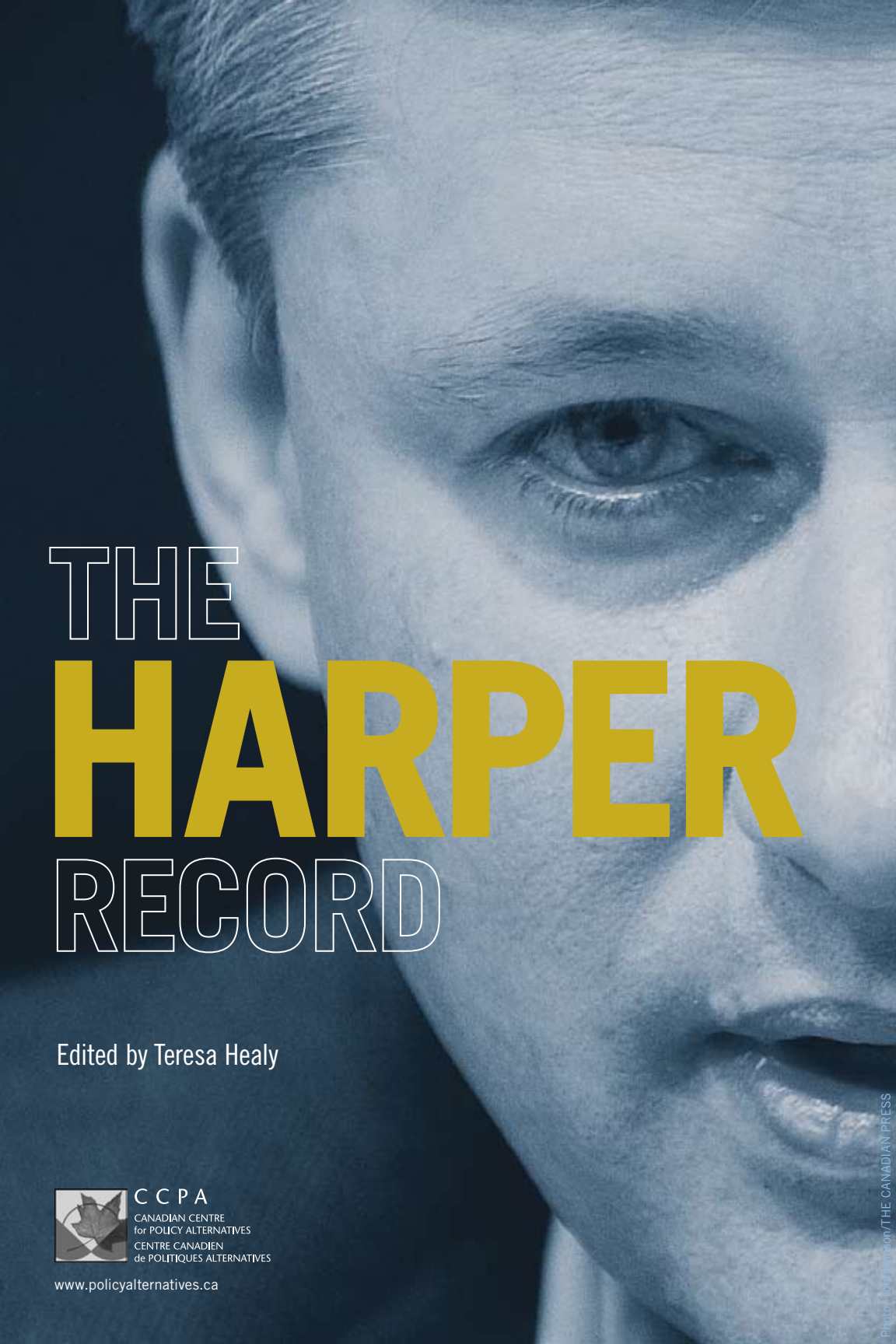

THE HARPER RECORD

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Prescription for Trouble

The Conservative government and big pharma

Julie White and Michael McBane

> The burden of a loved one being sick in front of you and going down with dementia, is enough. Last year we were $6000 in debt with drug bills. Now we are faced with losing our home. We both worked hard all our lives and I don't think that's right.
> — *Gretta Ross, Sarnia, Ontario.*

DOES ANYONE REMEMBER that the Conservative party promised, just four years ago, to implement a national drug plan? During the 2004 election, with health care a top priority for Canadians, the Conservatives made a commitment of $2.8 billion for a federal program to cover drug costs for individuals who had to pay more than $5,000 a year for their prescription drugs. It was part of a promise to spend a total of $13 billion of new federal money over five years on health care.

