CHAPTER FIVE

ADULTERATION OF FOODS AND DRUGS

Part A - Food Adulteration

One of the most widely practised and most despicable of all white collar crimes in India is the adulteration of food-stuffs, drugs, medicines, cosmetics and other essential consumer commodities of daily use. The depredations of adulterators have never been so vile as they are today. Using the feeble and ineffective provisions of the food and drug laws as a smoke-screen, the profit-mad traders, manufacturers and businessmen have been systematically bombarding the people with falsehoods and half-truths about the purity, healthfulness, and safety of their products, while they have been making enormous profits by experimenting on the unsuspecting public with poisons, irritants, impurities, harmful chemical preservatives, and dangerous drugs. Their misdeeds bring death, disease and disability in their train to thousands of people, but they seem not to care so long as they get rich and make their pile. It has been estimated that from 25 per cent to 70 per cent of most of the food-stuffs consumed in this country are adulterated or contaminated. Each year thousands of people are made seriously ill as a result of eating tainted or adulterated food. A still larger number suffer from malnutrition, functional weaknesses and infirmity reducing normal expectancy of life. Hundreds of people actually die every year of food poisoning and other associated ills.
Adulteration of food is a subject which has not attracted much public attention perhaps due to the fact that the evil effects of taking adulterated food are not so dramatic as an outbreak of cholera or plague. Hundreds of thousands of cases of food poisoning occur in this country without much public attention. Some of these prove fatal, some result in permanent disabilities and others cause slow poisoning with various physiological manifestations. A former Union Health Minister, Shri D.P. Karmarkar, in his inaugural address to the Hyderabad Seminar on "Prevention of Food Adulteration" in April 1958, had expressed the view that a murderer was more honest than a food adulterator. He had said that the murderer in any case was prepared to face the consequence of his action, but the food-adulterator having poisoned the food and having taken a good toll of lives, often escaped unpunished to continue his depredations against humanity. According to him food adulterators were "potential murderers and as such deserved the highest penalty". Similar view was also expressed by the former Union Home Minister, Mr. G.L. Nanda, when he inaugurated an exhibition of food adulteration in New Delhi (1965) organized by the Samyukta Sadhchar Samiti. He had characterized food adulterators as "murderers" and "India's Enemy No. 1".

**Common Adulterants and Adulteration Techniques:**

"Adulteration is the debasing of a commodity by admixture of foreign, inferior or harmful material or by reducing its grade below that which it is reported to be to the loss or disadvantage of the user, either in money or in service rendered".
Adulteration has now become a scientific and highly developed occupation. Recent scientific advances have played havoc in the hands of the unscrupulous food manufacturer and trader. Having created a certain degree of sophistication of food, these monied men of business are fraudulently attempting to increase the consumer's appeal by adding cheap, synthetic and prohibited colouring matters and flavours to make the food more attractive. They use poisonous and cheap preservatives and insecticides indiscriminately during storage of foodstuffs. Chemical substances of doubtful safety are added deliberately to disguise the food of its true nature. Apparent improvements in colour, taste and smell entice the consumer to buy adulterated articles.

From tests carried out in different parts of the country, the following are some of the important consumer items found adulterated in varying degrees ranging from 15 per cent to 80 per cent. The items are: Ghee, Rapeseed Oil, Mustard Oil, Coconut Oil, Spices, Tea, Washing Soaps, Pickles, Squashes, Common Salt, Wheat Flour, Gram Flour, Rice, Honey, Turmeric, Milk, Sugar Confectionery, Cosmetics, Ice Cream, Pulses, Eggs, Vinegar, Zeera, Hing, Paints, Cement, Coal, Charcoal, etc., etc. The adulterants used are those cheap substitutes which naturally give the price advantage to the trader or manufacturer as the case may be. They include sand and grit, chalk, papaya seeds, dried leaves, brick powder, blotting paper, saw dust, horse dung, poisonous chemicals, etc., etc.
Dairy Products

It has been found that the percentage of adulteration is the highest in dairy products, particularly milk, butter and ghee. To quote a few instances, during the period 1955-59, the percentage of adulteration of milk in the State of Madras was 65 per cent and for the same period in Uttar Pradesh it was 30 per cent and in West Bengal 43 per cent. The percentage of adulteration of ghee and butter is also extremely high ranging from 10 per cent to 86 per cent. It is estimated that the average percentage of adulteration of ghee throughout the country is as high as 70 per cent. A sample survey conducted by the Directorate of Marketing and Inspections of the Ministry of Food and Agriculture based on 84 samples of ghee from 34 towns located in different parts of the country showed that 56 of these were adulterated with vegetable fat and 21 were of doubtful purity. Only eight were found free from adulteration, but almost all these had developed a rancid flavour.

Milk is adulterated with water and often with dirty water. Starch and Singhara are mixed with milk to disguise the water content and to cheat the consumer. It is common for buffalo milk to be sold as cow's milk after mixing water.

Blotting paper and corn flour are mixed with 'Khoya' and other milk preparations.

