

Laetrile: Canada's legal position firm but pressure in the South grows

CHARLOTTE GRAY

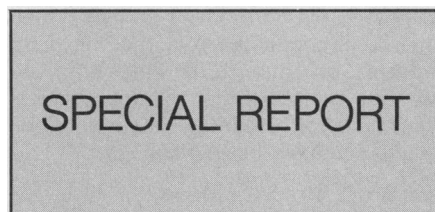
In September a circus came to Vancouver. But this was no circus of Russian bears, acrobats and tightrope walkers, except perhaps in the metaphorical sense. This was the Laetrile lobby, of self-proclaimed "internationally known lecturers, scientists and authors", busy organizing public meetings at \$3.50 a head, and keen to bring to the Canadian public the supposed benefits of the anticancer "wonder" drug. Their appearance in the West, together with recent legal moves in some states in the USA, heralds, the British Columbia Medical Association fears, a new round in the controversy surrounding Laetrile.

Quack cancer cures, from spiders' webs to Krebiozen and Essiac (see box on following page), have always been with us. But Laetrile has proved a more persistent nostrum than most due to intensive and manipulative promotion by its advocates.

Laetrile was discovered quite by accident in 1920, when Dr. Ernest Krebs Sr, a Californian physician, was trying to improve the flavour of bootleg whiskey by the addition of apricot pits. His son, Dr. Ernest Krebs Jr, claimed to have "purified" it in 1952, and set off down the dollar-studded road of medical quackery. Since then millions more dollars have been spent in investigating claims for Laetrile's efficacy. Repeated and properly controlled tests carried out by prestigious scientific establishments throughout North America, including the USA's National Cancer Institute cancer chemotherapy national service center and the Sloan-Kettering Institute for Cancer Research in New York, have failed to substantiate claims that the compound can cure, control or alleviate human cancer. Canada's National Cancer Institute decided there was no justification for supporting further investigations. Nevertheless, the then executive director of the NCI, Dr. Robert Taylor, informally pursued the matter further by consulting cancer clinic directors across the country about their assessment of

patients who had independently taken Laetrile. "There was no evidence that Laetrile had ever played any role in their treatment. It should have been thrown into the ashcan at that point," he reported.

So by all the accepted scientific criteria — animal studies, clinical examination and chemical analysis — Laetrile has been shown to be neither effective nor particularly safe, the two requirements that must be met for a drug to



be licensed by the federal governments of either Canada or the United States. Nor has any manufacturing company ever made a submission to the health protection branch of the Canadian government for a licence to market Laetrile, which is the orthodox route by which drugs secure legal status in this country.

The governments of neither Canada nor the USA recognize Laetrile as a drug. "All drugs sold in Canada must be sold in compliance with the requirements of the Food and Drugs Act and regulations," Dr. A.B. Morrison, assistant deputy minister at the health protection branch, emphasizes. "Laetrile would be considered a 'new drug' subject to proof of safety and efficacy prior to sale. No such proof has been submitted to us." Nor can Laetrile be legally sold as a food additive, since it is not on the list of permitted food additives contained in part B of the food regulations, nor as a vitamin since it is not one and sale under that label would be misrepresentation, nor as a food flavouring since "the sale of a foodstuff or a food flavouring under the name Laetrile would be considered a misrepresentation and may be considered a hazard dependent on the par-

ticular fact situation," according to Dr. Morrison.

But a substance derived from the same source as Laetrile, extract of apricot pits, is being sold in a different form in health food stores. According to Dr. Keith MacCannell, professor of clinical pharmacology at the University of Calgary, two substances said to be derived from apricot pits are on sale in health stores in Calgary: Amygdalin (another name for Laetrile), which is apparently sold in granule form, and Aprikern, which is said to be sold in tablet form. MacCannell does not know whether those who purchase them are seeking something akin to Laetrile, but in view of the general knowledge that their composition is basically similar, it seems extremely likely.

