

You say information, I say advertising...

Pharmaceutical policy in Europe

Barbara Mintzes and Teresa Alves
Health Action International (HAI Europe)
teresa@haiweb.org
bmintzes@chspr.ubc.ca

Ensuring independent medicines information in Europe
Brussels, October 2007



What this presentation covers

- Policy discussions in Europe
- Advertising or information: unbranded 'disease awareness' campaigns in Europe
- International experience with prescription drug advertising: a strong warning

Proposal for legislative change

- In 2002, the EU Commission proposed a pilot project to allow direct-to-consumer advertising in Europe for asthma, diabetes and AIDS drugs
- Rejected by the European Parliament
494 to 42
- Rejected again by the EU Council in 2003.

“This is not direct to consumer advertising. We are not introducing advertising for prescription drugs. What we want to do is, as a test case, with respect to three specific disease groups, is to make sure that validated and patient oriented information can be made available...”

– *Commissioner Erkki Liikanen, July 2001*

Memo 01/267 Reform of Pharmaceutical Legislation

Brussels, July 18, 2001

http://ec.europa.eu/enterprise/pharmaceuticals/review/doc/brief_m01_267_en.pdf

Better information

The Commission considered appropriate to abandon the strict prohibition of advertising of prescription-only medicines, since there is a growing interest and knowledge among the general public for information on medicinal products.

Proposed legislative change:

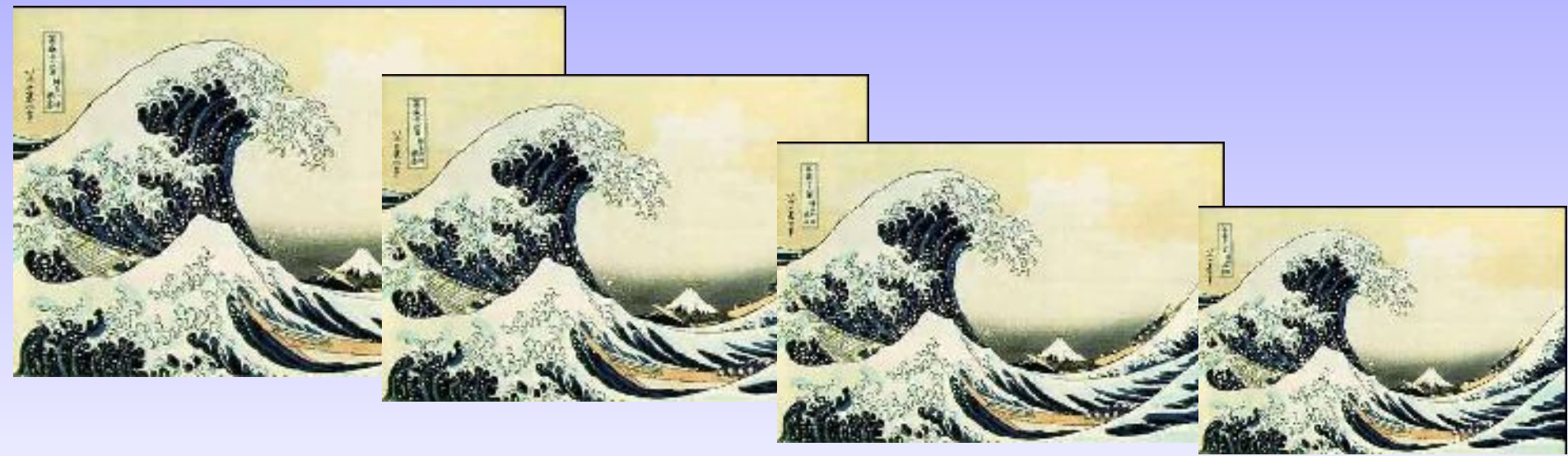
- “It is proposed that there should be public advertising of 3 classes of products...”
- Amendment to Article 88, which prohibits advertising of prescription drugs to the public;
- No explicit exclusion of any form of advertising, in any media.

