MRG Newsletter

Medical Reform Group of Ontario, P.O. Box 366, Station J, Toronto, Ontario M4J 4Y8 (416) 588-9167

Volume 8, Number 2 April 1988

"MEDICINE IS POLITICS WRIT LARGE" -*Rudolf Virchow*

Contents

Spring General Meeting

The MRG's semi-annual meeting this spring will be devoted to AIDS. The theme **'Is AIDS Special?'** will try to address the issue of whether AIDS is pointing out the inadequacies in the rules we use to deal with health care problems **or** whether the rules are being misapplied because of hysteria against people with AIDS (PWA's).

On Friday night on May 6, Dr. Margaret Duckett, a visting scholar from Australia, who is presently working at McGill University Centre for Medical Ethics and the Law, will speak on confidentiality, the necessity of double blind drug trials, refusal to treat PWA's, mandatory testing, quarantine, accessiblity to health care services and other related topics. The meeting will be open to the public and we hope it will be well attended, so arrive early to ensure a seat!

On Saturday morning, May 7, the business meeting will take place, and in the afternoon, there will be three concurrent workshops with guest speakers. The goal of the workshops will be to work out the proposed resolutions which are contained in this newsletter (see below). These workshops will be devoted to three major themes and there will be at least one resource person for each workshop.

The topics are:

1. Limiting the Spread of AIDS; resource person: Fran Scott (Public Health).

2. Professional Responsibilities and the Care of Patients with HIV-related illnesses; resource person: Skip Bassford, professor of Philosophy at York University, member of Casey House board, teaches ethics in various settings.

3. Issues around AIDS drug trials; resource person: Dr. Ian Henderson, senior medical advisor to the Health Protection Branch.

Several articles pertaining to the workshops are reproduced in this newsletter.

Cost for the weekend is $25 This includes Friday night, Saturday, and lunch. Cost for Friday night only is $4.

At the back of this newsletter is a poster. Please detach and use it in your place of work to advertise the meeting.

Child Care

Child care is available for the Spring General Meeting. If you require child care, please contact Catherine Oliver before April 20, at 964-7186 (H) or 964-2993 (W).

General Meeting Agenda

Friday May 6, 8 p.m.

'Is AIDS Special?': Do our health care rules pass or fail the AIDS test?, with Dr. Margaret Duckett. *At Oakham House, 63 Gould St. (between Dundas and Gerrard, just west of Church).* Admission $4. Cash bar. Public meeting.

Saturday May 7

At South Riverdale Community Health Centre, 126 Pape Ave., Toronto. Chair: Bob James.

9:00 - 9:30	Coffee and registration
9:30 - 11:45	Reports
	Toronto
	Hamilton
	Financial
	SPECIAL REPORTS
	Pharmaceuticals
	Canadian Health Coalition
	Administrative Charges
	Midwifery
	Abortion
	Steering Committee Report
11:45 - 12:30	**Resolutions**: Working Conditions
	Resolutions: Quorum and Constitution
	Resolutions: Disciplinary Reforms
12:30 - 1:30	Lunch
1:30 - 3:00	AIDS workshops
3:15 - 4:30	AIDS resolutions and plenary

*Please note that a resolution proposing a constitutional change regarding quorum is being presented at the meeting.

Proposed Resolutions

from AIDS Working Group

Resolutions on Drug Trials

Whereas AIDS is a rapidly fatal terminal disease and

Whereas in Canada presently, there are very few drug trials being offered; and

Whereas it is necessary that there be patient support of any effective drug trial,

Be it resolved that:

1. The MRG calls for a special government mechanism for any rapidly fatal illness, such as AIDS, so that prospective drugs be processed more quickly, and within this mechanism, if there is preliminary evidence that a drug is effective in treatment or prophylaxis and is less toxic than the disease, that further use of the drug not require placebo trials.

2. The federal government and research funding bodies be more active in encouraging the establishment of drug trials in Canada and in cooperating in international, multicentre studies with the goal of maximizing places in drug trials for any person with AIDS (PWA) who wishes to participate.

3. That the government encourage means whereby PWA's and people working with PWA's are consulted in the designing of drug trials.

Resolution on Anonymous Testing

Whereas confidentiality of HIV testing cannot presently be guaranteed, be it resolved that anonymous testing for HIV status be made available.

Resolutions re: Professional Responsibilities and the Care of Patients with HIV-related Illness

Resolution 1

Whereas, physicians and other health care workers have a duty to provide competent and humane care to all patients without discrimination, and

Whereas, the occupational risks to health care workers of contracting HIV are very low and there is adequate knowledge to reduce these risks even further and,

Whereas, health care providers have traditionally accepted some risk in looking after the sick and dying,

Be it resolved therefore, that fear of HIV should not be grounds for physicians and other health care workers to refuse to treat and care for patients with AIDS and other HIV-related illnesses.

Resolution 2

Whereas, refusal to treat and care for patients with AIDS and HIV-related illnesses often stems from ignorance rather than excessive risk,

Be it resolved therefore, that hospitals, professionals organizations, and other health care institutions provide:

a) intensive educational campaigns to inform all health care workers and ancillary staff about the nature of AIDS and its transmissibility, and

b) appropriate and readily available protective measures for health care workers to prvent contraction of any lethal antigens including HIV.

Resolution 3

Whereas, AIDS is transmitted largely by sexual contact and needle sharing, and

Whereas, AIDS will only effectively be controlled by voluntary changes of behaviour on the part of those most at risk, and

Whereas, such voluntary measures will require counselling and trust between the physician and his or her patient, and

Whereas confidentiality is central to the bond of trust between the doctor and patient that must be strengthened rather than weakened if AIDS is to be curtailed,

Be it resolved therefore, that confidentiality of reporting HIV-related illnesses and HIV seropositivity be protected to the greatest extent possible.

Resolutions on Mandatory HIV Testing

Resolution 1

Whereas, the identification of individuals as seropositive to HIV infection can cause significant harm to mental health and lead to significant stigmatization and other unfair discrimination such as the loss of housing, employment, or life insurance; and

Whereas, there is no known effective treatment to be offered to those who test positive and are asymptomatic; and

Whereas behaviours likely to limit the spread of HIV should be encouraged in all sexually active populations and not just those who test positive; and

Whereas, the screening of low prevalence populations for HIV infection may lead to unacceptably high rates of false positive results,

Be it resolved therefore that all testing for HIV status be voluntary and done only with informed consent and with pre- and post-testing coun

Resolution 2

Whereas, having a positive HIV test result has profound consequences for the individual, and

Whereas, variations in laboratory methods of HIV tests can lead to increased rates of false positive results,

Be it resolved therefore that HIV testing in Canada be carried out only in centralized and rigorously quality-controlled public laboratories.

Resolution on Education

In keeping with previous MRG policy on the importance of adequate funding of preventive medicine and,

Whereas AIDS is usually a rapidly fatal illness for which we have no cure, and

continued

Whereas we have good knowledge of how AIDS is spread and how this could be prevented through popular education, and

Whereas education is most effective if it is learner centred,

Be it resolved that the MRG calls for generous funding of diverse public education efforts for both the community at large and minority groups. These programs should candidly acknowledge and should not judge the sexual and drug use behaviours that contribute to the spread of AIDS.

Resolution on Quarantine

Whereas AIDS is not spread through casual contact or by airborne droplets, and

Whereas the activities that do spread AIDS are generally voluntary and consensual, and

Whereas a policy of quarantine for any class of HIV infected individual would be ineffective at eliminating the spread of AIDS, could lead to a false sense of security in the general public and would be both legally and administratively extremely difficult to enforce,

Be it resolved that quarantine is an inappropriate measure for containing AIDS and is a dangerous and massive infringement of civil liberties

Resolutions for Spring General Meeting

Proposed by the working group on Working Conditions and Call Schedules

Working Conditions and Call Schedules

Current working conditions and call schedules for residents entail prolonged periods of sleep deprivation and result in residents working an average 81 hours per week, more than double the hours of the average worker in this country. On-call duties increasingly entail crisis intervention and intensive patient care. The consequences of such working conditions include a high rate of affective disorders among residents.

Inasmuch as cutbacks in the number of residency positions in Ontario threaten to increase the workload borne by residents, and

Inasmuch as we believe that such working conditions are detrimental to both patient and physician wellbeing,

1. Be it resolved that the MRG urge the provincial government to establish an interdisciplinary commission to review residents' working conditions and their impact on patients care.

2. Be it resolved that the MRG endorse the policy that mandatory working hours of interns and residents be limited to a maximum 16 hours in any one day and 60 hours in any one week.

3. Be it resolved that the MRG reaffirm its commitment to the establishment of part-time residency positions.

Proposed Constitutional Amendment

Whereas the business of the MRG has on at least one occasion been held up by the lack of an official quorum, and, whereas as the organization grows this will become an even more frequent occurrence,

Therefore, be it resolved that the constitution of October 1979, amended October 1987, be amended so that section 30 read: "A quorum at such a meeeting be 10% of the paid up full membership at the date of the meeting", and section 42 be amended to include the sentence "Such a vote may be taken by mailed ballot".

Resolutions Re: Discipline Process

The following resolutions are being proposed as the position of the MRG on the discipline process of the College of Physicians and Surgeons of Ontario. (CPSO). Please see the article in the February 1988 issue of the MRG Newsletter for background discussion.

Don Woodside and Bob James

Publication of Discipline Hearings: Publication of the evidence but the withholding of names. The physician could be named only after a guilty verdict, as at present.

Composition of Discipline Panels: Panels should have a majority of physicians, on the order of 3 to 2, or 2 to 1.

Presence of Complainant: The hearings should be open to the public, as in recommendation 1.

Counsel; Status of Complainant: The complainant not be a party to the hearing.

Access to the Medical Record: That the patient have unlimited access to their medical record. This is to include the right to copy elements of the record. This new system would begin after a waiting period of, e.g., five years.

Practice Review: That the CPSO launch a study to ascertain whether complaints or discipline hearings regardless of outcome are useful indicators of substandard practice.

Retraining: That money be set aside either through CPSO or through OHIP to assist in physician retraining when it is ordered by the CPSO.

Complaint Assistance: That the complaints procedure be well advertised.

THE FETAL RIGHTS DEBATE

The "fetal rights" debate has been highlighted recently in Canada by two cases. A British Columbia court ordered a mother to undergo a caesarean section (1) and a Belleville Ontario judge committed a pregnant woman who had been living in an underground garage to a hospital to protect her 38 week old fetus. (2)

In the U.S., this debate has been raging for several years. A particularly startling case in 1984 involved a Nigerian woman who was in hospital expecting triplets. She and her husband opposed a caesarean section so the doctors, who claimed that the life of the fetus was threatened, obtained a court order which granted the hospital administration temporary custody of the triplets and authorized the caesarean. The woman and her husband, on learning of the order, became irate. The husband was forcefully removed by seven security guards while the woman's ankles and wrists were cuffed to the bed and the operation performed. (3) This was not an isolated case it seems. There have been at least fifteen other court ordered caesareans in eleven different states of the U.S.. As well, women have been ordered detained (usually under child protection legislation), in order to protect their fetus from the abuse occasioned by the mothers drug-taking or alcohol abuse. Courts have ordered women to undergo blood transfusions even when they have refused on religious grounds. A Michigan court ordered a diabetic woman to take all medical treatment including insulin injections to benefit her fetus.

WHY FETAL RIGHTS?

Why is it that "fetal rights" have emerged as a legal/medical issue? Some have argued that the emergence of this issue is simply a further expression of the historical attempt by men to control women's reproductive capacities. There is no doubt some validity in this type of analysis.

The anti-abortion movement, which clearly derives a great deal of its impetus from the desire to control the reproductive process, sees in the "fetal rights" movement a means to both erode women's control over their own bodies and to move the legal status of the fetus towards full "personhood", with the ensuing legal implications. Every decision which overrides a woman's rights in favour of protecting a fetus helps their ideological and legal struggle. So, too, do decisions which punish third parties for injuries to the fetus as opposed to injuries to the mother. For example, the prosecution for murder of an individual who attacks a pregnant woman and kills the fetus raises the status of the fetus to that of a live infant.

Such decisions are used by anti-abortionists to argue that if the fetus is equal to a person in one legal context then it ought to be in another, i.e. the abortion context. Of course, this conclusion does not necessarily follow since the law is flexible enough to grant the fetus different protections depending on the ends sought to be achieved.

If the end sought is the protection of the fetus from injuries occasioned by the acts or omissions of third parties the implications are very different than when the end sought is the protection of the fetus from the acts or omissions of the pregnant women who carries that fetus. Thus the law might treat the deliberate acts of a third party which results in the death of a fetus as murder while at the same time not punish at all the acts or omissions of the pregnant woman which lead to the same result. The anti-abotionists hope that this reality will not be recognized. But others must attempt to clarify this reality and separate the various contexts in which the protection of the fetus is the end sought. In particular it is necessary to analyse separately the cases in which the "rights of the fetus" may come in conflict with the rights of pregnant women. It is these cases which raise the hard questions.

The cause of fetal rights is also being championed by some doctors. The motivations of these doctors are varied. Some doctors are part of the anti-abortion movement and their concern for fetal rights arises from the same sources as others in their movement. Others, who may well respect a woman's right to choose an abortion, are seriously and legitimately concerned for the health of their "fetal patient" who just happens to be developing inside their other patient. The legitimacy of their concerns have been strengthened by increased knowledge and technique in the area of fetology, and neonatology.

The danger for such doctors is that they became too excited about the new possibilities of caring for their "fetal patient", too absorbed in the "interesting problem" and not sufficiently concerned with the fact that this patient is developing inside another.

It is hard to be denied the possiblility of using one's knowledge and skills because of what appears to be, and may well be, the irrational or irresponsible decision or behaviour of the woman whose body denies one access to the fetus.

Nonetheless the doctor may have to accept the notion that where a conflict arises the pregnant woman must be considered the primary patient to whom certain duties are owed and whose refusal to give consent can not be overridden. Of course, this is the view that is being questioned by the fetal rights advocates.

Finally, the increasing state-sanctioned control of one human's body by others is a general dangerous tendency in the world and a civil liberties problem. This problem arises with state sponsored searches. prisons, mental institutions, prohibitions against birth control, drug laws, sexual prohibitions, etc.. The attempt to control womens' bodies, although clearly having a specific foundation in sexist ideology, should also be seen as part of the more general problem. The reactionary thrust of the fetal rights movement may primarily be motivated by an anti-woman sentiment; but any legal precedent or legislation which sanctions the denial of pregnant women's rights to liberty or to refuse intrusions into their bodies will inevitably be cited as a legal precedent in some other instance where the state wishes to exercise control over the bodies of its citizens. For this reason reactionaries may view the fetal rights movement as part of a general struggle to increase state authority over individual rights. While this argument does not settle the issue it suggests a serious

continued

danger that must be considered when balancing the arguments for and against state coercion of pregnant women in the name of "fetal rights".

WHAT STATUS HAS THE FETUS HAD IN LAW? (4)

The Anglo-American tradition has not granted the fetus the status of a live infant or adult. In general for a fetus to inherit property or have the right to sue for a civil wrong it would have to be born alive. In the criminal law one did not commit murder if one killed a fetus.

At common law the abortion of an unborn child before quickening was no crime at all if the woman consented, a misdemeanor after quickening. If the women did not consent, the offence was an assault on the woman. Only if the child were born alive and then died of an intentionally delivered prenatal injury was a murder committed.

Even under the abortion law which the Morgentaler decision has struck down, the fetus was not granted the status of "personhood". The Morgentaler decision, like Roe v. Wade (the decision of the U.S. Superior Court) has merely asserted that the state interest in protecting the fetus in the latter stages of its development might overrule a woman's freedom to choose an abortion. But even in the latter stages of a pregnancy a woman's interest in life or health might overrule the state's interest in protecting the fetus.

However, as the two cases referred to at the beginning of this article suggest, courts have extended the definition of "child" in child welfare legislation to extend protection to the fetus at the expense of the liberty or security of the pregnant woman. As suggested earlier in this article, "legal personality" could be granted to the fetus at any point in its development though the law has in the past only done so in very limited contexts. In otherwords it is possible to grant legal personality to the fetus in some circumstances and not in others depending on the ends sought. The anti-abortion movement tries to obscure this fact when it suggests that Roe v. Wade (5) *, by restricting abortions in the third trimester, somehow sanctioned overridding women's rights in favour of fetal rights even to the extent of forcing caesarean sections on women. It should be obvious that allowing the state to interfere with a woman's choice to abort in the third trimester is a far cry from sanctioning forced caesareans or the jailing of women who have chosen not to abort.

In Canada the Morgentaler decision will not end efforts by the "fetal rights" movement to override the rights of pregnant women, even though some of the Supreme Court's language may place serious hurdles in their way.In the end the issue is a political one, since the law by its nature does not dictate any particular outcome.

*What the U.S. Supreme Court did say in Roe v. Wade was that criminal abortion laws (like the Texas law involved in that case) which except from criminality only a life-saving procedure on the mother's behalf without regard to the stage of her pregnancy and other interests involved, violated the Due Process Clause of the Fourteenth Amendment of the U.S. Constitution, which protects the right to privacy against state action, including a woman's qualified right to terminate her pregnancy. Though the State cannot override that right, it has legitimate interests in protecting both the pregnant woman's health and the potentiality of human life, each of which interests grows and reaches a "compelling"point at various stages of the woman's approach to term.

(a) For the stage prior to approximately the end of the first trimester, the abortion decision and its implementation must be left to the medical judgment of the pregnant woman's attending physician.

(b) For the stage subsequent to approximately the end of the first trimester, the State, in promoting its interest in the health of the mother may, if it chooses regulate the abortion procedure in ways that are reasonably related to maternal health.

(c) For the stage subsequent to viability the State , in promoting its interest in the potentiality of human life, may, if it chooses, regulate, and even proscribe, abortion except where necessary, in appropriate medical judgment, for the preservation of the life or health of the mother.

from the headnote to Roe v. Wade

IS THE SOLUTION TO FETAL ABUSE A LEGAL ONE?

Developing a strategy for the prevention of demonstrable abuse to fetal life is obviously a serious problem. Once a woman has decided to forego an abortion in circumstances where that choice is really available it seems obvious that she has some moral obligation not to behave in a manner that seriously threatens the life or health of the future child. However, the law does not necessarily impose legal sanctions to enforce moral obligations and one can certainly question whether this is an instance where it ought to do so. It is important, as well, to recognize that the law can provide many different remedies to this problem. The extreme remedies include court orders sanctioning forced caesarean sections or fetal surgery. Perhaps only slightly less serious are orders committing women to jail through the use of child protection legislation in order to protect the fetus.

Non-criminal i.e. civil remedies include "wrongful life" suits which in the U.S. have recognized the child's rights to sue its mother for damages done to it while in utero. As well, the state could charge women criminally for their behaviour.

