

The information to patients directive *déjà vu all over again*

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Relevant Health Information for Patients & Consumers
Public meeting, European Parliament, Brussels
2 December 2009



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EU Commission proposal 2001-2003

- Allow advertising of asthma, diabetes, AIDS drugs
- Stated rationale: information for patients
- Rejected by the EU Parliament: **494 to 42**
- Rejected again by the EU Council in 2003
- Mobilisation of civil society, health professionals
- Opposition from Member States



Why the 2001-2003 initiative?

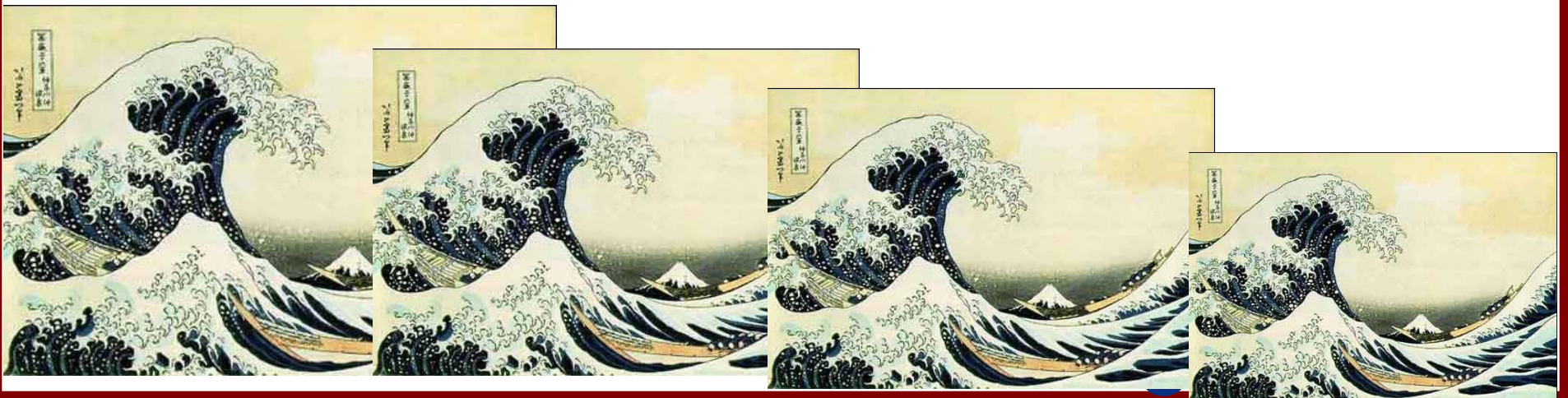
Described as patient information, but...

US had relaxed restrictions on direct-to-consumer advertising (DTCA) in late 1997

Spending increased rapidly; highly profitable

Intense pressure for deregulation elsewhere

First wave attempt at EU introduction



2008 to 2009

The second wave



Parliamentary request to report back

- Within 3 years of implementation of directive
- Commission report on current patient information
- Special attention to Internet
- Broad consultation requested – patients, doctors

Intentions?

- Focus on the Internet
- Compromise solution
- *Commission report strongly highlights industry*



What is being proposed?

- An amendment to EU legislation prohibiting prescription drug advertising to the public – Articles 86 and 88, Directive 2004/27/EC
- Article 88 states:
Member states shall prohibit the advertising to the general public of medicinal products which... are available on medical prescription only...



Proposed amendments

Exceptions to the ban on advertising:

- Approved product information – **already allowed**
- Medicines presented in context of a condition
- Information on measures to accompany drug use
- Cannot go beyond the elements of the approved labelling and public version of EPAR **but can state the information in a different way**
- Information on non-interventional studies



How would this be managed?

- No branded radio or TV ads permitted
- Specific media allowed
 - Internet websites
 - Health-related publications
- Stated information criteria
 - “must not contradict” approved labelling
- Pre-approval by national governments or equivalent but different mechanism



Effects of these changes?

