Barbara Mintzes

How did you get into the health field? When and where?
In the early 80s I was in Vancouver and very soon after finishing my undergraduate degree I ended up working -

The undergraduate degree was in what?
It was in geography and I have a story about that – it comes much later when I was working on my research for my thesis on direct to consumer advertising. Part of the project was a faxed key informant survey, which I added on because it was funded by Health Canada and they wanted it. I surveyed the industry and all the key players. Industry associations answered along with everyone else. I had good response rate because there was a change in the law being considered at the time, so people wanted to get their two bits in. A few months later I discovered that the head of RX&D, a brand name industry association, had written a letter to the deputy Minister of Health complaining about the fact that I was coordinating this survey mentioning my education background which was graduate student with a degree in geography and then it went on to say that my work was hardly scholarly and boarding on.

This was when?
This was about 2001. My degree was in 1982

So that's a long way from '82 to 2001. They're really digging up the past aren't they?
Yes they are.

What lead you into health from geography?
It was sort of environmental science geography. I only spent one year working in anything relating to that field and that was working on a bibliography of baseline environmental impact reports. It was a bit of an introduction to corruption actually. These were reports that companies, lets say mining companies or logging companies, would have to produce to show that their corporation was not having an impact on the environment. They had to be produced by an independent organisation so it was typically a consulting company that was hired by the company.

It taught me a bit about the effects of funding. I could see when results were fudged. You often had two reports, one by the government and one commissioned by the company about the same situation and explanations for why there were heavy metal

Naturally occurring heavy metal.
They were always naturally occurring. So it was a little bit of an introduction that was helpful to me later on when I was working in the health field. I started working with the Vancouver Women's Health Collective, so a local women's health organisation.

This was in?
I started volunteering probably around '81 or '82. I think what pushed me in that direction was an experience having a health problem. I was 22 or so at the time. I had no idea at the time what I was going to be getting into. For me it was an experience of lack of control in a fairly fundamental way. Which was really the trigger to start work with the women's health organisation.

And the people that you went to work with, was there any particular reason to pick the group you picked? Was there anyone in there who was very interesting or dynamic?

There was- It was a local feminist women's health organisation. It was probably the only one. In fact like what I was going through, they would have been helpful for me at the time when I was feeling very isolated going through the whole system, not sure how to negotiate it. It would have been helpful for me to be able to contact them and talk with them. At the time they were shut in some kind of 3-month reorganisation, internal discussions process. I think I was sort of thinking that I would get involved in that sort of counselling work.

From the point of view of the feminism in the group at that point in time compared with say now, what were the issues? Was it a doing thing or a thinking thing? You know we must take this approach towards issues or was it much more a hands-on lets kind of counsel people on things.
It was mixture, like many feminist women's health organisations, it was a mixture of service and advocacy. It had a health information centre and sort of a library and telephone line that was open too few hours, but was open some time during the week, at various times during the week. I started being involved in a project on pelvic inflammatory disease early on. So I volunteered with them for a period of time and then ended up getting hired in '83. So was my first long-term permanent job. It was meant to be three years and we were cut by 100% about three months later. It had been funded by the provincial government and there was a change of right wing government in power. But I continued to work with the organisation for probably eight or so years.

And the issues that were being covered by the group generally?
It worked on mental health issues. I was generally not involved in that side of things. It worked on reproductive health issues like concerns about the high and growing rate of C-sections. Which is ironic at present because the rate has doubled. So if you want to have a look at your long term effectiveness on things, mental health would have been concerns about lack of access to psychotherapy within publicly funded mental health services and that's still a problem. I worked as a birth control counsellor and also fitting cervical caps so we did a little bit of semi clinical work. Some things in retrospect I see as being really useless like teaching breast self exam. Well teaching cervical self exam was probably interesting more than anything else but breast self exam was mainly to younger women who wouldn't have been at high risk of breast cancer so it was actually useless. And then I was involved in a project that involved travelling around the province meeting with women's centres and with native women's organisation and doing workshops and producing health information materials at low literacy levels and doing training workshops for others to put on workshops. It was very grass roots.

Are there any things from that period that leap out at you? I mean just in the course of saying what you were doing, were there any scenes that came to mind as being very representative of the things you were doing?
You know you have those dreams, I have those dreams, sometimes that I'm meant to be speaking somewhere and I'm wandering round doing something else and I realise I'm not where I'm meant to be. So that's the first scene that comes to mind. I was travelling with a friend to a fairly isolated place off Vancouver island - you have first take a ferry to the island, drive and then take another ferry to a small island. There was some miscommunication about the times and place. We're on the little ferry that's going from Vancouver island to the smaller island where this community is and see the posters for our workshop and its meant to already be starting and here we are on the ferry. It was your worst nightmare because we arrived and it was a room full of women who were just sitting there silently. It turned out that they had been talking, things were fine, we got things going. You know for us it was a push to, we had as a feminist health organisation, we had worked a lot with women's centres

in small towns but often in in the north of British Colombia there were large native communities and we hadn't had any involvement before so this was a move to something that was different.

Working on these kind of issues back then, you'd have to literally be learning as you go, whereas if you were to go into this kind of thing now you could have had a degree in kind of possibly women's studies before hand. There's a good chance you'd gone though the issues in the degree you did. If you were to go in now, you know the kind of people who would go into this now would all have a background in the issues, but you couldn't have had one back then. There wouldn't have been any university courses in women's studies?
There would have been women's studies university courses. I think there were some. I mainly learned through an apprenticeship. For instance learning to facilitate a workshop or even learning about one of the technical subject matters that I was dealing with. For me that was great because I'd been extremely shy, to the point where as a student speaking to a group of 10 or 12 people I hardly could manage to get the words out. I think it was partly that the whole philosophy of the feminist women's health movement at that time was very supportive to me in a personal way in terms of developing my expertise on different things. I enjoyed the side that was answering the phone where you had no idea what the call would be about and working and counselling one to one with women who came in. Working out how to take someone through the system.

Mainly we would have people call us who had trouble already with their regular health care system, they'd been going to doctors and not getting anywhere or had in some ways - I mean the idea was one that was classic in terms of lots of misdiagnoses to the point where you would, as a non health professional, we'd hear similar kinds of patterns of what had happened in a persons previous contact with the health care system and be able to at least give her questions to ask in terms of getting closer to a proper diagnosis. It was often long-term pelvic pain and ending up more in the psychiatric system than actually dealing with the possibility of an infection. Of course you'd never diagnose, there's a limit to how much I'd practice medicine without a licence.

The main thing in terms of early on in is that I got much more interested in women and pharmaceuticals. And that came out of a very early meeting/conference I went to in 1983 in which one of the people who was speaking was Harriet Symond who started the DES Action Canada. She was speaking to people from other women's health organisations to try to get information out, basically awareness raising and support for women had been exposed because there hadn't been any alarm to the public about exposure. No information had gone out for basic information for women who needed gynaecological care following prenatal exposure. So that was in '83.

