OHC - URGENT ALERT
DRUG BILL (BILL 102) UPDATE
May 28, 2006

The various parts of the drug and pharmacy industries have moved into action in response to Bill 102, the Ontario government's plan to revise the Ontario Drug Benefits program. The drug and pharmaceutical companies have formed a variety of coalitions, lobbying is underway and advertising campaigns are starting to roll out. Hearings on the legislation will be held next week.

Contained in this update:
1) A correction to our preliminary analysis
2) Drug industry facts and figures
3) Model submission for those presenting at the hearings
4) Additional reading on the pharmaceutical industry

I) Important Note: One correction to our preliminary analysis

In the preliminary analysis we sent out earlier this week, we noted that the government was allowing a dispensing fee increase for pharmacies from $6.65 to $7.00. We noted that the pharmacies and the Conservative Party were advocating for an increase to $10 - $12. This is correct. However, we stated that these increased costs would be borne by Ontario Drug Benefits Plan recipients out-of-pocket. This is not correct. The increase in fees will be paid by the government and the $2 out-of-pocket fee (co-payment) for ODB recipients introduced under the Harris government will remain unchanged. We opposed the introduction of the $2 co-payment at the time and have not changed our position.

II) Pharma Facts & Figures

<u>Innovation or Marketing?</u>

FACT: The top US drug makers spend 2.5 times as much on marketing and administration as they do on research.
(source: Dr. Marcia Angell, *"The Truth About Drug Companies: How They Deceive Us and What to Do About It"* Dr. Angell is a doctor and lecturer at Harvard Medical School and the former editor of the New England Journal of Medicine.)

FACT: At least 1/3 of drugs marketed by the industry leaders were discovered by universities or small biotech firms rather than the big drug companies. (source: ibid.)

QUOTE: Dr. Angell calls the drug industry a "vast marketing machine" that thrives on monopoly rights and public-sponsored research.

STATISTICS CANADA reports that universities and teaching hospitals are by far the largest performer (ie. where R&D is done) in health Research & Development at $3.7 billion in 2005 compared to the business sector (which includes the pharmaceutical industry) at $2 billion. When combined, the public sector and universities/teaching hospitals fund health R&D more than the industry also. The higher education sector and the federal government sector combined funded health R&D expenditures by $2.7 billion in 2005 compared to $1.8 billion by the business enterprise sector (source: Statistics Canada, *"Estimates of total spending on research and development in the health field in Canada, 1988 to 2005"*, Minister of Industry, May 2006)

FACT: Of the 117 drugs with new ingredients introduced in Canada between 1998 and 2002, only 15

provided substantial improvement over existing drugs. The rest are "me too" drugs with few therapeutic advances, but are responsible for 80% of drug expenditure.
(Source: Morgan, S.G. et al. "*Breakthrough drugs and growth in expenditure on prescription drugs in Canada"*, British Medical Journal, Vol. 331. October 2005)

FACT: Drug companies spend more than $20,000 per year for every doctor in Canada on drug samples, sales rep contact, conferences, trips and giveaways. The Canadian Health Coalition reports that this figure can be as high as $37,000.
(source: Schafer, A. *Medicine, Morals or Money: Dancing with porcupines and sleeping beside elephants*. Manitoba, University of Manitoba Centre for Professional and Applied Ethics.)

Making a Killing

FACT: The top 10 pharmaceutical companies make more in profits than the rest of the Fortune 500 combined. (source: *Mother Jones* magazine)

FACT: The 2006 Fortune 500 ranks pharmaceuticals as the 5th most profitable industry just behind crude oil and banks. Fortune puts pharma profits at 15.7% of revenues.
(Source: http://money.cnn.com/fortune/fortune500/performers/industries/return_on_revenues/index.html)

FACT: Costs for Canadian prescription drugs rose 62.3% from 1994-2004.

FACT: Drugs now rank second after hospitals as a share of total health care spending, having overtaken physicians in 1997.

Others Do It Better

FACT: Using OECD data, out of 29 countries Canada is 4th from the bottom in terms of the percent of pharmaceutical spending that is paid for publicly (below Canada are Mexico, United States and Korea).

FACT: Australian government drug managers negotiate an acceptable price with manufacturers and pay about 10% less than Canadian prices. New Zealand achieved 50% savings using coordinated bargaining methods.
(source: Lexchin, Joel. *Intellectual Property Rights and the Canadian Pharmaceutical Marketplace: Where do we go from here?* Ottawa: Canadian Centre for Policy Alternatives.)