Three forms of empirical evidence

1. EU “information” campaigns that stretch the limit of the law... and beyond
2. Canada – partial introduction since 2000, with pre-approval, consistency with label
3. U.S. and New Zealand experience with direct-to-consumer advertising



Medicines in a health context Pfizer, France



MAUVAISE NOUVELLE :
Cette femme vient d'apprendre qu'elle court un risque élevé d'accident cardiovasculaire.



BONNE NOUVELLE :
Maintenant, elle et son médecin vont pouvoir agir ensemble.

Les accidents cardiovasculaires ne préviennent pas, mais vous pouvez les prévenir. Chacun peut ainsi faire baisser sa probabilité d'accident en adoptant une bonne hygiène de vie, un régime alimentaire adapté et en suivant un traitement médicamenteux, si le médecin le préconise.
Les accidents cardiovasculaires sont le résultat de l'accumulation d'un ou plusieurs facteurs de risque*.

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

Brochure gratuite d'informations sur les facteurs de risque cardiovasculaire disponible au :

N°Azur 0 810 741 741
gratuit d'un appel local
www.prevention-cardio.com

La Fédération Française de Cardiologie, la Nouvelle Société Française d'Athérosclérose et Pfizer agissent ensemble pour favoriser la prévention des maladies cardiovasculaires.

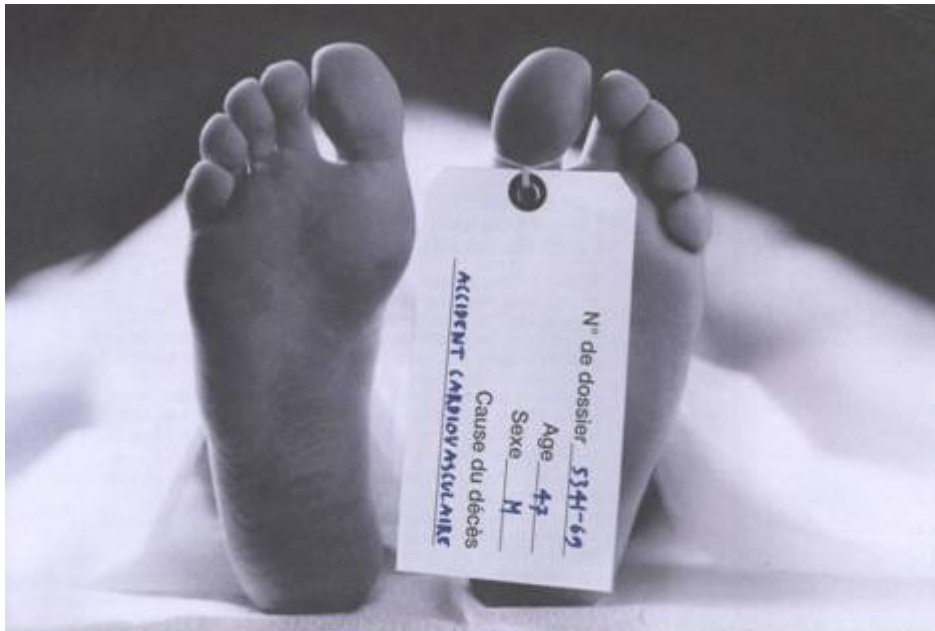
  

* Agence Nationale d'Accréditation et d'Évaluation en Santé (ANAES), Rapport d'octobre 2007 - Modalités de dépistage et diagnostic biologique des dyslipidémies en prévention primaire
Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS), Recommandations de santé publique (RSP) - Prise en charge thérapeutique des patients dyslipidémiques, Septembre 2005.

What is wrong with this message?

- Focus on cholesterol lowering because of Pfizer's cholesterol-lowering drug, Lipitor
- The image is of a healthy looking woman in early middle age, a low risk demographic
- In women without previous heart disease, benefits of statin use do not outweigh harm





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 qu'elles 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.

