II. CONTRACEPTION

A. Introduction

There is little contention in the modern Commonwealth about the right of individuals in principle to acquire knowledge of means of contraception. Although in some jurisdictions less than two decades have passed since communication of contraceptive knowledge to the unmarried was classified as a crime against morality, family planning services and knowledge of means to avoid unwanted pregnancy are now promoted with few legal limits. Constraints of taste may control means of advertisement of contraceptive services and methods, and explicit commercial advertising for instance on television is rarely found, but restrained public service advertising is being developed to carefully targeted populations.

Contraception may not be presented as such, because of negative and moral connotations. It is often more positively expressed as family planning and birth-spacing. Since the unmarried may plan not to build families until after marriage, "family planning" is not euphemistic, but relates to individuals' perceived needs. Further, it appeals to responsible males as well as to responsible females, although the burden of contraceptive protection continues to fall disproportionately upon women. Birth-spacing education is appropriate in many Commonwealth cultures where the costs of close births, in high levels of maternal death and sickness and reduced levels of infant survival and health, are known. Most of those who practice contraception intend to postpone but not to avoid future conception. In many countries, avoidance of conception is achieved by voluntary sterilization (see Chapter III below), which in worldwide terms has become the most widely practical means of birth-control.

The legal issues in contraception concern adolescents' rights of access to confidential services, permission of a power of spousal veto, definitional distinctions between contraception and abortion, with special regard to the newly perceived "contragestive" drugs and therapies, and consequences of contraceptive failure. Contraception fails not only when conception occurs, but also when infertility results, for instance due to pelvic inflammatory disease. Additional issues concern health personnel legally entitled to offer family planning services, for instance by prescription or invasive procedures, and information drug manufacturers must give ultimate users of their products, through package inserts. Courts have distinguished contraceptive products from therapeutic products, in that the latter are taken by sick people seeking control of disease, or by healthy people seeking to prevent disease, whereas contraceptives are used primarily by healthy people seeking to avoid the natural consequences of healthy

conduct. Accordingly, their informational needs and their options are different from those seeking to resist or prevent sickness.

B. Adolescent Contraception - The Gillick Case

Few cases regarding reproduction and reproductive health can have aroused as much commentary, both in England where it originated and in many other Commonwealth jurisdictions, as Gillick v. West Norfolk and Wisbech Area Health Authority, [1985] 3 All E.R. 402 (House of Lords). The case began in mid-1982, when Mrs. Gillick sued for a declaration that advice issued in late 1980 by the Department of Health and Social Security (the DHSS) was unlawful. The advice, which was a revised version of earlier guidance, stated or implied that, at least in certain cases which were described as "exceptional", a doctor could lawfully prescribe contraception for a girl aged under 16 years old without her parents' consent, respecting the minor's confidentiality. Mrs. Gillick wrote to her local health authority forbidding contraceptive or abortion advice or treatment to any of her four (later five) daughters while aged under 16 years without her consent. When the health authority replied, in accordance with the DHSS guidance, that such treatment is a matter for a doctor's clinical judgment, taking into account all the factors of the case, Mrs Gillick sued the health authority and the DHSS for declarations that the health authority and DHSS guidance were wrong in law.

Trial: The Mature Minor Doctrine

On trial in the Queen's Bench Division of the High Court, Woolf J. refused the declarations; see [1984] 1 All E.R. 365. There was no binding jurisprudence resolving the conflict between parental rights to control their children's medical care and adolescents' medical autonomy and confidentiality, but the trial judge found guidance in the judgment of Addy J. of the Ontario High Court in Johnston v. Wellesley Hospital (1970), 17 D.L.R. (3d) 139. This reflected the so-called "mature minor" rule, expressed in the celebrated language of Lord Nathan's text Medical Negligence (1957) at p. 176:

> "It is suggested that the most satifactory solution of the problem is to rule that an infant who is capable of appreciating fully the nature and consequences of a particular operation or of particular treatment can give an effective consent thereto, and in such cases the consent of the guardian is unnecessary."

Woolf J. observed that a doctor who was so ill-advised as to give contraceptive advice or treatment to a girl aged under 16 years, in order to facilitate her having sexual intercourse, which might constitute an offence by her partner against

England's Sexual Offences Act 1956, would be at risk of legal liability. It was expected, however, that responsible doctors would give contraceptive advice and treatment only when satisfied that the treatment is medically indicated by a girl's actual or imminently prospective sexual activity, and that she will take the risks of contraceptively unprotected intercourse rather than have parental involvement in the medical care decision.

