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Behind the scenes of scientific articles: defining categories of fraud and regulating cases

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1. Introduction

On March 7, 2012, the blog Retraction Watch¹ announced that Yoshitaka Fujii, Associate Professor of Anesthesiology, had just been fired from the University of Toho for having published nine clinical studies that did not comply with the current ethical guidelines. The blog also announced that one of the journals concerned, Anesthesia & Analgesia, whose subtitle is "the gold standard in anesthesiology," revealed communiqué that a study of the integrity of Dr. Fuiii's research had been launched in 2010 [1]. The journal's American editor-in-chief indicated that 24 other articles could be the subject of scientific fraud. He also stated that in 2000 his journal had published a letter from German researchers presenting a metaanalysis of 47 articles jointly signed by Dr. Fujii [2]. These authors underscore the remarkably identical frequency of headaches as side effects of anesthesia in all studies and concluded that only an underlying influence could explain this stupefying consistency.

Dr. Fujii had responded with a short jointly published letter, simply indicating had reported empirical observations and that they expected given the state of knowledge. This response was sufficiently convincing to the International Anesthesia Research Society that Dr. Fujii was able to publish 12 additional articles over the following decade. Yet the German researchers had pursued their meta-analyses, in 2001 showing in Acta Anaesthesiologica Scandinavica that 64% of the clinical published antiemetic for an originated from Dr. Fujii's team, even though his dosage results diverged substantially from those produced by all of the other laboratories [3]. Following this publication, the authors alerted the Food and Drug Administration and the Japanese regulatory agency, apparently to no avail.

In March 2010, an editorial in the British journal *Anaesthesia* described the

obstacles to demonstrating falsification and the invention of clinical data, taking as an example the suspicions weighing against Dr. Fujii's data [4]. This editorial provoked a large number of responses. leading editorial boards to engage in a reflection on their role in combatting scientific fraud [5]. Also, in 2011 when Dr. Fujii submitted an article to the Canadian Journal of Anesthesia, where he had already published 39 articles, the journal opened an inquiry with the University of Toho, which revealed that there was no Committee for protection of human research subjects. prompting investigations on all of his research production [6]. At the same time, a meta-analysis of 169 controlled trials cosigned by Dr. Fujii, initiated following the 2010 editorial and verified at length, was published as a special article in Anaesthesia on March 8, 2012. It concluded that the distribution of 28 of variables published correspond to what could be expected, with the probability of occurrence under the hypothesis of independence even reaching 10⁻³³ for one of them [7].

Finally, on April 9, 2012, a joint letter from 22 editorial directors was addressed to the leaders of nine institutions that had hosted Dr. Fuiii's research simultaneously published on some of the journals' web sites. It informed them of publication of this study and announced that the articles would be retracted, unless the institutions involved could provide proof that the articles were trustworthy: "for each study concerned, we request that your institution declare 1/ that the study was conducted as presented in the article, 2/ that you have examined the primary data and verified that they were authentic, and 3/ that the appropriate ethical framework was clearly established for the study" [8]. Answering that call, the Japanese Society of Anesthesiologists led an inquiry and concluded, in its 29th June 2012 report, that 172 articles jointly signed by Dr Fujii contained falsified data and should be retracted, which is an unequaled record for a single author.

¹ http://retractionwatch.wordpress.com/

How can one explain that Dr. Fujii was able to publish apparently falsified data for such a long time? Is this an isolated researcher who was particularly skilled in fabricating forgeries corresponding to the expectations of the scientific community. including those of his coauthors²? Is this a local institutional problem related to his mandarin status, as in the case of Professor W.S. Hwang, a Korean national hero and fraudulent inventor of human cloning [9]? Are we dealing with a disciplinary idiosyncrasy, since two other anesthesiologists have undergone similar waves of retracted articles and that 4% of the articles submitted to Anaesthesia have turned out to be plagiarized [10]? Or should we consider that any academic production is potentially tarnished, implicating scientific institutions (authors, financers, editors, journals) [11]?

