

Transparency and integrity in patient advocacy

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Transparency – why is it important?

- **Transparency**, as used in science, engineering, business, the humanities and in other social contexts, is operating in such a way that it is easy for others to see what actions are performed.
- **Transparency** implies
 - openness,
 - communication, and
 - accountability.
- All stakeholders are responsible
- Philosophical and psychological implications
- Contradictions between the need for transparency and how societies often work 🗑️ conflicts
- Transparency and integrity are **essential** for (patient) advocacy
- Impact of large corruption scandals in international NGOs

„there is a real trust gap around patient organisations’ links with industry. This has potentially serious implications for the credibility of patient organisations as partners in medicines regulation.”

Kaisa Immonen, 2019, <https://blogs.bmj.com/bmj/2019/05/24/kaisa-immonen-industry-links-with-patient-organisations-transparency-is-fundamental/>

The traps when not being transparent

What examples can you think of for non-transparent conduct?

The traps when not being transparent - examples

What you get

- Direct payments
- Conference participation
- Gifts
- Access to medicines
- Access to clinical trials
- Influence
- Fame and admiration

What you give in return

- Access to KOLs
- Positive opinions
- Credibility to campaigns and marketing work
- Impact
- **BUT ALSO:**
 - Integrity
 - Credibility before the patient community
 - Tax integrity
 - Conflict of interest that excludes you from certain work (e.g. EMA)

Transparency and integrity are long-term businesses!

Misuse of transparency information – how to deal with it

- Your information may be read differently by other people
- An ideological debate that may have profound impact on your position and work
- Focus on your and the patients' objectives
- Learn about the legal and cultural settings
- Don't need to be implied in the debate

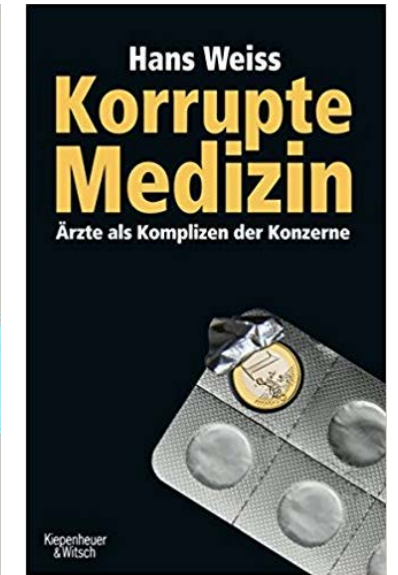
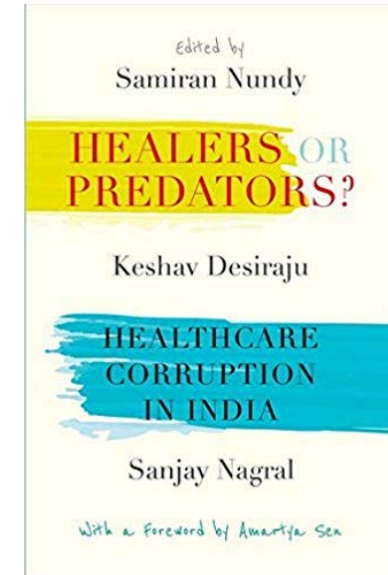
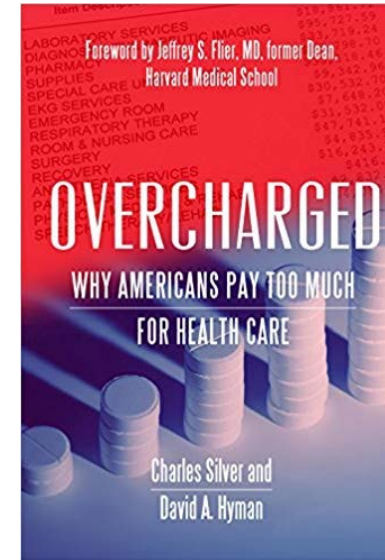
Healthcare Fraud, Corruption and Waste in Europe

National and Academic Perspectives



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The dos and don'ts on disclosures

- Be honest and straight
- But don't overshare
- What you must disclose
 - Funding for research
 - Funding received for any of the presentations directly
 - State / public funding for your research
- You don't have to disclose
 - Financial details of you, your family or organization
 - Annual reports or balance sheets
 - Incomes not related to the given piece of research or project

Disclosures

- No funding received for research
- Part of my salary comes from pharmaceutical companies indirectly
- Honoraria for speaking engagements donated to EUPATI or Patvocates
- Works open access under Creative Commons [CC BY-NC-SA 4.0.](https://creativecommons.org/licenses/by-nc-sa/4.0/)
- Special thanks to
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Presenter Disclosure Information (SAMPLE DISCLOSURE SLIDE)

In compliance with the Conflict of Interest policies, the International Society for Pediatric and Adolescent Diabetes requires the following disclosures to the participants during your presentation. You may use as many slides as needed:

[NAME OF PRESENTER]

[Type of Support – Categories and 1 example shown below]

Research Support: xxxxx, Inc.
 Speaker's Bureau:
 Board Member/Advisory Panel:
 Stock/Shareholder:
 Consultant:
 Employee:
 Other:

Sample Disclosure Slides

Information:

- A presenter must include Disclosure slides for each presentation – even if nothing to disclose
- Two slides are required (samples on next 2 slides):
 - Presenter Disclosure
 - Commercial Support Disclosure (for the Learning Activity)
- Presenter Disclosure will be included for each presenter
- The presenter will present the slides visually and verbally
- Commercial entity is any pharmaceutical or device manufacturer, distributor or marketer

Declaration of interest vs. Conflict of Interest

- **Declaration of interest:** You are open and transparent about what you do and what position(s) you hold
- **Conflict of interest:** What you do, or your position may impact the impartiality of your decisions and advice

What is Conflict of Interest?

