeutics into the third world countries. On the other hand, their monopoly, imperialist interests demand that a part of the surplus value created in the drug industry be pumped off to the imperialist centre; that the drug industry in the peripheral countries be dependent on the imperialist centre so that this sector remains one of the channels of more profitable investments and easier markets. The methods employed to achieve this aim are scandalously bad-production and marketing of the most irrational, irrelevant, and even harmful products at rapaciously high prices through blatantly unethical marketing practices; and the suppression of development of indigenous technology by recourse to 'fair' and foul methods characteristic of monopoly capitalism. The results are more disastrous than they are in the west, since the wastage of and suppression of resources means too much pressure on a weak economy and the impact of cheating and exploitation is much more significant for the poor people who constitute the majority in these peripheral capitalist countries. The contrast between the potentiality of using modern science and technology for the betterment of humankind and the reality of a stunted, distorted development is much more poignantly seen in case of the drug industry in the peripheral capitalist countries.

Contraceptives as a group of drugs need a special mention. The invention of the birth-control pill is regarded by many as one of the important milestones in the path of women's liberation. In reality it is only a defence mechanism for women in the world of patriarchal capitalism in which safe, effective male contraceptives are neither developed nor used adequately. Contraception is considered as the woman's responsibility. The availability of the effective pill in a society wherein women are seen as objects of sexual gratification for men has also meant women's bodies being available 'anytime' without the fear of them getting pregnant. This is convenient for patriarchal men since they can achieve the twin benefit of free sex, and small number of children, without any responsibility or botheration of use of contraceptives.

For the women in peripheral countries and of the ethnic minorities in the imperialist centres, hormonal contraceptives are becoming in addition, a burden on their already poor health. Patently unsafe injectable contraceptives and subdermal implements have given the capitalists, patriarchal state a powerful instrument to enforce its programme of population-control in these countries—at the expense of health of the poor women. Pharmaceuticals which are supposed to enhance feminity are another example of the crude sexism practised by the drug industry.

Pharmaceuticals in Socialism

Human beings would of course continue to fall ill under socialism and communism. The pattern of diseases would, however, be quite different from those in undeveloped capitalism or in monopoly capitalism since this pattern is decided primarily by the nature of social production and the set of relations encompassing it. It would be an idle speculation as to what kind of health problems would exist then and which drugs would be used. All that we can say with certainty is that in socialism and communism, there will be less and less of illnesses and hence less and less necessity of use of drugs in diseases.

In 'existing socialisms' alias state socialist societies (USSR, China, etc.) conditions are, of course, quite removed from this ideal. But the use of pharmaceuticals in these countries is not vitiated by the narrow needs of a profit-hungry drug industry and hence is quite rational. But there are some problems. For example, the widespread use of the injectable contraceptive, Net-En in People's Republic of China shows that patriarchal relations are present there to quite a substantial extent. In more developed societies—USSR and countries in the eastern block, the disease pattern is not qualitatively different from that in the capitalist west. This, however, does not mean that drugs are overused and misused like in the west since there is no profit-mongering drug industry in these societies. It would be interesting to study the precise nature of use of pharmaceutical in these societies, whether, and to what extent there is any irrationality in the production and use of drugs and why.

Standpoint of Left Movement in India

The Left parties and groups have criticised foreign drug companies as part of their anti-imperialist standpoint. During last six or seven years a lot of concrete work has been done to demonstrate how specifically MNC drug companies exploit and cheat the Indian people and how they thwart the Indian sector. There are, however, two problems in these criticisms—firstly, most of this work has been done by Left intellectuals as part of their research project or by Left activists, as part of the broader 'democratic' science or health-groups to which we belong. This has put certain limitations on the standpoint that is expressed in these analyses and has even put limitations on the very thinking of Left activists. There is a need to a pause and think about these limitations.

In certain academic institutions, financed by the government, there exists a liberalism among decision-makers and hence it is easier to get a research-project to study the impact of MNCs on the Indian drug industry. This liberalism is in tune with the interests of the Indian state; because such

studies fall within the limited anti-imperialist standpoint of the Indian state. The interests of the Indian bourgeoisie demand that MNCs be pressurised into allowing more and more leeway to Indian capital to exploit the Indian people. Studies focussing on the negative role of MNCs are, therefore, even encouraged by the Indian state. Such studies unearth a lot of valuable anti-imperialist material which can be used by people's movements in their thorough-going, revolutionary anti-imperialist struggle.

But a more or less exclusive focus in these studies on the role of MNCs by omitting a critique of the Indian sector is more helpful to the non-revolutionary anti-imperialist struggle of the Indian bourgeoisie. There is comparatively less concrete research in such studies on the anti-people role of Indian companies—and of the public sector. A critique of the Indian sector does not necessarily mean neglecting the distinction between MNCs, Indian private companies—(monopoly and non-monopoly) and the public sector. But a comprehensive critique is perhaps not encouraged. It is no accident that a majority of these studies directly or indirectly financed by the Indian state omit the Indian sector from their critique.

Popular education and propaganda, based on these studies have an ideological, political role of limiting the critique to only the MNCs. The fact that many Left analysts have a limited, anti-imperialist (understood in a narrow sense) political perspective which excludes an important role of a critique of the Indian sector, also helps to sustain this unnecessarily narrow focus. In terms of demands also, the focus of most of Left analysts is limited to the demand for nationalisation of MNCs. In our strategic demands, we should ask for nationalisation without any compensation and with workers' control/democratisation in the nationalised industry. These strategic demands are for the public education of what is possible in the coming stage of the revolution; and hence the fact that the health movement is too weak today, is no argument including this strategic perspective in our study and propaganda.

Criticisms mounted as part of a health or science or consumer group have an advantage in that such criticisms bring into focus the question of irrational and hazardous drugs; misleading propaganda by the drug companies about the efficacy and safety of their drugs and so on. Here again, misdeeds of Indian companies are generally not mentioned. But the demand for banning of irrational and hazardous products, is such that no concession can be given to the Indian sector whose performance on this score has been no better.

As a part of the 'democratic' health/science/consumer movements, Left activists have participated in bringing forward the medical (sometimes feminist) issues and demands. But many such groups do not take a political stand against even imperialism; leave aside Indian capital even though the concrete demands made by such groups and their implications are many times anti-imperialist, anti-capitalist. But a lack of a clear political anti-imperialist, anti-capitalist stand sometimes becomes a hinderance in the progress of analysis in such groups. Part of this problem is due to the fact that people's movements and hence the political culture in such anti-establishment groups has not advanced enough. But part of the problem is also due to the fact that the perspective of the Left activists working in such groups is limited to a purely anti-imperialist standpoint, (understood in a narrow sense). That is why even among Left-journalist, analyses about the drug industry from a comprehensive standpoint are a rarity; most of the writings being from purely anti-MNC viewpoint.

The editorial perspective in RJH is meant to delineate various issues (in a somewhat comprehensive fashion) germane to the theme chosen for the current number of RJH and to make editorial comments on some of them. In the foregoing, I have merged this two-step operation into a single step by making a summary-statement of a certain viewpoint on the three types of major issues which were thought to be central to the theme of this current issues of RJH. There are, of course, viewpoints different from the one outlined above. It is hoped that there will be further discussion and debate on these issues. Obviously, in this number of RJH it has been possible to cover only some of the issues.

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Impact of Patent System in India on Indigenous Drug Firms

sudip chaudhuri

A demand is often made by certain quarters to modify the Patents Act of 1970 to make its provisions less restrictive for the patentees. This paper examines the experience under the Patent and Designs Act of 1911 to argue that such a change will go against indigenous efforts to develop processes and manufacture drugs.

THE objective of this article is to briefly relate the experience of the indigenous drug firms with the Patents and Designs Act, 1911 in the context of the Patent Act, 1970 which replaced the former in 1972.

The Patent and Designs Act, 1911 did not categorically state what was patentable.[1] The interpretation followed by the Patent Office was that any new process for manufacturing a drug (whether old or new) was patentable. A new drug was also patentable provided the process of manufacture was described in the patent. The process, however, in such a case was not required to be new.[2] Under the Act of 1911, the indigenous firms have been legally prevented from manufacturing most of the new drugs introduced by the transnational corporations, during the life of the patent secured by the latter, i e, for 16 years, which could be extended to a maximum of another 10 years if the working of the patent had not hitherto been sufficiently remunerative to the patentee.[3] This had been possible because, as N R Ayyangar who was appointed by the Government of India to examine the patent law in India observed, the patentee, while patenting a new drug, could describe all the known and possible porcesses.[4] Actually the TNCs did so, as the experience of the indigenous firms suggests.[5] Even an old process, so specified by the TNCs, could not be used by the indigenous firms for at least 16 years. The latter were also forbidden from processing a patented drug into formulations or importing it.

The TNCs asserted their patent rights to proceed legally against firms which tried to manufacture or import the patented drug. Thus, Hindusthan Antibiotics Ltd (HAL), a public sector firm, e g, claimed that it has developed an indigenous process for manufacturing oxytetracyline Hcl. A plant, in fact, was set up and production began in 1961 without any external technical help. In the same year a TNC, viz, Pfizer too started manufacturing the same drug. HAL had to suspend production as Pfizer took legal action alleging infringement of patent rights.[6] A TNC was importing a drug at Rs 8 per 20 tablets. It sued an indigenous firm, CIPLA, when the latter started importing it at Rs 2 per 40 tablets.[7] Chloramphenicol and metronidazole are among the other drugs for which the TNCs took legal action to prevent the indigenous firms from formulating.[8]

The manufacturing activities of the indigenous firms were restricted to the old drugs or those new drugs for which it could develop new processes of manufacture. We will now discuss two cases which will give an idea about how the TNCs could prevent or delay the use of these new processes, developed through indigenous efforts even when these were not specifically covered in the patents of the TNCs.

Haffkine Institute, a public sector firm, worked out a process for manufacturing tolbutamide from locally available raw materials. A patent was also obtained. Unichem Laboratories, an indigenous firm obtained a licence from it and started manufacturing from 1961. Hoechst, a TNC, however filed a suit claiming that tolbutamide had been manufactured by Unichem on the basis of one of the formulas as mentioned in the former's patent granted earlier in 1956. The judgement of the Bombay High Court delivered in 1968 went in favour of Hoechst.[9] What is important to note here is that Hoechst won the case despite the fact that its patent did not specifically mention Haffkine's process. What clinched the issue was that Hoechst's description was open-ended. One of the claims of Hoechst was, in the interpretation of the judge:

> "Wide enough to cover all methods of eliminating sulphur from thioureas (to manufacture Tolbutamide) whether desulphurisation is effected by means of Hydrogen peroxide (as specifically mentioned by Haffkine) or by the use of any other substance[10] (phrases within brackets ours).

Strange as it may appear, such widely worded claims were permissible under the Act of 1911.

The same patent was also sought to be used for preventing Bengal Chemical and Pharmaceutical Works (BCPW), an indigenous firm, from manufacturing another drug, chlorpropamide. BCPW developed a new process for manufacturing it and obtained a patent in 1959. But in 1961, BCPW received a letter from Hoechst, alleging that the former had infringed upon the latter's patent under which Pfizer had been given a licence to produce it. Denying the allegation, BCPW sought legal action when it continued to receive such threats. Hoechst and Pfizer, on their part, filed a suit in 1962 in the Calcutta High Court against BCPW.[11] This time the judgement went in favour of the indigenous firm. The judge concluded that BCPW's patent was an independent one, not in any way influenced by Hoechst's patent which, in fact, did not relate to manufacture of chlorpropamide at all!

The case is quite revealing so far as the development of indigenous technology and the role of patent legislation are concerned. Hoechst's patent did not refer to any specific drug. It was for the broad group of sulphonyl Ureas. Forty examples were given, but it was claimed that other compounds could be obtained easily from the general formula and chlorpropamide was one of them. Hoechst, however, failed to establish in the court that chlorpropamide could be or had been produced on the basis of the process described in their patent. Even an expert witness appearing for Hoechst admitted that the information disclosed in the patent was not enough to carry out the experiment. But Hoechst could not give specific directions as to how to proceed. One of the specifications, in fact, was found to be chemically incorrect.[12] Significantly, out of the 40 examples provided, none referred to chlorpropamide.

One of the objectives behind the patent laws is to induce the inventors to disclose the inventions (in return for the exclusive right of using the invention for a specified period) so that knowledge may be diffused to facilitate further technological progress. The above-mentioned case illustrates

how the TNCs used the Indian patent law existing then to suppress indigenous growth. It is not only that Hoechst's patent contained inadequate and misleading information which prevents and distorts the diffusion of knowledge. The patent was of a general type, supposed to cover a large and unspecified number of products/processes. Thus, other firms could be threatened with legal consequences even when their product was not at all connected with the patent. All the patent disputes are not fought out in a court of law. A mere threat may be enough deterrant in many cases. Significantly enough, in 1968, before the court hearing started, Hoechst approached BCPW to settle the dispute ouside the court, which however the latter refused.[13]

Compulsory licence: An indigenous firm intending to manufacture a drug is required to obtain a licence from the patentee concerned, if the process of manufacture to be used is covered by the patent. Under the Act of 1911, this was the requirement even if the process in question was well known (but even so had been mentioned in the patent as in the case of new drugs discussed above) or additional technical data were necessary to implement the process and these had been developed by, or obtained from, other sources. Obviously, a patentee may grant a licence voluntarily to anyone on mutually acceptable terms. Compulsory licence is a licence granted by the Controller of Patents (or by the patentee as directed by the Controller) or a non-patentee to use a patent on payment of royalties to the patentee. The Act of 1911 provided for the grant of compulsory licence in case of misuse or abuse of patent rights.[14]

The Patents Enquiry Committee reported in 1950 that the foreign patentees did misuse or abuse their rights, e g, by importing the patented product rather than manufacturing it here, fixing the prices at high levels, not allowing others to manufacture the product even when it was not itself engaged in manufacture.[15] But, as the Committee observed, the provisions regarding compulsory licences were "wholly inadequate to prevent misuse or abuse of patent rights, particularly by foreigners".[16] The Panel on Fine Chemicals, Drugs and Pharmaceuticals, appointed by the government also reported earlier in 1946 that not a single compulsory licence could be obtained because of the wording of the relevant provisions.[17] For example, under Section 22, a compulsory licence could be claimed if "the demand for a patented article is not being met to an adequate extent and on reasonable terms". As the Patents Enquiry Committee commented, the Section unnecessarily also demanded that it has to be proved that as a result any trade or industry had been 'unfairly prejudiced'. Obviously, in practice it appeared very difficult to establish such a link.[18]

The provisions regarding compulsory licence (Sections 22 and 23) were amended in 1950, following the recommendations made by the Patents Enquiry Committee in its interim report submitted in 1949.[19] In 1952, an entirely new Section (23 CC) dealing specifically with drugs (and food, insecticide, germicide, fungicide, surgical or curative devices) was added. Under this section, the Controller of Patents was empowered to grant a compulsory licence to any applicant at any time unless there are 'good reasons' for refusing. The foreign patentees, however, were still in a position to effectively prevent or delay the use of compulsory licence.

The Haffkine Institute, e g, applied for a complusory licence, but the foreign patentee offered to give the licence voluntarily on the basis of royalties to be fixed through negotiations. They demanded an absurdly high rate of royalty of 25 per cent. It took more than four years to reduce it to 10 per cent, which however was still higher than the limit of 5 per cent stipulated by the Reserve Bank of India. By that time the Haffkine Institute decided to abandon the scheme.[21] Again, another indigenous firm Neo Pharma Industries entered into a technical collaboration agreement with an Italian firm for the technology to manufacture chloramphenicol.

