

Presentation by **Terrence Young**
to the Canadian Health Coalition
*National Roundtable on Health
Canada's proposed changes to
Health Protection Legislation*

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Check Against Delivery

Introduction: why Drug Safety Canada was founded.

What's been going on at Health Canada to improve safety in the last three and half years?

The Jury that investigated Vanessa's death in March of 2001 ordered Health Canada to report back within one year on – amongst other things - initiatives it had taken to:

1. “mandate pharmaceutical companies to clearly indicate information relating to adverse effects/comtraindications on documents such as product monograph, promotional materials and prescribing information.”
2. send out “in conjunction with the drug companies” “all Dear Health Care Professional letters” in a form that “clearly identifies the information as important drug safety information.”
3. enforce “mandatory reporting of all serious adverse drug reactions within 48 hours.
4. ensure that “only Health Canada approved drug information () is distributed in pharmacies...

To date, almost three years after they received the order they have to my knowledge done none of the above. On Nov 27th and 28th I attended one of their “deliberations” on legislative renewal at the King Edward Hotel in Toronto. I sat beside a young lady from Health Canada whose key responsibility is to help develop a new template for drug information...she informed me proudly. “Would it be compulsory?” I asked hopefully. “No, voluntary.” Health Canada also brags about improvements to its website. Almost three years later and they have done nothing significant to make our families safer!

It appears the reason why is that they are trying to get out of the safety business altogether.

1. They changed their name in 2000 from Health Protection Branch to Therapeutics Products Program, and now it's the Marketed Health products Directorate. They've gone from protection to administration to marketing support. It is no coincidence that the protection is gone. HC is currently facing law suits that add up to hundreds of millions of dollars for failing to do just that.

2. They have dragged their feet on any real changes to drug safety.
3. They continue to “negotiate” like supplicants with drug companies like Johnson and Johnson, who must have finally agreed this month that they could issue a real warning on the sub-coetaneous use of Eprex – 13 months after every other civilized nation in the world.
4. They spend their time and resources taking the Legislative Renewal traveling dog and pony show on the road – despite the fact that those in parliament entrusted to investigate all matters related to health, don’t even know they are out there or what they are doing.

Let’s be very clear. When a government is proud of a policy initiative, it announces it – several times – it often takes it on the road with a parliamentary committee and it debates it in the house. It goes into cabinet speeches. Ministers answer questions for the media – in other words, it comes under public scrutiny.

What we have instead is law made by bureaucrats BY STEALTH – to keep it out of the public domain. What’s increasingly clear is that the bureaucracy sees itself as marketing support group for the drug industry and wants to get out of the protecting the public.

This is a transition that is so significant it is hard to overstate its importance to Canadians. Because if our government is primarily there to help drug companies sell more drugs, who will protect Canadians from the numerous unsafe drugs that drug companies with put on the market to get a faster return on their investment?

These drugs will increase the 10,000 deaths a year that already occur in Canada and send injuries sky high? They are abandoning their role to protect our loved ones by placing safety first in exchange for a role to help the industry become competitive. Who ever gave them this mandate: a series of Ministers or a former PM. When was this ever debated in Parliament, or promised in an election? Never.

Most importantly they are deluding themselves and trying to hoodwink the public that one agency can do both – protect patients and help drug companies sell their drugs faster. We don’t let safety inspectors for tires rush inspections to help get tires to market faster, especially after the events of the nineties with Goodyear and others. And we don’t rush aircraft safety inspectors through their day, and ask the airlines to identify problems later.

How are they doing this? – under the disguise of “Legislative Renewal,” out from under the eye of Parliament. It sounds sort of innocuous doesn’t it “renewal” Everybody likes renewal. How could that be a concern? It’s new! Yet at recent Standing Committee on Health Hearings in Toronto, the Chair of the committee and other committee members were totally unaware that Health Canada was conducting so called consultations across Canada by this name! The Chair rightfully declared it must be administrative renewal...because legislation is under the exclusive authority of parliament.

