

# Direct-to-Consumer Advertising of Prescription Drugs

Barbara Mintzes

National Roundtable on Proposed changes to  
Canada's health protection legislation  
Safety Last: Ottawa January 28, 2004



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## Background: experience with DTCA

- Legal in 2 countries: the US and New Zealand
- First US ads in early 1980s; NZ more recent
- 1997: US relaxes broadcast ad regulations
- Pressure for legalization in many countries
- Oct 2002; European Union defeats proposal for pilot project for AIDS, asthma & diabetes drugs
- Dec 2003: New Zealand announces likely ban
- 1996-2004: repeated proposals for introduction in Canada



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## What does the law say?

### Food & Drugs Act

- Prescription-only drugs may not be advertised to the public
  - Limited exception in 1978 to allow price advertising: only name, price & quantity
- Companies may not advertise products to the public for prevention or treatment of listed serious diseases
  - ‘Schedule A’ diseases



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## Rationale for prohibition of DTCA

- Prescription-only status: manufacturers may not sell or advertise directly to public
  - More toxic and/or less well understood toxicity
  - Condition not easily self-managed
- Greater vulnerability of seriously ill
  - Medical treatment or consumer product?



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«...the limitations and prohibitions imposed are intended to minimize the risks to the general public associated with the use of drug products. »

-Valerie Robertson, Advertising Coordinator,  
Health Canada, October 1995



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## Health Canada policy paper November 2000

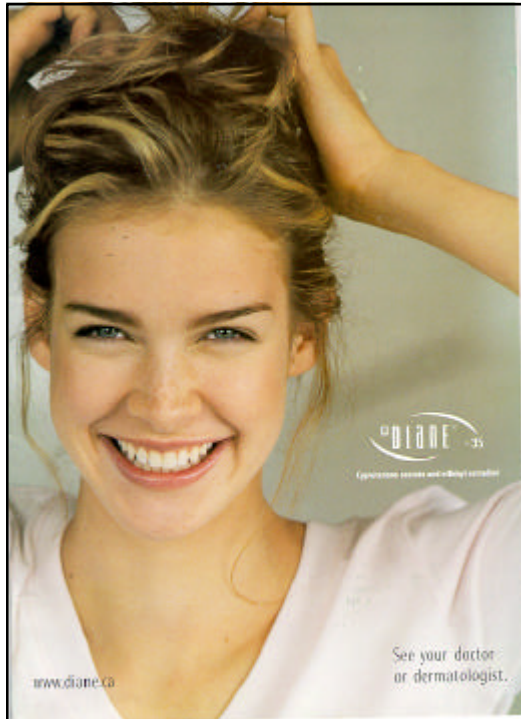
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### *In advertising campaigns:*

- Manufacturers may say drug name, but not indication (approved use)
- Or disease, but not name
- Justification? 1978 price advertising clause
- Neither in keeping with the spirit nor the wording of the law



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## Is this just 'name, price and quantity'?

- Diane-35 is only approved for severe acne in women who have not responded to other treatments.
- Safety advisories sent out by UK, New Zealand, Australian and Canadian governments – higher risks of potentially fatal blood clots.
- At least 6 deaths reported in Canada in which Diane-35 was the suspected cause.

## A powerful lobby for change:

"Advertising medication would ultimately, and most importantly, give the Canadian consumer a choice. Canadians would be empowered to take charge of their health like never before."

- Rx & D [[www.canadapharma.com](http://www.canadapharma.com)]



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## Arguments for allowing DTCA

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- Ads provide needed information on medicines
- Better doctor/patient communication
- People with undiagnosed diseases seek health care sooner, leading to health benefits
- Ads lead to better compliance
- A doctor's prescription is needed, so the patient is protected.



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## Why not allow DTCA?

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- Ads aim to stimulate sales; they cannot provide impartial, objective information
- Unsustainable increases in drug costs – threat to public health care
- Unnecessary & inappropriate drug use
- Pressure on doctors, and harm to the doctor/patient relationship



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## What do and don't we know?

