

THE CONTROL OF PATENT MEDICINES

By NORMA O'CONNOR

THE term "patent medicines" should, properly speaking, be applied only to medicines sold under letters patent which are still in force. This was held by the court in *Pharmaceutical Society v. Fox* (1896), 12 T.L.R. 471, a case decided under the Pharmacy Act of 1868, which exempted the "making and dealing in patent medicines" from the provisions of that Act. The word "patent" attached itself to medicine in England in the early eighteenth century. In 1722, a patent of royal favour was granted for the first time to the owner of a medical product. Usually these patent medicines were sold as complete preparations, the formulae from which they were manufactured being exclusive property of the manufacturers. The majority of medicines for which a patent exists today are ethicals and pharmaceuticals. The term, however, is usually applied to those classes of medicinal preparations which are put up in uniform packages and which are offered for sale under distinctive trade-marked or copyrighted names. They are not patented, but are more correctly designated as proprietary medicines because the manufacturers have proprietary rights in the formulae or trade names. The Victorian Health (Patent Medicines) Act 1942 uses the phrase in this latter and wider sense, and this is the usage adopted here. The Act (section 2) defines the term thus:

"Patent medicine means any substance or mixture or compound of substance or biological product which is intended to be administered or applied whether internally or externally to persons for the purpose of preventing, diagnosing, curing or alleviating any disease, ailment, defect or injury or for the purpose of testing susceptibility to any disease or ailment but does not include

- (a) any such substance, mixture, compound or product extemporaneously dispensed or prepared for a specific and individual case; or
- (b) any such substance, mixture, compound or product

- (i) which conforms exactly to a standard formula . . . prescribed in the British Pharmacopoeia . . . or in the latest editions of the British Pharmaceutical Codex . . . or of the Australian and New Zealand Pharmaceutical Formulary . . . ; and
- (ii) which is sold or proposed to be sold under any name ascribed to it in the said Pharmacopoeia, Codex or Formulary."

It is interesting to note that if a pharmacist makes up a mixture of his own at the request of a customer it is not a patent medicine, but that if he mixes half a dozen bottles and places them on his shelves the mixture comes within the definition. Apart from this instance, the Act defines patent medicines by the nature of the products themselves. This can be compared with the definition adopted in 1915 by the Council on Pharmacy and Chemistry of the American Medical Association where the indicia is free competition. Here a patent medicine is "a preparation used in the treatment of diseases if such article is protected against free competition as to name, production, composition or process of manufacture, by secrecy, patent or copyright, or by any other means." Taken literally, this definition is narrower than contained in the Victorian Act, but as construed its scope is much the same.

A logical classification of patent medicines would probably be impossible but a working classification is useful for purposes of elucidation. Although definitions of patent medicines vary somewhat, in practice the same thing is usually meant, so our classification of patent medicines will include those articles which generally are accepted as such. The first distinction to be drawn is between preparations labelled and advertised for use by the physician on his prescription—the pharmaceuticals or ethicals—and those which are labelled for the purpose of self-medication and are sold to the public as packaged medicines. This latter class can be divided into non-secret and secret remedies. The class of non-secret remedies, i.e. remedies whose formulae are published, can be sub-divided into three classes:

(1) Genuine drugs manufactured in pharmacological laboratories and sold under many names. Sometimes the process of manufacture is patented or the name may be a registered trade mark. An example of this group is asperin.

(2) Remedies which owe their value to skilful combination. These consist of new combinations of known drugs, depending for their palatable and assimilable qualities upon the skill with which they are compounded. Examples of this class are the various emulsions of cod liver oil.

(3) Remedies consisting of known drugs with formulae disclosed, mixed for purposes of convenience or attractiveness with minute quantities of medically inert substances, the nature of which are trade secrets.

The class of secret remedies, i.e. those with undisclosed formulae, can be divided into four classes:

(1) Simple household remedies which probably prove beneficial to uncomplicated ailments when there is correct self-diagnosis.

(2) Dangerous remedies and drugs for improper or illegal purposes. Some of these should not be sold at all, for instance abortifacients; others ideally should not be sold except upon a doctor's prescription; others should not be sold for the purposes for which they are offered, for instance for young children. This group is not very large today, and many have a very limited sale or distribution, due in part to the perils attendant upon advertising, particularly in the case of those for illegal purposes.

(3) Fraudulent remedies. This group consists of alleged cures for diseases and conditions whose causes are unknown or which cannot be cured by medicines. Examples are alleged cures for bunions, diabetes, cancer, fits, rupture and deafness. These are, and are probably known by their makers to be, cruel frauds.

(4) Remedies which depend for their sale largely upon extravagant promises and exaggerated claims. This group consists of medicines containing no therapeutical value whatsoever, but the ingredients are usually quite harmless.

Another possible classification of patent medicines would use as a starting point the distinction between those which are recognized officially as of some value, since they are listed in the British Pharmacopoeia or some standard work, and those which are not listed.

As to the class of non-secret remedies, in most cases little control would be necessary in the public interest, assuming patent medicines are accepted as part of our national life. Yet many of the criticisms applicable to the worst types of patent medicines are applicable to this group as well.