Moreover, until 3 months ago, Amygdalin tablets were selling at a dollar each in a downtown Vancouver pharmacy as a "bitter food seasoning" ("to take away the sweet taste of orange juice" — in itself an extraordinary rationale) at the rate of 3500 a month. The pharmacist was persuaded to stop stocking the tablets by the BC College of Pharmacists, who regard the preparation as Laetrile under another name even if not marketed as a specifically anticancer drug.

Why does the health protection branch not seize stocks of these products? The problem for the food and drugs inspectorate is that there have to be clear grounds for assuming a violation of the law — that either the product is being misrepresented as something it isn't or that the product is hazardous — for an action to be brought. Dr. Morrison points out that action would depend "largely on the fact situation and there may be circumstances where such a link with Laetrile is sufficient grounds to initiate a prosecution", but a prosecution is expensive to mount, the fines likely to be imposed are not particularly severe and as one brand name or labelled claim is declared illegal, another one

can be quickly invented and stuck on. If the customers are eager to buy the product, the entrepreneurs will supply it, in one guise or another.

Moreover, for those who want the "real thing" — Laetrile supplied under its own name and administered either orally or intravenously — there is an underground network of information as to how to obtain Laetrile treatment in Mexico. The cost of a month's treatment at a clinic there is between \$1500 and \$2500. Laetrile tablets, smuggled into Canada from Mexico, where they cost about 3¢ each to manufacture, sell for nearly \$2. Many doctors working in Canadian cancer clinics have come across patients who have made the costly pilgrimage and returned with empty pockets and deteriorating health.

In the face of such legal and medical condemnation, why is the Laetrile myth and trade so persistent? Why is the hope that apricot pits may be a miracle cure not scotched by the clear scientific evidence to the contrary and the American and Canadian government's ban on traffic in the substance?

The main reason is that the Laetrile advocates constitute a well-organized pressure group, which shifts the ground on which it claims Laetrile should be legalized to keep ahead both of legal requirements and actions and of public opinion. During its years of existence Laetrile has been described first as a cure for cancer, by virtue of the cyanide it releases in the body which "kills" cancer cells, and more recently, since marketing it as a drug was declared illegal, as "vitamin B17" which can "prevent" or "relieve" cancer, which Laetrile supporters now describe as a "vitamin deficiency disease".

"There is no vitamin B17 that is a recognized vitamin in human nutrition," points out Dr. Ian Henderson, associate professor of surgery and pharmacology at the University of Ottawa and chairman of the CMA subcommittee on pharmacotherapy. But the facts that vitamin B17 does not exist and that most of the public knows it is an error to describe cancer as a single disease susceptible to a single cure appear neither to embarrass its supporters nor deter customers. Nor does the apparent irreconcilability of the arguments — that Laetrile works either by supplying a missing "vitamin" or by destroying tissue. The Laetrile lobby is in the business of irrational miracles, not scientific validity.

This shift in the assertions of what Laetrile actually does has been mirrored by the shift in how it is made available to the public. The only legal action to date against Laetrile in Canada took place in 1964 when the Mc-

Laetrile is not the only quack cure for cancer now attracting attention. A supposed Indian herbal remedy is the subject of a recent statement by Dr. K.J.R. Wightman, medical director of the Ontario Cancer Treatment and Research Foundation and a former president of the Royal College of Physicians and Surgeons.

"In the past 3 months there has been considerable emotion and concern regarding an herbal remedy for cancer (Essiac)," declares the statement. "During this period the preparation as supplied by Nurse Caisse from Bracebridge has been tested by a reputable investigator on patients with a variety of malignancies. I am informed there is no evidence of any alteration in the disease process of any of the

patients. However subjective improvements in the sense of wellbeing were noted in a number of the patients, although this could or could not be a placebo effect. In one trial, out of 40 patients, 18 have died and 15 have been withdrawn because of definite deterioration. Four who had initially very slowly progressive disease continue on the preparation but have shown no response. The remaining three patients with chronic lymphatic leukemia had no change in any parameter of their disease status. Data on a further 25 patients are being compiled by a separate investigator with similar results. These unequivocal negative statistics refute any claims made as to the efficacy of this cancer cure with the material provided in the suggested dosage schedules."