A licence was sought from Parke Davis, which held the relevant patent in India. But whereas the subsidiary company in India pointed out that the matter was beyond its jurisdiction, the parent company in the USA insisted that Neo Pharma should first discuss with the local company. It took more than two years to decide as to who would negotiate. At last when the negotiations started with the parent company, they did not formally refuse to grant a licence but simply sat over the proposal. Finally, when a compulsory licence was sought for and was granted, Parke Davis went to the court and obtained a stay order.[22]

In fact, going to the court is a simple device the foreign patentees could employ. Even if ultimately the judgement goes against the patentee, the applicant would normally be prevented from using the compulsory licence during the period of the court case. The longer the time taken to settle a case, the smaller will be the relative benefit to the applicant for compulsory licence, because in any case after the expiry of the patent (normally 16 years) anybody was free to use the patent. The hazards of obtaining a compulsory licence, which include legal battles, perhaps explain why so few applications for compulsory licence were made under Section 23 CC. Till 1972, i e, when a new Act came into force, there were only five applications for compulsory licence, made by Hindustan Antibiotics Ltd (in 1959), Alembic Chemical Works (1963), Dey's Medical Stores (Manufacturing) (1960), Raptakos Brett and Co (1957) and Neo Pharma Industries (1961).[23] The applications were ultimately withdrawn in the first two cases. Compulsory licence was refused by the Controller of Patents in the third case.[24] The controller granted compulsory licences in the last two cases.

Patent System under Act of 1970

An important feature of the new Act, 1970[25] is the special provisions regarding drugs and a few other products. The life of the drug (and food) patents has been reduced from at least 16 years in the previous Act to five years from the date of sealing,[26] or seven years from the date of filing of complete specifications, whichever is shorter (sections 45 and 53), i e, for a maximum period of seven years. For other patents, the duration is 14 years. The new Act categorically states that drugs (and food and those manufactured by chemical processes) can now be patented only for a new method or process of manufacture, not for the products as such (section 5). Hence in contrast to the previous situation, the indigenous firms can manufacture new drugs by old processes without violating the Act. Obviously, as before it can continue to manufacture old drugs. Even in cases where new drugs cannot be manufactured by known processes, and so a new process is required, the indigenous firms are expected

to face less restrictions in developing such new processes. This is because the firm discovering/inventing a drug can no longer patent all the processes known to it even if these are new. For a particular drug, only one method or process—the best known to the applicant—can be patented (Sections 5 and 10).[27]

Under Section 87 of the Patents Act, 1970, every patent relating to processes for manufacturing drugs (or food or chemical substances) has to be endorsed with the words "Licences of right" after three years of the date of sealing. This implies that anyone is automatically entitled to a licence from the patentee for using the patent on payment of royalties, the maximum rate being fixed at four per cent of the ex-factory sales (Section 88). Even before expiry of three years from the date of sealing, the controller is empowered to grant a compulsory licence (and fix the rate of royalties) if "it is necessary or expedient in the public interest" (Section 97). There is also a special provision in the Act of 1970 regarding the use of patents by the government. Any time, a patent may be used for official purposes, including those of public undertakings. The maximum royalty payable for such a use, in case of drugs (and food) has been fixed at 4 per cent of the ex-factory sales (Sections 99 and 100).

It must be pointed out, however, that the actual use of a patent by a non-patentee still remains hazardous. For example, under Section 87, as mentioned above, while the right to obtain a licence automatically accrues after three years from the date of sealing of a patent, it cannot actually be used till the royalties are fixed either mutually or at the intervention of the controller. As before, the patentees can continue to prevent or delay the use of their patents by others by refusing to negotiate and then proceeding to the court in case of any intervening action by the controller. This has, in fact, happened in the case of each of the applications made to the controller till now by three firms for fixation of royalties. Incidentally, all these cases relate to products other than drugs. In the case of the application made in March 1976 by Catalyst and Chemical India (West Asia), the controller fixed the rate of royalty tentatively as per Section 88(4). The patentee (ICI), however, went to the court and by the time the case came up for final hearing (July 1977) the patent was about to expire (in August 1977). In the remaining two cases, as the patentees approached the court, interim injunction was granted and the Patent Office was directed not to proceed with the applications of Titanium Equipment and Anode Manufacturing Co and Coromandel Indag Products made in September 1980 and July 1981 respectively. The two patents in which Titanium was interested expired in February 1983 while the court case was still pending. Regarding Coromandel, too, while the case is yet to be settled, one of the patents has already expired in March 1982, while the other is due to expire in February 1986.[28]

Despite such hazards, the Patents Act, 1970 appears, on the whole, to be an improvement from the point of view of the development of indigenous science and technology, compared to the previous situation. A demand is often made by certain quarters to modify the present Act and make the provisions less restrictive for the patentees. If the experience under the Act of 1911 is any guide, then such a change will go against the indigenous efforts to develop processes and manufacturing drugs.

Notes

[This paper was written in 1984 and hence does not contain any references to later events.]

1. *Report of the Patents Enquiry Committee (1948-50)* (Delhi, GOI, Ministry of Industry and Supply, 1950), p 64; N Rajagopala Ayyangar, *Report on the Revision of the Patents Law* (Delhi, GOI, 1959), p 20.
2. Ayyangar, *Report*, pp 20, 34, 36.
3. See Section 14 and 15, "The Indian Patent and Designs Act 1911", reproduced in *Patent Office Hand Book* (Delhi, GOI, 13th ed, 1966).
4. Ayyangar, *Report*, pp 34, 36.
5. See the evidence of K A Hamied of Chemical, Industrial and Pharmaceutical Laboratories (CIPLA), *Joint Committee on the Patents Bill, 1965: Evidence* (New Delhi, Lok Sabha Secretariat, 1966), Vol 1, p 154 and of S G Somani of All India Manufacturers Association, *Joint Committee on the Patents Bill, 1967: Evidence* (New Delhi, Lok Sabha Secretariat, 1969), Vol 1, p 294.
6. *HAL, Annual Report, 1961.*
7. Evidence of K A Hamied of CIPLA, *Joint Committee on the Patents Bill, 1965: Evidence,* Vol I, pp 149-50.
8. *Report of the Committee on Drugs and Pharmaceutical Indu* (Hathi Committee) (New Delhi, GOI, Ministry of Petroleum Chemicals, 1975), p 92.
9. For the text of the judgement, which also provides the background of the case, see, *The All India Reporter* (Nagpur, AIR Ltd, 1969), Bombay Section, Vol 56, pp 258-73.
10. Ibid p 264.
11. Information on this Patent case has been obtained from the judgement of the Calcutta High Court (Suit No 1124 of 1962); the plaint; the written Statement submitted by BCPW (all available at the Calcutta High Court) and the BCPW Assistant Secretary's Note placed at the BCPW Board of Directors meeting held on 27 July, 1970.
12. Hoechst's patent mentions alkalation with primary amides which is chemically impossible. See Ibid.
13. Minutes of the meeting of the directors of BCPW, Calcutta, 5 December, 1968.
14. *Report of the Patents Enquiry Committee (1948-50)*, p 71.
15. Ibid, p 162.
16. Ibid, p 172.
17. *Report of the Panel on Fine Chemicals, Drugs and Pharmaceuticals* (New Delhi, GOI, Department of Industries and Supplies, 1947), p 15.
18. *Report of the Patents Enquiry Committee (1948-50)*, p 168.
19. Ayyangar, *Report*, p 1.
20. *Patent Office Hand Book*, p 32.
21. Evidence of C V Deliwala of the Haffkine Institute, *Joint Committee on the Patents Bill, 1967: Evidence*, Vol I, pp 451-52.
22. Evidence of N L I Mathias and A C Mitra of Neo Pharma Industries, *Joint Committee on the Patents Bill, 1965: Evidence*, Vol II, pp 487-88, 493-94.
23. Information obtained from the Patent Office, Calcutta. Apparently, the application by the Haffkine Institute, referred to earlier in the text, was made before Section 23 CC was added in 1952.
24. According to Rule 32B (inserted in 1953) of the Indian Patent and Design Rules, 1933, the Controller shall refuse the application, if "the Controller is not satisfied that a *prima facie* case has been made out for the making of an Order" (*Patent Office Hand Book*, pp 71-72).
25. For the provisions, see *The Patents Act, 1970* (New Delhi, GOI, Ministry of Law, Justice and Company Affairs, 1973).
26. A patent is sealed after it is granted.
27. For a discussion of the important provisions regarding drugs in the Act of 1970 vis-a-vis the Act of 1911, see S K Borkar, "Patent Act, 1970 and Its Effect on Drug Industry in the Country", in *Annual Publication* (Bombay, Indian Drug Manufacturers Association, 1974).
28. "Applications Filed for Licences of Right under Section 88(2) and 88(4) of the Patents Act, 1970", in *Journal of Patent Office Technical Society*, Vol 16, 1982, pp 80-81.

High Dose EP Drugs—I

Responsibility of Industry, Doctors and Government

amitava guha

The proliferation of irrational and dangerous drugs in India has generated a well-informed and dynamic drug consumer's movement. Of the several issues that it has taken up the issue of banning high dose oestrogen progesterone drugs illustrates best its capability. On the other hand, the issue has also revealed inefficiency of the drug control authorities, their inability to implement the rules in the book designed to protect the consumer.

This inefficiency on the part of government institutions is compounded by their close collusion with the drug inaustry. The medical profession has also played a crucial role in opposing the ban of these drugs. The article highlights the unethical practices and actions of the different sections who have been involved in pressing for the continued marketing of high dose EP drugs.

IN 1982, the Indian Council of Medical Research recommended:

> "Fixed dose combination of oestrogens and progesterone may be totally banned in the country, even for the treatment of secondary amenorrhoea as other substitute are available in the market for management of secondary amenorrhoea"

Based on this recommendation, the ministry of health and family welfare banned HDEP in June 1982. Today five and half years after, the drug is freely available in India! The industry, medical profession, courts of law even the government departments played their role in undoing the govt's ban order.

For the first time in India the question of banning of a drug is being discussed and debated; consequently it has exposed the low level of ethics followed by the people involved in the medico-technical establishment.

It must be pointed out that the issue of harmful effect of a drug and therefore, its banning had never been raised by the medical profession. Even the issue of harmful effect of 'thalidomide' was taken up by the journalists and the ripple created in the so-called 'lay press' raised a wave which not only washed away any effort to defend the crime made by Gruanthal (its manufacturer) but exposed the menace of the industry in collusion with certain famous opinion maker medical personnels. In India similarly nothing is being said or no action had been taken by the famous doctors or opinion makers against the horde of drugs banned in developed countries but freely and legally available in India. It is again the 'lay press' *Onlooker* which raised the issue through the write up—"Pregnancy Test Drugs can Detorm Babies—Ban them". The issue, thereafter was widely taken up by the press and excepting one or two write ups till date none of them had spoken against the ban of HDPE.

Role of Industry

Harmful effect of the drug on pregnant women was detected as back as 1967 for. Pioneering task in this area had been taken by Dr. Isabel Gal. She writes:

> "The unfavourable effect of synthetic sex hormones on animal reproduction was known long before the introduction of HPT products in 1958. Despite this the manufacturers recommended HPT products as a safe and reliable method of pregnancy diagnosis and gave assurance that it does not interfere with the physiological course of pregnancy"

Following the reports of adverse drug reaction with HDEP, Rousel in 1970, Schering in 1971 and Organon in 1970 did not refer to use of the drug for pregnancy test in UK. The government of India issued order that this drug should not be used for pregnancy testing and the order be printed on the labels of the drugs marketed. The drug was established in India as an abortificient. It was promoted widely for inducing abortion. Even after the said order issued by the government, the companies promoted the drug through marketing staff as an abortificient.

Immediately after the ban order was issed, Organon India Ltd., (now Infar) placed a writ petition in Calcutta High Court and was interested to see that the writ was not contested by the Drug Controller of India during its hearing. It happened exactly as desired by the company and the case was heard and injunction was passed exparte against the ban order. It is interesting to note that neither M/s. Organon nor M/s. Unichem and M/s. Nicholas contested the finding of ICMR on the potential hazard of the drug but simply challenged that the ban order was not issued in accordance with the provisions of law. It was submitted that Sec. 18 of Drugs and Cosmetics Act allows the state govts only to ban a drug after issuing official Gazette Notification. That too the Act only provides banning of misbranded, sub-standard or adulterated drugs. This was an eye opener for the legislators, who after much shouting from the consumers and by some Members of the Parliament amended the law later giving the same power to the Central Govt also. Even now the question remains that HDPE or any harmful drug, if banned, should be done according to which law?

The industry did a lot to utilise medical profession in their favour. In the submission to the Supreme Court and high courts, the company placed letters written by a number of general practitioners and gynaecologists stating that HDEP should not be banned. In reality this was again done with the help of the marketing staff who went to the doctors with the draft of such letters and requested them to write according to the draft, a letter on their own letterheads. Therefore, it was found that the letters are not only the matically similar but, so is the language and text of the letters. In some cases the marketing staff of the companies wrote the letters on the doctor's letter pad and asked the doctors to sign them. The text of these letters more or less read:

> "I support the order of the government in banning the use of high dose E. P. Drugs in pregnancy testing.
>
> The drug is highly needed for treating secondary amenorrhoea, dysfunctional uterine bleeding, endometriosis and dysmenorrhoea. I have used this drug for a long time and never seen any adverse effect. I recommend that this drug should not be banned".

The industry made another attempt to mislead the courts on the information regarding the status of the drugs in different countries. Organon (I) Ltd stated that

> "It's not a fact that many countries have banned these preparations. These preparations are available in countries like UK, West Germany, France, most of the Western European countries and many South West Asian and African countries" (Infar, 1987).

One can easily find out how far this is a fact. Table 1 will clarify the position (UN List, 1986).

Infar (I) Ltd had no reply when asked at the public hearing why HDEP was not allowed to be marketed in their

parent country, Netherlands. Similarly, the company could not say why the drug was not allowed to be introduced in many other developed countries. The company's honesty was again questioned when Hermann Schulte-Sasse of the Institute for Clinical Pharmacology, Hamburg confirmed that.

"Two German pharmaceuticals marketed such drugs in Germany but withdrew them at the end of 1979".

Was the company confident that Indian consumers did not have any access to information from 'civilised European countries'? In fact Dr N N Roy Chowdhury, the president of Federation of Obstetrics and Gynaecological Societies of India (FOGSI) wrote to DCI to the same tune of Infar Co that the drug was available in most of the developed countries. He had also submitted a list although he did not care to mention any reference. From this list it appears that 'Shering' (he does not know that the real name of the company is Schering Aktiengesellschaft) market HDEP in West Germany, UK, Turkey, Japan, Argentina, Mexico, Belgium, Denmark, Australia. The drug is not enlisted in the 'Red List' (Rote Liste) 1984, 1985, 1986, 1987, a list of drugs approved by the government of FRG. Corroborative statement from Schering issued by Dr H Richter informs that only one brand of HDEP was marketed by them in third world countries that two had been withdrawn from October, 1986.

In the absence of any system of dissemination of unbiased information to the medical profession, the industry takes the fullest advantage to misinform the profession to mislead them with the help of their own tailored and distorted facts. As regards high dose EP drugs, the industry had taken the fullest advantage of this situation. The Voluntary Code of Marketing Practices adopted by International Federation of Pharmaceutical Manufacturers Association (IFPMA) suggests that

"Scientific and technical information shall fully disclose the properties of pharmaceutical products as approved in the country in question based on current scientific information...

"Information on Pharmaceutical Products should be accurate, fair and objective, and presented in such a way as to confirm not only to legal requirements but also to ethical standards and standard of good taste." (IFPMA)

Classical example can be sited from the promotional literatures of Infar(I) Ltd as to how they have violated all such codes of ethics. Even the Guidelines of Introduction of New Drugs by Government of India say that "the product monograph should comprise the full prescribing information necessary to enable a physician to use the drug properly. It should include description, actions, indications, dosage, precautions, warnings, and adverse reactions."

A product monograph of Orgalutin, a high dose of EP used to promote the drug to the doctors is captioned as—'A Woman's Strength Is a Woman's Weakness'.

On page three of the monograph to emphasise that the drug is 'safe for the patients' the following lines are mentioned quoting a write up of two doctors Dr Choudhury and Dr Mitra that with the use of the drug there was—

"No alteration in blood pressure.
No alteration in blood-sugar level.
No hepato-toxic effect observed".