Most patent medicine advertisements are full of unfounded claims of efficacy in curing disease. Remedies beneficial in the treatment of uncomplicated ailments are often recommended for cases they cannot benefit. Drugs in the preparation may mask symptoms and lead to a false sense of security. All this involves delay in seeking medical treatment, which is hardly beneficial to the patient and may be dangerous. Some patent medicines are highly dangerous as they contain poisonous substances or habit-forming drugs; and it is a sad reflection that even in Victoria, where there is legislation to prohibit or to control this, it is rarely enforced for very few of these medicines are labelled "Poison" or "Caution" as required. Self-medication has another harmful aspect in that infectious diseases may spread unchecked when hidden from the physician. The psychological aspect of suggesting symptoms to the individual by way of labels and advertising cannot be overlooked. Moreover, the maker of a patent medicine can alter its composition at any time without warning. The variable composition and the variable dosage of some of these preparations, due perhaps to inaccuracy or carelessness in the measurement of the ingredients, could be dangerous. Any number of names can be secured as trade marks for the same drug; for instance, acetyl-salicylic acid is sold as "Aspirin" and "Aspro". Manufacturers invent names of their own for drugs, so that often one sees an ordinary drug put up as a patent medicine under a fancy name at a fancy price. This is one thing patent medicine manufacturers have in common—the ability to charge a price for a preparation out of all proportion to its cost. Secret remedies are often put upon the market by persons ignorant of the effect of the ingredients, particularly in connection with the complaint it is supposed to remedy. In this connection it should be noticed that as the medicine is not made to meet the specific case, remedies offered for the same complaint, a cough for instance, may effect it for good or for evil according to its nature or cause. Some remedies are expectorant mixtures to increase coughing; others contain drugs to stop the cough. Often a cough should be facilitated to remove the fluid, while a man, for instance, with a varicose vein in his uvula needs to have his exhausting and useless cough stopped. The manufacturer who may be too ignorant or too profit-wise takes no account of this in his directions. A large number of secret remedies contain nothing which springs from medical, therapeutical or chemical knowledge.

Many of the claims made by manufacturers for their wares are clearly fraudulent. Following are examples of fraudulent claims:

Rheumatism

Sciatica, Lumbago or any kindred ailments

FOOT PLASTERS

draw out the uric acid through the pores in
the soles of the feet.

— Co., Melbourne.

(*The Sun*, 24/2/48)

“Everyone Sends for More Fo-Ti Tieng, the Elixir of Life Plant”

Nature’s Supreme Tonic-Food Life Sustainer . . .

The only known source of the Youth Vitamin X.

Li Ching Yun, born 1677, died 1933, discovered and
used this herb.

(*The World News*, 3/4/48)

The advertisement bears a sketch of an aged Chinese with the caption “Aged 256”. It is marketed by a Sydney firm.

Diabetic Sufferers

— Laboratories have found this treatment
invaluable in the aid of this distressing
complaint. . . . 2 months course — £2.17.6.

(*The World News*, 3/4/48)

ASTHMA

In 30 seconds —

relieves the worst bout you ever had

(*The Sun*, 1/3/38)

These claims are fraudulent and not mere trade-puffing. Indeed, it is a wonder a reputable paper would print some of the claims made for patent medicines. This whole question will be dealt with more fully later when advertising is considered.

It is to be noted that the most attractive fields for the patent medicine manufacturer are among diseases which are widely prevalent, or sufficiently serious to cause considerable suffering and anxiety. The manufacturer, an expert in psychology, is the master of methods of approach which play upon the susceptibilities of the more credulous section of the community. He holds out hopes where the doctor can hold out none. Although he attracts custom by the fact that in minor complaints a bottle of his mixture is more inexpensive than a visit to the doctor, in ailments where cure by medical means is still uncer-

tain, there is no upward limit to his demands. Perhaps part of the popularity of patent medicines is due to their secrecy, for secrecy has a fascination for most people. This secrecy enables ordinary ingredients to be passed off as marvellous discoveries concerning whose virtues the medical profession still remain in ignorance.

It should be noted that although the ethicals and pharmaceuticals come within the definition of patent medicine in the Health (Patent Medicines) Act of 1942, criticism certainly cannot be offered of them on the above grounds. They are made by reputable firms who have no desire to bring their products to the notice of the public but only to the notice of the medical and dental professions. Also, as pointed out earlier, many products serve a useful purpose as far as minor ailments are concerned. Most patent medicines on sale in Australia today are made by reputable firms who have no desire to break the law and who follow a certain standard of behaviour in their activities. But of course even the most reputable manufacturer is in the business to earn the highest profits possible. There are enough abuses in Australia today to refute any argument against control of this industry, and regulation is necessary as long as there is a possibility of abuse arising.

The Position in U.S.A.

The U.S.A. offers vast fields for exploitation by the unscrupulous patent medicine manufacturer and examples of some of the amazing swindles perpetrated can be found in the Journal of the American Medical Association. Attempts have been made to control the industry by legislation, but these have not been particularly successful. In attempting to give protection to the public the state laws primarily restrain retail sale. Most states have food, drug and cosmetic acts and pharmacy and anti-narcotic laws, while municipalities exercise some little control through health ordinances.

There is no federal legislation directed specifically at patent medicines, but some indirect control is exercised under the Federal Trade Commission Act which regulates, although not apparently very effectively, the advertising of these and other articles, the Harrison Anti-Narcotic Act, the Marihuana Tax Act, the Serum and Virus Act, the Insecticide Act of 1910, the Caustic Poison Act and the Postal Acts. Under the latter legislation the Postal Department may refuse to transmit both

material of the nature of patent medicine concerning which false claims are made and literature making such false claims.

