

Patient, health care and pharmaceutical promotion – a critical inventory

Hans-Joachim Both

Neurologist, member of IPPNW group Berlin

mail adress : jboth@arcor.de

Declaration of my conflicts of interest : none

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Influence on public health“**

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“Modern” Types of Marketing

- Pharmaceutical sales representatives (PSR) & samples, gifts, sponsored continuing education
- Key physician „opinion leaders“
- Publication bias in journals, conflicts of interest
- Ghost-writing of journal articles
- Funding of patient groups, medical societies and even guidelines
- Observational non-interventional studies

New Medicines

- Are not necessarily better than existing treatment
- Tested on highly selected groups, most not on old and comorbid patients
- Over a short period, thus, rarely harmful effects not yet to be seen
- To be approved for marketing often compared with placebo, no need of advantage over existing therapies

New medicines and indications in France 1981 - 2004

Rating	Explanation	Number of new medicines or indications (%)
Bravo!	Major therapeutic advance	7 (0.2)
A real advance	Important therapeutic advance, with certain limitations	77 (3)
Offers an advantage	Some advantages, but not enough to fundamentally affect clinical practice	223 (7)
<i>Subtotal: Advantages over existing treatments</i>		<i>307 (10)</i>
Possibly helpful	Minimal advantages over existing treatments	467 (15)
Nothing new	No additional value	2,109 (68)
<i>Subtotal: Minimal to no advantage</i>		<i>2,576 (83)</i>
Judgment reserved	Inadequately documented safety and/or efficacy	126 (4)
Not acceptable	Real or potential disadvantages over existing therapies	87 (3)
<i>Subtotal: To be avoided - inadequately tested or worse clinical profile</i>		<i>213 (7)</i>
Total		3,096 (100)

La revue prescrire, 2005, Innovation en panne et prise de risques

Pharmaceutical Sales Representatives [PSR]

An estimated 15000 PSR pay 20 million visits to hospitals and private doctors every year amounting to estimated costs of approx. 2,5 billion €/year in Germany.

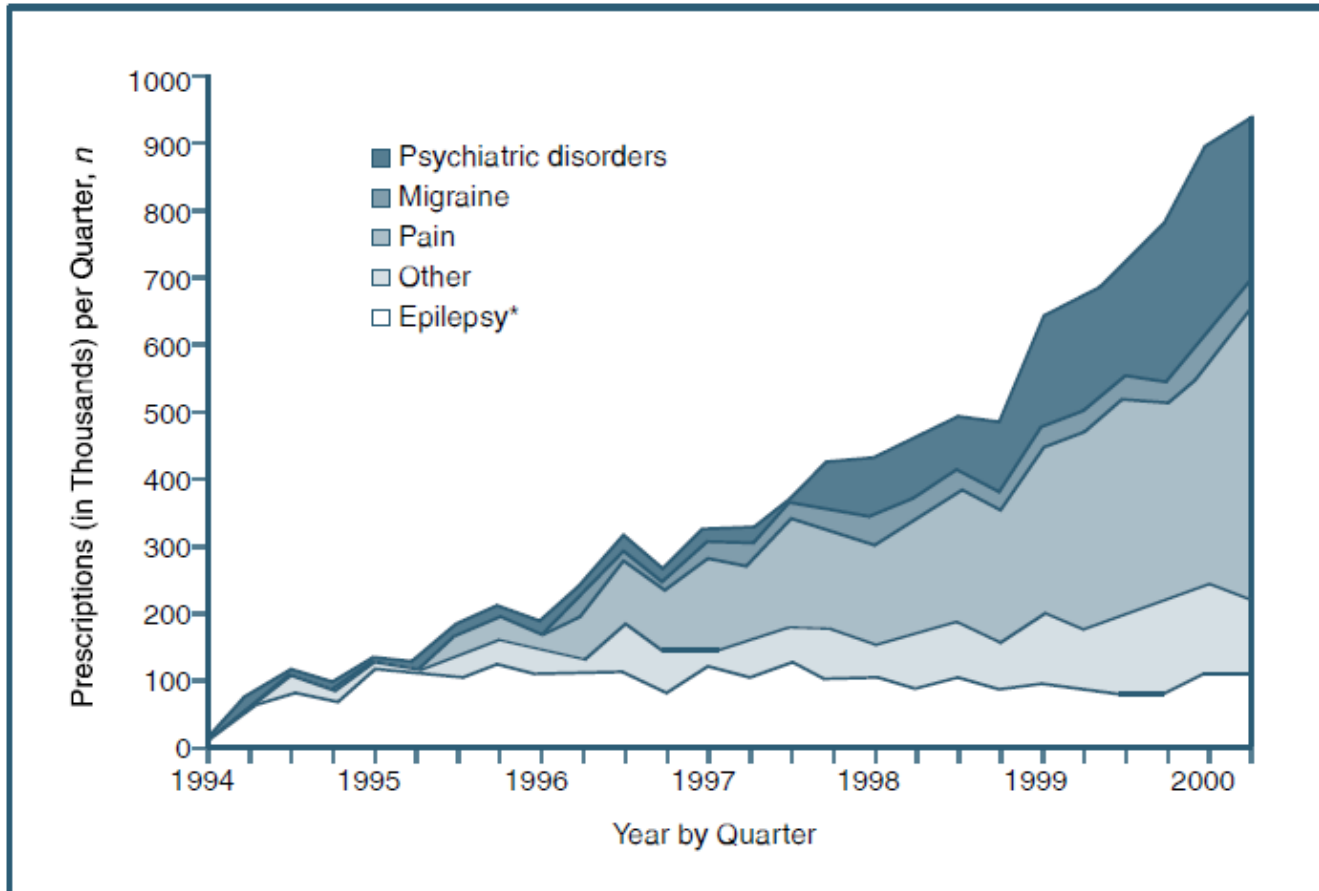
Consequently, for these and other reasons, marketing expenses are about double of those spent for research and development (Lieb, D. Ärztebl. 2010)