The said monograph had given indications of composition and dosage only but nothing was mentioned about precautions, warnings and adverse reactions.

If the warnings and precautions circulated by the company a few years back are consulted, one can find the following facts in the Therapeutic Index of the company and judge how safe the product could be,

"Since such preparations may cause an increase in blood pressure in predisposed women, this should be checked regularly. In case of serious hypertension the use of the preparation should be stopped immediately."

"Since the glucose tolerance may diminish during the use of oestrogen/progestogen preparation, diabetic patients should be kept under strict control."

"Hepatic adenomas have been reported in women on oestrogen-progestogen combinations."

This gives us an opportunity to question the standard of ethics maintained by the company and of the two doctors who had shamelessly concealed the facts.

It is also interesting to note that the manufacturers of HDEP were really frightened of the ban order issued by the governments. In the Therapeutic Index printed by Infar(I) Ltd at the time the ban order was issued, the company deleted all HDEP drugs namely, Menstrogen, Menstrogen Forte and Orgalutin. But their effort to promote the drug in the market remained unhindered. The company has never forgotten to mention these drugs in their price list!

Role of Statutes

Important statute applicable to import, manufacturing, etc of any drug is the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945. This is not only ancient but highly inadequate also. Although it is a central statute but it has given authority to the State Drug Controllers for approval of a drug for registration and sale. Because of such inadequacy of law, the Central Drug Standard Control Organisation has prepared 'Guidelines on Introduction of New Drugs'. We shall see how even the scanty restrictions under the said Acts and Guidelines have been violated by the industry.

Organon (India) Ltd, now Infar (India) Ltd had introduced the HDEP about 20 years before. Earlier, these hormones had been marketed separately as single ingredients or in combination as oral contraceptives. The drug was imported and the definition of a 'New Drug' under Rule 30A of the Drugs and Cosmetics Rules (DCR) says:

"The importer of a new drug when applying for permission shall produce before the licensiong authority all documentary and other evidences, relating to its standards of quality, purity and strength and such other information as may be required by the licensing authority including the results of therapeutic trials carried out with it." (Drugs and Cosmetics Rules)

At the time of introduction of the drug it could be defined as a Fixed Dose Combination (FDC) of the third group according to the Guidelines on Introduction of New Drugs. This Guideline requires:

"(c) the third group of FDC includes those which are already marketed, but in which it is proposed either to change the ratio of active ingredients or to make a new therapeutic claim.
For such FDC, the appropriate rationale should be submitted to obtain a permission for clinical trials and reports of trial should be

Table 1: Status of EP Drugs Worldwide

Countries	Status	Year
1. Norway	Withdrawn	1970
2. Sweden	Banned	1970
3. Finland	Banned	1971
4. Federal Republic of Germany	Withdrawn	1979
5. USA	Banned	1975
6. UK	Withdrawn	1977
7. Australia	Withdrawn	1978
8. Austria	Withdrawn	1978
9. Belgium	Withdrawn	1978
10. Italy	Withdrawn	1978
11. Greece	Withdrawn	1980
12. New Zealand	Withdrawn	
13. Denmark	Banned	1974
14. Bangladesh	Banned	1982
15. Venezuela	Banned	1975

submitted to obtain marketing permission."

The clinical trials required to be carried out in India before a new FDC is approved for marketing depend on the status of the drug in other countries. If the drug is approved/marketed, phase III trial is usually required to be conducted in India. If it is not approved/marketed, trials are generally allowed to be initiated at one phase earlier to the phase of trials made in other countries.

On going through the records one can easily find out that the company never obtained any permission to initiate clinical trials in India as required by Drugs & Cosmetics Rules (through form 11 and form 12) for a test licence. No protocols for any trials were ever submitted by the company—this is required according to the Guidelines for Introduction of New Drugs. No case report forms were ever submitted.

As required in the Appendix III of the said guidelines the following reports on the studies are to be submitted by the company. (1) Human/clinical pharmacology (2) Exploratory Trials. (3) Confirmatory Trials. This was never done. Neither the company nor the Director of Drugs Control, Government of West Bengal, who allowed the company to sell the drugs in India can produce the following records relating to trials supposed to have been conducted by the company and approved by the government authority.

Title of the Trial
Name of Investigator and Institution
Objective of Tribals
Design of Study: open, single-blind, or double blind, non-comparative or comparative, parallel group or cross over.
Number of patients, with criteria for selection and exclusion, whether written informed consent was taken.
Treatments given: drugs and dosage forms, dosage regiments method of allocation of patients to the treatment;
Observations made before, during, and at the end of treatment, for efficacy and safety, with methods used.
Results: exclusions and dropouts, if any, with reasons, description of patients, with initial comparability of groups where appropriate, clinical and laboratory observations on efficacy and safety, adverse drug reactions.
Discussion of results: relevance to objectives, correlation with other report/data, if any guideance for further study if necessary.
Summary and conclusions.

In order to maintain a minimum standard of ethics, trials should be conducted with any drugs prior to their introduction in the country. For the purpos, 'licence for examination, test or analysis' has to be procured under Rule 21(c) which was never done by Infar in this case. While applying for manufacture of 'New Drugs' as per Rule 75-B of the DCR one needs to supply "informations as may be required including the results of therapeutic trials carried out with it" (sub sec ii). This was never done either by the manufacturers of HDEP.

It is striking to note that a controversial drug was introduced in our country at the time when enough controversy was raised elsewhere. The manufacturers never cared to conduct any trials in India. They were not only given licence to manufacture such a drug but it was periodically renewed by the drug control authority.

The guidelines for the introduction of new drugs per sec 9.2 under the title 'Regulatory status in other countries' state. "It is important to state if any restriction have been placed on the use of the drug in any other country, e g, dosage limits, exclusion of certain age groups, warning about adverse drug reaction".

This was not done at any time—either at the time of introduction of the drug nor any time thereafter by Infar. On the contrary, as discussed before, the manufacturers have attempted to misguide authorities with false information that the drug is in use in many developed countries.

The guidelines also require (sec 9.3) a 'Free sale Certificate from the Country of Origin'. It would be almost impossible for Infar to submit such a 'free sale certificate' as it was never allowed to be manufactured and marketed in Netherlands, their country of origin.

Not only question of ethics but the failure of the regulatory authorities and the lacuna in the laws are exposed when we consider that the manufacturers have not cared to submit to the minimum requirements of law and the government guidelines and have developed a large market of Rs 6.18 crore yearly.

Role of Doctors and Professional Bodies

A famous gyaenocologist C S Dawn has written in his widely used text book.

Secondary amenorrhoea has had spontaneous cure rate in more than 50% cases where any treatment becomes empirical. New therapies of pituitary gonadotropin, clomiphene and bromocryptine showed promising results in the treatment of selected cases where these are indicated. Longer the secondary amaneorrhoea persists poorer becomes the prognosis.

He, as a professor, never vouched for the use of HDEP in secondary amenorrhoea in the classrooms and thus hid his other face. For, as a member of the Federation of Obstetrics and Gynaecological Societies of India (FOGSI) he says exactly the opposite. He attended the public hearings held at Madras, Delhi and Calcutta just to say that as an eminent teacher and famous gynaecologist he had never seen any adverse reaction with HDEP, and the drug was very much needed for treating secondary ameneorrhoea.

His notoriety had not stopped here. After the Delhi public hearing, he had submitted a study report on May 10, 1987 of a purported trial as a chairman of the family welfare committee of FOGSI. The report was titled as 'Use of Common Drugs in Pregnancy—Indian Experience'. It is only two-page monograph but the dimension of the study is enormous as the first paragraph of this report says:

"An all-India multicentric study was conducted during 1982 and 1983 by the Food, Drugs and Medicosurgical Committee of FOGSI by the author as the chairman of the committee. Fourteen teaching and rural centres participated in this study. Statistically controlled protocol was prepared in consultations with Department of Hygiene and Public Health, Calcutta. The protocol covers 78 factors".

No further methodology and materials used in the study was mentioned. The result was:

"There were 245 congenitally malformed newborns in this study. The incidence of congenitally malformed newborns at various centres varied from 2 to 10 per 1000 births".

The report never mentioned directly as to *how many pregnant women were covered in the study*. If the average incidence of malformation of newborn babies are considered, according to the study, say five per 1000 and a total number of malformed newborn babies reportedly were 245 then we arrive at the fact that in order to get such result, the trial covered 49,000 pregnant women. That such a phenomenally high number of patients were covered in only one year from "14 teaching and rural centres" is noteworthy as this type of trial is impossible even in developed countries.

In the Calcutta public hearing Dr. Dawn was asked that in order to prove that his trial was not fake, he should submit papers relating to the ten protocols as required by the government. Dawn is yet to prove that it is not fake. Obviously the sole objective of producing such a report, which has never been published in any professional journal was to prove that no congenital malformation could be found with the use of hormonal drugs during pregnancy. When the government had banned the use of HDEP during pregnancy and the manufacturers have accepted it, the eminent doctors like Dawn, C L Jhaveri, P K Khan, Sharma are all rejecting it.

Dr. Sharma of Delhi and Khan of Calcutta had without any hesitation said at the public hearings that they would continue to use HDEP for pregnancy testing. We are yet to see the Medical Council of India react to such violations by cancelling the registration of these doctors.

Dr. Jhaveri of Bombay, seniormost and famous gyaenocologist and many times president of FOGSI went even further that estoprogin (HDEP) drug came as a blessing. It had helped—in the second world war women who had been assaulted by the soldiers had used HDEP drugs to abort unwanted feluses! He stated in the Delhi and Bombay hearings that in his 40 years' of gynaecological practice he had used the drugs *for inducing abortion* and had not found a single case of malformation of babies. His statements were recorded by the Drug Controller of India during the public hearings.

One may conclude that Jhaveri had committed punishable offences in two cases. First, he had practiced MTP when it was not legalised. Second, that he had violated the government order in using the drug on pregnant women. We are yet to see that DCI take any action against Jhaveri. This octugenarian doctor was so loyal to the arguments put by the industry that he rushed to the dias at the Bombay hearing to assault one speaker who was dissecting a point of law placed by the industry.

A good number of famous gynaecologists have attend almost all the public hearings leaving their generally over crowded chambers and have said the same things repeatedly. They had not cared to place any pharmacological and clinical evidence in support of their statement that the drug is safe and necessary.

In the Delhi and Calcutta hearing N N Roy Chowdhury, president of FOGSI stated that the Federation had unanimously adopted a resolution that the government should not ban HDEP as they were safe and needed to treat secondary amenorrhoea, dysfunctional uterine bleeding, endometriosis, menopausal symptoms, etc. and there was no substitute for this drug. This statement was challenged by a professor of gynaecology at Calcutta who as a member of FOGSI wanted to know where and when such 'unanimous' resolution was taken. He also produced a statement by Dr J Mitra, Honorary Joint Secretary of FOGSI which states

> "I am of opinion that high dose combination of oestrogen-progesterone should not be used during pregnancy.
>
> I also feel that it is not essential to use this high dose combination for treating gynaecological condition like dysfunctional uterine bleeding, menopausal syndrome, etc. These combinations should not be used indiscriminately as there are potential hazards."

Roy Chowdhury could not provide any proof to substantiate his statement which was openly challenged.

Another instance of violation of minimum standards of ethics can be cited with reference to the activities of P K Banerjee, Honorary Treasurer of the Indian Medical Association. There are complaints by his professional colleagues that he is an obedient supporter of Infar (India) and defended the company's interest in using anabolic sterioid for promoting growth in children. Banerjee wrote a letter to DCI dated April 6, 1987 in the capacity of honorary treasurer, IMA stating that the drug is much needed and harmless. On inquiry, it was found that he had misused the good name of the IMA. As the President of IMA stated that

> I would like to mention that the letter issued by Dr Banerjee is his own view and he is not authorised to communicate the views of IMA. It is unfortunate that he has used IMA stationary for expressing his personal views".

It is necessary to mention here the role of the two doctors who were involved with banning the drug—P Das Gupta, Deputy Drug Controller and P K Dutta of World Health Organisation. The Deputy DCI had no scruples about favouring the industry openly. He tried to dilute the issue.

The Supreme Court had clearly asked the DCI to conduct public hearings on banning of high dose combinations of E P drugs. The Deputy DCI, at the Calcutta hearing, attempted quite something else. He stated that the question of banning HDEP should not be taken as an ego fight. Although the Drugs Controller's office had once banned it, it did not mean that they should stick to such decision for- ever. He also appealed to the gynaecologists that they should come forward and suggest a 'cut off' dose for estrogen-progestogen combinations. He wanted to confuse the issue on the question of high dose and low dose EP. He wrote letters without the knowledge of DCI to FOGSI and Indian Associations of Fertility and Sterility asking them to give their views on a questionnaire on estrogen progestogen combinations, dated March 23, 1987. He carefully dropped words 'high dose' in the questionnaire. The questions are tailored in the following way which is suggestive of the desired answers.

> 1. Whether fixed dose oestrogen and progestogen is necessary in the management of secondary amenorrhoea?
> 2. What are the possible side effects of fixed dose oestrogen and progestogen combination?
> 3. Do you feel that with a suitable cautionary label the use of fixed dose of oestrogen and progestogen combination in pregnancy be prevented?
> 4. Whether fixed dose oestrogen and progestogen combinations are marketed in other countries?
> 5. Whether fixed dose oestrogen and progestogen drugs should be banned?
> 6. Do you have any other suggestions on this issue?"

Nowhere in the above questionnaire had Das Gupta mentioned '*high dose* estrogen and progestogen'. It can be noted that oral contraceptives are also fixed dose oestrogen and progestogen combination. The president of these two organisations C L Jhaveri and N N Roy Chowdhury made full use of such questionnaires and pumped the arguments of the industry in their reply which was considered by Das Gupta as an important document at the public hearing held at Bombay where Prem K Gupta, DCI who was absent at the Calcutta public hearing said that this was done without his knowledge and offered an apology for the action of the Deputy DCI.

At the Calcutta hearing Das Gupta was openly supporting the manufacturers of HDEP. He, along with Dr P K Dutta helped the management of Infar to create a stir at the public hearing and cancelled the hearing with a plea that they may be physically assaulted when there was no valid reasons to do so.

It is necessary to mention the role of other doctors and professional organisations. The reactions of famous gynaecologists and pharmacologists of UK on the need of HDEP were different. Some of these doctors are members of the Committee on Safety of Medicines. Some of the responses are as follows;

> 1. "I feel strongly that there is *no justification* for the use of these drugs in amenorrhoea, menstrual irregularities and other "gynaecological disorders". Amenorrhoea and menstrual irregularities require investigation and specific causes identified and, if necessary, treated. If menstrual regulation is required in patients who have no periods and who have irregular (and perhaps heavy and painful) period then the treatment of choice is either the conventional *low dose* estrogen-progesterone oral contraceptive pill, or progestogen alone.
>
> I think it would be irresponsible and dangerous to encourage the use of high dose estrogen-progestogen combinations in management of these gynaecological symptoms". (Dr. Stephen Franks, Reproductive Endocrinology; St Mary's Medical School, London).
>
> 2. "I was alarmed and disturbed to learn that high dose combinations of oestrogen and progestogens are still marketed, and used in the Indian sub-continent. I understood that steps had been taken in 1983, to withdraw these products and I find it extraordinary that four

years later it is still possible to promote, prescribe and purchase such medicines.

They are associated with significant risks to the factus, if administered during pregnancy. The Committee on Safety of Medicines (of which I am a member) issued warnings to all doctors about these hazards in 1975 and 1977. The British Medical Journal drew attention to the problem in an editorial in 1974. As a result of these publications, and of professional opinion, pharmaceutical companies in the UK voluntarily withdrew their products containing high dose oestrogen and progestogen from the market. (M D Rawlins, Professar of Pharmacology, University of Newcastle upon Tyne).