Given the record of the minority Conservative government since it took office, it's hard to imagine that the Harper Tories once proposed a new federal social program. It runs counter to all that this government has done since January 2006 to undermine the role of the federal government in providing national programs that benefit all Canadians. Conservative policies have ensured a minimalist federal government by implementing massive tax cuts, thereby reducing revenue and leading inevitably to the curtailing of national programs.

Since October 2007, the Conservative government has committed to $60 billion in tax cuts through to 2012. Corporations in particular have had a bonanza of government support, with tax cuts that will reduce their tax payments by one-third from 2006 to 2012. The latest budget of February 2008 deepened the erosion of public finances, and Finance Minister Jim Flaherty boasted that he had reduced taxes to the level they were at 50 years ago. He did not mention that 50 years ago there was no national Medicare, no Canada/Québec Pension Plan, and no subsidized post-secondary education.

In the Speech from the Throne in 2007, Prime Minister Stephen Harper went further and outlined his government's intention to legally restrict federal involvement in social programs for all Canadians. He announced: "Our government will introduce legislation to place formal limits on the use of the federal spending power for new shared-cost programs in areas of exclusive provincial jurisdiction." Such legislation would prevent the federal government from introducing further nation-building programs, such as child care or Pharmacare. It also ignores the reality that provinces have chosen to opt into national programs with federal standards, both to access federal funds and to provide country-wide benefits and equality to Canadians. Provinces have not given up jurisdiction over health care, for example, by participating in the national Medicare system.

Moreover, in the case of prescription drugs, the provinces have been calling for federal leadership. In 2003, a meeting of First Ministers identified prescription drugs as a problem that needed to be resolved. A year later, the First Ministers from both levels of government established a Ministerial Task Force to develop a national strategy for prescription drugs. So, at the time of the election of the minority Conservative government in 2006, a process to increase federal involvement in prescription drugs was already underway, initiated by the provinces, with Québec attending meetings as an observer.

The Conservative government has withdrawn from its promise to initiate a national drug program, has systematically undermined the capacity of the federal government to implement such a program, and has wrongly argued that national social programs undermine provincial jurisdiction.

Why we need national Pharmacare

There are two major problems with prescription drugs: rapidly rising costs and unequal access. Solving these problems requires federal government involvement.

1. Paying for drugs

The rising cost of drugs is driving provincial and territorial governments to call for federal help. Between 1997 and 2005, expenditure on prescribed drugs by the public sector grew at an average annual rate of 12.2%,[1] sucking money away from other areas of health care expenditure and straining provincial budgets. This might be acceptable if these expenditures were cost-effective and appropriate, but they are not.

The way it works is that a drug company develops a so-called "new" product, which is not actually new. About 85% of all drug approvals by Health Canada are drugs that are the same, or similar, to drugs already on the market, with no therapeutic advantage.[2] It should be noted that drug companies pay for more than half the cost of the approval process at Health Canada; that research on drug safety is not made available to the public or to health professionals; and that, to be approved, a drug need only be better than a placebo, not better than an existing drug. It is hardly an independent, transparent, or cost-effective process.