### There is evidence on:

- Industry spending, type of product, DTCA content & quality, effects on drug costs
- Public awareness of DTCA & drug requests
- Effects on prescribing decisions

### No reliable evidence on:

- Effects on compliance (taking drugs as directed), hospitalizations, total health care
- Whether ads help people get needed treatment earlier



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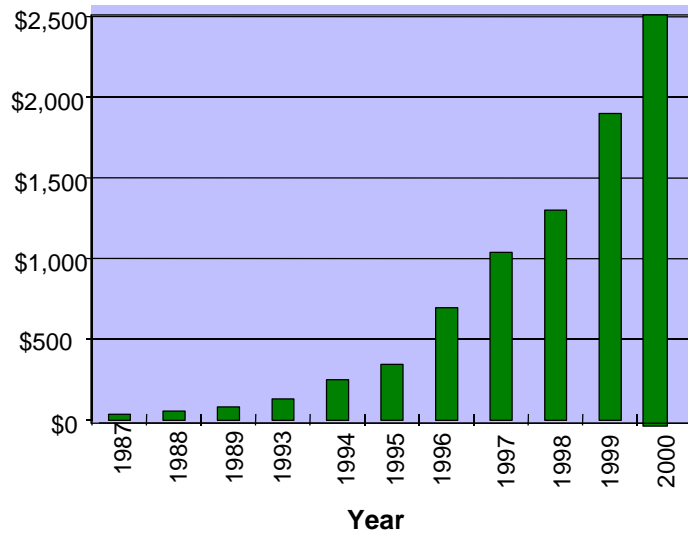
**Does DTCA affect  
drug sales and costs?**

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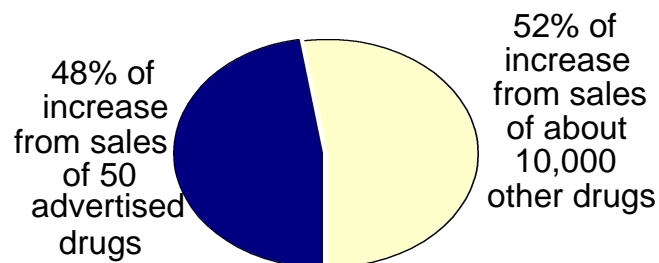
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## The United States: Spending on DTCA in US \$ Millions



## Effects on Retail Drug Costs

Increase in US retail drug costs 1999-2000  
US \$20.8 billion (Total = \$131.9 billion)