She was someone who at aged 22 had been diagnosed with vaginal cancer as a result of prenatal DES exposure. Her mother had known that she'd taken the drug in pregnancy and gone back to her doctor when the news had broken about, I guess it was in '71, about the vaginal adenocarcinoma with DES exposure and her doctor had said 'no, no it was progesterone'. It was a mother-daughter team that had started this organisation and that's my strongest thread in terms of work on pharmaceutical issues. Because I stayed involved with that organisation, in a sense I'm still involved.

Well let's go back and pick the organisation up then. This is both Harriet and her mum is that right?
Yeah Harriet and her mum Shirley Symond.

Shirley would have had DES somewhere around 1960, ’59, ‘60?
Maybe it would have been late ‘50s even I guess. DES first began being used in 1948. It was widely used in pregnancy to prevent miscarriage mainly but it was also promoted to make a healthy pregnancy healthier.

DES was never patented. It was first developed in 1938 by Sir Charles Dodds working for the UK Medical Research Council and it was never patented and so when it began to be produced for clinical use lots of different companies produced it. Eli Lilly was a major producer in North America and its one of the great drug disasters in fact because it was sold very widely for use in pregnancy to prevent miscarriage. One of the first well designed randomised clinical trials was in 1952, which showed that DES was not effective in preventing miscarriage or leading to better pregnancy outcomes.

The idea was that you would give large oestrogen doses to women and it would stimulate progestin. The theory was that women who miscarry had a drop in hormones prior to miscarriage and the theory was that you’d keep the level up. So there was a good pharmacological theory for why it would work but it didn’t. It continued to be use quite widely actually. It was used more recently in Europe even than in North America.

In North America the peak period of use was in the 1950s and then it was still being used in the 1960s but to a lesser extent because the message of lack of effectiveness had come out. In 1971 in a case control study, researchers in the Boston area had started to note that a rare form of vaginal cancer that would normally only occur in post menopausal women was happening in young girls around puberty or later. They couldn’t figure it out. It was one of the mothers who asked could it be this drug that she was given in pregnancy. And the Boston area had been an area where there had been a lot prescribing by two gynaecologists who were promoting it heavily in that area.

When Harriet was diagnosed with vaginal cancer she had to go to the US for treatment. She lived in Montreal. It turned out that actually there was quite a bit of prescribing in Canada but when she came back when she got a bit better then she and her mother started getting in touch with Health Canada trying to find out whether there were others who had been prescribed the drug as well. There was already in the United States a support and action organisation of woman who had been exposed to the drug that Harriet had been in touch with.

The first Health Canada response was no this was very unusual. They ended up going to the press and had thousands of phone calls and requests for information from women who had been prescribed something that in many cases turned out to be DES. And so I got involved in it because there had been no work done. It’s a situation where if a woman is exposed, so there are effects on the sons as well but less frequent, but women exposed prenatally needs a more intense gynaecological exam, colposcopy usually just to be able to diagnose the specific cancer that is related to DES exposure. There was a public health imperative to let people know. But there had been a lack of interest. There had been a concern probably from government side not to alarm the public.

They do tend to handle things like that? Why? Any ideas?
There’s the obvious product liability side. But there’s never been a successful product liability case in Canada.

In Canada, or Europe, or the UK. The occasional, terribly occasional. I mean it's just not an issue compared with the US say where it happens the whole time.
I mean on this particular drug in terms of a drug-induced harm because it was so clear-cut. In fact the cancer is not the most common health problem. It's not the most common teratogenic effect. Malformations of the reproductive tract are much more common, so a sort of T shaped uterus. Which of course nobody could see and nobody would know would exist except that it's related to higher rates of miscarriage and early premature births. The fertility problems are also much more common than the cancer but for the cancer the product liability suit should be very easy except for the fact that there are many many factors.

It's very difficult if a woman is not able to name the manufacturer whose product her mother used. Anyway there have been successful cases in the US and in the Netherlands. In both cases it was a real fight to shift the product liability law as well. In the US it was the decision that all of the companies were liable according to the market share. DES Action as an organisation in Canada, fairly early on, started to see ourselves as having a dual role one. One side that is support and advocacy for women who are DES exposed and most women involved in the group are DES exposed. I'm not but I'm from the same generation. The second one was more to try to see what we could do in terms of advocacy and regulatory policy to try to prevent this kind of tragedy occurring again.

So you heard a talk by Harriet in when?
1983. She was very pushy. She came with piles of brochures to take home with you and various other material like lots of background materials many of them had been produced, they all came from the US DES Action Group. It was later that the Canadian one started to produce the materials. I'm not sure if she already had funding for the organisation or just started to have funding. She had slide presentations and brochures and I started in a fairly, probably incompetent way to try to raise awareness in the press.

There are a few things I did. One was to see whether we could get a question on the form that physicians filled out when they did pap smears to ask was the woman DES exposed. That's also because there are malformations of the cervix that are fairly common. You know they are related to the effect of the drug on the reproductive tract development and there are so many things that could be misdiagnosed and were leading to unnecessary cryosurgery so leading to harm unnecessarily. So the idea of getting even a question on the pap smear form was one thing that I started working on. I wrote to, I can't remember who I wrote to, but I wrote to whoever was responsible. Got a letter back saying that it had been prescribed in Montreal but it hadn't been prescribed in British Colombia so it wasn't a problem here which was actually the same story that Harriet had originally had in Montreal. And also some misinformation which was kind of wrong dates in terms of it not being appropriate to put a question on the pap smear. And so I wrote back.

Vancouver is quite a new city and many people come from Ontario, Montreal, from the EEC, from wherever. Also just providing the information that was correct where there was information that was incorrect. And to whoever it was and I've completely forgotten who it was, to their credit they did actually turn around in response to that 2nd letter. We were able to get a question on the pap smear form. I don't know how effective that was as an action but it was at least one thing.

We would do some presswork. I was really the only one working on this within the Vancouver Woman's Health Collective so the colleagues I worked with were mainly in Montreal and then in other parts of the country. And whenever we did some public

event we would call a workshop or a meeting and women who had either taken the drug in pregnancy or had been exposed would come. You'd get a real range of people from different walks of life. In a sense it wasn't one of the hotter items, trendy issues to be involved in within the organisation even. People tended more to be working on I guess the mental health issues. Or there was a lot interest in natural health products, alternatives. It was probably where my work on pharmaceuticals really came out of this organisation I worked with. I ended up being on the board but we've sort of fizzled as an organisation about two years ago simply because of our annual funding getting down to $15000 a year and then down to zero.

We still exist as an organisation providing web-based information through a larger Canadian Woman's Health network so we don't have the resources any more to be functioning as a separate organisation. So that's the whole story of DES exposure. Because in North America most of the women exposed were born in the 1950s and 1960s and there haven't been any more exposures in pregnancy but this was a large cohort. There's no good quality information to help estimate the number of people exposed in Canada for instance or in many European countries

In the US, the Centre for Disease Control has fantastic information and lots of resources on their website. It's interesting. The US has funded publicly most of the research on what the health effects were. About 2 million women were prescribed the drug in pregnancy in the US so quite large in terms of the exposure. In Canada we just take the 10% rule, because it's 10% of the population, as a back of the envelope estimate. But it is this cohort of people where there was no known knowledge really beforehand of what would happen as they aged and a real concern of what would happen with this cohort of women who were exposed prenatally. It's the first known transplacental carcinogen. You know you have this situation where you had no sign really of any adverse health effects until the babies-

Until 18, 19? Ten to fifteen years later?
Or even more. Because as time went on, at first the mean age of the cancer was around 19 but it became older as time went on simply because the whole cohort aged. It's an old story but not in the sense that there are still women who were exposed and men prenatally who are now hitting their 50 and 60s.