Obviously, it is possible to argue in favour of some of these solutions while rejecting others. The "fetal rights" advocates, however, seem to see little problem with any legal solution. Robert Black, a professor of political science at Northern Illinois University in de Kalb argued in the Journal of Legal Medicine that once a woman decides to "forego her right to an abortion and the state chooses to protect the fetus" she "loses her liberty to act in ways that might adversely affect the fetus." John Robertson J.D., professor of law at the University of Texas and a leading fetal rights advocate speculated in the Virginian Law Review (6) that the state could prohibit any actions that might reasonably be thought to kill a viable fetus or cause it to be born in a damaged state; and that laws prohibiting women from obtaining or using alcohol, tobacco or drugs likely to damage a fetus would withstand constitutional challenge. Obviously, there is a slippery slope involved in this debate.

continued

WHY LEGAL SOLUTIONS ARE INAPPROPRIATE

The central argument that those opposing legal solutions seem to raise is that the cost of denying women their rights to control their own lives and bodies is far too great to justify any such action. This argument is premised on the notion that the rights to privacy, "to be left alone", to not be touched by others except with consent, to not be deprived of ones freedom of movement are all fundamental aspects of free and democratic cultures which purport to recognize the principles of equality. The prospect of having operations forced on women and seeing women locked up in the name of protecting their fetus may horrify some of us and we will therefore reject legal solutions which would result in such state action.

However it is clear that this reality does not seem to horrrify some doctors, legislators and others who have resorted to the courts. There are other arguments against such remedies. One very practical one is the fact that such actions will destroy the relationship of doctor and patient. Once women realize that their doctor may "turn them in" or apply to the courts to impose his/her medical views on them, they may well avoid risking this possibility. Certainly women addicted to drugs will not seek the medical help they require. In the end the cause of "fetal rights" will be undermined by court actions against pregnant women.

Further, we must question the legal procedures that are taken in the cases where doctors form the opinion that caesarean sections are necessary. First, these cases normally take place when a women is already in hospital and least capable of playing the legal game. Some of the cases have involved judges holding court in the hospital room. The Charter guarantees that one will not be denied "security of the person" except in accordance with the principles of fundamental justice. But can these cases really live up to that promise? In the U.S. the forced caesarean cases have certainly not complied with the demands of what they call "due process". There is usually not sufficient notice, adequate representation, explicit standards of proof nor realistic means of appeal. Certainly appeals lose a lot of their meaning after the fact of the caesarean.

Further, the wide variations in caesarean rates between hospitals and types of patients has cast doubts on the opinions made by doctors. The degree of medical uncertainty inherent in conflicts between birthing women and their doctors should weigh heavily against invasive nonconsensual treatment. The fact is that in three American cases where the court had ordered a caesarean section the women gave birth vaginally to healthy babies before the order could be enforced. (7)

When one combines the medical uncertainty with the great difficulties in ensuring procedures guaranteeing compliance with the requirements of fundamental justice and the likelihood that court enforcement of doctors decisions will actually encourage treatment refusals, one has a very strong argument against resort to legal remedies.

We should also note that the court ordered non-consensual surgery on one individual for the well being of another is unprecedented. One may therefore wonder why a pregnant woman should be forced to undergo serious surgery for her fetus but not be required to do so for her live born child. For example, the law will not require a mother (or any one else) to supply bone marrow or even blood to a child. The "fetal rights " advocates are therefore arguing for greater rights for the fetus than for the child.

Finally, we should be made somewhat suspicious of a society which is prepared to invade women's bodies against their will and lock women up, allegedly because of concern for the fetus, while at the same time providing no guarantees that pregnant women will have proper housing, clothing, food, counselling or (in the U.S. at least) medical attention so that they give birth to healthy children. Nor is there any great concern for the millions of children in the U.S. and Canada who are abused after birth by malnourishment or whose potentials are wasted by neglect, lack of opportunity, drugs, alcohol, glue and social conditions which destroy them. Why all of a sudden all the concern for the "fetus" of a drug taking pregnant woman when her child will be lucky if it too does not become an addict after birth?

So although there should be real concern about fetal abuse, it seems to this writer that the "fetal rights" advocates have a rather weak case when they propose to lock women up or invade their bodies against their wills by resorting to the coercive apparatus of the state.

The cost of such policies it appears cannot be justified. We must seek more intelligent and humane ways to reduce the likelihood of fetal abuse. Such efforts should be encouraged. We should not be tempted to accept the simplistic solution of force through the invocation of the law.

Footnotes:

1. Referred to in a Globe and Mail editorial
citation unavailable

2. Re Children's Aid Society of City of Belleville, Hastings County and T et al. (1987) 59 O.R. (2d) 204

3. This case is referred to an excellent article on the subject by Gallagher, Janet: "Prenatal Invasions and Interventions: What's wrong with Fetal Rights?", (1987) 10 Harvard Law Review 9

4. For a quick overview of this question see: Catton, Katherine and Weiler, Karen M.: "The Unborn Child in Canadian Law", (1976) 14 Osgoode Hall Law Journal 644

5. Roe v. Wade, 410 U.S. 113 (1973)

6. Robertson, J.: "Procreative Liberty and the Control of Conception, Pregnancy and Chilbirth:, 69 Virginia Law Review 405 (1983)

7. One of these was:

Jefferson v. Griffin Spalding County Hospital Authority, 274 S.E.(2nd) 457 (Ga. S.C. 1981)

Bob Kellermann

Bob Kellermann is a member of the Law Union of Ontario.

Abortion and the Law: What Now?

The powerful, and, to me, unexpected decision of the Supreme Court of Canada to remove Section 251 from the Criminal Code has left us with much to do. As one observer said, it is just the end of the beginning.

The media likes to paint a picture of the chaos that has resulted from the absence of a criminal law governing abortion. In fact, the so-called chaos is no different than what existed under Section 251: widely differing access to abortion services from province to province. There are already laws in all provinces governing the practice of medicine without a license. The medical establishment has always been far too effective in limiting abortion, especially mid-trimester abortion. Even under Section 251, many hospitals would not perform abortions past 10 weeks, let alone 12 or 18 or 24. This so-called chaos is a sham and only shows the reluctance of governments and the infrastructure of our political institutions, e.g. the medical establishment, to allow women to have reproductive control.

There is no doubt that this decision is a powerful victory for everyone, especially women. It is a testament to the fact that if people organize, we can fight against injustice and win, even against formidable opponents like the state and organized anti-choice. Certainly the strength and longevity of the pro-choice movement, which has been steadily building to defeat this law for almost two decades, is the primary factor responsible for the Court's decision. I believe there were a couple of other factors as well. The combination of repeated jury acquittals and a federal government that refused to re-legislate had created a mockery of the courts. Most major newspaper editorials reflected that view. The Court felt constrained to safeguard the integrity of the judicial system itself.

Another factor affecting the decision was the nature of the Charter. The Charter has been justifiably criticized by progressives for its failure to recognize collective and economic rights. The Charter is primarily a liberal document, aimed at protection of the rights of individuals. Women organize to seek from governments recognition of our fundamental right to control our bodies, our reproduction and our sexuality. These are basic democratic rights, as fundamental as the right to free assembly and the right to vote. The barriers to access to abortion created by the law fit into the liberal notion of protection of individual liberties quite nicely. And so we have a decision that recognizes the right of access to abortion, not the right to abortion itself.

The current position of the Pro-choice Movement vis a vis the law is that there should be no criminal regulation of abortion. That is not to say that some restriction is not acceptable, but that the use of criminal law in this regard is inappropriate and even unnecessary.

Without criminal law governing abortion, won't a woman be able to have an abortion at any time in her pregnancy -- even in the ninth month?

Even Section 251 did not prescribe time limits for abortion. Yet third-trimester abortions have always been a rarity. According to Statistics Canada (1) in 1985), 0.3% of therapuetic abortions (T.A.'s) took place after 20 weeks, and 0.03% after 24 weeks. In actual numbers: 20 - 24 weeks $n = 140$, >24 weeks, $n = 20$. (These figures are actually inaccurately high since they exclude all abortions performed in clinics, 17 in Quebec and 2 in Ontario.) We know very well that women who are 27 weeks pregnant are not knocking down our doors seeking abortions. This really is a red herring.

Women and their doctors will not contemplate a third trimester abortion without a compelling reason. Where a doctor is uncertain as to what constitutes the best medical practice under the circumstances, he or she will seek an opinion from another doctor -- the usual practice for any medical procedure. There is no need to reinforce this practice with criminal sanctions.

And in those few instances (when a woman is sufficiently unaware and/or has sufficient emotional and/or cultural baggage that denial of her condition creates a mid-trimester presentation) are we to further burden her with carrying an unwanted pregnancy to term, or, as often happens, insist that she have an induction rather than the safer D & E(2)? I think not. The solution to those situations is not punishment of the victim, but prevention through non-judgmental sex education and contraceptive counselling and through the development of contraceptive technology offering more effective and safer options for women and men.

Canada, after all, has one of the highest mid-trimester abortion rates of industrialized nations.(3) Women often spend costly time doctor-shopping to find an abortion. Doctors often refuse to refer. It was facts like those upon which the Supreme Court made its historic judgement. Ensuring full and equal access to medically insured abortion would do a lot more to limit mid-trimester abortion than will writing a new law.

Without criminal law governing abortion, won't women have abortions for frivolous reasons and rely on abortion as a form of birth control?

Implicit in this claim is an image of women as careless, irresponsible people who have surgical operations on whim and need to be reined in by criminal legislation. Moreover, if such irresponsibility did exist it would be entirely dysfunctional to respond to it by forcing women to complete a pregnancy against their will.

In addition, studies repeatedly validated show that abortion is not seen by women who elect it as a preferred or desired form of contraception (Osofsky and Osofsky),(4) that women's experience with abortion increases their desire for effective contraception (ibid.) and that the majority of women who elect abortion have been using contraception(5).

Isn't a criminal law needed to balance the rights of the fetus against the rights of the woman?

continued

Establishing fetal rights in criminal law would be a dangerous encroachment on the bodily integrity and fundamental rights of women. It could lead to convictions of child neglect for smoking or consuming alcohol. Women thought to be leaving the country to seek abortions could be apprehended. Coerced surgical intervention on pregnant women, which has already occurred in both the U.S. and Canada, would be difficult, if not impossible, to prevent.

Viability is not a functional criterion for establishing criminal limits for abortion. In the first place it is dependent on available technology. What is viable in Toronto may not be viable in Sioux Lookout. In the second place it is variable. If technology makes a 5 week fetus viable are we then to insist that women carry them to term?

Anatomy or embryological development is not a functional criterion either. There are not biological answers to this complex question. The answer to when does a fetus have personhood is based on morality. It is a socially mediated norm. In medieval times, when infant mortality was very high, the Catholic church defined personhood as beginning some time during the first year of life, well after birth. In our times, with an increasing recognition of the full personhood of women, the answer to the question when are there two persons must be "at birth". In any case, morality should not be legislated, certainly not by criminal law. It is the women's own morality that should govern these decisions. The laws should reflect that women are responsible moral agents. The state has no place in our bedrooms, and it has no place owning or controlling our wombs.

Even if, morally speaking, fetuses in an advanced stage of gestation were to have rights, the consequences of enshrining such rights in law would be very grave for Canadian women. Abortion is a complex ethical issue. But criminal law is a blunt instrument.

With no law, will unregulated profiteering clinics not proliferate?

Standards of care and the establishment of private clinics are already regulated provincially by Colleges of Physicians and Surgeons and Ministries of Health. Federal criminal law is not required. Concern about commercial clinics is a real one. That is all the more reason that provincial governments should be pressured to provide start-up grants and yearly budgets for existing community-based clinics to add abortion services to their existing programmes. The two Toronto free-standing clinics must be funded so that no woman has to pay, whether she chooses an abortion in hospital or in a clinic.

Full and equal access to abortion requires that it be a medically insured service. We have already seen Alberta deinsure IUD insertion, surgical sterilization and contraceptive counselling. Several provinces are currently attempting to de-insure abortion. This was certainly the direction taken by opponents of abortion in the U.S. After Wade vs. Roe recognized abortion on demand in the first trimester, the Hyde amendment restricted medicaid coverage for abortions.

The federal government must be pressured to use the Canada Health Act to protect the universality of women's reproductive health care. We must organize sufficient political pressure to force the federal government to withold federal transfer payments to provinces that refuse to maintain abortion as an insured service.

The CMA's recent position paper was encouraging in this regard. It states that abortion is a medical service and should be insured and equally available across the country. Unfortunately, but not surprisingly, it also states that abortions should be performed in hospitals only.

It is extremely important that doctors who oppose this hospital-based delivery system for abortion services organize with lobbying efforts and with a presence in the media and in public meetings. The effort to establish the publicly funded clinic setting as part of the delivery system for abortion services is crucial to eradicating the barriers to abortion that exist, to greater or lesser degree, all across this country.

Likely Legislation

Having stated a case for no criminal legislation governing abortion, we recognize that unless there is sufficient political pressure mobilized to counter the forceful anti-choice offensive that followed on the heels of the Supreme Court decision, we will certainly have restrictive legislation. The CMA has struck a committee to study legislation and will be reporting its recommendations in April. The CMA wrote the last law.

In Sweden the law guarantees that a woman can choose abortion up to 18 weeks and can not be refused unless the procedure threatens her life or health. Comined with excellent sex education and good availability of contraception information, the reasonable access to abortion created by this law allows Sweden to have an extremely low mid-trimester abortion rate.

At the time of this writing, the Canadian federal government seems to be considering a 12 or 16 week limit with either no later abortions or very strict requirements for all abortions after that limit. The consequences of such limitations will be disastrous for the health and well-being of women.

References:

1. F. Wadhara, Chief Statistician, Statistics Canada,personal communication, 1988.

2. Grimes et al., Family Planning Perspectives, Jan.-Feb. 1981: Vol. 13, #1, P. 30.

3. Christopher Tietze, Induced Abortion, A World Review, 1983: Population Council, New York, P. 10.

4. Ossofsy & Ossofsky, Emotional effects of induced abortion, Planned Parenthood, 1987, P. 7.

5. M. Powell, Report for Ontario Ministry of Health, 1982, P. 18.

Nikki Colodny

Physician, Morgentaler Clinic

I am indebted to John Bagelow and CARAL for their articles, from which I have freely drawn.

The Marlboro Cowboy Rides Again in the East

Turn on the television set and see a familiar trio of cowboy, horse and cigarette ride off into the sunset to the almost forgotten but still stirring beat of the Marlboro theme. Switch channels and watch a bevy of chorus girls pump away in the background, while a scantily clad cigarette girl smilingly offers her wares to the viewer. There is no health warning to spoil the fun. Go outside and walk past the outdoor cigarette vending machines, found on every block, making cigarettes available 24 hours a day, to adults and children alike. You are in the world's most expensive country, but you can buy a package of cigarettes for less than you would pay in Canada. "For your health, don't smoke too much", reads the lame package warning, the only public acknowledgement of the dangers of smoking in the world's most advanced economy.

Welcome to Japan, an embattled cigarette industry's vision of tobacco heaven. There are no restrictions on cigarette advertising (Japan is the only industrialized nation that still allows ads on TV and radio); over 60% of adult males smoke (in contrast to 30% in Canada and the U.S.); the cigarette industry has only a miniscule non-smokers' rights movement to contend with; and the Japanese government does not yet regard smoking as a serious threat to public health.

It seems fitting that Japan was selected as the site of the recent 6th World Conference on Smoking and Health. (The previous conference was held in Winnipeg in 1983.) In Japan, the cigarette industry has always been a state owned monopoly. Japan Tobacco and Salt Public Corp. was privatized in 1985 and became Japan Tobacco Inc., but the government still retains 100% of the company's stock, making it the equivalent of a crown corporation.

The Japanese built an imposing multi-level trade wall around their cigarette market - a 90% tariff, special sales taxes, and restrictions on marketing, price cutting and distribution. This effectively kept out the six large tobacco multi-nationals that dominate the world market and allowed an inefficient domestic industry to keep a grip on Japan's 32 million smokers. Without any competition, Japan Tobacco Inc. has been able to coast along with sales of 308 billion cigarettes a year, using lackadaisical marketing and darker, less flavourful tobacco than the American brands.

In a country that has since 1945 embraced American culture -- from baseball to ducktails -- there was every reason to believe the Marlboro cowboy (and other potent Western marketing models) would quickly ride roughshod over the Japanese market. Little wonder that the American tobacco giants -- Phillip Morris, R.J Reynolds, Brown and Williamson, and American Brands -- have besieged the Japanese tobacco fortress for over a decade. For the American tobacco industry, what is at stake is not only the lucrative Japanese market. Japan is an important precedent that could open the door to the other Asian markets, like South Korea, Thailand, Taiwan, and the biggest market of all, China. In all these countries, protected government monopolies are similarly vulnerable to aggressive foreign marketeers.

They were finally able to breach the barrier when they exerted their considerable political muscle in Washington and enlisted the U.S government to threaten trade sanctions. Japanese exports of desirable products like semi-conductors, were held hostage to the unrestricted marketing in Japan of a dangerous U.S product facing increasing consumer and government resistance at home. The story of Japan's cave-in on American cigarettes and what has since ensued in the free-for-all Japanese market, provides a cautionary tale for Canada in the midst of our current debate on the banning of cigarette advertising and promotion.

Dr. Greg Connolly, director of the Massachusetts Office for Nonsmoking and Health, uncovered the story in government papers obtained through the U.S. Freedom Act. The U.S. industry, although it spent $200 million on product development and marketing from 1981 to 1985, was only able to increase its share of the Japanese market from 1.2 to 2%. In 1985, the U.S. Cigarette Export Association initiated a complaint of unfair trade practices. President Reagan instructed U.S. Trade Ambassador Clayton Yeutter to investigate Japanese tobacco trade practice under the 1985 amendments to Chapter 301 of the 1974 Trade Act. In their submission, the industry estimated that market share would grow from 2% to 20% representing revenue of $5 billion, once the barriers were removed. The U.S. Trade Representative's Office took up the cause, and after a period of unproductive negotiations with the Japanese Ministry of Finance, recommended that retaliatory tariffs be placed on a list of Japanese exports, including super-computers, textiles and automobile parts.

For the administration it was a chance to build some needed I.O.U.s on other trade issues with the senators from the tobacco belt, in particular with Jessie Helms of North Carolina, the second ranking member of the Senate Foreign Relations Committee.

The trade blackmail worked. The Japanese decided that the health of their export industries took precedence over the health of their people, and in the fall of 1986 gave the U.S. tobacco industry all that it had asked for. On the same day, South Korea agreed to open its monopoly cigarette market. Among the lobbyists they had to do battle with were Michael Deaver, the ex-Reagan aide now on trial for illegal lobbying for Canada on acid rain. Deaver was hired by Phillip Morris and Alexander Haig on behalf of R.J Reynolds. Deaver was actually lobbying for Korea on other trade matters and in effect made a deal with himself.

By April of 1987, the U.S. industry had swung their advertising artillery into action.Japan resembles the market in North America before the 1964 Surgeons General's Report, when the majority of smokers were adult males. 62% of adult men are smokers, while less than 15% of women smoke. The corresponding figures for North America are 30% for men and 25% for women. In Japan, a highly male dominated society, the large male to female ratio reflects the stereotyping of smoking as a male behavior.

continued

Recognizing the huge potential market, the American companies set their sights on Japanese women, especially those now seeking entry into the overwhelmingly male middle and upper management ranks. Ad campaigns linking smoking with women's liberation have proliferated, just as they did in North America when the womens movement conveniently came along and was exploited by the industry at a time when the male market was starting to dwindle. The results can already be seen in a rising incidence of female smoking in large urban centres, especially among younger women.