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

- Homme de plus de 45 ans
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* Agence Nationale d'Accréditation et d'Évaluation en Santé (ANAES)
Rapport d'octobre 2000: Modalités de dépistage et d'agnostics biologiques des dyslipidémies en prévention primaire.

Des solutions existent, demandez conseil à votre médecin.

POUR PLUS D'INFORMATIONS, CONTACTEZ LE :
N° Azur 0 810 741 741



LA VIE, NOUS Y CONÇUONS NOTRE VIE

...“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 2003



Medicines in 'health' context

Bayer, Ireland 2009

http://lustforlife.ie/ Loading... X Google

G... Deficiency UBC Card - ...cation Card http://eur-l...3:FIN:EN:PDF Newcastle Ot...iteria scale Internationa... Advertising Pharmacritique Pharma M

**OVER 40?
HAVE YOU LOST
YOUR LUST
FOR LIFE?**

Introduction

What is Testosterone Deficiency (TD)?

What is Testosterone?

What causes Testosterone Deficiency?

Treatment of Testosterone Deficiency

Conclusion

Could it be low testosterone?

Introduction

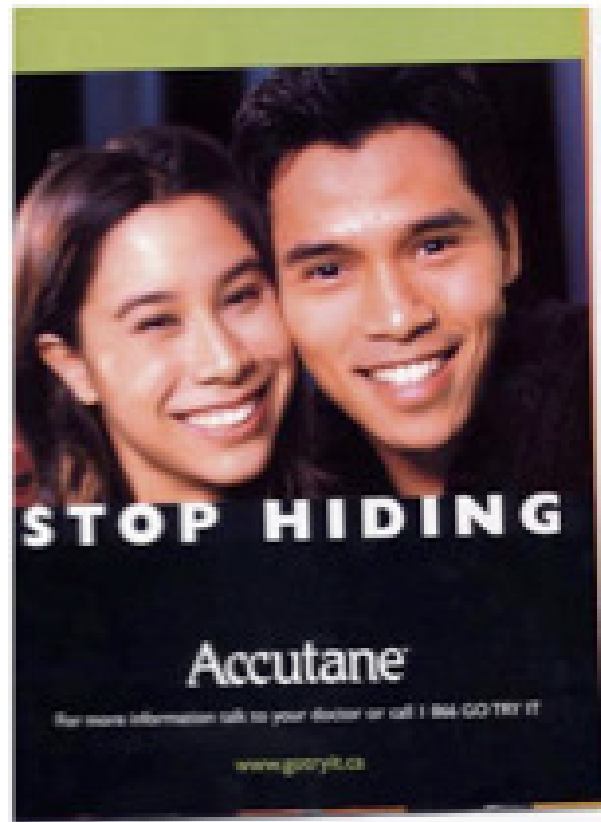
If you are aged 40 or more, you may have become aware of some changes in your physical appearance and general health such as increased weight gain, feeling depressed, disturbed sleep, loss of interest in sex. While most men will experience some of these symptoms during their life, if they are having a significant impact on you, then discuss these with your doctor. Testosterone Deficiency is one cause which may be considered.

What is wrong with this message?

- Disease awareness campaign or disease-mongering – testosterone for normal ageing
- Not an effective treatment for tiredness, weight gain, depression, sexual problems
- Increased risks of prostate cancer



Information that does not go beyond the approved product information Canada 2004



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What is wrong with this message?

