LAW FOR THE PUBLIC INTEREST

Tampering with our health: the shift from public to private

Prepared by: Elizabeth Sloss November 1996 .

INTRODUCTION

Health promotion and disease prevention are buzz words for health reformers. If we can maintain health there will be a substantial increase in the quality of life for all Canadians; prevention of disease would result in a proportional reduction in the cost of health care: a perfect formula for protecting the public interest.

Unfortunately that formula requires turning our whole system over - not an easy task even when you have the power, but a nigh on impossible one when you don't.

Under the present system, there are two distinct issues we need to address when we talk about 'health' in Canada. The first is protection of health in a broad sense -- seeing to it that our environment does not leach toxic chemicals to our food chain; ensuring that products that we purchase in fact contain what they say they contain; ensuring that children have enough to eat, that we have jobs and safe housing, education and social supports. The second is health care -- that at present more typically includes the provision of medical services when we are suffering ill health.

One of the sleights of hand which our political leaders have so effectively mastered is to separate out the issues which lead to a healthy population and to speak as though the cards that deal specifically with health care issues, hospitals, doctors etc. are the ones that really matter. In fact, as we lose the breadth and depth of our social safety net we will unquestionably see an increase in the demand for our health care services, for there can be no doubt that eating away at the determinants of health, those things which contribute to the health status of the population, will have a serious impact on health care, one of the places we pay for failures in the rest of the system.

It is important to recognize the distinction between health and health care because it is very easy to become focussed on one at the expense of the other. The public interest is best protected by a system which recognises the relative importance of both, and it is the duty of those of us trying to protect the public interest to ensure that we don't simply compromise issues on health in order to ensure that there is money in the pot to protect health care.

We are presently at an extremely important moment in the history of health and health care in Canada. Years of commitment and work by labour and grass roots lobby groups, with political assistance, led to a fairly sophisticated regulatory system to protect the public interest in many different fields. The environment and labour are but two of them. At the same time we developed a health care system, not so much within a strong regulatory framework, but with an enormous amount of public money aimed at providing services to the public, combined with a piece of legislation with high public recognition, guaranteeing certain things to the public: the <u>Canada Health Act</u>.

For many of the same reasons we presently face enormous de-regulation in other fields, we face a serious threat to the continued existence of our social safety net, including our universally accessible and publicly funded health care system. In the health care sector there is ample evidence to demonstrate that the multinational health insurance corporations are working at accessing the as yet relatively untapped Canadian health care market. Furthermore our national health care system is significantly different from the health care system of our largest trading partner, the United States, with health insurance costs in the US being a significant issue for employers. One of the basic principles of de-regulation is levelling the playing field.

The theme of the paper is the effect of the changing regulatory climate on the public interest in the health context. The changes to be described are not always regulatory or even legislative, although many of them are. More fundamental in the health sector are the financial changes which alter the way business is conducted and the concomitant reorganisation of the system.

De-regulation and the reduced emphasis on formal structures to guide corporate practice can have a huge negative impact on the health status of a population; for example, reduced environmental regulation can lead to increased environmental degradation which has a knockon effect on health, reduced labour standards can decrease worker safety. Within the context of the health sector de-regulation is a matter for serious scrutiny. In this paper we focus more particularly on health care in the country, from drugs down to your local health clinic.

WHAT IS IN THIS PAPER?

Unfortunately as the scope of this paper is so broad, most of the issues which are raised here will not be treated in any depth. The intention is merely to draw to the reader's attention the areas for concern and to propose some methods of ensuring that any changes made to the system are beneficial to the public interest and services are not merely slashed in the name of deficit reduction.

In this paper we will examine the forces behind health, starting with the impact of international agreements and on to the legislative framework for health in Canada, looking at the role of protector of health held by both the federal and the provincial governments. We will also examine the role of each level of government in health care. The focus of the provincial aspects of health care will be on Ontario; however, many of the issues being examined in Ontario are very similar to those occurring right across the country.

Section One will comprise an examination and explanation of the shadow of international interests on our health sector. Section Two will outline the Federal Government's role in health. Section Three is a review of the Provincial Government's responsibility in health, with a focus on the delivery of health care and proposed health reforms. Section Four will outline some of the strategies used to foster positive change in the health system and provide some examples of success.

SECTION ONE: INTERNATIONAL TRADE AGREEMENTS

There is money to be made in the health sector, big money. Access to it in Canada is contingent on the doors being open to private interests. Those private interests are strong and they are gathering strength as they smell blood in the Canadian health care system.

International interest in the potential for making big money in the health sector became very clear in March 1995 at The Health Care Summit hosted in Singapore by the Hong Kong-based Institute for International Research. Attended by bankers, investors, health insurance and pharmaceutical executives, hospital management consultants, lawyers, accountants, medical equipment manufacturers and government policy makers, the Summit focused on "corporatising, commercialising and privatising opportunities" in the "most rapidly expanding market in the world" – health care.¹

In March 1996 the matter was brought closer to home when Liberty Health, MDS Health Group, SHL System House and the Canadian Medical Association, hosted the "National Health Care Policy Summit" in Montebello Quebec.²

This latter meeting took place just before the final deadline

on registering reservations under the NAFTA - a critical time for the Canadian health care sector. In order to understand why this was so critical, some background on the NAFTA is in order.

THE NAFTA

The Canadian Federal government is signatory to a number of international trade agreements, the most important of which for the purposes of this paper is the North American Free Trade Agreement (NAFTA). As of January 1 1994, the NAFTA created a single free trade zone comprised of Canada, the United States and Mexico. The purpose of the agreement is to significantly liberalize the treatment of investment, intellectual property and services within the free trade zone.³

The NAFTA builds on the groundwork which was laid by the earlier Free Trade Agreement entered into by the United States and Canada and also on the Tokyo and Uruguay rounds of the General Agreement on Tariffs and Trade (GATT) which encompasses trading relationships between over one hundred trading partners.

¹Colleen Fuller, Restructuring Health Care: A global enterprise, September 1995, mimeo

²The Canadian Health Coalition's Intervention on NAFTA, p. 5

³Barry Appleton, <u>Navigating Nafta: A concise user's guide to the North American Free Trade Agreement</u>, Scarborough: Carswell Thomson Professional Publishing, 1994 at p. 1

The NAFTA is by far the most significant free trade agreement Canada is party to and it created the most significant inroads into national autonomy. The deal covers the trade in goods (customs and tariffs, specific provisions on energy and basic petrochemicals and agriculture); technical barriers to trade (the development of national and provincial standards); government procurement; investment services and related matters (which include investment, cross-border trade in services, telecommunications, financial services, competition policy, temporary entry for business persons); intellectual property; and then the final provisions on the administrative issues, dispute settlement etc.

One of the most significant differences between the NAFTA and the other trade agreements is that where the other agreements set out listings of the specifics covered by the agreement, the NAFTA lists general sectors with specifics being limited to those things excluded from the scope of the agreement.⁴

NAFTA CHAPTERS AFFECTING HEALTH CARE

The sections of NAFTA which are most relevant for health care are Chapters 11 and 12 in Part Five. Chapter 11 covers Investment and includes virtually all types of investment and provides protection to all investors (including private investors in the party states) ensuring them equal treatment with local investors (eliminating the option of a legislated preference for Canadian investors for example).⁵ There is further protection for party investors in that no preference may be afforded to a national of another country over that to one of the NAFTA parties. This is called 'most favoured nation treatment'⁶ meaning that investors from a party to the agreement are entitled to benefit from the most beneficial terms available to any investor regardless of their origin. This means that a party cannot set up a system giving preferential treatment to a non-party state at the expense of one of the parties to the NAFTA.

Chapter 12 of the NAFTA covers "Cross-Border trade in Services" and includes basically "the production, distribution, marketing, sale and delivery of a service".⁷ The same type of provisions govern this chapter as the previous one with regard to national treatment and most favoured nation treatment.⁸

Article 1205 restricts the right of a government to require that any service provider establish

⁴<u>ibid</u>. p. 4

⁶NAFTA art. 1103

⁷NAFTA art. 1201(1)(a)

⁸NAFTA arts. 1202, 1203

⁵ NAFTA art. 1102: National Treatment: treatment no less favourable than that it accords, in like circumstances, to its own investors with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other dispersion of investments

or maintain a representative office or any form of enterprise, or be a resident, in its territory as a condition for the cross-border provision of a service.

What these chapters mean is that our governments have lost their power to restrict ownership or management of services and businesses to Canadian run or operated businesses. This means that in any sector covered by the agreement, American corporations have equal right to do business here in Canada as Canadians do.

Within the context of the health sector, the NAFTA clearly raised a number of questions. As we have a predominantly public health care system with services provided by the state run insurance organizations, the things immediately at risk were those parts of the health care field which already have a private presence but still receive their revenue from the provincial coffers. For example, the ambulance sector in Ontario is run in large measure by private companies. This is in spite of the fact that it is fully funded by the provincial government, with the exception of the \$45 'co-payment' which must be paid by the user of the ambulance.

Other provisions in the NAFTA with as yet undefined impact on our health sector include the provisions in Chapter 14, the Financial Services chapter, which includes insurance. The risks related to this chapter are all the more real since the Ontario Hospital Association's successful sale of the heretofore publicly owned and non-profit Blue Cross to the for-profit multinational, Liberty Mutual.

Also included in the NAFTA are the provisions relating to Intellectual property. Concessions by the Canadian government in negotiating this chapter have already had a substantial impact on the cost of provincially funded drug benefit plans.

NAFTA RESERVATIONS

As the presumption in the NAFTA is that the substantive provisions cover everything, it was up to the parties to make express stipulation for those issues they wanted exempted from the purview of the agreement. There were two types of 'reservation' or exception: bound and unbound.

Bound Reservations

A bound reservation would recognize an existing law and allow it to continue after the implementation of NAFTA despite its potential conflict. The reservation is 'bound' because it does not give the government the right to change the matter reserved in any way. This means it is a protection of the status quo but does not exempt the matter from the purview of the agreement for all time; any changes to the exempted law would sweep away its reserved status.

Unbound Reservations

An unbound reservation allows a matter to be exempt from the NAFTA for the present and the foreseeable future; the law could then be changed or replaced without destroying the protection granted by the reservation.

The NAFTA Health Care Reservation

In negotiating NAFTA Canada had registered an unbound reservation in Annex II-C-9 which states as follows:

Canada reserves the right to adopt or maintain any measure with respect to the provision of public law enforcement and correctional services, and the following services to the extent that they are social services established or maintained for a public purpose: income security or insurance, social security or insurance, social welfare, public education, public training, health, and child care.⁹

At the outset the Canadian Government maintained that this reservation was enough to protect the Canadian health care system, arguing that 'public purpose' would be given the broadest possible definition which would therefore automatically cover the health sector. Having taken this position they then proposed that the provinces, who have jurisdiction over health and who maintain most of the relevant legislation, had no need to include extensive lists of exemptions under Annex I, the place sub-national governments were entitled to list their reservations. The Federal Government maintained that it could adequately protected the entire sector from the provisions of the NAFTA just with the one unbound reservation.¹⁰

The fact that the health care system already has for-profit enterprise operating and being funded in part or in whole by the provincial health insurance plans meant that the interpretation of 'public purpose' was critical to how restrictive our governments could be over who could operate those corporations: for example, the <u>Independent Health Facilities Act</u> of Ontario gives legislated preference to Canadian corporations for the operation of health facilities licenced under it.¹¹ That would be at risk under the new rules.

