THE PHARMACEUTICAL INDUSTRY: PRESCRIPTION DRUG INFORMATION CONTROLS IN AUSTRALIA AND THE UNITED STATES

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A. PRACTITIONER INFORMATION CONTROLS

1. Introduction

Prescription drugs are complex chemical substances which despite their undoubted benefits are capable of causing severe and in some cases irreversible injuries. The drug Thalidomide tragically demonstrated that adverse effects can extend to the unborn child. A more recent example is provided by the drug diethylstilboestrol (D.E.S.) which was widely prescribed some years ago to prevent miscarriages. Recent medical evidence suggests a link between the drug and adenocarcinoma of the vagina in the offspring of women treated with the drug. Because of the risk of injury to consumers if a drug is inappropriately prescribed it would be reasonable to suppose that advertisements would inform doctors of the possible side effects and adverse reactions associated with particular drugs. It appears however that in many instances, prescription drug advertisements do not provide adequate prescribing information, but instead employ image appeals and extravagant and excessive claims in order to persuade a doctor to prescribe the advertised drug.[1]

Prescription drugs are promoted solely to the medical profession in contrast to proprietary medicines which are advertised and sold direct to the public. The major ways in which prescription drugs are promoted are by means of sales representatives, direct-mail and journal advertisements. Journal advertisements include materials published in subscribed journals as well as materials in periodicals which are sent free of charge to practitioners. The latter category comprises drug company house publications and journals published by independent commercial enterprises.

A comprehensive documentation of misleading advertisements is contained in a recent American study which compared the content of prescription drug advertisements disseminated in the United States with

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1 G. V. Stimson, "The Message of Psychotropic Drug Ads" (1975) 25 (3) *Journal of Communication* 159; S. Chapman, "Submission to the Australian Senate Standing Committee on Social Welfare Medication Inquiry" *Hansard* 30 July 1979, 1360; G. V. Stimson, "Do Drug Advertisements Provide Therapeutic Information?" (1977) 3 *Journal of Medical Ethics* 7.

that of advertisements for identical products published in a number of South American countries.[2] The study compared the product information contained in an American commercial compendium entitled the *Physicians' Desk Reference* (P.D.R.) with that contained in comparable South American reference volumes. In the United States this type of product information is subject to the positive disclosure requirements of the *Federal Food, Drug and Cosmetic Act* 1938. No comparable information controls exist in any of the South American countries included in the study. In some countries there is a complete absence of government control. A general finding of the study was that:

> "[i]n nearly all of the products investigated in this study, the differences in the promotional or labelling material were striking. In the United States, the listed indications for each product were usually few in number, while the contra-indications, warnings, and potential adverse reactions were given in extensive detail. In Latin America, the listed indications were far more numerous, while the hazards were minimized, glossed over, or totally ignored. In some cases, only trivial side-effects were described, but potentially lethal hazards were not mentioned."[3]

It was specifically noted that Latin America did not provide an isolated example of this type of promotional behaviour. In the case of one particular drug similar differences were found in copy published in France, Spain, Italy, New Zealand and Australia.[4]

The lack of prescribing information in drug advertisements would be of less concern if practitioners had access to adequate, reliable and independent drug information. A problem common to all medical practitioners is to keep current their knowledge of newly introduced drugs. Knowledge gained in medical courses quickly becomes obsolete: although the number of significant new discoveries is small (usually not exceeding five in a year), there are approximately two hundred new brands launched on the market each year. Problems confronting the medical practitioner are compounded by the lack of post-graduate refresher courses. Because of the reliance placed by the medical profession on promotional materials as a source of prescribing information, it is essential that the law compels disclosure of adequate prescribing information in these materials.

2. American controls

(a) *Labelling Regulations*

In the United States prescription drug promotional materials are subject to the provisions of the *Federal Food, Drug and Cosmetic Act* 1938. The regulatory authority of the Federal Food and Drug Administration (F.D.A.)

[2] M. Silverman, "The Epidemiology of Drug Promotion" (1977) 7 *International Journal of Health Services* 157.
[3] Ibid. 159.
[4] Ibid. 161.

is derived from this Act. The F.D.A. has jurisdiction over "labels" which are defined as matter affixed to the package and "labelling" which is defined as material "accompanying" a product. Labelling materials include brochures, booklets, mailing-pieces, bulletins, catalogues, audio-visual materials and reference materials such as the *Physicians' Desk Reference*.[5]

A new drug may not be commercially marketed in the United States, (or imported or exported from the United States) unless it has been approved as safe and effective by the F.D.A. Approval is based on the contents of a New Drug Application (N.D.A.) compiled by the sponsor of the drug. Once commercial clearance has been granted, approved data including labelling may not be varied without F.D.A. approval.

