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CONFLICTS OF INTEREST AND PUBLICATIONS: 20 YEARS OF OBSERVATIONS IN MEDICINE

Hervé Maisonneuve

1. Introduction

Since the 1990s, I have investigated the problems of relationships and conflicts of interest in the biomedical field through publications.* Since 2009, I have published a blog on journals and scientific integrity. I have been looking at the main developments I have observed, in terms of concepts, research areas, or the awareness of those involved in the research. I have relied on posts from my blog and articles and books from my library.

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After qualifying as a doctor (1979), I became involved in a learned society (EASE, European Association of Science Editors). Later, I chaired EASE (1994-1997) and created the association's journal (*European Science Editing*). From the 1990s onwards, my involvement in medical writing, my initial job in clinical development in the pharmaceutical industry, and my academic activities have led me to reflect on the problems of misconduct in science.

I began publishing letters and articles on malpractice in medical research in 1990. It was not until 2000 that I began to publish more on misconduct, and I started my blog in 2009. I began speaking more freely when I retired (2014).

Cases of misconduct were initially described through the lens of the malfunctions observed in scientific journals; relatively few were addressed from the perspective of universities and research institutions. Such misconduct can be classified as fraud (fabrication and falsification of data, plagiarism) and dubious or questionable research practices. In the literature, these dubious practices seem to be discussed less frequently than fraud, even though they are common and affect at least half of all publications (Horton, 2015). In 2022, the *Revues et Intégrité* blog contained more than 3,000 posts on the workings of publications and integrity issues, and nearly 200 posts listed with the keyword “relationships of interest”. I have more than 20 books on conflict of interest in my library. These issues have been approached from different perspectives. I have observed how relationships of interest are perceived, particularly in the biomedical community and areas where public health is threatened (e.g., agri-food, tobacco, asbestos, lead, etc.).

2. The Current Dilemma in Managing Conflicts of Interest

There are many approaches to regulating relationships and conflicts of interest. These schools of thought have evolved, and organizations vary in their policies on conflicts of interest. For a while, researchers with relationships of interest may be excluded, and then a change in strategy may allow them to be accepted. Strategies evolve.

There are three schools of thought:

- **The Witch-hunt** banishes experts with conflicts of interest. At prestigious journals (e.g., *British Medical Journal*), these experts may never be asked to write training articles, editorials, or even literature reviews. In the case of public agencies and learned societies, experts may not serve on groups that advise on decision-making or draft practice recommendations. Regarding research articles, no restrictions apply, provided that interests are declared, which is logical. However, journals and institutions sometimes overlook the situation of reviewers, who are often anonymous when assessing a manuscript or research project. Furthermore, there are variations in practice among journals and institutions.
- **Transparency** refers to asking authors and experts to fill in forms several pages long providing all the information about their activities and relationships. These take the form of free declarations that are accessible on websites. Such declarations are not checked by journals or institutions, and under-declarations are frequent. In fact, checking them is impossible, so there are endless disputes over how to correct them.

- **Tolerance** considers that non-financial conflicts cannot be avoided; thus, there is no point in declaring them. Conflicts of interest are myths that jeopardize innovation and reveal an anti-industry movement (Stossel, 2015). Tolerance is justified because declarations of interest generate significant, even unnecessary, administrative work. Financial interests may be declared; however, this is left up to the discretion of the researcher, who declares only interests directly related to the work presented. There is no point in declaring everything. Various positions have been expressed, such as “having many relationships fosters the independence of the researcher” or “No conflict, no interest” (Nipp & Moy, 2016,).

3. A Brief History of Conflicts of Interest: Insufficient Research

Publications on the theme of “conflict of interest” in biomedicine are slowly increasing every year in the PubMed database. Depending on the search terms and limiting ourselves to the titles of articles containing “conflict of interest”, between 200 and 400 articles are indexed per year; this increase began in the 2000s. The PubMed database soon had 7,000 articles with the search query *conflict* of interest[TI] OR “Conflict of Interest”[MAJR:NoExp]*. Few high-quality research articles have been identified: most are editorials, comments, opinions, and literature reviews. More evidence is needed in every scientific field that analyses conflicts of interest.