What are the issues for men?
For men undescended testicles at birth and with undescended testicles at birth you end up with higher rates of testicular cancer and infertility, similarly effects on the reproductive tract.

So this is mid '80s. From the mid '80s you are getting into the issue of health and pharmaceuticals. What's the next thing to come on the radar for you apart from DES? At which point do begin thinking 'well its not just DES its almost all pharmaceuticals'?
I don't remember. I think in the other work that I was doing with this women's health organisation on information materials on birth control for instance we were much more critical. There were other things that were going on. There was the information that women were getting about the birth control pill, which was very one sided, very little information about any risk and even you'd have risk information presented in a framing that was unhelpful. For instance, as though it was either the pill or getting pregnant. Rather than what's the risk of pregnancy plus adverse events on the pill vs. pregnancy plus adverse events on condoms or the diaphragm or whatever else was around. Or what are risks of taking the pill vs. riding a motorcycle. So it was partly on contraceptive that I started hitting similar issues in terms of the information that the user had available about the potential for benefit vs. the potential for harm. I also did

work on things like infertility treatments, hormone replacement therapy and the medicalisation of menopause and childbirth. The latter wasn't a pharmaceutical issue as much but the medicalisation of menopause was a large one.

Very much a pharmaceutical issue. And that began to come on the radar for you with?
When I was working at the Vancouver Women's Health Collective, so somewhere in the mid '80s. I was working there 'til maybe '88 or '89. Also psychotropic drugs as well. It was the benzodiazepines much more at that point - of overprescribing.

At the point that you were working on HRT was it the osteoporosis issue? Or hadn't that come on the radar then? That came later did it? Osteoporosis was mid '80s when it began to rear its head a little bit.
I think so and I've looked at the trajectory with HRT where it was first being promoted for menopausal symptoms and then when the evidence came out about higher rates of endometrial cancer with unopposed oestrogen - afterwards there was a real dip in sales and prescribing. Osteoporosis came after that and I can't remember where this was going on in the '80s. I don't think it was on our radar as much as the construction of menopause as a disease. The whole oestrogen deficiency language.

And all that's come to light since. It's use and this guy Wilson and his book *Feminine Forever.* How much was that known then?
His pharmaceutical funding was not at all known then. That's come out really recently. I think after his death. In fact, it came out after the Women's Health Initiative results came out. It would have been 2003, 2004. So you think this was 20 years earlier. The influence of the book was well known. We were very angry about it.

Was he still around then? You didn't ever meet him?
No I didn't meet him. I was working with a very city-based organisation and it did some work provincially as well and was part of a network of Women's Health organisations that were working together nationally. Depo-provera was another one. We were very involved in work to keep it off the market in Canada which we were successful at for a certain period of time not forever. It was partly concerns about the human rights abuses with it - with it being provided to disabled women and native women and the whole shifty side in terms of consent and then also the health concerns. So I guess we were involved in a fair number of pharmaceutical issues.

I think the way the organisation would have framed itself to begin with was much more on an individualist patient rights perspective and really concerned about the way women were treated within the medical system. Paternalism within the medical system was a driving force. And there was a shift later to being more conscious of the role of the pharmaceutical industry.

Can you date that shift for you personally?
For me personally it was probably with work on DES so that was quite early. This conference in 1983 out of it there was a play called *Adverse Effects* that was produced. I wasn't involved in it but was a travelling road play that was also really focussed on pharmaceuticals.

Can the transcripts be got still?
Yes probably yeah. Some of the people I work with now were involved with that. I can't even remember which drugs it focussed on.

So this is the '80s and you are becoming aware of the industry as such and the role they are playing. Anything else that you can say to me about that because

there wouldn't have been a lot of people aware of the industry in that sense. There's a few books from the period. There's John Braithwaites' *Corporate Crime* book, which I think was 1980 or early '80s.
And the books involved I wouldn't have been aware of then. Even if I was working on pharmaceutical issues. I know that Joel wrote a book called *The Real Pushers* sometime in the 1980s so it was about the role of the pharmaceutical industry in Canada specifically. I must have been aware of that as well.

That's awfully early for a book like that.
I think it was late '80s or it could have been mid or late '80s. There were a few others. At the Women's Health Collective we got the newsletter from Health Action International.

HAI was formed in '81. But we used to get the newsletter and I don't think I ever read it. And what happened is that I, our family moved. I was working for the Women's Health Collective on a two-year project that had federal funding. We had core funding from the province for staff but that was cut in '83. After that we depended on some funding for getting people who are unemployed, subsiding their unemployment insurance and we had project related funding from the Federal Government and I was working on a 2 year project that I knew was going to end. And Anthony, my partner, was working at a job that he wanted to quit. So we had a plan. Our children were quite small. We had a plan to just work, save some money and go and live in Europe for a year.

As one does. *Revolutionary Road* almost. Have you seen the movie?
I just saw the movie. That is true but it wasn't for the same reasons. It was another era, it was completely different era. Our youngest was three and half and the oldest was eight when we moved. He was doing some work in collaboration with a group in Italy in Torino and the idea originally was that we would move to Italy. I'm fluent-

What was he working on?
This is a whole other story. The work with the group in Torino was on environmental one. One of those environmental disasters - Seviso. I can remember driving in Italy and stopping and looking at the stream.

I had another job before I started working for the Women's Health Collective, with him. There was a professor at Simon Fraser University, which is where we both did our undergraduate degrees, who was doing a range of different related work. I worked as a research assistant looking at occupational causes of breast cancer and lung cancer. Doing a review. Anthony also started to work with him at that point. He got funding from a mixture of different sources. I left when I started working for the Women's Health Collective so I had been involved in health work a little bit before then. Anthony worked on formaldehyde foam insulation type things. Then he started working on passive smoking – we both realise now that some of the work looking at occupational sources for lung cancer for instance, may have not been funded by who it seemed to be funded by but was being funded by tobacco industry as well.

To show that you don't want to believe that all these things are caused by smoking?
Exactly. So what had happened to Anthony at the point where we were saving money and thinking that we would head off to Europe, Anthony had gotten into large fights with his boss over information getting changed while working on passive smoking. So that's a kind of interesting background as well.

The thing about it is that you both have got the same concerns to come extent. It isn't the kind of relationship where the two people are pulling in the opposite directions then?
No but he's gone in a different direction from me now. He was involved in health work more.

He's an economist. He did a Masters on innovation economics. So he does a lot of surveys of firms on innovation strategies but he does have an interest in biotech and health and other biotech in general. So he comes at it from a different angle than me. But I can sometimes bring information to his work that is helpful for what he's doing.