Ghee, which is clarified butter fat obtained from the milk of buffalo and cow is usually produced from surplus milk in villages. The composition of ghee varies according
to the type of animal, feed, area and types of production.
The standards for dairy products prescribed under the
Prevention of Food Adulteration Rules are made on a regional
basis depending upon the type and breed of the cattle, and
the feed given to it. The standards prescribed are minimum
standards. Therefore, there is a possibility of adulterating
the natural product during certain periods of the season when
the standards of the genuine natural products are in excess
to that prescribed under the Rules. As for example, the milk
fat content in Buffalo's milk in Punjab has been reported to
vary from six to nine per cent and, therefore, there is a
margin of 3 per cent for the unscrupulous vendors to play about.
Similar is the case with the standards prescribed for ghee.
The R.M. value, which has been prescribed, is on the minimum
side and in the same region it has been noticed that there is
a natural variation in the R.M value which gives sufficient
scope to the dealer as well as to the trader to adulterate
in the general market.

Ghee can be so skillfully adulterated with cheaper
substitutes that "ad hoc" checking by taste, smell or appearance
cannot really help in detecting the admixture. The following
are some of the adulterants used for adulterating ghee and
the methods employed for adulteration:

(a) Hydrogenated Vegetable Oil: This is mixed
either at the finished stage when the ghee is being boiled
for final collection or it is mixed with milk before it is
boiled and converted to butter milk. In either case this
adulterant mixes very freely and is difficult to identify
either by taste or by smell. On the contrary it improves its colour and the granular solidification.

(b) Refined Vegetable Oil: - Commonly the oil used is that of coconut which is mixed at either of the stages mentioned above. The other refined oil used is the peanut oil.

(c) Sweet Potatoes: - They are boiled and thoroughly minced. The stuff is thoroughly mixed with ghee before it is packed into containers.

(d) Animal Fat: - This is mixed at the final stage when ghee is under boiling.

(e) Fish Oil and Groundnut Oils: - These adulterants are mixed while curdling the milk. They have the additional advantage of reducing the acid content, thereby conforming the sample to specification laid down for testing.

Edible Oils:

Like ghee, edible oils like Rape Seed Oil, Coconut Oil, Gingiley Oil etc., widely used for cooking purposes, are also subjected to large scale adulteration. Mustard oil, for example, is made of nearly eight different varieties of cheap oil. Groundnut oil is converted into mustard oil by adding colour. Different mineral oils are freely mixed with some of the edible oils.

Spices:

Samples showed that in powdered chillies, powdered husk of rice, red clay, lead oxide, saw dust and maize flour coloured red are mixed. Curry powder is adulterated with
horse dung. Powdered horse dung has been reported to have been mixed with powdered coriander (Dhania). Besides, dhania and zeera are ground with dried grass. Roots and tubers coloured with lead chromate and manganous yellow and suitably flavoured are sold as genuine turmeric. Lead chromate which has a deep yellow colour is a poisonous derivative of lead. Dried seeds of papaya are mixed with black pepper. Hing is made out of a synthetic compound made out of bitumen.

Foreign leaves dried and dyed with bitumen extracts are used for tea adulteration. The old washed-out leaves treated with a blackish dye are also mixed with tea leaves.

Soft drinks made from chemical clouding agents like brominated fats, synthetic colours, flavours, sweetening agents and a little pulp from fruits are sold as genuine fruit juice. Vineger is nothing but diluted acetic acid. Synthetic fluids with fragments of throw-away remnants of oranges and orange peels are used in making squashes. Tomato sauce is only pumpkin thoroughly meshed containing only a small part of tomato concentrate.

Common salt is abundantly mixed with chalk powder, soap-stones, stone powder and salt scrap. Saffron is mixed with flower petals, artificial coloured starch, paper giving artificial colour, leaves coloured with chicken blood and hair of maize cobs. Honey consists of sugar syrup and molasses.

Barfi and Kalakand, the well known sweetmeats.
have been found to contain blotting paper and corn flour. Maida is an open substitute for cheese in rasgoolas. Sugar confectionery is mixed with artificial coal-tar dye, atta and maida.

Washing soaps are adulterated with chalk, maida, soap stone and caustic soda sludge which is a waste product from the factories manufacturing vegetable oils.

Wheat flour is mixed with 'resultant' flour produced by the mills, and chalk, barley flour, extraction of gluten, powdered bran etc. The adulterants used in the case of rice are white stone crushed to small grain size, clay and inferior quality old rice. Addition of metallic yellow to pulses of old stock is a very common dangerous practice.

What is sold as hen's egg in many cases is tortoise egg, duck egg, spoiled egg and fertilized egg.

Pen adulteration is also extensively practised. Date palm seeds are substituted for betel nut.

The above is only a small list of selected items where adulteration is found to have reached menacing proportions endangering the health of millions of people. Some unscrupulous restaurant owners even indulge in still dangerous malpractices. They often use meat either from dead animals or birds or use discarded residues from meat-extract preparation and soups and try to mask this mischief with strong flavour and hot spices. The adulterants used for food articles in
restaurants and halwai shops are so vast that it cannot be listed comprehensively. Many of the restaurants and eating establishments throughout the country serve unwholesome food and violate health laws repeatedly.

