CHAPTER IX

CONCLUSIONS AND SUGGESTIONS

The present study revealed that the theory of freedom of contract is only an ideal relevant when the parties are assumed to be on equal footing. In a more complicated social and economic society, it ceased to have any relevance. Many countries in the world enacted legislations to protect the consumers of pharmaceutical products. Stringent enforcement measures have been undertaken by the governments all over the World to prevent the abuse by the manufactures and sellers of pharmaceutical products. India also enacted legislation and created administrative machinery to protect the consumers of pharmaceutical products. Basing on the study of these provisions and functioning of the enforcement machinery created for this purpose, the following conclusions are drawn.

The meaning of ‘consumers of drugs’ provided in the law is inclusive and not exhaustive one. The definition of ‘drug’ as interpreted by the courts is comprehensive enough to take in it not only medicines but also substances. The meaning of the word substances has been widened by the interpretation of the courts so as to include all the things used in treatment. The definition of the word ‘consumer’ has been liberally interpreted by the courts so as to provide protective net to a large section of the public. Hence it covers not only the buyer, hirer of the goods but also every conceivable user of the goods. In the case of pharmaceutical consumer, one can expect
that the courts will make the beneficial interpretation to cover persons who receive medicines from government hospitals free of cost and persons who could not get adequate quantity of medicines though they are eligible for such medicines from the government hospitals. Inability of the government to provide safe, efficacious and adequate quantity of medicines in such hospitals due to financial constraints should not be allowed as a defence to escape from the obligation in the light of the Supreme Court rulings. Still the pharmaceutical business in India revealed several shortcomings. The important among them are summerised below.

**Need for emphasis on production of essential drugs**

Majority of the Indian population suffer from diseases like malaria, tuberculosis and other non sexually communicable diseases. The production pattern of the pharmaceutical industry should provide adequate quantity of drugs to meet these needs. Hathi Committee which inquired into the drugs and pharmaceutical industry concluded that the drug companies have been concentrating on production of money spinning non essential and often irrational combinations of drugs. The studies subsequent to this report also revealed that there is a shortage of essential drugs necessary to cure local diseases like tuberculosis and malaria where as drugs containing vitamins and other combinations which are more profitable for the manufacturers are produced and marketed in abundance.
Doctors prescribing habits are found to be partially in response to the intense sales promotional pressures used by the manufacturers of drugs. Studies conducted in England showed that the industry incurs substantial expenditure as a cost of promotion for every doctor. Even if one considers that the benefits that a doctor receives from the manufacturer are of a trivial value, the kind of relationship that these promotional devices create between the doctors and manufacturer is not conducive to the best interest of patients.

Hence, there is need to confine the production and prescription of drugs to a large extent to the essential drugs list which is to be prepared keeping in view of the national needs and recommendations of the World Health Organisation. Use of brand names is to be avoided as far as possible both in production and prescription. Drugs are to be produced and prescribed in generic names. This would not only reduce the cost of the medical bill to the consumer but also prevents colossal national wastage of drugs arising out of the production of irrational combination drugs. New drug policy of 1994 do not envisage these measures. Rather it tends to abolish all the requirements for the licence to manufacture new formulations except in cases of specific cell or tissue targeted formulations. It also seeks to abandon the conditions stipulating mandatory production and supply of certain percentage of bulk drugs.

These measures may lead to large scale import of bulk drugs. the multinational manufacturing units have a tendency to introduce new
products of similar activities with slight differences. When they patent these products under the proposed patent regime, the prices of these drugs will be very high. Hence the new policy guidelines are clearly against the reasoned recommendations of the Hathi Committee and the directives of the Constitution. It is, therefore, necessary to revise these policy guidelines keeping in view of the national needs. The policy should state the ratio-parameters linking bulk drug production to the formulations and limit the use of imported bulk drugs as far as possible. The main consideration for granting licence for the manufacture of new drugs must have distinct advantages in India over the existing range of drugs. The production of drugs must be oriented to meet the needs of large sections of the people living in poverty. While framing such policy all the agencies who are concerned in this area are to be consulted. Then only comprehensive and meaningful guidelines can be brought out and can be implemented with their cooperation.

**Need for law regulating clinical trial procedure**

Another disturbing area is the conduct of clinical trial of new drugs and formulations. Research in medicine is a continuous process. When new diseases are noticed, new medicines to combat with these are to be found. Accelerating research in the field of medicine is a necessity. In the process of research and before marketing a new drug, sufficient safeguards are necessary to ensure that human beings are not unduly exploited by the
researchers and unsafe drugs are not marketed by the overambitious manufacturers.