3. "I find that I am in complete agreement with the opinions expressed by Dr Steven Franks and Professor Rawlins and I have no reason to change my own views, as expressed therein. Perhaps the only thing I could add is that now, with four years experience as a member of the United Kingdom's Committee on Safety of Medicines, I'd like to emphasise Professor Rawlin's point—that is, that these drugs would be unacceptable in the United Kingdom, that our attitude is that the obligation is on the pharmaceutical company to prove quality, safety and efficacy of preparation and not on the drug regulatory agency to prove the converse and that, while those drugs are certainly not banned in the United Kingdom, were any attempt to be made to introduce them I have very little doubt they would fail to secure a licence". (Dr H S Jacobs, professor of Reproductive Endocrinology, The Middlesex Hospital Medical School and University College, London).

The Public Hearings

Thus, famous professors of the medical institutions did not hide their surprise and disgust at the use of the drug and role of government regulatory authority, nor did a large number of the specialists in Calcutta and Bombay hearing. The DCI initially decided to close the public hearing after Delhi. About 150 doctors including professors of gynaecology and pharmacology wrote to the DCI to hold the hearing at Calcutta as well. Initially there was no respond from the DCI. This gave raise to such a reaction that at the instance of the Association of Health Service Doctors, West Bengal about 200 doctors assembled in a convention condemned the activities of the DCI and resolved to start a campaign against the drug manufacturer and the government of India for not banning the hazardous drugs. This compelled the DCI to announce public hearings at Calcutta and Bombay four months after the Delhi hearing.

During the Calcutta hearing, a large mass action for banning the drug took place. For the first time the trade unions, doctors, consumers and health activists demonstrated before a drug company and condemned them for production of banned drugs. It was encouraging to see that for the first time, famous doctors who had been vouching for the industry were challenged by other well-known professors, gynaecologists, pharmacologists.

At the Bombay hearing it was also quite amazing to see that when Jhaveri said, that he would give an award to anyone who could place any evidence of foetal malformation by HDEP, it was accepted by other group of doctors. The real drama took place at the Bombay public hearing when this group of doctors placed a little girl and her mother as evidence of the foetal abnormality and placed a letter which had congratulated them for their effort to detect such drug induced malformation of the baby. The author of the letter was none other than Dr. Jhaveri himself.

Role of People

Long back, after the publication of the write up in *Onlooker*, certain health activists tried to take up the issue but it could not spread. Even when the issue reached the Supreme Court, Vincent Panikulangara a lawyer from Kerala had to fight for a ban quite alone.

In Madras, Delhi and Calcutta hearing some people appeared as 'consumer activists'. Their expressed concern was more on 'illegal' and 'unjust' blames being attributed to the industry than on the harm to consumers. They forgot that this hearing was most important because for the first time merits and demerits of a drug were being publicly heard. They also forgot that their counterparts in developed countries have forced the companies to obey a minimum code of conduct and Infar was admonished by the International Federation of Pharmaceutical Manufacturers Association for violation of its voluntary code however biased, weak and ineffective that may be.

It has also true that the trade unions had palyed different role in different places. While at Madras and Delhi there was no scope for their intervention they responded remarkably positively at Calcutta. Unions of medical representatives, the Federation of Medical and Sales Representatives Associations of India (FMRAI) and the Organon(I) Ltd Workers Union organised a demonstration in front of the gate of the Infar factory. The workers attended it and the president of their union announced that if the company failed to convince them that the drug cannot cause any harm to the people they would refuse to produce it. The representatives of FMRAI appeared before the public hearing and narrated how they were being directed by their employers to misguide the medical profession with partially or totally false information. They also exposed how the Infar and Unichem had been entertaining and spending money for providing travelling expenses of a particular group of famous doctors who had been appearing before the public hearing on repeated occasions. They also stated that the drug was sold by the companies without any promotional effort. The companies are manufacturing the drug and through their distributioin channel it is reaching the outlets where it is automatically sold. The margin of profit in this drug is among the highest.

In contrast to this, the role of the Shiv Sena Union of Unichem at their Bombay factory not only favoured the industry but workers openly threatened the audience that if anyone spoke against their management, they would be forced to take drastic actions. There was a large number of Shiv Sena activists at the Bombay hearing who had been booing and shouting at the women's group whenever they expressed their concern which was often tinged with emotion. This shows the difference in level of consciousness among the workers of the two places.

There was remarkable response from womens groups. In 1979 some women's groups of northern and western India took up the issue. The issue of banning a drug cannot be solely seen in terms of exploitation of female by male. It is also not because Dr Isabel Gal was a women that she first explored the hazards of the drug. The question of banning a drug concerns the profit motive of industry and the low standards of ethics of some eminent opinion-makers of the medical profession in India. During the public hearings. Most of the women's groups identified the crux of the issue—that the existing condition in our country is conducive to industry-government clique. Some of them asked a pertinent question: Why had the court not first banned the drug in the interim which is said to be causing danger. Who would be held responsible for any damages which are being caused even now (if at all) the drug is officially banned in future? They have also declared that they would file litigations against any future malformation of newborns and would ask for compensations from the Drugs Controller and the industry. However the question remains that when there is dearth of ethics among all levels of the decision/opinion-making in the establishment can the judiciary remain un affected?

[While preparing this paper help had been sought from the excellent compilation of documents and different monographs prepared by Mira Shiva, Coordinator, All India Drug Action Network.]

High Dose EP Drugs—II

The Socio-Political Dimension

imrana qadeer

The EP drugs issue has brought into focus the sickness not only of the legal system, but of the medical system as well. How is it that we are fighting a case which should not have arisen at all in a sane society? In reality the very need for pregnancy testing is rooted in the maladies in the social situation and the inadequacies of the health system. Thus the movement against EP drugs and other such technologies must be woven into the wider political movement against a system which breeds, and protects such oppressive developments.

THE addition of high dose oesterogen and progesterone combinations to the long list of oppressive technologies for women is not recent. These drugs have been freely sold in the market for some time now, even though scientifically speaking—their use is not indicated. Its use however, has created such havoc that the victims, that is some of the women, could not bear it any longer. Their protests led to the banning of the drug. The ICMR had already recommended its ban as a drug for pregnancy testing and the court passed a judgment banning its sale. These steps by the authorities were brought to naught by the companies which used the loopholes in the legal system. They obtained the right to continue their business not because they proved the drug safe but because they argued that the Drugs and Cosmetics Act had no provisions to ban a drug (however lethal it might be)! Their victory over the petitioners (women), the referral of the case to the Drug Controller of India and the public hearings in the major cities have revealed a lot more about the sicknesses of not only the legal system but also the medical system.

This compels one to ask, how is it that we are fighting a case which should not have been there at all in a sane society? How is it that while life saving drugs are scarce, dangerous drugs are so easily available over the counter? How is it that the majority of those who flaunt the Hippocratic oath as a mark of their superior professional ethics, preferred to stay out of the controversy when the health of their clients was being jeopardised? How is it that for the sake of so called scientific advancement and the doctors' right to chose treatment for their patients, needy people are treated as guinea pigs whose lives seem to be of very little value?

When we ask ourselves these questions, it is not difficult to see that the issue is not confined to EP drugs but relates to the very nature of technology which is being propagated today in the area of population control. To give it scientific neutrality this area of research is called 'reproductive biology' and constitutes a part of the larger field of 'biotechnologies', all meant to intervene in natural biological and not social processes. They do however, become tools in the hands of some and thereby influence the social process in a way desired by only those sections who are in control. One, therefore, has to ask a very basic question, do the majority really need these technologies? And if they do, what should be the limits of their use?

In this age of modernity and high technology, such questions might sound backward, even anti-technology, but they are neither. Let us ask ourselves why do we need pregnancy tests? The reasons are simple enough.

1. These couples/women for some reason either do not want to have a baby or on medical grounds need to know their status so that adequate care may be given to them as in the case of pregnancy in diabetic or heart patients or in case of high risk mothers with high probability of congenitally malformed or diseased foetus.

2. Apart from these medical reason yet another reason for pregnancy testing is to make a timely choice for abortion if the sex of the baby is undesirable.

If the right of a women to avoid a pregnancy is accepted, then, why is it that despite years of research, in reproductive biology and contraceptive technology, despite millions of dollars that have gone into this research, we still do not have a contraceptive which is safe for the user, sure and cheap? The researchers have in fact sacrificed safety for surety and costs have never really mattered. A good example, is the use of NET-EN despite adequate evidence of its dangers, and the free distribution of oral pills despite their exhorbitant prices. Oral pills were accepted by the planners of the National Family Planning Programme for use in pilot projects for the benefit of rural women and Net-En was approved for marketing in India. All this because the focus had all through been, not on discovering or inventing safe technologics but on pushing those which fulfilled certain targets. Similarly, if we were serious about providing contraceptive or abortion services to women, these should have been an integral part of the most basic health services. This however, is not the case. Despite all the glib talk about health for all by 2000 AD and about full coverage of populations with minimum health services (Primary Health Care), the majority, specially the poor, still have no access to health services (GOI, 1983). People are much more familiar with targets, force, paycuts and withholding of increments for not getting 'cases' rather than with choices in family planning methods. They don't seem to know that the country's health services were in fact meant to provide these choices to them and all that goes along with making such a choice.

Yet another related issue is that a large number of women cannot avail even such services as are available, even if they want to. This is primarily because of the pressures exerted by the family and their own insecurity within that structure. Despite voluminous reports on the status of women, national celebrations of the international womens' year and huge amounts of money going down the drain into the so-called women's upliftment schemes, the status of women remains at a level where the majority have little say in matters as intimate as their own selves.

The problem of women who need the test for medical reasons or for failure of contraception is not very different.

Had they been given access to a good health service, the question of their becoming a prey to the greedy private practitioner, or the ill informed doctor would not arise. There are any number of safe and equally cheap pregnancy tests that the health service ought to be providing to women who really need it (*EPW*, 1987).

It is not difficult to see then that the medical establishment is not interested in safety for the user but in surety of contraception. It is not concerned with making services accessible to people but wants to catch them as targets for surer methods like sterilisation. It is not bothered about the poverty or backwardness of the people but is geared to control them.

The second reason for using pregnancy tests was the need to be selective about the baby's sex. A couple detects pregnancy, goes for amniocentesis and then opts for abortion if it is a female foetus. In Maharashtra alone, between 1982 to 1986 the number of clinics performing amniocentesis has increased from 10 to about 600. The estimated numbers of abortions done for expelling female fetuses in 1985 has been 40,000 (GOI, 1986). This pattern, frighteningly prevalent in most parts of the country, is yet another reflection of a social malady. Instead of provoking its professional ethics and fighting the evil openly, the medical profession chooses to keep quiet or fights against restrictions over the use of amniocentesis, in the name of freedom of the medical practitioners to choose the best for their clients. The medical researcher on the other hand continues to add to the list of oppressive technologies, techniques such as those used for sex pre-selection which promotes the practice of discrimination against female foetuses. At the same time they also make the obstetrician the complete controller who now diagnoses as well as dispenses and thus acquires godly powers!

These questions lead us to the reality that the very need for pregnancy testing in the majority of the cases, largely arises out of maladies located in the social situation as well as the inefficiency and inadequacy of the health service system. Focussing on this need and not its causes, finding technologies for satisfying this need without touching its causes, can at best be called a symptomatic approach to tackling deeprooted problems. Such technologies in fact not only divert attention from the real nature of the problem but also provide cover for the system's wider failures. Accepting them and using them for controlling female fertility amounts to accepting an out-right neo-malthusian strategy for the problems of population.

EP Forte is not the only drug which falls under this group of reactionary technologies. When in 1984 women protested against amniocentesis the government had expressed much concern at the loss of female foetuses and the exploitation of women by "clandestine private practioners". In a seminar organised by the Additional Secretary and Commissioner of Family Welfare in December 1986 at Nirman Bhavan, the steps suggested to tackle the problem included (1) Legal reforms, specially in the Medical Termination of Pregnancy Act 1971, (2) Social awareness through educational programmes and upliftment of women (3) Restricted permission for doing amniocentesis to public institutions (4) More than one doctor's recommendation for such a test. The government's representatives were very sympathetic to these ideas but they argued that the legal system could not be changed. This was perhaps because the MTP Act provides for abortion in a cases where contraceptions has failed and there is no way in which this could be disproved. It is well known that MTP has become a technology in use for the family planning programme and it is no wonder that the government is not inclined towards making this explicit. At the same time it is impossible to introduce stringent measures within the legal system without making the conditions under which abortions take place more restricted and explicit. The government's reluctance to change the law is projected as the 'helplessness' of its legal system. It is ironical that a government which passed the Muslim Women's Bill despite all the opposition and social presures should plead helplessness and invoke 'social awareness' to put an end to the misuse of amniocentesis.

Yet another example is the wide range of technologies used in Family Planing Programme starting from IUD, tubectomy, oral contraceptives, abortions and laparoscopy. All of these were considered for family planning and within the programme, acceptance and desire for family planning were simply taken as issues of availability of technology. The programme for a long time refused to take into account the major socio-economic dimensions of family. This very narrow approach to the problems of population is obviously not an un-intended accident. The waxing and waning attraction towards compulsion at one time and incentives at another time is in itself an indication of the limited range of options within which given technologies are expected to be effective. It also reflects the direction and nature of the overall developmental policies.

The latest in the barrage of technology is the case of Indo-US Vaccination Action Programme (*EPW*, 1987, correspondence). In the health programmes for mothers and children as well as the general population, vaccines have been in use since independence. Despite the availability of these well known technologies, the diseases against which they are effective continue to kill and maim. The only exception is smallpox, a disease that continued for decades despite the use of vaccines in this country. Finally, when it was contained, it was not only because there was a vaccine, but because a better understanding of the epidemiology of smallpox developed over time and provided an alternative strategy.

Suddenly, however, the faith of a set of experts in vaccines has been revived and they have signed a collaborative scheme with the US. Will they now test better vaccines on the Indian population? Even if we believe the argument that only vaccines needed in India will be tested like the cholera vaccine (or rabies and pneumonia vaccines etc.), we have to answer a very basic set of question. Firstly, what is the use of giving effective cholera vaccine to a people who are to perish in drought, without food and drinking water? Even if cholera is to be fought, have we shown that it is possible with the use of vaccines alone, rather than together with the provision of drinking water, food rations and sanitation? Over and above all this, do we have an understanding of the dynamics of morbidity and mortality caused by these diseases and their load and extent to be able to predict costs, set priorities and do some kind of monitoring? With obvious contempt for even the rhetorics of 'scientific rationality' vaccine technology is being glorified. This is not because what it prevents is our priority health problem but because

there is a technology which creates the aura of action and concern for the suffering of people without really touching the cause of that suffering.

These examples illustrate that again and again the system clutches at technologies which promise relief from suffering without really changing some of the social constraints.

Therefore, in the case of EP Forte and its widespread usage, it would be wrong to blame the lack of continuing education on non-availability of information to doctors. These may be peripheral reasons, the main reason being the underlying ideological bias of the 'scientific rationality' which is taught, accepted and propagated within the medical establishment. It is because of this ideological regimentation (where all technology available must be accepted and used and ill health should be seen as a medical problem alone), that the medical profession at large has failed to stand up together and speak in the interest of its clients. A good number in the profession have in fact taken advantage of the trend to make their own profits in the shape of money, position and security. This has been possible because they have been backed by those interested in actively or passively propagating technologies like EP Forte. The drug companeis who use these doctors, also paralyse the legal system which invariably finds itself 'helpless and incapable' of banning killer drugs. The control machinery has become ineffective and is listening to the 'impressions' and 'personal experiences' of the so called scientists (the senior medical practioners) rather than to the meticulously collected objective evidence presented by those who are demanding a ban on the use of EP Forte.

Where the inappropriate usage of EP Forte (and other medical technologies) can be traced to maladies at so many levels, then the issue is not of fighting against just one drug, one test or one technique. The issue is of weaving this protest into the wider political movement against a system that breeds, nurtures and protects oppressive technologies and ignores those technologies which could be better utilised in the interest of the people.