More direct control is exercised by the Federal Pure Food and Drugs Act of 1906. The object of this legislation was to protect the pockets and safeguard the health of the consuming public. By denying the facilities of importation and interstate transportation the Act prevents the sale in interstate commerce of products that are adulterated, misbranded or dangerous to health. It establishes minimum standards of strength, quality and purity for a number of drugs and sets up specifications for the labelling of foods, drugs, cosmetics and therapeutic devices. As interpreted, this Act prohibits neither the misbranding nor adulteration of food and drug articles, but only their shipment or delivery for shipment in interstate commerce. Section 8 prohibits inter alia the following types of misbranding:

(1) Where the label is affirmatively false or misleading. This includes booklets enclosed in a carton only where false or fraudulent therapeutic representations are concerned.

(2) Where the label fails to state the quantity or proportion contained in the article of ten drugs enumerated in the Act.

Prior to the Sherley Amendment, the Supreme Court held that the term "misbranded" meant false statements as to the identity or quality of food and drugs and not to declarations of therapeutic or curative effects. Such "false and fraudulent representations" are now prohibited by the amendment. It is necessary to prove actual intention to deceive, but this intention may be inferred from the circumstances of the case. The representation is not false if a real difference of opinion exists between rival schools of medical practitioners upon the subject; aliter if there is a consensus of opinion denying its truth. Judicial notice is taken of the advance of medical knowledge so that a preparation which is accepted in one decade may fail to pass muster in the next.

A large number of criticisms can be offered upon the scope of the Act and the manner in which it has been interpreted. In the recent case of the U.S. v. Seventeen Bottles it was held that even a label could legally be both false and misleading. Interstate shipment is the crime, but with skill the law on this point can be circumvented. In the field of therapeutic representations, the courts have drawn a fine line between those preparations which claim to "cure" a condition and those which

claim merely to "remedy" or "relieve". Further, other poisons beside the ten which must be enumerated and habit-forming drugs may be in the article without disclosure being required. The failure of the Act may be traced to the fact that it has become corrective rather than punitive or preventive. Many of the larger firms, immune as corporations from imprisonment, regard fines and confiscations as a moderate licence for carrying on business. The play of politics has had its effect in defeating the policy of the enactment.

However, the Act has achieved some positive results, as can be seen by the large number of cases which have been tried under its provisions. By 1932 there had been 18,450 such cases, but little publicity was given to them in the press. Moreover, in the years immediately following the Act a number of well known patent medicines disappeared from the market.

Voluntary, or private, control in the U.S. is quite advanced. Consumer co-operatives investigate claims made on behalf of any article and report on such claims to the individual members. The Council on Pharmacy and Chemistry of the American Medical Association asks manufacturers to send in their preparations to be tested. If the medicine consists entirely of, or contains as one of its constituents, some new drug the Council collects hospital reports on its efficacy. If the Council approves of the preparation it permits the manufacturer to affix a stamp to his product stating their approval, and the formula is printed in their publication *New and Non-Official Remedies*.

Both legislation and voluntary investigation have had sufficient effect upon the public mind to force the Proprietary Association of America to announce that it is engaged in a "long term public relations campaign" to vindicate the fair name of the industry. The Association issues propaganda pamphlets and the Vice-President, who is able to affix the imposing letters M.D. to his name, writes to the newspapers objecting to his Association's products being termed "patent medicines" and protesting that American advertising is not so blatant as the English, so that rules adopted by the Newspaper Proprietors' Association of England to curb improper medical advertising would be unnecessary in that country. Pamphlets point out that official remedies, pharmaceuticals and patent medicines all come equally within the compass of legislation designed to curb abuses in the manufacture and sale of medicines. A quotation concern-

ing what a pamphlet calls "a new trend in the proprietary industry" is of interest:

"Through acquiring pharmaceutical firms, the proprietary manufacturers are narrowing the gap between the two fields. . . . This may prove of great benefit to the public since, through advertising and direct sale, *proprietaries* are by and large the *greater money makers* in the drug field and their profits can be invested in pharmaceutical subsidiaries for increased scientific research."

This is an indirect admission, to say the least of it, that prices charged for patent medicines are out of proportion to the cost of the ingredients and also that the prescription of the doctor, which probably contains pharmaceuticals, is of "great benefit to the public" as compared with self-medication with patent medicines. However, the Association has improved matters in the industry. It is very strong, containing the manufacturers of 80 per cent of patent medicines in the U.S., and would not injure itself in its public relations campaign by including in its ranks disreputable manufacturers of patent medicines of the worst type. The Association also exercises some control over advertising by reviewing all copy *voluntarily* submitted to it by its members. A decided improvement in advertising could only be expected if the Association had powers of compulsion so as to be able to prevent its members, through a sanction of some kind, from infringing a certain minimum standard.