Labels are required to contain, amongst other things, the established name of a drug, the name and address of its manufacturer, packer or distributor, together with ingredient and dosage details.[6] Labelling on or within a drug package is required to bear "adequate information" for prescribers. "Adequate information" includes a statement of indications, effects, dosages, routes, methods, frequency and duration of administration together with any relevant hazards, contra-indications, side-effects and precautions. An identical requirement extends to all labelling (with the exception of reminder labelling) which contains information for use.[7] In order to ensure that medical practitioners receive information which is both accurate and presented in an appropriate form, the regulations provide that the latter category of labelling materials must contain specified information according to a prescribed format. Labelling information must not be of a promotional nature or false or misleading in any particular.[8] In determining whether labelling and advertising materials are misleading, the Act specifically provides that positive representations shall be taken into account together with any omissions of facts which are material in the light of such representations or with respect to the consequences which may result from use of the promoted drug under its advertised, customary or usual conditions of use.[9]

(b) *Advertising Regulations*

The F.D.A. also has jurisdiction in relation to prescription drug advertisements which include materials published in journals, magazines, periodicals and newspapers.[10] Advertisements are required to contain the established

[5] *Federal Food Drug and Cosmetic Act* 1938 (as amended) s. 201 (K), (M). 21 Code of Federal Regulations (C.F.R.) 202.1(1), (2).

[6] S. 502(b), (e); 21 C.F.R. 201.10.

[7] 21 C.F.R. 201.100(c)(1), (d)(1). "Reminder Labelling" may include the name of a drug together with other limited optional information but must not include indications or dosage recommendations for use. 21 C.F.R. 201.100(f).

[8] 21 C.F.R. 201.56; 201.57. False and misleading labelling renders a drug misbranded and hence subject to the sanctions provided for in the Act. S. 403(a).

[9] S. 201(n).

[10] 21 C.F.R. 202.1(l)(1). The term also includes advertisements broadcast through radio television and telephone communication systems.

name of the drug (in type at least half as large as that used for the brand name) together with ingredient and dosage details and a "true statement" in brief summary concerning side-effects, contra-indications and effectiveness.[11] Information relating to effectiveness need not include all the purposes for which the drug is intended, but may be limited to the particular purposes for which the drug is advertised. An advertisement may not recommend a use for a drug unless such use was contained in approved labelling.[12] Information concerning side-effects and contra-indications must disclose each side-effect and contra-indication contained in approved labelling for the product unless permission has been obtained for limited disclosure.[13] An advertisement will not satisfy the "true statement" requirement if it is false or misleading with respect to side-effects, contra-indications or effectiveness, if it fails to present a fair balance between information relating to effectiveness and that relating to side-effects and contra-indications, or if it fails to reveal material facts with respect to consequences that may result from advertised use. The "true statement" requirement applies to the entire advertisement and an untrue statement will not be corrected by the disclosure of true information in another part of the advertisement. If any portion of the advertisement would be false or misleading as a result of an omission or failure to qualify a statement explicitly made, the necessary additional information must be included.[14] Examples of advertisements which may or shall be considered false, lacking in fair balance or of a misleading nature are contained in the regulations. In order to aid compliance, advertisements may be submitted to the F.D.A. for comment prior to publication.

Substantial amendments are proposed to the American law by the *Drug Regulation Reform Bill* 1979. The Bill is designed to ensure that doctors will receive adequate and objective product information from a number of sources. The amendments require "practitioner information labelling" containing specified information to be provided with every prescription drug. Drug company sales representatives will be required to present doctors with these materials in respect of every drug promoted. "Promotional labelling" will be required to contain an adequate and balanced summary concerning dosage instructions, uses, effectiveness, contra-indications and adverse effects.[15] The F.D.A. may require corrective material to be issued

[11] 21 C.F.R. 202.1(a), (b), (d), (e). Certain advertisements are exempt from the true statement of information requirement including reminder advertisements which call attention to a drug's name but do not include indications or dosage recommendations for use.