PSR distribute drug samples and information brochures, invite to educational events promoting off-label-use and participation in observational non-interventional studies

Value of information brochures

- About 94% of doctors information brochures edited by pharmaceutical industry lacks valid scientific verification
- Relevant negative aspects are discarded whereas positive aspects are exaggerated
- References to published literature are mostly missing, resp. wrong or misquotations
- The brochures no longer indicate the price of the medicinal product

Gabapentin (Neurontin) use for unapproved indications = off-label-use

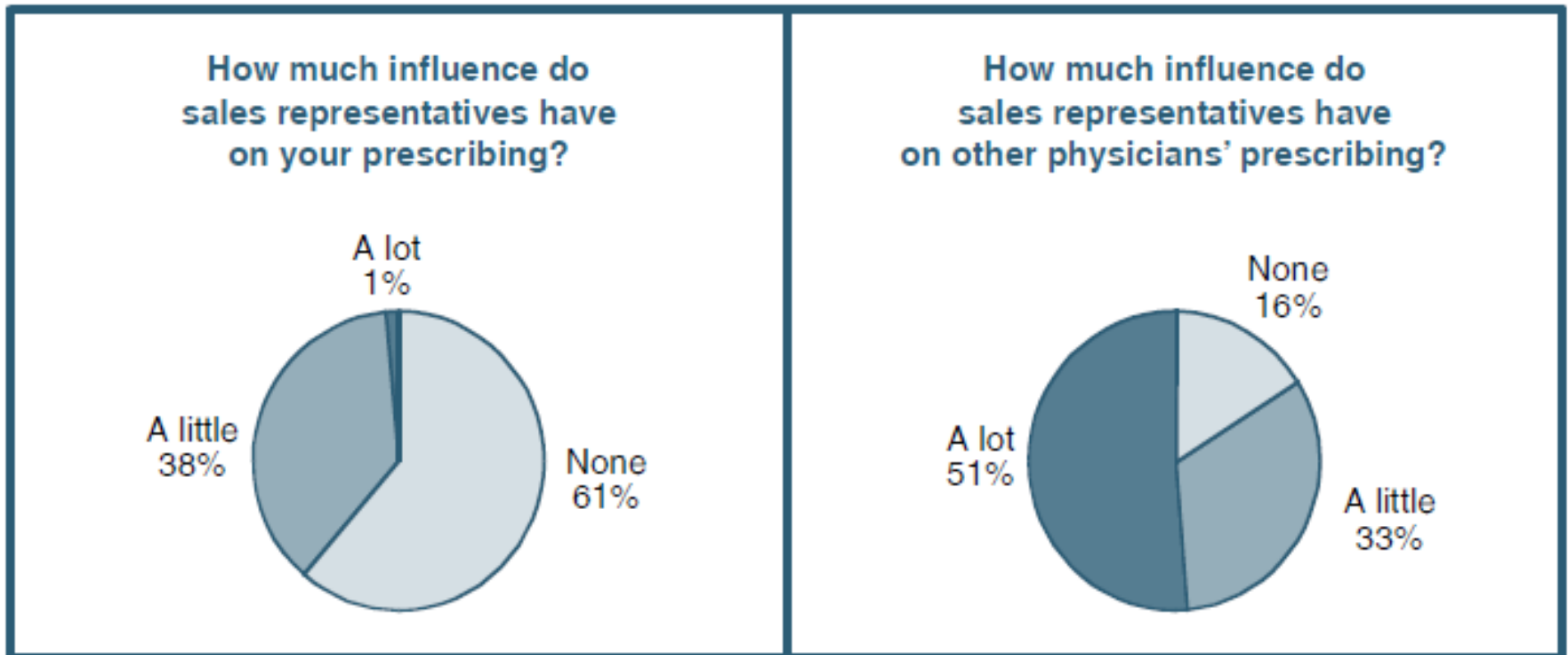


Steinman, MA et al., 2006, Annals of Intern. Medicine

Is Prescribing Influenced ?