The Position in England

There was no attempt at effective control of patent medicines in England until 1941, although there had been agitation and ineffective attempts at control before the turn of the century. In 1912, Parliament appointed a Select Committee "to consider and inquire into the question of the sale of patent and proprietary medicines and medical preparations and appliances and advertisements relating thereto". The committee reported upon the situation resulting from the existing law as follows: "For all practical purposes, British law is powerless to prevent any person from procuring any mixture, whether potent or without any therapeutical activity whatever (so long as it does not contain a scheduled poison), advertising it in any decent terms as a cure for any disease or ailment, recommending it by bogus testimonials and the invented opinions and facsimile

signatures of fictitious physicians, and selling it under any name he chooses, on the payment of a small stamp duty, for any price he can persuade a credulous public to pay." The committee carried out a thorough research into the industry and submitted findings which it hoped would lead to the abolition of abuses. The small extent of the effect which these findings and recommendations had upon the legislature can be seen from the statement made by Halsbury (Vol. 23, p. 378) of the law on the subject in 1936. Halsbury said: "The sale of proprietary medicines is not regulated by any statute save that certain proprietary medicines are subject to medicine stamp duty and might not be sold by persons without licence to do so."

The Food and Drugs Act 1938 (section 3) provides that if a person sells to the prejudice of the purchaser any food or drug which is not of the nature or substance or quality of the food or drug demanded by the purchaser, he shall be guilty of an offence unless he can prove *inter alia* that the article supplied was a proprietary medicine. The manufacturers and retailers would obviously be pleased with this section, although they might be caught under section 6, which contains no such proviso. That section states that it is an offence for a label, wrapper or advertisement to falsely describe a food or drug or to be calculated to mislead as to the nature, substance or quality of the article.

Protection of a more complete nature was given to the public by the Pharmacy and Medicine Act 1941. The restrictions in this Act apply to a "substance recommended as a medicine". The substance can be so referred to on the article itself, its label or wrapper or on any placard or document or in any advertisement published after the 7th August, 1941. The reference must be in terms calculated to lead to the use of the substance for the prevention or treatment of any ailment, infirmity or injury affecting the human body (section 17 (1)). It was held in *Nairne v. Stephen Smith and Co.*, (1943) 1 K.B. 17, that a run-down condition is a sufficiently specific ailment. By section 11, no person may sell by retail any article consisting of or comprising of a substance recommended as a medicine or supply any such article as a sample unless the composition of the medicine is written legibly on the article, its label or container. However, any article made up and supplied for the use of a particular person, being an article prescribed by reference to the needs of that person, is excepted from the operation of the section. Section 12 restricts the sale of medicines by unauthorized persons.

Those who may retail articles recommended as medicines are (a) registered medical practitioners, (b) registered dentists, (c) authorized sellers of poisons, and (d) pharmacists carrying on on their own account businesses which comprise the retail sale of drugs. Section 8 (1) of the Act prohibits any advertisement which refers to an article in terms which are calculated to lead to the use of that article for the treatment of human beings for an enumerated list of diseases. Section 10 provides that if advertisements refer to articles in terms calculated to indicate that they were manufactured, produced, imported or sold by the person charged there is a prime facie presumption that that person took part in the publication of the advertisement, but without prejudice to the liability of any other person.

Provision is made for the enforcement of the Act. By section 15 (1) the Pharmaceutical Society of Great Britain is under a duty to enforce these sections and for that purpose may employ their inspectors. A foods and drugs authority within the Food and Drugs Act 1938—any local council—has power to enforce these provisions and may institute proceedings (section 16). But no prosecution under sections 8 or 9 may be instituted without the consent of the Attorney-General or Solicitor-General (section 10 (4)). The Act abolished the stamp tax on medicines.

It should be noted that the Act suffers from the same defect as the American legislation as the penalties for breaches are fines or imprisonment. Companies might merely charge fines to their overhead expenses. There should be provision for liquidation of companies for repeated offences.

In 1908 and 1912 the British Medical Association published two books entitled *Secret Remedies* and *More Secret Remedies*, in which claims made for various patent medicines are investigated. The books contain "a juxta-position of analytical facts and advertising fancies!" These books received little notice or publicity from the press, some newspapers and journals refusing to receive copies. It is small wonder that the public continued to buy many worthless or even harmful remedies. A certain brand of "Pink Pills" received the attention of the B.M.A. in their books, and of the Parliamentary Committee, yet as there was no publicity these pills still continued to be in demand and are on sale in Victoria today. It may be that after disclosure firms might change and improve the formulae of their products, but even so, if the public had been made aware of the facts, the prestige and credit of the manufacturers would have suffered.

A considerable change of policy on the part of newspaper owners today can be seen in their adoption of rules to curb the improper advertising of patent medicines.

The Position in Australia

The Commonwealth Government has taken little interest in the matter. The Commonwealth Department of Health also is little interested, officially at any rate. The Commerce (Trade Descriptions) Act 1905-33, which is administered by the Customs Department, contains some provisions under which it is possible to control the importation of patent medicines. Under these provisions, claims made with regard to certain English medicines have had to be modified before they were allowed into Australia. An instance of this given to the English Parliamentary Committee was the deletion of a page of a booklet accompanying certain pills. By section 3, "false trade description" means a trade description which, by reason of anything contained therein or omitted therefrom, is false or likely to mislead in a material respect as regards the goods to which it is applied. Section 9 declares that "No person shall import any goods to which a false trade description is applied", and section 10 prohibits their import. It can be seen that this Act would provide quite a worthwhile means of control if its provisions were strictly applied.