Naughton Foundation was prosecuted in Montreal for distributing Laetrile as a drug claiming therapeutic properties without a licence. Dr. Henderson, then assistant professor of surgery at McGill University, was a prosecution witness. At the prosecution's request the McNaughton Foundation produced for his examination 12 patients who, it claimed, had undergone successful Laetrile treatment. "I looked at each case with an open mind as at that stage we really weren't sure whether it worked or not. But not one of the recoveries (and not all the patients were cancer-free) could be attributed to Laetrile."

The conviction was upheld on appeal by the Quebec Superior Court, which decided "it would be far more dangerous to suspend a law to safeguard the health of the general public than to deprive certain patients from acquiring a drug of dubious value that had not been tested for safety and effectiveness." And this 1964 position has not changed one iota in subsequent years, according to the health protection branch.

But as the claim that Laetrile could "cure" cancer was dismissed, and it was made clearly illegal to market Laetrile as a drug, the compound's advocates relabelled it to circumvent the law. The manufacture and sale of "Laetrile" was illegal: "Amygdalin", the alternative name for extract of apricot pits, had not been mentioned and Amygdalin products now appeared on health food store shelves under the guise of food or food supplements that avoided any claims for therapeutic action. Laetrile/Amygdalin supporters now suggested that it could be used as an adjunct to conventional cancer therapies — surgery, drugs, radiation — or as a useful (and, of course, unverifiable) preventative.

One company tried distributing Amygdalin in a milk shake mix called "Seventeen", which featured a bee on its package. The company claimed that the product was a food. In May 1975, US District Court Judge Malcolm Lucas barred further distribution of the product after ruling that it was an adulterated food, misbranded as both a food and as a drug. But like cancer itself, Amygdalin keeps reappearing in different form under different labels, as the reports from Calgary and Vancouver indicate.

Just as the guises under which Laetrile appears keep changing, and the claims for its effect and biochemical action subtly alter, so the arguments as to why the public should be given open access to it have shifted from decade to decade. And it is the most recent shift in its advocates' strategy that is now giving doctors and lawyers throughout North America headaches.

Civil rights

Now that Laetrile has been tried and found sorely wanting on scientific grounds, the issue has become one of civil rights versus consumer protection. The questions its supporters are now raising are not "Does Laetrile do any good?" but "Why can't we choose our own cancer cures?", "What is the point of governmental drug controls if they still make mistakes like thalidomide, saccharine and swine flu vaccine?" and, perhaps the most potent appeal, "Why cannot a person for whom orthodox remedies can offer no cure at least be free to hope for a Laetrile-inspired miracle?"

Laetrile supporters relied on this type of "human rights" plea in the Canadian Broadcasting Corporation's controversial TV documentary "Encounter with Cancer". They sidestepped the scientific

evidence of its uselessness by using anecdotal evidence and personal testimony, rich in dramatic and emotional impact. The wife of American entertainer Red Buttons described how, while suffering from cancer of the tongue, she had taken Laetrile and "life was returned when life was almost taken away." She attributed her recovery exclusively to Laetrile, despite the fact that she had undergone radiation treatment to which this type of cancer almost always responds well. The program did not weigh Ms Button's testimony against a physician's diagnosis. "The producer's attitude appeared to be 'Don't confuse us with facts or science, our mind is already made up'," Dr. John Bennett, CMA director of scientific affairs, remarks.