A very serious menace to our health in the foods we eat results not from the preservatives or decomposition nor from the cheaper adulterants mixed with it but from the careless, insanitary handling of food products both in production and distribution. A measure of the almost universal lack of sanitation, which the public has a right to expect in food producing and distributing establishments can be studied by a random inspection of few bakeries, confectioneries, restaurants, meat markets, public eating places and slaughter houses. The combination of open garbage cans and dirty toilets at the rear of a hotel, flies and unprotected and ill-cooked foods therein constitute a serious menace to public health, even in shops which show outward evidence of cleanliness.

Poisonous Preservatives

Another seriously dangerous practice is the use of toxic preservatives and insecticides for protecting food stuffs against damage by fungus and insects during storage. Common insecticides like B.H.C and other cumulative toxic substances are freely mixed with cereals and pulses to protect these from weevils and other insects; such dangerous practices can easily be avoided by fumigation with non-toxic and volatile ethylene oxide and bromides, but due to their
higher cost these are not used. Now the toxic insecticides also find their way into tinned foods like barley powder which has to be stored for long before consumption and their ill-effect on the children and on the sick can easily be imagined. Through the use of urethane and its derivatives to stop sprouting of potato during storage, the consumer can get a good dose of this potent carcinogen.

Lots of processing agents like poly-phosphates, cellulose esters, emulsifying and stabilizing agents of doubtful safety are used in the processed food at random.

Extent of Food Adulteration:

In India, prevention of Food Adulteration Act was enacted in 1954 with the intention of (a) protecting the public from harmful and poisonous foods, (b) preventing sale of sub-standard food containing harmful substances, and (c) protecting the consumer by eliminating deceitful and fraudulent practices. Though this Act is enacted by the Union Parliament, its implementation is a responsibility of the State Government who delegate the function to municipalities, corporations and other local bodies. Lack of proper laboratory facilities, shortage of qualified food inspectors and corruption in the administration combine to result in the inadequate enforcement of the Act. Many of the guilty who are brought to book escape punishment on some technical grounds or procedural lapses. Even when convicted they are penalised for paltry sums which make the adulteration law a laughing stock among the culprits.
The total number of food samples analysed under the Prevention of Food Adulteration Act in the country during 1960 is a little over 1,22,000 of which 37,837 samples were found adulterated indicating the percentage of adulteration as a little over 33 per cent. This figure refers only to samples sent for analysis. But the figure would go much higher on the basis of random sampling. The number of prosecutions launched in the year 1960 is 39,789 and number of convictions is 22,886. Total number of persons imprisoned is 601 and the amount of fines realised Rs.16,62,000. The statement that follows indicates the working of the Prevention of Food Adulteration Act, 1954 during the period 1955 - 1959.
<table>
<thead>
<tr>
<th>No of food samples sent to the public analyst</th>
<th>No found adulterated</th>
<th>No of prosecutions launched</th>
<th>No of convictions</th>
<th>No of acquittals including cases in courts discharged</th>
<th>No. pending and fined</th>
<th>No. imprisoned and fined</th>
<th>Amount of fine realised (Rs.)</th>
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<tr>
<td>64,251</td>
<td>58,292</td>
<td>63,698</td>
<td>17,898</td>
<td>595</td>
<td>6,147</td>
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<td>716</td>
<td>5,349</td>
<td>456</td>
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<td>884</td>
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<td>593</td>
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<td>1,149</td>
<td>1,117</td>
<td>707</td>
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<td>432</td>
<td>265</td>
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<td>11</td>
<td>58</td>
<td></td>
<td>4,945</td>
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</tbody>
</table>
The following table published by the Calcutta Corporation Laboratory in 1961 gives the percentage of adulteration in that city of some of the main commodities of food, procured from different parts of the city on the basis of random sampling.

**TABLE III**

*Food Commodities Found To Be Adulterated By Calcutta Corporation Laboratory in 1961*  
(Swasth Hind, March, 1963)

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Percentage Adulterated</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Butter</td>
<td>74%</td>
</tr>
<tr>
<td>2. Spices</td>
<td>51%</td>
</tr>
<tr>
<td>3. Tea</td>
<td>48%</td>
</tr>
<tr>
<td>4. Milk</td>
<td>43.3%</td>
</tr>
<tr>
<td>5. Chee</td>
<td>29.8%</td>
</tr>
<tr>
<td>6. Wheat (Atta)</td>
<td>20%</td>
</tr>
<tr>
<td>7. Mustard Oil</td>
<td>17.7%</td>
</tr>
</tbody>
</table>

In Delhi the results of the chemical analyses of various samples of foodstuffs revealed extensive adulteration of the whole range of food articles by harmful and poisonous ingredients, which lead to a slow poisoning of millions of consumers in the capital city of India. Following is the percentage of adulteration detected in some common food articles:

- Salt = 30 to 50 per cent
- Khoya from U.P. = 75 per cent
- Milk = 30 per cent
- Chee = 25 per cent
- Wheat flour = 25 per cent
- Zeera = 75 per cent
- Hing = 75 per cent
Reports from the various other State Public Health Laboratories show an equally high rate of adulteration of essential food articles. Though the number of prosecutions has increased considerably, the number of persons who finally get convicted is very few. Many a guilty person goes scot free because of some flaw in the taking and analysis of samples, in the presentation of the case before the courts, or because of the political influence or economic power of the offender or because of collusion of officials in the municipal administration. There are instances in Delhi where owners of eating establishments have been challenged 35 times but not convicted even once.

