

## “Embargo” on scientific news, a late breaking message from the Ministry of Truth (MiniTrue)

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The word embargo comes from the Latin “imbaricare” and refers to the legal prohibition of trade, the movements of goods – or by extension – the diffusion of news and information. An embargo is considered as an act of “war” with the purpose of isolating one country or group from the other. As to scientific news, embargo results in the delayed release of new information until certain conditions have been met. The intention is that this scientific embargo will reduce inaccuracies in the reporting of the breaking stories. Unfortunately, the embargo system is considered as being primarily driven by profit motives on behalf of various stakeholders. It has indeed become obvious that different pressure groups have different objectives, often worthwhile ones. The industries need return on their investment; marketing experts are keen on maximising turnover (hidden gems are of little use!); analysts are under strong pressure to please their customers and make “true” predictions regarding the evolution of the market; congress organisers are competing to craft the best possible program in order to attract as many delegates as possible; the various press bodies are looking for exclusivity, prime time releases or the “best selling” of (preferably bad) news; journal editors are obsessed by their impact factor and growth in readership.....and what about doctors? Doctors are influential, and all of the above mentioned pressure groups are trying (all too often successfully) to engage doctors in singing their song. While the professional and scientific community should care primarily (exclusively?) about progress in patient care, problems arise from conflict of interest issues as well as from the confusion of interest issues. Investigators may be sensitive to public exposure, better timeslots, wider exposure and therefore accept to delay data disclosure or select one forum rather than another for presentation of their results. Confusion of interest issues are even more difficult to deal with, that is when doctors are endorsing some of the above mentioned agendas, rather than living by one of the

essential duties expressed by the Hippocratic oath, namely the obligation to teach and share “know how” or any information that can be useful to patient’s well being.

“To hold him who has taught me this art as equal to my parents and to live my life in partnership with him, and if he is in need of money to give him a share of mine, and to regard his offspring as equal to my brothers in male lineage and to teach them this art – if they desire to learn it – without fee and covenant; to give a share of precepts and oral instruction and all the other learning to my sons and to the sons of him who has instructed me and to pupils who have signed the covenant and have taken an oath according to the medical law, but no one else.”

The very reason why scientific meetings remain popular while all the information is basically available on the internet is because meetings provide unique opportunities for face-to-face interaction between peers, discussion of good and bad fortunes, the sharing of tips and tricks. These opportunities are now increasingly often jeopardised by disruptive embargo rules and regulations.

As far as true “Late Breaking Trials” or “Hot Line” communications are concerned, some form of embargo is surely appropriate, especially when dealing with pivotal studies on drugs or devices that are commercialised by publicly owned companies. Financial and stock market operations that could be illicit or raise ethical issues can be prevented or at least minimised by the embargo process. It should, however, be noted that some form of minimal communication, like issuing a press release mentioning that a given trial did or did not meet its primary endpoint, without disclosing exact figures, can be deemed necessary in order to avoid potential legal issues with corporate governance rules. Specific issues with regard to publication embargo on behalf of major medical journals are complex matters and these have been analysed in full length in many articles.

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The present editorial refers specifically to embargo restrictions that are now often increasingly imposed on nearly all forms of scientific communication at congresses, including reports on trial updates or even presentations of any type of study, in the absence of direct financial implications. These rules are promoting a number of skewed behaviours, particularly on the behalf of younger researchers who feel compelled to adhere to the restrictions that congress organisers or scientific societies seem to be capable of imposing on them. For instance, while the audience is expecting data disclosure, presenters will interrupt their presentation when it comes to the results slide. The attendees are then invited to attend the next meeting that will take place in Krottenburg or else, and the speaker usually explains such unacceptable behaviour by a statement like: "Our abstract has been accepted for presentation here or there and I am not allowed by the meeting organisers to disclose the results until then". I have even attended a presentation during which the speaker/scientist teased the audience with great, provocative results and eventually concluded that he could not show any data because he was filing a patent. Under these circumstances you really wonder why someone should be submitting an abstract at all: it is clear that the submitter never had a plan to present any data. This doctor has replaced scientific communication by marketing and advertisement, the ultimate example of what I call confusion of interest. Other examples of skewed behaviours pertain to trading between study sponsors, meeting organisers and investigator/presenters. If you decide to present at our meeting rather than at theirs, we will provide you with an extended slot, at the best time of the day, on the day with the largest attendance, etc...and all sorts of fishy deals or practices like these, more genuine to belly dancing than to the world of scientific discovery.