The program was originally broadcast in January 1975, and the CMA and the NCI protested on the grounds that it did not balance unsubstantiated favourable comment against the scientific evidence, it suggested that there was a conspiracy to prohibit access to a useful drug and it actively promoted Laetrile treatment. The CMA's president, Dr. Bette Stephenson, condemned the CBC's "imbalanced, misleading and irresponsible journalism" and what she regarded as "an acute case of arrogance derived from ignorance". Five months later the program was rebroadcast. The CMA protested again to the president of the CBC, who explained that it had been rebroadcast by mistake, that steps would be taken to ensure no recurrence and (as CMA Director of Communications D.A. Geekie put it) "came as close as the CBC ever does to offering an apology."

But the damage had been done; once again the public was given the impression that "there's no smoke with-

out fire" and they were being denied something of real potential. To the Laetrile proponents all publicity is good publicity; as the NCI's Dr. Taylor remarks, "McNaughton in effect says I don't care what you say about Laetrile as long as you spell the name right."

Exactly the same tactics — personal testimony, an indictment of the medical profession as a monopoly to suppress unrecognized cures and an emotional appeal to the groundswell of anti-authority opinion — have also been used with enormous effect in the Laetrile movement's latest successes in the United States. The supporters of the compound have been organizing a clever "little by little" campaign to manipulate individual state governments into legalizing the manufacture and sale of Laetrile within their borders, thus circumventing the US federal government ban. So far 12 states have legalized Laetrile and legislation is pending in 7 others.

Bill HR54

There is also a bill in front of the House of Representatives subcommittee on health and the environment to repeal the efficacy clause in existing drug laws. This bill, "Bill HR54: the medical freedom of choice act", has more than 100 representatives and senators as co-sponsors; it would remove the necessity for proving a drug effective, requiring only that it be proved safe. Its passage would immeasurably help the Laetrile cause in the States and, by dint of public precedent, here. The bill would immeasurably damage consumer protection safeguards by clearing the way for the legalization of Laetrile and countless other ineffective remedies on the me-too principle as well.

These latest advances in the battle

to legalize Laetrile are the result of an unusual alliance. This includes right-wing libertarians, health food fanatics, the entrepreneurs whose much-publicized bank accounts are swollen with the proceeds of Amygdalin sales and for whom any publicity means a climb in the sales graph, and well-intentioned humanitarians who feel that *any* potential relief for cancer victims should be given a chance. This bizarre collection of representatives of different interests form the membership of the four organizations in the US that have been specifically established to promote unproved methods of cancer control, especially Laetrile: The International Association of Cancer Victims and Friends, Inc., The Cancer Control Society, The Committee for Freedom of Choice in Cancer Therapy, Inc., and The National Health Federation. These organizations have been hugely active in the state-by-state campaign, sponsoring seminars and conventions for cancer victims and their families and orchestrating write-in campaigns to influence state legislatures and Congress. The 28 000-strong Committee for Freedom of Choice in Cancer Therapy, which has been especially prominent in the political campaign, is dominated by John Birch Society members, the most well known of whom is its president Robert W. Bradford. Last year Bradford was convicted in San Diego of conspiracy to smuggle Laetrile into the US and fined \$40 000. Grant Leake, an agent of the California Food and Drug Bureau, estimated that Bradford, who has openly conceded that he was a distributor of Laetrile, takes in \$150 000 to \$200 000 a month on Laetrile sales.

In Kansas cars were plastered with bumper stickers proclaiming "Laetrile

What is the legal and professional position of a doctor who agrees to administer Laetrile to a patient?

If the physician himself obtains the supplies of Laetrile, he is breaking the law. "The Food and Drug Act regulations prohibit importation of Laetrile for sale," affirms Dr. A.B. Morrison, assistant deputy minister at the health protection branch of the Department of National Health and Welfare in Ottawa. "The importation by a physician of Laetrile for administration to his patient would be considered to be importation for sale and therefore prohibited."

If on the other hand the physician administers to a patient Laetrile that the patient himself has obtained, he would not be considered to be either "selling" or "distributing" Laetrile and would therefore not be committing an illegal act under federal legislation. "A

physician administering Laetrile to a patient should seek advice from the appropriate provincial licensing body since this involves the practice of medicine," Dr. Morrison states.