Appeal: Reversal

The Court of Appeal, by unanimous decision of its three judges, reversed the trial decision, and granted Mrs. Gillick the declaration she sought; see [1985] 1 All E.R. 533. Dominating the appeal judges' reasoning was an absolutist view of parental control of minor children's lives, and concern that, in the Sexual Offences Act 1956, Parliament had determined a policy of sexual abstinence by girls under 16 years of age which was incompatible with legal tolerance of contraceptive advice and treatment which would equip them to undertake with impunity the very conduct for which their partners could be imprisoned. Since sexual intercourse with girls under 16 years old is so proscribed, the judges found no licence in parents to consent to it, nor by implication to contraceptive advice and treatment which they considered to facilitate such conduct. They recognized an emergency exception, however, in which contraceptive services could lawfully be rendered to a girl below age, perhaps when she was abandoned by her parents, or wayward, beyond parental control and already determined to be or likely to become sexually active. The Court of Appeal's reasoning was reinforced by nineteenth-century precedents on rights of children's legal guardians to take decisions on their behalf, and to exercise control over their life styles.

In response to the Court of Appeal's decision, the DHSS withdrew its advice on adolescent contraception, pending appeal to the House of Lords. An interesting response in Commonwealth legal literature was publication of articles from a number of jurisdictions, including Scotland, New Zealand and Canada, explaining why the reasoning the English Court of Appeal found persuasive was inapplicable to circumstances in those jurisdiction. The literature drew attention to different legal provisions on the minimum age of female consent to sexual intercourse, and acceptance of the mature minor rule, or the emancipated minor rule, permitting legally effective consent to medical care by minors of sufficient capacity to understand its implications, or who had been left by their parents to make their own decisions.

Final Decision: Medical Discretion and the Mature Minor Doctrine Upheld

In October 1985, the House of Lords reversed the Court of Appeal, by a majority of three judgments to two, and reinstated the decision of the trial judge to refuse the declarations sought. The decision is of considerable importance, not only on the issues of contraception and abortion treatment for girls aged under 16 years, but also on the governing principles of minors' consent to medical treatment, for instance regarding psychiatric care and treatment for addiction to alcohol and other substances, and minors' rights to enjoy confidentiality in their dealings with health professionals. The dissenting two judges invoked the reasoning which had prevailed in the Court of Appeal, Lord Brandon of Oakbrook finding as a fact that (at p. 429):

> "... to give such a girl [aged under 16 years] advice about contraception, to examine her with a view to her using one or more forms of protection and finally to prescribe contraceptive treatment for her, necessarily involves promoting, encouraging or facilitating the having of sexual intercourse, contrary to public policy, by that girl with a man."

Lord Templeman's dissenting judgment was less committed to the views that contraception causes sexual activity and that the criminal character of such activity renders any accommodation to it unlawful. He found, however, that (at pp. 434-5):

> "The decision to authorise and accept medical examination and treatment for contraception is a decision which a girl under 16 is not competent to make. In my opinion a doctor may not lawfully provide a girl under 16 with contraceptive facilities without the approval of the parent responsible for the girl save pursuant to a court order, or in the case of emergency or in exceptional cases where the parent has abandoned or forfeited by abuse the right to be consulted."

The judicial majority in the House of Lords saw contraception as protection against pregnancy and premature motherhood or abortion, and considered that parental rights should be viewed pragmatically on the circumstances of each case, rather than as prevailing as a matter of legal doctrine due to the axiomatic incompetence of under 16 year-olds to make medical decisions. Lord Fraser of Tullybelton found that a doctor is legally entitled to advise a girl and to give her contraceptive treatment without her parent's consent or even knowledge provided that the doctor is satisfied on the following matters (p. 413):

(1) that the girl (although under 16 years of age) will understand the advice;

(2) that the doctor cannot persuade her to inform her parents or to allow the doctor to inform the parents that she is seeking contraceptive advice;

(3) that she is very likely to begin or to continue having sexual intercourse with or without contraceptive treatment;

(4) that unless she receives contraceptive advice or treatment her physical or mental health or both are likely to suffer;

(5) that her best interests require the doctor to give her contraceptive advice, treatment or both without the parental consent.