“The industry and DG Enterprise have repeatedly tried to disguise this advertising effort as a way to inform patients about their medicines. However, the Parliament clearly saw the proposal’s actual intent and defeated it.”

– *HAI-Europe, Amsterdam, Oct 2002*



Fast forward to 2007



EU Pharmaceutical Forum

- A surrogate of G10
- Chaired by DG Health & Consumer and DG Enterprise & Industry
- Large representation from industry
- Remit: to address public health issues & review of pharmaceuticals
- Working group on information to patients

EU Pharmaceutical forum

Working Group on Information to Patients

- Draft information package on diabetes
- Set of principles on good quality information
- Key aim is to involve the industry in the provision of information within public private partnerships
- Consumers, health professionals, insurers unimpressed:
 - Diabetes draft of poor quality; no comparative information; no quantified harms or benefits;
 - Quality criteria inferior to existing published standards for consumer health information;
 - Failure to address conflicts of interest and bias.

Pharmaceutical Review 2004 DG Enterprise & DG Sanco Report on Patient Information Mandated by Parliament (Article 88)

“The focus should be on the availability and quality of information, and not its source,”... “the pharmaceutical industry has the potential to be an important source of information...”

- *Draft Report on Current Practice with regard to provision of information to patients on medicinal products*
<http://ec.europa.eu>

Déjà vu all over again?

“...after an unsystematic review of information for patients available in Europe... the report states that the available information is not sufficient for patients' needs, and it suggests that the information possessed by the producers could plug this gap...”

- *Magrini and Font, International Society of Independent Drug Bulletins, BMJ 2007; 335: 526*

**“Curiously, the document never mentions
direct to consumer advertising”**

- Magrini and Font BMJ 2007





Attempt to undermine European ban on advertising drugs fails in France

Ray Moynihan BYRON BAY, AUSTRALIA

A controversial proposal to have drug companies' "patient compliance" programmes declared legal in France has failed.

Critics described the proposal as a backdoor attempt to introduce into France direct to consumer drug advertising, which is currently banned throughout Europe, but is legal in the United States, where such advertisements are common (see above).

politicians, cite examples from the business press in which compliance programmes are clearly described as a way of increasing company revenue.

Pharmaceutical compliance: still DTC | direct to consumer | subsequent patient (www.pharmaceuticalnewjob: boost

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Special report
Medicine and health

Coming soon: the shopping channel run by drug firms

Sarah Boseley
 Monday May 21, 2007
[The Guardian](#)

Four of the world's biggest pharmaceutical companies are proposing to launch a television station to tell the public about their drugs, amid strenuous lobbying across Europe by the industry for an end to restrictions aimed at protecting patents. Pharma TV would be a dedicated interactive digital channel funded by the industry with health news and features but at its heart,

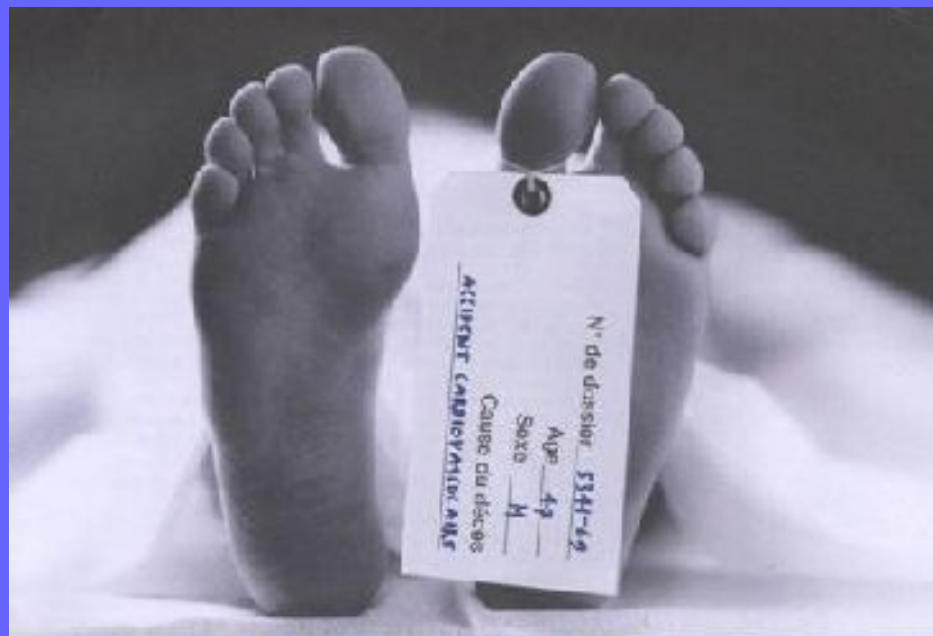
[Special report: consumer health](#)
[Medicine and health on trend stories](#)