Ontario Health Coalition
Model Submission on Bill 102
May 26, 2006

Introduction

The Ontario Health Coalition is a network of over 400 grassroots community organizations representing virtually all areas of Ontario. Our primary goal is to empower the members of our constituent organizations to become actively engaged in the making of public policy on matters related to health care and healthy communities. To this end, we seek to provide to member organizations and the broader public ongoing information about their health care system and its programs and services. Through public education and support for public debate, we contribute to the maintenance and extension of a system of checks and balances that is essential to good decision-making. We are an extremely collaborative organization, actively working with others to share resources and information. We are a non-partisan group committed to maintaining and enhancing our publicly-funded, publicly-administered health care system. We work to honour and strengthen the principles of the Canada Health Act.

Our members include over 70 local health coalitions in communities across the province; local health action committees; health professionals' organizations; physicians that support medicare such as the Medical Reform Group; medical students' groups that support medicare; non-profit service providers; health sector unions; women's groups such the Older Women's Network, Voices of Positive Women and the Immigrant Women's Health Centre; seniors' groups such as Canadian Pensioners Concerned, the Ontario Coalition of Senior Citizens Organizations, CAW retirees, Alliance of Seniors to Protect Social Programs; low income and homeless peoples' organizations including Low Income Families Together, Food Share of Metro Toronto, Ontario Coalition Against Poverty; social service organizations; workers' advocacy organizations; ethnic and multiracial minorities; the Ontario Federation of Labour; and other organizations such as the Canadian Council of South Asian Seniors (Ont.), the Association of Neurologically Disabled, Ontario Coalition for Social Justice, Social Planning Council of Metro Toronto, Native Women's Resource Centre, Aids Action Now, Birth Control and Venereal Disease Centre, the Canadian Federation of Students (Ontario division), Oxfam Canada and the Injured Workers Resource Centre, among others.

We are linked to the Canadian Health Coalition and provide provincial coordination of community-based health coalitions.

Overview

In this bill, the government proposes several key initiatives to control the cost of drugs in Ontario including supporting the widening of the use of generics to replace the higher cost brand name drugs, reducing the mark up on drugs and ensuring that the provincial government pays pharmacies for the actual cost of drugs rather than paying more than the pharmacies pay for them.

The bill also changes the process for deciding what is on and off the Ontario Drug Benefits Plan formulary and price levels for drugs. The creation of a new Executive Officer to replace cabinet as the final decision-maker on these items is one that has raised several questions for us.

The bill has been accompanied by several announced initiatives that are not actually in the legislation, including the introduction of patient representatives in the drug review process and a citizens' council. With the caveat that it is important for these patient and citizen representatives to be independent of drug industry influence, we support these initiatives.

In our view, the legislation is an important first step. We have consulted with medical experts who conclude that the evidence is that the initiatives contained in this bill will not harm the health of patients and will work to control drug costs.

Our approach to this bill is to balance the following:

- protect and extend the scope of the public health system under the principles of the Canada Health Act
- support access to drugs with proven efficacy and safety
- support access to needed treatments for those with rare and life-threatening conditions, and support democratic accountability and discussion in this process
- ensure the public interest in protecting the scope of the public health system - including non-pharmaceutical therapies and treatments - from being diminished by high drug costs
- protect against dangerous or unnecessary drugs
- support steps towards creating a national drug plan for all Canadians accompanied by an appropriate regulatory regime.

Initiatives supported by the OHC:

1) Widening availability of generic drugs. Previously brand name drugs had to be on formulary for generic to be bio-equivalent and listed. Under this legislation generics can be listed without brand name drugs being listed. We believe that this could increase access to bio-equivalent generics and lower costs without harming patients.

2) Widening what will be considered equivalent – e.g. under this bill, a pill and a tablet can be considered bio-equivalent. Previously only a pill and a pill could be considered equivalent. We believe this could increase access to bio-equivalent generics and lower costs without harming patients.

3) Conditional listings vs. Section 8 – Section 8 was an appeal used by doctors for coverage if a drug was not listed on formulary. There are no details about this in the legislation. We support the reduction of paperwork for physicians and the continued access to drugs for patients who need them. We believe the outcome of this initiative depends on what conditions will be placed before getting drugs on the listings. These must be reasonably rigorous to protect patients while allowing people with serious illnesses to gain access to lifesaving drugs.

4) Elimination of rebates for pharmacies. Previously the government would pay pharmacies the cost of drugs charged by the manufacturers. But the manufacturers would give pharmacies "rebates" as a way of getting them to stock their drugs – a kind of open "kick back". So the government was paying a higher cost for the drugs than the pharmacy was ultimately paying. This legislation proposes to eliminate the use of rebates and pay the actual transaction price that the pharmacy pays for the drug. This will save government (and the public) money.

5) Dropping price of generics by 20% to 50% of brand name. Currently 1st generic on market cost 70% of the brand name, the other generics cost 90% of the 70%. These were meant to be price ceilings but became floors. We believe this will reduce costs without harming patients.

6) Decreasing the mark-up on drugs from 10% - 8%. We believe this will reduce costs without harming patients.

