

Clinical trials in medical congresses: a study on conflicts of interest

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Abstract

This article seeks to investigate conflicts of interest involving the presentation of clinical trials in Brazilian congresses of five medical specialties between 2004 and 2018. A total of 407 abstracts in 22 annals were studied. After applying selection criteria, we reached a corpus of 77 essays. A higher frequency of conflicts of interest was found involving essays with drugs for which no generic/similar option was available (p=0.000), and 48% of those with a conflict of interest declared nothing. Favorable results to the test drug occurred in 90.9% of the total of essays, but 48.6% of them lacked the p-value. The most tested therapeutic categories were immunosuppressors and immunomodulators, antidiabetic, and antineoplastic, which, together, amounted to 68.9% of the total of the involved drugs. The results pointed to hidden conflicts of interest, overvaluing of positive results of test drugs, not always with sufficient evidence, and focus of production on high-cost drugs.

Keywords: Clinical trial. Drug industry. Conflict of interest. Research, ethics. Clinical conference.

Resumo

Ensaios clínicos em congressos médicos: estudo sobre conflito de interesses

Este artigo busca investigar conflitos de interesses envolvendo a apresentação de ensaios clínicos em congressos brasileiros de cinco especialidades médicas, ocorridos entre 2004 e 2018. Foram estudados 407 resumos em 22 anais. Após aplicar critérios de seleção, obteve-se um *corpus* de 77 ensaios. Detectou-se maior frequência de conflitos de interesses envolvendo ensaios com drogas para as quais não havia genéricos/similares (*p*=0,000), sendo que em 48% daqueles em conflito de interesses não houve declaração. Os resultados favoráveis à droga-teste ocorreram em 90,9% do total de ensaios, mas em 48,6% deles não foi reportado valor de *p*. As categorias terapêuticas mais testadas foram imunossupressores e imunomoduladores, antidiabéticos e antineoplásicos, que, juntas, representaram 68,9% do total de drogas envolvidas. Os resultados apontam conflitos de interesses ocultos, supervalorização de resultados positivos de drogas-testes, nem sempre com evidências suficientes, e concentração de produção em drogas de alto custo.

Palavras-chave: Ensaio clínico. Indústria farmacêutica. Conflito de interesses. Ética em pesquisa. Conferência clínica.

Resumen

Ensayos clínicos en congresos médicos: un estudio sobre conflicto de intereses

Este artículo analiza los conflictos de intereses en ensayos clínicos presentados en congresos brasileños de cinco especialidades médicas, realizados entre 2004 y 2018. Se analizaron 407 resúmenes de 22 anales. Tras aplicados los criterios de selección se obtuvo un *corpus* de 77 ensayos. Hubo una mayor frecuencia de conflictos de intereses en ensayos con medicamentos para los que no había medicaciones genéricas/similares (*p*=0,000), y el 48% con conflictos no hubo su declaración. Los resultados favorables para droga prueba están en el 90,9% del total de ensayos, pero el 48,6% de ellos no informó el valor de *p*. Las categorías terapéuticas más probadas fueron inmunosupresores e inmunomoduladores, antidiabéticos y antineoplásicos, que juntas compusieron el 68,9% del total de fármacos. Los resultados apuntan a conflictos de intereses ocultos, sobreestimación de los resultados positivos de las drogas prueba, no siempre con evidencia suficiente, y concentración de la producción en medicamentos de alto costo.

Palabras clave: Ensayo clínico. Industria farmacéutica. Conflicto de intereses. Ética en investigación. Conferencia clínica.

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According to a ranking published by Forbes magazine in 2015 ¹, the development of health technologies by transnational pharmaceutical companies was considered the most profitable industrial activity on the planet. A survey carried out by EvaluatePharma in 2018 estimated an annual growth of 6% in the revenue of these companies worldwide, reaching, in 2024, a total revenue of 1.2 trillion dollars ².

In the last three decades, the pharmaceutical industry's production strategy has received much criticism, on the grounds that, after the signing of the Agreement on Trade-Related Aspects of Intellectual Property Rights³, in 1994, production began to be directed to a specific niche of chronic-degenerative diseases, with a predominance of me-too drugs that seek to replace a previous product with an expired patent or compete with a successful drug produced by another company⁴⁻⁷.