What is prohibited under current EU regulations?

- Article 88 (a) prohibits **advertising** of prescription drugs to the public
- Article 86 (2) allows information on diseases, as long as there is no direct or indirect reference to a specific product

An international standard - WHO Ethical Criteria for Medicinal Drug Promotion

- Defines drug promotion as “all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase, and/or use of medicinal drugs.”
- Advertisements ... should not take undue advantage of people’s concern for their health
- Scientific and educational activities should not be deliberately used for promotional purposes.



Dire qu'un simple dosage de son **cholestérol** aurait pu lui éviter ça

Une crise cardiaque peut intervenir alors que l'on ne se croyait pas malade. On peut alors découvrir que l'on a, peut-être depuis des années, un excès de cholestérol dans le sang!

Saviez-vous qu'un excès de cholestérol peut provoquer des maladies cardiovasculaires? Et ce, car les sont la première cause de mortalité en France!

Faire doser régulièrement son taux de cholestérol est important, d'autant qu'il est relativement facile, aujourd'hui, de le faire baisser.

Des solutions existent, demandez conseil à votre médecin.

Si un ou plusieurs de ces points* vous concerne, il est temps de faire doser votre taux de cholestérol.

- Homme de plus de 45 ans
- Femme de plus de 55 ans ou ménopausée
- Antécédent familial de maladie cardiaque
- Tabagisme
- Diabète
- Hypertension
- Obésité

*Selon l'avis de l'Association Française de Cardiologie (AFC) et de l'Association Française d'Arteriosclérose et d'Hypertension Artérielle (AFAH).

POUR PLUS D'INFORMATIONS, CONTACTEZ-NOUS
N°Azur 0 810 761 741



Pfizer
 LA VIE, VOUS L'ORGANISEZ VOTRE-ÊTRE

Pfizer,
 France
 2003

...“the information used contained misleading statements and omissions likely to cause medically unjustifiable drug use or to give rise to undue risks.”