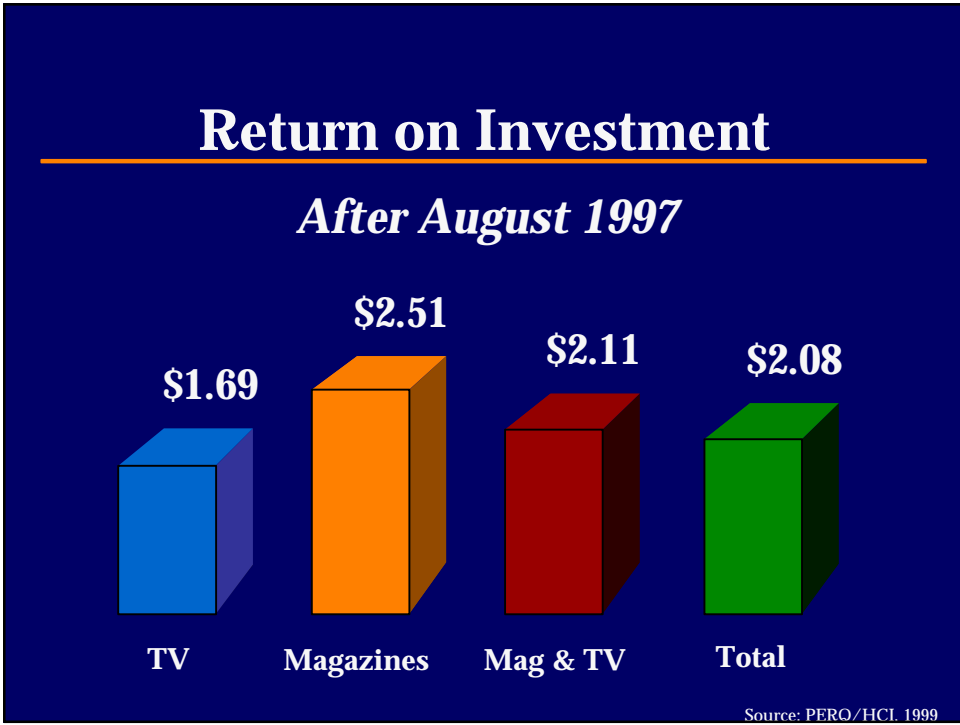
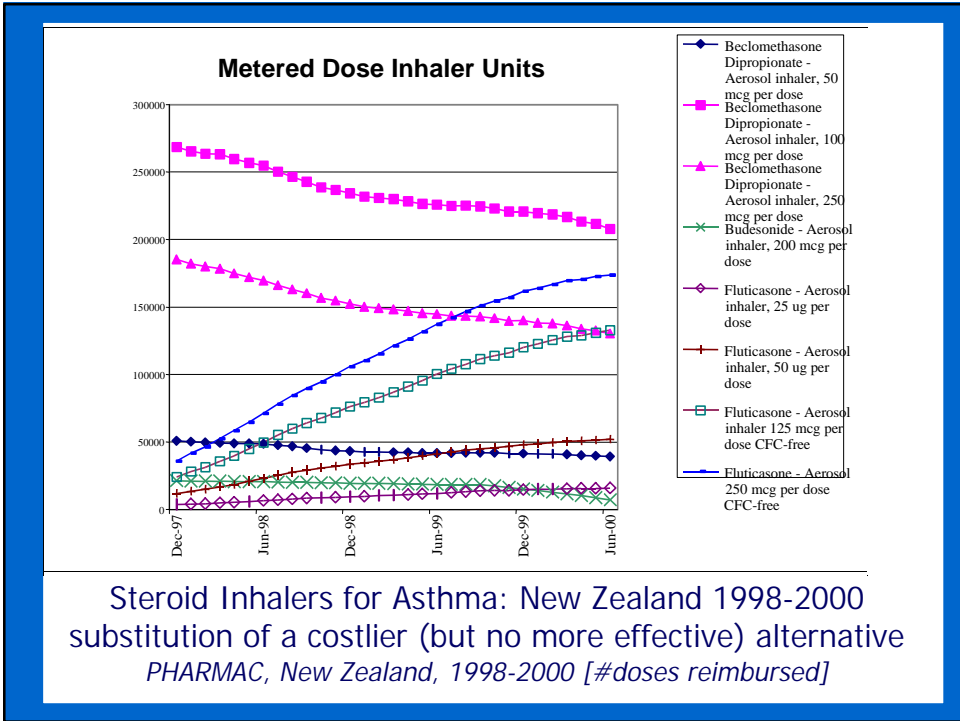


US National Institutes of Health Care Management

[www.nihcm.org](http://www.nihcm.org)



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## Does DTCA educate and inform patients and the public?

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## What products are being advertised, for which health conditions?

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- Nearly half of spending/year on 10 brands
- Most medicines are NOT advertised to the public
- New, expensive drugs, for long-term use
- Target large patient populations
- Morais: when is a DTC campaign worth pursuing?

Number of users X persuadable percent  
X percent of doctors prescribing X value  
per patient (duration of use x price)

## Educational value of print DTCA

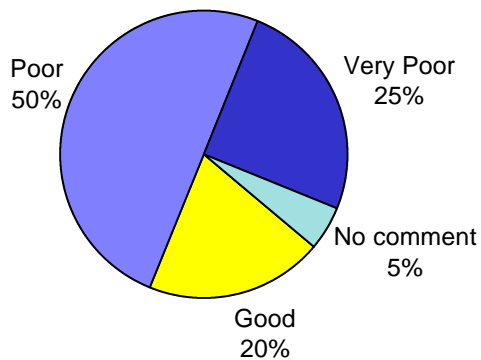
**320 prescription drug ads from 1989-1998,  
in 18 major US magazines**

<i>Does the ad say?</i>	<i>No, not said</i>
The likelihood of treatment success	91%
How long a person needs to take the drug	89%
Other helpful activities like exercise or diet	76%
Any other possible treatments	71%
How the drug works	64%

*Robert Bell and colleagues, 2000*

What do Canadian drug policy experts think?  
Feb 2001 survey, n=60 (76% response rate)

### DTCA Information Quality on Drug Benefits and Risks



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

If any of these apply to you, talk to your doctor about having your cholesterol tested:

- Women 65 years or older
- Men 65 years or older
- Heart disease (angina, heart attack, coronary bypass, stents, 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

For many, the first sign of heart disease is a heart attack. Did you know that one out of five adult Canadians 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. Not managing your cholesterol can be quite simple.