Factors Responsible For The Continuance Of The Menace Of Food Adulteration:

Among the many factors that encourage the increasing incidence of the evil of adulteration of food, the following are important:

1) Weak and ineffective enforcement of the Prevention of Food Adulteration Act.

2) Lack of deterrent punishments actually awarded.

3) Inordinate lust for more and more profit on the part of the trader/manufacturer.

4) Socio-economic conditions in society: general decline in moral values, corruption in public services, high prices due to scarcity conditions, cost-conscious consumers turning to 'cheaper substitutes' absence of organized consumer resistance etc.

5) Shortage of supply to meet the growing demand of food articles.

6) Paucity of qualified analysts, chemical laboratories etc.
Food, like water, is a primary necessity of life and supply of wholesome food, adequate in quantity and rich in nutritive value is an important factor in the prevention of disease. But, unfortunately in India, essential food articles have always been in short supply and the abominable practices like hoarding, black-marketing and profiteering on the part of the merchant community have further worsened the situation. The scarcity conditions, sometimes artificially created by the traders, coupled with the high cost of living have driven the vast mass of average Indians to satisfy themselves with adulterated food stuffs and cheaper substitutes. Finding quick means to make easy money the business community exploited the miseries of the people and devoted their ingenuity in adulterating the whole range of food articles with all sorts of harmful and poisonous adulterants that gave them the largest margin of profit. The damage to public health as a result of their criminal practices is incalculable.

It is indeed the realization of the widespread and persistent nature of the adulteration menace that is reflected in the provisions of the Prevention of Food Adulteration Act. The few provisions in the Indian Penal Code (sections 272-276) were found to be inadequate to meet the increasingly alarming situation and it was thought the new Act would be an effective deterrent against food adulterators. But this measure also did not bring the desired relief to the nation. The provisions of the Act and the rules thereunder came to be more often violated than obeyed. Under the cover of its feeble provisions and taking full advantage of the extremely poor
enforcement of the Act the offenders continued in their nefarious activity endangering the health and security of more and more people. The rules under the Prevention of Food Adulteration Act provide only the minimum standards required of a commodity which itself gives a margin to the unscrupulous trader. The food inspector also generally requires an extreme degree of adulteration to merit condemnation. In these circumstances the law itself provided shelter to the unscrupulous trader to carry on his anti-social practices within certain limits sufficient to jeopardise public health.

Of late, though the number of samples tested and the number of prosecutions launched have shown an increase, the number of convictions has not increased proportionately. The attitude of the courts has also not been helpful in deterring the offenders. In many cases courts of law in exercising their discretion awarded minor punishments (though increased penalty was provided by Parliament) and more often than not, even these minor punishments were further reduced on appeal by the High Courts. Added to this liberal judicial attitude towards the food adulterators there exists official corruption and political patronage which help the "murderers by food" to violate the law and get away with it. The municipal authorities endowed with the responsibility of protecting the public from the menace of adulteration have been complaining about lack of funds and paucity of personnel. The average citizen is a helpless onlooker of this strange spectacle!
The need for strengthening the law and tightening its enforcement is very evident. The battle against adulteration calls for sustained effort backed by sustained public vigilance. The increased punishment and the certainty of a minimum term in jail provided by the amending Act of 1965 are yet to prove their efficacy in deterring persistent food adulterators. In this connection it is of interest to note the minutes of dissent appended to the report of the Joint Committee of Parliament on the Prevention of Food Adulteration (Amendment) Bill, 1963, presented on 7th September 1964.

Condemning food adulteration as the biggest crime against humanity, Shri P.K. Deo M.P suggested that even public flogging may not be adequate for this offence of deliberate genocide. M/s. R.V. Kamath and Niranjan Singh, M.Ps wanted the maximum penalty of death or imprisonment for life for major offences of adulteration. They also advocated the confiscation of assets, deprivation of civil rights including the franchise and disqualification from any public office, membership of legislature etc., in the case of habitual food adulterators. On August 7, 1964, the Calcutta Corporation unanimously recommended to the Central and State Governments that the death penalty be applied, both to adulterators and to profiteers. The attitude of the public towards this type of criminality has also hardened and a majority of citizens advocate capital punishment to the offenders in this category. They also recommend confiscation of property and, in all cases of conviction, wide publicity through the press, cinema and the radio. Despite such strong public sentiments against adulteration and successive amendments of the law
plugging the loopholes and increasing the severity of sentences, the evil has continued to grow endangering the lives of millions of people and putting the whole nation into shame.