These so called "new" drugs are also substantially more expensive than existing brand name or generic drugs. Why buy more expensive versions which are no more effective? Because of massive marketing and promotion by the drug companies. The big pharmaceutical companies (known as Big Pharma) spend three times more on marketing than on research. It's not just bombardment advertising on television and in magazines, but also direct promotion to doctors through sales reps, giveaways, samples, trips to conferences, payment for papers, and so on — an estimated $30,000 per doctor per year.[3]

Research has shown that marketing is effective in influencing what doctors prescribe.[4] Research has also shown that prescribing less expensive but therapeutically equivalent drugs, either brand name or generic, would save millions of dollars.[5]

A huge issue for the provinces is that the federal government has major control over the cost of drugs, but the provinces pay the bills. The federal government approves drugs, regulates price protection for drug companies through patents, and is supposed to control drug advertising. However, the feds contribute just 3% of total national expenditure on drugs. Big pharmaceutical companies are among the most profitable companies in the world, and they continuously lobby governments to influence policy — in this case, a government that does not pay for its decisions.

A national drug plan with meaningful federal involvement would rectify this imbalance and give the federal government a reason to bring Big Pharma under tighter control. We need a more rational approval process, stricter controls on advertising, and more independent information for doctors on both research and costs.

2. Getting drugs

Canadians are not well served by our patchwork of provincial programs and work-based plans that offer inequitable and/or partial coverage. Getting the drugs you need depends upon where you live and where you work. Some provincial drug programs are more generous than others, and work-based plans vary from one employer to another. Recent public hearings across the country by the Canadian Health Coalition found that many Canadians are in serious difficulty, facing high costs for drugs that they cannot afford.[6]

Drugs should be a part of our universal health system, as is the case in nearly all other Western countries. Prescription drugs should be publicly provided to all Canadians, with some national standards and federal financial involvement, under provincial administration. There is no reason why this should not be a reality, and it would also be cost-effective. Currently, half of all Canadians are covered by work-based plans through private insurance. This means thousands of different work-based plans and millions of individual claims that have to be processed. Clearly, a single universal plan would be both more equitable and more cost-efficient. Other countries with national systems use their single-payer buying power to negotiate significantly reduced prices from the drug companies.[7]

The unhealthy Harper record

1. Government under the influence

One of the disturbing characteristics of the Harper government is the close personal relationships of the government with corporate interests. For example, Minister of Health Tony Clement owned a 25% stake in a pharmaceutical chemicals company, Prudential Chem Inc. Even as Health Minister, Clement initially saw no conflict, saying he would absent himself from decisions affecting the company. This caused a torrent of protest, given that policy affecting pharmaceutical companies is a major part of the work of Health Canada. "It is hard to think of a more flagrant conflict of interest," was one newspaper comment. "Hardly a week goes by during which Clement does not deliberate over an issue affecting the pharmaceutical industry."[8] After pressure both in and out of Parliament, Clement's chief of staff, Bill King, reported that the Minister had transferred his interest to the company's president with no compensation.[9]

Similarly, the government appears to be highly responsive to the influence of certain well-known and well placed lobbyists for the pharmaceutical industry. For example, in March 2007, the Harper government announced a $300 million fund for the controversial HPV vaccine called Gardasil, made by Merck Frosst Canada. This is the vaccine for young women that can prevent some types of cervical cancer. There has been criticism that not enough is known about the drug's long-term effects and that there was no public health crisis warranting such a decision.[10]

The funding was provided with remarkable speed. It took just eight months from approval of the drug by Health Canada to the announcement of a $300 million federal contribution for provinces wanting to provide the vaccine to young women. This was no accident. Merck Frosst hired the public relations giant Hill & Knowlton to push the immunization approach. Ken Boessenkool, a vice-president at Hill and Knowlton, worked on the vaccine campaign, but, as reported by *The Toronto Star,* he is also a close friend and advisor to Stephen Harper. He was the architect of the unpopular flat-tax proposal by Stockwell

Day and a chief advisor to the Conservatives during the 2004 federal election campaign.[11]

After his successful involvement in the cancer drug lobby, Boessenkool moved on to register as a lobbyist for Taser International, promoting the controversial police weapon.[12] Such close relationships between lobbyists for the pharmaceutical industry and the Conservative government are cause for concern.

2. Undermining the national initiative

It is discouraging to conclude, after a review of the record, that Harper`s minority Conservative government has undermined provincial and territorial movement toward a cross-Canada program for prescription drugs.