Lord Fraser immediately added that the result ought not to be regarded as a licence for doctors to disregard parental wishes whenever they find it convenient to do so. He found, however, that (p. 413):

> "The medical profession have in modern times come to be entrusted with very wide discretionary powers going beyond the strict limits of clinical judgment and, in my opinion, there is nothing strange about entrusting them with this further responsibility which they alone are in a position to discharge satisfactorily."

The judge considered principles derived from the Sexual Offences Act 1956 to be irrelevant to the question of parental rights and doctors' capacity to treat minors confidentially with contraceptive protection.

Lord Scarman based his decision not only on the grounds of Lord Fraser's judgment, with which he expressly agreed, but also upon the mature minor doctrine. He found that (at p. 414):

> "The case is the beginning, not the conclusion, of a legal development in a field glimpsed by one or two judges in recent times ... but not yet fully explored .... The contraceptive pill has introduced a new independence, and offers new options, for women; but has it in the process undermined parental right and duty? In my judgment, the answer is No, even though parental right may not be as extensive or as long lasting as [Mrs. Gillick] believes it to be."

Lord Scarman traced legal principles to show that [at p. 420] "The principle of the law ... is that parental rights are derived from parental duty and exist only so long as they are needed for the protection of the person and property of the child." It follows that when a minor has personal capacity for self-protection, measured by factual criteria of intellectual and emotional growth and not by a mechanical test of age, parental rights decline. The judge endorsed the modern law governing parental rights and a child's capacity to make his or her own decisions, expressed in the House of Lords' 1984 decision in R. v. D., [1984] 2 All E.R. 449, noting that (at p. 423):

> "The House must, in my view, be understood as having in that case accepted that, save where statute otherwise provides, a minor's capacity to make his or her own decision depends on the minor having sufficient understanding and intelligence to make the decision and is not to be determined by reference to any judicially fixed age limit."

Lord Scarman went on to conclude that (at p. 423):

> "In the light of the foregoing I would hold that as a matter of law the parental right to determine whether or not their minor child below the age of 16 will have medical treatment terminates if and when the child achieves a sufficient understanding and intelligence to enable him or her to understand fully what is proposed. It will be a question of fact whether a child seeking advice has sufficient understanding of what is involved to give a consent valid in law."

He added that a girl aged under 16 years considering contraceptive advice and treatment has much to understand, including questions of relationships with parents, long-term problems associated with the emotional inpact of pregnancy and its termination, and risks to health from sexual intercourse which contraception may diminish but cannot eliminate. Like Woolf J. below, Lord Scarman was helped by the Ontario decision in Johnston v. Wellesley Hospital.

Lord Bridge of Harwich primarily addressed procedural aspects of the case, but he expressly agreed with the judgments of Lords Fraser and Scarman, and approved the terms in which the trial judge, Woolf J. had disposed of the claim of a doctor's criminal complicity in giving contraceptive advice and treatment to a girl aged under 16 years, adding that (at p. 428):

> "On the issue of public policy, it seems to me that the policy consideration underlying the criminal sanction imposed by statute on men who have intercourse

with girls under 16 is the protection of young girls from the untoward consequences of intercourse. Foremost among these must surely be the risk of pregnancy leading either to abortion or the birth of a child to an immature and irresponsible mother. In circumstances where it is apparent that the criminal sanction will not, or is unlikely to, afford the necessary protection it cannot, in my opinion, be contrary to public policy to prescribe contraception as the only effective means of avoiding a wholly undesirable pregnancy."

Commonwealth Implications

The judgment of the House of Lords has many implications, by no means confined to the areas of contraception and abortion in which Mrs. Gillick sought her declarations. Its implications within Commonwealth jurisdictions are also profound, since it addresses the doctrinal underpinnings of the Common law and indicates relationships between criminal prohibition of intercourse with girls under given ages and medical advice and treatment designed to protect girls against pregnancy. It reinforces the literature through which authors distinguished their national laws from the position reached by the Court of Appeal, and illuminates the way in which many jurisdictions may interpret the provisions of their own systems regarding medical care of adolescents (for information on which to base worldwide comparisons, see J.M. Paxman and R.J. Zuckerman Adolescent Health and the Law (1986, in press, W.H.O. Geneva), chs. 4-7.)