So you both move to Europe. You were going to go to Italy because you are fluent you were saying.
In French and our daughter had already been going to French immersion primary school. And also it would have been more expensive -

Where were you born? Were you born on the East coast ad then move to the West coast?
No I was born in the US in Washington DC. I lived in France from when I was one and half to when I was seven, so I learned to speak to French as a young child and my family are all Francophiles. My father worked for the US embassy. We ended up in France not in Italy.

When we were there Anthony was going to Torino to do some work. We ended up for a while living in this village in the Alps and he would go to Torino to work with this research group he had been working with before. I ended up doing some work with the Dutch DES Action Group. Partly they were involved in assisting groups in other European countries to organise, helping them to organise a conference in Ireland. That was the first sort of launch conference of the Irish DES Action Group.

We wouldn't have had DES in Ireland, we didn't have sex so.
Somehow, despite not having sex. But I'm sure it wasn't prescribed there either. In fact because also in the English group as well, you often have very few people who start these organisations. In the Netherlands there were two women who had separately been told that they were the only women in the country exposed.

And these were who?
Eleanor 'th Hoen it means The Hen. And Anita Dureff. So two women who had both found out that they were exposed and both told that they were the only women in all of Holland. They were an amazing team in terms of getting an organisation together. In terms of how well organised the Dutch group has been. In comparison, if I look at what we did in Canada for instance we made sure that we had lists of doctors to refer women to that we knew knew how to do an DES exam, who were sympathetic to the idea that maybe this was a possible exposure. They had a whole network of gynaecologists that they were working with closely who were very supportive of the organisation. We were much more outside of the health care system than they were.

Being a small country there was very good coverage throughout the country. I worked with them a bit, assisted the French group that was getting going. In France there's been a lawsuit actually. A group of women who've had cancer from exposure have successfully sued. I assisted them with organising that.

They had an input into the formation of HAI did they?
DES Action is a member group of HAI. I don't know they had an interest. I don't know. I'm not sure when the Dutch DES Action group started up. I don't think they

were one of the founding groups. And because they were also much more nationally focussed. And when HAI was first formed it was more focussed on having an organisation from the North and West working with groups in developing countries. Working on double standards from pharmaceutical marketing was a key focus. It started on a similar model to the baby powder milk. There was a whole international organisation that was able to successfully get a code on marketing of breast milk substitutes. When HAI started one of the ideas was to have a code of pharmaceutical marketing that was similar, having seen similar patterns in terms of unethical marketing of pharmaceuticals particularly in developing countries.

DES Action when it started was very industrialised country focussed and I was working very locally and industrialised country focussed. So the connection for me to HAI was that when I worked with DES Action in the Netherlands in about '88, maybe '89 yeah '89. I was working for them for a 6-month period part time. I would go for two weeks at a time and work in a concentrated way and then come back. It was lots of fun in terms of being able to live in this village and not be working when I was living there.

I shifted to work with HAI while I was still working at the DES. We were running out of money so we were planning to move back to Canada and Alan told me about a job opening at HAI that I thought I didn't have a hope in hell of actually getting. We did move back to Canada and I applied for the job from Canada and got it. And started to work at the HAI office on press and communications and it's partly that I had a little bit of experience that was relevant to that. Because when I worked at the Vancouver Women's Health Collective I was working on publications and books and such.

Does this role handling the press issues ultimately lead into your DTCA interest?
Yeah. DTCA interest came out of when I was working with HAI. I wouldn't have been aware of DTCA when I was working in Vancouver.

No but just the fact that you move into the press role with HAI does put you in the frame where you are going to become aware of DTCA when it comes on stream almost inevitably.
It was partly because I started to work on drug promotion. I started out at HAI mainly editing other peoples work when I first was there and then I started also doing some writing myself. One of the projects was a book, well not a book more like a magazine type thing, called *Promoting Health or Pushing Drugs* with Andy Chetley and then that meant also researching on the effects of promotion. I think it was interesting also my trajectory with it. Because when we had of the text of the first draft and sent it out for review, one of the comments that I had back was that I really had to shift the tone away from hanging up doctors by their toenails. I think what struck me with it partly was the complicity of the medical profession with the pharmaceutical industry.

Was almost complete.
I think doing that research and we used a lot references from script and it was really a journalistic review article and that whole complicity really struck me.

I worked there from '91 to '96 and for me it was a very big shift from working with a more local health organisation that was tied into national groups to working with something on much more international issues. So I was very interested in that.

The issues HAI were involved in then were what?

I was very involved in work on psychotropic drugs. Charles Medawar, who has been involved with HAI from the beginning, had just released his book *Power and Dependence* just a few months after I came there.

The other area was problem drugs. So drugs with a benefit-risk profile and with double standards in marketing of medicines in different countries. A range of issues. You know some of them policy related and some related to specific products and classes of products. Not long afterwards Chetley wrote his book on problem drugs that was originally just a series of handouts and I was working as a publications and communications person.

How did HAI look then?
I was very surprised. I had seen the HAI bulletin when I was working at the Women's Health Organisation, so I was very surprised at the size of the offices which was just two fairly large rooms and there were two other professional staff in the office at the time when I started work. Much smaller than I expected. But that was partly because it was a network and so a lot of the work was being done by people involved in the network rather than actually in the coordinating office.

Who were the key people? What was the driving philosophy if any?
I think HAI set itself up as an international antidote against the excesses of pharmaceutical marketing. In terms of the key people it sort of depends on which areas you focussed because they tended to be people who worked on different areas. There would be very informal working groups. There were three coordinating offices at the time. I think there are now five if you include the global office. There is Balasubramamiam who's based in Sri Lanka and is a clinical pharmacologist has been very involved for years. In the European office Elen t'Hoen who now was working for the UNs patent office, Catherine Hodgkin; Charles Medawar, Andrew Herxheimer, Andrew Chetley, Phillipa Saunders in the UK as well. Roberto Lopez who is the coordinator of the Latin America network and I collaborated a lot with on different projects on drug promotion. Still very active with a very active network in Latin America. There isn't much in North America interestingly.

From the list of people you mention there is a conspicuous lack of people from North America.
Well Joel Lecsten I should of mentioned has been a long time HAI member, based in Canada. In the US we collaborated with Public Citizens Health Research Group but at the time in the early '90s they were very focussed on domestic issues much more than international issues. Lately there's been more collaboration. We used to also collaborate with groups in the US - there was even a church related organisation that would buy shares in pharmaceutical companies and then attend shareholder meetings and raise motions relating to activities in developing countries. It was a mixed bag in terms of organisations. Some of them very focussed on access to essential medicines and barriers to access in the poorer countries and some very focussed on double standards on marketing between different countries and others on what's going on in European or mainly European countries. Problems in their own countries. I think the other side, at the time I still had a fairly close relationship with World Health Organisation in terms of working on working with what was the Drug Action Programme which was involved in bringing in the central drugs policies and bringing in policies to improve the use of medicines. There has been some of that in work in informing the work in industrialised countries as well to support the ideas of a limited list and its actually very similar to the idea of having evidence-based reimbursement policies. There's a link to what I'm working on now in a sense in terms of systematic reviews of the drugs that are then used as a background to reimbursement decisions.