In 2004, federal, provincial and territorial First Ministers agreed to work on a national approach to drugs, called the National Pharmaceutical Strategy (NPS). A nine-point list of goals was developed to improve access to drugs, relieve financial hardship, and obtain better value for money. A Ministerial Task Force was established to determine how to implement the goals, with the federal government as co-chair and Québec as an observer.

In July 2006, a conference of Ministers of Health released a progress report on the NPS and discussed its future.[13] It was obvious that the process was in trouble when Tony Clement, Harper's Minister of Health and Co-Chair of the Task Force, did not attend the conference. Under Clement's care, the NPS has languished. Provinces and territories continued working in good faith, but now acknowledge that the NPS can go nowhere without the federal government at the table to provide leadership and discuss the federal contribution. Clement no longer convenes regular meetings of health ministers.

According to a recent report issued by the Health Council of Canada in June 2008:

> Significant gaps in coverage are still evident across Canada, and too many Canadians are vulnerable to personal hardship from needed drugs that cost more than they can afford. Canadians are also not adequately protected from inappropriate prescribing because we do not have the

> necessary systems in place to keep health care providers and consumers informed about drug safety and effectiveness. Governments have not made acceptable progress in creating the National Pharmaceuticals Strategy that was promised in 2004.[14]

Instead of providing leadership to implement the NPS, the Harper government is sabotaging the process by neglect.

3. More price protection for Big Pharma

In April 2008, the government made a blatant move to favour the bottom line of Big Pharma by extending its patent protection. Brand name drug companies already have 20 years patent protection, giving them a monopoly for that period to set prices with no market competition. But they had been extending this protection with court challenges against generic copies, obtaining an automatic two-year patent extension. Generic drug companies contested this artificial extension of the patents, and the Supreme Court agreed with them in a decision in November 2007.[15]

The Conservative government moved quickly to undermine the Supreme Court decision by proposing amendments to the regulations of Canada's *Patent Act*. The changes would allow the drug companies to continue to get automatic injunctions, thereby preventing Health Canada from approving lower-cost generic drugs. The federal government proposed its new regulations on April 26, 2008, with no prior consultation with the provinces or the public and providing just 15 days for comments.

Provincial governments objected to both the change and the process. New Brunswick asked for further consultation, stating that "delays in accessing those generic drugs will have a direct cost impact on the provincial drug plan." The British Columbia Health Minister also asked for an extension to the deadline (which was refused) and said, "One can probably predict that this will not be a happy eventuality for budgeting."[16] The patent extensions are a multi-million-dollar gift to Big Pharma and an added cost burden to provinces, employer drug plans, and individuals.

4. New legislation for the drug companies

The most troubling concession to Big Pharma by the Harper government comes in the form of Bill C-51, which was introduced in the House of Commons on April 8, 2008. The proposed legislation amends the *Food and Drugs Act,* in essence replacing the entire text on drugs. It is likely to adversely affect both cost and safety by:

- speeding up drug approvals with lower standards for drug safety and effectiveness;
- removing barriers to advertising of prescription drugs;
- restricting access to natural health products;
- enshrining corporate secrecy about the health effects of drugs; and
- eliminating liability for regulatory negligence by Health Canada.

First, the proposed legislation permits bringing new drugs to market before research on effectiveness and safety are complete. Instead, research on safety would continue after drugs are widely prescribed and used. Usually, post-market studies are carried out by manufacturers. This introduces a bias, as manufacturers have an interest in presenting their products in a positive light, and there are fewer rules to ensure rigorous scientific methods in post-market studies than in pre-market clinical trials. In effect, Canadians will be exposed to drugs that have not been adequately tested.[17]

This is unacceptable because, even in the current system, drugs are sometimes found to be dangerous. Thalidomide is remembered as one of the most tragic examples. Vioxx was recalled in 2004 in both Canada and the U.S., and is estimated to have caused between 88,000 and 139,000 extra heart attacks in the U.S.[18] Recent research in the U.S. has shown that drugs that are approved faster are more likely to cause problems once on the market than drugs approved under less pressure. This research compared drugs approved under a deadline to speed up the process with drugs approved at other times. The deadlines produced "adverse effects," including more drugs recalled for safety reasons, more drugs later carrying warnings about negative side-effects, and more

drugs voluntarily discontinued by the manufacturers. The research concluded that drugs subject to the deadlines "have a higher likelihood of unanticipated safety problems once they are in widespread use."[19] This highlights the need to strengthen, rather than erode, safety standards for approval for marketing.