The topic of control of patent medicines received Commonwealth consideration by the Department of War Organization of Industry in 1942-3. A scheme for registration of patent medicines and incidental disclosure of their contents was worked out in consultation with the medical profession and ultimately found form in the National Security (Proprietary Medicines) Regulations (1942-3). These regulations were drawn up partly to control the use of materials in wartime and partly to control the industry with a view to protecting the public. By section 3 "proprietary medicine" is defined as "any medicine or compound of medicines prepared according to any formula, whether secret or not, which is held out by advertisement, label, or otherwise in writing or by broadcast by means of wireless telegraphy, as efficacious for the prevention, cure or relief of any malady, ailment, infirmity or disorder affecting human beings, or for increasing height, increasing or reducing weight or increasing personality or reproductive capacity." By section 4 (1) manufacturers were to furnish to the Director-General (inter alia):

(a) The name of the manufacturer and, if the proprietary medicine is manufactured outside the Commonwealth, the name of the agent in Australia.

(b) A full statement of the formula of the proprietary medicine.

(c) A sample of every container and of every label, package, leaflet, pamphlet or other printed matter (whether packed with the proprietary medicine or not) used in connection with or relating to the proprietary medicine and a copy of the text of every advertisement relating to the proprietary medicine which was published in any newspaper between the fifteenth day of August, 1942, and the first day of September, 1942.

This was amended in 1943 in that the "regulation shall not apply with respect to any proprietary medicine which is prepared and sold according to the specifications for preparation and the standards of composition prescribed in the British Pharmacopoeia or the British Pharmaceutical Codex and is sold under the name under which it is described in the British Pharmacopoeia or the British Pharmaceutical Codex." By the amendment of 1943, it is provided that "any officer or employee engaged upon any duties connected with the administration of these regulations shall not disclose any information furnished in pursuance of the last preceding regulation except, in the course of his duties, to the Director-General" (section 2). By section 6, "the Minister may, by order, prohibit the manufacture or the sale of any proprietary medicine if he is satisfied that it has not the effects which are claimed on its behalf or does not satisfy the purposes for which it is sold, or that it is of a dangerous nature or is liable to produce abortion or miscarriage." Section 8 limits the scope of advertising, and section 3 of the amending regulation provides that "a person shall not, by way of advertisement or otherwise, in order to promote the sale of any proprietary medicine, publish any statement which is false or likely to mislead in any material respect as to the nature or composition of the proprietary medicine or as to its efficacy for the prevention, cure or relief of any malady, ailment, infirmity or disorder affecting human beings, or for increasing height, increasing or reducing weight or increasing personality or reproductive capacity, as the case may be."

These regulations were disallowed by Parliament in 1943 and were never put into operation, so that the Commonwealth

exercises virtually no control in this field. The section in the amending regulations dealing with advertisements provides an interesting attempt to tighten up the usual prohibition upon false and misleading statements. Although the regulations aimed ostensibly at conserving materials and newsprint, it is to be regretted that they were disallowed, as uniformity of control throughout Australia could hardly be anything but beneficial. Legislation varies from state to state, and although the average content of the statutes is more or less equivalent to that contained in the Victorian Food and Drug Provisions and Poisons Act, discrepancies do exist, as can be seen from differing formulae and the varied claims of efficacy made for the same patent medicine in different states, in an effort to comply with the local legislation. Victoria has possibly the strictest Poisons Act. That of New South Wales is not so strict; for instance benzedrine is sold over the counter in that state, and it is difficult to add new drugs to the poison list. Further, Victoria is the only state which has attempted direct control of patent medicines.

The Position in Victoria

Beside the Poisons Act and the Health (Food and Drugs) Regulations, control is also exercised in Victoria under the Health (Patent Medicines) Act 1942, which came into operation on 2nd February, 1948. The Act, which received little opposition on its passage through Parliament, is based upon the Stock Act which is designed to protect the health of animals, and contains some of that Act's defects plus a few peculiar to itself.

The purpose of the Act is stated in the preamble as "to provide for the registration of Patent Medicines and to regulate the sale and advertisement thereof." Section 1(1) states that the Act is to be read with Part XII of the Health Act 1928 and any Act amending the same. The definition of "patent medicine" in the Act was quoted above where an anomaly arising thereunder was pointed out. By section 3 an Advisory Committee is constituted. The committee consists of four persons: (1) a health officer of the Department of Public Health, who is the chairman and exercises a casting vote; (2) a teacher of or lecturer in pharmacology or materia medica; (3) a registered pharmaceutical chemist; and (4) a representative of the patent medicine manufacturers' section of the Proprietary Articles Trade Association of Victoria. The inclusion of the provision under which the last-named member of the committee

is appointed was the result of an amendment to the Act in the Legislative Assembly, and was criticized most strongly in the Council. The inclusion of such a representative would have, and has in fact had, little effect either way, except perhaps that it would serve to remind the committee of some of the essentially practical and everyday aspects of the problem.

By section 4 (1) every wholesale dealer in patent medicines must make an application for the registration of that patent medicine, supplying information, inter alia, upon—

- (i) the prescription, stating the constituent parts in their respective proportions, and those constituent parts thereof which are claimed to have prophylactic, diagnostic, therapeutic or susceptibility-testing value; and in the case of a patent medicine which is a biological product, the composition thereof;
- (ii) full directions for the use and administration or application of such patent medicine; and
- (iii) a statement of the purposes for which such patent medicine is claimed to be efficacious, i.e. a statement of
 - (a) diseases, ailments, defects or injuries which it is claimed to prevent, diagnose, cure or alleviate; or
 - (b) the diseases or ailments the susceptibility of which it is claimed to provide a test,when administered or applied in accordance with the directions.