Call toll free at 1-877-6-LOW-LDL (1-877-456-9333) or visit [www.aalinktoconnection.ca](http://www.aalinktoconnection.ca) and you will receive this free booklet describing the connection between cholesterol and your heart disease.

OFFICE OF THE MEDICAL EXAMINER

Case No. 5341-36  
Name T.B.  
Date of Exam 10/10/02  
Age 52  
Sex M

Call toll free at 1-877-6-LOW-LDL (1-877-456-9333) or visit [www.aalinktoconnection.ca](http://www.aalinktoconnection.ca)


A Link to Connection  
[www.aalinktoconnection.ca](http://www.aalinktoconnection.ca)

...“the information used contained misleading statements and omissions likely to cause medically unjustifiable drug use or to give rise to undue risks.” *J. Quick et al., Dept of Essential Drugs and Medicines Policy, W.H.O. Lancet Aug 30, 2003*

## US DTCA Information Quality

### Regulatory violations frequent


- 17 of 33 (52%) 1998 US TV ads violated US regulations
- 1997-mid 2001; 48 broadcast, 46 print ads violated US law
- Key reasons: inadequate risk information, exaggerated benefits, unapproved uses.
- Repeat violations common: Claritin(loratadine) 11x; Flonase/Flovent(fluticasone)14 x; Lipitor 4x



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**If you're HIV+ ...**

**CRIVIAN may help you live a longer, healthier life.**



CRIVIAN is a potent inhibitor that stops HIV. CRIVIAN can help reduce the chance of illness and death associated with HIV. CRIVIAN can also help lower the chance of HIV to sexually related "hard-to-get" one-year STD/STI count. Some patients may not experience these effects. CRIVIAN is not a cure for HIV or AIDS.

- **New NIH research showed people taking CRIVIAN in triple therapy lived longer and experienced lower opportunistic infections.**  
Recent year-long research conducted by the National Institutes of Health (National AIDS Clinical Trial Group) showed that people taking CRIVIAN along with ZIDV and AZT achieved a reduction in deaths and AIDS-related illnesses over those taking ZIDV and AZT alone. This reduction was significant enough for the NIH to recommend the study be repeated. Most of participants could benefit from the findings. Because the study was ended early there was insufficient data to determine the statistical impact of CRIVIAN on survival.
- **CRIVIAN in triple therapy continues to hold serum viral load down below the level of detection in 84% each year.**  
In a 100-week, ongoing landmark study over 90% of over 30 patients receiving CRIVIAN, AZT, and ZIDV achieved their HIV status level of viral load below the level of detection after 24 weeks. 84% maintained or improved their HIV viral load level below the level of detection after 96 weeks. The lowest number of patients who chose to stop with the study for longer periods of time maintained these results through the one-year mark.
- **CRIVIAN is generally well tolerated.**  
CRIVIAN can be taken with a light meal or on an empty stomach. There are side effects associated with previous medications. In general, CRIVIAN is well tolerated. Some patients treated with CRIVIAN may develop kidney stones. For some, this can lead to more severe kidney problems including kidney failure. Drinking or using a glass of water each day may reduce the chance of forming a kidney stone. Other side effects reported include upset stomach and muscle pain and liver problems. There are some common medications and AIDS-related medications that should not be taken with CRIVIAN. Changes of medication may be taking or given to you while you are taking. As with other protease inhibitors, increasing levels of liver enzymes with abnormal and elevated blood sugar levels or diabetes have been reported. Please read the following page for detailed information on side effects and drug.

Please read the following page for more detailed information about CRIVIAN.

Remember to ask your doctor about CRIVIAN.

**CRIVIAN**  
Atripla

Going the distance.

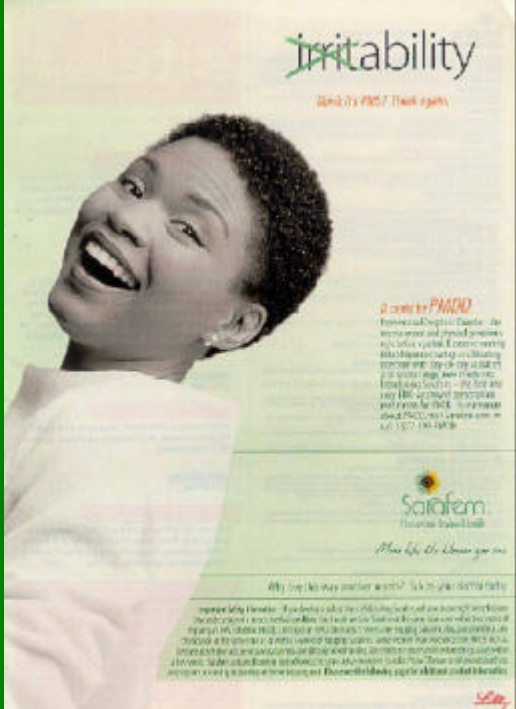
**UNREALISTIC IMAGES OF TREATMENT SUCCESS**