Since the Second World War, there have been several phases (Hauray et al., 2022): first, these notions emerged in reference to the proximity between government departments and private organizations. Subsequently, these issues were adopted by the biomedical research

community, once biomedical research entrepreneurs arrived on the scene. This was followed by international expansion and the use of these concepts to describe the influence of major pharmaceutical groups and agri-food groups. The last phase is marked by the politicization of conflicts of interest and the formalization of procedures to manage them.

Conflicts of interest are analysed differently depending on the field of research. All researchers analyse a common base (definitions and management), but they apply visions specific to each scientific community. For some, money is key, because it makes it possible to value and classify interests or even avoid certain behaviours. Non-financial interests, which are impossible to manage or avoid, are less important than financial ones. In medicine, conflicts of interest have been widely studied, in relation to scientific publications, medical training, drafting of practice recommendations, and clinical practice (Lo & Field, 2009). Most definitions apply the concepts described in the Bible, namely that “no one can serve two masters”, explaining that a decision is difficult when two interests conflict (*The Holy Bible*, Matthew 6:24-34).

Biomedical researchers were the first to describe the relationships between public institutions and private industry in the fields of health products, agri-food, and tobacco. The first book I bought on the topic was published in 1992 (Porter & Malone, 1992). This book shows the birth of these concepts, describing collaborations between institutions and the private research sector in the 1970s and 1980s. The driving forces behind research in the 1990s were curiosity, altruism, and glory; money was not the predominant motivation. Institutions, rather than researchers, were on the front line.

Gradually, the editors of biomedical journals have sought to improve transparency. They have slowly added requirements concerning relationships of interest to their instructions to authors. Controversy arose between those who demanded such declarations for all articles and those

who required them mainly for research articles. Some medical journals refuse contributions such as editorials, literature reviews, and commentaries if the authors have relationships of interest. In a large sample of high-impact-factor medical journals, it was estimated that, in 1997, 16% of journals required authors to declare conflicts of interest, whereas in 2008, 89% of journals had this requirement (Blum et al., 2009). Although requested in the instructions to authors, some journals do not mention relationships of interest for all articles: if authors “forget”, some journals make no demands, as this is deemed to be unnecessary administrative work.

Lawyers and administrators tend to discuss the regulations and moral aspects of relationships of interest, sometimes comparing them between countries (Rodwin, 1993, 2011). Conflicts of interest refer to trust and loyalty. They examine the introduction and interpretation of conflicts of interest in laws and regulations, as well as possible sanctions. The authors describe the consequences of conflicts of interest in health scandals. Going after the responsible researchers is not enough: the relationship between public and private institutions needs to be reviewed. Governments want to intervene to regulate these relationships of interest, for example, by creating administrative bases for all contracts between industries and health care professionals. Relationships of interest have major economic consequences, and some people even wonder whether all research should be publicly funded.

Economists believe that articles give researchers market value (Moosa, 2018). A researcher who publishes acquires value in the labour market and is allocated resources more easily. Sociologists also describe these mechanisms, whereby researchers and higher education establishments tend to maintain their domination (Merton, 1968). Like their colleagues in other sciences, they highlight the excesses of the “Publish or Perish” model. These are consequences of neoliberalism and

globalization, which have treated higher education as a private good. Researchers have moved away from teaching and other activities to concentrate on the volume of their publications, while reducing their quality.

Social science researchers explore the consequences for society and institutions, along with ways of preventing these abuses (Hauray et al., 2022). They note that, in some prestigious medical journals, over 75% of articles are signed by authors with relationships of interest and this has a major impact on the dissemination of knowledge. They describe the consequences for society such as abusive drug prescriptions linked to the manipulation of experts (e.g., antidepressants, antirheumatics, and antidiabetics). The concepts of manufacturing ignorance and creating doubt characterize these publications, which are designed to serve the interests of the industry at the expense of the interests of science and the public. Industries sometimes fund researchers and/or opaque institutions to conduct research on obscure theories. Experts who have been influenced may propose such theories to scientific communities and the general public. Industry management of opinion leaders is highly professional, and this has consequences for health. Some industries hinder, oppose, or delay publications, whereas others influence research by providing funding in areas of no value to public health.