It became clear however after some correspondence back and forth internally between the different governments within Canada and with the American Trade Representative through

⁹The reservation exists in relation only to certain provisions of the NAFTA: National treatment, arts. 1102, 1202, Most-favoured-nation treatment, art. 1203, Local Presence, art. 1205, and Senior Management and Boards of Directors, art. 1107

¹⁰Letter from John Weekes NAFTA coordinator dated January 31, 1995 wherein he stated Annex II should 'receive the broadest possible interpretation including a very broad interpretation of what constitutes a public purpose

¹¹Independent Health Facilities Act R.S.O. 1990 c.I.3 s.6

the latter part of 1995 that the definition of 'public purpose' was not going to be agreed upon quite so easily. Once this became evident as a result of hard fought battles by the Canadian Health Coalition and its allies across the country, the federal government altered its position and began to recommend to the provinces that comprehensive listings in Annex I might in fact be necessary. Annex I listings are bound reservations and such are protected only as long as the legislation listed therein lies unamended. If it is changed in any way it is once again open to the rule of NAFTA.

Pressure was kept up on the Governments in light of the growing clarity that our health sector was not adequately protected by the unbound reservation in Annex II-C-9. It became a matter for the national press, and with the consequent increase in political pressure the federal government took measures to ensure that a broad definition for 'public purpose' was endorsed by the other parties to the NAFTA.

The ultimate result was a tripartite agreement, in the form of a letter, giving the term 'public purpose' in Annex II-C-9 a broad meaning. Should a matter relating to this definition be brought before a trade panel for dispute resolution, this letter of agreement will unquestionably be given substantial weight, as a statement of intention, in the interpretation of the words of the Agreement.

SECTION TWO: FEDERAL JURISDICTION

At the time the Canadian Constitution was initially drafted, health was deemed to be a personal matter, health and health care were therefore not specifically enumerated in the Constitution with the exception of hospitals which were specifically attributed to provincial jurisdiction.¹²

Over time and with the help of the courts, the division of powers over health matters has become fairly clear: health care <u>per se</u> is a matter for the Provinces, certain health issues which have national importance may fall within the federal jurisdiction¹³ or may be matters of concurrent jurisdiction (meaning both levels of government may legislate – tobacco legislation is one such area).

THE ROLE OF NATIONAL GUARDIAN AND PROTECTION OF THE PUBLIC

By way of its role as guardian of the public or protector of the national interest, the Federal Government has legislated in a number of areas directly relevant to health: <u>The Hazardous</u>

¹²British North America Act 1867, S. 92(7)

¹³Report of the Royal Commission on the New Reproductive Technologies, Vol 1. p. 19

<u>Products Act</u>¹⁴ governs hazardous products other than those matters covered by the Food and Drug Act.

Tobacco

The tobacco field is a good example of how good lobbying can make enormous inroads into corporate interests. The Canadian anti-tobacco legislative framework has been one of the best in the world. This is due to the fact that there is a very well organized, well funded and well supported lobby effort.

Food and Drug Act

By way of the <u>Food and Drugs Act</u> the Federal Government regulates health and safety related to food, drugs, cosmetics, devices and drugs.¹⁵ It is by way of the regulatory framework authorized by that legislation that corporations are permitted to market their wares in Canada.

Drugs: safe for the taking?

The legal and regulatory framework for the approval of drugs in Canada is often described as among the best and most stringent in the world.¹⁶ That view is somewhat shaken when one examines some of the practices to enforce and maintain the regulatory framework.

The Health Protection Branch: Drugs Directorate

Before a drug can be marketed in Canada it must be granted a Notice of Compliance from the Health Protection Branch of the Ministry of Health and Welfare Canada. For any new drug, a pharmaceutical company must file a New Drug Submission (NDS), including the results of clinical trials on the drug; those trials may have been conducted outside of Canada and the data simply submitted here with the NDS.¹⁷

Once the NDS is filed it is then up to the Drugs directorate to review the submission and assess whether the drug is appropriate for the Canadian market. Upon approval the drug will receive a "Notice of Compliance".

The law states that post-marketing surveillance for the drug continues for seven years after the

¹⁵RSC. F-27 as amended

¹⁶Royal Commission Report, <u>op.cit</u>. vol. 1 p.404; Joel Lexchin, "Drug Makers and Drug Regulators: Too close for comfort. A study of the Canadian Situation", <u>Soc.Sci.Med.</u> Vol 31, No.11, 1990 pp.1257-1263 at p.1257

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notice of compliance is issued. This is commonly called the Adverse Drug Reaction Reporting Program.

It appears that there is a good review of the research stage of new drug compliance, that clinical trials are appropriately conducted and that there is collection of data on any adverse reactions caused by the drug for a good period of time after it hits the market.

Critics of the system argue that while this regulatory system looks great on paper, in fact there are huge shortcomings in how the approval process and the adverse drug reaction reporting program work in practice.

Due to cost constraints, any drug on the Canadian market which received a Notice of Compliance before 1963 has never been reviewed by the Health Protection Branch. All "old drugs" were "grandfathered".¹⁸ As for running clinical trials on pharmaceuticals, there are no set standards for collection of consent from those participating, there is no requirement that the protocols be approved by any ethics committee and there is no automatic review of the results by anyone.¹⁹

External Consultants and Conflict of Interest²⁰

The Conservative government under Brian Mulroney adopted the goal of minimizing "the cost to government of the drug product licensing program by optimum utilization of extragovernmental resources."²¹ In practice, this policy of minimizing the costs to the HPB has meant contracting out reviews of new drug submissions to external reviewers. As of August 1991, a total of 109 contracts had been issued for human drug products.²²

Senior people in the HPB have expressed confidence that the use of outside reviewers will not compromise safety,²³ but that viewpoint is not shared by former HPB employees and even people who have done some of the reviews. A former senior drugs manager was of the opinion that "this [outside-review] system will never work because too many interests are

¹⁹ <u>ibid.</u>

²⁰This Section was written and contributed to this paper by Dr. Joel Lexchin

²¹Drugs Directorate. Drug product licensing. Ottawa: Health and Welfare Canada, October 1990, p. 5

²²E. Somers, "New directions for the drugs directorate." Speech to the Canadian Association of Pharmaceutical Regulatory Affairs. Toronto, September 19, 1991

²³J. Ferguson, "Is drug policy pushing the limit?<u>Globe and Mail</u>, February 25, 1992, pp.A-1/A-6; N.Regush "Objectivity is an issue when reviewers have ties to drug firms". <u>Montreal Gazette</u>, June 6, 1992 pp.B-1/B-2

¹⁸Lexchin, <u>op.cit</u>. p. 1257

thrown into the pot and some people don't have the proper training to do an objective and thorough job."²⁴ Dr. Anne Holbrook, a pharmacoepidemiologist at McMaster University, who has done two outside reviews was also skeptical that proper standards could be maintained.²⁵

Margaret Catley-Carlson, then deputy minister in the Department of Health and Welfare, dismissed the suggestion that a conflict of interest could arise under this system: "It does not give me discomfort to think that people we are working with might also be doing tests on behalf of pharmaceutical companies."²⁶ At the same time, several staff in the HPB and outside reviewers feel that the potential for conflict of interest is significant²⁷ and there have already been several instances that raise serious questions on this point. In one case an Ottawa neurologist who participated in drug company funded studies on a product later reviewed the same product for the HPB and after the product was approved appeared at a press conference to promote the drug.²⁸

A more recent example of the potential for conflict and its implications for public safety is the recent controversy around a group of drugs known as the calcium channel blockers, specifically nifedipine.²⁹ The main manufacturer of nifedipine here in Canada is the multinational Bayer and its subsidiary Miles. These drugs are used to treat high blood pressure and angina, but there is increasing evidence that short acting nifedipine, and maybe others in the class, actually increase mortality in people with pre-existing heart disease. In response to the controversy, the Health Protection Board appointed a panel of cardiologists to advise the HPB on what action to take. One member was Dr. Martin Myers, from Sunnybrook Health Science Centre in Toronto. A year before the panel was convened Dr. Myers had been a member of a contingent from Miles which met with the HPB to discuss nifedipine. The chair of the panel was Dr. Frans Leenan a cardiologist at Ottawa Civic Hospital. A few months before he was appointed he signed a widely distributed letter to doctors down-playing criticisms of calcium-channel blockers. The letter was circulated by another multinational company, Pfizer, which makes its own calcium-channel blocker. In fact, although Dr. Leenan did sign the letter it was actually written by Pfizer. Dr. Leenan was also due to be a speaker for Pfizer as part of a medical education event taking place during a cruise on the Nile in Egypt.

26<u>ibid</u>

27<u>ibid</u>

²⁸Montreal Gazette, op.cit.

²⁹"The heart of the matter." <u>The Fifth Estate</u>, CBC Television, February 27, 1996

²⁴quoted in Montreal Gazette, ibid.

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²¹Drugs Directorate. Drug product licensing. Ottawa: Health and Welfare Canada, October 1990, p. 5

²²E. Somers, "New directions for the drugs directorate." Speech to the Canadian Association of Pharmaceutical Regulatory Affairs. Toronto, September 19, 1991

²³J. Ferguson, "Is drug policy pushing the limit? <u>Globe and Mail</u>, February 25, 1992, pp.A-1/A-6; N.Regush "Objectivity is an issue when reviewers have ties to drug firms". <u>Montreal Gazette</u>, June 6, 1992 pp.B-1/B-2

¹⁸Lexchin, <u>op.cit</u>. p. 1257

thrown into the pot and some people don't have the proper training to do an objective and thorough job."²⁴ Dr. Anne Holbrook, a pharmacoepidemiologist at McMaster University, who has done two outside reviews was also skeptical that proper standards could be maintained.²⁵

Margaret Catley-Carlson, then deputy minister in the Department of Health and Welfare, dismissed the suggestion that a conflict of interest could arise under this system: "It does not give me discomfort to think that people we are working with might also be doing tests on behalf of pharmaceutical companies."²⁶ At the same time, several staff in the HPB and outside reviewers feel that the potential for conflict of interest is significant²⁷ and there have already been several instances that raise serious questions on this point. In one case an Ottawa neurologist who participated in drug company funded studies on a product later reviewed the same product for the HPB and after the product was approved appeared at a press conference to promote the drug.²⁸

A more recent example of the potential for conflict and its implications for public safety is the recent controversy around a group of drugs known as the calcium channel blockers, specifically nifedipine.²⁹ The main manufacturer of nifedipine here in Canada is the multinational Bayer and its subsidiary Miles. These drugs are used to treat high blood pressure and angina, but there is increasing evidence that short acting nifedipine, and maybe others in the class, actually increase mortality in people with pre-existing heart disease. In response to the controversy, the Health Protection Board appointed a panel of cardiologists to advise the HPB on what action to take. One member was Dr. Martin Myers, from Sunnybrook Health Science Centre in Toronto. A year before the panel was convened Dr. Myers had been a member of a contingent from Miles which met with the HPB to discuss nifedipine. The chair of the panel was Dr. Frans Leenan a cardiologist at Ottawa Civic Hospital. A few months before he was appointed he signed a widely distributed letter to doctors down-playing criticisms of calcium-channel blockers. The letter was circulated by another multinational company, Pfizer, which makes its own calcium-channel blocker. In fact, although Dr. Leenan did sign the letter it was actually written by Pfizer. Dr. Leenan was also due to be a speaker for Pfizer as part of a medical education event taking place during a cruise on the Nile in Egypt.