Other studies have shown that the real innovations are focused on high-cost drugs aimed at congenital and autoimmune diseases and cancer⁸. Hoefler and collaborators⁹, in a study that investigated the therapeutic value of 236 new drugs analyzed and approved in Brazil between 2004 and 2016, demonstrated a discrepancy between public health needs and the objectives of clinical trials. According to the authors, only 14% of the total was deemed innovative, and this was also the approximate proportion of drugs incorporated into pharmaceutical care by the Brazilian Unified Health System (SUS)⁹.

Moreover, it is already well-demonstrated in the literature that industry-funded clinical trials result in favorable outcomes at a frequency many times greater than in independent trials for the same drugs, and that there is a systematic practice of banning the publication of negative outcomes and not making raw data of the trials available for independent checking of calculations ¹⁰⁻¹³.

For some authors, these scientifically dubious results have been the center of aggressive marketing aimed at physicians, including support for academic and social activities of the category ¹⁴. Clinical practice is also affected by these relationships, as drug prescription is encouraged by intense advertising and other industry efforts that, covertly, have the ultimate goal of collecting prescriptions ¹⁵.

Hence, the massive financial support of the pharmaceutical industry to medical congresses has caused a considerable concern due to the possibility of influencing clinical practice in a direction contrary to the patient's interest and disguising marketing activities as medical education, with the potential to reach thousands of doctors and students 16,17. In this regard, Massud 15 demonstrates that about a third of pharmaceutical companies' expenditures are directed to marketing; the prescribing rate increases when physicians attend company-funded symposia and receive samples; and that this practice is harmful to patients 15,18. A 2003 systematic literature review, still without update, showed that about a quarter of clinical researchers had some type of financial tie to the pharmaceutical industry, and that approximately two thirds of academic institutions had partnerships with companies for research funding 19.

However, the concept of conflict of interest is not consensual in the literature. Some authors ^{14,16}, in agreement with the World Medical Association ²⁰, consider that the conflict of interest is real or factual only when it is demonstrated that a secondary interest influenced the assessment of the primary interest, which would be the patient's well-being or the scientific contribution by rigorous interpretation of data. In this case, the mere existence of financial ties between industry and physicians would characterize a "potential conflict of interest," and not a factual conflict of interest.

For other authors ²¹⁻²³, the influence of interests on the results of a study already characterizes scientific misconduct, and not simply a conflict of interests. From this perspective, the conflict of interests would already be real when proving the existence of a secondary interest that could influence, albeit unconsciously, the primary interest or that could be perceived by the receiver of the scientific communication as capable of having been influenced. According to this definition, any financial tie between researchers and industry already characterizes a factual conflict of interest, although this does not necessarily imply any deviation from professional ethical conduct or lack of scientific integrity in the presented data. Thus, the "potential conflict of interest" would occur when there are reasons to assume an unknown financial tie or other situations that could involve nonfinancial secondary interests such as those of an ideological, political, academic, or religious nature, among others ²¹⁻²³. Important journals, such as *Nature*, use the later distinction in their publication policy ²⁴, as well as the Council of Science Editors ²⁵, and this is the perspective adopted by the authors of this article.

Studies evaluating conflicts of interest in clinical trials presented at medical conferences are important to inform the scientific community about the degree of impartiality of studies presented at these events, but they are still very scarce in the literature. The objective of this article is to investigate the existence of financial conflicts of interest involving authors of clinical trials published in the proceedings of Brazilian congresses of medical specialties, comparing their frequency in two categories of drugs:

1) those with generics available on the market; and 2) those for which there are still no generics and whose commercial exploitation is exclusive to only one industry.

Method

This is a documentary study whose corpus of analysis consisted of abstracts of clinical trials published in 22 proceedings of Brazilian congresses of cardiology, endocrinology, nephrology, psychiatry, and rheumatology. Specialty congresses were selected by convenience, seeking to associate the availability of access to the proceedings with the specialties involved in the treatment of chronic-degenerative diseases that, according to the literature ^{7,8,10,11}, have concentrated the largest production of new drugs.