Most significantly, the Gillick case shows that, in the absence of unambiguous legislation, there is no "age of consent" for medical treatment. Legislation or subordinate legislation may express ages lower than majority when minors may give legally effective consent to medical including diagnostic and surgical care, but such provisions alone do not show that minors lack competence to give such consent below the specified ages. They may be competent in individual cases, if they are found to have sufficient understanding of the implications of having medical treatment, and of foregoing it. In case of doubt as to an individual minor's competence, a doctor may obtain another reliable professional opinion. There is accordingly not an age of consent in most jurisdictions, but a condition of consent, namely competence or maturity to make an adequately informed decision on accepting or rejecting medical care which appears objectively to be in the minor's best interests.

In view of the disadvantages pregnant unmarried adolescents face in Commonwealth countries, a decision which will be likely to reduce the incidence of unmarried adolescent pregnancy is to be welcomed. Those who share Mrs. Gillick's conviction that access to contraceptive services increases adolescent sexual

intercourse may doubt, of course, that the House of Lords' decision will have that effect. Nevertheless, evidence shows that in 1978, twenty percent of England's adolescents had had sexual experience by the age of 16 (J. Senderowitz and J.M. Paxman, Population Bulletin - Adolescent Fertility: Worldwide Concerns, Population Reference Bureau Vol. 40, No. 2, April 1985, at p. 8) and that 40 to 50 percent of girls had had intercourse by the age of 17 ("Youth in the 1980s: Social and Health Concerns", Population Reports, Population Information Program, The Johns Hopkins University, Series M No. 9 Nov.-Dec. 1985, p. M-357).

Apart from the health risks of adolescent pregnancy, childbirth and abortion, in some countries pregnant schoolchildren may be required to leave school, and may be unable to continue their education even when they are not actually expelled from school. It has been noted, for instance, that:

> "In the Caribbean islands, about 58 percent of first babies are born to mothers aged under 19, and half of those are aged 17 or less. This means a substantial number of schoolgirls become pregnant and, in accordance with prevailing custom, leave school with no chance of readmission" (J. McKay (ed.), Adolescent Fertility: Report of an International Consultation (1983), Int'l Planned Parenthood Fed., 8).

More grave than this is the relatively high incidence of maternal mortality among young mothers. In Jamaica and Nigeria, for instance, it has been found that women younger than 15 years old are four to eight times more likely to die during pregnancy and childbirth than women aged from 15 to 19 (Population Reports, ibid., p. M-365). Prenatal care for young mothers is unavailable to many in developing countries, but it may be essential to save life. In rural Bangladesh the mortality rate for women aged twenty to twenty-four was 4 deaths per 100,000 live births, but a study of 22,000 Nigerian women showed a death rate among those aged 14 or younger of 500 per 100,000 live births where prenatal care was good, and 4,300 per 100,000 for mothers in the same age range who had not received care (Ibid.). In the face of such figures, a judgment which removes barriers to adolescent contraceptive care, where it is available, appears particularly humane.

C. Spousal Veto

Some jurisdictions retain laws or maintain practices by which a spouse may veto a partner's decision to have recourse to for instance a chemical or mechanical means of contraception. Such laws or practices may apply to both husbands and wives, but the fact that there are so many more means of contraceptive intervention in the reproductive processes of females than of males that are dependent upon third-party provision of services (as opposed to male contraception dependent upon simple acquisition of a condom), means that discrimination is found primarily against wives' access to contraception. In Papua New Guinea, for instance, legislation prohibits distribution of contraceptives to wives without their husbands' consent (Annual Review of Population Law 1979, U.N. Fund for Population Activities, 20). As clinic practice, furthermore, the Gambia Family Planning Association requires women aged under 21 to have parents' consent if single, or husbands' consent if married, before services are given, although the government's own Department of Medicine and Health imposes no age condition for autonomous consent to services (Letter from the Women's Bureau to the Commonwealth Secretariat Women & Development Programme).