*Quick et al. World Health Organization
Lancet Aug 30, 2003*



prevention-**cardio**.com



Pfizer, France, 2006

GOOD HOUSEKEEPING PROMOTION

Look after your sex life

Don't let menopausal symptoms come between you and intimate moments

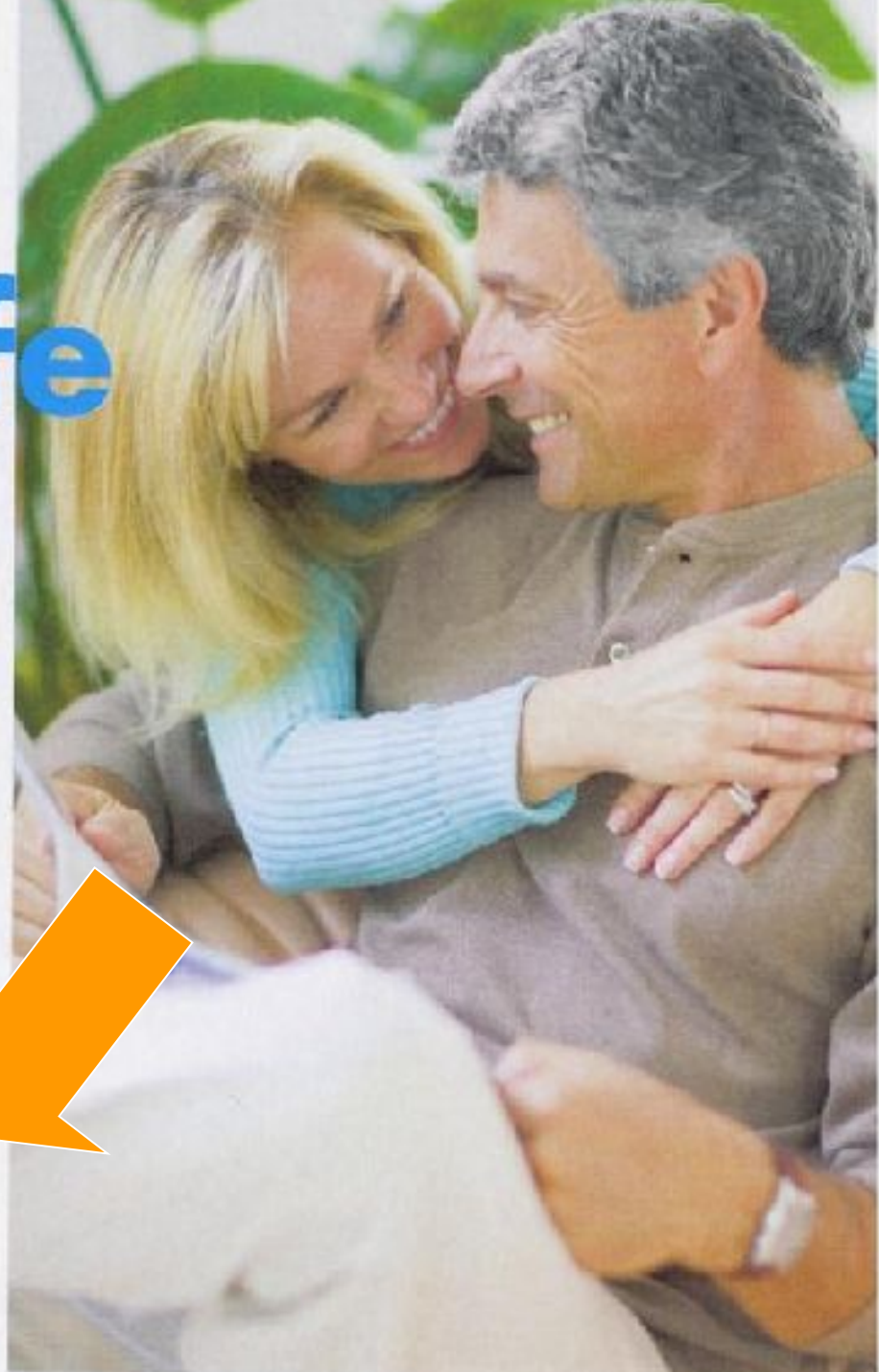
Many women are still reluctant to talk about how the menopause makes them feel – particularly if it's stopping them from having a loving, fulfilling relationship with their partner.

Fluctuating hormone levels around the menopause can lead to a number of problems. One that's remarkably common, though still something of a taboo subject, is vaginal atrophy – when a lack of oestrogen causes the vaginal lining to become thin, dry and tender – which can make sex painful.

In fact, half of all post-menopausal women will be

affected by vaginal atrophy, although only a few will seek help. Embarrassment, or not understanding what's causing the problem, stops some women from doing anything about it. But many more simply don't realise that vaginal atrophy is a medical condition that can be easily and quickly treated by your GP.

Local oestrogen therapy, where oestrogen is delivered directly to the vagina, can be extremely effective at relieving symptoms and is available in a number of different forms. So talk to your GP or visit menopause-secrets.co.uk for more information.



VARNING FÖR ALLERGI!



ATCHOO!