The studied proceedings were obtained from the internet or received from associations of specialists, as requested by correspondence. The period from 2004 to 2018 was defined to study drugs with less than 20 years of registration and, therefore, with protected patents, considering that the registration of the molecule is usually done a few years before the beginning of the first tests. Clinical trials of any phase were included, excluding preclinical trials and case studies.

Two sets of variables were analyzed. The first set consisted of variables related to the very clinical trials: therapeutic class of the test drug, according to its registration with the Brazilian Health Regulatory Agency (ANVISA); year of registration; proportion of outcomes favorable and unfavorable to the test drug; and presence of the *p*-value calculation for the outcome. The second set included variables related to the identification of conflicts of interest: evidence of sponsorship of the industries holding the patents for the congress where the trial was presented; and existence of a tie, which, according to the literature ²¹⁻²⁵, characterizes a financial conflict of interest between at least one of the authors of the trial and the industry holding the patent.

Subsequently, these sets of variables were compared between two groups of drugs: 1) those that did not have generics or similar options and whose commercial exploitation was, therefore, exclusive to a single industry; and 2) those that already have generics or similar options on the market. Information on the existence of generics and similar options was collected from the database of ANVISA.

The test of equality of proportions, with the Stata software version 12, was used to evaluate the statistical significance of the differences between the studied groups. The central hypothesis was that conflicts of interest would be more frequent in trials involving drugs for which there are no generics or similar options available.

The search for data on industry sponsorship was carried out from multiple sources: the proceedings themselves; general program of the congresses; website of the event; website of the medical society of the specialty related to the congress; Interfarma (Brazilian Researchbased Pharmaceutical Manufacturers Association) website; and direct search on search platforms by cross-checking the name of the industries with the name of the congress. The search for financial ties between the authors and the companies producing the drugs was carried out in publicly-accessible databases: laboratory websites; databases on health professionals and researchers; and previous articles published by the authors. A direct search was also performed by cross-checking the author's name with the name of the drug or laboratory. Upon finding the information that characterized the financial tie, this relationship was noted down, followed by a screen shot and archiving.

The following circumstances were considered a tie that characterized a financial conflict of interest:

- Receipt of travel assistance, honoraria, or study funding;
- **2.** Participation in laboratory research team or scientific consultant contract;
- 3. Employment relationship with the laboratory (it was also verified whether there was a declaration of conflict by the author in the publication, as required by Brazilian regulations).

The entire investigation was based on publicly-accessible documents and data sources, which is why this research does not fit among those that should be submitted to an ethics committee, according to Resolution 466/12 of the National Health Council of the Brazilian Ministry of Health ²⁶.

Nevertheless, all measures were taken to protect the confidentiality of the identity of the researchers involved in the trials.

Results

In total, 407 abstracts were found in the 22 proceedings studied in the time interval between 2004 and 2018. After applying inclusion and exclusion criteria, the corpus of analysis was established in 77 abstracts. In total, 28 different drugs were involved in these trials, and only six of which had 20 years or more of registration. Table 1 shows the general summary of the trials, the involved drugs, and the studied variables.

Table 1. General summary of trials

Drugs involved in the trials and year of registration with ANVISA	Number of trials per year of publications in the proceedings	Number of published drug trials in relation to the year of registration		Number of drug trials with outcomes favorable to the test drug		Number of drug trials with outcomes unfavorable to	Number of trials with one or more authors in conflicts	Presence of conflict declaration in the
		≤5 years	≥5 years	With p-value	No p-value	the test drug	of interest	publication
Abciximab 2001	1 (2015)	0	1	1	0	1	0	-
	2 (2015)	2	0	2	2	0	2	2
Baricitinib 2018	2 (2016)	2	0	2	0	0	2	2
2010	1 (2017)	1	0	0	1	0	1	1
Basiliximab 1998	2 (2012)	0	2	0	0	1	0	-
Cinacalcet 2010	4 (2012)	4	0	2	2	0	0	-
Daclizumab 1999	1 (2004)	1	0	0	1	0	0	-
Dapagliflozin 2017	1 (2018)	1	0	1	0	0	0	-
Dulaglutide 2015	1 (2018)	1	0	0	1	0	1	1
	1 (2014)	1	0	1	0	0	1	1
Etanercept 2009	2 (2014)	2	0	0	2	0	1	1
Fluvastatin 1997	2 (2004)	0	4	2	0	0	0	-
FTY720 2011	4 (2004)	4	0	1	2	1	0	-

continues...