Laws of this controlling purpose or effect may reflect the values of an indigenous culture, but it is questionable whether such international provisions as the Convention on the Elimination of All Forms of Discrimination Against Women are to be interpreted in accordance with principles of cultural relativism, which may recognize the legitimacy of discriminatory legal provisions in one jurisdiction when they are offensive in others. In any event, it may be observed that spouses commonly bear legal responsibilities to provide each other with necessaries of life, which include medical care. The proven danger that repeated pregnancy and short birth-spacing present to women's lives and health (see Chapter I, B above) may show that husbands have legal duties to make medical means of fertility control and birth spacing available to their wives, if other means of preserving their lives and health are not practised. Further, husbands may have no power to obstruct women from obtaining for themselves the necessaries of life husbands are bound to provide. It may be presumed that husbands intend to observe rather than to violate their legal responsibilities to protect their wives against reproductive hazards presented by pregnancies the wives do not want.

Husbands' consent to contraceptive care, even when required by legal form, may be expressed through the wives who attend for contraceptive advice and treatment, rather than be given by husbands in person. This is so not only because of the legal presumption that men intend to respect rather than to violate their legal duties, but also because of the respect

paid to them by their wives. In a brief prepared for this Report by the Fiji Medical Association, it is observed that:

> "It is relevant that only a very small minority of women will express an opinion contrary to one their husband has already stated; or agree to an operation or procedure, or go and seek medical attention, if their husband has expressed himself opposed to it."

Husbands who do not wish the presumption of their consent to prevail may be expected to take initiatives expressly to veto contraceptive care their wives seek.

In contrast to jurisdictions that legislate a spousal veto, others make clear that one spouse's best reproductive health care, determined in consultation with an appropriate professional, is not to be subjected to the veto of the other. The written permission of a husband for medical care of his wife may do violence to customary law, where a woman's family retains an interest in her well-being after marriage, and a husband does not have control in this area of her life. Rejection of spousal veto power can be justified on other grounds too. In Swaziland, for instance, both Common law (see Palmer v. Palmer, 1955 (3) S.A. 55) and customary law exclude the capacity of a spouse to control the other's health (see A.K. Armstrong and R.T. Nhlapo Law and the Other Sex: The Legal Position of Women in Swaziland (1985) at pp. 106-108). Reinforcing the point is a Ministry of Health memorandum of 23rd November 1978, however, which informs particularly staff of public health agencies that:

> "The objective of family planning is to improve the health of the mother and child and to protect the unwed mother from accidental pregnancy. During the health worker - client interviews, the health worker is professionally trained to assess the needs of each client in accordance with the above named objectives. To then ask the client to produce a signed consent form from either the parent or his/her relative is contrary to the professonalism of the health worker" (at p. 110).

In jurisdictions where spousal consent is sought in practice though not legally required, a similar ministerial directive could serve the interests of both spousal autonomy and spousal health.

D. Post-coital Contraception and "Contragestion"

An issue identified in an earlier Report, Emerging Issues in Commonwealth Abortion Laws, 1982, concerns the distinction drawn in law between contraception and abortion. It was noted

that, since legal analysis shows that abortion occurs only after implantation of an embryo in the uterine wall, means intended to prevent such implanation will not fall under prohibitions of abortion laws. Whether the means are applied in anticipation of intercourse or post-coitally, they will fall on the contraception side of the contraception/abortion distinction. How long after intercourse they may be used is a matter of judgment made in good faith influenced by biological or medical knowledge. In the United Kingdom, the Minister of Health observed in 1981 (see Emerging Issues, p. 41) that use within 72 hours from unprotected intercourse constituted legitimate contraception. A respected legal commentator, Professor Ian Kennedy, has claimed that, since abortion is dependent upon successful implanation, post-coital contraception is legitimate as contraception during "that time period which the consensus of informed medical scientific opinion states is the maximum time after intercourse before implantation takes place. This may be 7 days or 8 or 9 or 10" ("The legal and ethical implications of postcoital birth control" in H. Grahame (ed.) Postcoital Contraception: Methods, services and prospects (1983) 62 at p. 66).

With development of antiprogestin drugs, which neutralize the reproductive function that renders a woman's uterus hospitable to embryonic implantation, the expression "contragestion" has emerged as a refinement of contraception. In its origin, "contraception" applied to prevention of conception, rather than to prevention of post-conceptive reproductive developments; prevention not of conception but of subsequent gestation may appropriately be described as "contragestion". This expression may not be confined to use of antiprogestin drugs, since other drugs, devices and procedures, such as prostaglandin drugs and menstrual aspiration, may also be employed contragestively, that is for the purpose of preventing post-conception gestation.