*San Francisco public Health Dept, 2001*

- Those who had seen more ads for HIV/AIDS drugs were less likely to practice safe sex
- US FDA told companies to stop using unrealistic images to sell drugs.

**Normal life or an indication for drug treatment?**

**irritability**  
It's not just PMDD. It's a sign.




**It could be PMDD**  
Premenstrual Dysphoric Disorder (PMDD) is a serious and painful condition that affects women's lives. It's not just irritability. It's a sign of a serious condition that can affect your life. It's not just irritability. It's a sign of a serious condition that can affect your life. It's not just irritability. It's a sign of a serious condition that can affect your life.

**Sarafem**  
Fluoxetine (Prozac)

More life. Or, when you're...  
Why they let you smile in the first place? Talk to your doctor today.

Remember, Sarafem is a prescription drug. It's not a cure. It's a sign of a serious condition that can affect your life. It's not just irritability. It's a sign of a serious condition that can affect your life. It's not just irritability. It's a sign of a serious condition that can affect your life.

My asthma? I'm on top of it.  
Once a day SINGLAIR.  
Helps control your asthma for a full 24 hours.



SINGLAIR is not a steroid. SINGLAIR is an asthma controller medicine that's proven to help control your asthma all night and day. SINGLAIR helps lower the levels of inflammation in your airways, which can mean less coughing, less wheezing and fewer asthma attacks. In clinical studies, an asthma attack was defined as an emergency room visit, a hospital admission, an intravenous corticosteroid, or a need for oral corticosteroids or intravenous corticosteroids. SINGLAIR has also been proven to help you sleep on nights you're asthmatic. So go ahead, take a bit of fun. But first, see your doctor about SINGLAIR.

**SINGLAIR should NOT be used for the immediate relief of asthma attacks.** You should still have rescue medication available at all times to take your other asthma medications unless your doctor tells you to stop. SINGLAIR should be taken once a day, in the evening as prescribed, whether or not you have asthma symptoms. If your symptoms get worse or you need to increase the use of your rescue inhaler, contact your doctor at once.

In clinical studies, side effects were generally similar to a sugar pill. They were usually mild – including headache, flu, and stomach pain – and generally did not stop people from taking SINGLAIR. Your doctor can provide a complete list of reported side effects for adults and children. Check with your doctor if you're pregnant or nursing.

SINGLAIR is available in a 10mg tablet for adults and a 5mg cherry or raspberry flavored for children 6 to 11. SINGLAIR may be taken with or without meals.

Ask your doctor about SINGLAIR, and call 1-888-787-7228 or visit our website at [www.singlair.com](http://www.singlair.com).

Effectively helps control asthma. **SINGLAIR** (MONTelukast Sodium)

**MSD**

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Please see the Patient Information for this medication on the adjacent page and discuss it with your doctor.

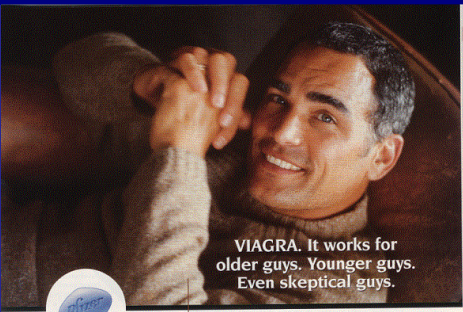
**“My asthma? I’m on top of it.”**

Independent evaluation:  
-not as effective as older standard treatment  
-“Average clinical effects are small and would be unlikely to be detectable by individual patients.”  
-[www.ti.ubc.ca](http://www.ti.ubc.ca)

Does DTCA affect  
prescribing decisions?



