

*Drugs, Devices
and Women's Health:
Advocating for Protection*

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Women and Health Protection

Halifax

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mini **SUCCESSES**

- The DTCA Charter Challenge
- HC 2005 breast implant hearings
- Women and statins

Serafem



~~mood~~ swing

Think it's PMS? Think again.

It could be PMDD.
Premenstrual Dysphoric Disorder — the intense mood and physical symptoms right before your period. If extreme monthly irritability, mood swings and bloating are messing with your life, now there's help. Introducing Serafem — the first and only FDA-approved prescription medication for PMDD. To learn more about PMDD, visit Serafem.com or call 1-800-585-7898.

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Serafem
fluoxetine hydrochloride

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Important Safety Information — If you develop a rash or hives while taking Serafem, call your doctor right away because this can be a sign of a serious medical condition. You should not take Serafem at the same time as or within two weeks of stopping an MAO inhibitor (MAOI). Don't take an MAOI for at least 5 weeks after stopping Serafem. Also, you should not take thioridazine at the same time as or within 5 weeks of stopping Serafem. Some women may experience side effects such as tiredness, upset stomach, nervousness, dizziness and difficulty concentrating. Side effects are usually mild and tend to go away within a few weeks. Serafem contains fluoxetine hydrochloride, the same active ingredient found in Prozac®. Be sure to tell your doctor if you are pregnant or nursing or planning on becoming pregnant. Please see the following page for additional product information.

 Lilly

Diane-35



Alesse subway



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YouTube

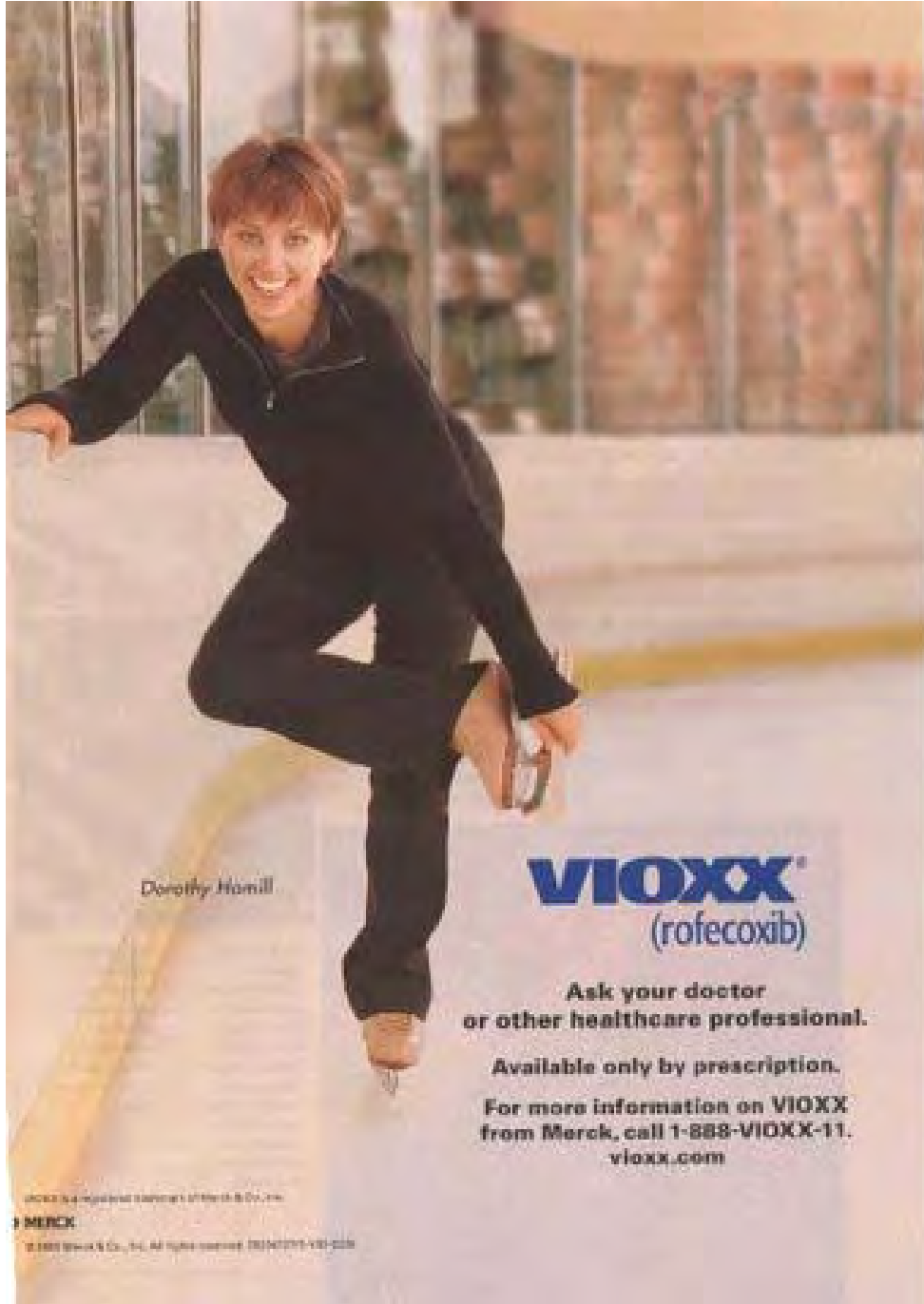
“Elevator Ads Saga”

