Industry as information provider – bias for free?

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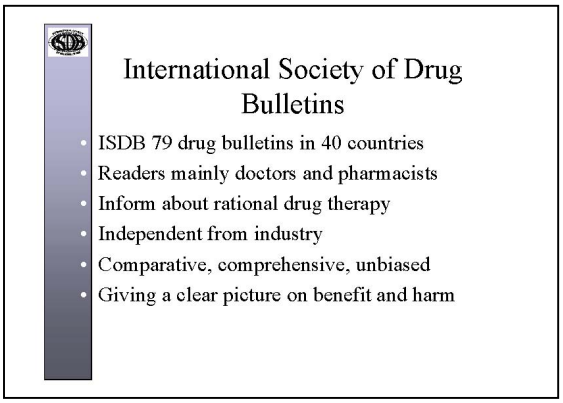
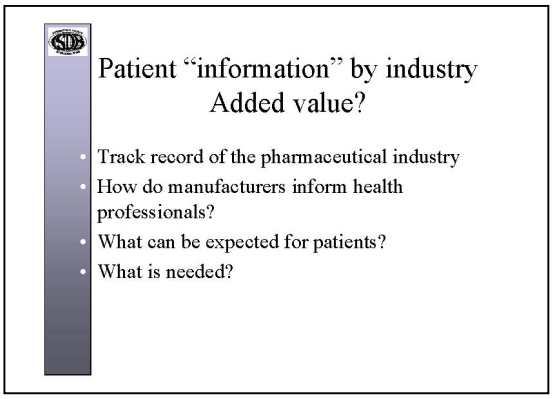
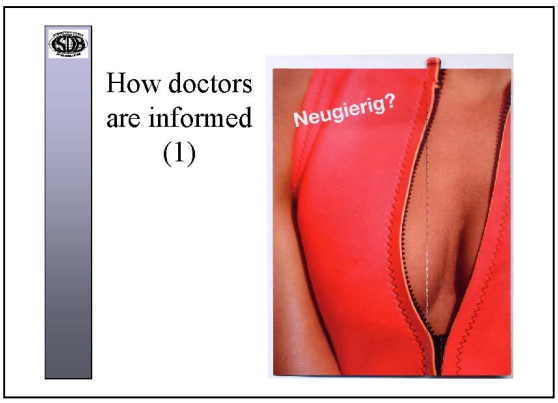


Drug bulletins are at the interface between scientific evidence and clinical practice. The International Society of Drug Bulletins represents 79 drug bulletins which inform mainly doctors and pharmacists in 40 countries around the globe about rational drug therapy. They give comparative, comprehensive and unbiased information. To secure this, ISDB members are independent from drug industry and do not accept advertising. We provide what doctors and patients need: a clear picture of benefit and possible harm of treatments.



The main change proposed in the "information to patients" directive is to give drug manufacturers a bigger role in communicating with patients directly. The crucial question: Is it worth the effort to give industry a bigger role? Or are better solutions needed?

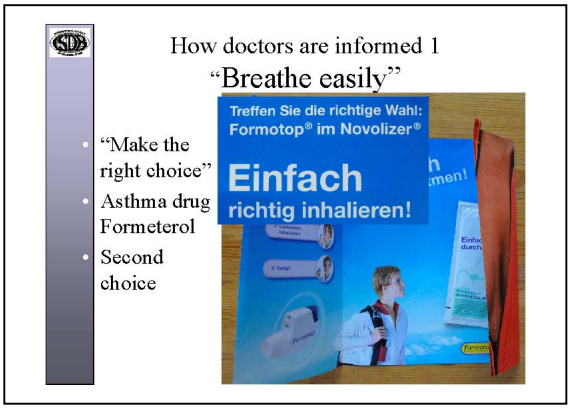
When we want to judge about whether the pharmaceutical industry is a good source of information for patients we could look how they perform in another sector: Providing information to doctors.



How doctors are informed (1)

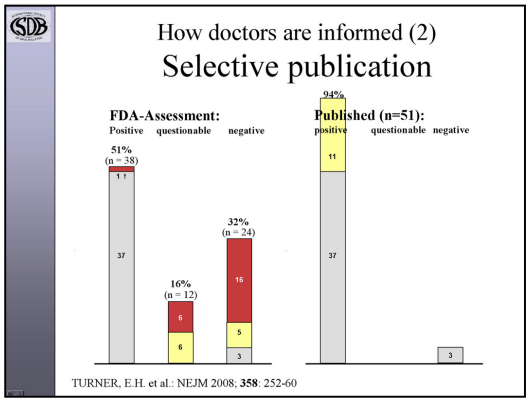
Not all information given to doctors by industry does look very scientific.