The study of the provisions in this regard revealed that the duty of the drug controlling authorities is confined to scrutinize the data of the clinical test already conducted by the sponsor of the drug. In practice, clinical tests conducted by the foreign companies and if the data has been accepted elsewhere is considered sufficient to support approval of the drug in India. It was found that the approaches of most of the countries for new drug regulations are similar. But it was noticed that the procedures envisaged under the U.S. law is more acceptable and close to the guidelines issued by the World Health Organisation, the European convention on human rights and other international conventions.

Study of the clinical trial procedure under the U.S. law revealed that there is a continuous supervision over clinical trials and controls are provided on the treatment use of an investigational product. The treatment protocols are to be examined by the regulating authorities. During the treatment use of the investigational new drug, treating physicians are required under law to obtain informal consent from the investigational subject or from his lawful guardian. At the same time procedures are also envisaged to expedite the approval process of new drug which is intended to meet the needs of patients for whom there is no standard therapy existing. This flexibility in the procedures is clearly restricted to such drugs which
make promising signs of providing some relief for people with AIDS and terminal diseases like cancer and who do not have satisfactory treatment options.

There is a need for similar provisions in India. The object of such law is to monitor the ongoing clinical trials and also to provide for the procedure to be followed in such trial to ensure safety and rights of the subjects participating in the trials. The law should allow the trial only when it can lead to conclusive data for approval. The system must allow for on-site inspection of the quality of the data. It must also ensure that protocols of clinical trials be submitted to the regulatory authorities in advance for its review. The regulatory authorities should be able to check the reliability and quality of the reported results. This would prevent the ambitious sponsors from manipulating the data.

In this context, the guidelines issued by the World Health Organisation, the Helsinki Declaration, European convention on Human Rights in biomedical research involving human beings are to be incorporated in the national legislation. The idea behind these guidelines is that in research on man, the interest of science and society should not take precedence over the considerations of the well being of the human subject.

Need for re-consideration of the proposed Patent Bill 1995

The idea in conferring exclusive right in the form of patent is that it stimulates research by rewarding the inventor. It induces investor to embark
on new lines of production which otherwise may not be profitable for him.

At the same time, it must be ensured that the exclusive right do not lead to
monopoly to the detriment of the public. Therefore, the law requires to
ensure that patented inventions are properly worked in the country to protect
the public interest.

An analysis of the provisions of the Patents Act 1970 revealed that it
took all the safeguards to reconcile the conflicting interests. It brought some
revolutionary provisions in the patent system to ensure effective protection
to the consumers of pharmaceutical products. The life period of the patent
for pharmaceuticals has been considerably reduced. Patentability has been
confined only to the process of manufacture of the drug and not to the
product. The Act allows only one process, the best known to the applicant,
to be patented. In addition to this, an elaborate compulsory licensing system
is provided to ensure that patent rights do not lead to monopolistic
tendencies to the prejudice of public. The Act provided ‘licences of right’
after three years of date of sealing. Even before the expiry of three years the
controller is empowered to grant compulsory licence if it is necessary in the
interest of public. There are special powers to use the patent by the
government or public undertakings for official purposes.

An analysis of the data provided by the studies in this area revealed
that Indian pharmaceutical industry prospered by leaps and bounds after the
enactment of the Patents Act 1970. It also revealed that the prices of the
drugs in India are reduced to below the international levels because of the competition among the foreign multinationals as well as Indian firms.

But the developments in the international trade and business brought pressure on India to sign the international trade agreement called Trade Related aspects of Intellectual Property Rights Agreements. As a consequence to this agreement, an attempt was made to amend the existing patent law. A brief survey of the provisions of the TRIPS agreement and the Patent Amendment Bill 1995 revealed that these provisions, if enacted, would take away the benefits that are presently enjoyed by the consumers of pharmaceutical products. The Bill provided for patenting a medicine or drug and thereby recognised product patent. It enabled the granting of exclusive marketing rights to the applicant to sell or distribute such patentable product. It also provided that the patent rights can be made available even if the product is not manufactured in India since the 'working of the invention' under the Bill, would mean selling and distribution of the patented article. By these provisions, a legislative attempt has been made to do away with the working of the patented product by way of manufacturing in India. It will also make the price control on these products most ineffective as they can be manufactured outside.

Hence, there is need to reconsider the proposed amendments to the Bill. It must ensure that the patented product is manufactured in India. The provisions should ensure that exclusive marketing rights are not abused by
the multinational manufacturers. Compulsory licensing system that is envisaged in 1970 Act should be retained to subserve the public interest. The proposed legislation may even provide protection to the consumers without violating the TRIPs agreement. It can invoke the objectives and principles laid down in the TRIPs which contain provisions for measures to protect public health and social and economic welfare in sectors of vital importance. Comprehensive compulsory licensing system and price control regime can be devised in Indian law as a part of the measures to achieve the objectives envisaged in TRIPs.