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Polio, Politics, Publicity, and Duplicity

Ethical Aspects of Development of Salk Vaccine

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This paper is an historical account of the discovery, testing, and early distribution of the Salk polio vaccine. The discovery posed fundamental dilemmas of medical research, pharmaceutical production and public health. This paper assesses the ethical problems which arose, and examines critically their resolution.

The great public demand which the discovery of the vaccine generated created a need for federal control which was only partly met. The federal government did not have sufficient institutional and legal mechanisms to assure the safety of the vaccine and protect the public. This discussion illustrates the failure of the government to keep pace with medical technology.

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THE introduction of a new biological pharmaceutical presents a host of medico ethical dilemmas. The debate surrounding the nationwide influenza vaccination programme suggests only a few of the multifarious difficulties involved. Each step in the process—from the initial funding for research to the testing, licensing, commercial production, and distribution of the drug—is wrought with serious judgmental considerations of both a medical and moral nature. If one accepts the public welfare as the preeminent value in the discovery and distribution of a new drug, the role of the government is of primary importance.

The history of the Salk polio vaccine is revealing in this regard. The discovery marks an important episode not only in the growth of immunology, but, most significantly, in the history of public health. The demands made upon the government and the government's response to these demands provide critical insights into the recent course of public health in America. This paper will examine the history of the Salk vaccine in light of the ethical judgments involved.[1]

The vaccine discovered by Salk in 1952 marked the culmination of the efforts of the National Foundation for Infantile Paralysis to secure an immunological agent against polio. The Foundation had grown out of efforts to raise funds for Franklin D. Roosevelt's Warm Springs retreat during the Depression. In consultation with public relations firms, Roosevelt's former law partner, Basil O'Connor, organised a series of "President's Birthday Balls" in 1934 with the slogan: "Dance so that others may walk" (3, p. 16). In 1937 Roosevelt announced the formation of the National Foundation for Infantile Paralysis (NFIP) for the purpose of ensuring "that every responsible research agency in this country is adequately financed to carry out investigations into the cause of infantile paralysis and the methods by which it may be prevented" (5). Basil O'Connor became the president of the new organisation. The creation of the Foundation signaled a major new direction in the history of American medical philanthropy. The appeal for funds now utilised sophisticated public relations techniques (6). Of significance was the dramatic extension of the traditional concept of philanthropy, as the National Foundation now sought funds from everyone, not just the affluent. Radio spots requested that dimes be sent directly to FDR in honor of his birthday on January 30, 1938. More than 2,600,000 dimes "marched" into the White House, inundating the mail room (3, p. 18). Thus was coined the title "March of Dimes."

The Foundation pioneered in the techniques of modern fund raising with its mass appeals, use of media, public relations, and a corps of volunteers. The unprecedented doorbell campaign—the "Mothers' March on Polio"—began in earnest; the Foundation put its cadres into the sheets. Their ability to raise funds, even during the most trying economic circumstances, must be rated remarkable. By the 1950s the National Foundation had developed the perfect form of philinthropy for the burgeoning consumer culture.[2] The concept of philanthropy as consummerism—with donors promised personal benefits—was to a great degree the contribution of the March of Dimes.

Why did poliomyelitis become the rallying point for millions of Americans? One logical answer is, of course, Franklin Roosevelt's personal battle with the disease. Despite FDR's attempts to conceal his infirmity, a new media age made polio the most prominent of diseases. But Roosevelt merely symbolised a more general perception that polio was a peculiarly American malady. More dangerous in affluent nations, polio became America's target although other diseases and medical afflictions were really more common.[3] An increasingly child-oriented society could not tolerate a disease which crippled its young.[4] In addition, the National Foundation had a remarkably powerful influence on the whole direction of American medical research and health care priorities, a topic that demands more attention than is possible here.

There can be little doubt that the Foundation put its funds into the right hands. Through the use of long-term, substantive grants awarded to eminent researchers and institutions, the NFIP insured the continuity of polio research. By 1948 a series of important epidemiological studies had been made under the Foundation's auspices. Most important was the discovery of Drs. John Enders, Thomas Weller, and Frederic Robbins, all of Harvard University, that poliovirus could be cultivated in nonnervous tissue (4, pp. 369-381; 9). This Nobel Prize-winning discovery virtually assured that a polio vaccine could be produced. A race, with bitter political and personal overtones, ensued.

Development of Salk Vaccine

Dr. Jonas Salk began his research on polio immunisation in 1951 under a grant from the National Foundation. Within a year he had successfully immunised monkeys in his laboratory at the University of Pittsburgh. Confident that he had found the key to immunisation in a killed virus vaccine, Salk proceeded to test his discovery on human subjects.

The first of these experiments was conducted on children from the D. T. Watson Home for Crippled Children. Risk was reduced by vaccinating these children, who had already had polio and were thus immune prior to injection. Salk inoculated 43 children with no adverse reactions. He later commented, "When you inoculate children with a polio vaccine, you don't sleep well for two or three months" (1, p. 139).

Salk continued his experiments at the Polk State School, where he again inoculated children with his test vaccine. Unlike the polio victims at the Watson Home, these children, who were mental defectives, had no history of polio and thus much lower antibody titer, significantly increasing the danger of the test. The ethical standards applied here, though in no way unusual in the 1950s, must be questioned. Dr. Tom Rivers, one of the most eminent virologists in the history of modern immunology, in reviewing an experiment similar to Salk's, voiced concern about the morality of such a test (10, pp. 466-467):

> I think that if someone wants to use adults as volunteers to try out a new drug or vaccine, that is perfectly all right, provided that the adult has been told about the nature of the disease he is exposing himself to, has been completely informed about the nature of the agent he is to receive, and has been told the chances for success or failure ... An adult can do what he wants, but the same does not hold true for a mentally defective child. Many of these children did not have mommas or poppas, or if they did their mommas didn't give a damn about them.

Fortunately, Salk's confidence in the vaccine was borne out by the results of these initial human tests. But Dr. John R. Paul, in his definitive history of poliomyelitis, pointed out what failure may have entailed (4, p. 418):

> Had the experiments gone wrong at this point there might have been a tremendous outcry. Some would have called it unnecessarily hasty to use so many subjects all at once... And others would have called it a crime to subject helpless children and adults to this sort of experimentation.

It would seem from this analysis that an experiment on human subjects is ethical if successful, unethical if a failure—a dubious formulation. No government guidelines or requirements for human testing existed at that time.

Salk's success buoyed his faith in the vaccine. In presenting his findings to the medical community, he was, however, more cautious (11):

> Although the results obtained in these studies can be regarded as encouraging, they should not be interpreted to indicate that a practical vaccine is now at hand. ... It will now be necessary to establish precisely the limits within which the effects here described can be reproduced with certainty.

The task of establishing the effectiveness and consistency of the new vaccine would not be Salk's alone.

Planning Field Trials

By the middle of 1953 the National Foundation had begun devising plans for a mass nationwide trial, the largest of its kind ever attempted. The Foundation established a Vaccine Advisory Committee (VAC) of eminent physicians and researchers headed by Tom Rivers to oversee the field trials. The NFIP's decision to conduct such a field trial meant that serious consideration of other forms of immunisation, particularly the attenuated vaccine, no longer was possible (4, pp. 423-425). The Foundation's position, though clearly understandable in light of the embryonic nature of attenuated vaccine research, sparked controversy and aroused bitterness. From this time onward, criticism of the Salk vaccine would be an indeterminate mixture of scientific judgment and personal animosity.[5]

The National Foundation conducted affairs on a grand scale; the field trials slated for early 1945 were to be no exception. The NFIP with its newly created Vaccine Advisory Committee proceeded to design the trials in a direct, almost autocratic manner. After his initial discovery, Salk found his influence diminishing over subsequent decisions concerning testing, as did a host of other scientific advisers to the Foundation. Basil O'Connor, anxious to move forward with all possible speed within the bounds of safety, pushed the VAC in the singular direction of conducting a definitive test (10, pp. 495-500).

Scientific advisers dashed over the design of the trials. Originally, the Foundation planned to vaccinate volunteers and compare the rate of paralytic polio among this group to a control group of nonvaccinated children. This format had the advantage of being easy to administer and evaluate, and in addition gave all volunteers the potential benefit of the vaccine. The Vaccine Advisory Committee insisted, however, that a "double-blind" test was necessary to eliminate the socioeconomic bias of the volunteer group and thus provide a scientifically unassailable evaluation. Under this test, half the volunteers would receive vaccine, half placebo.

This decision infuriated the increasingly confident Salk who called the double-blind test a "fetish of orthodoxy..." Salk clearly exposed the ethical dilemma of using a placebo in an impassioned letter to O'Connor (1, pp. 191-192):

> ...if we are aware of the fact that the presence of antibody is effective in preventing the experimental disease in animals and in man, then what moral justification can there be for the purpose of determining whether or not a procedure that produces antibody formation is effective...[?] I would feel that every child who is injected with a placebo and becomes paralysed will do so at my hands.

Such an experiment, argued Salk, "would make Hippocrates turn over in his grave."

It is not difficult to sympathise with Salk's viewpoint. With a double-blind test the effectiveness of his vaccine would essentially be proven by the contraction of polio among those children who received placebo. But the emotional content of Salk's plea would also seem to indicate the importance of removing the test from the hands of the discoverer. In a sense, Salk favored an early limited distribution of his vaccine as a test for efficiency, not a carefully controlled, scientifically conducted examination. Sure of the safety and effectiveness of his vaccine, he actually jeopardised its full acceptance in the medical community. This is not to question Salk's scientific ethics or his personal morality, but rather to suggest the difficulties of participating in the evaluation of one's own researches.

Though the National Foundation took full responsibility for the field trials, the VAC commissioned Dr. Thomas Francis of the University of Michigan to evaluate the trials. Francis, a pioneer in the fields of microbiology and immunology, commanded unquestioned respect in the scientific community. The Foundation assured the University of Michigan ample funds to assist in Francis' evaluation. He demanded complete control of the evaluation—with no outside pressure, timetable, or supervision—and O'Connor agreed to these stipulations. Francis also insisted on an injected control

group in at least some states. The decision to have Francis assess the vaccine insured an irreproachable trial.

Before a trial could be attempted, however, the difficult transition from an experimental, laboratory-produced vaccine to a consistent, commercially manufactured vaccine had to be negotiated. Until commercial laboratories could produce vaccine, all talk of a field trial was really premature. Although the National Foundation contacted five major pharmaceutical companies to produce vaccine for the field trials, a complete draft of the requirement for production did not evolve until early 1954, only several months before the trials began (1, pp. 207-211). The Vaccine Advisory Committee supervised the shift to commercial production, making two critically important recommendations. First, the Committee required that Salk conduct an initial trial on at least 5,000 children using commercially produced vaccine before undertaking nationwide trials. And secondly, *all* commercial vaccine for the field trials had to undergo safety tests in three laboratories—the producers', Salk's and the U. S. Public Health Service's Division of Biological Control (12).

The decision to test commercial vaccine in the federally operated lab represents the difficulty of the government's position. The government had no legal role in the trial; no licence was required for such an experiment. The Food and Drug Administration only required that the test drug be safe, not necessarily effective(13). A major medical advance was in the making, with the government's only capacity an essentially extralegal one. Moreover, when it came time for the licensing of the vaccine, the Public Health Service would be in the dark. "We wouldn't know enough about the vaccine and the ins and outs of its manufacture", remarked a Public Health Service official. "We would not be able to act on licence applications for months. But the public would want action in hours" (1, p. 209).

With no official role in the testing of the vaccine but badly needing most information, the Public Health Service gladly accepted the functions allocated by the Vaccine Advisory Committee of the National Foundation. Indeed, the Division of Biological Control, under the direction of Dr. William Workman, scrutinised procedures to the point of threatening the trials. Workman and other government officials realised that, although they had no legal sanctions, they had the responsibility of insuring a safe, effective vaccine (1, p. 208). Moreover, the National Foundation recognised the importance of having the blessing of the Public Health Service before conducting its trials.

Opposition to Trials

Scientific opposition to Salk's vaccine remained formidable as the trials approached. Some scientists had difficulty duplicating Salk's inactivation process in their own labs, while others questioned the viability of a killed virus vaccine. Dr. Albert Milzer had been unable to reproduce the Salk vaccine in his laboratory at the University of Chicago. He repeatedly found live virus in the vaccine—an ominous result. Dr. Albert Sabin, at work on an oral, attenuated vaccine, became Salk's chief antagonist. Only one month before the field trial was set to begin, Sabin called the test "premature". Salk and the National Foundation attempted to combat the criticism: "I give every possible assurance I can and that medical science can that the antipolio vaccine will be safe. I will personally be responsible for the vaccine", declared Salk (14, 15).

More troublesome than this criticism, however, were the continued difficulties of the commercial producers in their attempts to replicate Salk's vaccine *en masse*. Scientists at the Public Health Service's Division of Biological Control harbored serious doubts about the abilities of the manufacturers to produce consistently safe vaccine. This reflected, in part, inexperience in the histopathology of polio (10, p. 513). But it also revealed a very real production problem. In March 1954, Dr. William Workman suggested that the field trials be postponed:

> I again come to the conclusion that the specifications and minimum requirements. . .are inadequate to assure the reasonable regularity of production of a vaccine of acceptable safety to be used in the field study. Under the circumstances, I cannot escape the feeling that an occasional lot. . .which does pass the test, may actually contain living virus and be unsafe for use. My recommendation is that the proposed field studies be postponed until—(1) specifications and minimum requirements can be revised to give greater assurance of the safety of the final product; (2) it has been shown that the vaccine prepared in accordance with such specifications meets acceptable criteria for safety (1, p. 221).

It should be emphasised, however, that the government had no legal means of postponing the trials. The National Institutes of Health and the National Foundation agreed that, rather than revising the safety tests themselves, companies must produce eleven *consecutive* lots of safe vaccine for any to be acceptable for use. With this agreement, plans proceeded for the field trials.

Despite the persistent opposition within the scientific community, the National Foundation and the press stimulated public optimism for the vaccine's success. The dual role of the National Foundation—philanthropic and scientific—created tensions. The profusion of positive press release, essential to fill the Foundation's coffers, jeopardised scientific judgments (3, pp. 82-85). The National Foundation announced publicly the plans for a mass field trial months before a commercial laboratory had produced any vaccine (16).

The press played upon the drama of the situation; no medical discovery before or since has been covered as intensely. Beginning in 1953, progress in the vaccine's development was regularly front-page news in the *New York Times*. Press reports were often filled with speculation (17):

> If the vaccine fulfills the hope that at last a way has been found to cope with poliomyelitis as effectively as public health officers cope with smallpox or typhus, Dr. Salk will have scored one of the greatest triumphs in the history of medicine.

Although Salk and the National Foundation attempted to discourage such optimistic conjecture, Basil O'Connor's euphoria could not be contained. He declared that the development of the vaccine had brought the fight against polio to the "verge of victory" (18). The *New York Times Magazine* called the trials the "climax of a stirring medical drama" (19).

The vaccine's notoriety undermined the control of the scientific community. The public now clamored for the vaccine, making it increasingly difficult for scientists with reservations to resist the demand for mass testing. Sabin's attacks on the vaccine, became more personal in nature: "Let us not confuse justifiable optimism with achievement" (20). And Salk's defence became less scientific: "I have the courage of

my convictions. I couldn't do it unless I was more critical of myself than others are of me. It is courage based on confidence, not daring, and it's confidence based on experience" (21). Salk continued to announce that he would take "personal responsibility" for the safety of the inoculation—a courageous, if ill-advised stand (22). The *New York Times* felt qualified to endorse the trials, remarking (23):

> No matter how important a medical discovery may be, there are always skeptics who try to strip it of importance. We need these skeptics, but sometimes they may be nuisances.

At this point the skeptics were threatening the test. Several states withdrew, from cooperation in the trials after Walter Winchell announced on national television and radio that the vaccine "may be a killer" (24).