As an example, the antiprogestin drug RU486 has a wide range of potential applications, which are at present being explored through research, including clinical trials, in a number of Commonwealth jurisdictions. The drug may operate theoretically as a traditional contraceptive, as a contragestive affecting implantation, or as a method to correct menses delay. The drug promises a number of other uses, such as aiding safe childbirth. Its capacity to effect abortion must be tested and applied compatibly with a jurisdiction's abortion law, of course, but its contraceptive and contragestive capacities may not be subject to this limitation. For purposes of both legal analysis and medical assessment, the journalistic description of the drug as an "abortion pill" is therefore incorrect.

Removal of an embryo created in vivo for purposes of transplantation to the uterus of a second woman will be addressed in Chapter V below. It may be observed here, however, that for the legal reason explained above, such removal is not governed

by abortion law, since it is intended to occur before the process of implanation is completed.

E. Contraceptive Failure

Since all contraceptive (including contragestive) means bear an irreducible minimum risk of failure, it does not follow that contraceptive failure is necessarily legally actionable as negligence. If legally determined requirements of informing patients about contraceptive options and for instance risk/benefit implications of options are not met (see Chapter IIIB, below), legal action may succeed, but this is not because of the contraceptive failure *per se*. It may be the case, however, that contraceptive care was in fact negligently undertaken, for instance by prescription of a clinically contraindicated contraceptive drug, negligent fitting or instruction for fitting of a contraceptive device, or negligent conduct or checking of vasectomy.

Although contraceptive failure is usually indicated by conception and pregnancy followed by childbirth, still birth or spontaneous or induced abortion, it may also be indicated by consequent infertility. Where contraception is deliberately selected over voluntary sterilization for purposes of fertility control because a woman wants to have a child at a later time, a contraceptive means that causes infertility will be particularly injurious. Pelvic inflammatory disease associated for instance with improper design of or advice upon use or subsequent checking of an intrauterine device (I.U.D.) may be a cause of legal liability.

The basis of legal compensation for contraceptive failure is generally the same as that for sterilization failure, involving the central issues of whether and how conception and birth of a child is compensable as a species of legal injury. The issue is better addressed in the context of sterilization failure, (see Chapter IIIE, below) because the bulk of Commonwealth case-law has arisen in this area. Where negligent contraception results in infertility or in impairment of health not related to reproduction, such as development of blood clots due to an unsuitable contraceptive drug negligently prescribed or negligently compounded or delivered by a pharmacist, legal liability will follow the governing local principles of negligence law, reinforced perhaps by principles of liability for breach of contract. The type of disclosure which should be made to a women for whom a contraceptive drug has been prescribed has been distinguished, however, from information which should legally accompany prescription of a routine therapeutic drug.

F. **Contraceptive Drug Information**

In the case of Buchan v. Orth Pharmaceutical (Canada) Ltd. ((1986), 35 Can. C.L. Torts 1) the Ontario Court of Appeal upheld the decision of the High Court ((1984), 46 O.R. (2d) 113) that the scope of a drug manufacturer's duty to warn of dangers inherent in the use of oral contraceptives exceeds that applicable to regular therapeutic, diagnostic and curative prescription drugs. The case may prove to be of special Commonwealth significance because the Court found no decisions dealing specifically with oral contraceptives in Canada, England or other relevant Commonwealth jurisdictions, and therefore referred to and was influenced by United States' jurisprudence on products liability. This has been built upon the basis of liability established in the British Common law tradition by the House of Lords in Donoghue v. Stevenson, [1932] A.C. 562 (H.L.), especially through Lord Atkin's classic statement (at p. 599) that:

> "... a manufacturer of products, which he sells in such a form as to show that he intends them to reach the ultimate consumer in the form in which they left him with no reasonable possibility of intermediate examination, and with the knowledge that the absence of reasonable care in the preparation or putting up of the products will result in an injury to the consumer's life or property, owes a duty to the consumer to take that reasonable care."

The plaintiff in Buchan claimed damages because she suffered a stroke as a result of taking contraceptive pills manufactured and distributed by the defendant company. She alleged that the defendant knew of the drug's potential to cause blood clotting that could result in a stroke, and had failed to give her an adequate warning, by label or package insert. the trial judge found as a fact that the use of the contraceptive probably caused or at least materially contributed to the plaintiff's stroke, and the Court of Appeal, finding no evidence that there was transcending procedural error at trial or that the trial judge was plainly wrong, considered the law in light of that finding. The focus of the decision was on the duty of the manufacturer and distributor of the drug owed directly to the ultimate consumer, and not upon the duty of any intervening prescribing doctor.