**Need for a public liability insurance scheme for injuries caused by pharmaceutical products**

Many instances exposed the loopholes in the system of regulating drug manufacture and enforcing safety standards. Given the complex nature of the pharmaceutical product, it is difficult to control the quality and ensure safety. Frequent design changes in formulations make it much more difficult task for enforcement agencies to implement the standards of safety. These changes make the product susceptible to incorrect use resulting in fatal consequences.

However, the study of the provisions of the Drugs and Cosmetics Act and the rules framed under it revealed that the law in this regard is comprehensive to protect the consumer provided it is sufficiently supported by adequately equipped enforcement machinery. It stipulated conditions for
licence to manufacture. More rigorous conditions are provided in case of
certain drugs which contain properties that can cause fatal consequences if
any mishap takes place in the course of manufacture. Provisions are also
made for compulsory inspection of the manufacturing premises before any
licence or renewal of licence is granted. Severe penalties are also imposed
for manufacturing and selling of adulterated and spurious drugs. Procedures
are envisaged for taking samples of drugs from the site of manufacture and
send it to the laboratories for testing.

The study of these provisions revealed that the Act mainly
relies on administrative supervision and penal provisions to enforce the
standards. Liability of the manufacturers for the drug related injuries to the
victim is not considered by the Act. Though the amended provisions enable
the aggrieved person or the consumers association to take samples, send it
for testing and also initiate prosecution, the aspect of civil liability of the
manufacturers or the state which permits the manufacture is still governed by
tort law. In addition, the Act claims immunity to the state against any claim
from the consequences of its action under the law. The problem gets
compounded due to the limitations of law of contract and torts. To prove
negligence or causative factors is very difficult in the adversorial system of
litigation. To identify the defendant itself would be difficult in case of
injury caused by a generic drug and if the injury manifests after lapse of a
long period as demonstrated through the facts of Sindel's case, it is all the
more difficult. In addition to this it was found from the studies conducted in this area that cost of litigation would in many cases be equivalent or more in some cases than the compensation awarded to the victim.

Therefore, the traditional systems of redressal may not be of much help to the claimants of drug injuries. Special plans devised in developed countries like Germany, Japan, Sweeden and other Scandinavian countries appears to be more beneficial to the victim. Such plans are desired in India. The provisions of the Public Liability Insurance Act 1991 envisages compensation for injuries arising out of handling of hazardous substances. But the Act do not clearly cover the drug injuries. Rather the definition of hazardous substance would have the meaning given to it under the Environmental Protection Act 1986. It appears that the Public Liability Insurance Act 1991 was mainly intended to meet the consequences arising out of industrial hazards like Bhopal gas tragedy. These provisions can be made applicable to the injuries of hazardous pharmaceutical products by a strained extension only. But separate legislative provisions to compensate the victims of drug injuries is desirable in the light of drug disasters such as thalidomide in England and Europe and J.J. Hospital incidents in India.

Any such plan should envisage compulsory insurance on the part of the pharmaceutical industry and its importer. The scheme should cover all cases of personal injury and death resulting from defective drugs. It should also reach to non-negligent manufacturing defects and failures to warn. The
scheme should also envisage compensation to cover the developmental risks which are not foreseeable or known by the manufacturer at the time of marketing the drug in the light of existing scientific knowledge. It may provide for the establishment of drug injury committee which can decide the quantum of compensation in accordance with prescribed tariffs. Preparing such tariff may not be difficult since such criteria is already adopted in the case of motor accident injuries. The entitlement should depend upon no-fault basis and the victims should remain free to pursue their tort remedy. The premium payable by each manufacturer may depend upon factors like risk rate of the pharmaceutical product, and the market share of the drugs sold by the manufacturer or importer.

**Duty to prevent evasion of price regulation of pharmaceutical products**

Because of the imperfections in the market structure, price fixing cannot be left entirely to the free market forces. The drug manufacturing firms have been effecting the prices of their product without regard to the general economic principle of demand and supply and thereby reaping huge profits. Drugs price control orders are framed from time to time under the Essential Commodities Act 1955 to fetter and curb the profiteering in drugs. An evaluation of the provisions of the drugs price control orders disclosed that effective control is not possible under the existing rules because of the devices adopted by drugs manufacturers to evade the controls. The present system of price control operate through a single list of price controlled drugs
with a maximum allowable post manufacturing expenses of 100 percent on all the drugs. The criteria of including drugs under price control is based on the minimum annual turnover of a drug. High turnover of a drug is considered as an index of its extent of usage and is considered as justifiable ground to clamp control. It is made mandatory to furnish the details of cost of each scheduled bulk drug to enable the government to fix the price. The Government while fixing the price of a bulk drug has to consider factors like post tax returns on net worth or returns on capital employed. There is a different procedure for fixing prices of non-scheduled drugs. The provisions also empower the government to fix the retail price of any formulation in accordance with a formula laid down in the Order.