[12] 21 C.F.R. 202.1(e)(3)(ii), (4)(i)(a).

[13] 21 C.F.R. 202.1(e)(3)(iii).

[14] 21 C.F.R. 202.1(e)(3)(5).

[15] "Promotion labelling" is defined to include any written, printed, graphic or other reproduced matter including audiovisual materials which is not a label, "practitioner information labelling" or "patient information labelling". (Patient information labelling is discussed in detail below.)

where "promotional labelling" is published in breach of this requirement. The amendments provide that a comprehensive index of all prescription drugs is to be compiled and distributed to medical practitioners throughout the United States. The index will contain, amongst other things, information required to be included in practitioner and patient information labelling. Provision is also made for the establishment of a National Center for Drug Science which will be responsible for funding clinical pharmacology programmes at under-graduate and post-graduate levels. The amendments are also designed to curb unethical promotional practices. To this end no service or gift may be provided to any student or member of the medical or allied professions or their families which exceeds $10 in value.[16] The giving of drug samples to doctors for patient distribution will be prohibited, except in limited circumstances. Sponsorship of educational activities by drug companies must be revealed to participants. Finally, surveys of pharmacists' prescription records in order to determine prescribing patterns will be prohibited.

3. Australian controls

(a) *Commonwealth Regulations*

Legal responsibility for prescription drugs in Australia is shared between the Commonwealth and the States. Because the majority of drugs available on the Australian market are imported, they fall within the Commonwealth's customs power.[17] The *Customs (Prohibited Imports) Regulations* 1956 (Cth.) prohibit the importation of any therapeutic substances into Australia unless the importer is licensed or permission has been obtained from the Director-General of Health. (A licence confers a right to import therapeutic

[16] The giving of free gifts to doctors has been severely criticized as an unethical sales practice both in Australia and overseas. In the United States, Congressional inquiries have revealed practices such as doctors and pharmacists being presented with gift catalogues and awarded bonus points in exchange for prescribing a certain quantity of designated drugs; gifts listed in the catalogues, which included colour televisions, bicycles, radios and personal items were awarded according to the number of bonus points earned. In other cases, practitioners were given fully paid vacations for themselves and their families in exchange for the practitioner attending daily product briefing sessions: surveys were routinely carried out of pharmacists' prescription records in order to obtain information concerning individual practitioners' prescribing habits. Floor Statement of Senator Edward M. Kennedy upon Introduction of the *Drug Regulation Reform Act* 1979. 125 *Cong. Rec.* S. 5291, S. 5304-8 (3 May 1979). It is probably fair to say that Australian drug manufacturers have not gone as far in their promotional practices as their overseas counterparts. According to the Commonwealth Department of Health, gifts to doctors have included pens, clocks, calculators, stethoscopes, sphygmomanometers (blood pressure measuring devices) and financial assistance with overseas trips and conferences. Commonwealth Department of Health, submissions to the Pharmaceutical Manufacturing Industry Enquiry (1978) 66.

[17] A number of general prohibitions against false and misleading advertising are contained in the *Trade Practices Act* 1974 (Cth.). In addition the Act contains specific provisions (ss. 62 and 63) which may be used to require the disclosure of information in association with products in certain circumstances. At the date of writing no standards relevant to prescription drugs have been implemented pursuant to these sections.

substances for a specified period while the Director-General's permission is given on a case-by-case basis). In addition, and subject to limited exceptions, the Director-General's approval is required before an imported therapeutic substance can be marketed in Australia. The grounds on which the Director-General may refuse to allow the importation of a drug or the marketing of an imported drug are designed to ensure that only substances of reasonable quality, safety and efficacy are imported into Australia for marketing purposes. In addition to these quality controls, Regulation 5H(1) effectively prohibits the importation, among other things, of advertising matter relating to goods for therapeutic purposes that is false, misleading or extravagant.

In accordance with Departmental guidelines, manufacturers seeking marketing approval for a new drug must submit comprehensive documentation for evaluation by the Department evidencing the quality, safety and efficacy of the product. The process of evaluation includes a stage calling for agreement between the Department and the manufacturer on the contents of the "Product Information" document. This document contains essential, comprehensive information concerning a drug's chemical identity, approved name, uses and dosage, together with coverage of all known factors relevant to its safe and effective use such as contra-indications, adverse reactions, interaction with other drugs and any other precautions which should be observed.