"Curios?"



"Make the right choice"

Formeterol is second choice in asthma therapy only.

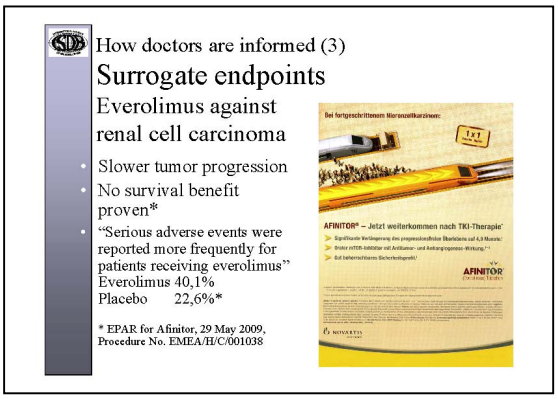


Selective publication (2)

Selective publication of study results distorts the perception of the benefit of a drug.

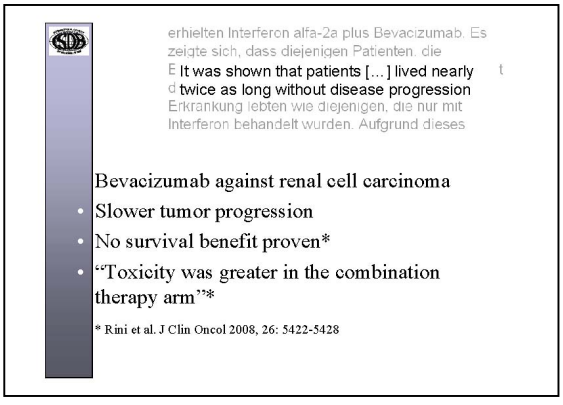
Case study on 12 antidepressants: For these drugs the FDA had 74 studies on file. 23 have never been published in medical journals (red). Which ones were not published? All but one with negative results or questionable outcomes.

Prescribers can rely only on published results. In the overwhelming majority of published studies (94%) the results were presented as positive. The FDA could look at all the evidence and judged that only just over half of all studies (51%) indicate that antidepressants work to a certain extent. Less than half of the unfavourable studies were published. In 11 of the 14 studies with negative or questionable results the outcomes were reported as positive in the publication (yellow). This bias leads to an overestimation of the effect of antidepressants by 1/3 (depending on the drug between 11% and 69%)[a]



Surrogate endpoints (3)

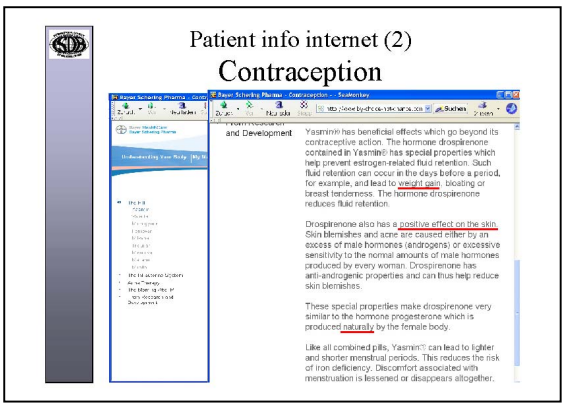
Another problem is the selective reporting about study results. This advertisement sends not only a strong visual message, but also makes a positive claim: "Significant prolongation of the progression free survival to 4.9 months." This is only a surrogate endpoint: slower tumor progression. From 1,9 to 4,9 months. But does that mean that the patients live longer? No. There was no benefit proven for overall survival.[b] Do the patients at least feel better? Serious adverse events are nearly twice as frequent for patients receiving everolimus (40.1%) than in those receiving placebo (22.6%). The ad claims that Everolimus has a "well manageable safety profile." The EMEA suspects that the death of three patients was directly caused by the drug.[b]



Patient information (1)

Though it is doubtful whether the websites for patients are compatible with the existing EU legislation they allow an insight into the quality of drug industry's patient information. Another drug against the same disease (renal cell carcinoma). The heading says: "Drug with a new mode of action". "It was shown that patients […] lived nearly twice as long without disease progression." Does the drug perform better? Slower tumor progression. But also no survival benefit.[c] Five drugs recently entered the market in this therapeutic area. Four of them couldn't proof a benefit in overall survival. Patients and doctors should know.