In June of last year I along with some of the others in this room today attended a Health Canada sponsored consultation. It was entitled a “Deliberation on Improving Canada’s

Regulatory Process for Therapeutic Products.” in Ottawa., and by all appearances was a open consultation conducted by Public Policy Forum a private organization. It was in fact a sophisticated ruse designed to create an illusion of consensus on *how* to bring prescription drugs to market faster in Canada to please the major international drug companies and a number of industry dependent interest groups.

So instead of actually acting on the many dynamic recommendations made by the Coroner’s jury to improve drug safety in Canada they have been working on how to get the drug company lobbyists and those they finance off their backs. This process shows what Health Canada has been up to for the last three years AND is a good example of how governments use special interest groups to create a tapestry of support (to replace real grass roots support) for plans they have already decided to implement.

So I’ve created a primer of sorts which shows how to make this happen...

A Primer for Governments
Rules for Creating a Façade of Grass Roots Support for a Policy You’ve Already Decided to Implement

1. Start with the outcome you want and work backwards.

In the 2002 Speech from the Throne the government committed to “Speeding up the drug approval process for drugs”. In the following budget Minister of Finance Michael Manley promised to spend \$ 190M over five years towards this end. This agenda was driven by the innumerable lobbyists for the major pharmaceutical companies who have built lucrative relationships with various Ottawa politicians and media outlets to perpetuate the following false premises:

1. A “partnership” relationship between the major international drug companies and Health Canada is appropriate and in the public interest.
2. It is appropriate for drug companies to pay to have drugs approved – creating a client/service relationship between those whose interest is profits and those who are sworn to protect vulnerable people.
3. Target times for drug approvals are in the public interest.
4. All drugs should be treated the same, weather they treat life threatening diseases - justifying greater patient risk, or they treat conditions such as hair loss, or higher than average cholesterol, which common sense would dictate should justify far lower patient risk.
5. That what is good for the drug companies is good for Canada...by claiming faster drug approvals create a competitive industry. No self respecting MP or journalist would ever allow airlines who had suffered many crashes to push for a faster inspections process to be more competitive, yet the government of Canada thinks somehow this is acceptable.

6. That Health Canada does a perfect job with pre-market approvals, and that only the post market surveillance needed to be improved. (Try and explain this to the victims of the six major drugs that were taken off the market after injuring and killing thousands of Canadians since 1997 – that never should have been approved)
7. That most new drugs are potentially life-saving drugs rather than evergreen or copy cat drugs, and those to treat life-style issues such as sexual dysfunction and hair loss.
8. That it is acceptable for the most profitable companies in the world to make veiled threats against our sovereign nation in our own newspapers to take their manufacturing and bottling facilities out of Canada unless our politicians move to get their drugs approved faster.

In a democracy voters tend to get a little upset if you appear to be determining public policy – the *structure* of our society – based on the interest of a group of corporations with loyalty to no nation. However, in reality we all know that money is the oil in the machinery of politics...and no one knows this better than major pharmaceutical companies.

So our starting position in 2002 was that prescription drugs would be approved faster in Canada...and the Canadian taxpayers, who already subsidize research for these companies, suffer hundreds of thousands of adverse reactions to these drugs yearly – including ten thousand deaths, is one of their biggest customers in the world, and pays all the health care costs related to adverse reactions would now pay another \$ 190 M to increase their own risk... with the hope that a handful of new life saving drugs would come to market faster without causing too many adverse reactions.

Nevertheless this was the outcome the government wanted and assigned to Health Canada officials in January of 2003.

1 Break the plan down into pieces and find new allies to help promote each piece on your behalf.

In this case – for faster drug approvals - certain patient groups and others that receive drug company money for research were there supporting this part of the industry agenda.

In November Health Canada consulted regarding the “theme” of DTC advertising. Here they picked up a whole range of new allies from the media groups who want to get their hands on the several hundred million dollars a year which will come their way if DTC ads are allowed in Canada.