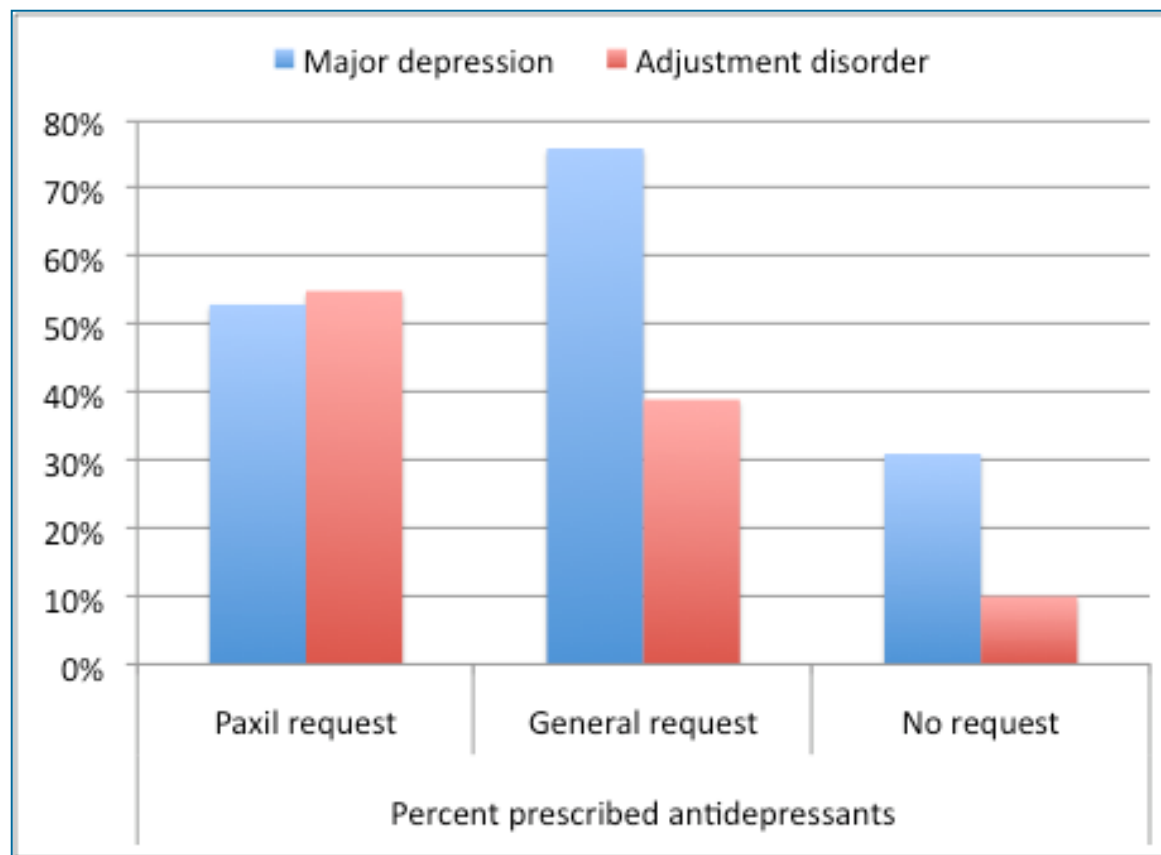
- Drug only approved for severe cystic acne
- Serious risks of birth defects
- Serious psychiatric risks
- A vulnerable population group