Sociologists and toxicologists such as Henri Pézerat and Annie Thébaud-Mony have devoted their professional lives to studying relationships and conflicts of interest in the field of public health. They have gone further in their reasoning, suggesting that some researchers are following mainstream thinking. They describe the corruption of science in the service of the private interests of industrial groups and their shareholders, with the complicity of the state (Thébaud-Mony, 2014). The number of cancer cases has increased sharply over the last 30 to 50 years. Under the leadership of epidemiologists and oncologists, resources are directed towards cancer treatment. The financial stakes are high (for diagnosis and

treatment). However, few resources have been devoted to identifying environmental causes and eliminating the agents responsible for cancers. That would be detrimental to industries aware that their products are carcinogenic. The public is satisfied with this situation.

4. Increasing Bureaucratization of the Process: Which Taxonomy Should We Choose?

One excellent American study is of particular interest (Kesselheim et al., 2012). The researchers compared clinical trial abstracts submitted to 503 internists. These abstracts either did or did not have declarations of relationships of interest; they were assigned randomly. The study's conclusion is worrying. The doctors were very good at characterizing the quality and rigour of the research presented. Declarations of interest had a negative impact on their perception of the conclusions, irrespective of the quality of the work. There is a gradation between "no disclosure of relationships", "existence of public relationships" (National Institutes of Health, in this case), and existence of "industrial relationships". Relationships with public-sector organizations have a negative influence on perceptions but less so than industrial relationships. The absence of personal or financial connections seems to reassure readers.

There is no taxonomy common to all players and areas of science. Scientific journals and public institutions use terms without specifying the variations and nuances in the concepts: public declaration of interest, relationships of interest, conflicts of interest, financial relationships or conflicts, non-financial relationships or conflicts, competing interests, disclosures, relationships, and activities.

The temporality of the relations to be declared varies; should only relationships from the last three or five years be considered or must one go back further? Should only research-related relationships, or all potential

relationships, be declared? Should we declare the relationships of spouses and children? There is additional confusion as some people clearly distinguish between relationships and conflicts of interest, whereas others equate the two concepts. How should formulas such as “the authors have not submitted a declaration” or “the authors have no conflict of interest related to this work” be interpreted?

In 1984, the editor-in-chief of the *New England Journal of Medicine* announced in an editorial the introduction of a policy of declaring relationships of interest (Relman, 1984). The *Journal of the American Medical Association (JAMA)* followed suit the next year. In 2002, the *New England Journal of Medicine* relaxed its rules (Drazen & Curfman, 2002). In 2006, *JAMA* required authors to sign a declaration of relationships of interest and to disclose these relationships at the end of the article (Blum et al., 2009). The relations in question were essentially financial. In 2018, journals in the *Nature* group strengthened their requirements by requesting a declaration of non-financial relationships (Anonymous, 2018). In 2019, the ICMJE group reviewed its recommendations and reporting forms. The terms “financial and non-financial relationships and activities” have now replaced the term “conflict of interest” in the declaration forms (ICMJE, 2023).

It is up to the reader to judge whether or not there is a conflict of interest. The reader has information about the relations and must assess whether there is a conflict of interest and judge the article accordingly. This requires critical thinking. Little information is available on how readers, users, and the general public perceive these concepts. Is it a matter of declaring relationships of interest without declaring conflicts of interest? This semantic nuance is worth thinking about in the context of the bureaucratization of declarations.

5. The Conflicts of Interest in Biomedical Journals

A book by Richard Smith, a former editor of the *British Medical Journal*, presents the trenchant opinion that prestigious biomedical journals are the armed wing of the pharmaceutical industry (Smith, 2006). He echoed the positions of the editors of the *New England Journal of Medicine*, in particular Arnold Relman and Marcia Angell, who had to fight to explain that medicine was for sale and lost their editorial positions (Steinbrook et al., 2015). There are major conflicts within journals, particularly those prestigious journals whose staggering revenues depend on pharmaceutical advertising and the sale of reprints (the right to reproduce published articles that are sold to industry to be distributed to prescribing doctors). The market prices of reprints sold by high-impact journals to the pharmaceutical industry are not publicly available. Discussions between experts on social networks estimate that the average price is one million dollars.