Two major interpretations are generally contrasted in this type of situation. The first tolls the bell of scientific integrity: it is mainly based on the massive increase of the number of articles retracted [12], on the fact that these retractions are strongly correlated with the journals' impact factor [13] or that the retractions for fraud take place in journals with a higher impact factor than the retractions for experimental or calculation errors [14]. It also responds to the high frequency of researchers having observed colleagues involved in practices they deem contrary to scientific ethics [15]. In contrast, the second interpretation ferociously defends tooth and nail a model of self-regulation. It is founded, for example, on the usually brief time between publication and retraction, the generally low number of citations related to these articles [16], the appearance in some journals temporary publication bans, and

considers the creation of specialized places such as the *Abnormal Science* and *Retraction Watch* blogs as extensions of peer review [17].

Our objective in this article is not to choose between these two positions, which stabilized over the 1980s [18, 19] and were regularly reactivated by other actors with each new case detected. Instead, from a sociology of science perspective, we wish to establish a general diagnosis on the regulation of publication practices and suggest methods of analysis, by reviewing both the recent cases and others, less recent, that they call to mind. First of all, this paper reviews how the practices deemed to be deviant have been categorized in the past by distinguishing the categories stemming from data integrity and the conditions of data production from those concerning the relationships between the authors of publications and their content. We will then analyze three specific problems and the institutional responses aiming to prevent them, channel them, and attempt to solve them.

2. Striking it rich with dubious data

Medical research for the most part has been marked by a progressive rise in ethical demands that strive toward defining the quality of the data produced. The need to collect informed consent subjects participating therapeutic research is a good example, the subject of a vast literature on its concrete manifestations [20]. Similarly, in the construction of all the instruments designed for direct or indirect use in epidemiological studies, protecting the subjects' anonymity is essential to conducting these investigations. These diverse ethical demands frame the conditions of data production: any time compliance is lacking, the reliability of the data is compromised for this reason alone, as seen with the case of Dr. Fujii. But the materials on which the results published are founded can be subject to tampering beyond these regulatory obligations.

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² Let us not forget the brilliant physicist J.H. Schön, covered with prizes and the lead author of eight articles published in *Science* and seven articles published in *Nature* between 2000 and 2001, but then fired by Bell Labs and whose dissertation was revoked by the University of Constance.

Several ways of contravening "good practices" can be identified in the series of affairs discussed herein. The first resides in the selection of relevant data to obtain more coherent results, a smoother curve, a more readable image. R. Fisher, an important statistician, geneticist, and support for eugenics, 80 years after the famous experiments by Gregor Mendel on his peas, showed, for example, that the probabilities obtained were undoubtedly too good to be true and stemmed more from a confirmation bias from than an observation. His research has contributed to designing tools to remove the biases introduced by experimenters, notably in controlled clinical trials [21]. In this process of selecting relevant data, the question of ill will is secondary to all the possible means of deviating from an experimental, observational, or statistical norm.

The second consists in conscious falsification activities, which can manifest as minor arrangements of experimental falsification material, of data. manipulation of images. D. Das, a surgeon working on the protective effects of resveratrol, explaining in fine the probable role played by wine consumption in the French Paradox, was suspected of having massively doctored Western blot images that were the basis of dozens of articles that he published. leading to his being fired from the University of Connecticut after 3 years of inquiry [22]. The multiplication of cases raising questions on the falsification of images reveals just how fragile and uncertain are the graphic representations that are held to be tangible components of scientific proof in the end [23], and raises debate on the nature of the data necessary to certify their integrity.

Finally, the third manner stems from fabrication pure and simple. Falsification extends here to all materials and is based on the pure invention of data. The example of the physician and dentist Jon Sudbø comes to mind, who, in 2006, admitted to having literally created 900 patients in a Norwegian cohort, 250 of whom had the same date of birth. This

allowed him to demonstrate spectacular effects of taking nonsteroidal antiinflammatory drugs on oral cancer in heavy smokers and to publish in *The Lancet* the year before.

distinction between selection, falsification, and fabrication is not selfevident and instead comes from ex post attribution when cases are revealed after investigations [15]. As in the affairs concerning Prof. Hwang, when there are no detailed admissions, it is impossible to distinguish between what has been authentically produced in the laboratory and what is instead voluntary or involuntary artifact. If the absence of reproducibility is often considered a clue to falsification, the opposite is not necessarily true: a highly skilled forger can produce a sort of retroplagiarism, arranging or fabricating data that others, through slow scientific work, will have actually produced and analyzed.