Adolescents form another potential new market. In Japan, it is technically illegal to sell cigarettes to those below age 20. Although cigarette advertising is legal on television, a voluntary code existed to limit ads to adult viewing hours. This has been tossed to the wind and ads are now shown during baseball games and youth oriented feature films. The ads make use of cowboys and other symbols calculated to appeal to a young audience. James Coburn, a popular actor among Japanese youth, appears in an ad for Larks. (Ironically, he recently died of lung cancer.) There is now cigarette sponsorship of motorcycle racing, and pop concerts, again a clear appeal to the youth market.

Japan Tobacco Inc. (JTI) has been forced to retaliate. They have introduced a new brand, Dean, that exploits the image of the young James Dean, the rebel with a cigarette. It sells in half packs of 10, easier for kids to buy and hide. J.T.I. has also introduced new brands, such as Misty, with female imagery to compete in the women's market.

Cigarette ads, two thirds of them American, now saturate the television airwaves. In April 1987, there were 2000 Western style cigarette ads shown on five Japanese stations, ten times the figure of two years ago. Ten years ago cigarettes were at the 40th spot in terms of advertising time; today they have jumped to number two.

The results have been dramatic. Within a year, the market share of American brands has jumped from 2% to 10% and will no doubt reach the predicted 20% level. But it is not just market share that has increased. The self-serving argument used by the Canadian cigarette industry in opposition to Bill C-51, that advertising does not induce non-smokers to smoke, but is only designed to grab market share, has been put to the test in Japan, and failed.

According to the World Tobacco Situation Report, a publication put out by the U.S. government, total consumption in Japan, has increased 2% during the ad war, reversing a 20 year downward trend.

Japan Tobacco Inc. was given a lucky break, when it was made public that the first shipment by R.J. Reynolds of Winston Lights was contaminated by the weed killer Dicamba. An uproar ensued as editorials, like one in the national Mainichi Shimbun: "Did Reynolds think that the Japanese have weeds growing inside their stomachs?", tore a strip off America for forcing shabby goods on Japan.

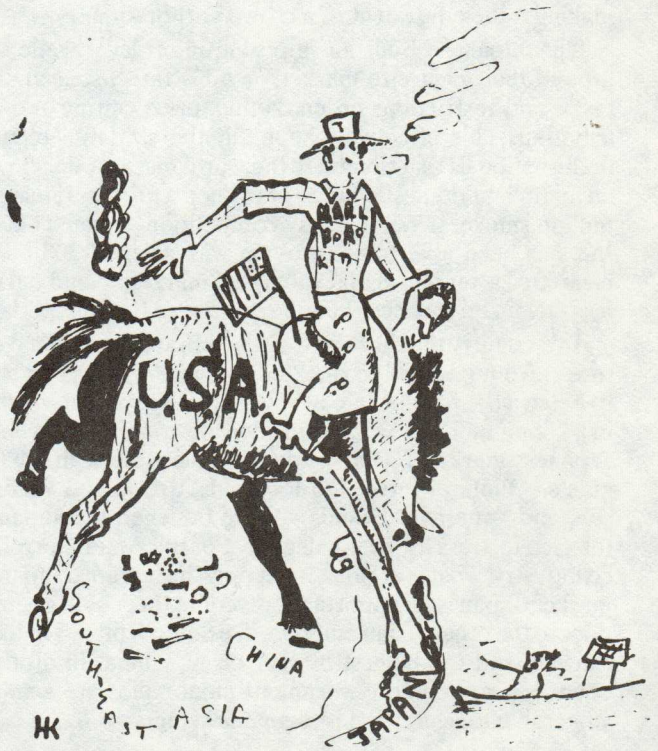
Some more basic questions beg to be asked:

- Is it trade reciprocity or trade extortion to link cigarettes to trade in legitimate and useful products? "The U.S is trying to sell to Japan what it can no longer sell at home, using methods it would not allow on its own territory," says Bungaku Watanabe, head of the Tokyo based Tobacco Problems Information Centre.

- Why are trade factors, both in the U.S. and in Japan being allowed to overide a country's responsibility to preserve the health of its citizens? Both governments are culpable. "The Japanese government is holding it's citizens' health hostage to foreign trade. The whole thing stinks," an angry Dr. Connolly charges. He has also uncovered evidence that the U.S. will view anti-smoking laws in a country with an American cigarette market as unfair trade practices. In a cable from the U.S. embassy in Tokyo back home to the Dept. of State, a series of proposed measures by the Japanese Ministry of Health to curb smoking are described as trade "counter-measures" that will be monitered closely on behalf of the American industry. In Hong Kong, a 1986 public health proposal to ban chewing tobacco, exported by the U.S. Tobacco Co., was met by threats of trade sanctions by four U.S Senators.

-Is it any coincidence that the same multi-national tobacco giants that control the cigarette industry in Canada, and that pour millions of dollars into opposing legislation to ban the advertising of a deadly and addictive product, are also engaged in a vicious advertising war in Japan? Their action speaks louder than their deceptive words about the ineffectiveness of cigarette ad bans. As the number of smokers in this and other Western countries steadily shrinks, they are using their political and marketing muscle to recruit new ones in countries that do not yet recognize cigarettes for what they are - the deadliest consumer product in history.

Jack Micay



IMPRESSIONS OF JANUARY 29TH

In order to prepare for a more detailed debate by the membership on the direction of the MRG, these personal views of the meeting are offered. The Steering Committee will be scheduling agendas for future meetings at local levels .It is important that if you have views on the subjects to be included that these should be relayed to your local chapter, or to the steering committee.

Impressions #1

Clearly for people at the meeting, there were two identified functions for the MRG .

(1) Mutual support as being part of a minority in the medical profession. (2) Being a forum to advance alternative strategies for development of health care in tandem with the people for whom health care is supposed to be.

To me those functions are not mutually exclusive. Moreover I feel strongly that only by forming shared intellectual positions, can joint mutual support be possible. What is there to be supportive of if you don't even know your MRG colleague's point of view? The problem with morale seemed to be related to length of time in the MRG, and failure to see new leading faces. I summarise this as exhaustion and dispiritedness. All of us have time constraints. The rational answer is to induct more people into policy formulation in the MRG. I also felt that there was a lack of recognition that in fact on several issues there are plenty of doctors out there who would welcome a more thought out philosophy . I'm not interested in simple minded doctor bashing. Even the OMA is dressing up in our clothes to some extent. What are we to be afraid of by being more adventurous in recruiting on the ground in medical schools, selling pamphlets on issues in any place that will sell them--including medical bookshops etc? Only energy and thrashed out intellectual positions are the limiting factors. It was pointed out (by Bob Frankford) that our 3 founding principles still require achievement. There's still work to be done. Look at them again.

Haresh Kirpalani

Impressions #2

About every two years, the MRG holds an evening session to look at its general directions and begin to formulate plans for the future. We recently held one such session. Those present were asked to put down some of their thoughts on paper for the newsletter.

I said the group was at a different development stage now than a few years ago. The societal issues are different, and our own priorities are different. When the group began some eight years ago, I was married but childless. My practice was young and not well-established. I had a lot of time. (And, being eight years younger, more energy.) The group was important to me and I spent a lot of time on it. There was also a single unifying issue: *extra-billing*.

Over the past eight years, I have 'acquired' two children. The extra-billing issue, while not won, is certainly closer to winning than it was. And I have less energy.

We began this group as a cohort, and have continued that way to some extent. Many of us in the last eight years have become families where previously we were single people or couples. Of necessity, our time constraints are different. Many of us have now entered into time-consuming practices, and this takes energy. For our stage of family and political life, it is not abnormal to want to cut down on our outside commitments. It is a lot more difficult now to leave your two children to go out to yet another meeting, than it once was to leave an empty house with your partner (who was likely involved in the same or a related political activity).

I think that it is time that the MRG recognize this change in its members, and organize accordingly. Most mature organizations (and that is what we are now) can only expect about ten percent of their members to be active at any one time. They function with a steering committee, or its equivalent, and many of the members pay their dues, but do little else. The degree of commitment that we have expected in the past cannot hold for the future, in my estimation.

If this is accepted by the group as necessary, then I can see a number of changes coming out of this. The constitution will have to be changed so that our "quorum" is not so large. (I have put a motion to this effect for the next spring meeting.) The Steering Committee will likely need to be modified to allow for a reduced commitment from its members. It may be necessary to have an "executive", by whatever name. Perhaps we can only have one General Meeting per year.

The MRG still serves a very useful function as a clearing house of ideas, as a place where like-minded physicians can get together, and as a forum for new ideas and new friends. But while these functions remain very important, the way in which we achieve them will have to change.

Bob James

such contact , the prevalence of infection may be even lower than 0.01%"

The Meaning of Positive tests

"Test sensitivity is not the issue ..to emphasise our concern with the false positive rate , our analysis makes the best -case assumption that the combination of enzyme immunoassay and Western blot testing ..is 100% sensitive , identifying all persons who are infected . The meaning of positive tests will depend on the joint false positive rate . Because we lack a gold standard , we do not know what that rate is now .We cannot know what it will be in a large scale screening program . However can be fairly sure that without careful quality control it will rise.

Bayes' rule allows us to calculate the probability that a person with positive tests is infected . Imagine testing 100,000 people , among whom the prevalence of disease is 0.01% . Of the 100,000 , 10 are infected ; 99,990 are not . A combination of tests that is 100% sensitive will correctly identify all 10 who are infected . If the joint false positive rate is 0.0005% , the tests will yield false positive results in 5 of the 99,990 people who are not infected . Thus of the 15 % positive results , 10 will come from people who are infected and 5 from people whoa re not infected , and the probability that infection is present in a patient with positive tests will be 67% "

Effects of screening in different populations, see figure:

"Implications .. depend on the joint false positive rate(JFPR) . THe horizonal axis shows a range of JFPRs from 0 to 0.5% . Unfortunately this is not true in populations at lower risk . The probability that infection is present in male army recruit with positive rates is 97% if the JFPR is 0.0005%, and 94% if the JFPR is 0.01% , but it will be only 62% if the JFPR rises to 0.1% . TH probability that infection is present in a female blood donor with positive tests is about 67% if the JFPR is 0.0005% , about 50% if the JFPR is 0.01% , but only 9% if the JFPR rises to 0.1%...at this higher JFPR , 10 women without HIV infection will be falsely identified as infected for each truly infected blood donor found . If the JFPR increases to 0.5% , as might occur in a single-stage testing program , then 50 women without HIV will be stigmatized for every truly infected person identified .The JFPR may rise if single stage testing is introduced into physicians' offices ; a false positive rate of 0.6% was recently reported for such a test . The JFPR will rise if tests are performed and interpreted less carefully when the amount of testing increases substantially . Finally it will rise if criteria for defining a positive Western blot test are less stringent that those observed by the military and the Red Cross. "

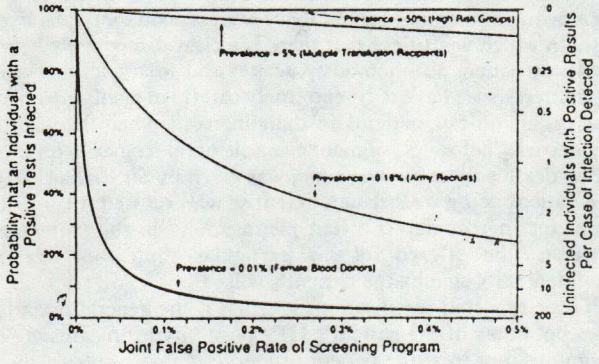


Figure 1. Meaning of Positive Screening Tests for HIV.

The horizontal axis shows the joint false positive rate of the tests. The left vertical scale shows the probability that HIV infection is present in a person with positive tests. The right vertical scale shows the number of uninfected persons falsely classified as infected for every infected person correctly identified. Sensitivity is assumed to be 100 percent. The four lines correspond to four populations that might be screened, each of which has a different prevalence of HIV infection. The boldface line represents low-prevalence populations such as those in which screening has recently been proposed.

The authors now overtly warn about the consequences of screening:

"Screening blood donors prevents transmission because we do not transfuse the blood . How much does screening change behaviour ?By no means all seropositive persons are persuaded to practice "safer sex". Apparently only a minority refrain from childbearing .....We should think again about the ethics of screening and bout the social consequences os positive tests for HIV antibody.

....sensitive information would ...in all likelihood not remain private .....most people consider a " positive AIDS test " to be a sentence to ghastly suffering and death . Patients with such results will take little comfort in Bayes' rule and will be offered little reassurance by their insurer , employers , and acquaintances .."

The authors conclude :"A time for Caution"

"The AIDS epidemic frightens us all . But we should not let our fear cloud our judgment . Hasty and indiscriminate screening for HIV is imprudent and potentially dangerous .....standardization and quality control should come first (before testing programs) . These will take time and money ; monitoring laboratory performance will require continuing effort , expenditure , and regulation .....If laws are to link our fates to tests results , should not due process be brought to the benches where those tests ate performed ? We will need guarantees not only of the confidentiality but also of the quality of the testing procedure .....How will we decide whose positive test we can scrutinize ? Who will weight the scientific evidence against the skepticism of the person who does not believe his positive results ? How often will we tests and re-test ....? Will we recognize .....tests.....in other countries ...? What are the trade offs? How many engagements should end to prevent one infection ? How many jobs should be lost ? How many insurance policies should be cancelled or denied ? How many fetuses should be aborted and how many couples should be aborted and how many couples should remain childless to avert the birth of one child with AIDS?".

Abstracted from the above citation , by Haresh Kirpalani

such contact , the prevalence of infection may be even lower than 0.01%"

The Meaning of Positive tests

"Test sensitivity is not the issue ..to emphasise our concern with the false positive rate , our analysis makes the best -case assumption that the combination of enzyme immunoassay and Western blot testing ..is 100% sensitive , identifying all persons who are infected . The meaning of positive tests will depend on the joint false positive rate . Because we lack a gold standard , we do not know what that rate is now .We cannot know what it will be in a large scale screening program . However can be fairly sure that without careful quality control it will rise.

Bayes' rule allows us to calculate the probability that a person with positive tests is infected . Imagine testing 100,000 people , among whom the prevalence of disease is 0.01% . Of the 100,000 , 10 are infected ; 99,990 are not . A combination of tests that is 100% sensitive will correctly identify all 10 who are infected . If the joint false positive rate is 0.0005% , the tests will yield false positive results in 5 of the 99,990 people who are not infected . Thus of the 15 % positive results , 10 will come from people who are infected and 5 from people whoa re not infected , and the probability that infection is present in a patient with positive tests will be 67% "

Effects of screening in different populations, see figure:

"Implications .. depend on the joint false positive rate(JFPR) . THe horizonal axis shows a range of JFPRs from 0 to 0.5% . Unfortunately this is not true in populations at lower risk . The probability that infection is present in male army recruit with positive rates is 97% if the JFPR is 0.0005%, and 94% if the JFPR is 0.01% , but it will be only 62% if the JFPR rises to 0.1% . TH probability that infection is present in a female blood donor with positive tests is about 67% if the JFPR is 0.0005% , about 50% if the JFPR is 0.01% , but only 9% if the JFPR rises to 0.1%...at this higher JFPR , 10 women without HIV infection will be falsely identified as infected for each truly infected blood donor found . If the JFPR increases to 0.5% , as might occur in a single-stage testing program , then 50 women without HIV will be stigmatized for every truly infected person identified .The JFPR may rise if single stage testing is introduced into physicians' offices ; a false positive rate of 0.6% was recently reported for such a test . The JFPR will rise if tests are performed and interpreted less carefully when the amount of testing increases substantially . Finally it will rise if criteria for defining a positive Western blot test are less stringent that those observed by the military and the Red Cross. "

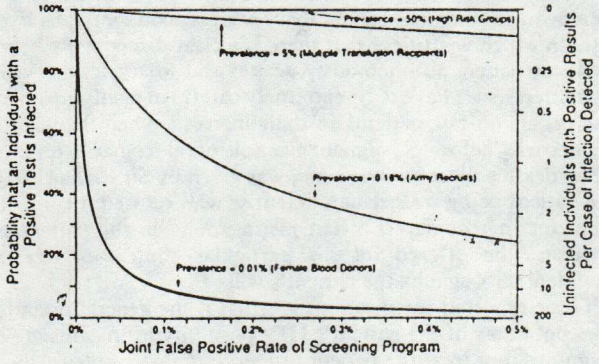


Figure 1. Meaning of Positive Screening Tests for HIV.

The horizontal axis shows the joint false positive rate of the tests. The left vertical scale shows the probability that HIV infection is present in a person with positive tests. The right vertical scale shows the number of uninfected persons falsely classified as infected for every infected person correctly identified. Sensitivity is assumed to be 100 percent. The four lines correspond to four populations that might be screened, each of which has a different prevalence of HIV infection. The boldface line represents low-prevalence populations such as those in which screening has recently been proposed.

The authors now overtly warn about the consequences of screening:

"Screening blood donors prevents transmission because we do not transfuse the blood . How much does screening change behaviour ?By no means all seropositive persons are persuaded to practice "safer sex". Apparently only a minority refrain from childbearing .....We should think again about the ethics of screening and bout the social consequences os positive tests for HIV antibody.

....sensitive information would ...in all likelihood not remain private .....most people consider a " positive AIDS test " to be a sentence to ghastly suffering and death . Patients with such results will take little comfort in Bayes' rule and will be offered little reassurance by their insurer , employers , and acquaintances .."

The authors conclude :"A time for Caution"

"The AIDS epidemic frightens us all . But we should not let our fear cloud our judgment . Hasty and indiscriminate screening for HIV is imprudent and potentially dangerous .....standardization and quality control should come first (before testing programs) . These will take time and money ; monitoring laboratory performance will require continuing effort , expenditure , and regulation .....If laws are to link our fates to tests results , should not due process be brought to the benches where those tests ate performed ? We will need guarantees not only of the confidentiality but also of the quality of the testing procedure .....How will we decide whose positive test we can scrutinize ? Who will weight the scientific evidence against the skepticism of the person who does not believe his positive results ? How often will we tests and re-test ....? Will we recognize .....tests.....in other countries ...? What are the trade offs? How many engagements should end to prevent one infection ? How many jobs should be lost ? How many insurance policies should be cancelled or denied ? How many fetuses should be aborted and how many couples should be aborted and how many couples should remain childless to avert the birth of one child with AIDS?".

