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**Den Bock nicht zum Gärtner machen !**

**Response to EU Consultation on Legal Proposals on Information to Patients – 7 April 2008** (slightly revised version)

As a doctor and concerned citizen that has worked for more than 35 years in clinical medicine and the public health field, and as member of the IPPNW regional group Berlin, International Physicians for the Prevention of Nuclear War/Physicians for Social Responsibility, that lately gave much attention to the growing influence of the pharmaceutical industry on medicine and the medical profession, I would like to comment on the legal proposal on information to patients that in fact would lead to ease restrictions to the ban on direct-to-consumer information (DTCA) for prescription medicines.

**1. Why no one should rely on a business for impartial evaluation of a product it sells ?**

As Marcia Angell, former chief editor of the highly reputated New England Journal of Medicine (NEJM) and now senior lecturer in the Department of Social Medicine at Harvard Medical School, said in her well known book „The Truth About the Drug Industry."„As in all other businesses, there is an inherent *conflict of interest* between selling products and assessing them."It is as simple as that and that is the main reason why the pharmaceutical industry can not provide good-quality, objective, reliable and non promotional information nor education, neither to citizens, nor to doctors. The money for „education, „information" and promotion comes out of the drug companies' marketing budgets. „That shows, what really is going on(p. 135).[1]

*Undermining the ethics and trust by des-/misinformation and data manipulation*

The evidence of misinformation, data manipulation, biased information, selected publishing, withholding relevant information about serious side effects of drugs even to regulatory bodies and doctors by the pharmaceutical companies is overwhelming and well documented . This causes great damage to patients.

*Recent examples are*: **(1)** Lilly deliberately held back for years information about the high risk of considerable adipositas and manipulated the risk of diabetes mellitus by its antipsychotic drug Zyprexa® (olazapin). Lilly had to pay so far 1.2 billion US Dollar for compensation to 28.500 affected patients (NYT, 8.1.2007). **(2)** GlaxoSmithKline held back study outcomes for 5 years on the inefficacy of its antidepressant drug Seroxat® (paroxetin) and the considerable risk of suicide in the application of this drug to children. This caused the British Government recently to ask for stricter laws against supression of data on study outcome on the european level [1]. **(3)** The famous study to Vioxx®, sponsered by Merck, had been forged two days before it was published in the New England Journal of Medicine (NEJM) by

[2] Marcia Angell, The Truth About the Drug Companies, N.Y. 2004. M.A.has worked for two decades with the NEJM. It is is because of this work that she is one of the best experts on drug companies , their influence on medicine and their marketing strategies. Time Magazine named her in 1997 one of the 25 most influential Americans. Her book on the drug companies is still certainly the best and most acknowledged book ever written on this subject by an highly competent and reputated independent expert.

removing the data of the patients who acquired a myocardial infarction in the Vioxx group while beeing on the drug. Vioxx® was removed from the market later on because of the high risk for just this side effect and Merck still has to defend itself before court [2].
**(4)** A study of the german „Institut für evidenzbasierte Medizin"in Cologne, found that 94 % of the industry's information handed over to doctors by pharma representatives are not backed by valid and comprehensible scientific evidence. 58 % of all information could not be varified because no reference to literature was given. From the information where references were given most information did not correspond with the scientific literature they pretended to be based on [3].
**(5)** The NEJM published January 2008 a metananlysis which showed that one third of company sponsered of the 74 FDA (US Food and Drug Administration)-registered studies of 12 antidepressive agents were not published, mainly because they were viewed by the FDA having negative or questionable results. This selective reporting gives a false picture of the efficacy of antidepressant agents. 94 % of the published studies show apparantly positive results, compared with only 51 % according to FDA analysis which included the studies with negativ results [4].
(**6**) Merck and Schering Plough helt back for more than a year the results of the studies on their $ 5.2 billion joint venture cholesterol drugVytorin® that combines Merck's Zocor® with Merck/Schering-Plough drug Zetia®. American cardiologists pushed for publication of the results, since the study had been finished two years ago. The ENHANCE study, which now has been competely published by NEJM March 31, 2008 showed that Vytorin® did not decrease plaque built-up in the arteries more than Zocor alone, which is available in a much less expansiv generic form. Employees and Managers of both companies knew about it and both companies are facing legal actions in the U.S. for misrepresentations to the general public over the drug's effectiveness in its marketing and withholding significant information in approval submissions and filings with the FDA. The American Heart Association now has recommended to prescribe the drug only if conventionel statines are not appropriate [5].