**Part - B - Drug Adulteration**

When we examine the problem of adulteration in the field of life-saving drugs and medicines the picture is more distressing and appalling. In a vast under-developed country like India, where the majority of people are illiterate, under-fed, and economically backward, disease and disability are only the natural destinies of many Indians. According to a recent survey of the World Health Organization, malnutrition is almost an universal phenomenon in India. People do not get adequate supply of wholesome food with the result that they are easily prone to diseases. In such a situation the monied men of business who manufacture and sell spurious and sub-standard drugs and exploit the miseries of the people to satisfy their lust for profit are no better than the worst criminals. They not only cheat the innocent victims but play ducks and drakes with the lives of millions of people.

The clever and ingenious violations of modern drug makers and spurious drug manufacturers outmanoeuvre the provisions of the law of fraud and cheating. One apparently harmless practice is to set in motion a host of fears about their health and vitality in the minds of the people through clever, expertly-disguised publicity in the newspapers,
in the magazines, and over the radio. Then they recommend their products which, according to them, would avoid the onset of disease and give quick recovery from diseases already contacted. But the fact is that many of the drugs and medicines, including some of the most widely advertised and sold, are not only worthless, but are actually dangerous.

Some of the poisonous ingredients of their medicines act slowly and insidiously over a long period of years bringing the onset of old age and infirmity earlier than it would otherwise have come. Poisons in food and drugs lower the normal resistance power of individuals and bring many an obscure type of illness like indigestion, constipation, pains, headaches, general weariness etc. In short, the drug fakers experiment on the public with their harmful products ignoring the consequences to the millions of human beings involved. As one American writer has put it: "In the eyes of the law we are all guinea pigs, and any scoundrel who takes it into his head to enter the drug business can experiment on us. He may be uneducated, even feeble-minded. If he decides to become a manufacturer, it is his privilege to take down a dozen bottles from a shelf, mix their contents together, advertise the mixture as a remedy for indigestion, or asthma, or coughs and persuade us to buy it. The mixture may contain arsenic, carbolic acid and other deadly poisons. But, in most cases, he will have violated no law, indeed will not have offended the ethical sense of the average judge or legislator. When the experiment has failed and several of us have died, damage suits may make the business unprofitable.
and so for the time being end it. But its owner may again take down the same dozen bottles and start over with a new name!"

The 'Unknown' Danger in Drugs and Cosmetics Trade:

Modern merchandising technique involves a large number of persuasive advertisements in a variety of subtle ways. Crores of rupees are spent annually to convince a credulous public that only in the cosmetics and hair preparations, toothpastes and antiseptics, tonics and vitamins lie security of health and happiness. Unfounded and imaginary fears are created in their minds that without those advertised articles, they will soon find themselves hairless and toothless and contact a host of infirmities and diseases the germs of which are lingering in their mouths, body and surroundings!

Millions of people in this country use almost every one of the well-advertised preparations, most of them of secret composition. Almost without exception, such preparations are of trifling worth for the galaxy of purposes for which they are advertised. According to expert medical opinion, the ordinary tooth-pastes widely advertised to have qualities of curing pyorrhea or mouth infections have nothing of such qualities and no tooth paste will destroy enough mouth organisms to make any difference in anyone's health or well-being. Those who rely on the manufacturer's/advertiser's honesty and therapeutic knowledge will suffer
avoidable diseases and ailments. The makers of some of these popular preparations are guilty not only of poisoning the public mind with a stream of groundless fears which business enterprise can translate into money, but often of causing incalculable harm by the postponement of proper treatment in cases where serious conditions actually exist and demand treatment of unquestioned effectiveness. They further drain from slim purses of the common man the money needed for bread and other necessities of life.

Every large drug store has dozens of preparations carrying meaningless and misleading names for the relief of headaches, pains and minor ailments of all sorts. For most people these preparations, unless taken in excess, are comparatively harmless. To a certain percentage who happen to be excessively sensitive to some ingredient, however, they are gross poisons and the concealment of the presence of these ingredients constitutes a grave danger.

Part from the patients administering drugs to themselves and thereby complicating the disease conditions, self-medication resulting from over-emphasized and indiscriminate publicity has also an unfortunate repercussion of promoting drug addiction. The West Bengal Drug Enquiry Commission, alarmed at the rate of increase in drug addiction, cautioned the authorities of the health hazard and the malpractice involved in the process. It is common knowledge that sedatives like barbiturates, stimulants like cocaine and tranquilizers are indiscriminately and surreptitiously being used by people without understanding the consequences.
Advertising has become the mainstay of sales of fraudulent and dangerous drugs, adulterated and sub-standard medicines and worthless cosmetics. Almost no advertising intended to influence the general public is honest in the sense that a true scientist understands honesty. That an advertiser says may be in a narrow and limited sense true, but he does not tell the whole truth. Ordinarily failure to tell the whole truth presents only an economic hazard or loss. In the advertising of medicines and drugs, however, such avoidance is definitely dangerous to the consumer. Many papers accept all sorts of advertisements, fraudulent and dangerous. In an important sense, therefore, the publishers of popular magazines and newspapers are more to be blamed than the advertising agencies for the continuance year after year of innumerable frauds. In India the problem assumes added significance in as much as many of the largely circulated newspapers and magazines are owned or controlled by those very businessmen who have interests in the industries connected with foods and drugs.