Abstracted from the above citation , by Haresh Kirpalani

AIDS and Medical Confidentiality

Consultants in sexually transmitted disease clinics dealing with patients with the acquired immune deficiency syndrome (AIDS) or positive for the human immunodeficiency virus (HIV) "are being over-protective of confidentiality," a general practitioner and member of the British Medical Association's central ethical committee is reported to have said.[1] On the other hand, the BMA in its third and most recent statement on AIDS says, "The traditional confidentiality of the doctor-patient relationship must be upheld in the case of patients suffering from AIDS and HIV seropositive individuals."[2]

Clearly, the advice from the BMA is disputed by many general practitioners. The Leicestershire Local Medical Committee, representing 400 general practitioners, wrote to the BMA complaining that its guidelines were "very wrong"; as with any other serious illness general practitioners should be informed by specialists who discovered important medical information about their patients, including infection with HIV.[3] In a straw poll three out of the four general practitioners questioned by a medical newspaper on this issue are reported to have opposed the BMA's policy and to have stated that general practitioners should be told.[4] At the BMA's annual representative meeting this year a variety of motions demand that they shall be told.[5] But in an excellent debate last week the annual conference of local medical committees, which represents all National Health Service general practitioners, rejected by 156 votes to 109 a proposal that family doctors had a right to be told if a patient was found to be positive for HIV and decided that patients were entitled to normal standards of confidentiality (p 1707).

The problem arises when people are found to be positive for HIV in a clinic for sexually transmitted diseases and refuse permission for the information to be passed on, despite advice about why it would be preferable for their general practitioner to be informed. The main justifications stated or implied in favour of breaking confidentiality in such circumstances are (1) that it is normal medical practice; (2) that it is in the interests of the patient by leading to better medical care; (3) that it is in the interests of the general practitioner and associated staff by reducing their risks of accidentally acquiring HIV infection; (4) that it may be in the interests of other patients who might risk becoming infected by the patient; and (5) that it is in the interests of society in general by helping to reduce the spread of the AIDS epidemic.

Normal medical practice?

Two questions need to be answered. Firstly, Is it normal medical practice to pass on medical information to other doctors against patients' wishes? Secondly, If it is, what follows?

To agree that specialists normally pass on information to patients' general practitioners in no way means that they normally do so *when the patient refuses to allow such transfer of information about him or her.* The fact that it is normal for specialists to pass on information to general practitioners surely only reflects the fact that in most cases patients agree, or can be reasonably assumed to agree, that it is in their interests for such information to be passed on. But when patients do not agree, or can reasonably be expected not to agree, then is it not also entirely "normal medical practice" for doctors to respect their patients' wishes? The two most obvious categories of such medical behaviour are when a patient is receiving psychotherapy or when a sexually transmitted disease has been diagnosed: the latter instance offers the most clearly relevant example in which it is precisely *not* normal medical practice for specialists to pass on medical information to general practitioners against the patient's wishes.

In any case, even if it were normal medical practice to pass on medical information against patients' wishes what would follow from this? Certainly not that the practice is therefore right. For it to be accepted right independent justification would be required, and the example of AIDS, as in so many other contexts, provides a stimulus for re-examining our normal practices. Some might argue (especially perhaps in other European countries) that to urge the breaking of confidentiality in cases of HIV positivity is a regrettable indication of how far we have already travelled down the slippery slope away from the absolute requirement of medical confidentiality demanded in the World Medical Association's international code of medical ethics[6] and also apparently, but equivocally, in the new European guide to medical ethics[7] (equivocally because as well as requiring a guarantee to the patient of complete confidentiality the guide also provides for exceptions "where national law provides for exceptions"). The claim that medical confidentiality is an absolute requirement has been thoroughly presented by one contemporary European medical writer[8] and in the face of erosions undoubtedly has its attractions. But, though I have argued previously that such absolutism is in the end untenable,[9] medical confidentiality clearly remains a strong medicomoral principle and should be broken only if yet stronger moral reasons prevail. A mere claim that overriding confidentiality has become normal medical practice, even if it were true, would not provide moral justification for doing so.

Is disclosure in the interests of the patient?

Given that a patient, because he perceives his own interests to be best served by confidentiality, rejects the view of a clinician in a sexually transmitted diseases clinic that it would be preferable to tell his general practitioner of his disease, it would surely be unusually arrogant for a doctor to persist in assuming that "doctor knows best" and that disclosure is in the patient's best interests. A vital aspect of the medical objective of doing good for one's patients is to discount one's own perception of what is good for them in favour of their own, autonomous beliefs about what is good for them. Even in cases in which we believe that there is a clear discrepancy between what the patient autonomously desires and what is in the patient's best interests we have to be extremely careful in justifying imposing our beliefs on our patients in their interests when they explicitly reject such "help." A poignant example of reluctance to do so, even when death will be the outcome, was given by Sir Richard Bayliss, the patient being a Christian Scientist who refused medical treatment for thyrotoxicosis.[10] Can justification "in the patient's best interests" be offered in this particular context of overriding confidentiality against the patient's will?

Three reported justifications are that if the general practitioner does not know of the patient's HIV positivity he may make wrong diagnoses, not treat the patient properly, or order potentially risky diagnostic tests.[3] Of course there is a higher chance of wrong diagnosis and inappropriate treatment, but patients who are positive for HIV tend to maintain a continuing therapeutic relationship with the clinician at the clinic for sexually transmitted diseases who made the original diagnosis; thus even if the general practitioner does not pick up disorders related to AIDS the clinician at the clinic is likely to do so and treat them appropriately. As for potentially harmful diagnostic tests, I wonder which ones and in what sorts of circumstances. Thinking of the typical diagnostic tests in general practice that I request, such as radiography, blood tests, and urine tests, it is not clear to me how, if the tests were clinically in the patient's interests without my knowing about his HIV

Imperial College of Science and Technology, London SW7 1NA

RAANAN GILLON, MB, MRCP, director, health centre; editor, *Journal of Medical Ethics*; deputy director, Institute of Medical Ethics; and senior fellow, Centre for Law and Medical Ethics, King's College, London

from British Medical Journal, Vol. 294, 27 June, 1987

continued

AIDS and Medical Confidentiality

positivity, they would be transformed into being against his interests if I did know. In any case patients who did not wish me to know about their HIV positivity would probably consult their clinician at the sexually transmitted diseases clinic before undergoing special tests recommended by me such as contrast radiography. Thus it seems unlikely, from the point of view of the patient's best interests, that diagnostic tests would be a problem, and the problems of imperfect diagnosis and treatment by the general practitioner are likely to be compensated for by the continuing care of the specialist in sexually transmitted diseases.

Like most general practitioners I would regret such lack of confidence by the patient in me, but I do not believe that overriding his wishes for confidentiality is likely to improve matters or to be in his best interests. Even if I did I can certainly see no general justification in "the patient's best interests" for imposing such transfer of information to me against his will.

Insurance medicals and patients' best interests

In the context of best interests it is worth recalling that benefiting one's patients should also be considered in the context of the harm that a proposed benefit risks: it is net benefit over harm that counts. A patient's interests are not confined to strictly medical interests, and a proposed medical benefit may result in non-medical harms. A single example should suffice to demonstrate this. It is usually the general practitioner who is contacted for medical information when patients want life and health insurance. If the general practitioner knows about his patient's HIV positivity he must, presumably, in honestly and professionally answering the relevant question disclose this information. If, however, the general practitioner does not know he can honestly say so. Thus in some cases it may well be in the patient's best interests for the general practitioner not to know.

Here, incidentally, is another example in which our current medical norms—those concerning insurance medicals—are called into stark relief by the AIDS epidemic. It seems clear that when we complete an insurance medical form we use information gathered in the course of a therapeutic relationship for an essentially commercial purpose, and this commercial purpose is in some cases likely to conflict with the best interests of the patient. It is of course done with consent, but the sort of consent that the patient in many cases would prefer not to have to give. Perhaps we ought to change our norms so that in all cases in which there is any doubt in the general practitioner's mind about whether completing an insurance medical questionnaire would be in the patient's best interests (1) the patient should be consulted and (2) if the patient prefers the general practitioner should return the insurance medical form uncompleted. The company could then arrange for an independent and explicitly "non-therapeutic" medical assessment. In addition, the choice of having an independent medical assessment should perhaps be explicitly offered by insurance companies to all applicants for insurance right from the start.

Is disclosure in the interests of general practitioners and other members of the primary care team?

This is essentially the argument that confidentiality is too dangerous for general practitioners and other primary care health workers including nurses to respect in cases of HIV positivity. I considered the arguments of danger in a previous article about refusal to treat patients with AIDS and those positive for HIV.[1] In summary, I argued (1) that the medical profession (including "the greater medical profession") accepted a certain degree of risk as part of its professional norms and (2) that the extensive empirical evidence currently available showed that the probability of accidental transmission of HIV to medical staff and families and other close contacts of patients positive for HIV or with AIDS was very low, given normal care with blood and other body fluids.

Is disclosure in the interests of other possible patients?

I find this the most difficult of the arguments in favour of breaking confidentiality, though at most it seems to justify disclosure against a patient's will only in exceptional circumstances. Thus if either a clinician in a sexually transmitted diseases clinic or a general practitioner knows or has strong reason to believe that a patient positive for HIV intends to have sexual intercourse with a new and uninfected partner or partners without telling the partner(s), and efforts to persuade the patient to tell have been rejected and there is a reasonable prospect of preventing the event(s), then efforts to inform such contacts do seem justifiable in order to try to prevent them from being infected with what is likely to be a fatal virus. This seems particularly clearly justified if the previously uninfected contact is also a patient of the doctor concerned (because of the special obligations doctors have to their patients), but it might also apply, for example, in the context of tracing contacts of patients with sexually transmitted diseases as part of a general concern to protect others from potentially fatal diseases.

Even against this very limited justification of breach of confidentiality, however, it might be argued, as I do below, that it is still better not to break confidentiality. Thus by being known to maintain a very strict level of confidentiality the medical profession has a better chance of maintaining the trust of high risk groups; it will therefore be better able to influence them and more effectively protect the health of others in general. Although I would agree that it is almost always likely in practice that preserving confidentiality will be the better course for precisely such consequentialist justification I find it impossible to rule out circumstances in which I, at any rate, would believe it right to break confidentiality. I can imagine, for example, a "psychopath" positive for HIV who makes it clear that he or she does not care about transmitting the virus to others, and indeed intends to do so, and when I know that another of my patients, probably uninfected with HIV, is a likely new partner.

The possible existence of such rare exceptions (for most patients positive for HIV like most other patients and people in general are not psychopaths and do care about others) is simply evidence for my earlier claim that medical confidentiality should not be an absolute requirement, only a very strong one. In the context of a just society strong evidence of likely and preventable death or severe injury to others can afford justification for overriding confidentiality, including the passing on of information between doctors and to new contacts. But such circumstances will be extremely rare. In most cases the probability of preventing death or severe injury by breaking medical confidentiality about HIV state will be low—and every time a doctor does break such confidentiality he or she will further reduce a trust in the profession that while it exists can itself be reasonably expected to help reduce the spread of the disease.

Is disclosure in the interests of society?

The final argument sometimes offered for passing on information about patients positive for HIV is that it is in the interests of society by helping to reduce the spread of AIDS. Justice, it might be added, requires doctors to take into account not only the interests of their individual patients of the moment but of society in general. Though the desire to minimise the spread of AIDS is doubtless shared by all sane people, and though the claim that doctors must include the interests of society in their medicomoral reasoning is one that I would strongly support, it does not follow that overriding the traditional norms of medical practice in the context of AIDS is the best way to achieve those objectives. I hope to return to this theme in a subsequent paper, but, in brief, the spread of AIDS seems most likely to be curtailed and the interests of society best served if the trust and cooperation of those at greatest risk can be obtained and maintained. Thus the consequentialist objective of minimising the spread of AIDS fortunately seems to point in the same direction as the traditional rules of medical deontology, including the norms of medical confidentiality. In the context of this paper it seems

particularly implausible to argue that the spread of AIDS will be curtailed if specialists in sexually transmitted diseases are routinely required to break medical confidentiality by passing on to general practitioners information about patients' HIV positivity against those patients' wishes. On the contrary, it seems far more probable that the interests of society will be best served if the medical profession in general, and perhaps specialists in sexually transmitted diseases in particular, can preserve their reputation, especially among those most at risk of infection, for conforming to a very strong—though not absolute—principle of medical confidentiality.

Summary

In summary, I have argued that the arguments offered or hinted at in favour of doctors' breaking medical confidentiality by passing on information about their patients' HIV state to others, including other doctors, when this is against the patient's considered wishes are generally unconvincing. Although in highly exceptional cases there may be justifications for overriding confidentiality, the requirement of medical confidentiality is a very strong, though not absolute, obligation. Patients, their contacts, doctors and their staff, and the common good are most likely to be best served if that tradition continues to be honoured.

References

1 Duncan N. GPs demand to be told results of AIDS tests. *Pulse* 1987;Jan 3:1.
2 British Medical Association. *Third BMA statement on AIDS*. London: BMA, 1986.
3 Beecham L. Support for confidentiality for AIDS patients. *Br Med J* 1987;294:1177.
4 Kennard N. Should GPs be told AIDS test results? *Pulse* 1987;Jan 17:25.
5 British Medical Association. Agenda of the British Medical Association's annual representative meeting 1987, motions 359-374. *Br Med J* 1987;294 (insert in issue of 6 June).
6 British Medical Association. *Handbook of medical ethics*. London: BMA, 1984:70-1.
7 Anonymous. European guide to medical ethics. *IME Bulletin* 1987;No 25:3-7.
8 Kottow MH. Medical confidentiality: an intransigent and absolute obligation. *J Med Ethics* 1986;12:117-22.
9 Gillon R. Confidentiality. *Br Med J* 1985;291:1634-6.
10 Bayliss R. A health hazard. *Br Med J* 1982;285:1824-5.
11 Gillon R. Refusal to treat AIDS and HIV positive patients. *Br Med J* 1987;294:1332-3.

Refusal to treat AIDS and HIV positive patients

from British Medical Journal, Vol. 294, 23 May, 1987, p. 1332-3

RAANAN GILLON

"I . . . reserve the right to decline to operate on those in whom recent or continuing infection with HIV is likely other than in lifethreatening circumstances."[1] Few doctors have been as bold as to say so in print. It seems clear, however, that the author of this assertion is by no means alone, and I have heard several anecdotal reports of doctors who have refused to see or treat human immunodeficiency virus (HIV) positive patients and of a general practitioner who removed a patient from his list after learning that the patient was HIV positive. As against such a stance a *BMJ* editorial suggested that the General Medical Council should take a leaf out of the Royal College of Nursing's book[2] and discipline any doctor who refuses to care for a patient infected with HIV.[3]

What are the proposed justifications for withdrawal of medical care from HIV positive patients? The surgeon who reserves "the right to decline to operate" implies that four types of risk and, in addition, the "voluntary sexual perversion or mainline drug abuse" of most HIV positive patients justify withdrawal of medical care. The risks he refers to are those to other patients, to the doctors and to their staff and their families "of contracting this terrible disease."

Empirical evidence

Part of the assessment of these justifications obviously depends on the empirical facts—just what are the risks to health care workers (and thus to their families) and to other patients if HIV positive patients are treated? In terms of the nature of the harm risked clearly it is indeed a "terrible disease" which is risked. However, the probability of that harm occurring as a result of health care workers treating HIV positive patients is very low according to the consensus of expert opinion.[4-10]

According to Miller *et al*, for example, there is a substantial body of evidence that the risk of occupational transmission "is negligible provided that basic standards appropriate for the care of all patients are applied" and "even in 'needlestick' injury the risk appears to be extremely small. . . ."[5] Volberding and Abrams, acquired immune deficiency syndrome (AIDS) physicians in San Francisco, "consider the risk of contracting AIDS from patients to be negligible,"[9] and the San Francisco task force on infection control in the care of HIV patients state that "the risk of nosocomial transmission of HIV is extremely low even after accidental parenteral inoculations."[10]

Imperial College of Science and Technology, London SW7 1NA
RAANAN GILLON, MB, MRCP, director of health service; editor, *Journal of Medical Ethics*; and senior fellow, Centre for Medical Law and Ethics, King's College, London.

Among the postulated reasons for this low probability of occupational infection are the notions that the HIV virus is a "pathogenetic weakling that is truly difficult to transmit except by sexual routes"[11] and the relatively low concentration of HIV virus particles in infected blood compared with, for example, blood infected with hepatitis B.[4] Nor does ordinary social contact present a risk of infection according to the official advice from the Department of Health and Social Security to surgeons and other doctors dealing with AIDS patients,[8] and Friedland *et al* found no transmission to 101 household contacts of 39 AIDS patients studied for between three and 48 months (median 22 months) and report that: "Except for sexual partners and children born to infected mothers none of the family members in more than 12 000 cases reported to the Centers for Disease Control (CDC) are known to have contracted AIDS (CDC, unpublished data)."[12] Sande concluded "that caring for AIDS patients, even when there is intensive exposure to contaminated secretions, is not a high risk activity."[13]

It must be said that occasional expert medical doubt is cast on this consensus. Seale, for example, in the *Guardian*[14] and at a recent London Medical Group conference on AIDS, suggested that there is a risk of salivary spread of HIV by kissing—a worry about saliva which was perhaps reflected in the ticket collector's concern about collecting chewed rail tickets reported in the *London Evening Standard*.[15] Smith's reply to Seale, from the Public Health Laboratory Service,[7] seems convincing and most of the empirical evidence indicates that the risk to doctors and other health care workers (and thus to their families) of occupational acquisition of AIDS virus infection is very low probability; and extrapolating the information available it seems even less likely that other patients will contract the infection as a result of AIDS patients being treated in the same operating theatres or wards, etc.

None the less, someone might argue that it is not just the nature of the harm and its probability that is important in risk assessment; it is also its perception. If a health care worker perceives the risk of acquiring AIDS as being very frightening, even if there is in fact only a low probability that this will actually happen, then ("in a free world") there is no obligation on him or her to participate in the infected patient's care. An appeal to the principle of respect for autonomy might be offered in support of such a claim—respect, that is, of the health care worker's autonomy rather than the patient's. Undoubtedly, the factor of risk perception is important,[16,17] and it is also true that a plausible case can be made for the claim that in a free society people in general should not be forced to do what they perceive to be dangerous to themselves to benefit others even if their perceptions of danger seem greatly inflated.

A moral obligation to help our patients

We come now to what seems to me the crux of this argument, for while it may be hard to justify the imposition of such perceived risk taking on all and sundry does the same apply to members of the medical and other health care

continued

Refusal to treat AIDS and HIV positive patients

professions? The counterargument is that as health care professionals we accept obligations to treat our patients even when this entails what might be called real risks, let alone when the risks, though fatal if they occur, are in fact very unlikely to happen. I have argued previously that this medical obligation to benefit our patients is not absolute (nor is any obligation).[18] It is, however, surely an important component of being a health care professional that one takes on a special and supererogatory obligation to benefit one's patients—an obligation, that is, which is greater than the ordinary obligations we all have to benefit each other.[19,20] Such a claim is by no means universally accepted. Downie, for example, argues that doctors have no greater moral obligations to their patients than anyone has to anyone else.[21,22]

If he is right then there would seem to be no particular moral obligation for doctors and nurses to treat their AIDS patients if they feel the risk is too great—no more at any rate than there is on any one else with appropriate skills to help an AIDS patient despite feeling threatened by the risk. But for those of us who believe that both corporately as a profession and individually as members of that profession we still commit ourselves to the characteristic medical obligation to benefit our patients that is referred to in the Hippocratic Oath and its modern successors,[23-25] there can be little doubt that Dr Smith is right[3] and that it is indeed part of a doctor's duty to treat his HIV infected patients even when his perception of the risks makes these risks more alarming to him than they are to the profession as a whole.