The information received as to the prescription is deemed confidential. The section also makes provision for applications for registration of additional or altered patent medicines. All applications for registration are submitted by the Chief Health Officer to the committee for its report and recommendation. Registration is allowed for "approved uses" only, that is for those purposes which the Chief Health Officer, upon the receipt of the committee's report and recommendation, determines.

Section 6 (5) provides that a patent medicine shall not be registered if it fails to comply with the Health Acts, Poisons Act and regulations thereunder.

A manufacturer may appeal from a conclusion to the committee, from there to the Chief Health Officer, and from there to a judge of the Supreme Court. By section 8 (1) the Chief Health Officer is directed to keep a register of all patent medi-

cines which in accordance with his determination or the judge's decision are to be registered. The register is to show the name of the medicine, its prescription, and the purpose for which it may be recommended. By section 9(1) every package of a registered patent medicine shall bear thereon the words "Registered under the Health (Patent Medicines) Act 1942", and no other reference to the Act may be made. This prevents any suggestion that a medicine is approved or recommended by the Government. Section 10 provides for registration to be cancelled on certain offences by a wholesale dealer, namely if the patent medicine does not conform with the registered formula, or if an unregistered medicine is sold. The Act is not very clear upon the punishment of the offence of selling an unregistered patent medicine.

Section 208 of the Victorian Health Act 1928 corresponds to section 3 of the 1938 English Food and Drugs Act mentioned earlier, and contains the same proviso. The Act contains an early attempt to control patent medicines. By section 223 the Commission of Public Health has power to examine and report on any food or drug which is advertised or offered for sale. Section 225 provides that:

- "(1) The Commission may on the advice of the Food Standards Committee prohibit the sale of any patent or proprietary medicine which in the opinion of the Committee is deleterious to health.
- (2) Every person who sells or advertises for sale any patent or proprietary medicine the sale of which has been so prohibited shall be guilty of an offence against this Part.
- (3) For the purposes of this section 'patent or proprietary medicine' means any medicine or medicinal preparation for external or internal use which the maker or vendor has any exclusive right to make under the authority of letters patent or which is recommended to the public by advertisement price list handbill or label for the prevention cure or relief of any human ailment or physical defect."

Notice that the definition of patent medicine in this section is narrower than that in the Patent Medicine Act, but the later and wider definition should prevail.

Regulation 76 (7) of the Food and Drugs Standard Regulations (1939) provides as follows:

“No person shall publish any label or advertisement relating to any drug, medicine, or medicinal preparation for sale which contains any statement or claim which directly or by implication indicates or suggests—

- (a) that it will remedy or cure asthma, Bright's disease, cancer, tuberculosis, cerebro-spinal meningitis, diabetes, dropsy, epilepsy, fits, gout, infantile paralysis, plague, influenza, locomotor ataxia, lupus, paralysis, rupture, scrofula, venereal disease, blood pressure, rheumatoid arthritis, pyorrhoea, piles, eczema, gall-stones, or any disease or abnormal condition arising from sexual intercourse or sexual gratification; or
- (b) that it is a universal panacea, infallible, a kidney cure, liver cure, blood purifier, a skin food, a hair food, a rejuvenator, or a nerve food; or
- (c) that it is a cure for baldness, corpulence, female complaints, or for drunkenness or the liquor habit; or
- (d) that it will develop the bust, raise the height, or eradicate wrinkles; or
- (e) that it is an abortifacient; or
- (f) that it is beneficial for sexual weakness or impotence.”

Regulation 76 provides that certain drugs are to be declared on the label.

The Poisons Act aims to prevent the placing in medicines of dangerous substances or substances which are better prescribed by a physician. Concerning the less dangerous drugs which are permitted as ingredients, the Act required that the amount of such drugs should be printed on the label, which should be marked “Poison” in red. The committee set up under the Patent Medicines Act has had numerous medicines submitted to it containing undeclared poisons. It is estimated that the Act is observed only in 10 per cent of cases, yet there have been scarcely any prosecutions under the Act. A Scientific Advisory Committee considers all new drugs, and if there is any danger of toxicity from over-dosage a new drug is placed on the Dangerous Drugs List.

How the Health (Patent Medicines) Act 1942 Works

The Act must be read in conjunction with the Poisons Act and the Health Act and regulations thereunder. The Pharmacy Board administers the law in relation to poisons and dangerous

drugs. The Health Department administers the food and drugs regulations. There were only few prosecutions under these provisions, partly because manufacturers were sufficiently ingenious to circumvent the words used. Medicines are not claimed to "cure" or "remedy" the diseases listed in Regulation 76 of the Food and Drugs Standard Regulations, but any day in any newspaper one can read that medicines will "smash" or "relieve" such listed diseases as asthma, diabetes, fits, influenza, rupture, blood pressure, rheumatoid arthritis, pyorrhoea, piles and eczema. Advertisers run directly contrary to the provisions of subsection 7 (b) and (c) continuously.

The committee has found the blanket provisions of Regulation 6 (6) very useful. This provides: "No person shall include or cause to be included in the label any statement, claim, design, device, fancy name or abbreviation which is false or misleading in any particular concerning the food, drug or substance contained in the package or concerning the quality or the physiological action or the therapeutic or nutritive value or in relation to the place of origin of the said food, drug or substance."