All promotional material prepared by a manufacturer is required to incorporate and be consistent with information contained in the Product Information document. To police this requirement, the Department pre-clears all promotional literature during the first three years that the product is on the market. After that time, the manufacturer may revise and distribute promotional material without prior departmental approval, provided that it continues to include the approved product information.[18]

The scheme is subject to a number of shortcomings. First, the regulations apply only to promotional literature for imported drugs. Consequently materials associated with drugs manufactured in Australia from locally produced ingredients are not included.[19] Secondly, the regulations apply

[18] Submission by the Commonwealth Department of Health to the Senate Standing Committee on Social Welfare Medication Inquiry *Hansard* 20 June 1979, 26-7, 86.

[19] Where a drug is manufactured in Australia from imported raw materials, information must be given to the Department concerning both the imported ingredients and the intended end product; however, in some cases, the raw material is imported not by the manufacturer himself, but by a distributor and in these situations the Department has indicated that, due to shortages in staff and facilities, it frequently has difficulty in pursuing the end use of the material. The system in this respect is, in the Department's words, "anomalous [and] unsatisfactory both from the point of view of importers and some manufacturers . . . and from the point of view of the general public, since only some of the available pharmaceuticals have been fully evaluated". Commonwealth Department of Health, Submission to the Senate Standing Committee on Social Welfare Medication Inquiry *Hansard* 20 June 1979, 41-2.

only to promotional literature prepared by the manufacturer and do not extend to locally produced materials. As a result a significant proportion of advertising materials including advertisements published in professional journals are excluded.[20] Thirdly, Departmental surveillance of promotional materials ceases three years after a drug is marketed. Although drugs already on the market may be classified as "designated substances" and so re-subjected to departmental scrutiny, the procedure is available only in limited circumstances.[21] Finally, under the existing system advertising standards are wholly a matter of administrative discretion. Instead of the present scheme it is suggested that requirements governing the form and content of prescription drug advertisements should be enacted as legislative standards so that they are readily accessible to manufacturers, importers and consumers.

(b) *State Regulation*

Control over prescription drug promotional materials is vested in the respective State Departments of Health. The Victorian *Health Act* 1958 is broadly representative of the position in all States. The term "advertisement" is defined in s. 259(1) to include direct mail and journal advertisements and detailers' literature. The principal shortcoming of the legislation is that it does not specifically require disclosure in advertising of stipulated information about the drug in question, but only prohibits the making of false or wilfully misleading statements (ss. 249(1) and 267(1)). Another defect is the ad hoc nature of the monitoring procedures in relation to advertising materials. In no State is there any continuing basis for review (whether prospective or retrospective) of advertisements in medical or trade journals or of direct-mail advertising and dealers' literature. At best, advertising materials are sporadically examined by Department of Health officials and corrective action taken as limited resources allow.

(c) *Industry Regulation*

The National Media Medical Council (N.M.M.C.) was established in 1973 by a group of publishers of major medical journals who believed that short-comings in government controls over prescription drug advertising could best be remedied by a system of voluntary regulation. To that end the N.M.M.C. developed a Code Relating to Ethical Advertising and established the Advertising Approval Authority to ensure observance of the code. This surveillance system was abandoned however in 1976. Thereafter the responsibility of determining whether advertisements complied with the code was left to individual publishers.[22]

[20] Ibid. 87.
[21] Ibid. 12-13.
[22] National Medical Media Council, Submission to the Senate Standing Committee on Social Welfare Medication Inquiry *Hansard* 1 August 1979, 1812.

Interacting with the N.M.M.C. code is the Australian Pharmaceutical Manufacturers Association (A.P.M.A.) Code of Conduct for the Pharmaceutical Industry which is directed to drug manufacturers and includes provisions governing promotional practices. The A.P.M.A. comprises sixty member companies which are responsible for supplying 97 per cent of prescription pharmaceuticals available on the Australian market.

The A.P.M.A. Code provides, amongst other things, that where the purpose of printed promotional materials is to provide doctors with information upon which to make a prescribing decision, it must include a clear and concise statement of the drug's indications and side-effects, precautions and contra-indications, together with ingredient and dosage details. In addition the name and address of the manufacturer and a statement that additional information is available on request must also be included. This requirement may be waived however where the purpose of the promotional material is to remind doctors of the availability of a drug and its main indication, or "where it is demonstrably and obviously impracticable" to include the required information. Exempt materials must contain a statement of ingredients, the name and address of the manufacturer and a statement indicating the availability of full prescribing information.