It seems ultimately though to be extremely few people. How does HAI achieve the impact they do?
I think that it's a mixture of key people and then some of the organisations that are member groups of the HAI network are much larger than the coordinating offices in terms of the impact. So I'd say one of the types impact would be in collaborations and specialising in expertise on pharmaceutical policy and being able to collaborate for instance with other larger NGOs like Oxfam or Save the Children. And to some extent I'd say HAI don't have the kind of impact in the press or the awareness that other organisations have – let's say in the environmental movement. But came out a similar consumer-public interest collaboration to try to shift the pharmaceutical policies on a national or international level.

I'd say it's a bit of a mixed bag. HAI has been fairly involved in international trade work as well and in improving access to essential medicines as well as collaborations with some of the AIDS activists groups in terms of access to AIDS medicines.

Was there any particular philosophy in HAI other than you had a group of people who were interested in issues to do with drugs?
A philosophy of medicines as a social force that can have a very positive impact on health and so the idea of realising that impact on health by improving the access to needed medicines and preventing unnecessary and inappropriate use of medicines that can lead to harm. There's a link in viewing medicine as a social goal rather than simply another commercial commodity. People who become members of the HAI network are independent of any funding from the pharmaceutical industry but are actively working on pharmaceutical issues. The idea was to build a network of people who were active in field and interested in collaborating with people in other countries.

What was it like to join HAI?
I found it a lot of fun. I guess mainly because of the people who were very committed in the work that they were doing and meeting people from different countries. For me it was a real sort of opening up. I learned a lot. It was push for me in terms of personally where I was going in my work-life trajectory. When I applied for the job at HAI I didn't think I had a hope in hell of getting it simply because I didn't have the international experience. It turned out to be very interesting in terms of pushing the boundaries of the work I was doing and I can say now that I am better at some of it and worse at other parts of it. I'm terrible as a lobbyist for instance. I tended to focus much more on writing and editing and I think it was also a bit of shift for me after a period of time on project management. I was involved in a project with a consumer group in Poland. That was there first sort of push to find out more about what the public's information needs were for medicines and also to do some awareness raising. So very interesting.

Why do you suppose there was things you were poor at? What was it about going to try to lobby? Is it just that you didn't like it?
It was more…I can remember the first lobby team. I was the only French speaking person on a fairly small team to begin with. It was just the side of having to strike up a conversation with African ministers of health. You know it was basically shyness and feeling insecure in that position. It was one of those situations where in fact our lobby teams were always much more effective when we had people from a specific region who were lobbying the ministers from that region. Other people are much more able to be very focussed on the aim which is to get a specific resolution passed; to try to at least engage in a conversation on what kind of pharmaceutical policies changes might be needed– it's not that I was absolutely at loss at it…

Ok so how did DTCA come into your life can you remember when it first appeared for you?
In the early '90s when I was at the HAI office, it was around the time at the beginning of the growth of DTCA in the US and we were aware of it and following it. We were often following international trends. One of best sources of information is SCRIPS the pharmaceutical bulletin that comes out of the UK - its an industry bulletin but excellent in terms of reporting. I was working on a few of our publications and also strategy documents on drug promotion and one of the areas that we saw as a real problem was the growth of DTCA.

I think in Canada I'd already been aware of some of this. I hadn't been aware of advertising prescription drugs to the public through television or through magazines but I was aware of some of the new promotion through the media of specific conditions, now called disease mongering. I worked on a report kind of like a report produced like a magazine called *Promoting Health and Pushing Drugs* with Andrew Chettley in which we had short articles about different promotional practices that were problematic in different parts of the world and then came out with a series of strong recommendations at the end. So that was probably the first publication and it was linked as well to other advocacy efforts. So it was a bit of a mix producing publications that were educational but were also awareness raising and then also lobbying for specific changes in either regulatory policy - which is a real mess when it comes to drug promotion - or even policies in organisations and health professional health groups.

Can you date all this for me?
Promoting Health and Pushing Drugs probably came out in about '95, '94 or '95 and then I worked on another. I left the HAI office in '96 but I came back. I was working there in the summer of '97 on a publication called *Blurring the Boundaries* which was focussed much more on direct to consumer advertising. Both in terms of the direct advertising and the disguised advertising that was going on. It was focussed on the blurring of the boundary between advertising and promotion and is there any education and science in media reports. So that was when I really started to focus on DTCA. I worked there in '97, it came out in '98.

This is around the time when things do begin to change in the States and we have the first proper DTCA adverts turning up in TV. Is that right?
The first DTCA campaigns in the United States started, lets say the first DTCA campaigns post prescription drug status, so I'm starting late rather than early in a sense. There certainly were medicines being advertised to the public around the beginning of the 20th century and there was investigative journalism into the promotion of snake oil etc.

Prescription only status came in I think to begin with in the US around 1938 and in Canada I know our first Food and Drugs Act was in the early '50s so I'm not sure when we first brought in prescription drug status. It's different in different countries but in terms of the first DTCA campaigns post prescription drug status in the US they started in the early '80s. They were mainly print campaigns.

Then there was one very intensive public relations campaign by Eli Lilly for the arthritis drug, Benoxaprofen. Which occurred in 1982 and that was a drug that was just on the market for about 5 months in the US. It was withdrawn in the UK as well very soon after its approval. The arthritis drug that was associated with liver toxicity and deaths mainly in the elderly. After that in 1983 very few months after the US FDA called a voluntary moratorium on direct to consumer advertising. At that point there were very few drugs that had been advertised to the public.

There was some industry opposition to direct to consumer advertising concerns that it would open up product liability in a new way and it would be very problematic. That moratorium lasted for two years and the FDA carried out some research on consumer responses to different types of fake ads and also some opinion surveys. They ended the moratorium just with a statement that DTCA could be regulated under existing regulations. In the US there were no specific laws, there was no new legislation passed to allow direct to consumer advertising. It was simply the case of no specification of target audience in the existing law of pharmaceutical advertising. So in '85 they just said well they had researched it and that basically things could go on as they stood. There were some statements being made in the press about very heavy lobbying by congress of the FDA commissioner at the time so I don't really know what went on behind the scenes. You then had the situation where there was a gradual growth in the advertising spending but quite restricted.

It started to take off in and around the early to mid-1990s. There was also very heavy lobbying of the FDA to open up television advertising. So the existing regulations were exactly what is needed for an advertisement in a medical journal. Which meant that the advertisement had to be accompanied by what's called the brief summary in the US. The brief summary is all of the risk information that's in the approved product labelling. It's neither brief nor summary in fact. In an advertisement in a medical journal it will be all of the fine print on the back of the ad. For television advertising that would have meant that the advertiser would have to provide all of the text on television. Only one advertiser actually produced a full product ad with that kind of information, which was scrolling through pages of text. That was Upjohn for depo-provera, an injectable contraceptive.

Otherwise what was happening on television were branded reminder ads. And then disease-oriented ads. They were a loophole to get around having to provide risk information. If a company just provides the name of the drugs they don't need to provide the risk information.