This section is more helpful than section 10 (1) (c) of the Patent Medicines Act, which provides that any person who so publishes an advertisement which contains "(ii) any claim or statement which is false or wilfully misleading shall be guilty of an offence" (under the Act).

"False or wilfully misleading" is wider than "false and misleading" in the narrower field in which it applies, for "wilfully" extends the scope of the section to include a false promise.

As to the subject matter with which the committee deals, although it includes ethical preparations, biological products and anything used for testing, as well as packaged medicines, the committee has no power to interfere with a patent medicine mixed extemporaneously by a pharmacist. This is the result of proviso (a) of section 2. As about 900 pharmacists in Victoria make up their own medicines, it can be seen that there is a definite gap in the law.

A difficulty also arises under the system of appeals. It is quite possible that a judge of the Supreme Court would order the registration of a patent medicine which had been refused for a good reason by the Chief Health Officer and the committee. A judge might accept as authoritative a book which modern medicine would not accept. The layman does not

realize that there is a difference between pharmacy, which is the mere compounding of drugs, pharmacology, which is the study of the action of drugs, and therapeutics, which is their employment in medicine. Now there are two or three books which have had their origin in pharmacopoeias and are standard works. To the pharmacist who has had little training in the action or use of drugs these books are of quite good standing, although many of the things in them are not of good scientific standing; for instance they contain a lot of old-fashioned home remedies which according to modern pharmacology and therapeutics have no scientific basis whatever. As these books are accepted by many pharmacists, it is possible that they will be accepted by the court, and in this way much of the committee's work will be undone. Further, it should be noted that the function of the committee is merely advisory, so that their expert opinion can be disregarded by the Chief Health Officer.

It should be noted that the committee cannot refuse registration if a medicine is dangerous provided its claims are true, and also provided it does not run foul of any other Act. The committee lacks power to prohibit the use of any preparation at all, but it can prohibit on the grounds of infringement of the Health and Poison Act, and the blanket provisions of the regulations are useful for it makes it impossible for a medicine containing nothing of therapeutic value to be registered, even if it contains nothing definitely harmful.

The committee can only modify or disallow claims made by the manufacturer for his products; it cannot suggest alteration of these claims. In practice, the committee does suggest alterations, but the manufacturer is not bound to accept these. The committee has power merely to strike out all or some of the claims. It cannot exercise any control over the price the manufacturer asks for his wares, and yet overcharging is probably one of the greatest abuses it meets. Some of the best work of the committee has been to enforce regulations and provisions which have remained unenforced for as much as twenty years. A difficulty facing the committee is that once a medicine is registered it is impossible to deregister it if future scientific research shows it is worthless.

It is interesting to compare the method of control adopted in Victoria with that adopted in England. The English Pharmacy and Medicine Act aims at control through restriction of the retail trade to certain registered persons, plus the disclosure of

the formula on the article, while the Victorian Act aims at control through registration of the article. The English Parliamentary Committee did not think the exhibition of formulae was of any practical value. They urged that the public would not know what was meant by such terms as "phenolphthalein" or "acetyl-salicylic acid", while manufacturers would use the most impressive words they know for commonplace objects, so that soap, for instance, would pose as sodium-oleate and stearate. The committee recommended a system similar to that adopted in Victoria. The Victorian Parliamentary Committee on Patent Medicines also achieved no immediate practical results and even less publicity; most of the copies of its report have been destroyed.

It is too early yet to see what effect the Victorian legislation will have as the committee has been constituted barely two months. However, it is very keen to exercise its powers to the limit and to put into effect provisions which have hung in abeyance, for all practical purposes, since they were passed. During the Parliamentary Debate upon the matter, members estimated that from 20,000 to 30,000 substances or mixtures will come under the Act. The manufacturers must feel that the new legislation will provide effective control, judging from the following extract:

"A conference representing the leaders of the drug and allied trades in Australia decided today to protest against the proclamation of the Victorian Act to provide for the registration of patent medicines and to regulate the sale and advertisement of them. It was pointed out that not only was the time inopportune for the proclamation of such an Act, but, with the present tendency of overseas companies to establish plants within Australia, the coming into effect in Victoria of the measure would tend to be interpreted by them as restrictions from which they were in many cases escaping. The view was also put forward that other States would benefit at the expense of Victoria. Complaints were also made that the Act was discriminatory against the manufacturer." (*Age*, 24/3/48.)

However, on the wording of the Act it should be noted that single samples can still be sent on request to Victoria by post from other States. Many magazines in which advertisements of patent medicines are published are distributed through many States.

Advertising

Even persons who do not object to certain facets of the patent medicine trade must object to certain of its advertising practices. There has been a marked improvement in Victoria over recent years due in part to newsprint rationing and in part to the voluntary adoption of a code by the manufacturers, to whose ethical committee advertisements are submitted. But the quack or charlatan whose one object is to defraud the public would have no desire to belong to a reputable association. His advertisements would meet the minimum requirements only of the newspaper proprietors and lethargic officials. It should be remembered too that many large firms in England, Australia and U.S.A. do not advertise directly to the public: these are the manufacturers of ethicals or pharmaceuticals. They advertise in medical journals and to medical men and dentists via the post.