Regular surveillance of journal advertisements is undertaken by one of the A.P.M.A.'s sub-committees which is composed of individuals with pharmaceutical or scientific background or training. Breaches of the code are ultimately dealt with by the A.P.M.A.'s Council which is empowered to suspend or exclude a member or to take any other action it deems appropriate. The effectiveness of disciplinary action by the Association is open to some doubt. The Executive Director of the A.P.M.A. has suggested that expulsion would bring a company into professional disrepute and adversely affect its market position. He conceded however that in the case of a widely-prescribed drug, disciplinary action would be unlikely to affect sales.[23]

4. Conclusion

There is now widespread recognition of the need to provide doctors with accurate and adequate prescribing information concerning prescription drugs. Because of practitioner reliance on advertising materials as a source of prescribing information the need for affirmative disclosure regulation for these materials has been recognised in Australia by a number of expert bodies.[24]

[23] Statement by the A.P.M.A. Executive Director before the Senate Standing Committee on Social Welfare Medication Inquiry *Hansard* 1 August 1979, 2046.

[24] Commonwealth of Australia, *Report of the Senate Select Committee on Drug Trafficking and Drug Abuse* (1971) 51; Commonwealth of Australia, *Report of the House of Representatives Select Committee on Pharmaceutical Benefits* (1972) 12; Commonwealth of Australia, *Report of the Pharmaceutical Manufacturing Industry Inquiry* (1979) paras. 442-4.

A recent study has examined the effect of legislation and voluntary codes on the content of advertisements published in American, British and Australian medical journals.[25] The findings suggest that after the implementation of legislation in the United States in 1962, the information content of prescription drug advertising rose markedly. The authors state that no comparable changes occurred in Britain following the adoption of a voluntary code by the Association for the British Pharmaceutical Industry (A.B.P.I.) in 1974 or in Australia following the implementation of the N.M.M.C. code in 1975.[26] The conclusion is that "it is difficult to identify clearly any impact attributable to the voluntary code"[27] and that the "overall pattern . . . clearly shows that Australian and British doctors have received less information about potential dangers than their American counterparts".[28] Similar conclusions were reached by a British survey in 1977 of journal and direct mail advertisements in that country which found a high rate of non-compliance by A.B.P.I. members with the provisions of the advertising code.[29]

The implementation of positive disclosure legislation in Australia modelled on the American regulations would greatly improve the quality of product information addressed to the medical profession by the pharmaceutical industry. Clearly the responsibility of providing doctors with adequate prescribing information should not rest solely with industry. There is also a need for an independent drug information service which would provide objective and comprehensive drug data. A service of this nature is presently being developed by the Australian Government. Finally the provision of information whether from government or industry sources must be supplemented by basic and continuing education in drug therapy. Benefits to consumers as a result of these proposals would include a reduction in the incidence of irrational prescribing and the consequent risk of injury to drug users. It is suggested that any resultant costs to industry are acceptable given the anticipated benefits to consumer health and welfare.

B. PATIENT INFORMATION CONTROLS

1. Introduction

Accurate and adequate prescribing information concerning prescription drugs is of fundamental importance to medical practitioners. In response to the thalidomide disaster a number of countries imposed legislative controls governing the content of prescription drug promotional materials.

25 J. M. Najman, V. Siskind and C. Bain, "Prescription Drug Advertising: Medical Journal Practices Under Different Types of Control" [1979] 1 *Medical Journal of Australia* 420.
26 Ibid. 423.
27 Ibid.
28 Ibid.
29 G. Stimson, "Do Drug Advertisements Provide Therapeutic Information?" (1977) 3 *Journal of Medical Ethics* 7, 10-11.

Recently the need to provide patients with written information concerning the drugs they take has been recognized by consumer groups, doctors and government administrators.

Arguments in favour of patient information labelling stress that although doctors have an obligation to warn patients of adverse effects likely to accompany a drug's use, many in fact do not. Moreover, even when such information is given it is suggested that patients may not pay attention to, understand, accept or remember it. Although package inserts containing prescribing information accompany a number of drugs, these leaflets are generally intended for practitioner use. In a number of countries it is usual for pharmacists to remove the package labelling and substitute their own label bearing the prescriber's directions for use. For these reasons patient information labelling is regarded as an essential document for prescription drug users.