Disease resulting from voluntary activities

Is there, however, some additional moral weight to be given to the last part of the argument purportedly justifying the withholding of treatment—the argument that since the infection "is likely to have been acquired during the course of some voluntary sexual perversion or mainline drug abuse" this somehow cancels the normal obligation of a doctor to treat his patient? Note that even if this argument were sound it would still leave the treatment of those who had acquired HIV through other routes unclear. After all, such patients will be no less risky to their doctors and other carers than the homosexual and drug addicted carriers. If the risk is found acceptable in the case of these other categories but not with the homosexuals and drug addicts it suggests that the risk to others is not the real reason for withholding treatment so much as the "voluntary sexual perversion or mainline drug abuse."

The implicit argument is by no means clear but is open to at least two interpretations. It might mean that doctors need not feel obliged to treat *any* patient whose illness results from a voluntary activity. Alternatively, it might mean that doctors need not feel obliged to treat any patient whose illness results from a voluntary activity of which the doctor disapproves. The former claim is obviously absurd and can be ignored. (It would, for example, allow doctors to opt out of treating voluntarily pregnant women—or car crash victims, even if they *had* put on their seat belts, let alone those who hadn't.)

Disapproval and the withdrawal of treatment

What about the second interpretation? May doctors withdraw from their normal obligations to treat their patients (assuming of course that we do have such obligations) if the patient's illness has resulted from some voluntary action of which the doctor disapproves? This, like so many of the medicomoral dilemmas of AIDS, is not a novel idea. Doctors are occasionally to be heard arguing that drink-drivers should not be treated, and that smokers should not be treated, and that attempted suicides should be left to die. Perhaps one of the simplest ways of seeing the unacceptability of such proposals is to imagine oneself in the role of the patient with the doctor disapproving of one's own actions or lifestyle, or both. Suppose, for example, a surgeon who reserves "the right to decline to operate" contracts syphilis and in the venereal disease clinic encounters a bigoted gay doctor who disapproves of heterosexual intercourse. Would the latter be justified in withholding medical treatment for syphilis on the grounds that it resulted from a voluntary activity of which he or she disapproved?

The norms for withholding medical treatment simply do not include moral disapproval by the doctor of his patient's lifestyle or actions. Patients, society, and the medical profession would, it seems uncontentious to assert, be far the worse off if this was changed. Meanwhile the principles of professional conduct laid down by the General Medical Council, and representing the profession's and the public's agreement about how doctors in Britain should behave, seem explicit and unambiguous on such matters. Under the heading: "Neglect or disregard of personal responsibilities to patients for their care and treatment" the GMC's "little blue book" states: "In pursuance of its primary duty to protect the public the Council may institute disciplinary proceedings when a doctor appears *seriously* to have disregarded or neglected his professional duties, for example by failing to visit or to provide or arrange treatment for a patient when necessary."[26] Thus there seems little doubt that a patient would have at least a legitimate prima facie case for complaint to the GMC about any doctor who failed to operate or provide or arrange other necessary treatment solely on the grounds that the patient was HIV positive or had AIDS. If the facts of the case were as hypothesised it is difficult to see how any such doctor could justly escape being found guilty of serious professional misconduct.

References

1 Guy PJ. AIDS: a doctor's duty. *Br Med J* 1987;294:445.
2 Royal College of Nursing Working Party on AIDS. *Nursing guidelines on the management of patients in hospital and the community suffering from AIDS*. London: Royal College of Nursing, 1986. (Second report.)
3 Smith T. AIDS: a doctor's duty [Editorial] *Br Med J* 1987;294:6.
4 Geddes AM. Risk of AIDS to health care workers. *Br Med J* 1986;292:711-2.
5 Miller D, Jeffries DJ, Green J, Willie Harris JR, Pinching AJ. HTLV-III: should testing ever be routine? *Br Med J* 1986;292:941-3.
6 Wells N. *The AIDS virus—forecasting its impact*. London: Office of Health Economics, 1986.
7 Smith JWG. HIV transmitted by sexual intercourse but not by kissing. *Br Med J* 1987;294:446.
8 Department of Health and Social Security. *Acquired immune deficiency syndrome (AIDS). Booklet 3. Guidance for surgeons, anaesthetists, dentists and their teams in dealing with patients infected with HTLV III*. DHSS. London, 1986.
9 Volberding P, Abrams D. Clinical care and research in AIDS. *Hastings Center Report* 1985;15: 16-8.
10 Gerberding JL, and University of California, San Francisco Task Force on AIDS. Recommended infection control policies for patients with human immunodeficiency virus infection—an update. *N Engl J Med* 1986;315:1562-4.
11 Osborn JE. The AIDS epidemic: multidisciplinary trouble. *N Engl J Med* 1986;314:779-82.
12 Friedland GH, Saltzman BR, Rogers MF, *et al*. Lack of transmission of HTLV III/LAV infection to household contacts of patients with AIDS or AIDS related complex with oral candidiasis. *N Engl J Med* 1986;314:344-9.
13 Sande MA. Transmission of AIDS. The case against casual contagion. *N Engl J Med* 1986;314:380-2.
14 Seale J. An AIDS challenge on the dangers of kissing. *Guardian* 1987 Jan 20:12.
15 Anonymous. "AIDS" ticket scare. *London Evening Standard* 1987 Mar 2:13.
16 Anonymous. Risk [Editorial]. *J Med Ethics* 1982;8:171-2.
17 Nelkin D, Hilgartner S. Disputed dimensions of risk: a public school controversy over AIDS. *Milbank Mem Fund* 1986;64:(suppl 1):118-42.
18 Gillon R. *Philosophical medical ethics*. Chichester: Wiley, 1986:73-9.
19 Gillon R. More on professional ethics. *J Med Ethics* 1986;12:59-60.
20 Gillon R. Do doctors owe a special duty of beneficence to their patients? *J Med Ethics* 1986;12:171-3.
21 Downie R. Professional ethics. *J Med Ethics* 1986;12:64-5.
22 Downie R. Professional ethics: further comments. *J Med Ethics* 1986;12:195-6.
23 British Medical Association. Hippocratic Oath. *The handbook of medical ethics*. London: BMA, 1984:69-70.
24 World Medical Association Declaration of Geneva. In: Duncan AS, Dunstan GR, Welbourn RB, eds. *Dictionary of medical ethics*. London: Darton, Longman and Todd, 1981:132.
25 British Medical Association. World Medical Association International code of medical ethics. *The handbook of medical ethics*. London: BMA, 1984:700-2.
26 General Medical Council. Professional conduct and discipline: fitness to practise. London: GMC, 1985:10.

German engraving of a 17th-century plague doctor in protective clothing

Look Doctor, I'm Dying, Give Me the Drug

Discover, August 1986

BY DENISE GRADY

A man finds out that he has a fatal disease. He has about two years left, maybe less. His doctor asks him if he wants to try a new, experimental drug that seems to have helped the first few patients who took it. Sure, the man says. What have I got to lose? Well, the doctor says, we're not sure it works. It may have side effects. It may even make the disease worse. Look, the man says, I know what will happen if you *don't* do anything. Give me the drug.

If you qualify for the clinical trial, the doctor says, you'll have to come to the hospital for a lot of blood tests and different kinds of examinations, and you'll also have to take pills every four hours around the clock, even during the night. And you can't take any other medications unless we say so. Fine, says the man. Give me the drug.

Wait, says the doctor. This is a clinical trial. A double-blind, placebo-controlled, randomized clinical trial. So? says the man. The only way we can find out if the drug really works, says the doctor, is to compare it with no treatment at all: a placebo, a sugar pill. You have a fifty-fifty chance of being assigned at random to the control group, the patients who get the placebo. Neither you nor I will know which you're getting. I don't want a placebo, says the man. Look, doctor, I'm dying. Give me the drug. Leave me out of the clinical trial and just write me a prescription. I'm sorry, says the doctor. The only way to get the drug is to enter the trial.

Variations on this scene have been played out 260 times during the past few months, at a dozen medical centers in eight American cities. The 260 patients have AIDS, and the drug they're testing is AZT, or azidothymidine.* For months, AIDS victims and their families have been calling its manufacturer, the Burroughs Wellcome Co., in Research Triangle Park, N.C., to plead for AZT; some have tried to buy their way into the trial or to bribe employees to get the drug, which Wellcome keeps under lock and key, like a narcotic. One man in the trial says that acquaintances who also have AIDS have told him to hide his bottle of capsules when they visit, because they might not be able to resist stealing it. Wellcome declines even to reveal all the entry requirements for the trial, for fear patients will falsify their medical records to get in. The potential market for AZT, or for any drug that fights AIDS, is large: 10,000 Americans have the disease, 100,000 have related illnesses caused by the AIDS virus, and a million and a half more are thought to be carriers. The World Health Organization estimates there are 50,000 cases of AIDS in Africa alone, and that 10 million people around the world are infected with the virus.

AZT testing has moved remarkably fast: spokesmen for Wellcome say that in 18 months the drug has arrived at a stage of development that most drugs take four years to reach. The company, now involved in secret patent negotiations, is investing $20,000 a patient, for a total of some $5 million, in the trial, which is scheduled to end in December.

The AZT trial has raised scientific and ethical questions about medical research on human beings, particularly those who are dying. It can be difficult to design experiments that treat these people fairly and at the same time yield the needed information. The ideal experiment would benefit the participants as well as future patients, but this doesn't always happen, and so one must ask how much hardship, mental and physical, it's fair to impose on human subjects in the name of research. The current trial, widely regarded as the fastest and most efficient way to test the drug, is also considered a model for future experiments. But some scientists have suggested that, without jeopardizing the science, AZT and other drugs meant to fight AIDS could be dispensed in a more humane way. And they've taken their complaints to Congress. The issue took on added importance on June 30th, when the federal government announced a $100 million program to test new AIDS drugs, including AZT, at 14 research centers. The new trials, to include a thousand patients in the first six months, will also be limited to small groups of patients who meet specific requirements, and some of them will be given placebos, too.

AZT, an altered form of one of the chemical building blocks of DNA, was synthesized in 1964 by Jerome Horwitz, a chemist at the Michigan Cancer Foundation, who thought it might be useful in treating tumors. It wasn't, but when scientists found, late in 1984, that AIDS was caused by a retrovirus and therefore depended on an unusual enzyme known as reverse transcriptase to reproduce itself, they realized that certain features of the AZT molecule might block that enzyme. Burroughs Wellcome, which is equipped to make the drug but not to work with the AIDS virus, asked Samuel Broder and his colleagues at the National Cancer Institute (NCI) to investigate. Using cultures of AIDS-infected human cells, they showed by February 1985 that AZT didn't kill the virus but did stop it from multiplying. In July they began testing AZT in patients.

In the March 15 issue of the British medical journal *Lancet*, Broder and 17 other scientists cautiously reported that AZT might have made a bit of headway against AIDS. They had given it for six weeks to eleven patients with AIDS and eight with AIDS-related complex, or ARC (which means they were infected with the AIDS virus but had illnesses that didn't fit the official definition of AIDS).

The results, Broder says, were unlike any he had ever encountered. Fifteen patients showed improvements in lab tests that measured the working of their immune systems, two had chronic fungus infections clear up without any other treatment, and six stopped running fevers or having night sweats. In several of the patients who took the highest doses of the drug, cell cultures no longer yielded any traces of the AIDS virus. And although AIDS victims generally waste away, most in the study gained weight: an average of five pounds apiece. Side effects—headaches and lowering of the blood-cell counts, both red and white—weren't severe enough to halt the treatment, except in one case, in which they might have been caused by another drug the patient was taking. AZT crossed the blood-brain barrier, an essential property, because the virus so often attacks the central nervous system. By July 1986, between seven and twelve months after they started taking AZT, 16 of the original 19 patients were still alive. Even though a few had become so anemic that they needed transfusions, most were continuing to use the drug.

As promising as the results were, the scientists considered them good enough only to justify further testing. The first study hadn't even been designed to test AZT's effectiveness but to determine whether it could be tolerated and at what doses. Some of the changes in immune function were small; because AIDS often runs an up-and-down course, and because so few patients were studied for such a short time, it wasn't clear whether the changes were spontaneous or due to the

*Its chemical name is 3'-azido-3'-deoxythymidine; it's also known as Compound S, and BW A509U.

drug. They could also have resulted from the placebo effect, any improvement that occurs simply because a person thinks he ought to feel better because he's being treated; besides, raised spirits may increase the appetite, and eating better may in turn enhance the immune response. Finally, just participating in a study can benefit patients, because they tend to get more medical attention than usual. But even if the gains associated with AZT were real, this first study was too short to predict whether they would last. The virus might somehow develop resistance to the drug. More side effects might emerge with long-term use, or the existing ones might worsen. The researchers insist they don't even know what to make of the fact that so many of the original patients are still alive, because the disease is too unpredictable to assign life expectancies to individuals.

The trial now in progress was designed—mostly by Wellcome, with some help from participating doctors and the Food and Drug Administration (FDA)—to resolve those uncertainties. To qualify, the patients had to have either full-blown AIDS, defined for the purposes of the study as one bout of *Pneumocystis carinii* pneumonia during the previous three months, or ARC. Their results on certain lab tests also had to fall within specific ranges. The idea was to choose subsets of patients so similar to one another that any differences emerging between those treated and the controls could safely be attributed to the drug rather than to differences in the progress of the disease.

After six months the 260 patients are to stop taking their capsules for a month and undergo tests. Wellcome is tabulating the findings, which the twelve treatment centers are submitting continually during the trial. If it's determined that AZT works and is safe, says Dannie King, a microbiologist and Wellcome's AZT project director, "all the patients who participated in the trial will get the drug if they want it." They're protected by several safeguards, he says. First, the original plan may be altered: if there's any indication that a patient would be harmed by withdrawal, the drug won't be taken away, not even for a month. In addition, an independent review board will look at the data every two months during the study, and if one group is faring much better than the other—either because the drug is working wonders or because it's poisoning the subjects—the trial will be halted and all patients will either be offered the drug or taken off it. The first examination of the data will take place in August. "But I can tell you," says King, "it's going to have to be one extraordinary effect to stop that trial."

Wellcome would consider the drug effective, says King, if a statistically significant number of patients improved in the same ways that the original test group did, and if those results were supported by additional gains in overall health and in tests of the immune and nervous systems.

Why, when so many Americans are suffering from AIDS, is this experiment set up to allow only 130 to try such a promising drug? Virtually every researcher interviewed by DISCOVER, as well as a spokesman for the FDA, said the drug was in such short supply that there wasn't enough to treat very many more patients. Some blamed a worldwide herring shortage, because herring sperm is one source of the thymidine needed to make AZT.

Pleading scarcity would be an easy out, ethically: you can't deprive people of what you haven't got. This argument can justify the use of placebos, too: it's not that the drug is being withheld deliberately from the controls but that there's not enough for them anyway, and so they're just being studied as a basis for comparison. This is what happened during the field trials of polio vaccine in the summer of 1954, says Robert Levine, a professor of medicine at Yale who also teaches medical ethics and has written a book about clinical trials. Almost 500,000 children received vaccine that summer, while more than a million acted as controls because not enough vaccine could be made for them.

But scarcity, though a problem in the past, is now a false issue, says King. Wellcome is using synthetic thymidine instead of extracting it from herring sperm, and the company could make enough AZT to treat 5,000 people by the end of 1986. But it won't. The number of Americans taking AZT will increase during the next few months, but only to about 1,500, and they will have to enroll in studies at specially designated research centers. Outside these studies, no one can get AZT. It isn't available for "compassionate use," a discretionary category set up by the FDA to allow doctors to prescribe experimental drugs, which must usually be supplied free by the manufacturers, for seriously ill patients. "It's not our charge to manufacture tons of material at great expense, and jeopardize our other clinical programs, just to make sure everybody who wants it can have it," King insists. The drug is "very, very expensive to make," he says. "I have to provide a stimulus to do this." By which he means solid evidence that the drug works.

The real limiting factor in AZT trials, King says, is ethical. Because the drug may yet prove harmful, the number of patients must be kept small—no larger than needed to provide enough data to stand up to statistical analysis—to minimize the risks. If the company made a single exception for compassionate use, "we couldn't say no to anyone." In that case an unproved drug—possibly worthless or even dangerous—would come into widespread use. That, says King, would be unconscionable.

It would also make it virtually impossible to do a placebo-controlled trial: Who would consent to an experiment that offered only a fifty-fifty chance of getting the drug, when requesting it through a doctor would guarantee treatment?

The history of medicine is filled with cautionary tales about unnecessary or harmful treatments that eluded testing, gained acceptance, and hung on for years: radiation therapy for tonsillitis, a brain operation to prevent strokes, a drug for herpes encephalitis that made patients worse, and diethylstilbestrol (DES), an ineffective drug that has caused cancer in the daughters of many women who took it in hopes of preventing miscarriages. Yet if a procedure has become standard practice, and doctors believe in it, it's considered unethical to withhold it. Controlled trials then become hard to justify, which discourages the development of better forms of therapy.

Nonetheless, some question Wellcome's position. Although 260 patients is "an adequate number for this drug trial, it has more to do with hard cash than with altruism," says Dan William, a New York physician who devotes most of his practice to AIDS patients. "I'm almost certain that was the limiting factor." The company is, after all, paying the entire $5 million cost.

Even if AZT fails, says King, Wellcome is determined to gain something from this trial—namely, a method for testing the next AIDS drug, and a sense of which lab tests and symptoms truly reflect the course of the still poorly understood disease.

Some patients in the trial feel that this information is being gathered unfairly at their expense. "It's guinea pig city," says one. "They're rather arrogant. They know they've got you, because they're holding out this thread of a chance of life. They give you just enough capsules—oh, maybe a couple extra—to keep you going until your next appointment. You have to take the capsules every four hours, even during the night, and you're not supposed to take them within an hour of eating. That's the hardest part, planning your meals, because AIDS does strange things to your appetite. And then you realize you're going through all this agony and you might be bringing home sugar pills."

One of his nightmares is that he'll be dropped from the trial. He thinks certain illnesses could disqualify him, but he doesn't know which ones. "I had a real shock one week when I casually mentioned that I had taken aspirin," he says. "They practically went into orbit. They want you cold turkey on everything. I've taken some drugs to control other things, and I haven't told them. I don't tell them all my symptoms, either. This is life and death. The word is that once you're on the study they really don't want to throw you off, because they don't want to lose a patient, lose the data. But who wants to take a chance?"

The people who draw blood and ask questions at the hospital never tell him how he's doing, and he doesn't ask. "I assume all the blood is sent away, and they don't even know the results themselves, because it might bias them. And if they did know anything, I assume they wouldn't tell. But I'm having tests run, trying to monitor it on my own. I'd like to take the capsules to a lab and have them analyzed to see if they're placebos, but I haven't gotten far with that." If he learned he was getting a placebo—and he's convinced that he is—he wouldn't let on. "I'd probably keep going through the motions so as not to hurt my chances of ever getting the drug," he says. "I wish I were getting this drug. I really do."