In general prescription drug liability cases, it has been held that what in the United States is called the "learned intermediary" rule prevails. This holds that since a prescribing physician can and must take into account the propensities of a drug and the susceptibilities of the patient, and is primarily relied upon by the patient to exercise judgment, there is no direct responsibility upon the drug manufacturer to inform the

patient of the drug's characteristics; indeed, drug manufacturers may be legally constrained from advertising prescription drugs to the general public. In contrast, non-prescription ("over-the-counter") drugs can be advertised to the public, and are selected by consumers usually without a doctor's recommendation or intervention. The defendant invoked this principle of prescription drug law to show that no legal duty existed to inform the plaintiff directly of the drug's known tendency to cause blood clotting, and that legal liability was discharged by giving of appropriate information to prescribing physicians.

The Court distinguished contraceptive drugs from others by observing that, unlike therapeutic, diagnostic and curative drugs, which are taken by those who are sick or suspected to be sick, contraceptive drugs are taken by healthy persons who wish to prevent the natural consequences of sexual intercourse. Contraceptive drugs are potent products voluntarily sought by healthy women. They go to doctors for the purpose of obtaining prescriptions which will entitle them to repeated supplies of drugs for protracted times without any new medical examinations. The decision to take the drug involves an individual woman's active exercise of choice; it is unlike other decisions in that it is primarily directed by the patient's choice of life style rather than the doctor's clinical or medical judgment. Accordingly, the Court found a different principle of manufacturer liability to disclose known risks of taking the drug. The Court concluded that a legal duty was owed directly to the consumer, and that there should have been a label or package insert specifically warning consumers of known adverse effects of the product upon general health. The Court was influenced by the fact that the drug was marketed in the United States by the same parent drug company with the warning which the plaintiff alleged would, if given with the Canadian product, have deterred her from taking the drug and thereby becoming liable to the stroke she suffered.

G. Administrative Issues

A number of Commonwealth jurisdictions have legal provisions on the power of nurses and other personnel to prescribe contraceptive drugs and, for instance, fit intrauterine devices. In Malaysia, for instance, ayurvedic practitioners may prescribe various herbal contraceptives when suitable to patients' conditions and health, although this may be an analogy with individual rights of self-medication by means of non-prescription substances (see 1 Mal. J. Repro. Health (1984), Supplement at pp. S.97-98). More actively involved in delivery of contraceptive services in, for instance, Dominica, are health visitors, district nurse/midwives and family nurse practitioners. They are entitled, in the absence of identified contraindications, not only to conduct physical examinations of women for contraceptive devices, but

also to insert intrauterine devices, and remove them when appropriate.

In Barbados, the Barbados Family Planning Association Act authorizes the Association to determine its own objectives, but services themselves are not controlled by legislation. A physician staff-member is available for consultation, advice and instruction, but qualified nurses counsel and advise those seeking services. Para-medical personnel provide the basic and practical family planning services (see N. Forde and J. Dyrud, _A Report on the [Barbados] Law Relating to Fertility and Population Growth_, for U.N. Fund for Population Activities (1983) 37). An issue of legal interest is whether personnel who are not physicians are deemed to act under the staff-member who is medically qualified, along extended lines of authorization, or whether they are acting independently and engaging in the practice of medicine. Nurses are governed by the laws and regulations relating to their own profession, and are liable to its discipline. Where non-physicians' professional relations to physicians are not regulated, however, a legal issue concerns whether they are engaged in the practice of medicine.

Two Commonwealth traditions exist, one not limiting the practice of medicine by law but controlling unqualified personnel who hold themselves out or permit themselves to be supposed to be physicians, the other rendering it a punishable offence to engage in the practice of medicine when not qualified and locally registered. If giving contraceptive services is the practice of medicine, para-medical personnel cannot engage in this in jurisdictions following the latter tradition, unless authorized by specific legislation. Some Commonwealth countries have legislated a medical monopoly on rendering of health services, and so limit the supply of contraceptive care by para-medical personnel to populations with no access to doctors, although a number of these have legal concessions in favour of nurses. See also Chapter I, D above, on approaches to traditional birth attendants.