A bare reading of the formula envisaged under the Order and the annexure provided in the Order through which the government intends to obtain the information from the manufacturer reveals that the decision to fix or revise the price of a drug depends mainly on factors like, cost of the raw materials, conversion costs, cost of packaging material, packaging charges, capital employed, persons employed, their grades and emoluments and transport and selling expenses. The main difficulty for the authorities is to obtain accurate information of the costs of materials used and other expenditures shown to have been incurred by the manufacturers. This will be doubly difficult given the ability of the manufacturers who engage in devices like over invoicing of imported materials and transfer of pricing
methods. The experience showed that the manufacturers invoke the power of the government to review the prices of drugs frequently on the pretext of hike in the cost of imports and devaluation of rupee. In addition to this, the power of exempting a manufacturer from the operation of the provisions are also vulnerable for abuse. While exempting a manufacturer the authorities have to take into account factors like number of workers employed, the capital invested, range of products manufactured and its sales turnover. Many big multinational companies get certain products manufactured by small scale units through loan licensing arrangement and market them through their brand name. By all these devices the manufacturing firms evade price control provisions.

Hence, effective steps are to be undertaken to prevent the evasion of the price control provisions. This requires effective means of information channels to ascertain the prices of the material in the national and international market. Then only the authorities would be able to ascertain the cost of the materials and compare the cost shown in the records submitted by the manufacturing firms. The loan licensing system should be dispensed with to prevent abuses of accounting and transfer of turnover devices. Otherwise, the system should enable the authorities to include the turnovers of the small scale manufacturing unit with that of the multinational or other company with whom such arrangement was made. Unless these measures are undertaken, the price controls on drugs may not be effective.
Need to have a body to screen advertising of drugs

The study of the legal provisions regulating pharmaceutical advertisement disclosed that they fail to prevent misleading information from reaching the public as well as medical professionals. The provisions of Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 and rules framed under it prohibit certain advertisements and regulate certain other advertisements. These provisions are intended to prevent self medication by the public and prevent the advertising by unscrupulous advertisers. The law also lays down the procedure to send certain advertisements to the medical professionals. Though the Act ideally reposes trust on the doctors when it insisted that certain advertisements should only be directed to doctors and other professionals, it cannot prevent the misleading information from reaching the medical professionals. Studies show that most pharmaceutical advertisements directed at physicians are false or misleading and can cause doctors to prescribe drug improperly. It was noticed that virtually every medical journal contains advertising that is one way or the other either false or misleading and most of them have little or no educational value. It was also found that majority of them would not lead physicians to proper prescribing practice. Substantial percentage of advertisements that addressed issues of side effects and contra-indications did not appropriately highlight the side-effects. Most of the doctors mainly
rely on these advertisements supplied to them by the pharmaceutical companies either by post or by their salesmen.

Thus the scope of misleading information in pharmaceutical advertisement is so broad that it is beyond the capability of authorities to correct without substantial new funding for enforcement. In this context the experiment made in developed countries like Canada may be appropriate. The Act of 1954 can be amended to provide for a pharmaceutical advisory board which may be empowered to approve in advance all the advertisements before they are addressed to physicians and other professionals in the medical field. The board may consist of physicians, consumer groups, representatives of medical journals, pharmaceutical companies and advertising industries. The drug control authorities also can have an ex-officio member in the board. The pharmaceutical companies can be charged a fee for each advertisement submitted for review so that there will not be any additional financial burden to the government.

Such regulation may invite the wrath of the pharmaceutical companies. The provisions are to be framed in such a way that they survive the test of constitutionality. This danger is imminent in the light of interpretation given to the right of advertisement in *TATA yellow pages* case and elevating it to the status of freedom of speech by overruling *Hamdard* case. Now the restrictive power of the state of this right is made limited by the Court. This interpretation, it may be submitted, is unwarranted in the
light of the remnant commercial advertising which has admittedly lost any educational value.