2 Keep repeating, “we don’t have an agenda.”

It is critical that the policy appears to flow from the public, not the politicians. If you never admit you have a plan, you can never fail, and you will not become a target for those opposed to the plan. What you need is “consensus”. Despite an agenda that was constantly steered back to HOW to improve drugs faster in Canada the moderator, Janice Elliot VP of Public Policy Forum (and a Ph.D.) told us repeatedly “we don’t have an agenda here”

3 Don't stick your neck out unless you have to.

It's helpful to review here how governments create policy they are proud to talk about...as opposed to this stealth effort. Policy goes from the key cabinet committee, then to the bureaucrats to write the legislation, then to full cabinet for comment and approval, then to Parliament for the first vote. Then it goes on the road with a standing or select government committee of Parliament both for public input, but also to get the backbenchers and public a chance to buy in to it. The media then have ample opportunity to scrutinize and criticize it before it comes back for second and third readings. Then the Senate have a kick at the can.

When you aren't particularly proud of a gov't initiative and don't really want to get into a long drawn out public debate about it, you try to make it happen by a decree of cabinet – otherwise known as regulations. In order to do this without appearing high handed, if you get caught, you should have a lot of written materials – ideally a number of thick detailed reports written in cryptic language only senior bureaucrats could ever understand which purport to have been written after months of deliberations and consultations – albeit bureaucratic ones done with a far lower level of opposition and media scrutiny. Ideally have the bureaucrats hire an outside consulting firm to move your issue along for you by “consulting” with Canadians. Don't put anything in writing. Let them. Keep it low key. If the whole thing comes unraveled, it was their mistake. They got it wrong. You always intended to bring it to Parliament for a full debate. Move one of them to a different job out of sight to make it appear they acted alone – like Lee Harvey Oswald.

(By the way always pass the regulations when greater issues occupy the media and opposition who are over loaded and spread too thin already)

4 Hire people you know and pay them well, well enough to be loyal if things get off track.

In this case with \$ 190 M committed in the budget there is lots of money to make it happen. The principles you hire must have a credible image, thick CV's and not appear too close to the government. PPF fit the bill. Impressive resumes all – and interestingly their volunteer board includes Ian Green, Deputy Minister of Health, and Alex Himlefarb, Clerk of the Privy Council.

5 Don't ever say what you mean. Someone might notice what you are up to.

For example, when you mean speed up the process, never say speed up the process, that would imply compromising safety; say “timeliness”. Who could be against timeliness?

During the process the Public Interest Groups said the approval process is done in secrecy. PPF said this “protects proprietary contents”.

During the session where our concerns were written down on paper on the wall. we

asked Janice Elliot Ph.D. and VP of PPF to write down ‘undue influence’ of the industry regarding the client/service relationship. She wrote down only “influence” and repeatedly led the discussion to another track .

We asked her to write down ‘corrupt practices’ at Health Canada, such as closed door meetings between Health Canada drug reviewers and drug company officials where no notes are taken. She refused to write the term down writing instead “management practices”.

We were concerned about fees paid to approve drugs . They call it cost recovery.

In fact it became so biased a small group of us met at the much break and discussed boycotting the rest of the meeting, deciding instead to stay and try to be heard. Representing Drug Safety Canada I called Janice and Health Canada officials to withdraw, attending no further sessions and insisted they take the name of Drug Safety Canada off any further publications, so they could not undermine our credibility with a biased and predetermined report.

6 Make sure the consultation is done quietly. The quieter the better, with no media.

In fact, these consultations were conducted in Ottawa during a week in May when the MP’s and media were back in the ridings or on vacation. There was little chance the opposition, rebel government members or the media would be nosing around to start raising questions in the house: unfair questions like why isn’t the process open, and why isn’t a parliamentary committee hearing about this information from Canadians.

7 The consultation must not be open, but must appear to be open.

(You might find out that Canadians actually don’t like the plan)

In this case Public Policy Forum sent out a hand picked list of participants that included none of the drug safety advocates I had met in three years, yet many of those who had pro-industry positions. There were no newspaper ads placed or open invitations to my knowledge. I told them it appeared that the fix was in and I would only come if they invited a list if others I sent them, which they did. Several came.

8 Don’t invite other governments to participate.

Although they pay for the drugs and deal with the health care outcomes from adverse reactions the provinces weren’t invited. They might just have disagreed with the plan.