26<u>ibid</u>

²⁷ibid

²⁸Montreal Gazette, op.cit.

²⁹"The heart of the matter." <u>The Fifth Estate</u>, CBC Television, February 27, 1996

²⁴quoted in <u>Montreal Gazette</u>, <u>ibid</u>.

²⁵Globe and Mail, ibid.

Not surprisingly, based on the advise from its committee, the HPB issued a weak warning to Canadian physicians on the use of short acting nifedipine. The letter did suggest that Canadian physicians stop prescribing the product, but it did not convey any sense of urgency about the problem³⁰ and it steered clear of any specific concerns about the longer-acting forms of the drug.³¹

The Royal Commission on the New Reproductive Technologies recommended that external reviewers be relied on in the new drug approval process. This is proposed to ensure that the drugs are being reviewed by the most appropriately qualified person to do the review, an expert in the relevant field. In light of the example above, contribution above perhaps it is not so curious that they include the following proviso:

provided the external reviewers are objective (their objectivity would be compromised, for example, if they performed contract work for both the Drugs Directorate and pharmaceutical companies) and they have the appropriate training and expertise in regulatory matters if asked to conduct complete drug reviews.³²

Drug Monographs and Adverse Drug Reaction Information

As part of the NDS the company is obliged to submit an Official Drug Monograph. The Monograph is essentially a summary of the scientific data on the product. It is a critical document in that it is basis of the information which goes out to professionals to describe the drug – the entry in the Compendium of Pharmaceuticals and Specialties "the most widely consulted source on therapeutic information in Canada".³³

There is evidence that there is no systematic monitoring of the Monographs to ensure that the information is current, despite the regulation under the <u>Food and Drugs Act</u> requiring an annual notification confirming the accuracy of the information filed with the HPB.³⁴

As for post-marketing follow-up:

No systematic post marketing surveillance is conducted; there is no encouragement for

³³Lexchin, op.cit. p. 1259

³⁰Health Protection Branch. Safety of calcium channel blockers in the treatment of patients with hypertension and coronary artery disease. Dear Doctor #44, 1966

³¹End of contribution by Dr. Lexchin

³²Royal Commission Report, vol 1 p.407

³⁴Lexchin <u>op.cit</u> p. 1259 referring to: Berger and Johnson "Information to help ensure judicious use". <u>Technical report No. 7: Program evaluation study of the drug safety, quality and efficacy program</u>, Ottawa: Health and Welfare Canada, January 1989

physicians or hospitals to submit adverse drug reaction reports; feedback to physicians who do report is virtually nonexistent; and what information that is collected cannot be analyzed and disseminated to health practitioners in a timely manner to educate them on hazardous drug products and hazardous use.³⁵

The Commission recommended that:

74. The federal government require pharmaceutical companies marketing fertility drugs to contribute funding for studies found by Health Canada to be required based on incoming adverse drug reaction data. This funding should be administered by national research funding agencies...

It is shocking to realize that there is no mechanism for tracking the long-term effects of any drugs on the Canadian market. The Canadian requirement is for seven years of reporting. Even if there was an efficient system for mandatory reporting for those seven years, with the likes of fertility drugs, the long-term effects may not even begin to surface until a generation of children resulting from them are in their reproductive years. And yet, even with our experience with thalidomide, the anti-nausea medication used in the '50s to fight morning sickness, but which caused severe birth defects, nothing has been done to require and facilitate long-term adverse drug reporting.³⁶

Cooperation or Regulatory Subversion

Each of the problems noted above are symbolic of inadequate financing or inadequate regulation of the drug approval process. The problems extend much further than that.

The Health Protection Branch (HPB) of the Federal Ministry of Health and Welfare has exclusive responsibility for the drug approval process. In the process of conducting its business, the HPB has developed a strong 'working relationship' with the Pharmaceutical Manufacturers' Association of Canada (PMAC), the association representing all of the multinational pharmaceutical companies operating in Canada. Despite what looks to be a strict regulatory framework for the drug approval process, PMAC often plays a significant role in how the processes are carried out, a fact which often distorts the objective of the regulatory process, and, one can argue, also compromises the safety of Canadians.

Note the following excerpt from a column by Dalton Camp:

The MP who chairs the House committee about to review a controversial drug patent

³⁵Turriff C.L., Berger J. and Overstreet R.E. Program roles and responsibilities, resources, systems and procedures. Technical report No. 9. Program evaluation study of the drug safety, quality and efficacy program Health and Welfare Canada. Ottawa, May 1989

³⁶Royal Commission Report, vol.1 at p.409

bill (C-91) has been soliciting drug companies to attend a fundraising dinner in his honour. The letter of invitation was signed by his bagman, a discretion remarkable for its ingenuousness: it presumably allowed the MP to hold the high ethical ground.³⁷

Self-Regulation -- A Challenge to Safety

One of the most glaring problems with pharmaceuticals is the fact that in order to be effective once they actually hit the market, physicians, the prescribers of these drugs, must have appropriate and full information about them. We noted above the problem with the contents of the drug monographs. However, another frightening fact is that most physicians make their prescribing decisions based on information obtained through some form of product promotion by the manufacturer.

When 200 Canadian general practitioners were asked where they could get reliable information about prescribing, 91% named CME (continuing medical education) sponsored by pharmaceutical companies, 79% said company-sponsored dinner meetings with guest speakers, and 56 percent said detailers.³⁸

The author further notes that:

Six separate studies conducted in Belgium, the Netherlands, the United Kingdom and the United States have all consistently found that physicians who have a negative view of promotion are more appropriate as prescribers and, not surprisingly, that the more physicians rely on promotion sources for their information the less appropriate they are as prescribers.³⁹

So, if we know that doctors are relying on promotional material or contact with product 'detailers' (sales representatives), clearly the methods used for advertising their products should be a matter for thorough scrutiny and strict control: after all, inappropriate prescribing puts

³⁷Dalton Camp, "Here's to your health -- and to your wallet", The Toronto Star, Oct. 13, 1996, F3

³⁸ D. Woods, "PMAC to spend almost \$1 million annually to reach 'stakeholders'." 134 <u>Can.Med Assoc. J</u> p.1387, at p. 1389, 1986, as quoted by J. Lexchin "Canadian Marketing Codes: How well are they controlling pharmaceutical promotion? <u>The International Journal of Health Services</u>, vol 24, No.1, 1994 pp.91-104 at p. 99

³⁹<u>ibid</u> referring to: M.H. Becker, et al. "Differential education concerning therapeutics and resultant physician prescribing patterns." <u>I.Med.Educ.</u> vol 47, pp.118-127; Linn and Davis, "Physicians' orientation toward the legitimacy of drug use and their preferred source of new drug information." <u>Soc.Sci.Med.</u> vol 6, 1972 pp.199-203; Mapes, "Aspects of British general practitioners' prescribing" <u>Med.Care</u> vol 14, 1977, pp. 371-381; Hayer, "Rational prescribing and sources of information" <u>Soc.Sci.Med.</u> vol 16, 1982, pp.2017-2023; Ferry, Lamy, and Becker, "Physicians' knowledge of prescribing for the elderly: A study of primary care physicians in Pennsylvania" <u>I. Am. Geriatric Soc.</u>, vol 33, 1985, at pp. 616-621; Blondeel, et.al. "Prescription Behaviour of 358 Flemish General Practitioners", Paper presented at the International Society of General Medicine meeting, Prague, Spring, 1987

people at risk -- and costs the system enormously. "At least 200,000 illnesses among people over sixty-five are due to bad reactions to drugs that are often not needed".⁴⁰

PMAC, in response to threats of government action by the federal government back in the 1970's, formed the Pharmaceutical Advertising Advisory Board (PAAB). PAAB developed a Code of Advertising Acceptance for the review and preclearance of printed advertising material, and since January 1993, of all audio, visual, audio/visual, electronic and computer means of communication. This code is not legally binding or enforceable, it is purely voluntary.

Along side the Code of Advertising Acceptance there is the PMAC Code of Marketing Practices, which covers other forms of promotion such as product detailers, and continuing medical education programs.

As with any voluntary code of practice maintained by an industry, the voluntariness can compromise the effectiveness of the code. Unless there is rigorous scrutiny of compliance with the Code by government and threats of more formal regulation if the code is not followed, there is no way of ensuring that standards are met. Bear in mind that the PAAB was established in the first place in response to threats by then Minister of Health Marc Lalonde that the matter would be dealt with by regulation if the industry did not clean up its own act.

Advertising of pharmaceutical products clearly has substantial payoffs: the industry spends approximately \$750 million a year in Canada on drug promotion: they clearly expect their promotion to work. And it does. Canadians now spend more on pharmaceutical products than they do on doctors. That is a staggering figure, a full \$15.1 billion per year.⁴¹

NAFTA AND THE DRUG COMPANIES

It used to be that Canada was looked to by the rest of the world as a fine example of how a democratic and independent nation could control the cost of pharmaceuticals. We had a system of compulsory licencing of pharmaceuticals still under patent protection. This meant that drugs could be produced by competitors during the life of the patent. In 1987 Bill C-22 restricted compulsory licensing and, in preparation for the NAFTA, in 1993 Bill C-91 was passed by the federal Tories effectively abolishing all forms of compulsory licensing in the drug field.

The reasons given for this extension of full patent rights to the drug companies to 20 years was that it took the companies such a long time to develop the drugs, and it was such a huge investment, it took them that long to begin to make a profit of their labour. They also argued that if we gave them full patent protection, they would re-invest here in Canada and that

⁴⁰Rachlis and Kushner, <u>Strong Medicine</u>, Toronto: Harper Collins Publishers Ltd, 1994, p.127

⁴¹Hugh Armstrong; CHC

would mean "Jobs, Jobs, Jobs".

In exchange for the extended patent protection the industry promised the creation of over 3,000 jobs in scientific and research-related fields.⁴² There is no evidence that has occurred, and in fact there have been job losses in the generic drug industry as a result of the loss of licence rights.⁴³

In changing the playing field, the Government extended the right to exclusive access to pharmaceutical revenues for the multinationals at a direct cost to our health care system. It is worth noting that patent protection does not simply apply to exciting new breakthrough drugs, where one might be able to argue that the patent extension has some validity. It applies equally to those drugs which are slight alterations of an original formula.

From January 1988 to December 1991 a total of 271 new patented drug products were marketed in Canada for human use. Out of that number only 13, or less than 5%, were felt to be either "breakthrough' medications or substantial improvements over existing therapies. With the rest being line extensions (46%) or moderate, little or no therapeutic improvements (41%).⁴⁴

And as for their profits:

The average price per prescription (excluding the dispensing fee) in Ontario has gone from \$12.48 in 1987 to \$24.09 in 1993, a rise of 93% compared to an increase in the Consumers Price Index of 23.1%. Over half of the rise in prescription costs is due to the introduction of new drugs, specifically new(since 1987) patented medications.⁴⁵

Dr. Lexchin concludes with:

The adoption of these more expensive products by physicians in the absence of a strong clinical rationale for doing so makes a compelling case for the need to promote cost-effective therapy not only for health reasons, but also to restrain the rise in prescription prices.⁴⁶

⁴⁵<u>ibid</u> p.4

⁴<u>6ibid</u>.