He has no idea what will happen to him at the end of the trial, if he lives that long. If he's getting the drug, he assumes it will be withdrawn, at least until the results are analyzed. If he isn't, he's been assured he'll be on the list to get it if it works. "But God knows when they'll have the results. And time is such a factor in this disease."

Some researchers say this attitude is fairly common, and understandable, among patients who find that a placebo-controlled trial offers them their only chance to try a drug that might help them. Other scientists profes horror that a patient woul break his word and do things t undermine the trial. Two doc tors, both of whom conduc clinical trials with AIDS pa tients, commented on this pa tient's story. Dr. B also com mented on Dr. A's remarks.

Doctor A: A patient like that doesn't belong in a clinica trial. Frankly, it sounds to me as if he has psychiatric prob lems.

Doctor B: That sounds like a doctor who shouldn't be running a clinical trial. *He* is the one with the psychiatric problem: he doesn't know what it's like to be ill.

Another patient with AIDS, who says he believes in the trial, is also taking other drugs secretly, simply because he thinks he needs them. And he too—with the cooperation of his personal doctor—is concealing important symptoms from the researchers, for fear of being kicked out of the trial. A third patient likes being part of the experiment because he feels reassured by having his health monitored so closely, because he'll be among the first to get the drug if it proves to be effective, and because he likes the idea of helping to bring about something that may benefit others. The researchers discuss his test results with him; he doesn't think information is being withheld. If he takes an aspirin or a sleeping pill, he tells them, and they just record the information. He wouldn't consider taking prohibited drugs or having his capsules analyzed or doing anything else that might ruin the trial. But, he says, he has a very early case of ARC, and, "according to the doctors, I'm the healthiest person on the protocol. Things might be different if I were deteriorating."

Many AIDS patients are apparently taking antiviral drugs on their own. Given these circumstances, is it even possible to conduct a placebo-controlled trial? King thinks eight out of ten patients are following the rule that bars other medications, mostly out of respect for the purpose of the trial. "I'm counting on the wisdom of these patients," he says. He's also counting on blood and urine tests to tell him who's cheating. Patients found to be taking drugs that interfere with the experiment will be thrown out, he says—"although I can't think of an occasion when we've thrown a patient off for this. In fact, we've stretched our imaginations to keep them on the study. I think sometimes our clinical investigators [the doctors running the trials at the medical centers] scare the hell out of patients" on this point. "It makes them comply," he says. But he's impressed by the ingenious forms that noncompliance can take: "We have two patients manifesting things we know to be traits of very sensitive responders to AZT. Yet one of them is supposed to be on placebo." He thinks the two have tried to improve their odds of getting AZT by swapping half their capsules.

King says that only rarely are patients dropped from the trial because they develop infections or other disorders. Patients who get sick, he says, are given whatever drugs they need in addition to AZT—unless their illness appears to be caused by AZT itself, or to require such "extremes of medical management" that they can no longer participate in the trial. He declines comment on a case reported by Barbara Starrett, a New York internist who has treated more than a hundred AIDS patients. "I had one patient who had just started on the study when he got cryptococcal meningitis and was thrown out," says Starrett. "There was concern because the medicine for meningitis is so strong. I had to Federal Express his medication back to the company. His father wrote them a letter, saying 'My son did his part, and now you won't let him continue.' It was really heartrending."

Starrett has other serious reservations about the trial: "It doesn't make sense to have half the patients getting placebos when you know they're just going to die, or get sicker. You know the natural course of this disease over six months. Double blind, control groups, and so on—it's all very academic. With AIDS, you don't need it. And I think they could get statistically significant information in less than six months. Another problem is that they want people on no other drugs, not even prophylaxis for pneumocystis pneumonia." Starrett and other doctors believe that certain powerful antibiotics do work, not against AIDS itself, but in warding off some of the devastating infections it brings. "For the placebo group, it's horrible, putting them on a study and telling them they can't take anything to prevent opportunistic infections," she says.

Such arguments aren't easily dismissed. More than half of the 22,000 AIDS cases diagnosed in the U.S. since 1981 have ended in death. The average life expectancy from the time of diagnosis is two years; those who come down with opportunistic infections like pneumocystis pneumonia may survive only six months. And many researchers now think that even before symptoms develop, the virus has already invaded the brain, where it may do irreversible damage.

Last May, at a public meeting in New York about AIDS, Mathilde Krim, a scientist who has taken up the cause of AIDS patients with a particular passion, described the AZT trial as "morally unacceptable." She cited the small number of patients, the use of placebos, Wellcome's refusal to release AZT for compassionate use, and the six-month treatment period, during which, she predicted, many of the controls would die. "AZT currently appears to be the most promising treatment," Krim says. "Ten thousand victims are being denied the drug that they and their doctors believe holds the most hope. It should be possible to resolve the need for scientific data with justice and compassion."

Krim, a Swiss-trained geneticist and associate research scientist at the St. Luke's–Roosevelt Hospital Center in New York, began studying AIDS in 1982. She and a colleague run a private foundation that recently awarded $1.6 million to other scientists working on the disease. In addition, she has served on several national advisory panels concerned with medical and scientific ethics. Krim suggests ways of testing AZT that get around the problem of leaving the control patients untreated. At the top of her list are the use of "historical controls"—the medical records of untreated patients of the past—as the control group, and the comparison of AZT to ribavirin, an antiviral drug whose effect on AIDS isn't known but whose toxicity is; she suggests "crossover" experiments that would let each group try both drugs.

She also believes that AZT should be supplied for compassionate use to patients who don't qualify for clinical trials and who have very little time left—those who have had pneumocystis pneumonia more than once, for instance, or who are showing signs of brain infection. If Burroughs Wellcome can't or won't make enough AZT, she thinks the federal government ought to let contracts out to other companies and supply it to patients without charge. "What about the guy who can expect to live six months?" she says. "If he's willing to take a chance, if he wants it so badly, why not give it to him? They'll say, 'It may be toxic, we've killed mice with AZT.' That's idiotic. We can kill mice with sugar and salt and mother's milk. We're too paternalistic, and in this case paternalism coincides with commercial interests."

Krim made her case again on July 1, before a hearing in Washington held by New York Democrat Ted Weiss's House subcommittee on intergovernmental relations and human resources. "Do we not owe all those who are dying a small measure of hope, if we can provide it, and the dignity they so want, to fight to the end?" she asked. Three other witnesses supported her: two AIDS patients and a Cleveland physician, who criticized the lack of government funding for AIDS trials in Ohio, which has made it impossible for most of his patients to get experimental drugs. But other witnesses—including researchers and representatives of drug companies and federal health agencies—differed. Massachusetts General Hospital physician Martin Hirsch said, "Our goal must not be to have everyone on some drug of uncertain value, but to have every patient in a clinical trial from which useful information may result."

"Dr. Krim has a very strong, compelling argument," says King. "I've heard it used in the past by people who had decided for whatever reason that an agent was effective. If you accept her premise that this agent is effective, then you have to agree with her. I don't accept her premise. Perhaps she has come away from that *Lancet* paper, as many have, with wishful thinking. And if another agent had been available to test AZT against, neither the FDA nor the institutional review boards [the medical-center groups that must approve research involving human subjects] would've allowed placebos. I think Dr. Krim is so desperate for an agent to be effective that she's not thinking too clearly about it."

Krim herself acknowledges that she isn't an expert in the design of clinical trials, and indeed many researchers more experienced than she in this area say her suggestions just wouldn't work. It's true that placebos are considered ethically unacceptable once an effective, well studied drug is available for use as a basis for comparison. But there's no such drug for AIDS. In this situation, says John C. Bailar III, a physician and medical statistician who teaches at the Harvard School of Public Health, a control group that receives supportive therapy when needed—but not the test drug—"is mandatory." AZT doesn't appear to exert what he calls a "wham-bang effect: you don't see patients rising from their death beds." Without an untreated group, it would be too easy—particularly in a disease with such a variable course—to miss less dramatic, though still important, effects. Historical controls are out of the question, Bailar says, because new patients differ from old ones in two key ways: the disease tends to get diagnosed earlier

nowadays, and, as doctors gain experience treating the various infections and cancers, the course of the disease, and even life expectancy, may be changing.

Comparing AZT to another drug instead of a placebo could be not only confusing but dangerous, according to Broder. Suppose, he suggests, that researchers unwittingly chose as a basis for comparison a drug that actually made patients worse. Then even ineffective test drugs would look good. This could confound trials for years to come. Nonetheless, Broder says of Krim's opinions, "I respect that view very much. But declaring a drug to be effective before you know it to be effective and safe won't help anybody."

Levine agrees that placebo-controlled trials are the most efficient means of testing new drugs, but says, "There are limits to what we do in the name of efficiency. To justify the use of placebos, or of any controlled trial—and I think there's pretty near consensus on this—you must have no reason to believe there's any difference between the two things you're testing." When the early evidence in favor of a drug is strong, he says, controlled trials are unwarranted. In the case of AZT, the first trial didn't provide enough evidence, so controls are needed. Placebo controls would be acceptable with patients who have ARC, he told Weiss's subcommittee, but "almost impossible" to justify in patients with full-blown AIDS. Because the prognosis is so bad, it would be ethically preferable to treat them.

William is also ambivalent. "I hate it and I love it," he says of the AZT trial. "I hate it because it's very unfair to all the people who are waiting for answers, because the inclusion criteria are so narrow, because they have patients getting up at four o'clock every morning for months and months to take placebos, and because they're drawing blood and examining and testing them all the time.

"I love it because narrow inclusion criteria and a long follow-up are the best way to get answers fast. It's a clean study"—statistically clean, in that it should prove beyond a doubt whether or not AZT works—"but it's mean."

Ronald Grossman, another New York doctor who treats many AIDS patients, takes a different view: he wants experimental drugs for his patients, and thinks such drugs should be available on a compassionate basis for those who can't get into trials. And the trials themselves ought to be conducted without placebos, he says; one alternative would be to treat all the patients, but with different doses of the same drug, and compare those results. But this approach would take longer, he acknowledges, and perhaps yield fuzzier data. "It's a terrible dilemma," he says. "Dare we sacrifice scientific methods, or dare we let thousands die in the lag period, for the so-called greater good?" He favors choosing as controls those patients who don't want drug treatment. They do exist, he says, though of course in small numbers. This summer, Grossman and Krim will meet with Otis Bowen, secretary of the Department of Health and Human Services, to urge more government spending to make new AIDS drugs available.

Some scientists point to the past year's experience with a drug called suramin as an omen about what can go wrong with a treatment that starts out looking right. The drug had been in use for many years as a treatment for several parasitic diseases, when Broder and his colleagues tested it for six weeks in ten AIDS patients; their results aroused a great deal of hope and enthusiasm, because suramin stopped the AIDS virus from replicating in several of the patients.

"Here was the first hint of a possibility on the horizon of an antiviral drug to treat this dreaded disease," says Bruce Cheson, who coordinated a series of suramin studies sponsored by the NCI. "We of course were flooded with requests from patients, their relatives, and institutions, asking us to release the drug on a compassionate plea basis. We took a fairly strong position." Because of side effects—rashes, fevers, and changes in liver function—and uncertainties about dosage, Cheson says, the NCI concluded that making suramin widely available to doctors "wasn't a safe thing to do." Instead, it set up studies at six hospitals for only about a hundred patients in all.

"Suramin had substantial antiviral activity," says Cheson. "But it produced no immunological improvement, and clinical responses were uncommon. And it didn't cross the blood-brain barrier." Most important, more than a quarter of the patients who took it developed adrenal insufficiency, a potentially serious and completely unanticipated side effect. Since some of its symptoms mimic those of AIDS itself, the adrenal disorder might not have been recognized had the drug been widely distributed instead of being tested at academic centers that routinely ran lab tests to gauge adrenal function. Suramin may have even killed a few patients, according to Cheson, by damaging their livers. "Suramin taught us to limit compassionate use," he says. "We need to take a firm stand on this, to avoid harming people."

Another drug, HPA-23—the one that Rock Hudson went to Paris for—has been in use for several years, but doctors still don't know whether it works. And most researchers agree that the confusion is due to the lack of controlled trials of the drug.

Dr. Anthony Fauci, the director of the National Institute of Allergy and Infectious Diseases, which sponsors a great deal of the AIDS research in the U.S., is incensed by ideas like Mathilde Krim's, particularly when they come from scientists who, like Krim, work in the laboratory and don't treat patients. "I spend most of my life treating AIDS patients," he says, his voice rising to a level between talking and shouting, and staying there for about forty minutes. The very idea that an ethical problem might arise from the use of untreated controls seems to strike him as absurd. "Untreated? Untreated with what? *There is no treatment, no proved drug.* Do you think there's some kind of conspiracy among researchers to use placebos and let the patients die?" AZT has received more publicity than it deserves, he says. Fauci insists that except for "miracle drugs," which he asserts AZT is definitely not, there's no alternative to a placebo-controlled trial. Releasing the drug for widespread use now would make it virtually impossible to study, he says. "It would be an absolute tragedy if five years from now, because of being compassionate, with good intentions, we had no idea what worked and what didn't. Because by 1991, there will be 271,000 people with AIDS in this country alone. Yes, we have to have compassion for the individual patient, but we also have a responsibility to the larger group."

But what about compassionate use restricted to patients with the very worst outlook, those with signs of brain infection, for instance, or those who fit into some narrowly defined group, as do the patients in the current trial? "What if there's a shortage of the drug?" asks Fauci. What if there isn't? "What if there's a chance that the drug will kill them off just before another drug is proved effective?" asks Fauci. What if they want to take that chance? 'I don't see how it could be done," he says. The rules would be impossible to enforce. "Those things break down." But finally he says, "If it didn't interfere with the ability to answer the question"—meaning the question of whether the drug is effective—"I wouldn't object."

With AIDS victims dying at the rate of about 175 a week in the U.S., it's hard to argue with a scientific approach that's so widely regarded as the fastest way to figure out whether AZT works, and that may help researchers evaluate other drugs more quickly. If AZT proves effective, it will probably never be necessary to do another placebo-controlled trial again, because AZT will become the standard that other drugs will have to measure up to. But if the results are equivocal, the end of the current test may just mean the beginning of more tests. And yet, if such experiments fail to provide the needed information, it may become harder and harder to justify them to patients. At the same time, if it's possible to carry out rigorous, tightly controlled trials, it should be possible to let drugs out on a limited, tightly controlled, compassionate basis, for patients who are willing to take a chance and whose time is short. Research can serve the individual and society; compassion and responsibility aren't mutually exclusive. In the words of a 33-year-old AIDS victim, "All I have to cling to is hope. And hope comes in the form of new drugs." □

The price of treating AIDS

Profits play part in trials of key drug

BY JOEL LEXCHIN

Dr. Lexchin is an emergency room physician in Hamilton, Ont., the author of The Real Pushers: A Critical Analysis Of The Canadian Drug Industry and a member of the Medical Reform Group of Ontario and Health Action International/Canada.

ZIDOVUDINE, OR AZT, is currently the only drug that has been proved to help patients suffering from acquired immune deficiency syndrome. Last week the British medical journal The Lancet reported a study in which AZT "significantly" lowered the virus levels and improved the immune system in 13 of 18 AIDS carriers.

Marketed around the world by Wellcome PLC, a British company, AZT is not a cure and is not without side effects — which can be very serious, including bone-marrow suppression requiring major blood transfusions — but it can lengthen and dramatically improve the quality of life for some people with AIDS.

In the fall of 1986, officials from the federal Health Protection Branch (HPB) and Burroughs Wellcome, the British company's Canadian representative, agreed to sponsor two 18-month studies in Canada to investigate the safety of AZT and its effectiveness in patients suffering from pneumocystis carinii, a lung infection associated with AIDS. Burroughs agreed to supply the drug free to patients enrolled in the studies.

However, last April, just a few months after the trials began, Burroughs told the Canadian authorities that after May 1, the company was going to start charging almost $1,000 per patient per month for the drug. And if AZT was not licenced for prescription sale by then, Burroughs would stop supplying it. According to Linda Houle, a clinical research scientist at the company's Canadian headquarters in Montreal, "the criteria that the parent company has given worldwide is, if you want AZT, you're going to have to issue a licence to sell it."

Health and Welfare Minister Jake Epp's response was that he was angry because "we had a protocol with Burroughs Wellcome."

Burroughs justified its decision by claiming that it had invested $3.4-million in research trials in Canada and wanted to start making back its investment. But Canadian officials were worried that, with AZT in limited supply, if it were made available by prescription, there would not be enough to satisfy the demand.

Eventually, a compromise was reached between the HPB and the company. Burroughs would receive full payment for all the AZT used in Canada and AZT would be given a limited notice compliance, which would still restrict its use to patients involved in the ongoing trials, although the trials would also include patients with AIDS-related diseases other than just pneumocystis carinii.

By June, the provincial governments had agreed to pay for the AZT, although they were none too happy with the situation. Murray Elston, then Ontario's health minister, expressed "disappointment" over the way the financing of the drug was essentially "dumped onto the provincial Government's lap."

What takes all these machinations over AZT out of the realm of the usual world of medical politics is the role that Burroughs has actually played in the research and development of AZT. AZT was discovered in 1964 by Dr. Jerome Horowitz at a National Cancer Institute lab in Detroit. Dr. Horowitz was hoping to use AZT as an anti-cancer agent but the drug proved too toxic, and the patent fell into the public domain.

In 1984, Dr. Samuel Broder of the NCI in Washington found that AZT had promising results against the AIDS virus. Only then did Burroughs become involved, when Dr. Broder turned his data over to the company for further tests on AIDS patients.

Burroughs has no patent on AZT, but it has tied up the entire world's supply of thymidine, the raw product used in making AZT. Pfizer, a U.S. multinational drug firm, makes thymidine, and Burroughs has a contract requiring Pfizer to give it first option on all the thymidine it produces. So without a patent, or even unique know-how, Burroughs has legally ensured that no one else will be able to make or sell AZT.

Burroughs has invested heavily in expanding the production of AZT and in conducting trials, somewhere in the neighborhood of $80-million worldwide over and above normal capital costs for a new drug. According to the president of Burroughs' U.S. subsidiary, the company disrupted normal production schedules and committed the majority of its research effort to the production of AZT once the drug was found effective in checking the AIDS virus.

However, Burroughs has been unwilling to justify publicly its monthly price of $1,000 a patient. When Kathy Bartlett, public affairs officer for Burroughs in the United States, was questioned about sales figures, pricing and profitability of AZT, her response was: "That information is normally considered proprietary information, not given out by the company. It's price-sensitive information that can have competitive value. I am not at liberty to discuss any breakdown in costs." Asked if the company was trying to pay for its investment before other competitors got into the act, Ms Bartlett admitted that was a possibility.