DRIP DROP



TÄPPA



SNIFF SNÖRVEL

Allergi kan leda till astma. Snerra, nästärpa eller röda, irriterade ögon kan vara allvarigare än du tror. Allergier kan också leda till dig kan leda till astma. Allergi kan också leda till sömnlöshet, smärta, dig trött och okoncentrerad under hela dagen. Många allergiker undervisar sig i sjukdomsfall. Kontakta därför din läkare för rätt diagnos och behandling.

TESTA DIG SJÄLV.
BESVÄRAS DU AV NÅGRA
AV DESSA SYMPTOM?

- DU HAR NÄSTÄPPA
- DIN NÄSA RINNER
- DINA ÖGON ÄR RÖDA
OCH IRRITERADE
- DU NYSER OFTA
- DU VAKNAR TÄPPY
- DU MÅSTE ANDAS
MED ÖPPEN MUN

TA MED DIG TESTET TILL
DIN LÄKARE FÖR RÄTT
ALLERGI-BEHANDLING.

allergi.nu

 Boehringer-Ingelheim

**BEWARE OF ALLERGY
ATCHOO DRIP DROP
STUFFY NOSE
SNIFFELY SNIFF**

**Allergy may lead to asthma.
Snotty nose, stuffy nose or red,
irritated eyes may be more
serious than you think. Allergy is
a disease that, in itself, may lead
to asthma**

Schering website: Menopause and Hormones

Accessed October 2, 2006

The screenshot shows the Schering website page for 'Menopause and Hormones'. The page features the Schering logo at the top left, navigation links for 'Menopause and Hormones', 'Prevention and Treatment', and 'Well-Being', and a header image of a woman with the text 'finding balance'. The main content area is titled 'Cardiovascular Disease' and includes a list of symptoms, a paragraph about the prevalence of cardiovascular disease in women, a detailed paragraph about atherosclerosis and thrombosis, and a section on 'Causes and Risks'.

SCHERING
we help medicine work

| Glosary | Contact | Sitemap |  

finding balance

| Menopause and Hormones | Prevention and Treatment | Well-Being

Cardiovascular Disease

- Irregular menstrual cycles
- Menopausal symptoms
- Vaginal dryness
- Urinary incontinence
- Depression
- Osteoporosis
- **Cardiovascular disease**
- Early detection of cancer
- Gynecological checkups

Diseases of the heart and the circulatory system are the most common cause of death in women over 45.

Atherosclerosis (hardening of the arteries) is considered the chief cause of cardiovascular disease. Deposits of fatty material (plaque) on the inside walls of the arteries cause narrowing and hardening which can impair the flow of blood to the tissues. Blood platelets (thrombocytes) can attach to the altered vascular wall and form a blood clot (thrombus). A thrombus can break away from its site of origin and be carried to other parts of the body by the bloodstreams. If it then becomes lodged in smaller vessels or at junctions between vessels the blood supply to vital organs can be cut off. Depending on the site of the obstruction a heart attack or stroke can occur.

Causes and Risks:

Women of childbearing age are largely protected from heart attack and stroke compared with men of the same age. This protection is attributed mainly to the estrogens. After menopause there is a steep increase in heart attacks in women. Estrogen deficiency is therefore considered an important risk factor for cardiovascular disease.



Heart attack risk and age

“Estrogen deficiency is therefore considered an important risk factor for cardiovascular disease.”