DTCA in Canada

- 1975 - name, price and quantity
- Led to extensive “reminder ads”
- States brand name but makes no direct health claims
- Suggests “ask your doctor”
- WHP: multiple reminders to enforce the law

Issues for Women

- frequently targetted to women
- lead to unnecessary prescribing - promote single drug solutions when less harmful and more cost effective solutions might be better
- encourage use of on-patent drugs that are taxing drug benefits plans excessively
- minimize risks, exaggerate benefits or promote off-label uses (e.g. Vioxx and HRT heavily promoted, both later found to be problematic)



Dorothy Hamill

VIOXX[®]
(rofecoxib)

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or other healthcare professional.**

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CanWest Charter Challenge

- December 2005
- "an unjustified infringement of the company's freedom of expression, as guaranteed under Section 2(b) of Canada's Charter of Rights"

Federal response

- justified under section 1 of the Charter because of the potential risks and harm associated with DTCA

Intervenor Status

- WHP
- CUPE
- Comm'n, Energy & Paperworkers' Union
- Cdn Health Coalition
- Cdn Fed'n Nurses Unions
- Medical ReformGroup
- Society for Diabetic Rights
- Drug Safety Canada

Our Arguments

- “Do the rights of the corporate “person” trump the public’s right to health and safety, especially those individuals who are most vulnerable?”
- A question of stronger enforcement

www.whp-apsf.ca

Public Forum on Silicone Gel Breast Implants

- September 2005
- Response to filing for re-consideration by 2 mfgrs: Inamed & Mentor
- 1992 moratorium
- Special dispensation in legislation relating to Medical Devices

Use at time of hearings

- roughly 200,000 women in Canada
 - 80% for cosmetic breast augmentation
 - 20% for cosmetic reconstruction after mastectomy or to correct under- or non-developed breasts

Problems

- Tweed, A. “Health Care Utilization Among Women Who Have Undergone Breast Implant Surgery” BCCEWH, 2003
- more than half reported at least one additional implant-related surgery
- women with implants used more medical services than comparable women without implants

Problems (2)

- break and can leak to breasts, lungs, and lymph nodes (long-term risk of leakage still unknown)
- still without long-term safety studies (min of 10 years required)
- suspicion of link between silicone and connective tissue and auto-immune disease
- increase in suicides among women with breast implants

Expert Advisory Panel

- day before public forum 4 panel members found to have served as expert witnesses in support of Health Canada in litigation launched against the gov't
- not part of their CofI declaration

Implants Approved

- October 2007
- Class IV licence with conditions
- Voluntary registry

Small Success

- "...to advise the Expert Advisory Panel (EAP) of any relationships, interests, affiliations (financial or non-financial), that you may have with any organization likely to be affected by the outcome of the EAP meeting. An example of this information would be payment for your travel, accommodation or other expenses in connection with your attendance at this meeting"

Women and statins

- Lipitor most widely prescribed drug in Canada
- No gold standard study done on statin use in women: evidence based on studies and use in men

Which would you rather have, a **cholesterol** test or a final exam?

For many, the first sign of heart disease is a heart attack. Did you know that one out of two adult Canadians is at risk of developing heart disease because they have high cholesterol?

And that cardiovascular disease is the leading cause of death in Canada?

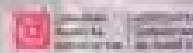
High cholesterol is a major risk factor for heart disease but managing your cholesterol can be quite simple.

If any of these apply to you, cut this scissor line out and ask your doctor about getting your cholesterol tested.

- Women 65 years or older
- Men 65 years or older
- Heart disease (angina, heart attack, coronary bypass, stroke, angioplasty)
- Diabetes
- Family history (mother, father, sister, brother or grandparent) of heart disease or high cholesterol
- Two or more of the following:
 - Overweight
 - Physically inactive
 - Smoker
 - High blood pressure



Call toll-free at 1-877-4-LOW-LOL (1-877-456-9533) or visit www.makingtheconnection.ca and you will receive this free booklet describing the connection between cholesterol and heart disease.



Making the Connection



www.makingtheconnection.ca

Statin use in Canada

- 2005 (6 Cdn provinces) - over 7 million prescriptions for statins dispensed for women aged 15 to 76 (and older)
- of those, 285,420 to women aged 15 to 45, i.e. women of child-bearing age

Women and statins

- Poor evidence in the literature of value to women in this age group (Wright and Abramson, 2007)
- Emerging data on problems with concomitant use of statins and OCs
- Emerging data on birth defects and statin usage
- may increase the risk for rhabdomyolysis (muscle disorder)

Heart disease and women

- Biggest killer... *but only when women reach their 80s*
- Cholesterol hypothesis of heart disease in question
- Inflammation may be a bigger factor in women