Just what do you mean precisely by a reminder ad?
A reminder ad is what allows a sales representative to provide a physician with a pen that says Lipitor on it without having all of the fine risk information. It's a real question in terms public health perspective why this kind of advertising would ever be allowed. Anywhere. For physicians and for the public.

It's a reminder of the brand name in fact. Under US advertising regulations a reminder ad can be provided for a drug as long as there are no either direct or indirect health claims mentioned of the drugs indication. If the advert doesn't say '*Lipitor will lower your patients cholesterol'*, the advertiser does not have to provide the risk information.

The companies used those provisions to start to run ads on television saying, particularly for example, the allergy drug Claritin they had say a woman walking through a field of grass and then Claritin. And as long as the FDA didn't find the field of grass to be enough of a hint about hayfever and allergy they were allowed to do that. The FDA held a hearing on direct to consumer advertising, public hearings in 1995, in which time the industry was strongly pushing for a limit to the risk information provisions so that they could provide what are called full product ads on television.

David Kessler when he was FDA commissioner stated that he saw no interest in increasing the scope of direct to consumer advertising and so he resisted the push to

open up television advertising to full product ads. He left his position in 1997 and just months after, in late 1997, the FDA published a draft administrative guidance which in effect opened up television advertising, radio ads and also telephone ads. It allowed the companies to meet their risk information provision requirements, regulatory requirements, by just providing information on major and most common risks as long as then they referred people to other sources of information. So those other sources of information would be a website, an advertisement in a magazine or a toll-free telephone number where they could phone the company.

It was quite an interesting move in terms I guess of the shift through an administrative policy alone that led to a new interpretation of the law. Also of allowing advertisers to refer people to directly contact the company so in terms of the whole collection of individual information privacy issues it certainly raises concerns. That's what happened in terms of opening up the television advertising.

It was in the mid-1990s as well that DTCA started to take off in New Zealand. New Zealand like the US never had a specific law allowing that advertising. Television ads started to take off in New Zealand. Those ads were quite different from ads in the US and they have continued to be quite different from the ads in the US and that's because the US relies on direct government regulation of drug promotion so it's up to the FDA to actually judge whether an advertisement is consistent with the law or not. New Zealand, like many other countries, relies on industry self-regulation so they delegate the regulatory activity. In the case of New Zealand it's to an advertising association and in effect there's very little to no risk information in the television or other ads in New Zealand.

The European Union and Canada also began to feel very heavy pressure for the introduction of DTCA around the mid-1990s.

Why did the EU not go down the same route? Was it because of groups like HAI?

I think you can say that at a later date. To begin with no one decided to go down this route. It was an opening in legislation in the US and in the US it was very linked to the introduction of managed care and to a shift from most people paying for their drugs out of pocket to being covered by insurance plans. And then also those insurance plans mainly being the HMO's health management organisations who were trying, because they were providing the full gamut of health care, to limit their costs in a range of ways and one of the ways was to start to bring in some limits on what was reimbursed and what was not and in terms of physicians contacts with sales representatives. So there was some pressure in terms of traditional marketing that certainly there's been some discussion in marketing and the medical press in terms of the shift to managed care being one of the reasons that the industry went into DTCA as an additional marketing technique.

It's grown enormously in terms of the proportion of the marketing and the proportion of the spending on marketing but it remained a minority of the marketing spending. The European Union and Canada, Australia South Africa all the other industrialised countries actually had specific wording in their legislation that prohibited the advertising of prescription drugs to the public. So one of the reasons that the European Union did not go the same route as the US is that it couldn't just come in. It had to be introduced through new legislation.

There was an attempt to bring in that legislation starting in 2001, the European commission proposed the introduction of regulations that would have permitted DTCA for asthma, diabetes and HIV drugs. What was interesting is that if you look at

the lead up to the introduction of the legislative proposals, there were statements made by the enterprise commissioner responsible at the time to say 'we are not introducing US style direct to consumer advertising. This is not direct to consumer advertising.'

What changed in terms of it being obvious that it actually was advertising was that once the proposals for legislative change were published on the web it was very clear that they were changed and they would not have excluded advertising in any media for these specific drugs. I think what I find interesting in it is that there was a recognition that it would probably have not been popular within the European union to bring in DTCA as in the US.

I mean that European countries are treating pharmaceuticals differently than the US treats them in the sense that they are funded mainly publicly as part of publicly provided health care services and so the whole role of commercial commodification is going to be seen quite differently. So that's one side but that did not prevent the commission from proposing a what was seen to begin with as a pilot project to introduce DTCA. Health Action International was very involved with a large coalition of European organisations in fighting that proposal successfully. I think in making it clearer part of that is providing information about what was actually being proposed in terms of what was the legislative change that was under discussion. Because there were a lot of confusing things being said by the commission.

When did you from a personal point of view really get hooked on the DTCA issue?
I started to do a PhD on it in late '96 - it was probably out of my work on Burring the Boundaries which I'd been working on in the months previously that I decided to go into DTCA as a focus for my PhD and so that meant then that I was working on a comprehensive literature review.

The Canadian government was holding national consultations in 1998 looking at the possibility of introducing DTCA. So, it was an issue that was very much under discussion from a policy perspective. In Canada we have this difference with a federal government being responsible for conditions for marketing of pharmaceuticals for drug approvals for the regulation of drug approvals such as it is. And the provincial governments are responsible for provision and administration of public health services including a very spotty and different set of drug plans.

The provincial governments had raised concerns about the first proposals to potentially introduce DTCA. The first consultation was in 1996 and at that point there had been concerns from the provincial side and they had asked for research to be carried out to look into what the effects would be on pharmaceutical costs and public health. When Health Canada put out a request for proposals, with colleagues at UBC I applied for it as a way of funding my PhD research and so we ended up getting funding through Health Canada to carry out the research.

I ended up doing it. They were interested in opinion surveys and I was much more interested in looking was happens in doctor's offices. One of things that's striking about DTCA is that a person sees the ads on television and it certainly seems clear from the increase in spending on the television ads that those ads are working to promote sales but in order for the company to successfully make a sale that person has to see the advertisement, go into their doctor's office request the advertised medicine, receive a prescription and then buy the product. So there's a chain of events that really hadn't been explored that I was interested in looking at. That a bit of a side-line from terms of what was going on in Europe.

When the European proposals were underway I was immersed in the research. I had already done my literature review to look at what research had been carried out on both the content and the policy discussions and then also the effects of DTCA and so it was certainly helpful for me to be able to work with people at HAI and other European organisations in terms of passing on information about what does this advertising look like in reality because you have a lot of very vague statements being made about information on medicines and information being good which are often very abstract compared to the reality of what a pharmaceutical advertisement looks like and what it actually conveys to the watcher. I was able to be helpful by providing examples about what was going on the US.

For instance one of the categories of drugs was for HIV AIDS for which there were going to be ads introduced in the European Union. In the US the San Francisco Public Health Department had carried out a survey of men who attended STD clinics and it found that those who reported more exposure to the advertisements were more likely to see HIV AIDS as a less serious disease than it had been in the past and to report that they had had unsafe sex within the last month than men who had been less exposed to the ads.