Dr. George Stanley of the U.S. Food and Drug Administration was blunt about his view of the rationale behind the price of AZT. "It's the price you pay for living in a capitalist society. Once the drug is out in the marketplace, the company controls the

The price of treating AIDS

Globe and Mail, March 1, 1988

pricing." The British magazine The Economist had no illusions about the reason for the high price of AZT. In its issue of last April 11, it commented that "the price clearly has more to do with the temporary monopoly which Burroughs Wellcome enjoys than with research costs."

So far, Burroughs has not made any profit on AZT, but if no better drugs against AIDS are found and approved by 1990, the company will then be selling more than $5-billion worth of AZT a year, and by 1991 its total profits from the drug will soar beyond $2.5-billion.

Burroughs seems to be doing its best to ensure that AZT will remain the premier treatment for AIDS. When AZT was shown to be successful in slowing the progression of AIDS, the company was effectively given the final say on whether a whole range of important studies involving the drug could be conducted at all.

A story in The New York Times last April 12 exposed how Burroughs had delayed a variety of studies. U.S. officials wanted to test AZT in combination with alpa interferon, an immunity booster made by Hoffman LaRoche. However, Burroughs also makes a version of alpha interferon and for five months refused to discuss the proposed study. Finally a compromise was reached, allowing AZT to be tested with both brands of alpha interferon.

Similarly, The Times said that Burroughs was withholding permission to test AZT with interleukin-2, a drug it does not make, and yet had approved studies of AZT in combination with products it does make.

The company is caught in a conflict of interest when it must decide whether to sell the drug for $10,000 a year per patient or to provide it free for additional studies, or when it must choose between studies that might expand its own markets and studies that might help a competitor's drugs. So far, Burroughs has been careful in making these decisions to ensure that its own interests are protected. This behavior is out of keeping with the company's own history.

Before 1986, Wellcome PLC was controlled by the Wellcome Foundation, a charitable trust, and it had a reputation for putting medical need before money. It was noted for its vaccines and medicines for Third World diseases, neither of which made significant profits. However, in 1986, the company went public on the London Stock Exchange and, according to the British newspaper The Guardian, "Now, without reference to morality or patient welfare, it is making as much money as it can, as quickly as it can, to cover its costs and then to maximize profits for shareholders."

Demand for shares in Wellcome PLC were keeping Wall Street's international desks hopping last spring. Burroughs was one of only three AIDS-related stocks listed as possible "buys" by Prudential Bache Securities. Share prices for Wellcome PLC went from around $2.45 before the announcement that AZT was useful against AIDS to a high of between $6.75 and $8.50 in 1987.

Burroughs and AZT seem to epitomize the question of whether private profit can be equated with public responsibility when it comes to health care.

Insurance firms breaking law

BY JOAN BRECKENRIDGE
The Globe and Mail

Canada's life insurance companies, which test applicants for AIDS, are not complying with provincial laws requiring that positive tests be reported to public health authorities. The companies say it is not clear the law applies in their case.

"They're bypassing their legal obligation to report," said Dr. Philip Berger, a spokesman for Ontario's Medical Reform Group and a Toronto physician with AIDS patients in his practice.

They're circumventing the law so "they can assure people the results won't be reported so they won't hesitate to buy insurance," Dr. Berger said.

The industry announced in November that an AIDS test would be mandatory for people buying large amounts of life or health insurance. Those who refused to take the test would be denied coverage.

"Insurance companies have always been concerned about confidentiality," said Charles Black, vice-president of insurance operations for the Canadian Life and Health Insurance Association.

"It's also not clear the medical directors of companies are required to report by law," he added. He estimates that fewer than 10 applicants test positive each month in Canada.

In six of the 10 provinces, provincial health law requires physicians who request the AIDS test to report positive results. Most insurance companies order the test through their medical directors who are also doctors.

In Ontario, the Health Act states that a physician who provides professional services must report someone with an infectious disease to a local medical officer of health, said Dr. Richard Schabas, Ontario's chief medical officer of health.

But he said medical officials disagree about whether a medical director who requests the AIDS test is a physician providing a professional service.

To comply with the spirit of the law, the medical director may inform an applicant's personal physician about a positive test. This shifts the burden of reporting to the doctor who receives the results.

Dr. Berger said these physicians are also not going to breach a patient's desire for confidentiality by telling a health official about a test of which no record exists in this country. (Insurance companies are having AIDS tests done at a large laboratory in Kansas City, Mo., that is run by the insurance industry.)

Dr. Schabas said this lack of physical evidence of a positive test is also the reason that no legal action can be taken against a company.

Mr. Black said about 3,000 AIDS tests are being performed for the Canadian insurance industry each month. Dr. Schabas estimates the numbers are much higher, with more than 100,000 tests being done annually in Ontario alone.

Mar. 1/88

Will Ontario meet obligations in AIDS fight?

By Dr. Philip Berger

In October, 1987, a patient referred to the Toronto General Hospital AIDS clinic was told that the clinic was not taking new referrals. The patient's physician then phoned the clinic and was advised that indeed the clinic was closed indefinitely to new patients. At the same time, specialists at other hospitals were expecting that increasing numbers of AIDS referrals would soon saturate their practices. The dozen or so family physicians providing primary care to the majority of patients with AIDS and AIDS-related illnesses in Toronto were uneasy over the pressure of more infected persons and the complexity of caring for these patients.

The system of delivering medical services to persons infected with HIV (human immunodeficiency virus) remains fragmented and chaotic. Waiting times for non-urgent referrals to specialists are lengthening, and the availability of rapid out-patient investigation and experimental drugs is inconsistent. Most family physicians in private practice lack the crucial support of nurses, social workers and counsellors. Even patient access to family physicians familiar with HIV disease is a hit-and-miss proposition. Some patients take months to find their way into the "system" of health care — their first contact often being in an emergency department.

In the back of the Toronto doctors' minds is the emphatic warning from experts in other jurisdictions with large numbers of HIV-infected patients: Do not wait until the numbers of patients overwhelm an unprepared system, plan now.

Many Toronto family physicians and specialists feel that there is already a city-wide crisis in the medical care of HIV-infected persons. But the crisis is not limited to the medical care of patients. There is a serious crisis of confidence in the will and the ability of the Ontario Ministry of Health to properly manage the system and prepare for the future.

Proposals before the ministry calling for the establishment of expanded hospital-based AIDS clinics have been made in the absence of any consultation with family physicians or patient groups. These clinics, just approved by the ministry, will only cope with current patient loads and are insufficient for the continuing rise in numbers of infected patients. Furthermore, these clinics do not provide for the integration of primary care community physicians into the system and stand in total contradiction to the ministry's espoused support for community-based services.

Public education is almost invisible in Ontario. Nowhere to be seen are television or radio commercials promoting risk-reducing behavior. (The Manitoba government, with far fewer cases, has purchased time on television and radio to promote safe sex practices.) No attempts have been made to reach the prostitute community, a crucial group who deserve protection for themselves and could serve as conduits of education to their clients. No plans are in place to disseminate needle-cleaning information to the estimated 5,000 (at a minimum) intravenous drug addicts in Toronto.

The mythology surrounding AIDS rises unabated with profound consequences for HIV-infected persons and society at large. Private schools are instituting compulsory HIV antibody testing; employers are firing HIV-infected persons from their jobs; gay men and AIDS patients in Toronto have been evicted from their homes. Yet, the Ministry of Health is silent.

Support services for AIDS patients in the community are haphazard and disjointed. Patients are caught in the bureaucratic web of home care services. Admission to home care is difficult and dismissal from the program occurs summarily. There is no comprehensive service for patient and family counselling, no support systems to keep patients at home and no mechanism to educate family and friends who act as caregivers to dying AIDS patients.

The Ministry of Health is not taking the AIDS epidemic seriously. The ministry has not anticipated the social and health consequences of AIDS, has stalled on instituting adequate measures for prevention of the spread of AIDS and has failed to make long-term plans to provide for the medical care of HIV-infected persons. The ministry has failed to do what a political leadership should do — recognize and act on a calamity in the making.

But the frustration felt by physicians caring for AIDS patients in Toronto has not yet yielded to hopelessness. These doctors will be asking the Ministry of Health to organize a consensus conference on AIDS with family physicians, specialists and ministry officials. These doctors will be asking the ministry to meet its obligation to provide appropriate health care services to AIDS patients. The ministry will be asked to do its job. The answer, it is to be hoped, will not be silence.

□ Dr. Philip Berger is the co-chairman of a recently formed group of Toronto primary care physicians who treat many AIDS patients.

from Toronto Star, Jan. 29, 1988

Doctor calls education programs inadequate

BY LILA SARICK
The Globe and Mail

An increase in AIDS infections among women in Toronto indicates that government education programs are inadequate, says a Toronto doctor who treats acquired immune deficiency syndrome patients.

"Public education is basically invisible anywhere you go," Philip Berger said. "I know how quickly the Government moved in responding to the shellfish poisoning. There's as much urgency in dealing with HIV." HIV is the virus that attacks the body's immune system.

"There's been very little attempt (by the city) to reach out to high-risk, hard-to-reach groups," Dr. Berger said.

Women accounted for 4 per cent of new AIDS infections reported in Toronto in 1987, compared with 1 per cent in 1985, said Barbara Yaffe, Toronto associate medical officer of health.

About 40 per cent of the women were infected by the AIDS virus through sexual contact with infected men, Dr. Yaffe said. The majority of the others were intravenous drug users, one of the traditional high-risk groups.

Dr. Yaffe said it is unlikely that many of the infected women are prostitutes. Studies show the rate of infection is low among prostitutes since they tend to use condoms, she said.

"The message is getting out to men but possibly the message is not hitting heterosexuals. People are not changing their habits," Dr. Yaffe said.

"But the fact that the numbers aren't increasing as fast as some people had anticipated is a heartening trend," she said. "Education programs have been somewhat effective."

But if the virus follows the same path that it has in many African countries, AIDS will eventually become a heterosexual disease, Dr. Berger said. In Canada the disease still primarily affects homosexual men.

Last July, Toronto City Council earmarked $10-million for a campaign against AIDS. More health workers were hired by the city and posters were placed in bus shelters. Radio and television messages are scheduled to begin soon, but the city cannot afford prime-time spots, said Alderman Jack Layton, chairman of the health board.

Mr. Layton said the city needs to commit more money to the AIDS fight. He plans to ask council for several hundred thousand dollars more to finance specific proposals. Toronto's AIDS team of 80 people is the largest in Canada but cannot reach all 600,000 Torontonians, the alderman said.

Dr. Berger said the board of health has alienated many physicians and high-risk individuals by not consulting with health workers and by pressing for mandatory reporting of patients who have tested positive for the virus.

"If they were to spend time in the streets, they would have a better understanding of social policy," he said.

As of Feb. 5, according to Toronto health department records, 342 cases of the disease had been diagnosed in the city and 141 of those people were still alive, said Art Wood, chairman of the AIDS Committee of Toronto.

Globe and Mail, Feb. 27, 1988

He says he's developed a chemical dependency on three meals a day.

Doctors opposing the use of placebo in test of AIDS drug

By Lillian Newbery Toronto Star

A group of general practitioners who treat AIDS patients in Toronto are advising them not to participate in a planned Canadian study of a drug to prevent the pneumonia that commonly kills people with AIDS.

The doctors object that half the patients would randomly be assigned to take a useless and inactive drug, Dr. Philip Berger said in an interview.

It is standard practice in scientific drug studies to use an inactive drug or another drug as a comparison with the drug being tested.

Urges compassion

"There must be a more compassionate way," Berger said in a letter to Dr. Mary Fanning, head of the AIDS clinic at Toronto General Hospital. She's one of the specialists who proposed the study to the federal Health Protection Branch. It must also be approved by the University of Toronto ethics committee.

The anti-pneumonia drug, pentamidine, is delivered in a mist form. Unofficial consensus has already been expressed in medical journals that aerosol pentamidine prevents the pneumonia, Berger says.

On behalf of "more than 20" Toronto physicians called the HIV Primary Care Specialist Group, Berger wrote that unless the placebo arm of the study is removed entirely, or patients are given the choice of being picked randomly in the study or given the drug, the group will advise patients not to participate.

Berger says the study outline calls for 300 volunteers who have had just one episode of pneumocystis carinii pneumonia and there probably aren't that many who fit the definition. Excluded are those who have survived more than one bout of pneumocystis or who have survived more than six months after their first episode.

Taking drug

In addition, he argues, some patients are already travelling to the United States to buy the drug and administer it to themselves, and if they enter the study to get the drug free, that will skew the results.

James McPhee of Toronto, whose immune system has been damaged because of the virus that transmits AIDS, but who has not yet had a bout of the pneumonia, has been taking the drug.

McPhee said in an interview he wouldn't want to be one of those people who took an inactive drug in the experiment, got pneumonia and thus helped to prove that pentamidine works.

"From a purely scientific point of view it's nice to have a placebo, but from a human point of view it's not appropriate" with AIDS, McPhee said.

Toronto Star, Feb. 27, 1988

Doctors continue to extra-bill

By Matt Maychak Toronto Star

Some doctors in Ontario are still extra-billing their patients more than 18 months after the practice became illegal.

But the provincial government, anxious to smooth relations with doctors after their 1986 strike, has yet to prosecute a single physician for charging more than medicare rates for services.

In the past six months, the health ministry has received an average of about 30 complaints each month from patients who believe they are being extra-billed.

Since extra billing was banned in June, 1986, the health ministry has received 683 formal complaints from patients, according to ministry figures obtained by The Star this week.

Deduct fees

The Ontario Health Insurance Plan (OHIP) has reimbursed 512 patients a total of $44,152. It has recovered $30,400 from the doctors involved.

A ministry spokesman said there's a gap because patients are reimbursed quickly while physicians are given time to plead their case.

Under the legislation, the government can deduct extra fees charged from other OHIP payments to the doctors.

Those who are convicted for extra-billing can be fined $250 for a first offence and up to $1,000 for subsequent offences.

Health Minister Elinor Caplan said she is not alarmed by the figures.

"We're seeing a decline and the act is working well," Caplan said in an interview.

In the first 12 months of the ban, the ministry received an average of about 40 complaints a month.

Caplan said the figures must be compared to the insurance plan's total number of medical claims (78 million in fiscal 1986-87 alone) and their total value ($2.9 billion in 1986-87).

But a spokesman for the Medical Reform Group of Ontario, 150 doctors who split with their colleagues and supported the ban on extra-billing, says the bottom line is some doctors are still extra-billing.

"The reported amount (of extra-billing) is just the tip of the iceberg, just as complaints before Bill 94 was passed were just the tip of the iceberg," said Dr. Michael Rachlis, a Toronto physician.

"What it comes down to is it's very difficult for patients to complain to the government about their doctors."

The reported figures represent "easily less than 10 per cent, maybe less than 1 per cent" of the amount of the extra-billing that's occurring, he said.

"It's definitely happening. We continue to be concerned about the whole thing," Rachlis said.

"The main problem with the whole process is it relies on the patient to complain."

Toronto Star, March 11, 1988

AIDS: Medical Resources - Hamilton

CONSULTANTS

McMaster University Medical Centre
Dan Sauder, immunology
Irwin Walker, hematology (mainly HIV positive hemopheliacs)

St. Joseph's Hospital
Michael Achong, infectious diseases

Hamilton General Hospital
Stephen Landis, infectious diseases

(There is no specific AIDS Clinic in Hamilton yet (March 1988). There is a sub-committee of the AIDS Academic and Research Committee of the Regional Health Council looking at clinical services (Chair: George Flight) which plans an HIV out-patient clinic run at MUMC by Drs. Achong and Landis.

FAMILY PHYSICIANS (with an AIDS interest)
Bill Seidelman (Hamilton General FP teaching unit)
Phil Hebert (Hamilton General FP teaching unit)
Mark Kornfield
May Cohen (MUMC FP teaching unit)
John Feintner (MUMC FP teaching unit)

COMMUNITY GROUP
HANDS (Hamilton Area Network for Dialouge and Support)
Executive Directory: Alex Barry

NEWS DIGEST

Canada's population all lives in Ontario-says OHIP computer.

A new computer will be required for the Ontario Health Insurance Plan (OHIP) to enable a new OHIP number to be given to everyone in the province. The old computer (1971) is "dying ", and " cannot produce statistics of the patterns of illness."

A legislature committee is investigating OHIP's problems "because provincial Auditor reported last fall that the computer has files for three times as many people as live in Ontario and contains records of such impossibilities as hysterectomies for men. None of the MPPs on the committee was very critical of the Health Ministry officials yesterday, although Lake Nipigon New Democrat Gilles Pouliot called the high number of registrations "more than a small discrepancy...an astounding situation.."

Mr.Gibson (OHIP General Manager) and Dr. Martin Barker (Deputy Minister of Health) explained that: "OHIP's claims reference files contain about 25 million participants, although Ontario's population is about 9.1 million...."

From Globulus, 17.02.88

Legislating "snake oil?" US policy on drugs for desperately ill.

"New US rules.. allow desperately ill patients to receive experimental drugs could be used by drug companies to skirt the approval process, says James Sammons, executive vice president of the American Medical Association. Doctors support the principle behind rules on treatments of last resort, Dr. Sammons said.....but...the AMA fears ...safeguards in the new US Food and Drug Adminstration regulations may not be strong enough to prevent the drug approval process from being compromised.....The new rules .... took effect last June.....some patient groups in Canada are pressing federal Health Minister Jake Epp to adopt a similar regulation. The US rules permit drs. to treat desperately ill patients with new drugs that are still being investigated under the FDA'S regular rules requiring clinical testing before a drug can be commercially licenced.....The (normal) approval process from laboratory tests on animals to final marketing.. can take up to 8 years. Pressure from patient advocacy groups and the deregulatory climate fostered by the US administration led to the rule change.....Dr. Young, head of the FDA said :"we have no intention of offering snake oil to t he public." There are 4 general criteria the must be met before an experimental drug can be used in treatment: the drug must be intended to treat a "serious or immediately life threatening disease"; there is no comparable or satisfactory alternative drug or therapy; the drug is under investigation in a controlled clinical trial; and the drug maker is pursuing marketing approval with "due diligence". Drs. must also obtain consent.."

From The Globe, 17.02.88.

If you can't beat them with argument - burn them.

"Pro-Life"activities

"The weekend before the Supreme Court decision on abortion, someone climbed on the roof of the Morgentaler Clinic in Toronto and tried to burn through a plastic bubble skylight with a propane torch. There's nothing new in anti-abortion forces using illegal methods to intervene with the activities of the clinic. Over the past 3 years the clinic's carpenter..David Butt has suffered beatings, threats to his life, and a host of assault charges laid by demonstrators that judges have never found valid ...In August 1985 he was standing outside the clinic when an anti-abortionist demonstrator hit him over the head with a stick placard.....His left eye was temporarily blinded and blood poured down as another demonstrator struck him with a sharp object, cutting his right hand to the bone. As he flailed around trying to protect himself, other demonstrators piled on. Police intervened and laid numerous charges against his assailants, some of whom were convicted. But one of his attackers went to City Hall and laid a private charge of assault against the carpenter. His trial lasted 2 days and he was acquitted. His legal bill, which he only recently succeeded in paying was $3,800 and there is lasting impairment to his left eye . He was advised that he would be killed. Strangers accosted him on the streets screaming "God will punish you ". On the Don Valley .. his jeep went out of control , he got to the shoulder safely and discovered that the bolts had been loosened on one wheel. Last fall Butt was served a flurry of summonses on assault charges laid by anti-abortion demonstrators. With police ...attesting to his innocence....charges against him have been dismissed repeatedly but he has been left with legal charges ...totalling more than $7000."