3. Circumventing proof of originality

One of the fundamental principles of scientific activity consists in producing original results, as indicated by the categorization of journal articles that distinguishes "original research" from "letters", "reviews", "editorials." and According to this principle, recognition of one's peers and the awarding of prizes are strongly related to the priority of original discovery. No importance is supposedly accorded to second place. Among the different ways to get around this requirement, this section will emphasize the question of plagiarism and authorship.

3.1. Plagiarism and self-plagiarism

In these conditions, the temptation is sometimes great to cite only partially and sporadically the similar work that has preceded, or even to totally omit its mention. In our era of electronic publications and cut-and-paste, there is no simpler operation than to insert one or several paragraphs written and published earlier by others into an article being

written, for example by copying a piece of text from an article on nosocomial infections in Brazil into an article on the same subject in Spain [24]. The same clearly holds true for data, figures, and images.

At times fraud is not limited to partial plagiarism: at the end of the 1970s. E. Alsabti. an alleged researcher oncoimmunology, without a doctorate, succeeded in climbing the ladder of an academic career by putting together an impressive list of publications in barely 3 years [18, chap. 3]. His tactic was simple: he copied entire articles that had already been published, modified the title, replaced the authors' names with his own, and submitted the manuscript to a less well-known journal. He succeeded accumulating more than publications in this way, in joining 11 scientific societies and in working in several prestigious American institutions.

Rather than borrowing from others' work. it can be even simpler to dig into one's data. What researchers own clinicians have long designated as a "pressure to publish" [25] has turned into the proliferation of articles based on the same research, the spawning of similar results into a variety of texts and the preference for quantity to the detriment of quality [26]. The practice of selfplagiarism has developed to such an extent that it has progressively given rise to terms such as "least publishable unit" [27], "salami slicing" [28], and even "duplicate publication" [29], and the meta-analyses effects on can be considerable [30]. Even if, contrary to others, plagiarizing this censured concealment is interpreted in a variety of fashions, everyone agrees that the basis of the problem lies in the absence of a citation of the original study [31].

3.2. Authorship

An alternative manner to bypass the requirements for originality is to maneuver around the edges of authorship. In many domains, the guidelines regulating access to article byline place value on significant intellectual contributions. Yet the suspected articles often carry the name of researchers whose contribution is considered minimal, if not inexistent, and therefore these individuals have a very distant contact with the research conducted and the results published. Since the end of the 1980s, researchers and journal editors have produced, in what is generally called "honorary authorship", three categories of authorship to denounce these situations that they judge unacceptable [32, 33].

The first designates "guest authorship", which separately treats people whose name is recognized: these are particular names that change the status accorded to an article by their presence alone. The presence of these researchers' names potentially increases the chances of the article publication and its future visibility and thus figures as a sign of quality. This practice is current and arises in many cases. The affair of the cardiologist J.R. Darsee, one of the most closely followed and documented in the 1980s, brought this practice to the light of day: other than the presence of falsified and entirely invented data, the 55 publications that were retracted often carried the name of his mentor, E. Braunwald, who had little knowledge of their content, and who had not been worried during the detailed investigations of the NIH investigators [34].

Another category, which plays less on this distinction of status or renown, emphasizes more the offer of authorship governed by the principle of reciprocity. as a gift in view of a counter-gift ("gift authorship"): it is not exceptional that researchers accept to make room for someone so as not to offend a partner making the request, to encourage future collaborations. to maintain aood cooperative relations, to thicken a list of publications, or to return the favor [35]. In this context, the above-mentioned case of E. Alsabti, nonetheless revealed an extreme and particular form of gift at the time: some of his articles included the names of fictitious authors whom E. Alsabti, at the beginning of his fall, blamed entirely for the abuses for which he was denounced.

Finally, as with other types of writing, notably literary, the name of the writer is not systematically the name of those who appear on the byline ("ghost authorship"). This is notably the case when a researcher, who does the greatest share of the work and writes all or nearly all an article, allows only his students or less experienced colleagues to be the authors of the article so as to assist them in publishing in a prestigious and thus lengthen iournal publications list.