This is not to argue that the press and public should have no role in a medical discovery, but rather that, in this kind of atmosphere, where public demands and expectations are great, sound scientific judgment may be jeopardised. *The Salk vaccine was sold to the public before its safety and efficacy were proven.*

The National Foundation must bear some of the responsibility for the public fervor which surrounded the field trials. Perhaps the most objectionable of all the Foundation's pronouncements was that the test was exclusively designed to test the efficiency of the vaccine. According to the Foundation, safety had already been conclusively demonstrated. In light of the production difficulties, this was a particularly bold assertion. The NFIP struck the word "experiment" from its literature; this was a "trial" vaccine, not an "experimental" vaccine. Although the test was conducted on a voluntary basis, the *quality* of informed consent is thus highly questionable.[6]

On April 25, 1954 the Vaccine Advisory Committee set up final guidelines, giving its approval for the trials. The United States Public Health Service issued the following statement (26):

> We believe that the judgment of the Vaccine Advisory Committee is sound and that the National Foundation for Infantile Paralysis is justified in proceeding according to the Committee's recommendation.

The next day the field trials began. With more than 1,800,000 children participating, the trials mark the largest clinical test using human subjects in the history of medical science. No medical experiment ever held such public attention. According to a Gallup Poll conducted in May 1954, 90 per cent of the American people knew of the field trials, more than could identify the full name of the President of the United States (1, p. 268).

The test, conducted in 45 states, used placebo controls in 84 areas and observed, nonvaccinated controls in 127 areas. More than 400,000 children received three injections; about 200,000 of these actually received salt-water placebo injections rather than the test vaccine. Along with blood samples to test antibody titer, Dr. Thomas Francis now had the information needed for a conclusive evaluation of the vaccine (1, pp. 238-261).

Speculation was rampant concerning the results of the field trials, but Francis promised no annuoncements until the spring of 1955. He had more than 144 million pieces of information to assemble and review. Some days the Evaluation Center's morning mail filled an entire elevator (1, p. 255).

A critical problem faced the National Foundation during this interim period while awaiting Francis' report. Without a federal licence (which could not be obtained until the vaccine was finally evaluated) and without advance orders, the pharmaceutical companies could not afford to continue to produce vaccine. It was not difficult to foresee a situation in which the vaccine would be found to be safe and effective, and yet there would be no vaccine available for the 1956 polio season. Basil O'Connor, with typical boldness, ordered $ 9 million worth of vaccine from six pharmaceutical companies—an expensive gamble on the vaccine's approval. Of course, if the Congress had been willing to allocate funds, this risk could have been avoided. But the government seemed content to let the National Foundation carry the ball.

On April 12, 1955, the tenth anniversay of Franklin Roosevelt's death, Francis released his evaluation, one of the most comprehensive epidemiological studies ever conducted. According to Francis, the safety of the vaccine was "powerfully affirmed" (27, 28). This is an interesting observation in view of the National Foundation's reluctance to consider the trials a test of safety. Francis found the vaccine 80 to 90 per cent effective in placebo-controlled areas, slightly less in observed controlled districts (28, pp. 15-19). In short, the vaccine appeared to be a tremendous success. The nation celebrated; for many parents, it seemed, the anxious summers were over.

The successful development of the polio shot characterised the Eisenhower years as the moon shot did a later era. The image of the scientist-hero, unhampered by government intervention, held great appeal. The press proclaimed Salk a national demigod, while some colleagues, resentful of all the attention he received, suspected him a demagogue. The vaccine became a perfect cause for an age in which ideology was suspect.[7] The scientific atmosphere of the 1950s was wrought with Cold War overtones. The vaccine, an affirmation of American scientific and technological progress, was viewed as a triumph of the American system. American science, pragmatic and purposeful, demonstrated the continued viability of the promise of American life.

In Washington, Ms Olveta Culp Hobby, Eisenhower's Secretary of Department of Health, Education, and Welfare, signed licences for six companies to produce vaccine. These companies had, of course, been producing vaccine all along; the licences gave them authority to distribute it.[8] The National Foundation's vaccination programme for school children began immediately, with youngsters who had received placebo during the field trials given top priority. For all intents and purposes this should have been the dramatic conclusion to the conquest of polio. Unfortunately, it was not.

The Cutter Crisis

On April 26, 1955, two weeks after Francis' Ann Arbor proclamation of safety, five cases of paralytic polio were reported among children who had just received vaccine. All five victims, it was found, had received vaccine from the Cutter Laboratories in California. Surgeon General Leonard Scheele requested that Cutter recall all its vaccine pending an investigation. Remarkably, the government had no power to order the Cutter Labs to withdraw the vaccine, but Cutter readily complied. The infamous "Cutter Incident" would, however, eventually encompass 25 states and Hawaii, 260 cases of polio, and 11 deaths (1, p. 316).

These cases of polio cast an ominous cloud over the Salk vaccine, the National Foundation, the pharmaceutical companies, and the National Institutes of Health. What had gone wrong with the most rigorously tested drug in medical history? The most obvious cause of the problems was that the careful triplicate testing of the field trials had not been continued for the licensed vaccine (12, pp. 329-331). Written protocols submitted by the manufacturers to the Division of Biological Control were the only legal requirement. The Division had the right to make spot checks, but did not exercise this option. Moreover, the consistency standards of repeated safe batches which had been devised for the field trials were not required of licensed vaccine. In brief, safety precautions for commercially produced, licensed vaccine fell far short of the guidelines used for the field trials.

During a series of meetings of top virologists and advisers called together by Surgeon General Scheele, it was decided to let the vaccination programme continue. But this consensus began to erode quickly. Dr. John Enders, regretting his approval for continuing the programme, wrote to Dr. William Sebrell, the Director of the National Institutes of Health (32):

> I am forced to conclude that active virus might be present in certain finished lots of vaccine prepared by any or all of the manufacturers concerned. I cannot, therefore, longer assert my confidence that the poliomyelitis vaccine now being distributed and injected consists solely of inactivated vaccine and in consequence, of harmless virus.

On May 7, Scheele *requested* that the national vaccination programme be suspended pending further studies.

Scientific criticism of the Salk vaccine intensified. In June, Enders and Sabin testified before a House subcommittee investigating the crisis that the vaccination programme should be stopped and the licences withdrawn until safety could be conclusively proven. But they were overruled by an equally eminent group of scientists who expressed confidence in the quality of the vaccine if properly produced (33).

On June 9, Scheele released a Public Health Service "Technical Report" on the Salk vaccine, an attempt to explain and correct the problems which produced the Cutter crisis. The "white paper", though not a complete whitewash, was carefully written to avoid directing blame (34).

> The Salk vaccine applies new principles in the production of vital vaccines. The speed of its development, which reflected the increased tempo of all medical research, created problems in biologics control amenable to solution only with the accumulation of knowledge and experience. It is likely that problems of equal complexity will be raised by the development of other new vital vaccines.

This analysis obscured the inadequate preparations made by the Public Health Service for testing the vaccine. Despite the easily predictable demand for the vaccine, the Bureau of Biologics staff remained at only 35, insufficient to carefully scrutinise the commercial production process. Moreover, the protocols required of manufacturers did not provide enough information for proper safety-evaluation. The contrast between the careful tripartite testing of the trial vaccine and the testing of the commercial product is a remarkable example of the lackadaisical attitude of the government toward biological control.

The irresponsibility of the Cutter Laboratories must not be overlooked in evaluating the crisis. Repeated difficulties in producing safe vaccine were experienced by the Cutter Labs; 9 out of 27 lots produced had contained live virus and were discarded. Yet Cutter failed to report this inconsistency to the Bureau of Biologics; the company only submitted protocols for batches which passed their safety test (34). Cutter officials never asked for assistance from NIH or Salk. *Their ethical commitment to produce safe vaccine must thus be seriously questioned. But it must also be remembered that they acted entirely within the letter of the law.* The NIH had no consistency requirement and did not require reports on discarded vaccine or production difficulties.

The Public Health Service's "white paper" explained the manufacturing problems in terms of inadequate sensitivity of the safety tests (34, p. 17):

> Each producer had had difficulties in processing and testing materials at various stages of production. Because some lots were obviously unsatisfactory they were not submitted for release, and therefore no protocols on them were submitted by the manufacturers. These experiences showed the need for more sensitive and better controlled testing methods, and for greater attention to the history of consecutive lots.

The Public Health Service revised the minimum requirements for production in light of the Cutter incident, making them mandatory standards. The Division of Biological Control was reorganised, becoming the Division of Biologics Standards with larger facilities and a fourfold increase in staff.

The relationship between the commercial producers and the federal government lay at the heart of the Cutter incident. This association became the target of serious investigations in the days following the tragedy. Victor Haas, the Director of the National Microbiological Institute, a division of NIH, evaluated the government-pharmaceutical connection in a series of memos to Sebrell in May 1955.[9] Haas argued that the responsibility for safety must ultimately rest with the manufacturers, and that the government could not (and should not) participate intensively in the safety testing of biologic products (35):

> It has been the principle of operation that this intensive participation in what is essentially a part of the manufacturing process, properly should be only a temporary activity for the Laboratory of Biologics Control. Once it has been established that manufacturers can produce safe material (and production experience and field trials of last summer formed the basis for licensing manufacturers for polio vaccine), this principle of operation would assume that periodic plant inspection, knowledge of the capabilities of supervisory personnel, review of protocols, and spot-testing of materials would suffice to assure us of continuing acceptability of any product within the limits imposed by available knowledge and human acceptability to error.

Intensive and continuous testing in government laboratories, Haas believed, would destroy industrial initiative and responsibility. According to his evaluation, more testing and inspection would not have prevented the Cutter incident. This is a dubious assertion, for certainly the manufacturing difficulties experienced by Cutter and the other pharmaceutical companies would have been revealed, raising questions of safety.

Finally, Haas suggested that it would be improper to overreact to the Cutter incident by revising existing standards of control. He ascribed the current fervor to the tremendous publicity which the polio vaccine had generated (35):

> Had the poliomyelitis vaccine been used on the same quantitative scale that applies to other biologicals and had an incident occurred, there would have been very little attention given it other than by the constituted authorities. The many factors which have gone into creating a demand for a safe and effective poliomyelitis vaccine, which would be available at the earliest possible time, should not force us to abandon careful and sound judgment as to what is the best method for the operation of biological control over the years.

The Cutter incident exposed the inherent weakness in the

argument for governmental laissez-faire with regard to biologics control and pharmaceutical production. The limited role of the federal government clearly reflected the Eisenhower political philosophy. Olveta Culp Hobby eventually lost her job, largely because of the vociferous criticism of her handling of the vaccine programme. In addition, the government's action was circumscribed by the miniscule legal powers of the Public Health Service, essentially unrevised since 1902, a time of relatively primitive pharmaceutical production. The government continued to assume that industrial interest in producing a safe product would ensure the public's safety.

In view of the federal government's minor role, the National Foundation assumed massive responsibilities in the development and distribution of the vaccine. Combining the functions of fund-raising, research, testing, and distribution, the National Foundation often found its multiple roles conflicting. Although well-intentioned, the publicity mill created an atmosphere in which demand threatened to outstrip sound scientific decision making. In such an environment, ethical questions can become obscured. The field trial, for example, though brilliantly engineered and promoted, and meticulously evaluated, lacked truly informed consent.

The ethical aspects involved in the development and distribution of the Salk vaccine are varied and complex, and the historian must be leery of second-guessed, overarched generalisations. But three key issues which demand continued attention emerge. First, testing with human subjects presents a series of problematic considerations, from the suspect use of mentally defective children to the use of healthy, parent-volunteerd youngsters. High ethical standards for defining risk-benefit ratios must be exercised in such investigations; use of placebos complicates such assessment. Moreover, informed consent is liable to compromise (36). Second, the obligation of pharmaceutical companies to manufacture safe products cannot be assumed, especially when pressures to market a new drug become intense. The third point is most striking: the federal government's minimal role in a major scientific advance. Although the government cannot be the final arbiter of ethical medical judgment, it is the only body which can provide a central direction and standard for these practices. By abdicating a more active role, the government invited the possibility for crisis. The Salk episode seems to indicate a less than complete commitment by the government to the public welfare.

In the years since the discovery of the Salk vaccine, the problems of pharmaceutical control have expanded rather than diminished. The capacity of the government has remained limited in overseeing industry. The Government Accounting Office, Congress' investigative arm, recently attacked the lax attitude of the Food and Drug Administration's drug testing (37, 38). According to the GAO's report, human subjects are exposed to unnecessary risks and the FDA has approved new drugs for public use on the basis of highly questionable data. FDA attempts at self-investigation have proven largely useless (39). The FDA has failed to enforce its standards and, according to many reports, has served as a lackey to the major pharmaceutical companies (40). In its mission of public protection, the FDA, by any standards, has proven to be grossly inefficient.

The history of the Salk vaccine, from the initial research through testing and production, speaks clearly to the present. The institutional connections through which a new drug is channelled from laboratory to market remain uncertain, subject to frequent short-circuit. The time between discovery and production has steadily decreased, augmenting the difficulties implicit in regulation. Most importantly, the federal government has failed to keep pace with the rapid innovations in medical and pharmaceutical practice, at great cost to the public welfare.

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Notes

1. Several studies of the development of the Salk vaccine have been written, although none is definitive. The most comprehensive of these is *Breakthrough: The Saga of Jonas Salk* by Richard Carter (1). Rich in detail, though weak in analysis, this book was particularly helpful in my study. Also recommended are Jo[illegible] R. Wilson's *Margin of Safety* (2) and Aaron K. Klein's *Trial By Fury: The Polio Vaccine Controversy* (3). The definitive medical history of poliomyelitis is *A History of Poliomyelitis* by John R. Paul (4).

   The archives of the National Foundation have unfortunately been closed to researchers. This rich collection of materials contains valuable information pertaining to the development and distribution of the Salk vaccine.
2. For a more extended analysis of the implications of consumer culture, see reference 7.
3. Nations with high standards of sanitation and personal hygiene actually prove to be more susceptible to enteric viral infections such as poliomyelitis (4, pp. 364-365).
4. For an explanation of attitudes toward children in the postwar era, see reference 8.
5. See references 1 and 2 for extended discussions of the bitter relationship between Salk and Dr. Albert Sabin of the University of Cincinnati.
6. Parental consent was required for a child to participate in the trial. Excellent essays on informed consent and human testing are contained in reference 25.
7. Excellent discussions of political and cultural life in the 1950s are contained in references 2 and 30.
8. One of the six companies was the Cutter Laboratories of Berkeley, California. The Region Oral History Office of the University of California at Berkeley recently completed an oral history memoir with individuals from this organisation, documenting its involvement with the vaccine (31).
9. These memoranda, marked "confidential" have only recently been opened to researchers as a result of a Freedom of Information suit. They are a highly valuable source for deciphering the government's view of its role in the development of the vaccine (35).

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Pharmaceutical Industry in Latin America

BOTH the transnationalisation and oligopolisation of the pharmaceutical industry is well known. A few companies occupy a large percentage of the worldwide market. In 1985, the fifteen largest companies in the world were responsible for 37 per cent of the total pharmaceutial sales (US $ 79.8 billion).

This same phenomenon can be witnessed in Latin America, which accounts for 7 per cent of the world pharmaceutical market, or approximately US $ 5.5 billion. In 1985, the 10 leading companies in Latin America—all transnationals—captured 30.5 per cent of the pharmaceutical market in the seven countries studied (Argentina, Brazil, Columbia, Chile, Mexico, Peru and Venezuela). Sales in these countries reached US $ 4.13 billion that year.

The largest markets for pharmaceuticals in Latin America are Brazil, Mexico and Argentina, which are also the countries with the largest populations. In 1985, the total market in Latin America was valued at US $ 5.5 billion; 69.3 per cent of these products were sold in these three countries.

The most frequenfly sold products in the region are antibiotics, cough preparations, antirheumatics, analgesics and vitamins. This illustrates well the pattern of pharmaceutical consumption in this part of the world. On the one hand, while it is true that there is a high-incidence of infectious illnesses justifying the use of antibiotics, these products are often used indiscriminately. Of more concern, however, is the fact that "cough and cold preparations", many of which are simply useless for the purpose intended, occupy second place on the list of sales. Analgesics and antirheumatics—symptomatic drugs—also occupy a preferential place, while products containing vitamins represent a considerable proportion of the sales, thanks to promotional campaigns which try to present them as a solution to the nutritional problems of the Latin American population.