7) Creation of best-practices prescription guidelines

8) Increasing representation of patients on councils regarding the formulary. We support these initiatives with the proviso that adequate protections against influence of the drug industry are included. No patients, citizens or patient groups that are affiliated with, funded by or otherwise supported by the drug industry should be allowed to sit in these positions.

Comments:

- Brand name drug companies argue that generic substitution is bad for health. They fund and influence

some patient groups and coalitions to put out this information. All major credible studies show this to be untrue.

- One other option is reference based pricing as in BC in which only the cheapest of a class of drugs is covered by the government plan. Patients wishing a more expensive product must pay the difference. If there is a genuine medical need for the more expensive product the government will pay for it in full. Studies in BC have never demonstrated any adverse health outcomes from this policy.

Recommendations:

- Money being saved through the measures contained in Bill 102 should be invested in healthcare or social programs.

- The legislation creates an Executive Officer. The EO will have powers cabinet used to have to determine what is on and off the formulary. The EO will also negotiate deals regarding price and bulk buying with drug companies – a role formerly not done by anyone in the Ministry.

> To the extent that the creation of this position is motivated by a desire for the government to more effectively negotiate the price of drugs and use its buying power to get the best possible value for Ontarians, we are supportive.
>
> On principle we believe that the decision about what is listed and not listed on Ontario's formulary must be one that is accompanied by democratic accountability. In shifting the resposibility to determine what is listed to the Executive Officer, we would like to see clearly that the responsbility for the contents of the formulary remains with our elected government. We would support additional initiatives to ensure that this Executive Officer operates with the maximum possible public transparency and the minimum possible influence of the drug industry.

- The section of the legislation relating to rapid review of breakthrough drugs may or may not be a good thing. It could just get more drugs that do not provide additional benefit on the formulary. This depends how rigorous the controls are. The need for rigorous protection of patient safety and assurance of efficacy of drugs needs to be balanced with patient need and demands for access to drugs in urgent cases and in cases of rare conditions.

- Some pharmacies are arguing that the reduced revenue for them resulting from some of the initiatives in this legislation will lead to closures of pharmacies in rural areas and in the north. It is impossible for us to verify these claims without having access to their financial reports. While we obviously support protecting access to pharmacies, if their financial viability is based on "rebates" from the drug companies to stock their profits then another system to ensure access to pharmacies would be more ethical and should be considered.

- Any additional initiatives to control the drug industry lobby would be positive, including increased democracy and transparency, reduced corporate donations to political parties, and additional steps regarding drug company influence over physician prescription practices.

- We support the Canadian Health Coalition’s pharmaceutical strategy and encourage the Ontario government to advocate at the federal level regarding these initiatives. See More for Less: A National Pharmacare Strategy at: http://www.healthcoalition.ca/

Conclusion

We believe that the government - through this proposed legislation - attempts to balance the need for drug cost control with protection of patient access to needed drugs and safety issues. Based on the available information and the evidence, we conclude that the legislation will likely work to contain costs and will not harm patients. This legislation will provide benefit to Ontario's health system and will protect access for Ontarians using the Ontario Drug Benefits Program. This is an important first step.

But Ontarians need more. Canada and the United States stand out among industrialized countries as two of the wealthiest nations without national drug plans. Yet, pharmacare has long been envisioned as an essential step in the evolution of Medicare, recommended by Justice Emmett Hall in 1964. While we support this legislation, we also strongly support the Ontario government advocating at the national level. All Ontarians and all Canadians need a safe and affordable national pharmacare program that would provide equal access to prescription drugs, be publicly funded and controlled and cover essential drug costs. While provincial governments pay the costs of provincial drug plans and have some regulatory powers, many regulatory powers rest with the federal government. We hope that Ontario's government will play a leadership role in advocating for a national formulary, an independent agency with more rigorous practices for drug approval, patent reform, post-marketing safety monitoring, enhanced controls on drug company advertising and other measures that would improve our drug regulation regime as well as a national pharmacare program.

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Additional readings and resources suggested on following page:

V) Additional Reading and Resources on Drugs:

See the Canadian Health Coalition's "More for Less: A National Pharmacare Strategy" at:http://www.healthcoalition.ca/

Books and articles by Dr. Joel Lexchin. Dr. Lexchin is a professor of health policy at York University and an emergency room physician at the University Health Network. He is an expert on drugs and the pharmaceutical industry and has written a number of books and articles on these subjects.

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Moynihan, Ray and Alan Cassels. *Selling Sickness: How the World's Biggest Pharmaceutical Companies are Turning Us All into Patients.*

Hawthorne, Fran. *The Merck Druggernaut: The Inside Story of a Pharmaceutical Giant*, 2003.

Fried, Stephen. *Bitter Pills: Inside the Hazardous World of Legal Drugs*

Old but good: Lexchin, Joel. *The Real Pushers: A critical analysis of the Canadian drug industry*