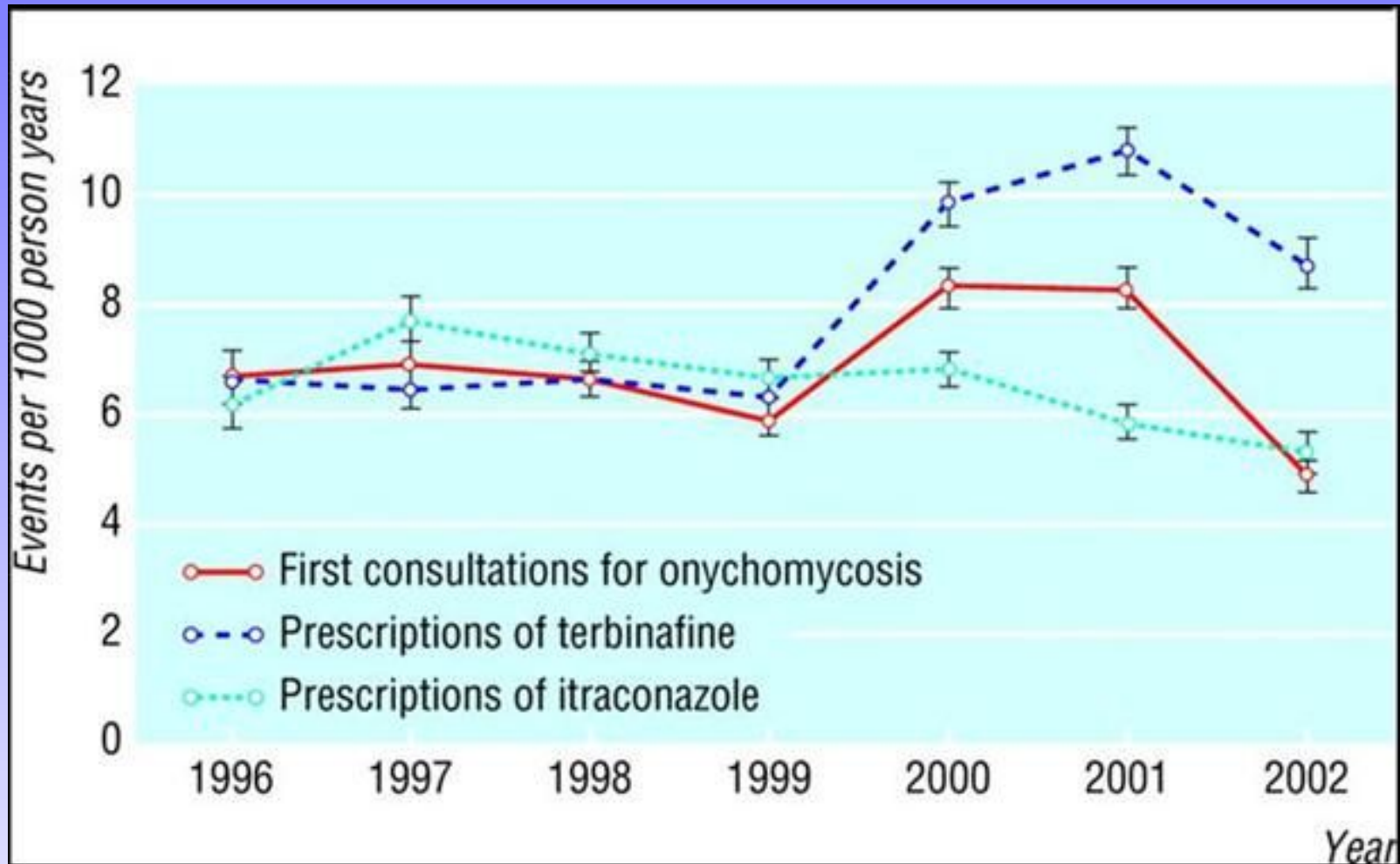
What is left unsaid: hormone therapy fails to protect against cardiovascular disease. Instead, it causes heart attacks, strokes and venous thromboembolism.

Many examples of unbranded pharmaceutical advertising

- “Disease-mongering” – expanded disease definitions in order to increase sales
- Inaccuracies about disease prevalence, risks, potential treatment benefits
- Failure to comply with standards in WHO Ethical Criteria
- Regulatory response is generally inadequate

NOVARTIS 'disease-awareness' TV ads, the Netherlands

Ethical Criteria definition of promotion: stimulates sales



- 't Jong GW et al. *British Medical Journal* 2004;328:931


Why be concerned?

Can prescription drug advertising lead to harm to health or sustainability of public health care?

DOROTHY HAMILL

VIOXX[®]
(rofecoxib)

Ask your doctor
or other healthcare professional about
prescription VIOXX from Merck.