From Globulus-An Orlandish Swipe

"In 1983 the last full year he graced the deputy minister's office of the Ontario Ministry of health, Graham Scott made a salary of $76,000. He left at the end of the year to take up a more lucrative career with Toronto law firm of McMillan Binch.....he is currently paid $250/hour to head up a task force into increasing utilization of the Government's health system. The going rate at McMillan Binch .....For the task force the Government has budgeted a mere $750,000 - $100,000 for administration cost (to be matched by OMA) and a further 650,00 for research.....big numbers never frightened Mr.Scott.As Dep. Minister in 1982,he played a key role in the Government's golden fleece award to the OMA to buy peace with the drs.....After the sunshine of McMillan Binch, Mr. Scott took on directorship at CDC Life Sciences Inc. and Connaught Labs. The former has now purchased the latter so Mr. Scott now holds a directorship in only CDC which rewards him with $10,000 -$12,000/year and he also holds 300 shares. Connaught Labs makes vaccines and other related medical materials, adding an inter-

esting side to Mr. Scotts' career that he does not consider a conflict of interest in his new part time job.....

Premier Petersen boasted.. Ontario had been liberated from " cigar smoking Tories operating out of some club."Mr. Scott is a director of the Albany Club, a famous Tory hideyhole....".

From The Gloobule 6.02.88

Who's An Old Fogey ? British Medical Association vs Thatcher

"The nurses are only the most recent to join the chorus of complaints. Perhaps the most devastating critique came from none other than the heads of the three ancient royal medical

colleges, who made their case last fall. The Government is not accustomed to having its knuckles rapped by persons so discreet and so exalted. Even the British Medical Association, which 40 years ago led the fight against the very idea of the NHS had become a trenchant critic.On the day the nurse held their strike, the BMA called for an immediate cash injection of 1.5 billion pounds. What is more the BMA dismissed the various schemes for alternative funding, such as hospital charges and private insurance being examined by the government. As BMA chairman John Marks noted, lotteries and other stunts do not provide long term money. The NHS must be financed by taxation . "There is a crisis in the health service,...stemming from chronic underfinancing..we spend far too little of our wealth on health. We are at the bottom of the European league "....The solutions offered..by Cabinet...involve an expansion of the private sector, particulary insurance. One suggestion has been a tax credit on medical insurance. On that the BMA was surprisingly blunt .John Marks:"The great consumers of health care are the under 5's and the over -65s. They don't pay insurance. The chronic sick are not insurable".

From Globe and Mail 20.02.88

Between a rock and a hard place.The Government Quandry re Abortion.

""Health and Welfare Minister J.Epp and Justice Minister R.Hnatyshn face nightmarish choices on the abortion issue, as activists on both sides push for a clear national policy...pro-choice activists are urging Mr. Epp to use the power he holds under the Canada Health Act to withhold funds from British Columbia because the province refuses to pay for abortions. Instead of changing its policy, the province could begin to close hospitals for lack of funds. An alternative nightmare...if abortion is outlawed, as pro-life activists wish, is a return to the era of backstreet abortions. The problem the 2 ministers face is both political and territorial. Abortion falls under federal control ..under the Criminal Code But the actual adminstration of abortion as a medical procedure is purely under provincial control. If Ottawa...makes policy about..provincial obligation to pay for abortions in free standing clinics - or even to pay for abortion at all - senior officials warn it could establish an awkward precedent. If the Government (interferes) on health adminstration..matter of provincial jurisdiction- on grounds...of national obligation to provide equal quality services nationally, what might follow?...legislation on pupil-teacher ratio? Or welfare rates? Or minimum wage?.....Without invading provincial jurisdiction there are at least 4 avenues for Government. (1) Section 33 of the Charter of Rights and Freedoms; the so called "notwithstanding "clause to exempt the old law (just struck down by the Supreme Court)....Unlikely that Mr.Hnatyshyn would protect a law which has been discredited and attacked pointedly by the Supreme Court.....(2) Study of the 3 different explanations offered by the Supreme Court judges to work out new legislation making abortion a criminal offence after a certain stage of pregnancy...making early abortions legal..this would not answer ..pro-lifers...Pro-Choicers...argue ..late abortions only occur when women are unable to get early access to abortion (3) Simply defer to the Provinces. (4) Use the almost unlimited power in the Canada Health Act to withhold money for provincial health systems unless provinces agreed to pay for abortions. More than any past Liberal government, the Mulroney Government has been scrupulously respectful of provincial jurisdiction in social policy..not using its spending powers to set social polices...provincially."

From Globe and Mail.5.03.88

Buddy can you spare a dime ? Manitoba Medical Association

Manitobans face a drs. strike on April 5 unless the provincial government agrees to binding arbitration as solution to fee contract disputes says Manitoba Medical Ass. (MMA)..Manitoba Premier Pawley....said province is not eager to go back to arbitration with the drs. after past awards that cost more than the politicians wanted to pay .....Health minister Parasiuk said drs.are asking for a 14% increase in fees, which works out to an average $16,000 a year. The Government has offered 3% this year and 3% next. The MMA refused to be specific..but said Mr.Parasuik's figures were "totally remarkably erroneous ", and drs.incomes in Manitoba are 25% lower than other provinces. Federal Statistics from Health and Welfare show average professional income per dr:Ontario $108,000 Manitoba $86,000;Saskatchewan $96,000; BC. $94,000."

From Globe 05.03.88.

Exhalations of fire and brimstone, by appointment.

Van DerZalm or Zeus.

"In a gore dripped public attack on abortions and the women who have them BC Premier VanDer Zalm this week further unsettled his friends and enraged his enemies.....he talked of agony afflicted babies being ripped apart in the womb "at the slightest whim or notion of women.... without so much as an anesthetic being given to the baby...no-one here can imagine such suffering and no one ever lived to tell about it "....the speech was immediately denounced by medical authorities as the product of folklore and fanaticism instead of fact..a growing number of Social Credit party officials.. expressed their dismay at the Premier's determination to impose his personal views upon an uncomfortable province....many reckon that the courts will save them from long term political damage by declaring his refusal to finance abortions as illegal or unconstitutional. In his speech, VanDer Zalm made it clear that he believes he is engaged in a struggle against barbarism."

From Globe 05.03.88

"Van Der Zalm in Powell River... was overcome by questions about victims of rape and incest: "Don't ask me those questions I don't want to hear them. I don't like those questions. I don't want to hear them "..The Premier clasped his hands over his ears, squeezed his eyes shut and stepped away...He does not concede that poverty may influence a woman's decision about having children, or that his actions place an unfair burden on the poor...he repeatedly suggested that the vice of selfishness is the biggest factor in motivating women to have abortions..."

From Globule 13.02.88

Not only AIDS a problem. Incidence TB on rise in US

"TB cases nationally have started to reflect the New York trends. The Center for Disease Control reported.. in 1986 TB cases showed their first nation wide increase since Federal recording began in 1953. TB cases in New York declined to a low of 1,307 in 1978 (17.2/100,000 residents). But since then caseload has risen to 2,223 in 1986(31.4/100,000)....an 83% increase...Officials blame its rise on the proliferation of AIDS, (oh and by the way perhaps also because of-) and on the increase in homeless people ...Among proposals is that the city open one or more residential centers to treat contagious patients who fail to take medication on their own, with special units too; lock up those who require court ordered quarantine...city officials said the proposal was under consideration.....the highest rate was among black males 35-44yrs...who had 9x the city average....Neighborhood variations were also extreme....historically TB has been disease of the impoverished."

From New York Times, 24.01.88

College and Government

"Certain subtle shifts in the College's (of Physicians and Surgeons of Ontario) outlook..suggest the body wants to be seen as more helpful and responsive to doctors....CPSO registrar Dr.Michael Dixon described the changes as part of the college's natural evolution. They stem from events of 1986 extra-billing ban as well as polled drs' views on the role of the college. Respondents to the survey indicated they favour more frequent communiques. 0% also want the college to become more active in health policy issues.....Dr.Dixon: "we've started to address issues we wouldn't have looked at in past years.."... He cited the college's recent review of certain treatment modalities (specifically HCG and chelation therapy) and its adoption of regulations defining the use of these treatments as professional misconduct. Dr. Dixon: "Of course the profession might look at t his skeptically and say that's all very well but we're going to be held up to that standard,' and the answer is yes, probably will be and you probably should be. ".....The new approach will be to develop standards prospectively "We will begin to develop some guidelines in areas where there are problems."Other areas the college is looking at to develop standards are: The appropriate training requirements for physicians staffing emergency depts, obstetric care in smaller hospitals particularly those lacking anesthetic and surgical support; and guidelines for Px of deep venous thrombosis.....OMA General secretary Ed Moran said he suspects the college will not rush to get involved in the larger issues: "Because they function under a legislative mandate that tracks back to the ministry, I think it would be awkward for them to find themselves with a profile on an issue that was anti-government ; it might cause them problems if they were pro-government with their other audiences..."

From Ontario Medicine, 18.01.88

Prepare for lessons from the private sector-Ted Ball

"Private sector incentives, techniques and indirect participation in some areas of the health care system will have increasing significance on the delivery of health care in Ontario," says Ted Ball, President of PoliCorp Inc; and Chief of Staff for the Ministry of Health under the former Conservative Govt.Ont. Mr.Ball said..because of skyrocketing costs of health care, there should be a merger between the private sector and the current public system. He feels that hospital managers can learn a great deal from the private sector in terms of management techniques and incentives....he predicts an economic recession in 1988."

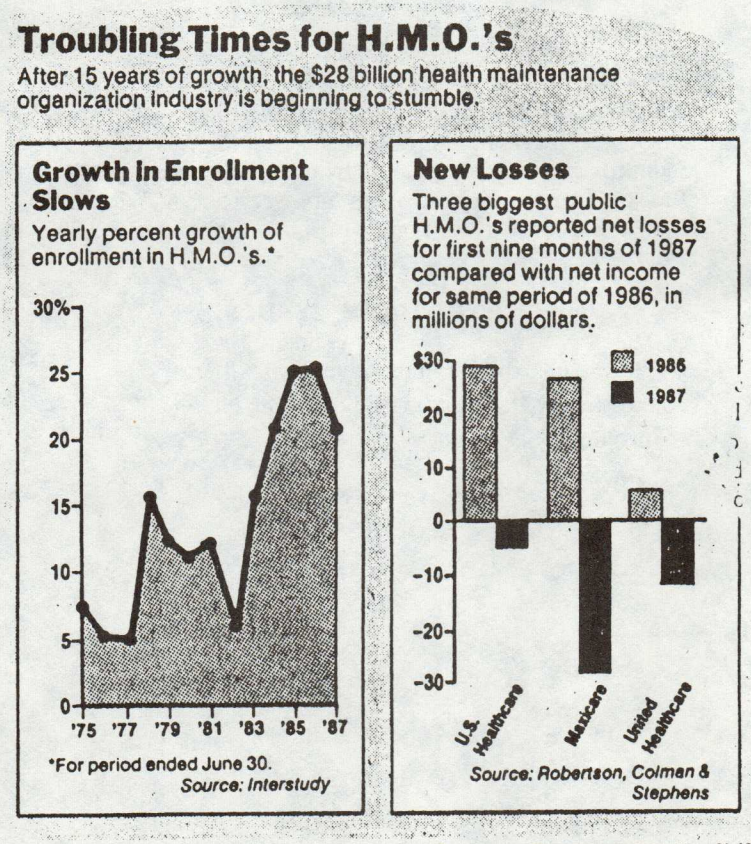
From Toronto and Region Hospital News, Feb. 1988

HMO's Overgrown-Pruning time

"After 15 years of spectacular growth in which Hospital Maintenance Organizations (HMO's) have enrolled nearly 30 million Americans, there are signs that consumers are losing their enthusiasm for the plans which offer comprehensive medical care for a set fee. Many HMO's are raising their fees...employers who pay most of the bills are demanding tighter cost controls, and drs. are protesting HMO's efforts to hold down their compensation .....at least 16 HMO's disappeared in 1987 because of mergers or business failures....experts predict....the $28 billion industry becoming dominated by a handful of giants. For ..consumers..these are important concerns.....employers have held the increasing cost down by pitting plans against one another ....many HMO's are instituting tighter control over the treatment patients receive. They are also bearing down on the fees paid to the 200,000 physicians they employ or contract to....physicians in Minneapolis even threatened to unionize....Jerry Baker an analyst at..an investment bankers :"To be profitable HMO's will continue to clamp down on payments to drs."....Incentive systems for physicians to control their costs have been tried : "If the health plan has losses the drs. lose part of their yearly income..some argue that such incentive systems compromise the quality of care. One such group is Physicians Who Care Inc., represents 2000 drs in practice in Texas and California..".Drs get paid more if they refer less. The concept is immoral ".But most non-partisan studies have found that the care provided by HMOs is as good as any....concentration of larger concerns will grow....Executive vicepresident of US Health Care A.F.Wise: "For people who do things right and survive it is going to be a great business" From N.Y. Times, 31.01.88

Environmental Toxins implicated for Parkinsonism

"P.Spencer et al..describe..primate data supporting the notion that certain neurological diseases such as Parkinsonism, Alzheimer's and motorneurone disease... may be caused by environmental toxins.....monkeys given doses of an amino acid (b-N-methylamoino alanine -BMAA) "developed corticomotorneuronal dysfunction, parkinsonism, and degeneration of motor neurones ."....the monkeys display symptoms that occur at very high incidence in the Chamorro people of Guam. Until recently the Chamorro ate large quantities of seed of the false sago plant Cycas circinalis (source of BMAA)..the link has taken 30 years to unravel.....Spencer:"...the fact that motorneurone disease, Parkinson']s, and Alzheimer's... can each be triggered by the same neurotoxin implies that the disease may be linked at a fundamental level. Another is that just because a disease may occur at high frequency and affect individual families throughout generations does not necessarily mean it is genetically caused as is often inferred.....but the key lesson is the notion of early exposure to a neurotoxin whose effects are expressed clinically only many years later e.g. Many Guamanians who left the island at the age of 20 to live in the US have developed the disease 30 years later: hence Spencer's term slow toxin ....Spencer "I expect our search will lead to a class of environmental chemicals that act as triggers for neuronal death.." From Science 31.07.87



"Asylum": A Film Review

On Sunday, February 6, CBC Television broadcast "Asylum", a look into the back wards of the Hamilton Psychiatric Hospital. I found the program to be both attractive and disturbing. If it is true that a society can be judged by how it treats its most oppressed, then "Asylum" showed us how far we have yet to go.

It was, to me, fascinating to see what still goes on behind those often-locked doors. As an intern and medical student in the Sixties and Seventies, I was walked through those wards -- quickly. I was disturbed when I saw my first patient with a phenothiazine slur and gait. R.D. Laing was a hero to me, and I *knew* that all those schizophrenics were really intelligent people -- there against their will. Ken Kesey's "One Flew Over the Cuckoo's Nest" reaffirmed that prejudice.

So-called "primitive" societies also have people who are "different": (we would call them psychotic): psychosis is not a product of our society alone. However, I like to think of Western medicine as being more advanced or humane than those of either older or poorer societies. A lot has happened to that idea in the last decade. I did some of my training in psychiatric institutions. I dealt directly with patients with psychiatric illness. I even tried a "freer" way of dealing with these people in the community. But I was frustrated and disappointed in my efforts.

Perhaps we need to look at what we mean by "asylum" in 1988. The dictionary defines it as "a safe place". The CBC program did show us that these wards are the "safe places" for their citizens. The life of the chronic schizophrenic or person with a personality disorder is often one of taking trips away from this asylum to the street or to a community-based lodging home -- but usually returning to the asylum. Some -- like one woman in the program -- suicide and thus escape. Others accept and live relatively contentedly in the system.

The strength of the program was that it also showed us to what an extent the asylum also represents a "safe place" for those of us who call ourselves normal. Those people are "up there". We like to know that they are not mistreated, and we kid ourselves that they are being treated, and not just kept. But my experience has been that these people will always be as they are. The genesis of their illness may be genetic, political, or social. At some point, I -- we -- would rather not think about it any more. The asylum represents a safety for us as well, and we need it to be there. The asylum seen in the movie "Amadeus" served this purpose as much as our current asylums do.

We *have* progressed: some people *do* get helped through their illness and do return to the community; there is now a Patient Advocate, whose job is to protect the limited rights that our psychiatric patients have.

But there are miles to go before we sleep.

Bob James

Announcements

Newsletter Deadlines

The publication date for the next MRG Newsletter is June 1, 1988. The deadline for that issue is May 16. Longer opinion and feature articles should be submitted earlier, by April 28.

The publication date for the subsequent issue is August 2, 1988. The deadline for that issue is July 18. Longer opinion and feature articles should be submitted by June 30.

Healing Our Planet

The International Physicians for Prevention of Nuclear War is holding an international conference: **"Healing Our Planet: A Global Prescription"** on 2 - 6 June, 1988 in Montreal. Details from Toronto Chapter, c/o Dr. Douglas Alton, Department of Radiology, Hospital for Sick Children, 555 University Ave., Toronto, Ont. M5G 1X8.

Family Physician

Unique multi-disciplinary service organization requires full-time physician. Staff of two doctors, four nurses (clinical, public and mental health). Social and legal workers. Salaried position $64,000 - $67,000, depending on years of experience. Full benefits. Hospitals privileges arranged. Languages an asset. Start date negotiable. Will consider locum for two to three months from March 14th. Apply to Duncan Farnan, York Community Services, 605 Rogers Road, 6th floor, City of York, Toronto, Ontario M6M 1B9. Phone: (416) 653-5400.

Forthcoming Issues:

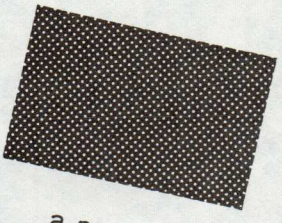
Trudy Richardson: United Nurses of Alberta
Haresh Kirpalani: Rise and Fall of the NHS (UK)
Toronto 2000 Project.

PLEASE POST

The Medical Reform Group
of Ontario presents
an evening symposium

IS AIDS SPECIAL?

Do Our Health Care Rules Pass or Fail the AIDS Test?



Dr. Margaret Duckett* addresses the issues:

- **confidentiality**
- **drug trials**
- **mandatory testing**
- **refusal to treat**
- **quarantine**

a presentation
and discussion
cash bar following

Friday, May 6, 1988

at 8 p.m.

Oakham House (Ryerson)
63 Gould St., Toronto
(one block north of Dundas off Church)

Admission $4.00

* **Dr. Margaret Duckett** is a research immunologist, public policy planner, special advisor on AIDS to the Australian government, and visiting scholar at the Centre for Medicine, Ethics and the Law at McGill University.