The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, is intended to regulate advertisements in respect of drugs, appliances, and magic remedies such as talismans, rings, amulets etc., which claim to cure or mitigate certain diseases and conditions specified in the Act, which require prompt treatment in consultation with qualified medical practitioners and where self-medication may aggravate the disease to a point when it may not be amenable to treatment. The object of the Act is therefore
to prevent the danger to public health from self-medication which may result from such advertisements which appeal to the credulity of the gullible lay public. The Act is administered by both the Central and State Governments. The Central Government regulates the import and export of objectionable advertisements while the State Governments exercise control over the publication of advertisements within their territories.

The enforcement of the Act by States is wholly inadequate. While objectionable advertisements relating to drugs are increasing at a tremendous pace, the progress of prosecutions indicate the brutal indifference on the part of State authorities to curb the growing danger to public health. Excepting the State of Maharashtra, in all other States the administrative machinery required for the purpose is non-existent or ridiculously inadequate. There is practically no screening of advertisements and follow-up action on cases reported by other States are generally not taken. The West Bengal Drugs Enquiry Commission observed: "Electric lamp posts and such other places are plastered with advertisements which offend the provisions of the Drugs and Magic Remedies (Objectible Advertisements) Act, 1954. Some of the remedies advertised are really formulations for affecting abortion, but they are advertised as remedies for correction of irregular menstruation." The Commission analysed the existing legislations in the various advanced countries and formulated the following statutory prohibitions
in the control of drug advertisements:

1) Self-medication of specified drugs;
2) Advocating self-medication;
3) Creating panic;
4) Recommending a remedy as infallible or possessing magic power;
5) Tendering free information for self-administration;
6) Issue of samples to the public;
7) Offering money back if treatment is unsuccessful;
8) Displaying medical certificates or testimonials;
9) Publishing letters of thanks; and
10) Describing symptoms of certain diseases.

The Indian Act, however, prohibits only advertisements of certain drugs for treatment of certain specified diseases and misleading advertisements relating to drugs. If the above prohibitions were to be applied to Indian advertisements appearing in the numerous journals, papers and other media in the various languages existing in the country, it would indicate the tremendous extent of danger posed to public health through such advertisements. Further technical advertising in India is not subject to any restriction, except that it has to be communicated to the registered medical practitioners or wholesale or retail chemists through confidential channel.

Drug Control in Historical Perspectives:

India was largely dependent on foreign imports for drugs of modern medicine until after the First World War.
As a result of the unsettled conditions that followed the war there was a mushroom growth in Europe of unethical drug manufacturers who began to trade in faked and adulterated drugs with the East. During the years 1919-23, the Indian Market became flooded with adulterated, sub-standard, faked and spurious drugs. The absence of any organisation to control and check this menace added to the misery. The protests from the public to this open fraud led to the appointment of the Drugs Enquiry Committee in 1927. The Committee's findings also testified to the existence of widespread drug adulteration. The Committee observed: "Owing to the unprotected condition of the Indian market, the facilities and the temptations for the sale of all kinds of inferior and deteriorated products are many and irresistible. Many foreign firms, which exported drugs to India, manufactured them specially for India, and exported drugs of a quality that were condemned by the authorities for their home consumption."

As a result of the report of the Drugs Enquiry Committee, 1927, the Government of India passed in 1940 the Drugs Act to regulate the manufacture, distribution, import and sale of drugs. Drug Rules were also framed in 1945 to serve the purposes of this Act. Under this Act, the Central Government controls only the standards of imported drugs while the State Governments control the manufacture, sale and distribution of drugs within the country by the establishment of an adequate machinery consisting of licensing authorities, inspectors and government analysts.
The institutional and legal framework provided under the Act was soon found to be wholly inadequate to meet the growing menace of spurious and adulterated, sub-standard, and misbranded drugs. According to the Pharmaceutical Enquiry Committee, 1954, the introduction of Drugs Act and Rules thereunder had not brought about the desired results in improving the quality of products manufactured and/or offered for sale in the country. "Through advertisement in the press and propaganda, tall claims are being made for useless preparations and the gullible public are being exploited". While the market was getting flooded with products under fancy names of secret composition and without any guarantee of quality, and while complaints from the public become too frequent, the machinery required for the supervision of manufacture, distribution and sale of drugs remained largely inadequate, ill-equipped and neglected.

**Extent of Adulteration in Drugs and the Factors Responsible Therefor:**

For an appraisal of this aspect of the problem it is necessary to have an idea of the various definitions involved.

A drug (or pharmaceutical preparation) is any substance or mixture of substances manufactured, sold, offered for sale for treatment of disease.