But the ethical and professional position of a physician who becomes involved in Laetrile treatments is less clearly defined. The Quebec Medical Act, for instance, specifically forbids the supply and administration of drugs the scientific value of which is unproven. On the other side of the country, though, Dr. William McClure, registrar of the BC College of Physicians and Surgeons, has stated that it is up to the individual doctor's conscience as to whether he agrees to administer supplies of Laetrile; his college will accept the physician's decision. The BCMA, in contrast, firmly discourages doctors from using Laetrile, even as a placebo.

Says Dr. D.M. Aitken, registrar of the Ontario College of Physicians and Surgeons: "The legal position of a physician who administers Laetrile is at best questionable." One of the tenets of the Ontario college, as of other provincial colleges, is that members should "maintain the standards of the profession."

It is this questionability of status that worries Dr. F. Norman Brown, secretary treasurer of the Canadian Medical Protective Association, who feels that a doctor involved in the administration of Laetrile is making himself vulnerable. "I would be concerned with his position vis-à-vis his college of physicians and also vis-à-vis the courts should a mishap occur giving rise to a malpractice suit. It could be difficult to defend him, given the current medical consensus on the effectiveness of Laetrile."

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works! You bet your life", and the same motto appeared on teeshirts in Sacramento. State politicians were besieged by constituents on a "freedom of choice" crusade. In the present anti-federalist, anti-Washington, antimedical-establishment atmosphere in the US, the Laetrile issue proved a good grassroots issue for aspiring local politicians faced with angry pressure groups.

When the campaign first began, the US government and the American Cancer Society (ACS) just did not realize what was happening. "The establishment took a long time to get organized," reports Dr. G. Congdon Wood, assistant vice president for professional education and a member of the ACS's committee on unproven methods of cancer management. "Fraudulent remedies for cancer have always been around; we didn't appreciate how much organized political effort was behind this one, or how other issues like civil rights were being implicated. But now we are running our own educational information campaign to point out the facts behind Laetrile — that the sum total of findings from all the tests we have carried out so far is that there is no biological activity produced by this material at all."

Dr. Wood is confident that the Laetrile crusade is now on the wane in the States. "Since mid-August we've had the feeling that the drive is slowing down as the government and medical authorities have marshalled their forces to fight the movement. I think it is likely that there will be pressure on the 12 legislatures who have approved Laetrile to revoke their legislation. Bill HR54 is in limbo; its sponsors are keeping a low profile, and I hope it stays that way."

According to staff on the House subcommittee, the sponsors are not actively pushing the bill. And the declaration in August by US Surgeon General Julius Richmond, that, far from being a harmless quack medicine, Laetrile can be a hazard both on grounds of its cyanide content and because of adulteration of and impurities in supplies has cut further ground from under the feet of its supporters.

The position as regards Laetrile of the Canadian government, the Canadian NCI and the Canadian Medical Association has remained consistent throughout events south of the border. The drug is not approved by the health protection branch and the use of a drug the scientific value of which is unproved is condemned by medical authorities. The position of a doctor asked by a patient to administer Laetrile is less clear (see box on page 1070).

Inevitably, however, the moves in the States have caused a spillover of in-

terest into Canada, especially since one of the states that have given the green light to Laetrile is the border state of Washington. The same questions are being raised here that provoked the state legislatures there to give the substance legal status within their borders, despite federal disapproval. Doctors here are now having to marshal their arguments against free use of Laetrile not on grounds of the compound's therapeutic invalidity but on ethical and humanitarian grounds.