⁴²Rachlis and Kushner, <u>op.cit.</u> p.147, referring to GreenShield Pre-paid Services, Inc., "A report on drug costs," Toronto: GreenShield, April 1992

^{43&}lt;u>ibid.</u> p.144 <u>et.seq.</u>

⁴⁴Lexchin, <u>Medicare Monitor</u> August 1996 p.3

DOWNSIZING, DEREGULATION AND PRIVATIZATION⁴⁷

In the 1980's, in response to government-wide fiscal restraint the Field Operations Directorate of the Health Protection Branch which is charged with drug plant inspections and the drug sampling program undertook "resource conservation measures". A study team looking into the Canadian Drug Safety, Quality and Efficacy Program documented a drop in the number of regular plant inspections of 15% between 1983/84 and 1985/86 with a corresponding increase in the number of partial inspections.⁴⁸ According to the study team,

it is not clear whether Partial inspections cover the right area on an annual basis...the split between Partial and Regular inspections has resulted in a biased data base on company compliance history. This in turn creates difficulties in planning for future inspections.⁴⁹

One possible consequence of this reduction in plant inspections seems to have been that regulation of clotting factors used by hemophiliacs was not closely monitored. This lax regulation may have been a contributing factor to allowing contamination of these products by HIV.⁵⁰

Cost Recovery -- Who Will Set the Priorities for the HPB?

On January 1, 1995 the Drugs Programme instituted a policy of cost recovery, that is charging fees for government services. In practice this has meant that the government is charging companies an annual fee for each drug it markets and fees for the evaluation of drug submissions, for licensing manufacturing establishments and for a number of other services.⁵¹

The industry has been especially vocal in its opposition to the idea of collecting fees for reviewing drug submissions, not out of any ideological position, but because industry wants a system of cost recovery implemented in tandem with a commitment by the HPB to speedier drug approvals.⁵²

⁴⁹<u>ibid.</u>p.17

⁵¹Cost recovery. Working in Partnerships: Drug Directorate Newsletter No. 8, February 1995 p. 1

⁵²Pharmaceutical Manufacturers Association of Canada. "The drug approval system in Canada: an urgent need for change" no date.

⁴⁷The following portion of the text was contributed by Dr. Lexchin. The author's text resumes at the History of the Federal Role in Health Care.

⁴⁸J. Berger, "Regulatory Compliance. Technical Report No.8 Program evaluation study of the drug safety, quality and efficacy program Health and Welfare Canada. Ottawa: Health and Welfare Canada, May 1989

⁵⁰D.Vincent, "Blood probe grills ex-bureaucrats". <u>Toronto Star</u>, November 4, 1995 p. A-16

Industry's demand for changes to the approval system raises serious questions about what the overall effect of a cost recovery scheme will be on the priorities of the HPB. Pharmaceutical policy in Canada has traditionally been formulated through a very closed and nontransparent process.⁵³ Without access to information and openness how does the public know the basis for the priorities in drug policy that are set by the HPB? This question is especially worrisome with the advent of user fees. As funding for the operations of the Drugs Directorate shifts from the government to the drug companies a situation is created where the drug companies could be perceived to be setting the priorities, whether or not that is true. After all, if a substantial proportion of the funding is coming from the industry then the perception could be that the industry is setting the priorities especially if a situation arises where certain actions that might be detrimental to the industry are given a low priority.

Is this an unwarranted fear? Perhaps not. In the United Kingdom, the Medicine Control Agency (MCA) is now almost entirely funded by licensing application fees from the pharmaceutical industry. The MCA now essentially runs as a business selling its "regulatory services" to the industry and promoting itself as one of the fastest licensing authorities in the world for new drugs. In the view of John Abraham, Director of Science Policy Research at the University of Reading in England, such a move merely perpetuates corporate bias in drug testing and regulation. In his book <u>Science, Politics and the Pharmaceutical Industry</u>, Abraham documents how such a bias on the part of the regulatory authorities in the UK and the USA allowed dangerous medications to be marketed despite the lack of good evidence for their effectiveness and in the face of clear evidence of their potential danger.⁵⁴

Advertising prescription drugs to the public

Government has traditionally allowed industry to self-regulate promotion to physicians. Industry has responded by developing weak marketing codes, which are poorly enforced and which lack effective sanctions.⁵⁵

Up until now government regulations have barred direct-to-consumer advertising (DTCA) of prescription drugs, but sometime within the next 6-12 months that is likely to change and we will soon be seeing ads for a wide variety of prescription medications in our newspapers, magazines and perhaps on our TVs. Events are being propelled forward by a number of factors. Chief among them are the proliferation of drug information on the internet, the direct to consumer ads in American magazines that come into Canada and the recent defeat in the Supreme Court of the <u>Tobacco Products Control Act</u>. This last point has convinced many

⁵⁵Lexchin, "Canadian Marketing Codes" op.cit.

⁵³Lexchin, "Drug makers and drug regulators: too close for comfort. A study of the Canadian situation", <u>Soc.Sci.Med.</u> vol.31 1990, pp.1257-63; Lexchin, "Who needs faster drug approval times in Canada? the public or the industry." <u>International Journal of Health Services</u>, vol. 24, 1994, pp. 253-264

⁵⁴London: UCL Press, 1995

observers that the prohibition against direct-to-consumer advertising would not withstand a court challenge. Industry, of course, is all in favour of DCTA, ostensibly around the issue of "a better informed consumer", but in reality in the hope that the DCTA will further increase sales and profits. There is no proof that DCTA will contribute to better health for consumers, but there is proof from the United States that it leads to more sales.

According to a 1989 survey 84% of the doctors polled said they would at least consider the drug a patient requests and 19% were very likely to prescribe the drug the patient wanted.⁵⁶ This survey is trumpeted in an ad encouraging drug manufacturers to advertise in the magazine USA Weekend. The caption on the ad says "84% of doctors consider prescribing a remedy if a patient asks for it by name. We get your name into 38 million adults overnight."

HISTORY OF THE FEDERAL ROLE IN HEALTH CARE

The history of our health <u>care</u> system, as distinct from other aspects of health, is extremely important to a full understanding of how the power structure within the health care industry developed. As a result of the manner in which funding was allocated we have made an enormous investment in physician and hospital-oriented care (rather than in a system which includes a broad base of different types of providers such as acupuncturists, nutritionists, homeopaths, or even nurses or nurse practitioners). In addition our society has embraced the notion of science and scientific progress wholeheartedly. Medicine, represented by doctors and hospitals, has grown to represent the scientific method of dealing with illness and disease, a fact which has led to enormous confidence in physician-based services.

The history of financial investment in health care is enlightening when one looks at how the power structure lies. The federal government successfully nudged its way into the social safety net fields essentially around the time of the second world war⁵⁷ by using its more extensive powers of taxation to bribe the provinces into participating in national programs.

THE CREATION OF A NATIONAL HEALTH SERVICE

Public funding of health care began with a federal grants program to provide cost-shared financial support for health planning, public and mental health demonstration programs, professional training and, most significantly, hospital construction.⁵⁸ Hospital construction and an increase in the number of hospital beds resulted from the institution of this program.

⁵⁶C. Ukens, "Consumer advertising found to pack prescribing punch", <u>Drug Topics</u> vol 136, no. 21 1992, pp. 24,26

⁵⁷Canadian Bar Association Task Force on Health Care, <u>What's Law got to do with it?</u> Health Reform in <u>Canada</u>, Ottawa Canadian Bar Association

⁵⁸Chrichton, Hsu and Tsang, <u>Canada's Health Care System: its funding and its organization</u>, Ottawa: Canadian Hospital Association Press, 1990 at p. 31

Some years later, the federal government passed the Hospital Insurance and Diagnostic Services Act, 1957 which provided cost-sharing of hospital operating expenses.⁵⁹ It became clear relatively quickly that health care was not necessarily best provided in hospital, and that the country needed some measure of broader health care system. Saskatchewan led the country when it introduced the Saskatchewan <u>Medical Care Insurance Act</u> which was passed in November 1961. This was in the face of significant opposition from the doctors who went on strike for 23 days to protest the invasion of public insurance into the free enterprise system.

The Federal Government's Royal Commission on Health Services in 1964 (The Hall Commission) resulted in the Federal Liberal Government introducing and passing the shared cost programming of the <u>Medical Care Act 1966</u>⁶⁰ to provide publicly funded health insurance to cover physician services as well as the hospital services already available.

The fact that the federal government's liability for health care was open-ended soon caused considerable consternation and resulted in a new formula for cost-sharing. In 1977 the federal government passed the <u>Established Programs Financing Act</u>. The EPF provided each province with a block grant for health care and post-secondary education which was not linked directly to the actual or an average of actual cost of the program as the earlier formula had been.

The EPF was calculated as a percentage of gross national product combined with the rate of growth of the population averaged over three years.⁶¹ Payment to the provinces was made through a combination of cash contribution and the transfer of tax points. With the latter what the federal government did was to lower its income tax rates (both personal and corporate) and allow the provinces to increase their tax level proportionately. In order to determine how much of a cash contribution the federal government was to make to a province it would calculate its total commitment under EPF, it would then calculate the revenue raised by the tax points which were transferred to the province. The first number minus the last number equals the amount of the cash commitment.

The <u>Canada Health Act</u> was passed in 1984 and was aimed at preventing the provinces from using the money in the block grants (made up in part by the additional tax revenue from the transferred tax points) for any other purpose than that for which it was intended. The stated purpose of the <u>Canada Health Act</u> 1984 is to "establish criteria and conditions that must be met before full payment may be made under the Act of 1977 in respect of insured health services and extended health care services provided under provincial law".

⁵⁹<u>ibid.</u> p. 32

⁶⁰for details please see Chrighton et. al. <u>op.cit.</u> and Malcolm G. Taylor, <u>Health Insurance and Canadian</u> <u>Public Policy</u>; <u>The Seven Decisions That Created the Canadian Health Insurance System</u> Montreal: McGill-Queen's University Press, 1978

⁶¹Canadian Bar Association <u>op.cit.</u> at p. 10

It is worth noting that the full title of what we refer to as the Canada Health Act is: <u>An Act</u> relating to Cash Contributions by Canada in respect of insured health services provided under provincial health insurance plans and amounts payable by Canada in respect of extended health services. This was clearly a piece of fiscal legislation.

The <u>Canada Health Act</u> set out the five criteria⁶² referred to frequently now as the backbone of our system:

- (a) public administration
- (b) comprehensiveness
- (c) universality
- (d) portability, and
- (e) accessibility

The Act also explicitly prohibits extra-billing ⁶³ and hospital user fees.⁶⁴ The provinces were given three years to draw in line with the principles of the <u>Canada Health Act</u> and by 1987 all provincial governments were in compliance.⁶⁵

Starting in 1985, the not so old health care system began suffering its first serious cuts: In 1985 the Tory Government cut the formula for increasing the EPF to growth domestic product minus 2%. In 1989/90 they reduced it a further 1% (to GDP minus 3%). In 1990/91 the funding level was frozen for two years, then extended right to 1995/6. The net effect of this is that between 1985 and 1994 an estimated \$22 billion was drained from the health system.⁶⁶

In the intervening period the government changed. Hope was renewed that the funding for the social safety net would be restored.