9 All the communications around its implementation must be couched in terms of public interest.

In this case Health Canada let the patient groups take the lead in pushing for faster drug approvals, giving them their own day of consultation. Some of them were actually formed by the industry, and most receive “unrestricted educational grants” from the

industry (cash payments in exchange for their support) Some, such as the Canadian Diabetes Association and the Lipid Nurse Network act as a front for the industry in stealth adds on TV and in newspapers, paid for by drug companies to drive worried folks into their doctor's offices to ask for pills so they won't die. Others are already on record in support of the plan to approve drugs faster.

On industry day, the industry folks talked about saving lives, better medicines, and making Canada competitive...instead of profits and the value of their shares.

#10 Provide documentation with a lot of headings which looks very comprehensive and keeps everyone busy deliberating how to implement your plan, rather than opposing it.

#11 The policy must appear to have been forged with the support and expert advice of professionals with a lot of letters behind their names. If the majority support your plan, ignore conflicts of interest.

We learned this lesson in Ottawa at the Regulatory Process Forum. But in November at the DTC consultation Health Canada refused outright to ask those present to declare any potential conflicts of interest or where their funding comes from. So we asked them to do so voluntarily. This led to some pretty vague answers from those who did not want to reveal their industry connections and at least one loud argument as one was exposed.

Many have benefited, and will continue to benefit from the generous largess of the most profitable companies in the world. They will say of course this does not affect their professional judgement, or colour their clinical judgment in any way. We are to assume that the industry provides all the free dinners, electronic appliances, ski weekends and payment for favourable academic papers out of kindness.

12 The plan should have the support of drug safety advocacy groups if possible. If that's not possible, divide and conquer.

We were identified in discussion as Janice kept repeating things like " IF Health Canada approved drugs faster, how can they do it safely?" Where there was consensus this was documented carefully by staff in the corner with laptop computers. Consensus is gold! When we disagreed that was quickly documented. It's gold too! They used the disagreement as justification for taking the discussion back to their agenda and for ignoring what they didn't want to hear!

However what they did do was clever, if transparent, and that was to **arrange four sessions of consultation on different days**, three dominated by industry or those funded by industry, most of whom were on the record in favour of a speedier process. That meant their outcome had a 3/4 chance of getting the result they wanted – ideas for how to create faster approvals.

13 Ignore all previous commissions and reports on the subject matter. None of them will completely support your plan.

...including the most recent and comprehensive one, the Romanow Commission. Create your own new documentation to justify your plan.

14 Phase II: Repeat Phase I in a plenary session!

This time they were empowered by knowing what everyone thinks before they enter the room. They used the transcripts from all four meetings to identify the gold: 1. the “common ground” that supports the plan and 2. the inevitable disagreement that will allow you to ignore whatever was said. In some cases, where there is disagreement in support part of their plan, they used it overrule the dissenters in the final report by claiming those in support out-number those who didn’t (no one was counting at the first meetings) or they had better evidence to support their case.

15 Invite the Minister to participate by large screen video so she can hear your controlled consensus. (but not actually have a chance to speak with the participants and hear their concerns)

This was done and the Minister thought it was wonderful. She started to tell me all about it when I spoke with her months alter and was speechless when I told her what the public interest groups thought of the whole thing, that I has insisted our name be removed from all documentation and that she should go back to the drawing table.

16 If all this fails to produce a report which supports your plan that the elected officials will accept, don’t give up, consult some more.

Minister’s letter to participants of October 2.2003 “ I have asked my officials to work with PPF on a focused consultation event.”

17 If all else fails, delay until a cabinet shuffle gets you a new Minister, then carry on where you left off.

It will be months before the new Minister has time to look at the long drawn out process that got you this far. Few Ministers even read the bills they sponsor. Legislative Renewal would certainly not be a priority for any new Minister and is certainly not with this new one – who also holds another portfolio - Intergovernmental Affairs and is Minister Responsible for Official Languages. Somehow I don’t think Pierre Pettigrew will spend his weekend reading the PPF Report on drug approvals. He’ll likely want a few bullet points – which – and I don’t want to be too cynical here but – will likely refer to (dare I say it) – the competitiveness of the drug industry in Canada, life saving drugs and how many jobs these companies provide in his riding.

THE END