There are many cases of misconduct, which are often revealed as a result of information divulged by whistle-blowers. There is a lot of concealed money in medicine. Some cases have led to corrections by journals but rarely to articles being retracted. Connections between opinion leaders, directors of learned societies, and industries are common (Moynihan et al., 2020). I will discuss two cases, but they are far from uncommon. They show that journals publish what authors disclose without checking the validity of their statements.

In the case of the *Journal of Spinal Disorders & Techniques*, the editor-in-chief was an orthopaedic surgeon specializing in spinal prostheses (Fauber, 2009). His journal published numerous articles on research funded by an industrial company (70 favourable articles in 56 issues between 2002 and 2009). The editor-in-chief is said to have received US \$20 million from the manufacturers of these prostheses. No relationships of

interest were declared by the journal or its editor-in-chief. How common is this type of behaviour? And how many editors-in-chief are loyal to particular schools of thought or beliefs (e.g., religious, anti-abortion, against medical aid in dying), with or without financial stakes, in making decisions that should be neutral and factual?

Dr José Baselga was a renowned expert and head of the Department of Oncology at the Memorial Sloan Kettering Cancer Center, New York (Ornstein & Thomas, 2018). He was also the editor-in-chief of an oncology journal, chairman of working groups in learned societies, and member of six boards of directors of pharmaceutical companies. He did not disclose any relationships of interest in his approximately 100 published articles. According to data in the ProPublica database, he received several million dollars from the pharmaceutical industry. It was revelations in the *New York Times* that prompted the journals to react, in particular, by correcting the declarations of relationships of interest in 17 articles published in prestigious journals. This case shows the passivity, if not naivety, of the communities of researchers and editors of scientific journals. Dr Baselga eventually resigned from his position at the hospital to take up a post as the medical director of a pharmaceutical company.

The COVID-19 crisis provided evidence of a suspected but poorly described phenomenon. There were no data on the practices of journals that preferentially accepted articles by certain authors, regardless of their interest or quality. The practices of Prof. Didier Raoult's team in Marseille eventually aroused many people's suspicions, as described in detail by Locher et al. (2022). The institute that Prof. Raoult heads up also controls several journals. Several researchers employed by this institute are influential members of editorial boards and even editors-in-chief. Researchers on the Marseille team publish a great deal in these so-called self-promoting journals (their manuscripts are never rejected), which have extremely short publication turnaround times. However, such journals may earn a

certain reputation in the scientific community... Occasionally, researchers draw attention to the need to disclose the interests of editors-in-chief, editorial board members, and even reviewers (Dal-Ré et al., 2020). The relationships of interest of editors and editorial board members should be accessible on journal websites, but they rarely are. At the very least, reviewers' potential conflicts of interest should be declared to editors-in-chief.

Some journals have no explicit policy regarding declarations of interest in their instructions to authors. Most of these journals also fail to specify the protection of whistle-blowers and the policy in force regarding researchers found guilty of misconduct. Some journals that do have guidelines do not apply them. These are mainly small, lower-quality journals that do not have the resources of the prestigious journals. The same can be true of journals in non-English languages or profit-oriented journals that do not control their publication content.

However, there is an alternative to these obvious conflicts of interest. When it comes to research on smoking, some medical journals refuse to consider studies that are partially or wholly funded by the tobacco industry. Prestigious journals from the PLOS and BMJ groups have implemented these strategies (Godlee et al., 2013). Why would scientific journals not apply the strategies they use to exclude research funded by the tobacco industry to also exclude publications funded by industry in other areas of research? Some biomedical journals in our field, the French journal *Prescrire*, do not accept pharmaceutical advertising or publications by authors with relationships of interest. These journals are financed solely by subscriptions from readers who, like the editors, have a militant spirit. This business model shows that readers are prepared to pay the price of independence. However, let us be realistic; this not-for-profit model has only been adopted by a few scientific journals.