**(7)** In the US, where DTCA is allowed, regulations against misleading information are frequently violated and drug companies are fined with billions of US Dollars. Thus, between 2003 – 2005 9 drug companies were fined with $ 2.4 Billions for proven misleading information [6] . In 2007 the drug company „Perdue" as well as 3 of ist top managers were fined with $ 634 millions , because they deceived the public by playing down the dependancy potential of its pain drug Oxycontin® (oxycodone)(„Frankfurter Rundschau", 23.7.07)

**(8)** Nowadays drug companies in the US are investigated on large scale for illegal promotion of off label use of their drugs, i.e. application of drugs to disorders they have not been approved for by the FDA [7].The real incidence of violations should be much higher, since the FDA is understaffed (or reluctant ?) to control effectively.

The mentioned practices together with „ghost writing" (to disguise who are the real authors and origins of the study), managed publishing, manipulation of study designs post hoc, favouring the positive results and playing down the risks and side effects of drugs are common not only in the promotion of products, but in „information" and medical „education" delivered or sponsored by the drug companies as well. These practices lead to misinformation, partial information, biased outcome about the efficacy, risks and side effects of drugs which has lead to considerable harm to patients. This effects the common welfare as well, since the public, the citizens and insurers have to pay for the drugs, who might not be effective as falsly claimed, and the damages they might cause. Good medical practice has to rely on objective, impartial and comprehensive information that includes alternatives to drug

treatment as well. There is growing concern about Big Pharmas' ethical behaviour and lack of transparency which has undermined heavily the trust in the conduct of the pharmaceutical companies.

Given this evidence does the Commission really wants to give increased access to patient information to such a proven unreliable and partly untrustworthy actor?
*Drug Companies - due to fundamental conflicts of interest - cannot give unpartial objective und reliable information !*
Since the drug companies' „information" in many aspects is already misleading today, what makes the commission believe it will change its conduct when given extended rights ?

**2. Why a clear distinction between advertising and information is not possible ?**

The Commissions proposal implies the assumption that „a clear distinction between advertising of and information provided on prescription medicines" will be possible in line with the proposed structure for monitoring the quality of information .
I am convinced that this notion is fundamentally wrong (or would lead to an immense burocratic structure, which nobody wants and which would not be in line with one of the declared main policies of the proposal, avoiding „unnecessary bureaucracy").

*What are the reasons for why this is not possible?*

Marcia Angell commented in her above mentioned book on the fiction that the pharmaceutical industry provides medical education. Her arguments can be applied to patients information as well. Let me quote:
„Drug companies are in business to sell drugs. ... I am not saying that all of the the information drug companies provide is false. Some of it is useful and valid. But information from drug companies comes mixed with hyperbole, bias, and misinformation, and there is often no way to tell which is which." ....."There is no question that it influences educational content. The result is that doctors not only receive biased information but learn a very drug-intensive style of medicine. They come to believe that there is a drug for everything and that new drugs (of which they have many free examples) are always better than old ones" (p. 250).

In regard to the notion that drug companies can both market and educate [inform] she continues to comment: „...the only problem being they need to be clearer about when they are doing which – they need a „firewall" [a notion the Commission shares]. But in fact there can be no firewall, because the drug companies are not really in the educational [information] business. (If they were, they would *sell* their educational programs, not to give them away or pay people to accept them.) The problem with separating the educational programming from the marketing is that it is *all* marketing."(p. 151)
And she concludes in her Chapter on „Marketing Masquerading as Education:"
„The masquerade leads to no end of problems – the corruption of the profession, the misuse and overuse of expensive prescription drugs, and ... an avalanche of governmental investigations and lawsuits based on the spurious notion that the pharmaceutical industry provides bona fide medical education and it is therefore possible to distinguish lawful educational expenses from illegal marketing. If we acknowledged the fact that the pharmaceutical industry cannot possibly be expected to provide unbiased educatioin about ist own products, there would be no need to persue the hopeless task of trying to differentiate „educational grants"from kickbacks ..." (p. 155)

**3. Why then this legal proposal against all evidence ?**

With the exception of the US and New Zeeland all other countries in the developped world have a strict ban on DTCA. The European Parliament in the passed has refused all attempts of the Commission to introduce DTCA in the EU for good reasons by an overwhelming vote. Allthough the Commission's proposal says that the ban on DTA will be maintained, the proposal will be the first stepp and gateway to DTCA.
From the reported facts and arguments all evidence speaks against the liberalisation of the ban on DTCA by easing the drug companies' access to patients, consumers and the public. The ban, however, should be strictly kept and even strengthened because in practice it has already been undermined in many concerning ways.