A NEW ERA UNDER THE FEDERAL LIBERALS

At the end of the five years of frozen EPF payments we had a social safety net which, while decreasing, did have national scope and power was vested in the federal government to ensure that each province complied with the national terms. The safety net included both the EPF

63<u>ibid.</u> s. 18

64<u>ibid.</u> s. 19

⁶⁵Chrighton et.al. <u>op.cit.</u> at p.35

⁶⁶Maude Barlow and Bruce Campbell, <u>Take Back the Nation</u>, Toronto: Key Porter Books, 1991 at p. 74

⁶²Canada Health Act, s. 7

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⁶⁶Maude Barlow and Bruce Campbell, <u>Take Back the Nation</u>, Toronto: Key Porter Books, 1991 at p. 74

⁶²Canada Health Act, s. 7

which covered health and post-secondary education and the <u>Canada Assistance Plan</u>, or CAP, which provided a Guaranteed Income Supplement for low income people 65 years and older, and welfare for people in need under 65 years of age as well as shared cost financing for a number of other social programs.⁶⁷

The CAP was established in 1966 by the federal government as a cost-shared program with the federal government reimbursing the provinces 50% of the cost of all eligible expenditures. This remained the formula until 1990 when the federal government unilaterally placed a cap of 5% per year on the CAP for the three wealthiest provinces: Ontario, Alberta and British Columbia. As with the EPF and the <u>Canada Health Act</u>, the payments under CAP were conditional on the provinces fulfilling national criteria. The legislation required provinces and territories to provide assistance to all people judged to be "in need".

The Canada Health and Social Transfer (CHST) was the creation of the Liberal Government in the 1995 budget. It combines the payments previously made under CAP and EPF and reduced those entitlements by \$2.5 billion in 1995 and \$4.5 billion in 1996/7 and 1997/8 respectively.⁶⁸

Because of the formula used to calculate the cash transfer portion of the federal contribution, the actual impact on transfer payments is even larger. The value of the tax points in real terms will go up as the economy grows. As the CHST is not fully indexed to reflect economic growth, it means the tax points will account for a larger amount of the entitlement.⁶⁹ It is estimated that the cash transfers will run out entirely by 2006-7.⁷⁰

THE CHST: RENDING THE SAFETY NET

For everything except health, and with the exception of the mobility condition for welfare benefits, payment of the CHST is no longer conditional upon compliance with national standards. This means that the only conditions with any clout are those under the <u>Canada</u>

⁶⁷CAP included the welfare portion - including basic assistance, assistance for people with special needs, and legal aid in non-criminal cases; subsidized child care; adoption services; casework, counselling, assessment and referral services, including services to abused or neglected children etc; community development services; consulting, research and evaluation services on welfare programs; homemakers, home support and other services to help out in emergencies or as an aid to independent living for older people and people with disabilities; rehabilitation services; administrative services related to the delivery of welfare and social services. For further detail, please see <u>The 1995 Budget and Block Funding: A Report by the National Council of</u> <u>Welfare</u>, Ottawa: Min of Supply and Services Canada, Spring 1995

⁶⁸Michael Mendelson, "Looking for Mister Good Transfer: A Guide to the CHST Negotiations", Ottawa: Caledon Institute of Social Policy, October 1995

⁶⁹Mendelson, "Is there life after death (of federal transfers)? Vancouver: UBC Centre for Health Services and Policy Research, January 1996, HPRU96:ID at p. 1

⁷⁰Medicare Monitor, vol.10, No.1 April 1995 p. 7

<u>Health Act</u>.

With a decreasing allocation, and no conditions on other services, it is clear that the provinces will have no choice but to allocate an increasing amount of the CHST to the health care sector to the detriment of the other aspects of our social safety net.⁷¹ Within the current Canadian political context, it is clear that welfare and related programs do not stand a chance when pitted directly against something of such clear value to all Canadians as the health care system.

THE DETERMINANTS OF HEALTH

With regard to health care, the impact of the CHST is less immediate. Having said that, the one thing that we are certain contributes to ill-health or a lower health status is poverty. The correlation has been demonstrated time and again. There can be no doubt that withdrawing money from the welfare system and for other social programs will have a serious long term effect on population health status which then has a rebound effect on health care.⁷²

The final report of the Royal Commission on the New Reproductive Technologies includes a chapter on the Canadian Health Care System. Therein they state unequivocally the importance of income to health status:

First, research in Canada and elsewhere shows clearly that there is a direct relationship between health status and income. The higher the income, the longer and healthier the life, despite the fact that medical treatment is available and used throughout the country, and even when smoking, nutrition, and other factors are taken into account. In the aggregate, low socioeconomic status, not lack of health care, is the greatest correlate of poor health. Second, research in Canada, the United States, and elsewhere shows that the rate of use of certain medical procedures, including certain types of surgery varies very widely between similar communities, yet high use makes no appreciable difference to health status...

..money spent to provide medical care is then unavailable for purposes such as affordable housing, education, income security, and environmental protection, which also have a great potential impact on the overall health of the population. Allowing these other determinants of health to deteriorate by devoting insufficient resources to them is risky. We have reached the point where paradoxically, the further allocation of dollars to health services could actually

⁷¹For further analysis of the impact of the CHST please see: "Our Country Under Attack: A report on the CHST and what it will do to our way of life", Ottawa: CUPE, May 1995; <u>Medicare Monitor</u>, vol.10, No.1 April 1995; Paul Steinhauer, "The CHST: A threat to; the Health, Development and Future Productivity of Canada's Children and Youth" Ottawa: Caledon Institute of Social Policy, November 1995; "Undoing Health Care: The Canadian Health and Social Transfer and how the 1995 federal budget will affect medicare", CUPE Research Dept., Apr. 1995

⁷²Please see Dr. Steinhauer's analysis, <u>ibid.</u> for an extremely good analysis of how funding for social programs have a broad impact on society as a whole.

have detrimental effects on health.73

A further problem is that any protection which has been maintained for the health care system is weak and short-term at best. As was noted above, it has been calculated that at the present rate of decline, the transfer of cash payments to the provinces will halt by around 2007. As soon as that happens, or even as that time approaches, there will be no incentive at all for the provincial governments to pay any attention to the national standards of the <u>Canada Health</u> <u>Act</u>. Each government will proceed as far as politically tenable in their own jurisdiction, paying no heed to the empty threats of the federal minister of health.

At the time of drafting this paper, the battle between the provinces and the federal government raged in the newspapers day after day. The provinces stating the objective of getting the federal government out of standard setting for social programs. One proposal put forward was national standards developed by consensus of the provincial governments but with no enforcement mechanism. Saskatchewan Premier Roy Romanow is quoted as saying "It's like a marriage: You enter into it voluntarily (and) you have rules by which you abide...In an era of co-operative federalism...the issues of enforcement or compliance become very, very much irrelevant."⁷⁴

David Dingwall, Federal Minister of Health continues to play the role of defender of the health care system as we know it: "We're not just a 'Chargex card' for provinces, Dingwall says" ⁷⁵ Those who understand the impact of the CHST know that the emperor has no clothes: without cash transfers to hold out as bait, he would have no hope of ensuring the provinces comply with any national standards.

At the same time as this debate, the Canadian Medical Association publicly battles over whether or not Canadian doctors support the notion of a two tier health system: a system which would expand the role of third party ensurers and thus the boundaries of their income potential.⁷⁶ A narrow defeat of the two-tier proposal at the recent CMA convention led to agreement that the CMA begin a public debate on Medicare and find out what the mood of the public is on this matter. The governments have a happy emissary on this issue – let the doctors go out and fight the case for changing the system: the doctors have the best chance at stirring up the fear that our system is falling apart and people are going to being dying unnecessarily because of lack of funds unless we begin to develop more 'public-private

⁷³<u>Royal Commission Report</u>, vol.1 at p. 74. See also: Robert Elgie "Health care cost containment – US and Canadian Comparisons" <u>Health Law in Canada</u> vol. 15 no.1 pp 3-9 at pp.6-7, quoting M. Angell "Privilege and Health – What is the Connection?" <u>New England Journal of Medicine</u>, vol 329 no.2 July 8, 1993 at pp. 126-27

⁷⁴Toronto Star, Saturday Aug. 24, 1996 pp.A1 and A9

⁷⁵Lead, <u>The Toronto Star</u>, p.A1

⁷⁶Toronto Star, Aug. 22, 1996 "Breathing new life into old two-tier medicine"

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DE-REGULATION OF EXTENDED CARE

It is worth noting that while the federal government has vowed to protect our national health care system, in the legislation implementing the budget⁷⁷ there was one further change to the Canada Health Act which was inconsistent with the purely financial aspects of legislation aimed at implementation of a budget. That was the deletion of all references to "extended health services". The Act defines "extended health care services" as:

- (a) Nursing home intermediate care services
- (b) adult residential care services
- (c) home care services, and
- (d) ambulatory health care services.

Clearly, the <u>Canada Health Act</u> no longer binds the provinces to ensure that these services are covered by the public health insurance plan. That means that these sectors are up for privatization without penalty. The federal government has removed its power to ensure that the provinces protect this sector. In light of our aging population and the thrust within the provinces to more 'community care', moving individuals through the hospital sector more quickly, this has huge potential for the cost to individual users of the health care system.

IS THE DECLINE IN THE SAFETY NET INTERNATIONAL TRADE RELATED?

In recent years the deficit reduction/budget balancing rhetoric of the politicians has dominated the political stage. There has been enormous popular buy-in to the belief that we must do what is necessary to reduce the cost of government in order to balance our books. The landslide victory of the Conservative party in Ontario is one sure indicator of the public mood (perhaps the more recent re-election of the NDP in British Columbia and the election of the NDP in the Yukon signals the beginnings of a shift?). The reasons for the success of this political positioning have been examined in depth in other places ⁷⁸ but it is worth noting that it has been argued that there is a correlation between this positioning and the new wave of international trade deals.

It should be pointed out that the slashing of social programs in this budget is an attempt to satisfy the pressures of NAFTA. The free trade agreement obligated Canada to harmonize its public expenditures in line with the skeletal social system of the United States. Part of that pressure is aimed directly at medicare, and the withdrawal of federal funding for health is consistent with the demands of free enterprise and open trade between Canada and the United

⁷⁷Bill C-76

⁷⁸See for example, Linda McQuaig, <u>Shooting the Hippo: Death by Deficit and other Canadian Myths</u>, Toronto: Penguin Books Canada Ltd, 1995

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States.79

The Conservative government's planned withdrawal from Medicare by the end of the decade is not a coincidence. It corresponds to the seven-year deadline to reach a common subsidies code under the free-trade agreement. The Americans have long viewed Medicare as an unfair subsidy and raised it during the original negotiations. It would undoubtedly be on the table during the subsidies round, so what better way to avoid the embarrassment of being seen to be caving in than by dismantling the system before the issue comes to the table. ⁸⁰

SECTION THREE: PROVINCIAL JURISDICTION

As was stated above, the provinces have jurisdiction over health care under the Constitution. We have also outlined the incentives which were given to the provinces to develop a health care system, starting with funding for hospital construction and moving on to funding for the actual provision of services.