Medicines today are advertised everywhere—in wrappings, pamphlets and newspapers, on bill-boards and over the air. A frequent device is to link the product with the medical profession in some way, for instance by photographs of alleged doctors in advertisements, by the name of the product itself—for instance Dr. Williams' Pink Pills, Dr. Jones' Tonic Tablets—or to advertise over the air through a serial concerned with the medical profession. Most publications carry advertisements for these products and those which contain some of a particularly fraudulent kind usually carry a number of other advertisements from which the credulity of the readers is evident. A typical device of the advertiser is to suggest symptoms to the mind of his victim. Here is a typical example from *The Sun* (1/3/48): "If you are losing weight, worn-out, nervous, depressed, with no appetite, heed these warnings—or worse may come!" Other devices occur readily to mind—testimonials, references to new scientific discoveries, photographs of scientific apparatus and slides of bacteria and so on.

There have been a number of statutory provisions dealing with advertisements, but they have had little effect, due in the main to the fine distinctions courts have drawn in the interpretation of the Acts, as well as to the fact that there is no official specifically charged with the enforcement of the provisions. By section 226 (1) of the Health Act—

"(1) Every person who publishes or causes to be published any statement which

- (a) is intended or apparently intended by such person or any other person to promote the sale of any article as a medicine preparation or appliance for the prevention cure or relief of any human ailment or physical defect; and
- (b) is false in any material particular relating to the ingredients composition structure nature or operation of the medicine preparation or appliance or to the effects which have followed or may follow the use thereof,

shall be guilty of an offence."

"Publications" here apparently does not include labels or packets. A publisher of a newspaper can be convicted under this section. Sub-section 4 makes it an offence to sell in Victoria any publication published outside of Victoria containing any statements which infringe (a) and (b). It is quite obvious that these sections can have had little operation.

Regulation 76 of the regulations made under the Health Act 1939, which is referred to above, is certainly not observed, as the following advertisements show:

Asthma
Quick Relief with ——— (The Sun, 1/3/48)

Eczema, Psoriasis,
Dermatitis, Hives,
Infantile Eczema
Our Genuine Special Lotion gives amazing
results even in chronic cases.
(Worlds News, 3/4/48)

Wake up your liver bile . . .
get those two pounds of bile working and feel
up and up. (The Sun, 1/3/48)

Other instances of the advertising of diseases which patent medicines may not "remedy or cure" have been given before. Advertisers get around this difficulty by offering to "fight" pain, give "quick relief" or "results", or "smack" infection. It is often amazing to note how advertisers offer to cure with the same product conditions which are superficially similar but fundamentally different.

Sub-regulation (8) provides that "no person shall publish any label or advertisement which includes any fictitious testi-

monial." Regulation 103 provides, inter alia, that every person who—

“(c) publishes any advertisement or statement or uses or exhibits in any manner whatsoever any pictorial or printed matter in relation to any food, drug, article, substance, or appliance which is false in any material particular, or misleading, or likely to mislead”

shall be guilty of an offence against the regulations and be liable to a fine. The blanket provisions of Regulation 6 (6) are useful with regard to “false or misleading” statements on the label.

The most recent provisions upon the subject are contained in the Health (Patent Medicines) Act 1942. Section 10 (1) provides that any person who publishes an advertisement which contains

- (i) any claim or statement as to the efficacy or suitability of such patent medicine for use for any purpose other than those in respect of which it is registered, or
- (ii) any claim or statement which is false or wilfully misleading

shall be guilty of an offence against the Act. As pointed out above, the addition of “wilfully” extends “misleading” to cover a false promise.

With the legislation on the subject thus re-enforced, it should be possible to lift the minimum standard of advertising. Actually, to make for certainty in the application of the statutes, an amendment is necessary to prevent advertisers escaping by a clever choice of language.

It has always been difficult to obtain convictions for fraud regarding the claims made for patent medicines. To prove fraud it is necessary to show four things: (a) a false representation, (b) of fact and not of opinion, which (c) was made with the intention that it should be acted upon by the other party (d) which representation must be the inducing cause of that other party's act. A prosecution usually breaks down for one of two reasons: (1) it is impossible to prove guilty knowledge—that is, the wilful mis-statement or false representation—because the medicine is sold by ignorant persons; or (2) the defendant is able to produce witnesses who state that the medicine has been beneficial to them.

The Commonwealth regulations referred to above also made provision with regard to advertising.

Conclusion

After a comparison with the situation in two countries whose system of law is familiar to us, it appears that the situation in Victoria is relatively good. Certain gaps and anomalies in the new law have been pointed out but these do not constitute serious weaknesses. It is too early yet to say whether the new scheme will be allowed to lapse like those of the past, but if not, a process of rapid reform should result. The committee has already made a good start.

The argument of manufacturers is that the family medical chest is an institution, and one that should be encouraged, but publicity and education should do much to make the public realize that self-medication cannot pay except in clear cases of minor ailments. It is to be hoped that regulation of patent medicines will not in the future be turned into a political question, and that the judiciary should be keen to put into operation the policy of the legislation, and not allow defendants to escape upon mere technicalities.

It is unfortunate, however, that there is no uniformity in the legislation upon the subject among the states. If this is not achieved by Commonwealth legislation it is to be hoped that it will be by co-operation between states. The people should consider the uniform control of patent medicines not a matter of war-time emergency but a matter of peace-time necessity.