The public health department were very angry because there had been billboards all over the city as well for HIV AIDS drugs showing healthy men climbing mountains and things of this sort. So, the FDA contacted all the manufacturers and told them to stop running those unrealistic images. So looking at what has actually been happening in the US has been helpful.

There was an article I can remember from the New England Journal of Medicine I think in the late 1990s, possible in 2000, by David Kessler saying well you know DTCA has really turned out to be quite a good thing. It does provide the educational benefits. How naive do you think people were when they put forward the argument that it is a good idea to inform the consumer? Do think the people that put forward this argument really thought that or do you think it was just using a good form of words to use for the time?
It's interesting that David Kessler quote was very heavily cited. I have mainly seen that argument from industry spokespeople or people with financial links to the pharmaceutical industry. It has certainly been repeated a lot. The FDA also in their materials was making that argument. There has certainly been a large shift in the US. I mean I found it an interesting argument coming more from a consumer perspective the idea that the way that a member of the public would get information that might help them to make informed health decisions would be by watching a pharmaceutical advertisement I found just incredible. Amazing that people like David Kessler were saying this with a straight face. You certainly saw it repeated a lot in the United States. There was quite good research being carried out as well in the US just looking at what was the educational content of the advertising because that's an open question- that is it accurate? A group, Robert Bell, Richard Cravizt and Michael Wilkes, a group out of the University of California - Davison mainly- carried out research. They carried out an analysis of magazine advertisements. They first carried out a survey to identify what were the key elements of information that were needed both about the condition and about the drug in order for the person to help make a shared informed decision about medicine use. And identified five of each of those, five key elements that were things like, the condition that was treated, how likely the drug is to work, so on and so forth. I can give you a list of what those elements were. Then they had a very low bar for educational content in the advertisements. They just looked at the presence or absence of those elements of information. They didn't look at if they were present whether were they accurate or not. So what they've found was

that in the large majority of cases basic information like how long a person needed to take drug, what other options were available, how likely the treatment was to work were completely missing and similarly for the condition. That just the name of the drug and the name of the condition treated were most often there. So in terms of educational content it was certainly a myth busting piece of research.

There's been more recent research. Quite an interesting study that looked at the content of television advertising as well in a systematic way. The group that did it as more as a qualitative analysis, this was Dominic ?Frosh. He was the lead author. It was published in the Annuals of Internal Medicine I believe.

They looked at the key messages and both the key informational and persuasive messages and again they found very similar to the print advertising in terms of the lack of that kind of key information. But what they found about the persuasive messages was very interesting as well in terms of the large majority making a link between the drug use and happiness. So it's not even only the mental health drugs but in terms of the sort of images used. They often have a sort of story line where you have the condition pre drug use situation and then the post. In the pre situation you have loss of control over one's life and distress with the condition. In the post what I found interesting as well is that link not only to happiness but also social approval of medicine use. So you have images of a person surrounded by friends and family laughing and enjoying themselves with someone with their arm around them, very much sort of contained and that very sort of happy social situation post drug use. And the pre drug use often had much more social distance in it. So what they pointed out was with these kinds of analyses- anecdotally looking at the specific advertisements you had the consistent use of persuasive messages that were very different from an educational message - what you would want as a person who was facing a health problem and trying to decide what to do for yourself or a family member in terms of coming up with the best possible treatment decision.

I've been on a lot of panels with a person from the industry or from an industry funded research patient group often actually what I would call an Astroturf patient group who, particularly in the Canadian setting, where we've had several rounds of consultations about the introduction of direct to consumer advertising. The person on the other side of the debate is always arguing that this is information and education and that people want more information and education about their medicines. I agree that people want more information about their medicines. It's really a question of who provides that information and should that information be accurate and unbiased and comprehensive. But what I find interesting is that I was showing examples of advertisements in order to illustrate what DTCA is really like. I've never seen an example of an advertisement in the debate or a link to a debate that is calling it information. It's often very abstract and vague and you get the argument.

So the European Union, you are probably aware is going through another round of an attempt yet again to introduce some forms of direct to consumer advertising of prescription drugs and yet again 'deja vu all over again' was one of the ways the High office has talked about this second round of attempted introduction. That again it's being described as information and education and one of the statements that was made in a report by the commission on this was that what matters is for people to get information rather than the source of that information. So it's a bit of a blurring of the boundaries between information and education vs. adverting and promotion.

When did you begin to become a public figure on the DTCA issue? When did people begin to have you on the radar either for good or bad? That you began to be asked along to meetings or that you began to get pilloried?

It was probably around 1999, 2000 or so perhaps. In 1998 I started to become involved in Canada in the discussions publicly on DTCA. And partly that was because we had a consultation that has been called repeatedly for legislative renewal, with the idea of getting rid of our Food and Drugs Act – the main argument being that it's very old and needs to be updated and modernised.

As part of this, under the table, one of the things that was being discussed was the introduction of DTCA that had not really been flagged in these consultations on legislative renewal. There was workbook that was provided for the stakeholders and members of the public who would attend those consultations with an introduction that discussed population, social determinants of health and gender-based analysis. But yet when you looked at the proposals for legislative changes those concepts somehow were not really there.

Together with a group of people from women's health organisations in Canada we formed a working group called Women and Health Protection to take the government up on its proposal for looking at legislation and regulation of pharmaceuticals from a more gender-based perspective. One of the things we began to look at was DTCA. Within that group I focussed on DTCA. We looked at a range of different issues related to regulation and to the proposals in general which were deregulatory and really based on speeding up the regulatory process. That round of proposals never ended up resulting in any legislation.

A few years later there was another very similar round, and again DTCA was part of that but not proposed on its own as in the European Union. That's when I became involved in terms of speaking on the issue publicly. Probably with my research as well.

Ok, what have the consequences been for you to be this kind of person, you know the person that is picked out as being a figure who is in the way of DTCA?
I found it interesting actually when I was in one of these rounds in Canada of the proposals for legislative change. With a colleague, Barbara Mains, I wrote an editorial in one our national newspapers- a commentary on this proposal for introduction for DTCA and why we thought it was a bad idea from a public health perspective and women's health perspective.

The paper ran a commentary in response by a woman who she was the president of a new organisation called Consumer Advo-Care which had just sprung out of nothing. She accused me, I was in the midst of my PhD research at the time on DTCA I had not begun data collection yet, and she already knew the results of my study accordingly. I thought 'you know why bother, I'll just go to her and perhaps they'll give me the PhD without having to bother to do the research'. She certainly was already making statements in public media saying that without any reference to the methodology that the research was biased because I had expressed opinions that from a policy perspective it was a bad idea to introduce DTCA.

I found that quite problematic in the sense that I would not be carrying out research unless I had a question I didn't know the answer to so that I could then design a study in order to find out more about what was actually going on and similarly I doubt if my department would have ever granted a PhD for such research. In terms of being a public figure at the same time as carrying out research on an area which I think happens with many people because if you are passionate about something you want to know more about what's actually going on with it in the real world that has lead to some situations with public attacks on my research as well as you know.