 **MERCK**
VIOXX is a registered trademark of Merck & Co., Inc.
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For more information about VIOXX, call 1-888-VIOXX-11 or visit vioxx.com.

Vioxx (rofecoxib)

Images, celebrity
endorsements,
spoke louder than
words

VIOXX (rofecoxib): why was prescribing so widespread?

On the market from 1999 to 2004

- US spending on advertising \$550 million
- More than Pepsi-Cola in 2000 – same year as VIGOR trial published
- VIGOR trial: 4-5 times risk of heart attack
- No more effective than other anti-inflammatory drugs for arthritis
- Estimated 88,000-140,000 extra heart attacks in U.S., 40% fatal (Graham et al. *Lancet* 2005)

Estimated percent of Vioxx sales from DTCA

Based on year 2000 spending and sales data

DTCA spending in 2000 ¹	\$160 million
US Vioxx sales in 2000 ¹	\$1,518 million
Mean returns (ROI) per \$ invested ²	\$3.66
Estimated sales from DTCA (<i>DTCA spending x ROI</i>)	\$588.5 million
Estimated percent of total sales	39%
<i>Estimated no. of extra DTCA deaths</i>	<i>~17,800 ³</i>

1. Findlay S. 2001 www.nihcm.org

2. Gascoigne D. *DTC at the crossroads: a direct hit... or miss?* IMS Health 2004

3. 39% of estimated deaths in Graham D et al. *Lancet* 2005;365:475-81

Informed, empowered patients?

“Nearly 107 million prescriptions for rofecoxib [Vioxx] were dispensed in the US between 1999 and September 2004, when the drug was withdrawn from the market, and none of the people picking up those prescriptions had the opportunity to consider the true balance of its risks and benefits.”

– *Krumholz et al. BMJ 2007;334:120-123*

Peaceful, restful sleep.

Lunesta
eszopiclone
1, 2 AND 3 MG TABLETS

Discover Lunesta™, a sleep aid that can change your nights.

Even when your restless mind keeps you awake, Lunesta can give your body and mind the soothing sleep you need. Lunesta not only helps most people fall asleep fast, it helps you sleep all through the night. Peacefully, uninterrupted. Lunesta works quickly, so you should only take it right before bed. And Lunesta is non-narcotic, and approved for long-term use. Of course, do not use sleep medicines for extended periods without first talking to your doctor.

Now's the time to catch the sleep you need. If you've been hesitant to take a prescription sleep aid, be sure to ask your doctor about Lunesta.

Important Safety Information: Be sure you have at least eight hours to devote to sleep before becoming active. Until you know how you'll react to Lunesta, you should not drive or operate machinery. Do not use alcohol while taking Lunesta. All sleep medicines carry some risk of dependency. Side effects may include unpleasant taste, headache, drowsiness and dizziness. See important patient information on the next page.

Leave the rest to Lunesta

1-800-Lunesta www.lunesta.com

42 million US prescriptions for sleeping pills in 2005, 60% increase in 5 years. Why? Strong competition for market share