The importance of patient information labelling has been recognized by a number of European countries. In 1974 the ten countries participating in the Council of Europe's Partial Agreement (on matters of social affairs and public health) adopted a resolution requiring information leaflets to accompany prescription drugs. The resolution requires that these materials contain the name of the product and its manufacturer, dosage, administration and storage instructions, indications, contra-indications, side effects, advice to report any side reactions to the prescriber or dispenser and a warning to keep the preparation out of children's reach. Although the participating countries are not under any legal obligation to adopt the resolution, they are morally committed to do so.[30]

2. American controls

Since the late 1960s the F.D.A. has required information labelling to be provided to patients with a number of drugs including oral contraceptives and oestrogen preparations. During the past ten years the administration has reviewed scientific literature, undertaken research and conducted discussions with interested parties in order to evaluate current and model information labelling materials.

The F.D.A. is currently proposing patient information labelling regulations which apply to the majority of prescription drugs and which, subject to limited exceptions, require patient information labelling to be dispensed to drug users.[31] The labelling must be written in non-technical language,

[30] T. D. Whittet, "The Viewpoint of the European Experience" (1977) 11 *Drug Information Journal* 26S.

[31] "Prescription Drug Products; Patient Labelling Requirements" 44 *Federal Register* 6 July 1979, 40016. The obligation to distribute these materials will be waived where a patient is blind, is in the course of emergency treatment, is legally incompetent, institutionalized, where the prescribing practitioner has requested that the dispenser withhold the labelling or where the patient's first language is not English.

devoid of promotional material and must contain both a summary and detailed statement of product information. The summary is to include a statement of major indications, contra-indications, serious adverse reactions and potential safety hazards together with a recommendation that the patient read the detailed product information. The detailed information must identify both the product and its manufacturer and contain a statement of indications, potential safety hazards, contra-indications, serious adverse reactions, precautions, side-effects, administration, storage and handling instructions. In addition the labelling must caution that the drug has been prescribed for the sole purpose of treating the patient's condition and that it should not be used for other conditions or given to other individuals. It must also inform the patient that the drug's safety and effectiveness depend upon adherence to the instructions for use and stress the importance of not using the drug for any purpose other than the prescribed purpose. Finally, the date of the most recent labelling revision must be prominently stated.

In order to assess the effectiveness of the proposed regulations, an evaluation programme is being designed by the F.D.A. together with the Institute of Medicine of the National Academy of Science. Similar requirements for the provision of patient information labelling materials are also contained in the *Drug Regulation Reform Bill* 1979.[32]

3. Australian controls

In Australia there is no legislation at Commonwealth level requiring patient information labelling to accompany prescription drugs. As previously discussed imported drugs are subject to the provisions of the *Customs Act* 1901 (Cth.) and regulations passed thereunder. The evaluation of an imported drug for marketing approval includes a stage calling for agreement between the Department and the manufacturer on the contents of the

[32] The Bill provides that dispensers must distribute patients with information labelling materials at the time of dispensing a prescription drug. Patient information labelling materials must contain the following information:

"(A) a summary of the benefits and risks associated with the use of such drug;
"(B) adequate directions for use, including—
"(i) the purposes or indications for which the drug is intended,
"(ii) the proper method of administration of the drug,
"(iii) precautions to be taken during the use of the drug, and significant side effects and adverse reactions that may result from the use of the drug, as well as instructions for treating or obtaining treatment for side effects and adverse reactions, and
"(iv) warnings against unsafe use of the drug;
"(C) information concerning the proper storage and handling of the drug; and
"(D) any other information which is determined necessary or useful to inform patients about the risks and benefits associated with use of the drug, promote the safe and effective use of the drug, or to protect the public health with respect to the use of the drug."

The obligation to distribute these materials will only be waived where a patient receives emergency treatment or where the Secretary of Health, Education and Welfare has determined in relation to a particular drug to grant medical practitioners the authority to withhold labelling materials in appropriate circumstances.