4. Institutional regulations

Common reactions in the event of practices deemed deviant consist in reaffirming the general principles at the foundation of scientific integrity: disinterestedness, organized skepticism regularly held as cardinal virtues [36, 37] and stipulated in charters professional agreements or through specialized structures within professional or learned societies [38]. These reactions also require more restrictive concrete operations aiming to prevent and limit these phenomena by indirect actions. We will examine here three specific operations relative to responsibility. negative results, and conflicts of interest.

4.1. Restore responsibility

In an evaluation system that values individual performance, the increase of the number of authors per article is regularly described. Although guest and gift authorship cast doubt on the attribution of scientific credit, other forms are even more surprising. Some cases, most particularly the above-mentioned J.R. Darsee affair, revealed that some authors were not aware that their name had been adjoined to the suspected publications. The journals consequently took control to defend their selfregulatory function. They sought to return responsibility to the authors in two major steps. The first resulted from the many cases of fraud that shook the 1980s: statements are required, signed by all of

an article's producers to ensure that they approve the content and that they indeed intended their name to appear on the article.

The second step played out between 1996 and 2000, following heated debates between researchers, journal editors, and research administrators [39, 40]. They aimed to set up traceability of research operations so as to be able to reattribute responsibility in case of a future problem [41]. After several conferences and an experimental phase, iournals opted for a new procedure, called "contributorship", which promotes transparency: systematically describe the individual contributions in a section of the article specifically designed for this Before publication, purpose. each contributor is now invited to either describe his or her contribution in a written note, or to fill out a form that delineates a taxonomy of research operations. Thus the producers of articles should approve the final version of the text and date their engagement: each one dates and signs the letter or form manually. This procedure reinforces judicial responsibility of handwritten signature and forces each contributor to take responsibility for his or her contribution.

4.2. Publishing negative results

Whether the result of self-censure or fraudulent practices on the part of researchers, or the practice of journals for visibility or financial reasons [42], publication biases favoring positive studies are well known [43, 44]. The additional effect of this bias is relegating negative results to second-rank journals [45] or even non-publication. This has been demonstrated for antidepressants. for example [46], and for a number of substances approved by the Food and Drug Administration between 1998 and 2000 [47], to such an extent that certain researchers now take the rate of positive results published as a transdisciplinary indicator of fraud or bias [48] and others speak of "evidence-biased medicine" [49].

Tο solve this problem, two complementary solutions have been proposed. For clinical studies, this means founding academic evaluation of drugs based on applications made to the regulatory agencies rather than on the published literature [50]. In addition, certain journals propose systematically publishing negative results for all types of research, such as the Journal of Errology or the Journal of Negative Results in Biomedicine, which has an "unofficial" impact factor of 1.1. These journals consider that unexpected and failed important in results are scientific knowledge, thus returning to one of the founding principles of experimental practice of the seventeenth century, initiated notably by Robert Boyle at the Royal Society of Sciences of London [51].

4.3. Uncover and reduce conflicts of interest

A third question brings together all of the problematic aspects described in the first sections: conflict of interest. This notion was imported into the scientific world in the 1960s to describe the increasing relations between public research and industry, and the problems that this could raise, in particular in expert consultations with health and environmental regulatory agencies [52]. It is through this prism of conflict of interest, for example, that the accusations of scientific fraud against Dr. Needleman were interpreted by two of his colleagues while the Environmental Protection Agency had just adopted restrictive measures for the lead industry [53]. More generally, in environmental epidemiology, the consequences in terms of regulating results in public health have led the chemical, tobacco, and asbestos industries to not only finance research that was favorable to [54], but also to maintain uncertainty over the long term to fight against stabilized knowledge being established [55].

With the ever-increasing meshing and merging of financing from the pharmaceutical industry and academics, the notion of conflict of interest in its

contemporary sense truly appeared in the 1980s [52]: it was thus repeatedly demonstrated that financing industry or pharmaceutical laboratories influenced the results produced [56-59]. including on subtile modalities such as the favorable presentation of hormone replacement treatments well after their risk-benefit ratio was challenged at the beginning of the 2000s [60]. In this context, Elsevier was denounced for creating six seemingly scientific journals actually financed that were bν pharmaceutical laboratories and designed to present compilations of articles that were favorable to them [61]. Certain forms of ghostwriting also stem from this practice: through specialized companies, the pharmaceutical firms. once the research and articles had been completed, requested researchers who were reputed in their specialty to sign the publications in exchange financial compensation consequential [62, 63].