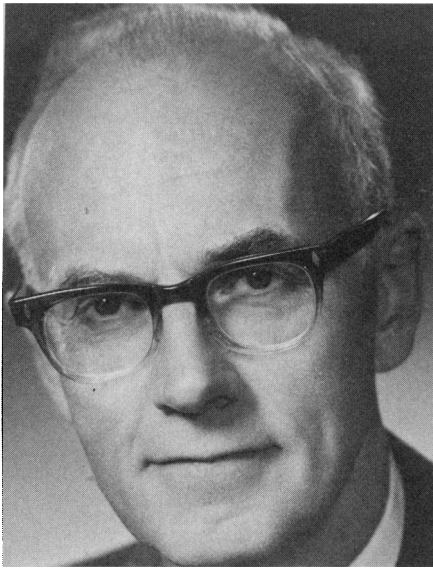
Most doctors agree that their arguments on these grounds are just as strong as their scientific justifications for disapproval. The Laetrile supporters' contention that the substance is at least harmless and that doctors are in league with the pharmaceutical companies in their refusal to recognise unorthodox treatments, is met with mounting evidence that apricot pit products, whether named Laetrile or Amygdalin, are more dangerous than the public has hitherto been told.

"Taken intravenously," reports prominent anti-Laetrile campaigner Dr. Victor Dirnfeld, a Vancouver internist and member of the Board of Directors of the BCMA, "They probably pass straight through the body without much effect. But taken orally they can produce nausea, headaches, skin rash, liver disease and diffuse muscle cramps. And we have been hearing cases of children dying from cyanide poisoning after swallowing Laetrile tablets they found in their parents' medicine cabinets."

The charge that Laetrile is being "deliberately suppressed by the medical-pharmaceutical company monopoly" arouses derision: "We are committed to healing not profit — unlike the sharks who push Laetrile."

So it is not even accurate to describe Laetrile as a harmless quack potion with a potential placebo effect. On the other hand, children have been poisoned by swallowing their parents' supplies of aspirin or tranquillizers. Should we allow the terminally ill to take Laetrile for its (unproved) placebo effect, if they ask for it, when the issue is anyway more one of hope than safety? "No; there are much cheaper placebos available," argues Dr. David Klaassen of the Ottawa Civic Hospital cancer clinic. "But anyway, we don't use placebos; it is dishonest to the patient. We would use pain relievers or some drug that has proved anticancer activity."

Moreover, the suggestion that Laetrile should be administered to terminal patients on demand, when conventional medicine can offer no hope, would be a dangerous "thin edge of the wedge" move that would play right into the hands of the insidious Laetrile cam-



Taylor: hypothesis already established

paigners. "If we allow it to be used with the terminally ill, it is somehow 'legitimizing' it," points out Dr. Dirnfeld. "Patients may assume that if it is good for the terminally ill, it may be good for the minimally ill and then finally that it should be released for cancer prevention. And the Laetrile advocates will argue that it has little or no effect on the terminal patients who opted to take it, because it was administered too late."

"They will then demand a proper trial, with patients whose diseases are not so far advanced," anticipates Dr. Henderson. "And this would involve denying patients accepted therapies, the effectiveness of which is proved, just to see the effect of Laetrile, which has failed all the scientific tests." As Dr. Taylor of the NCI forcefully puts it: "If we allowed Laetrile to terminal patients, we would then have to allow any old snake juice."

The same objections to giving Laetrile any kind of semirecognized status were made when George Crile, surgeon at the Cleveland Clinic, suggested last year in the *New England Journal of Medicine* that legalization of the use of Laetrile should be coupled with a campaign proclaiming its uselessness. This would be confusing quackery with serious medicine, horrified members of the profession replied. Stated a Georgian group of oncologists in a letter to the same journal: "The public should be adequately informed to come to the conclusion that this substance has no role in the management of cancer."

What disturbs every oncologist is the danger that patients whose disease is diagnosed early may decide to undergo expensive and worthless Laetrile treatment rather than orthodox treatments with proved effectiveness. Physicians know all-too-well the public fear of

cancer and the social stigma it carries. The lure of a so-called "safe drug", which involves no terrifying side-effects or disfiguring surgery, is enormous. The advocates of quack cures have always exploited these fears, and none more avidly than the Laetrile salesmen. But, too often, patients return to the fold of orthodox medicine with more-advanced disease. "The people who are victimized by this racket are just those who can least afford it in time or money," comments CMA's Dr. Bennett. "When people are most desperate they are an easy prey for rip-off artists. Life is precious, and they are willing to pay anything for the promise of extending it."