Adulterated drugs can be categorised spurious and/or sub-standard, whereas the term 'misbranded drug' as used and defined in the Drugs Act is a composite one. Sub-standard drug is the one which falls below the standard
set out in the schedule to the Drugs Act. The term "Standard" is with reference to quality. The term "misbranded" has reference to display.

Section 9(B) of the Drugs and Cosmetics Act, 1940 defines "adulterated drug" as under:

a) if it consists in whole or in part of any filthy, putrid or decomposed substance; or

b) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health or;

c) if its container is composed, in whole or in part of any poisonous or deleterious substance which may render the contents injurious to health; or

d) if it bears or contains, for the purposes of colouring only, a colour other than as prescribed; or

e) if any substance has been (i) mixed or packed therewith so as to reduce its quality or strength; or (ii) substituted wholly or in part therefore.

The West Bengal Drugs Enquiry Commission (1964) defined "spurious drugs" as those which are deliberately adulterated and used the word "adulterated" to mean that, part of the ingredients of the drug has been taken out or substituted by products other than those specified. Some drugs are entirely spurious; that is, they do not contain any of the ingredients declared in the brand; some are partly spurious in the sense that they do not contain the declared quantity and the specified quality of the ingredients. Sub-standard drugs can be: (a) drugs which have deteriorated because of indifferent storage, or where the shelf-life of
drug has expired and (b) drugs which are not up to the specified standard because of ineffective quality control at the various stages of manufacture which may be due to defects in the raw materials used or lack of proper laboratory facilities and technical expertise.

Spurious drugs or drugs which are below standards are not only therapeutically ineffective, but can also jeopardize the life of a patient by allowing the disease to take a retrograde course by its not being checked in time.

There is no conceivable method to assess with any degree of certainty the extent of adulteration of drugs. People in the professions of medicine and pharmacy are in a position to know about it and a good section of them hold the evil as fairly widespread. The various Drugs and Pharmaceutical Enquiry Commission/Committees appointed by the Central Government and a few State Governments as well as the State Drug Control authorities also testify to the extensive prevalence of spurious and sub-standard drugs in the country. From the findings in these reports as well as from the progress of prosecutions launched under the Drugs and Cosmetics Act 1940 and the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 one can gauge the magnitude of the problem, though the statistics indicate only a fraction of the violations. Table IV below indicates the progress of prosecutions under the Drugs and Cosmetics Act 1940 for the period 1959-63.


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<tr>
<td>1. Prosecutions launched</td>
<td>... 314</td>
<td>248</td>
<td>204</td>
<td>139</td>
</tr>
<tr>
<td>2. Cases decided</td>
<td>... 232</td>
<td>236</td>
<td>184</td>
<td>89</td>
</tr>
<tr>
<td>3. Acquittals</td>
<td>... 40</td>
<td>52</td>
<td>22</td>
<td>10</td>
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<tr>
<td>4. Convictions</td>
<td>... 192</td>
<td>184</td>
<td>162</td>
<td>79</td>
</tr>
<tr>
<td>5. Fines realized</td>
<td>... Rs. 28,024</td>
<td>Rs. 34,440</td>
<td>Rs. 23,911</td>
<td>Rs. 30,171</td>
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<tr>
<td>6. No. of cases in which imprisonment awarded</td>
<td>... 17</td>
<td>5</td>
<td>7</td>
<td>3</td>
</tr>
<tr>
<td>7. No. of Prosecutions for sale and manufacture of spurious drugs</td>
<td>... -</td>
<td>42</td>
<td>30</td>
<td>61</td>
</tr>
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It is estimated that there are about 3,500 major, medium and small drug manufacturers in the country holding manufacturing licences. Most of them are concentrated in the States of Bengal and Bombay. Out of these, manufacturers having
a capital investment of more than Rs. 10 lakhs number not more than 150. This means that the large bulk of pharmaceutical products in the market comes from medium and small manufacturers. The quality control facilities at the disposal of such medium and small manufacturers are either deficient or absent. These mushroom units produce poor quality products under fancy names without any guarantee of quality.

According to the Pharmaceutical Enquiry Committee, the spurious drugs trade flourishes in India to a colossal extent due to several causes. First and foremost is the greed for making cheap money, taking advantage of the popularity of a drug by selling clever imitations as genuine products. The second cause is the tendency of the public to buy cheap drugs from unlicensed dealers like grocers and "walking chemists" who maintain no establishments according to the various laws. The third cause is the shortage of medicines of established reputation. This shortage may be real or artificial by hoarding large stocks. Another cause is the high retail price of certain drugs and medicines that are so much in demand due to their life-saving property. The Committee also attributed the existing inadequate legislation for this menace. The profit earned by the faker is so enormous compared to the punishment, imposed when convicted, that it is always an attractive proposition to manufacture spurious drugs. The inter-state barriers are exploited fully by the anti-social elements and where
sufficient understanding and liaison does not exist between the Drug Control Administrations of different States, maximum use is made by the parties to dump such products on to neighbouring States. The facilities for the testing of drugs at the disposal of drug control organizations are also generally poor and the procedure cumbersome adding to the advantage of the unscrupulous manufacturer. The Government’s purchase policy for military and civil hospitals is also held to be responsible for the manufacture of sub-standard drugs. When purchases are made on a tender basis without caring to ensure proper quality, it is no wonder that sub-standard products are bought by the Government and their manufacture is encouraged.