6. Mapping Shows a World that is Neither Regulated Nor Transparent

Several countries have databases for identifying potential conflicts of interest. Industries disclose all financial flows directed to researchers and research teams (fees, collaboration contracts, and travel and hospitality expenses). These databases enable one to compare the information with the relationships declared during the research. Some authors also suggest that national databases should be created containing all the up-to-date declarations of researchers' relationships of interest (Lichter & McKinney, 2012). In 2021, some researchers conducted a scoping review showing the existence of a major network of relationships between health care product industries and all parts of the health care ecosystem (Chimonas et al., 2021). The authors analysed 538 articles from 37 countries. Unfortunately, despite the number of publications, not all the potential relationships were sufficiently described. For example, there is a great deal of discussion about the behaviour of health care professionals, but less about administrations and governments.

Several questions remain at this stage of our investigation. Would the most studied relationships of interest be those involving research published in journals? Are relationships disclosed and managed in relation to oral training in universities? Are relations between groups of experts who select the products purchased by a health care establishment more or less significant and better controlled than those involving the authors of a publication? We have not mentioned conflicts of interest in clinical practice, which have been well studied (e.g., excessive prescription of biological or radiological tests to be carried out by the practice of a spouse or a child with a different family name).

Outside the field of relationships and conflicts connected to publications, the behaviour of opinion leaders has been investigated according to their level of involvement with the health care industry. Public websites

can be used to trace sums allocated to researchers in the medical field. In France, virtually all learned societies have at least one board member with industrial relationships (Clinckemaillie et al., 2022). It has been observed that the practices of French GPs with no industrial relationships outperformed those with relationships (Goupil et al., 2019). Finding a network of relations that is insufficiently regulated, poorly controlled, and even opaque, these authors called for more research and regulation in the interests of citizens and confidence in the health care system.

During the SARS-CoV-2 pandemic, there were numerous debates about the relationships of interest of researchers who spoke in public about treatments and vaccines. These debates were sometimes violent; for example, researchers linked to Gilead, particularly in the field of AIDS, spoke out against hydroxychloroquine and promoted Gilead's future development of COVID-19 treatments. It was speculated that the experts' opinions depended on the amount of compensation they received from Gilead. A journalist summarized this situation in an article that cited the reactions of infectious disease specialists (Gutierrez, 2020). This case shows how difficult it is to interpret the impact of relationships and conflicts of interest because hydroxychloroquine did not in fact work against COVID-19. So were these experts expressing opinions based on the absence of evidence or were they favouring Gilead?

7. Conclusion

Conflicts of interest will always exist; fortunately, we all have relationships of interest. This article describes three strategies for managing them: witch-hunting, transparency, and tolerance. If it were up to me, I would opt for an impossible combination of these three strategies.

- **Witch-hunting** implies depriving ourselves of competent experts who have been identified by industry precisely because of

their skills. Their knowledge of all sectors of research is an asset if they know how to manage different opinions fairly and choose wisely. Some of these experts are indeed intelligent and highly persuasive; should we do without them? Exclusion is a policy that showed its flaws during Prohibition (and McCarthyism) in the United States. A medical example: Can a circumcised man write an article about circumcision? The witch-hunt strategy calls for his exclusion, but who is to say he is not qualified to write the manuscript?

- **Tolerance**, for all its risks, appears to me to be a reasonable position. We must have confidence in people: most researchers are honest. Deviant researchers comprise a minority. We all possess values of altruism, integrity, and honesty that should not be systematically doubted. Tolerance has the advantage of not adding to administrative red tape, which consumes time and resources. It requires a critical mindset to interpret facts.
- **Transparency** allows for the bureaucracy that appeals to our leaders. I have always defended this principle; however, I have often suffered as a result. I am a self-employed manager and shareholder in a commercial company (H2MW) for which I provide training and publish a blog. All of our financial data are easily accessible (registry office and www.transparence.sante.gouv.fr). Following my public denunciation of the deviant practices of researchers in Marseille, social media have spread the word that, in 2021, this limited company received €26,000 from the pharmaceutical industry, which was true, but which was supposed to explain my views on the researchers in Marseille. Wonderful! This caused me a lot of trouble on social media, and defending myself would only have increased the suspicion and mistrust. Uninformed members of the public have assumed that

this money is in my pocket, whereas it is supporting charitable activities, my business expenses, and the maintenance of a website open to all.

Transparency also has its limitations: disclosure of any kind of relationship, including a public relationship, leads to suspicion. However, let us have faith.

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