The most startling fact, however, may be that "Novalgina", produced by HOECHST, occupies first place in the sales list, in spite of the fact that its principal active ingredient—Dipirona or Metamizole—has been withdrawn from the markets of many countries because it can produce agranulocytosis, a sometimes fatal blood condition.

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Beyond Medical Solutions

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TAKING SIDES. The Choices Before the Health Worker by C. Sathyamala, Nirmala Sundharam and Nalini Bhanot. ANITRA, 1986, pp 320, copies available at B-7, 88/1 Safdarjung Enclave, New Delhi 110 029. Rs 70.

THE authors address this sort of committed rural health, handbook written in English to middle level health workers' engaged all over the country in rural health services. They take as a starting point, on the one hand, the arguments raised in the last 10 to 15 years against the effectiveness of modern medicine, and the other hand, the failure of the alternative tried out to substantially improve the health situation in rural India. The reason for both is assumed to be the exploitative nature of a society of which the social, political and economic forces by shaping the way of life of the people produce the disases affecting by and large the population.

Those who immediately and hopelessly confront this social and economic reality of the people they work with, are the middle level health workers upon whom the health services actually rest. Yet, "it is these workers who are least involved in a critical examination of their work". Firstly, being located in the lower rungs of the hierarchy of medical services, they are just expected to follow orders. Secondly, their training does not prepare them to conceive, let alone to suggest, appropriate alternatives. Frustration, insensitiveness or despair eventually overcome them. Even so, out of their experience of training programmes, the authors are convinced that those scattered and isolated health workers could and should achieve a lot once helped to develop the proper perspective required with regard to rural health care. The four sections of the book make, therefore, an attempt to help middle level health agents to learn from their disillusion, and instead of relapsing into the apathy or the self-complacently irresponsible stands of public health employees, lead them towards attitudes and practices of social health activism.

The first section describes the baffling experience of Radha, a woman health worker who happens to leave her city hospital to work in a rural dispensary. Absolutely unprepared for this by her training and previous experience, she is progressively confronted with a series of puzzling questions regarding unexpected attitudes and behaviour of the villagers. She painfully realises that her medical knowledge and skill prove of little use. Unable to cope with too many doubts, she feels out of place; she is frustrated: she comes back to her city hopsital.

Around eight common incidents which helplessly bewilder her in the course of ther work, are structured eight chapters which discuss the issues involved. They clarify the health riddles that Radha could not solve on account of her inability to understand the nature of the constraints which inexorably bear upon people's lives. She had only medical answers of a curative type to issues and needs which required first of all a social and psychological analytical insight. The inadequacies of her technological responses lead her to experience that as a pure medical agent she is unfit to meet the health problems of a common man. The following are the questions which pushed her to the limit and that the book, in a second part of the section, helps the health worker to firstly come to terms with while embarking in tasks of rural health care:

> Why don't people rush to get treated early?
> Why do people have faith in local healers?
> Why don't common people have satisfactory access to health services?
> Why are rural areas wanting in good medical practitioners?
> Why do people not implement even simple health messages?
> Why should a health worker know whether and to what extent people are poor or rich, influential or looked down upon? Aren't diseases independent of any other consideration?
> Why do people prefer to impoverish themselves with too many children?
> Why is it that a few people avail of so many health facilities and so many have so little of them?

The first section shows how the health care system as a development asset, no more no less than land, water, credit system, etc., obtains the status of a commodity socially appropriated by those who can afford it or snatch it in proportion to their social, economic and political position of power. As a consequence, ill-health is an unequal access to health commodities when these latter are made unavailable to some—actually many—by others—a few. Ill-health, therefore, mirrors and measures the state of deprivation of the subaltern. Ill-health is injustice and no simple natural disorder, no less than deforestation, unemployment, hunger and malnutrition, starvation wages, etc. The survival strategies of the deprived sections do not bear witness to their ignorance and backwardness but to the sway of iniquitous social forces. Once socially unaware and naively well-intentioned health workers like Radha understand this, they may hopefully realise that they had better feel anything but frustrated, if they really mean to avail the common man of their professional capabilities. But then, a second stumbling block threatens them.

Limitations of Established Modern Medicine

The second section deals with the inadequacies of the health workers which should not necessarily be ascribed to personal failure or inability. They are largely due to the inherent limitations of established modern medicine itself, the assumptions of which need questioning. Its development is as much based on scientific and rational principles as shaped by powerful economic and political groups. The second section expounds how the interests of doctors and big businessmen while contributing to the development of modern medicine, created also a limited view of health, diseases and healing process. New theories shifted the focus of disease causation from the social conditions that bred disease to the

immediate cause which was the germ, and the attention was diverted from poor nutrition, bad living and working conditions, exploitative labour and sex relations, etc. Disease became a physical event within an individual's body and care focussed on drugs, surgery and hospitals. Preventive measures dealt with immediate environment and diseases at the individual level. Health became a neutral and purely technical subject with its experts wielding absolute authority and monopoly on medical research management and health care policies. Big industrialists prompted modern medicine in order to increase the productivity of their workers through control of diseases by therapeutic techniques dealing with the immediate cause rather than the primary reason of illhealth, i e, the exploitative social relations of production. Modern medicine served the interests of those in power and developed to the extent it served these interests. Medical theories justified even the inferior roles of women.

As a matter of fact, the potent remedies and techniques developed with the support of businessmen had a very small part in reducing morbidity and mortality in the western countries. Their major decline had already taken place before specific medical technology was introduced. Death rates for measles, scarlet fever, tuberculosis and typhoid were already negligible by the time effective medical interventions were discovered. This tremendous achievement was not the effect of drugs nor doctors. It was due to improvement in living standards and public health measures. Biomedical technology once introduced had a very limited impact in improving the health status of the population and was responsible for no sharp decrease (except for polio) in mortality rates due to infectious diseases. Only 3.5 per cent of this decline took place because of medical interventions.

Ill-health in Independent India

The third section looks at the development of health services based on modern medicine in independent India with regard to the activities commonly undertaken by health workers in rural areas. Their limitations are pointed out and explained by the fact that they have not been planned keeping in mind the social and economic constraints of the majority of the villagers. As a result, health workers fail to meet the people's needs and by-pass the major causes of ill-health. Examining the policies of the government regarding these rural health programmes it is shown how health needs are actually used as a cover for serving the interests of the wealther sections of the rural population. A comprehensive review of the following rural health problems provides the essential results of the studies in the matter together with an analysis of the inter-related factors: a health-worker can afford to ignore neither of them. In each case the inadequacies of the government health policies are exposed and shown as basically due to the narrow health concepts of a purely curative medicine system absolutely blind, to the structural-social dimensions of health issues.

Health of children: Data on high mortality and diseases occurrences are related to structural constraints such as low nutritional status, low education status of women, inadequate access to medical care at birth and clean water, switch-over to tinned food, sex discriminations etc.

Health of women: Sex-ratio, life expectancy, mortality patterns and causes of death, maternal mortality, nutritional status, access to medical services; amniocentesis, infanticide are determined by the discriminatory effect of the social and/or economic degraded status of women on the one hand and on the other hand, by the medical profession being concerned not with women's health but with their (male) child's issue.

Health of adults: Given the over-all importance of their undernutrition, the reasons for this and the inadequacies of the nutritional programmes are exposed at length. No health worker may fail to be conversant with the misleading debates and approaches in the matter, with the deceitful talks on the so-called minimum wage, with the criminal exports of high protein food, with the decrease of acreage under cheaper coarse grains, with the export of rice, with the wasted buffer-stocks of cereals, etc. In such circumstances, "feeding programmes and minimum wages themselves become oppressive strategies in the long run".

Health education: Some examples show how the official health education as much as health advertising, resembles a harmful brainwashing by its explicitly or implicitly false or socio-culturally repressive messages, and by its concealment of important aspects. The demystification through a critical reading of all health messages may indeed prove a skill difficult to acquire when everybody takes for granted that education is merely a useful transfer of necessarily objective information. Actually, the assumptions of health education as commonly practiced should be denounced as often biased in such a way as to prove in the long run to actually impair the health status of the majority of people. The emphasis on individual responsibility and fault, the theory that health problems cannot be solved without a lot of money, the persuasion that the poor being ignorant, illiterate, superstitious and backward cannot but turn a deaf ear to health advice, the greater importance of men's health, the dependence on modern medicines and the knowledge of doctor's who alone know best, etc are message which conveniently remove the responsibility for ill-health from those who create and maintain "the exploitative practices" conducive to the poor's helplessness.

Family Planning Policy, (FPP): The theoretical and use-effectiveness of the commonly used contraceptive methods are examined and advice in given to make them helpful in improving women's health, as they are a meaningful way to this effect. The present failures are shown to be due to the implementing strategies and false assumptions such as the primary interest for population control at all costs, the belief that population growth is the cause of poverty and underdevelopment, etc. Family planning methods will succeed only if they are accompanied by an overall improvement in the socio-economic conditions of everybody. Failing this, the failure of the FPP can be considered an effective 'resistance' by the poor against the detrimental effects in their everyday life of government agricultural, social and economic policies: a survival strategy in front of socio-political mechanisms of deprivation.

The Village Health Worker's Scheme (1977): It is discussed and evaluated in relation to one basic principle, viz, the selection of the workers by the village community.

Curative services: Overuse and misuse of drugs, harmful role of drug companies, cost of drugs, etc. such problems are discussed and suggestions are made to help health workers overcome them.

Setting Off Again on the Right Foot

The fourth section takes stock of the principles for an adequate practice on the part of health workers: focus on changing the social environment for long term improvement in the health status of the most affected groups among local communities; understanding of and dealing with, the root causes of ill-health; choice of identifying oneself with those who are the most likely to fall sick; decision to operate with all of them as a collective; will to develop their insight into the reasons of their ill-health and foster their collective strength to act against them; attempt to make use of all resources available at the village and block level in a self-help spirit and with the firm conviction of one's own right to health vis-a-vis the government health services, etc. Then, an alternative model of health practices and health education is chalked out for the guidance of a middle level health worker already working in a rural hospital, dispensary or health centre but willing to spare time and resources to operate along the above guidelines although deprived of any experience of village work. Criteria are suggested regarding the selection of two or three villages to work in/around her centre; directives are given to help her develop a proper understanding of those villages through a close relation with people and renewed patterns of communication; the necessity is stressed of bringing people together for them to consider collectively their own needs, find out the reasons of their ill-health and seek solutions; the modalities of selection and training of a voluntary village health worker are clarified; explaining how to keep a diary, conduct a survey or a group discussion on health, from a permanent group of concerned people, deal with problems in a manner really conductive to the group's collective initiative and ability to act on its own, organise people to get due services from the government.

We thought proper to give this rather extensive account of the contents of the book under review to convince the health workers it is addressing of the many practical advantages they cannot fail to draw from it: well-researched statistical information compiling the most relevant data on each topic, didactic synthesis summing up studies otherwise scattered and lengthy, eight pages of referential documentation, a glossary. Considering the alarming and relentlessly resilient extent of ill-health of this country, one cannot but expect many health workers to make choices and definitely take sides along lines expounded in this reference and guide book. Every medical practitioner should hopefully have the opportunity of getting through this book and honestly questioning his practices and the methods of his/her institution in the light of the critical insights provided by this challenging appraisal of rural health problems.

The approach rightly avoids two pitfalls. The first one is to simply ask for multiplying the rural health services (doctors, drugs, dispensaries, injections, surgical equipment, etc) as others agitate for more dams only to bring more health and irrigation facilities to those who can lay hands upon them, with the same result in both cases: the majority of the needy is kept deprived of the means to meet its primary needs of health care and of the water required for irrigating its staple food crops. An unflinching sociological insight only may preserve us from short-sightedly lapsing into this trap. The most commendable quality of this review of rural health problems is its permanent claim to refer health issues to related structural-social factors and the overall marginalising dynamics engineered by them. Disparities in health status measure the extent of social discrimination and unequal appropriation of the means of health. There is no health nor ill-health *as such*: this approach has been the treachery of the purely curative or biomedical modern medicine for reasons known to its promoters. Both of them are outcomes and symptoms of a given social structuring on the one hand, and socio-cultural/anthropological systems of representations on the other hand.

The two critical questions to be raised concern, firstly, the exploitative social relations of health based on the present system of established modern medicine, and, secondly, the system of cultural-anthropological health representations. If the first question, focus of the book, is methodically dealt with, the second dimension, although occasionally and commendably tackled (for instance, illness seen as the result of falling out of harmony with the universe, p 14-17, or the women's inferior value as an explanation for women's lower health status, p 148, 151), would yet deserve a wider and independent consideration that the somehow narrow socio-economic perspective of the authors overshadows.

Let us stress the importance of this second aspect with the example of the exorcism practices performed by religious healers. Around these latter, symbolic sets wave together in ritualistic health practices, the sick, the sacred power, the departed, the go-between-the holy man, the enemy, the genders, etc. (Poitevin). Especially in a traditional agrarian community, health, death, disease, injury, wound, infection, healing are no natural events. Body, blood, hair, sex, menses, birth, injections, etc, are invested with far-reaching and interconnected meanings. They are socio-cultural constructs before being subject to the specific and restricted medical constructs, outcome of the particular and alien assumptions of modern medicine. We cannot take for granted that these latter will easily erase the previous constructs. On the contrary, the traditional meanings are likely to turn up the new speech in such a way as to give it a fitting place in their midst. The point at issue is here that the working of the "exploitative forces" so often rightly referred to, would still be better understood once are discovered both the autonomy and the interdependence of those two levels of analysis. (Althusser, 1970). They overlap in reality as two aggregate dimensions the cumulative effect of which is to be understood in each given social formation under consideration.

A common and easy example may illustrate this interplay. Why do rural people feel a deep and pressing urge for injections? Some traditional unconscious drives and representations (for instance, expectation of a sudden and miraculous recovery through some mysterious device: pricking and pain may act here as a substitute to the ritualistic cutting the throat of a cock) have to be explored and brought out under conscious light. Why do medical practitioners not try to scientifically demystify and reveal to their trustful clients, the quasi-religious nature of their demand, instead of promptly complying with the people's expectations, if not anticipating them, often without any medical necessity? And why do they not, as a principle, entrust this task only to the nurse care? The reasons are known. In doing so, male doctors invest themselves with this very power otherwise attributed to the local healers whose practices are no less mysterious and

knowledge no more transcending their reach and consequently calling for the same complete trust (an important message conveyed by the health education programmes, as appropriately stressed by the authors, p 185). One difference: instead of accepting free gifts, the modern practitioner will claim substantial fees taking advantage of the anxiety and faith of his client—biting again into the starvation income of the needy. In short, in the process, the traditional set of feelings and representations as well as the passive, helpless and submissive relations of health woven around the sacred healers' practice provides the rationale for the acceptance and social sanction of the exploitative practices and the overall male domination of the modern class of medical practitioners. This acquires a specific gender dimension when we remember that it is mainly women who resort to the ritualistic healers (Herzlich and Pierset, 1984).

The book keeps clear also of a second pitfall which usually consists in resorting to health services offered by voluntary agencies with technical qualities and appropriateness of which the public health care system is deprived. The main concern is here for professional performance. This is short of the political will and thrust required to cope with the remote and determinant causes of ill-health as well as with the public dimension of a national service. Each citizen, especially the deprived one, is entitled to health as a right and not as a commodity to be made available even at a lesser cost and served wrapped in humanitarian feelings.

Strategically speaking, it follows from this that health for all cannot be achieved unless it is health by all, i e, obtained as a right by the majority of all those who are kept deprived of it. As neither the public health care system as it operates nowadays nor the troups of NGOs in rural health care can be expected to secure health for all in no century, those concerned with obtaining their right share of health facilities are left with one single alternative, viz, to fight and vindicate their right. This is the right perception which upholds the whole approach.