There were some similar statements in a response to a parliamentary question at a much later date. Which is quite a different issue because in this case it was a person who was a spokesperson for an organisation funded by the association of pharmaceutical manufacturers in Canada. In contrast, this organisation when it was first set up, it was hard to see that it had more than one member. It seemed to be lobbying on this just one issue, which was to bring in DTCA in Canada. And she, the same person, was often there to respond to me when I spoke publicly. It was an interesting process for a few years.

That was one thing that happened. My research was funded by Health Canada and early on we made very sure that the contract that we had with Health Canada we had copyright because originally in the first proposed contract the copyright – actually in Canada a contract with the federal government is a contract with the Queen. We wanted to make sure that rather than the queen having copyright that the researchers had copyright and particularly my PhD supervisor as well was one the members of the research team and wanted to make sure that there was no interference with my completion and publication of the PhD as well. Towards the end of the process when we were very close to publication, the first publication of the research was in a short report in the BMJ.

That was when?
2002. So it was actually around the time as well that the EU was in the midst of discussions about introductions of DTCA as well. It certainly added to the base of existing research evidence in terms of what are the effects of this advertising. And so in February 2002 we were late in terms of publication of the final report to Health Canada several months beforehand but negotiated with them not to make it public until the BMJ report was coming out. So they were under pressure with Freedom of Information requests from PR companies and from I'm not sure from actually who in total made those information requests

So they were under a lot of pressure, and putting pressure on us to make the results public. We did get them to agree to have a launch at the same time as when the BMJ report came out which was what the journal wanted. So my project officer set up that we would have a tele-conference to plan the launch together. We sort of set up about 10 days before the tele-conference occurred and something happened between then and the tele-conference itself. Because instead of it being a planned joint launch between us and Health Canada and after all this was a contract with Health Canada, it was commissioned research. It was also unusual that they would also have a research project that would then be published in one of the major medical journals worldwide you would think that they would have been interested in promoting that. That tele-conference had a number of people on it who had no involvement in the project at all including people from the drug regulatory agency and including, their press and communications person – ok that made sense, but very much the message from the Health Canada side was this is your project you are the experts you release it to the press.

I would characterise the way that they dealt with it as damage control rather than as something that they were proudly releasing as an important new research project that they had published. So that was rather an interesting switch that had occurred and certainly wasn't what was being planned not even very long beforehand in terms of the conversations that my project officer and I had had, who was very keen to make sure we planned this launch jointly. What happened then, so the project in fact was funded by another arm of the federal government in that my PhD fellowship was being funded by the Canadian Institutes of Health Research. They put a big splash

about this research project on their home page and their press and communications people were involved in promoting it as a project that they had funded. Which they had partially funded it but it was certainly dealt with in a very unusual way by Health Canada. My interpretation is that they found the results politically inconvenient.

What was the worst thing that happened to you? I mean having a PR conference where they tried to help control the issues is not too bad really?
I guess I see it as indicative. So this was in 2002. In 2004 there was a parliamentary enquiry, the Parliamentary Standing Committee on Health, 2003 or 2004 carried out an enquiry on pharmaceutical policy including DTCA.

One of the members of that committee, the health critic for the NDP which is the left wing party in Canada, put a number of questions to Health Canada as part of that enquiry including questions about the results of my study which certainly raised some concerns in terms of appropriateness of prescribing in response to patient requests to advertised medicines. Why then were they continuing to pursue a policy to introduce DTCA? This was among a set of 25 questions or so that went to Health Canada that were part of the whole process of enquiry.

The response was interesting. The response on my study had nothing positive to say in terms of anything of use to policy development. And just raised some critiques - like it was only in one setting, that it wasn't national, that the sample had tended to be higher socio-economic status, which was the case. There were actually people of all socio-economic status involved in both settings but there was a bias towards higher socio-economic status. Also that it had not directly looked at health outcomes so it wasn't a definitive study. So raising methodological concerns. Fine.

There was nothing about useful that had come out of the research. And then there was a statement about the need for unbiased research on the effects of DTCA. I certainly saw that as problematic in terms of how the department was dealing with the research, that I believe had something useful to add to the whole range of research evidence on the effects of direct to consumer advertising. That was the only empirical research in a Canadian setting.

The other thing that happened in the meantime has to do with this court case. The other thing that has happened to me that perhaps has some other sides is that as part of this research I carried out an opinion survey- a Kegan Forman survey in Canada as well as in NZ and US - of people in different sectors that were effected by DTCA including the pharmaceutical industry and including the advertising industry association, so it was a faxed survey. I received a response from Rx&D which is the brand name industry association in Canada, as well as everyone else. Fine I mean the survey is published now.

Several months later I was in Ottawa and heard that a letter had gone from Rx&D to the assistant deputy minister of health responsible complaining that I was responsible for this survey. So I submitted a Freedom of Information request and received a copy of the letter and I also received a copy of the response from Health Canada. The letter referred to me as a graduate student with a BA in Geography, which was my status, which went on to question why Health Canada would have given me responsibility for co-ordinating this study and referred to my previous writing as being far from academic and boarding on pamphleteering. And then went onto critique the research centre that I was associated with because they had invited an ex Health Canada regulator who had quit because of safety concerns and had spoken at a conference, and then querying why carry out research on DTCA anyway because everyone knows it's positive. And so I think you could say that kind of letter to

government in a way is laughable. But perhaps it does have a sort of signal effect in terms of saying well don't give contracts to these people in future.

What about the Canwest case? How did that come about?
So Canwest. If you look at the whole trajectory, the move to introduce direct to consumer advertising in Canada, we had a very I would say rather bad supreme court decision on tobacco advertising in 1995 where a judge stuck down a law prohibiting advertising of cigarettes on the basis that Health Canada had not shown that a full ban on advertising of tobacco was going to meet it's public health objectives to a greater extent than a partial ban. This was divided; it was a 5 to 4 supreme court decision but very relevant in the sense that in the consultations that had occurred in 1996 Merck had argued in their submission that the law banning DTCA of pharmaceuticals would similarly not stand up to a charter of rights and freedom of expression challenge.

When I had meetings with people from Health Canada over the decade afterwards and I have had many meetings in which I've raised concerns about the inadequacy of the enforcement of the law. And some shifts in administrative policy that have introduced reminder advertising on television in Canada, so ads where you have men dancing to *'We Are The Champions'* and then a big Viagra thing at the end saying 'Ask your doctor'.

Whenever I've raised questions about this enforcement or the other kind of non enforcement - which is that we have US media streaming over our border in satellite and cable television and in magazines that are sold in newsstand in Canada that have advertisements that are illegal in Canada but as long as they are produced in the US the regulator turns a blind eye. The issue that's always been raised is that if the law is challenged there was a legal opinion I believe internally that it would not stand up. I don't know whether there was a legal opinion or – I shouldn't say that. That's a conjecture that nobody has ever said to me. But that concern as well about the law came up and no pharmaceutical company has brought a case forward but a media company did in December 2005. The final hearings of which were due to occur in mid June, so just a month ago and they pulled out just days beforehand and requested a temporary adjournment because of financial insolvency. They are the major media company in Canada. We have a real problem with media concentration. They own about 60% of print media in Canada and they have been the brink of bankruptcy since about January or February, so nothing new occurred in June in terms of the bankruptcy but that case has been sort of adjourned.