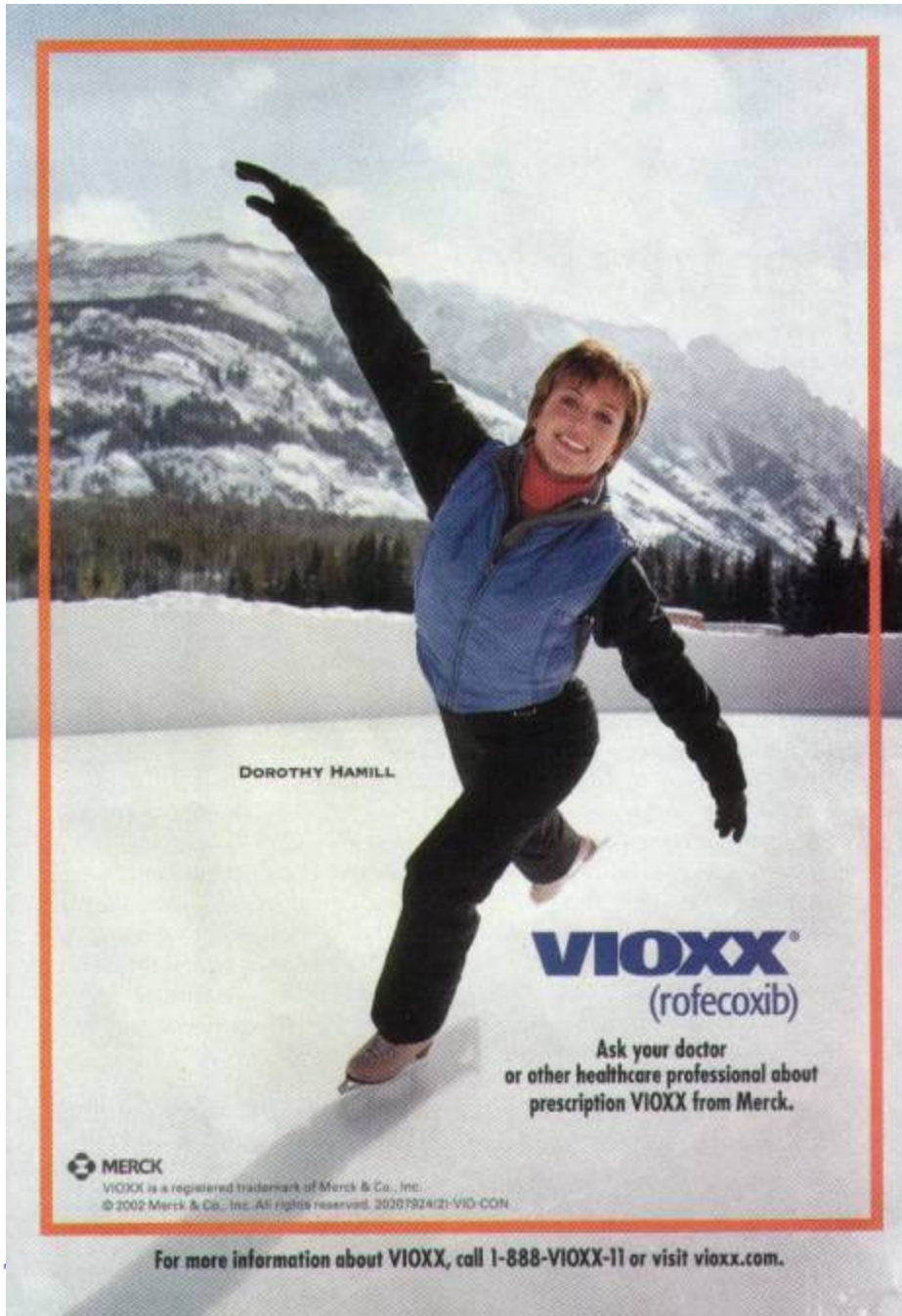


U.S. research evidence

Patient requests for advertised medicines can drive prescriptions for mild, unapproved uses –

Kravitz et al. JAMA 2005; 293(10):1995-2002





The U.S. experience widespread harm

**Vioxx (rofecoxib)
1999 to 2004**

**Among the most heavily
advertised medicines; no
effectiveness advantages
An estimated 40,000 to
60,000 deaths from heart
attacks**

- Graham et al Lancet 2005



In summary: no public health rationale

- Some communication previously called advertising would be defined as 'information'
- No evidence **direct** or **disguised** advertising promotes better health or quality of care
- Disease-mongering is common
- Marketing priorities drive product choice
- Pre-approval does not prevent misleading images or persuasive messages on drugs or diseases
- At risk: safety and sustainable health care costs



The patient information directive Advertising or information?



*A rose by any other name would
smell as sweet...*



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