"Best expertise vs conflicts of interests: Striking the right balance"

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- First Observation : the workshop's titles reflects a wrong framing of the debate as independence cannot be balanced against expertise : in a public health agency, independence from the pharma industry is part of the expertise needed!

This is actually well reflected in the regulation :

*« Members of [...] committees, rapporteurs and experts shall not have financial or other interests in the pharmaceutical industry which could affect their **impartiality**. They shall undertake to act in the **public interest** and in an **independent** manner, and shall make an annual declaration of their financial interests. »* (Extract from Article 63(2) of Regulation (EC) No 726/2004)

See also this great quote by D. Michaels (now head of OSHA in the US),

*"Conflict of interest can be managed" is the current mantra. Well-meaning administrators of these committees believe they desperatey need the leading researchers in their fields, regardless of how conflicted they may be. In some areas of medicine, it is difficult to find experts completely unaffiliated with the drug companies because so many physicians, especially the most respected academic ones, have received money from them. […] A common response from scientists with financial conflicts is that their judgment is not influenced by their employment relationships. To give them the benefit of the doubt, most of these scientists honestly believe this, but evidence strongly suggests otherwise: **financial ties cloud judgment**. If we cannot predict which scientists will be influenced (and all evidence is that we cannot), we need to limit the use of all conflicted scientists. Moreover, the headlines about these conflicts look bad; the public is justifiably skeptical about these panels' objectivity, and that skepticism threatens the value of their work. […] I am convinced that **conflict of interest cannot be "managed". It must be eliminated**. Too much is at stake.*

("**Doubt is their Product**", David Michaels, Oxford University Press, 2008, Chapter "Sarbanes-Oxley for Science", p. 255-57)

- **Second Observation : a policy on COIs is not about chasing morally dubious individuals but protecting a public administration's political integrity**, particularly in a time when the « revolving door » phenomenon between the public and the private sector is becoming systematic.

- Such provisions against COIs are **very common in the private sector** in the form of non-compete clauses in employment contracts, reasonably limited by geographical and time limits.

- A clear example as far as the EMA is concerned is the consultancy NDA group, which **hired EMA's former executive director** as well as several other high-level EMA executives to advise corporate clients to better prepare their their market authorisations dossiers. According to a critical NGO expert, up to half of NDA's experts would have worked for EMA in the past !

- In our experience, **regulators and media often have a simple, dramatic picture of the problem** (infiltration by an industry « mole », corruption) but this misses the point : regulatory capture is about subtle, systematic and long-term influence strategies. A quote from a 1978 industry publication describes it well :

"*Of course, there are also important tactical elements of lobbying. This is most effectively done by identifying the leading experts in each relevant field and hiring them as consultants or advisors, or giving them research grants and the like. This activity requires a modicum of finesse; it must not be too blatant, for the experts themselves must not recognise that they have lost their objectivity and freedom of action. At a minimum, a programme of this kind reduces the threat that the leading experts will be available to testify or write against the interests of the regulated firms*."
(From : Owen BM, Braeutigam RR. The regulation game: strategic use of the administrative process. Ballinger Pub. Co., 1978. Via Goldacre B. Bad Pharma: How drug companies mislead doctors and harm patients. Fourth Estate, 2012)

The International Institute of Life Sciences (ILSI) f.i. is a clear incarnation of this strategy : it presents itself as a neutral platform for debate involving scientists from all origins, while systematically creating working spaces on current or upcoming regulatory issues, inviting top experts to contribute to scientific debates controlled by the industry (i.e. sugar industry sponsoring research on the links between obesity and fats or lack of physical exercice).

Third Observation : there is a vicious circle between agencies' tarnished reputation and their attractivity for the best scientists, particularly young ones.

- At present, involvment in regulatory work is rarely considered an attractive option in a scientific career -> EFSA experts tend to be individuals who are either industry consultants (the closest you can get to the « industry mole » situation) or whose career is mainly behind them, which introduces a conservative bias because scientists whose career is over will tend to try to protect their past work against possible contradictory new ideas.

- This can also be explained by the fact that these experts are typically not paid, despite their competence, and because their work usually cannot be published in « normal » scientific, peer-reviewed literature (industry data usually covered by commercial confidentiality).

=> **Reinforcing agencies' attractivity for scientists should be an important objective : aligning agencies' work on normal scientific practice (notably in terms of transparency and access to raw data), giving them the means to self-task (or, even better, « blindly » commission research to independent labs) and reinforcing their independence must be part of it.**

Fourth Observation : the only source of information on scientists' interests available to agencies is these persons' self-assessment. Public third parties information, even from national agencies, is not used for checks. Furthermore, culture and knowledge of existing scientific literature on regulatory capture seems to be entirely lacking (at least this is the case within EFSA). These are crucial flaws in the system.

- External individuals bear the responsibility of the institution's independence.
- **Data is inconsistent and unreliable** (one cannot be judge and jury) => the policy cannot be rigorously enforced, meaning media scandals will keep coming, endangering public trust and undermining the whole independence policy.
- The paperwork and bureaucracy involved by checking individual DOIs is huge and probably disproportionate in view of the above.
- This policy is usually disliked both by officials in charge of checking the information (usually heads of units with several other operational responsibilities) and by scientists themselves, who feel under suspicion.

=> more capacity for checking COIs, with experience and knowledge of industry influence tactics, must be built within agencies so that they can pro-actively and consistently take care of their independence.

Fifth Observation : COIs tend to be assessed too restrictively, with inconsistencies and sometimes too much room for arbitrary assessment (can you actually measure the intensity of a COI with industry? Is an indirect COI always worse than a direct one ?). Cases of authorisations given because an interest in a given company was not about the product on the agenda, however made by the same company.

=> more clarity and consistency would be needed : strictly banning COIs with industry and industry-sponsored activities is paramount. Scientists with COIs whose contribution would be seen as indispensable can always be invited for hearings by the panel, without them having drafting and decision-making powers.

Sixth Observation : financial and intellectual COIs cannot be assessed in the same way for scientists working for a public health agency.

Financial COIs are measurable and concrete since they arise from links with commercial entities (something EMA actually seems to recognise well in its policy's wording); but intellectual COIs, on the other hand, are difficult to avoid as soon as a certain degree of specialisation is required (« independence » doesn't mean much in absolute terms).

=>This category remains relevant for chairs and vice-chairs, who have a duty to moderate the discussions and therefore have to stick to a certain neutrality, but extending it to members in a strict and consistent manner is probably excessive (diversity of opinions and scientific backgrounds on the other hand should be encouraged).

Seventh and last observation : the idea that only industry scientists would be competent and available for agencies is solidly established as a mainstream cliché, but is untrue and self-defeating.

- French lobbyist for the pharma industry: « independence is a guarantee for incompetence ». J. Dalli, 2011 : « it is impossible to exclude industry scientists ». In general, the competitiveness mantra and its translation into the research policy (15 years of incentives to establish PPPs between academia and industry) and the excessive political influence enjoyed by corporations is endangering the reliability of the risk assessment of industry products.

- Recent Health Affairs paper (US): 47,2% of life-science academics responding to their survey reported no relationships with industry http://content.healthaffairs.org/content/28/6/1814.full.pdf+html
- the EU has dozens of universities and thousands of scientists that are still independent from industry (despite 15 years od EU and national research policies favouring academia-industry PPPs).
- Training is always an option.

=> Scandals about industry influence over regulation, with the public losing trust in regulators, translate in real additional public health problems (vaccines scares f.i.), particularly now that IT tools enable a better sharing of information. Public health agencies relying on industry experts ultimately undermine their very raison d'être.