The public way to peer-review

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There is a substantial divergence between the standards of integrity associated with "good science" and the problems imposed by the conflict of interest on research, specially in the biomedical field. There are at least as many ways in which information may be altered and the production of new scientific knowledge may be affected as there are links that can be established between researchers, private companies, and editors and staff of the specialized press. The pressures resulting from this high number of connections can affect all stages of research, from trial design to data analysis, from result publishing and dissemination to who will be the author of the articles.¹

The imposing presence of private companies has an influence on communication that goes beyond the publishing on specialized journals of the scientists' works. Drug companies have found very effective ways of influencing the circulation of medical and scientific information. These involve universities, patients associations², physicians³ and

¹ Bodenheimer T. Uneasy alleance – clinical investigators and the pharmaceutical industry. "N Engl J Med" 2000; 342 (20): 1539-44

² Herkheimer A. Relationship between the pharmaceutical industry and patients' organizations. "BMJ" 2003; 326:1208-10

³ Wazana A. Physician and the pharmaceutical industry: is a gift ever just a gift? "JAMA" 2000; 283 (3): 373-80

their families⁴, the mass media⁵, and public institutions which should be supervising the creditability of the research.⁶

The extent of this conflict of interests reveals the particular characteristics of the communication system that exists around biomedicine.

This system involves a wide variety of social actors, often with conflicting aims and motivations, and must be studied bearing in mind the presence of drug companies and their altering effect on the production and circulation of scientific and medical information.

This is a distortion factor with at least two remarkable characteristics: it is widespread at different levels and it cannot be easily quantified.

The possible reactions

The scientific and publishing communities have been searching for solutions for quite some time.⁷

In Italy, growing concern about a conflict of interest in the biomedical field has led a group of researchers, physicians and experts in science communication to create a Coordinating Committee for the Integrity of Biomedical Research (CIRB). The CIRB⁸ is endeavouring to solve the problems posed by the conflict of interest starting from the assumption that individual researchers, institutions and health administratives have a limited capacity of reaction. The CIRB has made an appeal in favour of transparency and scientific independence of clinical research and public health care. The appeal stresses the need to find modes of communication guaranteeing the credibility of research results, the independence of scientists, and the safeguard of citizens' rights. The editors of scientific journals have been asked for a formal commitment to "openly

⁴ Mc Kinney WP, Rich EC. Gifts to physicians from the pharmaceutical industry. "JAMA" 2000; 283(20):2656-2657

⁵ Cassels A, Hughes MA, Cole C, Mintzes B, Lexchin J, McCormack JP. *Drugs in the news: an analysis of Canadian newspaper coverage of new prescription drugs.* "Can. Med. Assoc. J.", 2003; 168: 1133 - 1137.

Similar research was conducted on Italian scientific journalists. It can be viewed at <u>www.cirb.it</u>. It is also quoted by Pietro Dri in his article *Professione: giornalista critico* published on "Scienza Esperienza" and available at <u>www.scienzaesperienza.it/news/new.php?id=0254</u>

⁶ Michaels D, Wagner W. Disclosure in regulatory science. "Science", 302, 2073.

⁷ Giancarlo Sturloni, *Niente da dichiarare? Narrazioni di confine sul conflitto di interesse*, "Jekyll.comm", n. 8, marzo 2004

⁸ For CIRB's proposals and initiatives, see <u>www.cirb.it</u>

report any potential conflict of interest which may concern them or their editorial staff".9

The CIRB's appeal is in line with the sensational action taken in 2001 by thirteen editors of major international biomedical journals, who wrote a joint editorial stating that in future they would not publish articles on studies carried out under contracts that did not give researchers full responsibility on the conduct of their research and the circulation of data and results.¹⁰

The *JAMA* and the *BMJ*, leading journals in this field, have been studying the procedures adopted to select and publish scientific works for several years. Starting in 1989, they have been organizing every four years increasingly succesful conferences on peer-reviewing and biomedical publishing. These meetings have become fundamental for those scholars and scientists who are concerned about the future of scientific publishing. In the next conference, which will be held in Chicago in 2005, the conflict of interest is presented as one of the major topics of discussion.¹¹

This and many other initiatives show the effort that the scientific community and biomedical journals are making to find a solution to the conflict of interest. Many of these attempts address communication processes, which are sometimes the cause, and sometimes the effect of the conflict of interest.