In 1962 a large number of complaints from different parts of the country were received regarding the quality of distilled water for injection manufactured by certain firms in West Bengal. Similar complaints again appeared in respect of the following drugs: (1) Aminophyllin (2) Glucose and (3) Atropine - also believed to be manufactured by West Bengal Firms. On tests these were found to be sub-standard and unfit for use. Large stocks of these products were seized and destroyed by the Drug Control Administration in Maharashtra, Mysore and Kerala. Reports came in from different quarters that there are large number of manufacturing concerns in West Bengal producing sub-standard and spurious drugs and marketing in other parts of the country. In the face of these allegations the West Bengal Government constituted a Commission of Enquiry to probe, among other things, adulteration of drugs.
The Commission’s findings and the evidence given before it by witnesses on the extent of ‘malpractices’ in the drug trade are shocking. Experienced criminals manufacturing spurious drugs from factories located in unknown places are aided by medical practitioners, financiers and technical experts. Dealers in different areas in collusion with the manufacturers sell the spurious drugs. A few manufacturers have also built up an extensive and lucrative business in the sale of formulations containing ingredients of the British Pharmacopoeia under Unani or Ayurvedic names.

The Drugs and Equipment Standards Committee constituted by the Central Government was specifically asked to assess the extent of spurious as also of sub-standard drugs in the market. The Committee issued detailed questionnaires to medical and pharmaceutical associations, hospitals, manufacturers and State Drug Control authorities asking them to furnish details on the manufacture and sale of spurious drugs known to them. The Committee could not draw any positive conclusion on the extent of spurious drugs on the basis of the replies received as it felt the information to be inadequate. Nonetheless, the available data indicated the prevalence of spurious drugs in the market “though not of a considerable magnitude”. However, it was reported by the State Drug Control authorities that quite a number of cases of spurious drugs under the following categories were detected:

(a) Drugs whose labels show them to be manufactured by firms which are non-existent.
(b) A drug which is a close colourable imitation of a well-established brand of drug.

(c) A drug which is found to be different from what is claimed on the label.

(d) A drug which is manufactured by a party other than the manufacturer shown on the label.

On the question of sub-standard drugs, the Committee noticed that about 20 per cent of the samples were reported to be not of standard quality. Vitamin preparations constitute the major component among the sub-standard drugs. A detailed statement showing the total number of samples of drugs analysed during 1959 to 1964 in the country, samples found standard and number of samples found to be not of standard quality during these five years is given in Table V.

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<tbody>
<tr>
<td>1. Total No. of samples analysed.</td>
<td>4911</td>
<td>5358</td>
<td>5383</td>
<td>5233</td>
<td>4882</td>
</tr>
<tr>
<td>2. Samples reported standard</td>
<td>3822</td>
<td>4317</td>
<td>4455</td>
<td>3863</td>
<td>4028</td>
</tr>
<tr>
<td>3. Samples reported to be not of standard quality.</td>
<td>1091</td>
<td>1041</td>
<td>928</td>
<td>1350</td>
<td>854</td>
</tr>
<tr>
<td>4. Percentage of samples reported to be not of standard quality.</td>
<td>22.22%</td>
<td>19.43%</td>
<td>17.24%</td>
<td>25.6%</td>
<td>17.5%</td>
</tr>
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Some unscrupulous manufacturers, the Committee found, have been taking advantage of the prohibition scheme prevailing in most of the states and have been marketing alcoholic preparations and medicinal tinctures.

The menace of sub-standard drugs is even more serious than that of spurious drugs as the former, often products of fairly well-known firms, are more difficult to detect. Often the potency of drugs found sub-standard is only half of what is claimed on the label and sometimes as low as merely 10 per cent of what is expected! There have been instances of sub-standard injectibles which not only failed to have the desired curative effect on the patients but proved positively harmful.

According to reports of the Central Drug Control Organization, there is a certain quantity which is sub-standard in imported drugs as well. Control over the quality of imported drugs is exercised by the Central Government through its officers at the ports of Bombay, Madras, Calcutta and Cochin. On an average 6 to 12 per cent of the samples examined are found to be below standard. Contravention of labelling provisions and cases of date-expired drugs are also detected in a number of cases of imported drugs.

The evidence unmistakably indicates the persistence of the racket in sub-standard and spurious drugs. The drugs control machinery remains weak and faulty. The
punishments awarded to drug fakers are far from deterrent. The unwary and the gullible public fell easy prey to the machinations of the unscrupulous section of the industry and trade and it is impossible to assess the extent of damage thereby caused. Furthermore the practice of adulteration of drugs strikes at the very root of scientific medical practice and thereby indirectly helps the development of quackery and charlatanism.