The second problem with Bill C-51 is that it will eliminate the current restrictions on direct-to-consumer advertising of prescription drugs. As it stands, the *Food and Drugs Act* recognizes that drugs are not the same as clothes or soap powder or autos. Someone with a grim diagnosis or a seriously ill child needs accurate information about treatment options, not advertising hype that can lead them to less effective, less safe, or more costly products.

The massive advertising of drugs allowed in the U.S. has added enormously and unnecessarily to drug costs.[20] In Canada, we are bombarded with ads on U.S. television channels, but this should be controlled to comply with our more restrictive legislation. We should strengthen and enforce our controls on drug advertising, not weaken them.

Third, Bill C-51 will impose severe restrictions on natural health products that are low-risk, while it weakens the regulation of prescription drugs. The legislation would give Health Canada officials unprecedented and arbitrary enforcement powers to force natural health products off of the market and impose fines up to $5,000,000 on family-owned businesses. Many Canadians rely on natural health products to help prevent disease and illness.

Fourth, Bill C-51 will enshrine secrecy and commercial confidentiality for the first time in the *Food and Drugs Act*. It introduces a definition of confidential business information into the Act, so that anything that affects a company's bottom line may be kept secret. Bill C-51 defines as confidential any information —

> a) that is not publicly available,
>
> b) in respect of which the person has taken measures that are reasonable in the circumstances to ensure that it remains not publicly available, and

> c) that has actual or potential economic value to the person or their competitors because it is not publicly available and its disclosure would result in a material financial loss to the person or a material financial gain to their competitors.[21]

In other words, pharmaceutical companies will have the right to keep information secret if it is already secret, if the company is actively keeping it secret, and if making it public could affect their bottom line.

Access to independent research information is already limited, leaving doctors prescribing drugs on the basis of information from drug companies. This Bill will make the situation worse. Instead of enshrining rights for Canadians and health professionals to information about drugs, Bill C-51 gives drug companies the right to maintain secrecy about key health and safety information, including less than stellar clinical trial results and serious side-effects.

Last but not least, Bill C-51 will lower the Minister of Health's "duty of care," so that Health Canada can evade liability for regulatory negligence when Canadians are harmed by inadequately tested prescription drugs. If this Bill becomes law, Canadians could lose recourse to the courts for claims of regulatory negligence. This is of particular concern, given the lower standards established by other parts of Bill C-51, which increase the likelihood that Canadians will need recourse to the courts.

Bill C-51 poses a threat to the safety of Canadians. It denies the public's right to information on drug research, adds to the high cost of drugs through advertising, restricts access to natural health products, and decreases the responsibility of Health Canada for protecting our health.

Conclusion

The Canadian Health Coalition has just completed hearings across Canada on the problems of access to affordable prescription drugs. Many Canadians went to the hearings to explain how their health is being put at risk because of the high cost of drugs.

Stories were told by people seldom heard in the corridors of Parliament Hill:

> According to the government, we make too much money to qualify for drug coverage. But I don't know too many people who can take $1000 a month off their net income and not have it have an effect. I think there's something wrong. And I also think I'm not unique. We need to start to look at the stories behind the numbers…Generally it's the sickest of the sick that have to deal with all this stuff. The people that need it the most are the people least able to fight for it. And it's a fight.
> — *Tracy Gilles, Charlottetown, PEI.*[22]

Prime Minister Harper and his Minister of Health, Tony Clement, are failing to provide for the well-being of Canadians. They are systematically placing the profits of pharmaceutical companies ahead of the needs of people like Gretta Ross and Tracy Gilles.