**Need for a comprehensive law for storage and distribution of blood and blood products**

It was found in this study that the Drugs and Cosmetics Act 1940 and rules framed under it provides for a comprehensive system of control on sale, storage and distribution of drugs. The law considers that the drugs are not like any other commodities which can be sold by any person and stored at any place. The Act mainly relies on licensing and inspection system in this regard. The drug licensing authority must ensure that the applicant complied with the conditions for granting licence. Conditions have been imposed depending upon the degree of hazardous properties that the drugs for the sale or distribution of which the licence is sought. The facilities that a pharmacy should provide before obtaining licence are also provided in the Act.

There are also provisions in the Drugs and Cosmetics Rules 1945 to regulate the storage, supply of blood and blood products that was made available through blood banks. The rules provide for equipment that is required for a blood bank. It also provide for the requirements such as equipment for the laboratory, technical staff and accommodation for blood bank. These rules also prescribe requirements for collection, processing and distribution of human blood and its components. Under the provisions,
licence for blood banks can be granted or renewed only by the approval of the Central Licence Approving Authority.

However, a report submitted to the government highlighted the deficiencies with regard to facilities of testing blood, licensing of blood banks and the problems of professional donors. It was found that most of the blood used is being supplied by the unlicenced commercial blood banks. It was found that the blood is procured from high risk professional donors and their health status is not examined. Most of these blood banks including government hospitals where blood is stored were found to have no facilities like refrigerators and other storage facilities. The blood was found to have been collected and stored under very dirty conditions. The middle men seems to have been dictating the charges to be paid for the blood. It was found that trained personnel were not available in blood banks.

Therefore, it is necessary to make a comprehensive law on the basis of the recommendations made by the Supreme Court in the Common Cause. The Court recommended for launching effective motivation campaign for stimulating voluntary blood donations. A comprehensive training programme for the personnel operating blood banks and the supervising officials is recommended. The licensing system should be further strengthened. The professional blood donors should be discouraged. The law should envisage creation of an autonomous representative body at national level to monitor every aspect of blood banks.
Need for strengthening the administrative set-up

A study of the provisions dealing with quality control and safety measures in manufacture, import, sale and distribution reveals that the drug control agencies are entrusted with enormous powers and responsibilities. It was made compulsory for the inspectors to visit the manufacturing premises and evaluate the facilities, equipment and other requirement existing at the site of manufacture and submit a report to the licensing authority before any licence or renewal of licence is granted to any manufacturer. It is the duty of inspectors in case of establishments licensed to manufacture Schedule C and C(1) drugs to inspect the plant, the process of manufacture, the means employed for standardisation and testing the drug, the methods and place of storage, the technical qualifications of the staff employed and cumulative effect of all these on the purity and potency of the product and submit a detailed report. Similar responsibilities are also entrusted to the inspectors inspecting sale and distribution units. They are also empowered to take samples and get them tested and if necessary initiate the prosecution against the wrong doer under the law.

All these provisions indicate the need for elaborate administrative set up. This agency must be fully equipped with personnel qualified and trained in the field. It must be furnished with adequate facilities like laboratories, technical staff and other facilities. But the study revealed that drug control organisation at the Centre as well as states have been facing the problem of
inadequate number of qualified and trained personnel. As per the yardstick prescribed by the Task Force, there must be one drug inspector for every 25 manufacturing concerns and one drug inspector for every hundred sales concerns. A drug control laboratory at every state headquarters is required to achieve a target of analysing a minimum of 3000 drugs per annum.

The drug control organisation remained as it was several years ago though there have been a constant growth in the number of manufacturing and sales units. The Drug Controller of India admitted that the staff available is only one fourth of the number required by them. There is no intelligence wing to unearth spurious drugs. It appears that there is not even a single vehicle available at the disposal of drug inspectors in each district without which it would be difficult to check the movement of spurious drugs from one place to others and take timely action and to conduct surprise checks.

It was found that most of the states do not have laboratories to test the genuineness of drugs and those that do have laboratories, do not have the staff to conduct these tests. The Ferguson Committee reported that the regulating authority which is expected to ensure appropriate functioning of the blood banks do not themselves have trained personnel. It is equally true of drug regulatory agencies throughout the country.

Therefore, unless the enforcement agencies are strengthened with sufficient trained personnel and with all the facilities, one cannot expect any
improvement in its functioning. Any sound system of legal control should be able to integrate all the agencies in the system and co-ordinate them in an effective manner so as to achieve the desired objective. There appears to be no such integration and support in the matter of enforcement inspite of the availability of comprehensive legal provisions of control.

It may be submitted that situation in the area of control will be improved to a great extent if the above recommendations are implemented. As the things stand now, there is an inadequate protection to the consumers of pharmaceutical products in the country.

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