*The negative consequences of DTCA in the US*

The consequences of a liberal regulation of the pharmaceutical industry, the result of extreme pharma lobbying and a government open to radical neoclassical economic thinking, can be studied in the US, where now there are arduous efforts by governments, legislators, and litigations and concerned public organisations to change drug policies . This not least to limit the risks of ever exploding expenditures for prescription drugs that undermine the base of any affordable, accessable and need orientated health care system. Notably the most reputated academic centers in the US, like the Medical Schools of Yale, Stanford, the University of Pennsylvania, the University of California and others, are the ones who take the lead in addressing this issue. As a first result, based on an remarkable article in the Journal of the American Medical Association [8] they recently have adopted very strict rules regulating the relationship between their institutions and its members and the drug companies in the interest of their patients, the sensibility for the professional values and scientific integrity. There, too, is a broad and critical public debate in the US about the role of big pharma (and the role members and organisations of the medical profession play ), including even Wall Street Journal [9] and the British House of Commons expressed its concern in its Report on „The Influence of the Pharmaceutical Industry", presented in March 2005.

Though the Commission claims its proposal is in the interest of the consumer, I know of no consumer organisations so far, who supports the proposal. The „European Consumer Organisation" (BEUC), the „European Consumer Consultation Group"(ECCG) as well as the „Bundeszentrale Verbraucherverband Deutschland" (the german consumer organisation) have all clearly disapproved of the proposal in their reponses to the Commission. So did many medical organisations including the British Medical Association (BMA), the UK National Health Service (NHS), the „Arzneimittelkommission der Deutschen Ärzteschaft"(the drug Commission of the German Medical Association). The legal proposal, as far as I know, will not find the support of the „Bundesärztekammer", nor that of the Ärztekammer der Länder ( the official associations of German doctors) neither. The coming parliament of german doctors ( „Deutsche Ärztetag") is expected to vote against the proposal. I hardly can imagine that patient groups with full understandig of the consequences will welcome the proposal, except they are sponsored by the drug companies and thus not independant. There is a very critical debate on this issue, too.

*What is it really all about ?*

So far it seems that the main interest in the legal proposal lies with the industry and the Commission.

This does not surprise, since the industry looks for additional ways to promote their products and to extend markets, particularly in a situation, where the pipline of innovative drugs appear to run out . The direct access to the consumer/patient would be an ideal way to this aim with all the negativ consequences mentioned above.

So this proposal apparently is in the interest of the Commission, DG enterprise and industry. Article 88a of the Directive 2001/83/EC, the legal base for the initiative, asks for a strategy to ensure good-quality, objective, reliable and non promotional information on medical products *and other treatments* and shall *address the question of the information source's liability* including all stakeholders. The Commissions proposal seems to me counterproductive to these ends.
It greatly ignores the results of the precceding consultations concerning the issue. It neither contains a information *strategy* including *all stakeholders* which was asked for by the Directive, nor does it address the issue of the reliability of information source adequately by ignoring the pharmaceutical industry's evident malpractice and its fundamental conflict of interest, nor is the important issue of „other treatments"information (other than medicines) addressed. Leaving the information to the drug companies, I am sure, all information will be centered about drugs.

Is the assumption so farfetched that the reason for the Commission's support is due to the influence of the Pharma Lobby and the „Pharmaceutical Forum", in which the industry is so strongly represented ?
A very recently published investigation of „Alter EU, the umbrella organisation of 160 european NGO's, showed that in one quarter of the reported expert groups that work for the Commission more than every second(!) expert was on the pay role of the industry (Die Tageszeitung, 26.3.08). This is a matter of great concern for the public (even though this investigation may not have included all of the 1200 expert groups who work on behalf of the Commission).
Is it so farfetched, too, to assume that the primary aim for the Commission is about„industrial policy", instead of „health policy", which should better be dealt with by the Commission's DG Health and Consumer Protection. If it were so, it would have been better to admit that all is about regional economic policy, not health and patient information. Then everybody would know what it is all about. Instead, the maxim of the proposal should be putting the interest of the patients first. I cannot see how the legal proposal will contribute to this end.

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