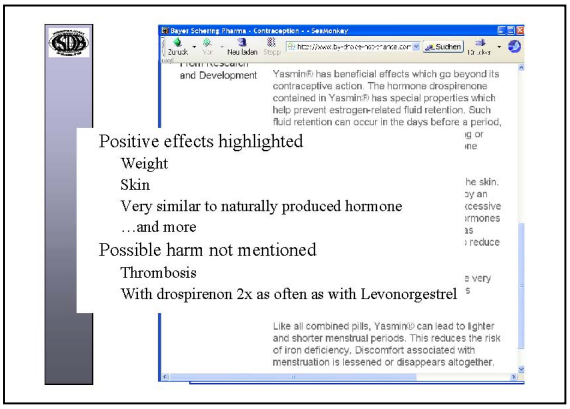
a Turner et al N Engl J Med 2008;358:252-60
b EPAR for Afinitor, 29 May 2009, Procedure No. EMEA/H/C/001038
c Rini et al. J Clin Oncol 2008, 26: 5422-5428



Promotional information on contraception (2)

What information do consumers find on company websites?[a]

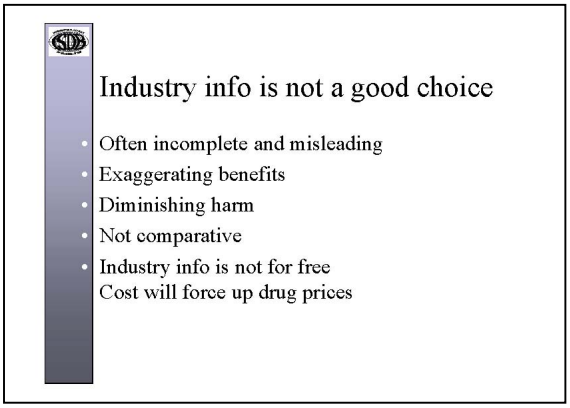
Supposed positive effects are highlighted: Less or no weight gain. A positive effect on the skin. "Very similar to the hormone […] produced naturally by the female body." …and more



Possible harm is not mentioned on this website.

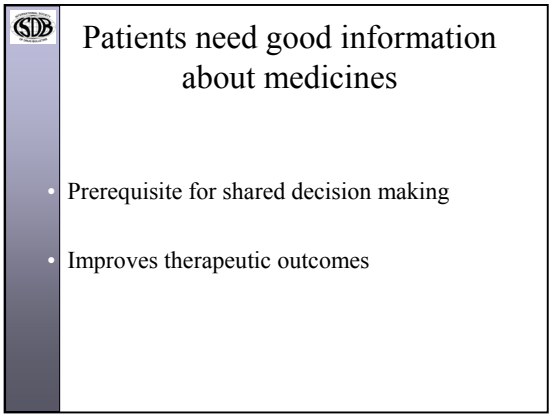
Thrombosis is a rare but serious risk with hormonal contraception.

Thrombosis occurs with drospirenon 2x as often as with levonorgestrel.



Industry information is not a good choice

- Often incomplete, misleading
- Exaggerating benefits
- Diminishing harm
- Not comparative
- Industry info is not for free. The expenses will be added to drug prices and unnecessary consumption promoted.



Patients need good information about medicines.

Why? Because it is at the heart of rational drug therapy.

•It is a prerequisite for shared decision making

•and improves therapeutic outcomes

[a] From www.by-choice-not-by-chance.com (accessed 22 Nov. 2009)

What is good information?

- **Reliable**
  Based on science, up-to-date, sources
- **Unbiased**
  Independent, traceable
- **Comparative**
  treatment options, benefit and harm
- **Understandable**
  Easy to handle, adjusted to users

Good information

Reliable: Based on science, up-to-date, quoting the sources used

Unbiased: Independent from commercial influence, the affiliation of the authors should be clear.

Comparative: Compare the benefit and possible harm of available treatment options, including what happens if a condition is not treated.

Understandable: Easy to handle, adjusted to users (age, social background etc.)

Gute Pillen – Schlechte Pillen www.gutepillen-schlechtepillen.de

What is needed

- More good information is needed
- PIL must be improved (boxes with core information)
- Promotional and other bad information must be better controlled

- Independent info needs public support
- Means better health
  and avoids unnecessary cost

What is needed

- More good independent information is needed.
- The Patient information leaflet (PIL) needs to be improved. In the US an interesting proposal was just tested: If boxes with core information were provided, patients were getting a much better understanding of benefits and harm.[ab]
- Promotional and other bad information must be better controlled, otherwise the good information will be submerged.
- Independent info needs public support, it may cost a bit of extra money, but it will improve health outcomes and avoid costs through inadequate or unnecessary treatments.

[a] Schwartz, L et al. Ann Intern Med. 2009, 150: 516-527

[b] Schwartz, L and Woloshin, S. N Engl J Med 2009, 361; 18: 1717-1720