- Lunesta \$200 million
- Ambien CR \$100 million

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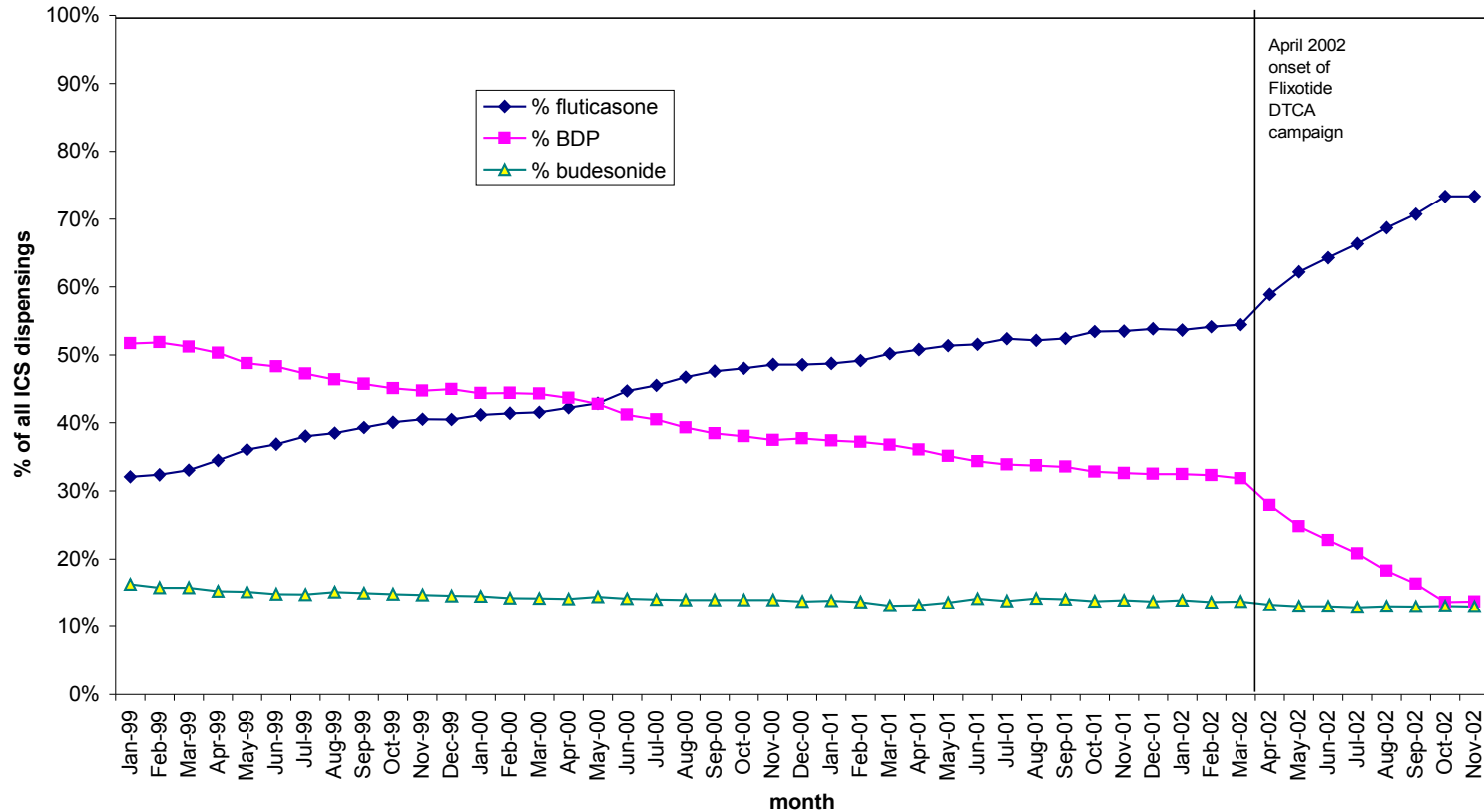
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Substitution of drugs that are more expensive but no better

Mix of ICS dispensings (each agent's proportion of total ICS dispensings), 01/1999 to 11/2002



New Zealand PHARMAC data, Toop et al, 2003

“The lesson from the New Zealand experience for Europe is clear. Pandora’s irresistible jar contained within it the misfortunes of mankind. Europe is staring at the lid of pharma’s jar and, once opened, hope enough will not be enough to undo the damage. Having seen what lies inside, Europe should find nothing in there to tempt it to take that risk. Allowing industry funded objective information will serve only to manipulate consumer choices.”

– *Toop and Mangin. BMJ 2007; 335: 694-695*



In Conclusion

Put public health and welfare first

- The public needs unbiased, accurate, comparative information on the pros and cons of all treatment choices, including the option not to treat – not disguised or undisguised advertising.
- Article 88 must remain intact and enforced.
- Industry has a clear role to play:
 - Improve quality of product information, packaging and patient information leaflets;
 - Full public disclosure of all pre- and post-market drug effectiveness and safety studies

Thank you

For more information, visit
www.haiweb.org