The historical perspective is important for an understanding of the power structures inherent in our health care system. The Ontario health budget is 17.4 billion dollars annually, the largest expenditure in the provincial budget by a large margin. The power brokers for that allocation have a huge vested interest in ensuring that their portion of the pie is not altered. At the same time there are many others eagerly awaiting their chance to share some of this market – and to benefit from the huge growth potential therein.

HOW IS HEALTH CARE IN ONTARIO ORGANIZED?

While there appears to be a move afoot to make fundamental changes to the way health is organised both internally within the Ministry of Health and externally in the manner in which services are delivered, at present, health care in Ontario is organised by who gets financed through which pool of money from the Ministry of Health. The management systems within the Ministry of Health reflect this way of doing things as there are management silos for each different funding envelope and there is little cross fertilisation between the silos.

A basic breakdown of the Ontario provincial health care budget looks like this:

TOTAL EXPENDITURE: \$17.4 BILLION

Ontario Health Insurance Plan - 27% Community and Public Health - 4% Hospitals - 42% Long Term Care - 12%

⁷⁹CUPE Research Department "Undoing Health Care" April 1995 p. 17

⁸⁰Barlow and Campbell, <u>op.cit.</u> at p.71

Ontario Drug Plan - 5% Other - 10%⁸¹

THE ONTARIO HEALTH INSURANCE PLAN

What the law says at present is that all 'medically required' services will be funded by the public health insurance plan.⁸² Nowhere across the country is there a real definition of what the phrase 'medically required' or 'medically necessary' actually means in practice. What happened was the Schedule of Benefits, the list of those items covered by the provincial insurance plan, simply grew as and when practices were developed and, as health care budgets grew at a rate of about 10% each year until the early '90s, this list was simply accommodated.

At present the Schedule of Benefits is determined by way of recommendations made to the Government by the Central Tariff Committee, which is a committee of the Ontario Medical Association (OMA). The process for negotiating what is included in the Schedule of Benefits is not a public one. Neither is there any systematic scrutiny of the scientific or evidence-based merit of any particular procedure before it is listed in the Schedule. The fact is the expansion of the Schedule has never been a particularly contentious issue, and 'medically necessary' has developed a rather broad definition.

It is fascinating and at the same time profoundly shocking to discover that the process for defining what treatments are most appropriate for what problem is at best ad hoc. Just as the public has a right to believe that the drugs being prescribed and sold are safe to take as directed, it would seem logical to believe that faith can safely be vested in the procedures recommended by your health care practitioner. It appears that is not always the case:

The vast majority of medical technologies, which are foisted on an unsuspecting population and paid for out of the public purse, have never been proven as to their safety or effectiveness.⁸³

According to the final report of the Royal Commission on the New Reproductive Technologies, "The evidence before the Commission suggests that a significant proportion of

⁸¹Ontario Nurses' Association, <u>Dialogue on Health Reform: A Vision for Saving Medicare</u>, Summer 1996, p.29

⁸²<u>Health Insurance Act</u>, RSO 1990 c.H-6 s. 1 "'insured services' means such services of hospitals and health facilities as are prescribed by the regulations, all services rendered by physicians that are medically necessary and such other health care services as are rendered by such practitioners and under such conditions and limitations as are prescribed by the regulations"; Royal Commission Report, vol 1. p.82

⁸³Rachlis and Kushner, <u>Second Opinion</u> <u>op.cit.</u> at p.49

medical care is ineffective, inefficient, or unevaluated."84

We have allowed a system to develop where those practising in the field determine what procedures should be paid for by the public purse and we have set no standards for evaluating them. We have simply dug deeper and deeper into our collective pocketbook. The public has grown to accept that procedures recommended by physicians should be available and covered by public insurance.

The fact is, the general public is not aware of the lack of proof behind medical procedures. We have a system built on faith and there has never been an effective method of challenging that faith.

As for medicine, the public believes more than ever that practitioners have special healing powers. As medicine adopted the new trappings of science – the laboratory, the shiny new instruments, the jargon, the ubiquitous white lab coat – the distinction between medicine and science blurred, and doctors became indistinguishable from scientists. No one seems to notice that medicine has only the look, not the substance, of science, that it has never wholeheartedly adopted the scientific method. In medicine, science is only skin-deep.⁸⁵

Even where effort is put into explaining why certain procedures are not appropriate, the public has a hard time swallowing the possibility that there is no magic cure. Antibiotics do not cure viral infections. Colds, even really bad ones, are caused by viruses. How many people take the prescription for the antibiotic offered by a doctor in the misguided hope that somehow it will have an impact on the cold? Doctors often offer prescription medication as a panacea and patients tend to walk away feeling better about their visit to the doctor. It also means the doctor can spend less time with the patient because he or she is given a 'cure' to take home.

One way of tackling the health funding 'crisis' would be to limit those elements of the Schedule of Benefits to those things which have been proven to be 'medically necessary' and which have an evidence-based track record. This is basically what the State of Oregon did in establishing a priority list of items for public funding.⁸⁶

The difficulty with this approach here in Canada is two-fold. First, de-listing anything from the Schedule causes enormous public outcry. Unless and until the public is educated about what constitutes really good health care, delisting will do nothing more than create a need to be met by the private sector. Just because the government has deemed something not

⁸⁶Tim Caulfield, <u>op.cit.</u>

⁸⁴<u>op.cit.</u> at p.70; see also: Tim Caulfield, "Oregon's Health Care Plan: An Answer for Canada?" <u>Health</u> <u>Law Journal</u>, vol.2 No.2, pp.19-23 at p. 20 referring to J. Wennberg "Outcome Research, Cost Containment, and the Fear of Health Care Rationing" <u>The New England J. of Medicine</u> (1990) vol.323 at p. 1202

⁸⁵Second Opinion, op.cit. at p.58

medically necessary does not mean that patients will believe that a recommended procedure is not medically necessary for them. Secondly it is a way of seeing health care as simply illness care. What it does is list procedures or illnesses rather than looking at health as a much broader spectrum of qualities. Primary health care would be even more limited to a number of procedures rather than a process which involves looking after the whole person.

HOW THE OHIP POOL IS ACCESSED

Payment to practitioners from the Ontario Health Insurance Plan is made upon rendering an account of the number of listed services provided through the billing period. This is the 'fee-for-service' part of the health care system which is much in the news these days.

The doctor bills the plan for a service that is included in the Schedule of Benefits. All approved items may be billed to the Government for reimbursement. If a particular procedure is not included in the Schedule of Benefits, the practitioner may bill the patient directly for it. For example, while routine circumcision used to be in the Schedule, it was removed in the early '90s therefore non-medically necessary circumcisions must be privately paid for. As we have seen, the <u>Canada Health Act</u> specifically prohibits extra-billing for insured services (your doctor cannot top up his or her billing to the government by getting you to pay a little extra) but does not prevent private payment for non-insured services.

What this fee-for-service billing system means is if your doctor regularly spends 30 minutes with each patient, he or she will earn substantially less than a colleague who spends only 10 minutes. The physician receives a set amount for each billable procedure. The time explaining the procedure, or how to use the medication etc. is not billed. It means that there is an inherent disincentive to spend time talking with patients to explore other matters relating to their health status which could educate the practitioner as to how best to treat the patient. The wealthiest doctors are the ones who treat the most patients, it is as simple as that.

COMMUNITY AND PUBLIC HEALTH

Each province and the federal government maintains an office dedicated to 'public health'. In Ontario there is the Public Health Branch of the Ministry of health with Public Health Units set up across the province. The governing piece of legislation is the <u>Health Promotion and</u> <u>Protection Act</u>.⁸⁷

The purpose of the <u>Health Promotion and Protection Act</u> is:

to provide for the organization and delivery of public health programs and services, the prevention of the spread of disease and the promotion and protection of the health of the

⁸⁷RSO, C.H-7

The Act establishes a number of mandatory health programs and services including: community sanitation, control of communicable diseases, preventive dentistry, family health, home care services, nutrition services, and public health education. The Boards of Health are responsible for inspections of premises to prevent, eliminate and decrease the effects of health hazards.⁸⁹ This also includes responsibilities regarding occupational and environmental health⁹⁰ and inspections of food premises.⁹¹

The powers and responsibilities of the Medical Officers of Health and the health units are extensive. However, the legislation can only be as effective as the resources allocated to the field allow.

Under the umbrella of Community Health, the Ministry of Health funds grant programs as well as an alternative primary care model quite apart from the OHIP billing model noted above. Primary care most simply defined means the care provided at the first point of entry into the health care system. For most people, that is the office of their family physician. Most family physicians are paid on the fee-for-service basis described above and either work in solo practices or group practices.

The Community Health Branch of the Ministry of Health provides global budgets to Community Health Centres (CHCs), of which there are 56 in Ontario. CHCs are set up as primary care clinics governed by community boards elected by the clinic membership. Typically the CHCs provide all primary care services to those members within a specific geographic area. The clinics were given provincial funding on the basis of having defined a needy target population (typically an under-serviced population). The elected board of directors then decides how the global budget will be spent – typically retaining an Executive Director and hiring physicians on salary. They tend to aim at a multi-disciplinary approach to care and teams often include a Nurse Practitioner, a health promoter, a community outreach person, and perhaps a nutritionist, a social worker or whatever type of professional their particular clientele is deemed to require.

The Ministry of Health also funds 77 Health Service Organizations (HSO's) which are group practices (physician-based) which receive their income by way of capitated fee for the clients registered or rostered with their clinic. A 'capitation rate' is a flat fee set for each person

⁸⁸<u>ibid.</u> s.2

⁸⁹<u>ibid.</u> s.10

⁹⁰s.12

⁹¹s.16

registered as a patient with the HSO. The HSO then receives a standard monthly amount for the patient regardless of the number of times he or she visits the practice. To make it work, the patient agrees to receive all his or her primary care from the HSO and the practice agrees to provide all necessary care and referrals. There is a penalty paid by the HSO each time a patient receives primary care from another provider paid on a fee-for-service basis. (For example if a patient visits a local after-hours walk in clinic, an amount is deducted from the capitation payment made to the HSO doctor.) The HSO program receives funding from the Community Health pool as well as from OHIP.

Shortly before printing this paper a document was leaked to Tom Walkom of the <u>Globe and</u> <u>Mail</u>, which indicated that the Government is considering off-loading public health and community health centres, and a multitude of other services, to the municipal governments, with no funding. This would be done to offset the increased cost to be incurred by the province for assuming responsibility for education.⁹² Should this occur, it signals a monumental shift in ideology from previous governments in relation to health.

HOSPITAL SERVICES

Hospital care is the most expensive part of the health care system, consuming 42% of the health care budget. In Ontario, hospitals must be set up as non-profit corporations.⁹³ They receive global funding from the Ministry of health from which they must pay for the "hotel services" (that is the cleaning and feeding parts of the hospital service) as well as the technical machinery, maintenance of the surgical unit, paying those on staff (predominantly the nurses, and other technical people with the exception, for the most part, of physicians, although there may be some physicians who are being paid directly by the hospital).