- 84% of all medical doctors [MDs] believe that they are almost refractory to respective attempts. These MDs believe that the probability of their colleagues being influenced is 3-4 times higher as compared to themselves.
- A study shows that MDs causing high prescription costs are more likely to be in contact with PSR and / or sponsored educational events than those with low prescription costs (Lieb et al. Dt. Ärzteblatt 2010)

Survey of hospital doctors about sales representatives' influence



Steinman MA et al., 2001, American Journal of Medicine

Observational Non-interventional Studies

- Were conceived for getting information about risks and efficacy of a particular drug if applied to a wide variety of patients
- In fact, respective results are not used for increasing drug safety and/or efficacy but rather are discarded
- Most of such „studies“ are perverted to a pure marketing instrument
- Result in a win-win situation for MDs/industry

Educational training + Journals

- So-called peer group leaders are paid for giving talks about new medicinal products
- Publications are written by so-called „ghost-writers“ and talks for medical training by marketing agencies
- Well known specialists/professors only give their names – another win-win situation !

National guidelines

- Professional associations are responsible for establishing their specific treatment and “best practice” guidelines
- Therapeutic treatment schemes should be:
 - established on highest scientific standard
 - evidence based, unbiased etc.
- But in fact, often up to 100% of the members of commissions responsible for national guidelines have conflicts of interest!

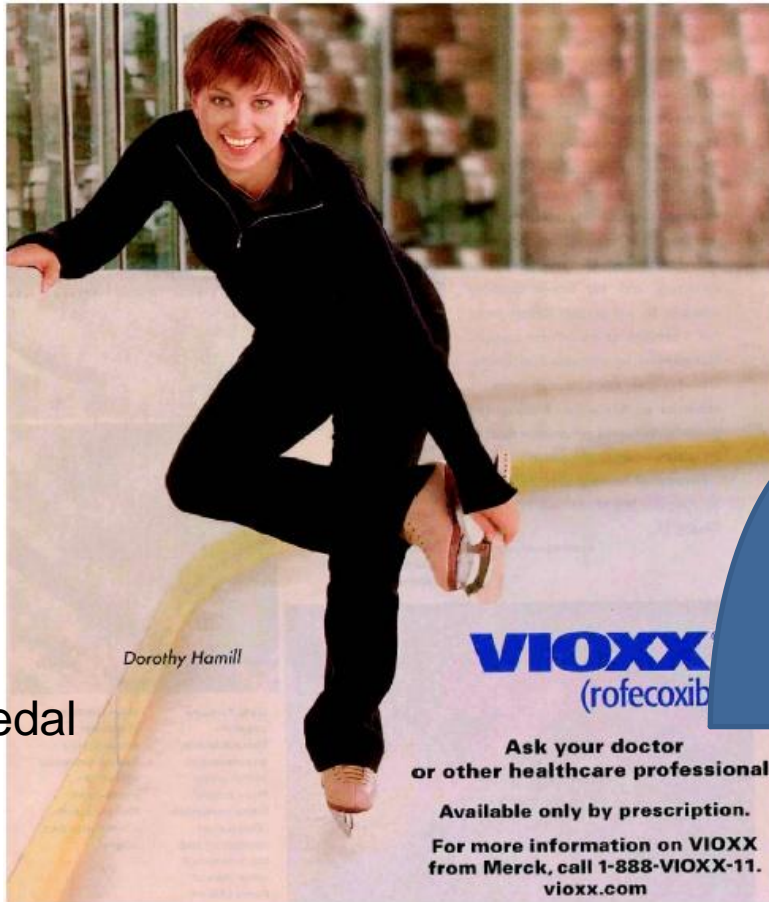
Publication Bias

- With respect to a marketing authorisation, FDA and EMA mandate the submission of all studies performed with a new drug
- But in medical journals studies are frequently manipulated: positive results for test drugs are exaggerated, whereas negative results are discarded or attenuated
- Therefore, benefits and risks of a new drug described in publications can differ substantially from those in the FDA/EMA data

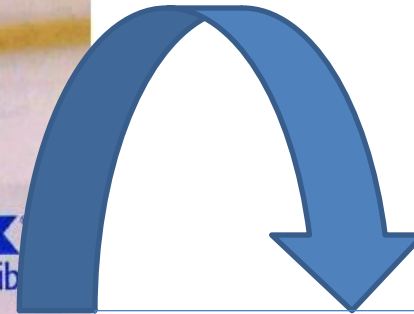
Patient organizations

- For about 10 years, pharmaceutical marketing is directly and substantially influencing the consumers/patients
- High costs of medicines for special diseases are directly associated with strong sponsoring of such patient groups
- The respective Commission (Brussels) is under increasing pressure regarding an opening of the market for prescription medicines and for “Direct To Consumer Advertising (DTCA)”

Advertisement for Vioxx



Dorothy Hamill
Olympic gold medal
in 1976



**Ask your doctor or other
healthcare professional**

From: www.todayssenionetwork.com

Medical doctors taken in tow by industry

More than 90% of doctors in private practice get their knowledge about medicinal products through a closed network:

Like in a vicious circle, pharmaceutical companies pay on different levels for all needs of a medical doctor - from samples, gifts regarding social and educational events up to an increasing number of publications in medical journals is tainted with conflicts of interests.

→ Hardly any chance to escape !