Need for Tactical Model of Action

To the tactical question "How to go about it?", the answer is that the proposed alternative approach is firstly to be monitored from within the low ranks of the health care system, by the middle level health professionals transforming from within their concept of health and practice of health care. They are staged as the sensitive category through which defiance and innovation will arise. Why we may ask, do the authors assume that this category is potentially fit for spearheading the envisaged radical changes which will reconstruct the established health system? From their own experience? From the fact that this category of workers remaining close to the common people while being technically trained, may prove immediately operative, provided they only shift their socio-cultural allegiance from the class interests of the medical profession towards the lower sections of the rural population? But then, why do the same authors, from the last chapter, characterise these middle level workers as short of experience of village work, deprived of proper training, used only to follow orders and the least involved in a critical examination of their work?

In the fourth section, they are shown a plan of action, and equipped with pedagogical skills enabling them to raise, mobilise and train village health workers in two or three villages around their dispensaries. From where and how do they become all of a sudden motivated for investing their time, energy and thinking capacity in tasks for which, as a professional category, they could only feel shy or have aversion? And we know that as a rule such is actually the case. Before showing how motivated health workers might motivate village health workers, we would also like to know how the low-rung health workers as a category could themselves become enthused in a proportion sufficiently significan as to make them a category and not only a few individuals, initiators pioneering the envisaged alternative methodology of health practice.

Barring exceptional cases which make no use of tactical model of action for social change, one fails to realise how an individual woman from the middle rung health workers may embark alone in such attempts without at least two minimal pre-requisites. The first one is institutional backing, however loose or informal it may be, not only to support her after she has started but to secure since the inception precisely what is taken for granted, viz. the means of a radical reappraisal of her whole training and practices. To put in her hands *Helping Health Workers Learn* (Werner and Bower) is no sufficient answer: a book does not offer a supportive group. In their final inset (p 307), the authors have themselves raised the question to leave it open: does the health worker continue to spend most of her time in her dispensary or in the village? Does she want to radically transform her role? Can she do it within her present institution or should she work with another group? How can she build up support for her work and herself? Unable to visualise a definite plan for mobilising the category they address, the authors satisfy themselves with calling those concerned to chalk out for themselves their course of action.

Here comes the second prerequisite. Irrespective of the forms and nature of the 'institutional' framework, the health worker will not be able to act according to the new role she wishes to assume unless groups of villagers either raised by her or anyone else, organise themselves and through a sustained effort of cultural action develop among themselves and the population that dynamics from the bottom required to put them on the way towards what we have labelled health by the people. Following the catalytic effect of the health worker, it is this organised strength, embryo and basic element of a wider health movement, which may come to effectively bear upon the health system to force it to change in the long run. One may finally wonder whether in the scenario imagined by the book under review and the course of action to be chalked out, the leading role is not to be more plausible ascribed to the villagers' organisation. Without this organisational prerequisite, an isolated female health worker in rural areas cannot achieve much whatever the clarity of her choices; but as a health professional taking sides with such organised groups of villagers she may, for sure, work wonders. To this effect, the chapters 3 and 4 of the 4th section deserve a careful attention.

Many paramedics trained by or working in, christian institutions especially in southern states, may be able to take advantage of this book directly in English. For the many others, let us hope that translation will appear in vernacular languages to make this precious handbook actually available

to all those whom it addresses.

The authors have made a successful attempt to wirte in a clear and accessible language without compromising the necessity for health workers and health activists to master the relevant terms and facts. The presentation of the tables and graphs deserves a special mention for its clarity, careful selection, relevance and attractiveness. Many graphs may not fail to impress even illiterate readers, such as the set showing the decrease in mortality due to infectious diseases for the USA, 1900-1973, in relation to specific medical measures (p 110): one is immediately, visually convinced of the very low significance of the medical interventions in the matter. No professionally competent health activist may afford to do without this handbook. We even consider that no health worker worth the name may go without the basic knowledge imparted by this book. We wish all institutions dealing with rural health care adopt it as a basic vade-mecum for all their workers. A didactic style and the arrangement of the contents in about 35 more or less self-sufficient units, make the book easy to be used as a reference book, to be read piecemeal or utilised a la carte, according to one's daily requirements.

The authors deserve felicitations too for enlivening their technical expositions with pictures and drawings which try to give a graphic visualisation of abstract ideas and often carry the appropriate emotional import. The big size of the book (21.5 cm x 25 cm) was skillfully taken advantage of to device a well-spaced out disposition of the drawing and matter, each page being divided into two parts with short lines: this facilitates the reading and helps to grasp and memorise the matter of each paragraph.

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Dalkon Shield Battle Continues

IN late January 1986, a former Dalkon Shield user suggested that the Women's Health Information Center (WHIC) was the appropriate body in Israel to organise a campaign to notify Dalkon Shield users of their right to apply for compensation for damages. The WHIC, a project of the Israeli feminist movement, consists of small group of volunteers who for several years have provided health information and education to women through a weekly open phone line, health fairs, lectures and other activities. We knew that the manufacturer of the Shield had been required by the Court in America to notify users of their right to sue, but that the company had made little or no effort to do so here. We decided, in February, to take on the job of locating Shield users. We also decided to work with an American lawyer, who could give us information and guidance and could later represent the women we located, if they so chose.

We knew that Robins claimed to have sold the Shield in Israel, but had no idea of how many were actually inserted in Israeli women. The Ministry of Health told a reporter from a local newspaper that there were none in Israel. However, in mid-February we placed a small ad in the same newspaper and over 100 women responded immediately! Some of them definitely used the Shield; others strongly suspected that this was the IUD they had once used. Daily calls poured in, and, helped by volunteers from the Feminist Center and the Rape Crisis Center, we responded by sending out information and forms, and listening to the horrifying stories of complications women experienced with the IUD.

In February and March the WHIC sent information to the press and some ten articles were published about our campaign in Hebrew, Arabic and English newspapers. We also spoke on radio and placed another small ad in a women's magazine. Women from every corner of the country-cities, villages, kibbutzim-requested help filing claims. In April we held a meeting to give potential claimants an opportunity to meet with the lawyer, ask questions and discuss problems they were having getting medical records.

Among the claimants was one who had already verified that the IUD she received at Kalpan Hospital was indeed a Dalkon Shield, and that she had been one of 500 to get a Shield as part of an experimental program. After several weeks of negotiation with officials of the Health Ministry, Kalpan Hospital and the General Health Insurance authorities, we received permission to notify these 500 women. Unfortunately half of the addresses had been lost in the hospital archives, so we were able to write to only 250, and we lost many of these women due to lack of forwarding addresses from their previous homes.

After the April 30th deadline, Kalpan Hospital suddenly FOUND the misplaced list of the other 250 women—but now it was too late to put in claims!

Meanwhile, women continued to call us even after the April 30th deadline passed. There is a definite possibility that not all Dalkon Shield users in Israel were located, due to the limited time and money that were available to us.

When women began to request their medical records they discovered: that many files had been destroyed (they seem to save files for only 7 years here); the hospitals would not cooperate with them; details were not carefully listed—only the word IUD appeared; most private doctors had no files; and some doctors were no longer alive.

[Information from WHIC, Israel from Women's Global Network].

Reinterpreting Homoeopathy

ch v subha rao

IF homoeopathy is to take its rightful place in the health care systems of the 21st century, it must be re-interpreted from the standpoint of dialectical materialism. Samuel Hahnemann, the celebrated founder of homoeopathy, was never so dogmatic as to rule out new interpretations. He says that natural laws cannot be capitalised or kept under the seal of human authority. People may utilise natural laws and yet may not be able to understand the crux thereof. Thus Hahnemann indirectly admits that natural laws may be more fully understood by future generations. He terms as *probably correct* his explanation of the mode of action of homoeopathic medicines. He expressly states that others can form their opinions in the matter. He prepared six editions of his magnumopus *The Organon* in his lifetime and he was constantly innovating. Nearly 150 years have elapsed since the deathof Hahnemann. It is high time somebody reinterpreted homoeopathy and surveyed medical science in general in the light of subsequent developments in philosophy and science.

In his book *Principles and Art of Cure by Homoeopathy*, Herbert Roberts tried to demonstrate that homoeopathy was based on the bedrock of natural laws. More effort on those lines is required now. In the Soviet Union, philosophers and medical scientists are trying to develop modern marxist concepts of life, health and disease. Hahnemann's role in medicine may be compared to that of Hegel in philosophy. Both were philosophical idealists. The rational kernel of their teaching was enveloped by a mystical shell. Marx accepted Hegelian dialectics but rejected idealism. Similarly, it should be possible to separate homoeopathic therapeutics from its idealist shell.

During Hahnemann's lifetime (1755-1843) there were hardly any scientists who were consciously and consistently materialistic in their world-outlook. It is, therefore, not surprising that Hahnemann was deeply influenced by and deeply dissatisfatied with idealist philosophers. He was a deist and a religious free-thinker. He wrote: "The ever-beneficent Godhead animating the infinite universe dwells in us also".[1] He felt attracted by philosophy, but the philosophers and their works offered him little satisfaction. He said: "Philosophy is not only the highest of all sciences, it is also the basis and the fundamentals of all others. No science can exist without philosophy, for without its help it falls to the level of a handicraft or at any rate of a subsidiary subject. This is true above all of medicine" (Haehl).

Hahnemann's biographer Richard Haehl says: "What particular philosophic system he supported is not discernible from his writings or his letters. It seems very questionable whether he definitely accepted any special system. He should rather be regarded as an eclectic who selected from each system the best for his own view of life and the world. From his schooldays onwards he had followed Descartes, Spinoza and Leibnitz (whose systems dominated the schools of the time) and then proceeded to vitalism and to the naturalism of Schelling and Hegel. *He advanced beyond this to spiritualism* and for a time lost his way in occultism. In temperment and development, both as man and as physician, he was a strong opponent of materialism. With all his emphasis on scientific exactitude and empiric certainty as the starting point of his therapeutic reform he rejected materialism equally as an outlook on life and as a fundament of his new theory:... But, on the other hand, he took for his own purposes the basic thoughts of doubt from materialism. He took up a definitely conscious standpoint from facts of experience and rejected every philosophic speculation which did not agree with the latter. For this reason Kant was too impracticably abstract for him and not clear enough in his manner of presentation. Of Plato he complains that he is only valuable when he speaks intelligibly and expressively. His criticism of the philosophers after Kant is that they wrote 'even more mystically' than Kant, that they composed too freely in fancy and that that they had therefore not kept to the bounds of experience" (Haehl).

For Hahnemann, theory was of minor importance (Haehl). Engels, on the other hand, attaches great importance to theory. "However great one's contempt for all theoretical thought, nevertheless one cannot bring two natural facts into relation with each other, or understand the connection existing between them, without theoretical thought. The only question is whether one's thinking is correct or not, and contempt of theory is evidently the most certain way to think naturalistically, and therefore incorrectly. But, according to an old and well-known dialectical law, incorrect thinking, carried to its logical conclusion, inevitably arrives at the opposite of its point of departure. Hence, the empirical contempt for dialectics is punished by some of the most sober empiricists being led into the most barren of all superstitions, into modern spiritualism" (Engels, 1982).

Let us now turn to Hahnemann's concept of vital force. "In the healthy condition of man, the spiritual vital force (autocracy) the Dynamis that animates the material body (organism), rules with unbounded sway, and retains all parts of the organism in admirable, harmonious, vital operation as regards both sensations and functions... The material organism without the vital force is capable of no sensation, no function, no self-preservation; it derives all sensations and performs all the functions of life solely by means of the immaterial being (the vital principle) which animates the material organism in health and in disease" (Haehl).

On the concept of vital force Engels says: "If by this (vital force) is meant that the form of motion in the organic body is different from the mechanical, physical, or chemical form and contains them all sublated in itself, then it is a very lax manner of expression, and especially so because the force-presupposing transference of motion appears here as something pumped into the organism from outside, not as inherent in it and inseparable from it, and therefore this vital force has been the last refuge of all supernaturalists" (Engels, 1982). And again: "*The Organism is certainly the higher unity which within itself unites mechanics, physics, and*

chemistry into a whole (emphasis original) where the trinity can no longer be separated. In the organism, mechanical motion is effected directly by physical and chemical change, in the form of nutrition, respiration, secretion, etc., just as much as pure muscular movement." Thus it may be necessary to modify or even altogether abandon some of the concepts of Hahnemann.

All this, however, should not detract from the merits of homoeopathy which are many and solid. The patient is treated on the basis of 'totality of symptoms'. The uniqueness of each patient is recognised. Permanent cures are accomplished in the gentlest manner possible. The pills are sweet and incredibly cheap. The efficacy of homoeopathic remedies is beyond question. Indeed, allopathic treatment is said to be absolutely necessary only in a new cases. Homoeopathy provides prophylactics as it did when encephalities was taking a heavy toll of lives of children in our country.

We are chasing the mirage of Health for All by 2000 AD. In a rational world there will of course be great emphasis on prevention of disease. It will be a non-violent, nuclear-weapon-free world. It will be free from pollution. People will consume unadulterated and uncontaminated foods free from toxic food additives. There will be excellent sanitary arrangements. Everyone will get food, clothing and housing. Occupational hazards will be minimised. Consumption of narcotics, alcoholic liquors, cigarettes etc, will be drastically reduced. There will be less stress and fewer deaths due to accidents. Nowadays goods are being produced, advertised and sold without the slightest regard for their harmful effects on the consumers. The elimination of profit motive in production is a pre-condition to achieve the goal of Health for All.

If the masses are the real makers of history, it follows that the above goal cannot be reached without a people's movement. In India, progressive forces have been demanding the nationalisation of drug industry and rationalisation of drug policy. They have not met with much success. Drugs constitute one important area of multinational swindling. Our dependence on transnational drug manufactures and on drugs themselves must be reduced. Right now state aid to systems like homoeopathy, ayurveda, and unani is just nominal. It is nobody's case that the baby should be thrown away along with bathwater. The dialectical method should be applied to the facts of medical science and health care. Such a comprehensive critique will enable us to see things in proper perspective and to assign to each system the role it deserves. The quest for truth and for cures must be the motive of such an inquiry and neither passion nor prejudice nor private profit should be allowed to hinder it. The reinterpretation of homoeopathy will form part of such a critique.

Much basic research has to be done if homoeopathy is to gain wider acceptability. For instance the mode of action of homoeopathic remedies has not been satisfactorily explained so far. The materia medica can and must be enriched. Potentisation of drugs can perhaps be explained in terms of the law of transformation of quantity into quality. The law of cure 'Similia Similibus Curantur' may have something to do with the law of negation of negation. If sufficient funds and talents are pumped into homoeopathy, it may develop into the healing system *par excellence* of the future.

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The Hungry Sparrow

The hungry sparrow
flew about in search of grain.
The grain was trapped in the wood of the grinder.
The sparrow said to the carpenter:
Brother carpenter, brother carpenter, the grain
is locked in the grinder.
What shall I eat?
How shall I cope with my hunger?
What shall I carry to another clime?

The carpenter split the grinder;
Out flew the grain.
and the sparrow after the grain.
But the wicked grain lodged in the royal
granary, guarded by a sentry.
Said the sparrow to the sentry:
Brother sentry, brother sentry, the grain
is lodged in the granary.
What shall I eat?
What shall I eat?

The sentry took the matter to the minister.
The minister to the monarch.
The monarch summoned the commander-in-chief
Who appointed a magistrate to study the case.
The magistrate read through reams of law,
and argued back and forth:
Why, in the first place, the magistrate wondered,
did the sparrow have to be hungry?
At any rate, if hungry she was,
Why did she have to pursue the grain?
The grain that of its own desire lodged
in the royal granary.

News spread rapidly.
The papers carried it end to end:
'Sparrow versus the grain' was the cry everywhere.
It was plain that
the sparrow was hungry without rhyme or reason.
Her guilt was beyond doubt.
The hungry sparrow was shot.

Gorakh Pandey
(Hindi)

[From: *Thema Book of Naxalite Poetry* edited by Sumanta Banerjee, Calcutta 1987]