With reform in mind, institutions and journals began including the financing and conflict of interest sources disclosures as a solution to these problems, with, for example, regular guidelines by International the Committee of Medical Journal Editors beginning in 1993³, even though their implementation took an exceedingly long time in the eyes of their detractors [64]. Others have suggested radical reforms of complete separation between private interests and public research [65], a position recently found on expert parliamentary testimony in the discussions after the Mediator French scandal. However, everyone agrees that internal transformations of scientific production, most particularly biomedical research, has made a large number of

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³ These guidelines were revised in 2000, and the member journals of the ICMJE took a position on conflicts of interest the following year in a common editorial titled "Sponsorship, Authorship, and Accountability" praising transparency and academic independence. A conflict of interest disclosure form common to all the ICMJE journals was established in 2010.

researchers true entrepreneurs [66]. The case of A. Potti illustrates these tensions: as soon as his first articles on genomic markers of the sensitivity of different chemotherapies were published Nature Medicine and the New England Journal of Medicine in 2006, Duke University and his team boasted of "personalized medicine" that they were going to develop so as to attract patients, grants. well as the as pharmaceutical laboratories, so that they could conduct large-scale trials. But a few years later, Dr. Potti was implicated both from inside the science world by biostatisticians [67] and from the outside, through professional letters showing the "enhancements" manv that had appeared on his resumé [68], and then by his patients' families attracted by the potentially revolutionary character of his practices, who had sued for having been deceived.

5. Conclusion

Emphasizing how long these problems have been around, we had a double objective: first, showing the emblematic value of certain cases, truly striking episodes that have produced preventive measures so that these practices would not continue; second, taking stock of the increase in the number of affairs revealed that have led to the retraction of articles as a clue to a "surveillance bias." Just as certain fraudulent practices have become simpler to carry out, the detection and dissemination of behaviors considered problematic has been largely facilitated. For example, journals such as Anaesthesia routinely use plagiarism detection software, but it is also possible to construct tables that juxtapose text from several articles, showing how close they are, putting together a series of an author's variable conflicts of interest, or

anonymously denounce image falsification by circulating a video clip⁴.

The recurrent stakes in all of these problematic situations revolves around the scientific community's ability to selfregulate. Nearly all of the institutional measures describe herein directly involve academic authors. Yet for the last 15 years, we have seen the journals themselves be targeted, notably in recurrent debates aiming to assess the independence of journal editors [69] and to reform peer review [69]. What should be thought of the responsibility of A&A which for years published Dr. Fujii's articles after the first meta-analyses? How should the process leading the Journal of Clinical Microbiology to publish a plagiarized article published a few years early in its own columns be qualified⁵? Like researchers, journals are also subjected to conflicts of interest [71,72] and to the imperatives of success, partly founded on their impact factor, that incite them to introduce references motivated solely by journal citation [70], a practice recently qualified as "coercive citations" [71].

Symmetrically, the case of Dr. Fujii reminds us that journals have a tremendous collective organizational power, widely implemented in authorship and conflict of interest reforms. In addressing their letter to research institutions, journals have placed them before their responsibility, thus attempting to reverse the burden of proof. However, the distribution of the responsibility between the actors of academia is also played out on another level: the responsibility with regard to patients, the eventual victims of deviant behaviors [72]. Indeed, research having consequences in terms of treatments, prevention modalities, or,

http://www.youtube.com/watch?v=FXaOqwa nWnU

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http://retractionwatch.wordpress.com/2011/0 9/01/should-journals-apologize-to-victims-of-plagiarism-more-on-journal-of-clinical-microbiology-case/

more generally, public health is at the heart of conflicts of interest, opening it to nonacademic actors allows new criticisms to be expressed and taken into consideration through judicial and political action on the part of users and citizens.

Conflict of interests

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