Hospitals within the tertiary and quaternary care sector are also similarly funded. Tertiary care is defined as "care that requires highly specialized skills, technology and support services that are usually provided in facilities servicing a large region or the province as a whole such as the Sick Childrens Hospital and Princess Margaret Hospital".⁹⁴

Quaternary care is defined as "highly specialized tertiary services usually available in a single site servicing a large urban population such as the Toronto Hospital's liver transplant program." ⁹⁵

It is the hospital sector which is presently being squeezed the hardest by the present

⁹³Hospitals Act

95<u>ibid</u>

⁹²Tom Walkom, <u>Globe and Mail</u>, November 21, 1996 p.A37

⁹⁴Ontario Nurses' Association, <u>Dialogue on Health Reform</u>, Summer 1996 at p. 31

government because, it is argued, therein lie the most savings.

LONG-TERM AND HOME CARE

These are general terms to include all long-term services provided most often to disabled and elderly people who require a different type of care from the care provided by an acute care facility, and cannot survive in the community without some form of assistance.

It is this sector which was so directly hit by the recent change to the <u>Canada Health Act</u> noted above. It has also historically been a part of the system which is unquestionably two-tiered, with many services available privately and residual services available publicly. This area as a whole closely draws on social services as well as health.

With early release planning for hospital services, home care is a growing field. Many patients who have undergone surgery are now being released back into their homes when they are still not able to function fully on their own and still require some measure of assistance.

...as new non-invasive techniques revolutionize surgery and budgets are slashed, hospitals are discharging patients in much less time – 'sicker and quicker' – than would have been dreamed about 10 years ago.⁹⁶

ONTARIO DRUG PLAN

Ontario spends 5% of its total health care budget on drugs. The Ontario Drug Benefit Plan provides drugs to those receiving Social Assistance, everybody over 65, people with special drug needs, and people granted Ministers permits.

This 5% allocation is a substantial portion of the budget. If you look back at the detail outlined above about the rise in the costs of pharmaceuticals, the lax approval process, and the extension of the patent rights of the manufacturers you see the link directly between the international trade deals and the cost of providing a service to the population.

IS HEALTH REFORM NECESSARY?

It has frequently been argued that Ontario does not have a health care 'system' at all.⁹⁷ It is quite probable that that could be said about the rest of or most of the rest of the Country. What we do have is a series of services available to the public and independently regulated and relatively unmonitored. There is little or no systems coordination and no way of tracking what

⁹⁶Jane Coutts, "Privatizing care for patients at home an issue on the boil", <u>Globe and Mail</u>, April 17, 1996, p.A-8

⁹⁷Jane Cornelius, president of the Ontario Nurses' Association quoted in <u>Dialogue on Health Reform;</u> Rachlis and Kushner, <u>Strong Medicine</u>

happens to any patient through the number of visits to different practitioners or facilities.

One of the problems inherent in the system is the Ministry of Health manages the sector in silos. There is limited information sharing between the divisions. In part this is due to the shear volume of material, but it is also symbolic of internal turf wars which prevent the merging of ideas and programs where such would be of benefit to the public. As was noted above, it appears that the government is committed to changing this. Change in this area is probably a good thing, however, there is huge potential within the context of this change for a hiving off of chunks of the system to the private sector.

Reform <u>is</u> necessary to ensure that users of the system benefit from some level of service integration to ensure quality health care through the spectrum of providers and facilities. To be effective systems reforms must be paralleled by reforms of how the system is managed by the Ministry of Health.

If the focus of the reform is on devising a better way of meeting the health needs of the public there is potential for a significantly improved system. However, if reform is focussed on medical care alone and not on the determinants of health, it is likely we will see considerably less room in the system for health to be seen as more than simply the absence of illness and disease.

While there is a strong contingent of health reformers proposing changes to the health care system to ensure better integration, of late, the voice of the fiscal conservatives has dominated. Reform initiatives, with a view to saving money, are being pushed forward before a plan for systemic change has been agreed upon. This is an extremely risky approach.

HOW DOES HEALTH REFORM RELATE TO DE-REGULATION?

If one can argue that the motivation behind the de-regulation movement is the satisfaction of a corporate objective to facilitate doing business as freely as possible and thereby make more money, health care reform can fall clearly within the same category.

The federal government has substantially weakened its capacity to enforce the conditions of the <u>Canada Health Act.</u> There is ample evidence that the provinces are beginning to redraw the line between public and private health care. The private sector is already gearing up for the change, conference after conference is being hosted on the public-private partnership model for health care.⁹⁸

⁹⁸For example the conferences and associated background information organized by Insight Information Inc. One video is entitled: "Private Partnerships in Health Care: Prescription for Our Economic Dilemma". The video cover summarizes the contents thus:

[&]quot;Discusses the opportunities and challenges when merging both the private and public delivery system, including ethical concerns, international examples, and strategies for integration."

SO WHAT REFORM?

There are many different ideals for what a fully publicly funded health care <u>system</u> would look like. It would be impossible in a paper of this nature to do justice to the intricacies of the debates on the merits of the various proposals or types of proposal. It would also be impossible to describe each of the different types of proposed system changes in any way that did them justice.

The focus here is on the impact of a climate of de-regulation on the health sector. It is important to look at the actual delivery of health services in the province because there can be no doubt we are at a critical stage in the history of our system. The next few years will dictate in large measure whether or not we have a full public health care system into the next century or not. However, it is also important to recognize that we can be so intent on devising the perfect plan that we aren't paying attention while actual change is taking place.

Primary Care Reform

Up to now we have relied on a very simple definition of what primary care is, describing it most simply as the first point of access into the health care system. When discussing what form reform should take it is helpful to look at the generally accepted definition of primary care set by the World Health Organization in 1978 in its Alma-Ata declaration:

Essential health care based on practical, scientifically sound and socially acceptable methods and technology made universally accessible to individuals and families in the community through their full participation and at a cost that the community and country can afford to maintain at every stage of their development in the spirit of self-reliance and selfdetermination...It is the first level of the contact of the individual, the family and the community with the national health system, bringing health care as close as possible to where people live and work, and constitutes the first element of a continuing health care process.⁹⁹

If we take that definition as our bottom line, then what we are looking for in the creation of a primary care system, is a community based, fully participatory health care system which is not simply a primary medical care system. We are not looking to entrench even further the notion that health care and medical care are synonymous.

As the existing health care system is predominantly controlled by the interests of the doctors, and funding is primarily allocated to satisfy the needs of the doctors, a switch from a primary medical care system to a primary health care system is a fundamental shift in ideology. Over

⁹⁹Canadian Medical Association, "Strengthening the Foundation: The Role of the Physician in Primary Health Care in Canada", Ottawa: CMA, 1994 p. 1 quoting from: World Health Organization: <u>Primary</u> <u>Health Care: Report of the International Conference on Primary Health Care, Alma-Ata, USSR, 6-12</u> <u>September 1978</u>, Geneva: World Health Organization, 1978; see also: Association of Ontario Health Centres, <u>Building on Success: A Blueprint for Effective Primary Health Care</u>, Mimeo, 1995

the last few months, millions of dollars have been pulled from the hospital sector and a substantial amount of those savings were reallocated to the doctors. The Ontario Nurses' Association expects to lose up to 15,000 nurses over the next few years, and yet the doctors, who never have to complain of unemployment, are receiving an increase in their allocation.

It has been argued time and again that fee-for-service payment of physicians acts as a disincentive to good primary care practice.¹⁰⁰ It encourages treatment over prevention, it discourages allocating time according to a patient's needs in favour of billable time. The bottom line of practising <u>good</u> family medicine within a fee-for-service payment system is that the physician doesn't take home a lot of money.

The bottom line for reformers, almost across the board, is to change the way primary care is funded. Consensus appears to be growing that some form of capitation-based funding method would lead to positive change and a more equitable distribution of health care dollars across the province (or any province). It would mean that a person, regardless of where they lived, would have the same value attached to him or her as a comparable person anywhere else in the province.

Capitation funding is based on the principle that each resident of the province should have a dollar figure attached to him or her. That figure would be calculated according to criteria such as age: we know that elderly people and very young people access the health care system more often than other age groups, and the presence of disease etc. The formula for the calculation can be a simple one or it can be very complex depending on the number of characteristics one plugs in.

In order to access the funds linked to an individual, a health care practitioner or a health organization (like a Primary Care Organization which is described below) would enter into an agreement with the individual that they would provide all primary health care needs to the person with the return promise that the person would not seek care from another primary care source, except in extenuating circumstances. The person would then be included in the practitioner's roster, and the roster would be the basis upon which the practitioner or practice would receive funding from the government.

At present the large urban areas are seriously 'over-doctored' while in the outlying areas there is often a severe shortage of physicians. By attaching the money to the people, practitioners would have no choice but to go where there was unclaimed capitation moneys available and set up practice where they can earn a living. The alternative of remaining in the over-doctored areas is that income would unquestionably drop.

In 1995 the Federal and Provincial Health Ministers formally considered a document describing

¹⁰⁰For more detail please refer to Rachlis and Kushner, <u>Strong Medicine op.cit.</u> where they provide the arguments about the delivery of health care in detail which is impossible here.

Primary Care Organizations (PCOs) structured upon a capitated payment basis.¹⁰¹ Essentially the document simply outlines how funding and or payment could be changed in a way which would allow the development of these PCOs. The PCO could be established by "regional or district health authorities, physicians, other providers, community organisations or universities.'¹⁰² The funding would flow into the PCO on the basis of a rostered population. It would then be up to the organization itself to determine how to pay staff including physicians.¹⁰³

Early in the mandate of the present Conservative government of Ontario a Committee, referred to as the PCCCAR,¹⁰⁴ was struck to review 16 major health reform reports with a view to distilling fundamental principles for positive change in the system. The stated objectives were to:

- 1. Improve integration and co-ordination of local health services.
- 2. Ensure people in every community have access to an appropriate range of primary health care services on a timely basis.
- 3. Support involvement of an appropriate range of health practitioners.
- 4. Support evidence-based decision making and use of information technologies to improve the quality of care.
- 5. Improve the distribution of primary care providers.
- 6. Increase the responsiveness of the funding system to the stated objectives for improved distribution and mix of practitioners, service comprehensiveness, and quality of care and the need for funding predictability.¹⁰⁵

This committee concluded that a move to rostering populations was good and that payment should be made by way of capitation fees with extra money for exempted services (like obstetrics, surgery assists, home visits, and bonus payments for meeting specific health targets such as screening rates). There would be a further pool of money available in the form of a special needs fund to provide extra money for special needs populations.

¹⁰²<u>ibid</u>. p. 11

¹⁰³<u>ibid</u> p.12

¹⁰⁴PCCCAR stands for Provincial Coordinating Committee on Community and Academic Health Science Centre Relations

¹⁰⁵PCCCAR Report, "New Directions for Primary Health" April 1996, a never released document of PCCCAR. Access to the document has been tightly controlled with copies marked to prevent further copying.

¹⁰¹Miles Kilshaw, "A model for the Reorganisation of primary care and the introduction of populationbased funding' July 18, 1995, The Advisory Committee on Health Services.