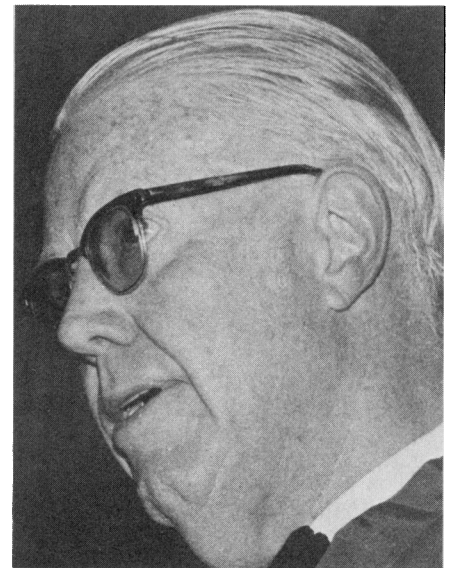
As Illinois State Representative Eugenia Chapman has said: "Persons victimized by cancer should not be twice victimized."

Nevertheless, as Dr. Henderson points out, "People are taking Laetrile in one form or another all over the place." Marci McDonald suggested in *Maclean's* last year that "50 000 people on this continent are currently taking Laetrile illicitly, and of these more than 3000 are Canadians." This has led some doctors to question attitudes within the profession both to Laetrile and to cancer treatment generally — not to make Laetrile legally accessible or to run yet more scientific studies, but to investigate what is happening and why the compound is so persistent. "I think we should examine every case we can find across the country of people who have taken Laetrile to see whether we can find any effect on any type of cancer or with any particular personality type," Dr. Henderson says. "We should have done this straight after the CBC program to demonstrate that we are not just an anti-Laetrile lobby. And we are now hearing a fairly consistent story that when people take Laetrile they do get pain relief, though why this should be so is unclear. It might have some anti-inflammation effect we didn't look for before."

Dr. Henderson does not anticipate making any startling discoveries, and says he would never consider using Laetrile in his own practice, but he feels that the profession should be more responsive to public opinion.

Other doctors deplore the idea of raising the question of Laetrile again. "There is no new medical justification," Dr. Taylor states. "The only reason for any new investigations would be public pressure. Personally I would not want to waste my time putting a lot of effort to prove a hypothesis that has already been established."

But there is a feeling that there should be some kind of reevaluation not of Laetrile, but of how recognized



MacKenzie: not enough support

cancer programs treat their patients. Dr. Walter MacKenzie, executive director of the Provincial Cancer Hospital Board in Edmonton and former dean of medicine at the University of Alberta, believes that "when our patients go to Mexico, it is usually because we haven't done our job properly. We haven't given enough psychological support to accompany the different therapies, or explained techniques or terms like remission adequately."

The Laetrile suppliers succeed, Dr. MacKenzie believes, because they are extremely reassuring and supportive to their customers, even when there is really no hope to be given. "We ourselves should be taking a more positive holistic approach. We should look at why patients are turning away from our services, and be prepared to alter our attitudes."

Dr. Klaassen feels that the medical profession is itself partly to blame for the fact that some people cannot come to terms with the concepts of incurability and death. "To whip up dollars for research we have often overemphasized minor advances, so people cannot accept that there is no miracle cure, and death is a fact of life."

Meanwhile, as the controversy continues, more desperate and uninformed Canadian cancer sufferers are likely to make their expensive pilgrimages to Mexico or West Germany, the quack-cure meccas, or rely on dubious health store preparations. Dr. Wood of the American Cancer Society sees it as an ironic twist of fate that pressure on Canadian doctors may be beginning to mount again. "It's completing the circle, isn't it? After all, Andrew McNaughton, the man who has done more than anyone else to promote Laetrile throughout North America, is Canadian." ■