When it comes to "Hot Line" sessions, breaking an embargo is seen as a breach of trust and can result in sanctions. It should be noted that the three major cardiology societies (ACC, AHA and ESC) have attempted, but failed, to reach a global agreement. Indeed, they were not able to design a common policy with respect to rules, regulations and possible reactions in case of breaches. Late breaking communications at major US meetings have been taken off the program because of disclosure or leaks to the press, either intentional or accidental. The dispute between the American College of Cardiology and Dr. Martin Leon at the occasion of the alleged premature disclosure of the COURAGE trial has received massive attention on the internet (see for instance the relevant documentation on MedPage Today). The interested reader can find a detailed account of the events that led to the proposed disciplinary action and I will not comment on this, except by observing that current embargo rules at TCT conferences are probably the most stringent of all cardiology meetings, an illustration of the old French saying, "ce sont les braconniers qui font les meilleurs garde-chasse" (It is the poacher that makes the best game-warden). At the ESC, and certainly at EuroPCR, regulations are rather mild. Embargo rules are restricted to true "Late Breaking" communications, meaning the première public disclosure of major, clinically-relevant, randomised clinical trials.

So what would be a reasonable compromise between wild, irresponsible, possibly inaccurate communication versus excessive

embargo rules that only serve the war between various stakeholders for control of the information world?

From a clinical scientist's perspective, I consider free access to information as one of my fundamental human rights. Extension of embargo rules to virtually all forms of scientific communication, as we are witnessing, is totally unacceptable. It can be seen as yet another attempt at reducing professional leadership. When this trend is continued, it eventually implies loss of data ownership on behalf of any investigator. I see it as our collective duty to resist these pressures, no matter from which corner they are coming.

As a matter of fact, a reasonable compromise should be based on a number of simple, common sense rules. These can guide your decision to endorse or to... resist the embargo that anyone would like to impose on your freedom to communicate.

– Embargo rules should only be applied to true "Hot Line" or "Late Breaking Trial" presentations, exclusively for studies that have direct financial strings attached.

– Of course, scientific data should only be released when validated, robust, complete and thoroughly analysed.

– In this flat world, whether the data are first presented at this or the next meeting should depend exclusively on random effects, i.e. the first moment at which the study results become available, without consideration for geography, origin of the data, institution of the principal investigator or anything else.

– For sponsored studies, communication plans are discussed and agreed upon at the time of protocol implementation, making sure that the investigator's prerogatives are respected.

– Central to the physician's agenda is the patient's well being. Therefore, we shall not take part in manipulative communication of marketing plans, we will not show slide presentations prepared by the industry without being fully in control and understanding their content, we shall never agree to delay – let alone keeping under cover – valuable or relevant information. The latter is particularly compelling when a given product, device or drug under study is already available to doctors and patients.

### Timing for 2009 EAPCI Elections

EAPCI is preparing for its upcoming elections concerning the positions of President-Elect, Secretary and Treasurer for the terms 2009-2011.

Deadline for application to any of these positions is the 30th of January 2009.

All applications must be sent to A. Lafont, President of the Nominating Committee.

This event is crucial for the future of our association. These elections concern every member and in order to participate in the electoral process, you must join the EAPCI as soon as possible.

Applications for membership can be found on the website of the ESC: "[www.escardio.org/constituent\\_bodies/EAPCI](http://www.escardio.org/constituent_bodies/EAPCI)"