Physician as Gatekeeper

As the 'gatekeepers' of the system for the most part General Practitioners or family physicians are the ones who determine what the rate of utilization of other more specialised health care services is.¹⁰⁶

As gatekeeper, at present the GP or family physician plays a enormously important role in the way the other services in the health care system are used. If the gatekeeper is encouraging people through the gate to the next stage of care, there can be no question that the system will cost more money. A more effective gatekeeper, a gatekeeper with some incentive to ensure that only those really requiring access to other parts of the system, will keep costs down.

Integrated delivery systems

It doesn't appear to be enough to reform the primary health sector. Horizontal integration of that sector would be good but according to many, it would not have all the benefits of a fully integrated health care system.

An Integrated Delivery System (IDS) is "a network of organizations that provides or arranges to provide a coordinated continuum of services to a defined population and is willing to be held clinically and fiscally accountable for the outcomes and health status of the population served".¹⁰⁷

In Ontario work has been done for many years on a Comprehensive Health Organization model of care delivery. The CHO model is frequently referred to in the literature although it never really got off the ground in Ontario and is still in the developmental stages.

The principle of the CHO and of many of the IDS models is that all types of care should be centrally coordinated to ensure that patients within the system receive continuous and appropriate care from first contact to last. If funding were attached to the organization responsible for coordinating the care, incentives could be built in to encourage health promotion and disease prevention and money saved at any stage in the system could be reallocated to another part of the organization.

There is enormous criticism of the IDS model of health care delivery for many reasons. On the other hand, organisations like the Ontario Nurses' Association have endorsed the development of this type of model. Unfortunately the structure of this paper does not lend

¹⁰⁶ Rachlis and Kushner, Strong Medicine, op.cit. p.53 et.seq.

¹⁰⁷RR Gilles et. al. "Conceptualizing and Measuring Integration Study', Findings of the Integration Study, <u>Hospital and Health Services Administration</u>, vol.38, No.4 Winter 1993 p. 468, quoted in Hume Martin, "Toward an Integrated Health System for Essex County: A Conceptual Framework and Next Steps" mimeo, June 20, 1996

itself to an analysis of the risks and benefits associated with this or any other model of delivery.

PROBLEMS WITH REFORM PROPOSALS

When examining reform proposals it is important to focus on the reasons for reform. If the proposal is primarily intent on resource allocation there is likely a problem with the impact of the proposal on health care. If on the other hand the focus is on improving the system (a byproduct of which might be better resource allocation) there it is more likely that the public stands to benefit.

In those documents which focus on funding and financial allocations, there is very infrequently a question of quality of care, and of meeting the definition of primary care set by the WHO. It is not enough that we can devise a system of allocating health care funds which allows us to save some money. Unless we utilize our health human resources in a different way, we will still end up with the same sort of problem. We have not created a more efficient system where practitioners do what they are trained to do.

We would all benefit from a system where each professional group was providing services appropriate to their qualifications. For example doctors, the most expensive professionals to train and to retain, should not always have the responsibility for health promotion, there is a specific provider, called a health promoter who is less expensive both to train and to pay. Nurse practitioners could carry on well-baby clinics, and do much of the standard health care check-up work and a broad range of other tasks, again at less cost. Nurses could be used to provide the skills they have been trained for in such a way as to ensure that patients receive an appropriate standard of care.

As the number of medical interventions seemingly has endless capacity for growth, it is critical that we begin to use the system more effectively and more efficiently. If we fail to do that there is no way we will ever contain costs, and if there is no way to contain costs, there is no way our public system will survive.¹⁰⁸

Unfortunately it is impossible to address all of the issues relevant to assisting the reader in deciding which formulation is the most appropriate one for the next stage of the health care system. The sides in the debates involve some glaringly obvious differences as well as a number of very subtle ideological differences. The most important things to watch out for when reading the material with a critical eye are that the proposals are based on devising a health care system which promotes health as its primary objective, not saving money or simply shifting the system around. Critical appraisal of how decisions would be made, who has control over the decision-making process, and the relative roles of each of the different

¹⁰⁸Please see, for further analysis, Rachlis and Kushner, <u>Strong Medicine op.cit.</u>; Pat Armstrong and Hugh Armstrong, <u>Wasting Away</u>, Toronto: Oxford University Press, 1996; Association of Ontario Health Centres, 'Building on Success: A Blueprint for Effective Primary Health Care', 1995

professional groups are all important to assessing the reports. Of course, the final issue of over-riding importance is to examine what interest the private sector would have in the newly formatted system.

HOSPITAL RESTRUCTURING COMMITTEE

While all the debates rage on about how to reform the primary care system, what benefit there is in integrated delivery, how to get more services for our dollar, the government has begun to make substantive changes.

Bill 26, the Omnibus bill introduced early in the Conservative's mandate included a number of changes to the legislation in the health sector. One of the matters it dealt with is the governance structure of hospitals.

Bill 26 created The Hospital Restructuring Commission. This Commission was vested with the power to go in and review the hospital services in any jurisdiction and usurp the authority of the existing Board of Directors and give direction to them as to how to proceed with restructuring recommendations. The objective of the Commission is to rationalize the hospital sector and to provide the Minister of Health with any recommendations it feels are appropriate in any other part of the health sector. ¹⁰⁹

According to the report of the Commission after completing its review of hospital services in Thunder Bay, the determination of which hospitals should be down-sizing and closing is done on a business-plan kind of basis. The basic premise appears to be that having identified what the provincial average is for length of stay, etc, it is possible to direct the hospitals in a community to adopt the configuration of the average or even better than average hospital in Ontario. That means closing three of the five hospitals in Thunder Bay.

Now if we remember that the primary medical sector acts as the gatekeeper to the system, simply directing hospital closures may save money but it is certainly going to raise an enormous fear in the community at the same time. The physicians in the community have been given no reason and no incentive to alter their referral practices. There will be patients believing they require hospitalisation and there will be no hospital bed to send them to. The public perception of their health needs will scream crisis.

Crisis in the health sector means more money. No more public money means the search for public-private cooperative ventures.

With a view to the future

In Toronto we have a recent addition to the 'hospital scene' (although it is not technically a

¹⁰⁹Text of speech by Dr. David Naylor "Chairman's Representative and Special Advisor, the Health Services Restructuring Commission, March 29, 1996, Insight Conferences.

hospital because it was not given a licence by the Provincial Government). King's Health Centre is housed in the beautiful old Bank of Canada building on University Avenue. Newly renovated, it offers the most up to date equipment.

This new Health Centre is staffed at present by a group of general practitioners carrying on OHIP practices and it scoops 40% of the OHIP billings to cover overhead. King's Senior Vice President Scott Addison "says there's no reason why King's couldn't co-operate with the public system in financing and sharing facilities. Health care may even evolve to the point where the public system covers only traumatic or catastrophic care, he adds - in which case there will be more need for private health care than ever."¹¹⁰

SECTION THREE: STRATEGIES FOR THE FUTURE

The problems associated with organizing a constructive resistance to the 'de-regulation' procorporatization agenda of our present governments in the health sector are enormous. The first and most critical issue is information. There are so many facets of the health sector and so many of the issues are complex and difficult to deal with, it is difficult to focus media attention on what is going wrong.

To describe to people why tobacco is such a health hazard, and to convince people to support significant lobby efforts to restrict the sale and use of tobacco products has been extremely successful. One of the reasons for this is that it makes perfect sense, it has the backing of dignified and respected bodies like the Canadian Cancer Society and the Heart and Stroke Foundation, the Canadian Medical Association and on and on. The lobbyists have worked extremely hard to arouse people's interest but they have in their favour the fact that antitobacco slogans make great sound-bites, the perfect catch for media attention. The fact that smoking kills people, lots of people, makes arguing against it irrefutable.

It is more difficult to sustain attention on the issues raised in the paper regarding the federal government's role in the approval process and regulation of the sale of pharmaceuticals. The stories are frightening but the drugs discussed in each one are not usually readily recognised by the general public, and the fact is it is hard for people to allow themselves to believe there may be fundamental problems with the drugs they or their children are taking. One perfect example of this is the steady increase in media coverage for the over use of antibiotics and the growing incidence of antibiotic resistant bacteria. People do not seem to connect their own behaviour with the increase in these deadly bacteria. A visit to the doctor, particularly with a small child frequently results in a prescription for a wonderful banana-flavoured antibiotic.

With regard to the reforms pending in the health care system, we still have hope. The public is extremely concerned about the impact closing hospitals will have on them and their loved-

¹¹⁰John Spears, "Where money heals all The old Bank of Canada building is now a plush private health centre" <u>The Toronto Star</u>, June 6, 1996

ones. Reducing health services has never been politically viable and in a time where reductions are coming fast and strong, we can only hope that remains the case.

One very frightening reality is the growing assumption that the introduction of a parallel private health care system is one way to prevent the total decline of our public system. That assumption itself might spell the end of medicare as we know it.

The reality is that the introduction of a second, private tier of medicine will not make health care more affordable. It will simply allow the costs to spiral forever. While in the early 1960's the United States and Canada spent similar percentages of their GDP on health care. In the United States, there are approximately 40 million people with little or no health care, yet by 1991 they were spending a total of 13.3% of its GDP on health care, as compared with Canada where we spent 9.9% of our GDP on health care and EVERYONE received care.¹¹¹

There is no doubt that changes are coming. There is no doubt there is a wonderful opportunity in the health sector to improve the quality of care vastly with the right strategies. There is also no doubt that the whole thing can fall apart.

WHAT TO DO:

- We must endeavour to develop networks across the country to ensure that efforts toward saving our universal health care system are coordinated.
- We must coordinate and support the efforts of those taking the matter into the public forum. In order to do that most effectively, we must develop a set of simple guidelines against which to measure proposals being discussed. The difficulty we have at present in fighting change is that we have no simple alternative to pose in a way the media is likely to pick up.
- The Canadian Medical Association has announced a plan to organize public discussion of a two-tiered health care system, there must be organized opposition present at each of their events. Given the history, the press will likely follow the CMA's public process, it is critical that they not receive publicity which supports the notion of a twotiered system.
- The Canadian Health Coalition has developed a plan for dealing with the challenges ahead, which they call 'Defending Public Health Care from Private Greed'.
- One risk we unquestionably run is allowing our differences to destroy any cooperative efforts. If that happens, those interested in opening the door to private services will have an easy time conquering the field, we divide, they conquer.

¹¹¹Rachlis and Kushner, Strong Medicine, op.cit. p. 193

- Huge efforts must go into educating the public that there are ways of ensuring we have a quality system without having to rely on private funding or private services.
- The efforts of the Hospital Restructuring Commission in Ontario must be challenged. Forcing shorter stays in hospital without altering primary care referral patterns is a recipe for disaster. It is also important to remember that shorter stays mean more reliance on home care which as we know has been removed from the <u>Canada Health</u> <u>Act</u>.
- Planning health human resources must be a consideration for any initiative. We have thousands of trained workers who are losing their jobs at an incredible rate in the health sector, particularly in the field of nursing. This is not only bad for the quality of care delivered to patients, it is bad for the overall health status of the communities in which these people live.
- Raising the public profile of the nurses and the importance of contributions to health care by practitioners other than doctors is critical. If we allow the public to buy into a notion of primary medical care as the way for reform to proceed, we have lost the game.
- A federal election call will occur soon. There can be no doubt that the issue of the federal government commitment to enforceable national standards on health care must be a significant issue of this election.

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