Despite these efforts, the impression is that up to now no solution has been found by scientists and publishers: it seems that the conflict of interest is becoming just another working condition rather than a factor to be eliminated.

For a collective peer review

The scientific community alone is not able to ensure the trustworthyness and transparency of research because of the distorting effects of the conflict of interest. This could provide a new interpretation of certain emerging phenomena which are increasingly characterizing communication: it could be that the various groups involved in the production and publishing of biomedical studies are able to act on them through a

⁹ Taken from the CIRB's appeal, available at <u>www.cirb.it/appello</u>

¹⁰ Davidoff F, DeAngelis CD, Drazen JM, Hoey J, Hojgaard L, Horton R et al. *Sponsorshio, autorship and accountability*. "JAMA" 2001;286(10):1232-1234

¹¹ Fifth International Congress on Peer Review and Biomedical Publication. "JAMA" 2003; 326: 563-564

new form of peer review, not as strict and codified as the one adopted by scientists, but with noticeable effects on research.

According to this hypothesis, not yet confirmed, such a pervasive conflict of interests between the various social groups might work not only as a source of distortion, but also as the initial stimulus to the circulation of information. The conflict of interest, in other words, could set off a collective reaction which, disorganised as it may be, would be crucial in ensuring the integrity of research and the scientists' freedom of choice.

To complement our view on the issue, we would like to recall a story, not yet finished, which involves the National Institutes of Health (NIH), the public institution which directly carries out or coordinates all biomedical research in the US.

The NIH have been for some months now at the centre of a controversy because of the private funding which some of their researchers have been receiving for years. The accusation is that, as a consequence of very well paid consulting deals with drug manufacturers, some NIH researchers have produced poor science. Relations with drug companies, it must be said, are allowed by the institute's regulations. Indeed, the scientists who have received both public and private money are not being accused of breaking the law, but of having failed to act as supervisors and become too intimate with those who were to be supervised, with negative consequences on the independence of their research.

It all started with a four-page investigative report published on December 7, 2003 by David Willman in the *Los Angeles Times*. Willman's article on the conflict of interest involving the largest American biomedical research institute was complemented by an editorial about the possibility of subversion of the US public health care system.¹² The concerns expressed by the *Los Angeles Times* reached the ears of politicians, in particular Arlen Spencer, Republican and chairman of a special Senate subcommitte in charge of financing US public medical research, and Tom Harkin, Democrat and ranking minority member in the same subcommittee, who asked Elias Zerhouni, head of the NIH, to report to the Senate on how the institute was going to ensure the transparency and quality of its research.¹³ Spencer and Harkin are major supporters of the NIH which is why they acted so promptly following the *Los Angeles Times* reaching \$27,000 billion.

¹² Marshall E. Zerhouni pledges review of NIH consulting in wake of allegations. "Science" 2003, 302, 2046

¹³ Kaiser J. Senators probe alleged financial conflicts at NIH. "Science" 2004, 303, 603-4

Zerhouni accepted. The head of one of the largest public research institutes accepted to undergo a public examination on the problems posed by conflicts of interest. He also accepted to be judged not only by other researchers or by his peers, but also by representatives of civil society, in an attempt to find a remedy and guarantee the quality and reliability of the research done by the NIH. He is now looking for solutions to the problems posed by the conflict of interest and he is doing so together with politicians who have been moved to action by a journalistic inquiry.

It may be argued that there is nothing particularly surprising about this, nor particularly relevant to the hypothesis that we are putting forward. After all, how was Zerhouni supposed to react to a request by those people on whose support the very existence of the NIH depends? What's new about a newspaper inquiry raising scandal and two senators asking political authorities for clarification? What are the consequences for communication and what's peer-review got to do with all this?

The question is whether this and other similar stories show an incapability, inherent in the biomedical community, to assess the quality of the science it produces when a conflict of interest is present. Also, we have to ask ourselves whether or not scientists, unable to solve the problem relying exclusively on their professional ethics, have to seek the help of civil society.

This would mean extending peer-reviewing to social actors outside the scientific world, which would be necessary in some cases not only to test the honesty and transparency of individual researchers, but also to give a collective validation of the process through which scientific knowledge is produced.

The outcome of the NIH affair remains uncertain, but this is certainly a good example of how the communication system can find new ways of directing research and negotiating conflicts.

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