Examples:



NEPOTISM
Giving favors to relatives and close friends.



SELF-DEALING
When someone acts in their own interest rather than the interest of the organization.

When it is Illegal:



PUBLIC SECTOR

- Judges must recuse themselves if there is a relationship with one of the parties in a case.
- If the legislator attempts to profit from knowledge, this is an example of insider trading.

PRIVATE BUSINESSES



If a company has proof that a board member profited from their role on the board, the board member can be taken to court.

BOARD MEMBER



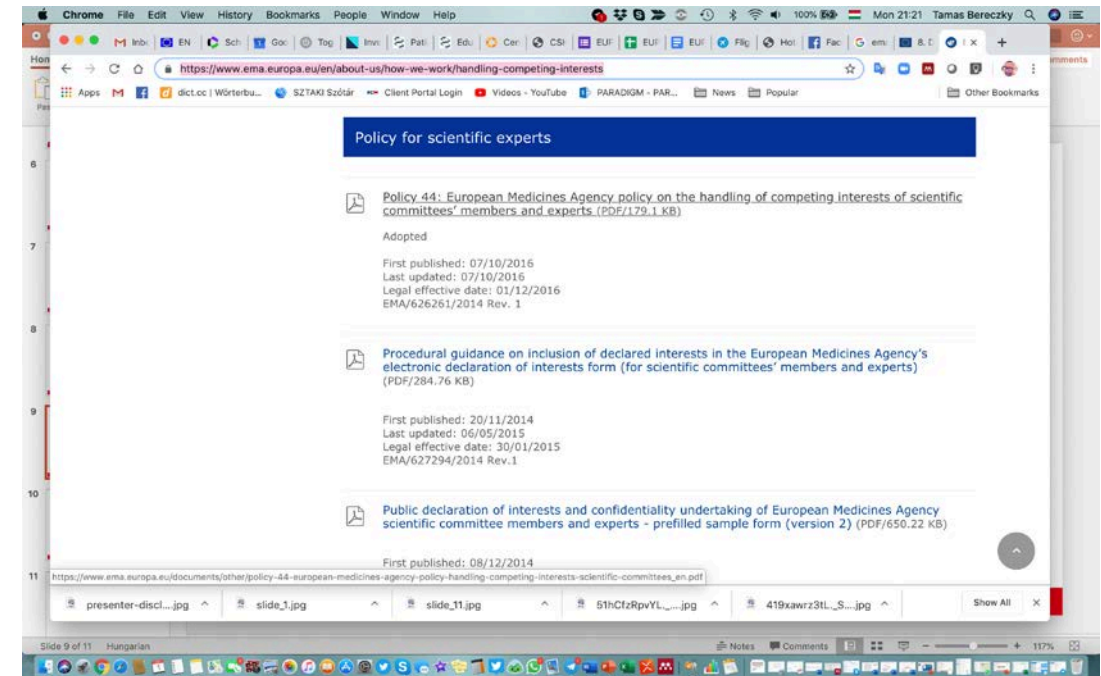
<https://www.thebalancesmb.com/what-is-a-conflict-of-interest-give-me-some-examples-398192>

The dos and don'ts on consents

- Read what you sign!
- Forms tend to be overly general and generous – with your data and information!
- Agree to
 - Sharing the slides and presentations
 - Sharing pictures of the event with you in them
 - Sharing videos/interviews with you
- Don't agree to
 - Blanket use of anything you said in marketing materials
 - The association of your name and face with a product
 - Unlimited use without any time or geographical limitation or description

How to fill out the EMA Declarations of Interest

- Start by reading the instructions:
<https://www.ema.europa.eu/en/about-us/how-we-work/handling-competing-interests>
- Read the transparency guide of the EMA:
<https://www.ema.europa.eu/en/about-us/how-we-work/transparency>
- Follow the step-by-step instructions:
https://www.ema.europa.eu/en/documents/presentation/presentation-declarations-interests-practical-guide_en.pdf



Existing transparency codes of conduct

- EMA: <https://www.ema.europa.eu/en/about-us/how-we-work/transparency>
- EPF Transparency Guidelines: <http://www.eu-patient.eu/globalassets/library/toolkits/epf-transparency-guidelines.pdf>
- EURORDIS Code of Practice: <https://www.eurordis.org/sites/default/files/thumbnails/0904-PO-Code%20of%20practice.pdf>
- EUPATI Guidance Documents: <https://www.eupati.eu/guidance-patient-involvement/>
- Kaisa Immonen in the BMJ: <https://blogs.bmj.com/bmj/2019/05/24/kaisa-immonen-industry-links-with-patient-organisations-transparency-is-fundamental/>