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**VIAGRA. It works for older guys. Younger guys. Even skeptical guys.**

Think you're too young for VIAGRA? Do you figure "it only happens once in a while, so I'll just live with it"? Then nothing's going to change, especially your sex life. See, erection difficulties, such as erectile dysfunction (ED), are a health condition. ED can be caused by many common factors, including smoking, stress, and high blood pressure. In fact, 1 out of 3 men of all ages have ED to some degree. Fortunately, VIAGRA can help men both get and keep an erection. Which is why **more than 9 million men** have turned to VIAGRA to treat their ED.

For more information, call 1-888-4VIAGRA or visit [www.viagra.com](http://www.viagra.com). VIAGRA has already helped many love lives. How can it help yours?

**VIAGRA**  
(sildenafil citrate) tablets


**Join the millions. Ask your doctor if a free sample is right for you.**

VIAGRA is indicated for the treatment of erectile dysfunction. Remember that no medicine is for everyone. If you use nitrate drugs, often used to control chest pain (also known as angina), don't take VIAGRA. This combination could cause your blood pressure to drop to an unsafe or life-threatening level. Discuss your general health status with your doctor to ensure that you are healthy enough to engage in sexual activity. If you experience chest pain, nausea, or any other discomforts during sex or an erection that lasts longer than 4 hours, seek immediate medical help. The most common side effects of VIAGRA are headache, facial flushing, and upset stomach. Less commonly bluish vision, blurred vision, or sensitivity to light may briefly occur.

©2003, the copyright owner(s) of information on VIAGRA. (21-Aug-03) 100 mg tablets on the following page.

For ads to translate into sales, patients must visit doctors and request prescriptions.

**“Join the millions. Ask your doctor if a free sample of Viagra is right for you.”**



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## Sacramento/Vancouver survey on prescribing in primary care

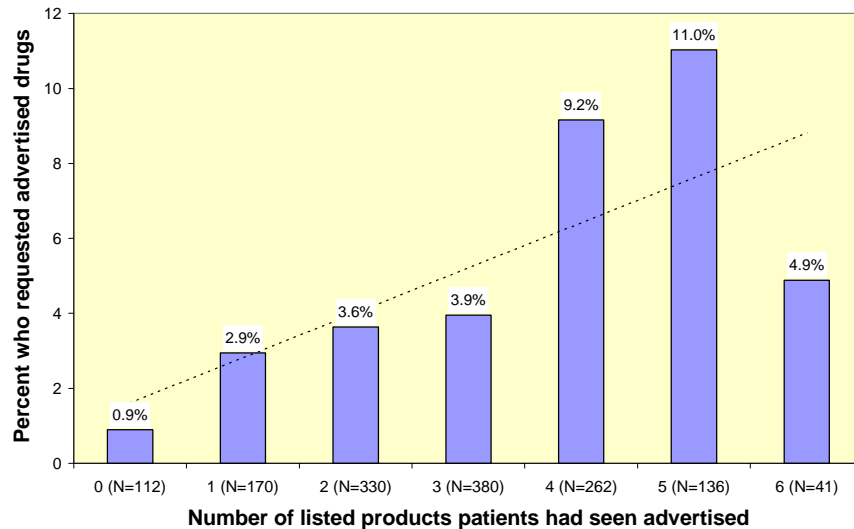
*(Mintzes et al, CMAJ 2003)*

- 1431 patients in 78 family doctors' offices; paired patient/doctor questionnaires
- In Sacramento: patients twice as likely to request an advertised brand
- Both cities: most (75%) who asked received Rx for the specific brand
- Doctors were ambivalent about the choice of treatment half the time.



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### Advertising exposure versus DTCA Drug Requests (n=1431, entire sample)



### US consumer surveys: DTCA works

- FDA survey, 2002: 1 in 14 asked for a specific brand; 70% received a prescription
- Over 8 million Americans/ year request a prescription for an advertised drug and receive it. – *US General Accounting Office, 2002*

### Misplaced faith in regulation:

- California survey, 43% --nearly half -- thought only **completely safe** medicines could be advertised – *Bell et al, 2000*





## ...Or how advertisers put it

"Today's patients are the new spokespeople for your brand. Their active voice influences the medications physicians prescribe and the profits you make."

- [www.HealthEd.com](http://www.HealthEd.com), 2002, NJ



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## A strong educational message

- In 1999, Americans saw an average of 9 TV ads per day
- Taken together the message is:
  - Whatever the problem, you can always pop a pill
  - You think you're healthy? You've got to be kidding.



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