"Product Information" document. This document is devised primarily for medical practitioners and is not usually included with medicines dispensed to consumers except in the case of injectable preparations. Should the Director-General of Health consider it essential for consumers to be provided with product information, manufacturers are requested to prepare a patient information leaflet for inclusion in the drug package or for distribution at the time of dispensing. Patient information leaflets are currently required in relation to oral contraceptives and oestrogen preparations for replacement therapy.[33] It appears however that a request by the Director-General to pharmacists to distribute patient information labelling relating to oestrogen preparations was not supported by a number of State governments. As a result the Commonwealth Department of Health is presently considering alternative methods of distribution.

At State level patient information labelling requirements are contained in recent amendments to the Tasmanian *Poisons Regulations* 1975 which provide that a pharmacist, medical practitioner or dentist shall not supply a listed substance unless it is accompanied by an approved information sheet. This requirement is waived if the prescribing practitioner endorses the prescription with instructions not to supply such information or where a doctor or dentist who supplies a listed substance to a patient believes that it would not be in the best interests of that patient to supply such information. To date, one substance has been listed.[34]

In 1974 the National Therapeutic Goods Committee (N.T.G.C.) recommended to the Commonwealth and State Ministers of Health that legislation be enacted requiring supplementary labelling to be provided to consumers by pharmacists or dispensing medical practitioners. According to the N.T.G.C.'s recommendations, the labelling would be required to contain specified information including a statement of major hazards and appropriate warnings together with detailed dosage instructions. The obligation to furnish information would be waived should either the pharmacist or prescriber consider it in the best interests of the patient not to receive labelling information. To date however, these recommendations have not been enacted on a uniform basis.

4. Conclusion

There appears to be a substantial body of opinion both lay and professional concerning the need for patient information labelling. While many arguments in favour of these materials have been most forcefully put by consumer activists, a number of scientific studies reviewed by the

[33] Submission by the Commonwealth Department of Health to the Senate Standing Committee on Social Welfare Medication Inquiry *Hansard* 20 June 1979, 27-8.

[34] *Poisons Amendment Regulations* 1980 (Tas.). Propoxphene has been listed under Schedule VIA of the regulations.

F.D.A. indicate widespread support for these materials as a necessary supplement to practitioner advice.[35]

Proposals for increased legislative control of prescription drug labelling are likely to be opposed by industry on the grounds that they will lead to increased production costs. Further criticisms are likely regarding the increased legal liability of manufacturers, doctors and pharmacists. A draft regulatory analysis of the economic consequences of the proposed regulations has been prepared by the F.D.A. and on the basis of this analysis the administration believes that the economic impact of the regulations is acceptable in view of the anticipated benefits to consumers.[36] In reply to arguments based on increased legal liability the F.D.A. responded as follows:

> "[I]t would be both inappropriate and unreasonable for F.D.A. to base its patient labelling policy on whether patient labelling affected the legal liability of the manufacturer, physician, pharmacist or other dispenser of the product. . . . Although the labelling may have an impact upon . . . civil liability . . . that impact will likely be in keeping with traditional notions of legal responsibility."[37]

As against these costs, a number of anticipated benefits to consumers should be considered. The principle benefit of patient information labelling is that it will provide consumers with accurate information concerning the drugs they take. If such information is heeded, this should result in better therapy or refusal of a course of treatment where a particular drug is contra-indicated, inappropriate or unnecessary. Informed drug use may be expected to reduce the number of hospital admissions for avoidable adverse reactions and possibly the number of worker disability days. Given the serious nature of side-effects which may accompany drug use, coupled with the brief consultation periods between doctors and patients, the provision of patient labelling is in the interest of public health and welfare.[38]

The F.D.A. has stated that patients have a right to be informed of the benefits and risks associated with the drugs they take. There appears to be no good reason why a similar right should not be acknowledged on behalf of Australian consumers. Because the provision of such information is clearly in the public interest, it should not be the responsibility of a voluntary scheme but should be subject to legislative control.

[35] For a summary of the data considered by the F.D.A. see 44 *Federal Register* 6 July 1979, 40016.
[36] Ibid. 40024.
[37] Ibid. 40023
[38] For a detailed cost benefit analysis of the regulations see S. R. Moore, "The Cost and Benefits of Proposed Regulations for Prescription Drug Labelling for Consumers—A Regulatory Model". Paper presented at the Pharmaceuticals and Cosmetic Manufacturing Expo '80, Chicago, 13 May 1980.