Table 1. Continuation

Drugs involved in the trials and year of registration with ANVISA	Number of trials per year of publications in the proceedings	Number of published drug trials in relation to the year of registration		Number of drug trials with outcomes favorable to the test drug		Number of drug trials with outcomes	Number of trials with one or more authors in	Presence of conflict declaration in the
		≤5 years	≥5 years	With p-value	No p-value	unfavorable to the test drug	conflicts of interest	publication
Fondaparinux 2017	3 (2014)	3	0	3	0	0	3	1
GQ-16 No registration	1 (2012)	1	0	0	1	0	0	-
HD203 No registration	1 (2014)	1	0	0	0	1	0	_
HTK No registration	1 (2004)	1	0	1	0	0	0	-
Immunoglobulin 2006	1 (2008)	1	0	1	0	0	0	-
	1 (2013)	0	1	1	0	0	0	_
Ivabradine 2007	1 (2015)	0	1	1	0	0	0	_
2007	2 (2016)	0	2	2	0	0	2	_
Liraglutide 2016	13 (2016)	13	0	8	5	0	10	-
Lixisenatide 2017	5 (2014)	5	0	4	0	1	5	-
Paliperidona 2011	1 (2016)	1	0	0	1	0	1	-
Palivizumab 1999	1 (2016)	0	1	0	1	0	1	-
Rituximab	1 (2014)	0	1	0	1	0	1	_
1998	3 (2016)	0	3	1	2	0	2	_
Secukinumab 2015	4 (2015)	4	0	3	0	1	4	-
Semaglutide 2018	1 (2016)	1	0	0	1	0	1	-
Sirolimus	4 (2004)	4	0	2	2	0	3	_
2000	4 (2008)	0	4	2	2	1	1	_
Tirofiban 1999	1(2013)	0	1	0	0	1	0	_
Tocilizumab 2009	3 (2017)	0	3	1	2	0	3	-
Tofacitinib 2014	1 (2015)	1	0	0	1	0	1	_
Triamcinolone 1988	1 (2014)	1	0	1	0	0	1	-
Total 28 drugs	77 trials	55 <5a	22 >5a	43	34	8	47	_

A tie involving one or more authors of the trial with the industry responsible for the drug was identified in 46 of the 77 analyzed trials (59.7%). In only 24 of these 46 (52.2%) the conflict was declared. The characterization of the financial tie showed that in 38.1% of the cases, travel assistance, honoraria, or research funding were received; in 23.8%, there was participation in a research team or contract as a scientific consultant; and 19% had an employment relationship. The remaining 19.1% refer to situations in which the author declared a conflict of interest, but it was not possible to characterize the nature of the tie by the search procedures used by the authors of this article.

With regard to industry sponsorship for congresses in which drugs of interest to this industry were presented, it was only possible to confirm this in 13 abstracts of clinical trials. In 11 of them the outcomes were favorable to the test drug, representing 90.9% of the total of 77 trials. It is worth noting that, in 48.6% of the abstracts

(34 out of 70) that presented favorable outcomes to the test drug, the authors highlighted the positivity of the findings without statistical confirmation by presenting the p-value or other significance indicator.

Table 2 shows the result of the test of equality of proportions of the studied variables in the comparison between groups of drugs with and without generics. The occurrence of authors in conflict of interest was significantly higher in clinical trials with drugs without generics, that is, 36 out of 42 trials, versus six trials with generic drugs out of 42 trials, which resulted in a value of p<0.001. Sponsorship for the congress in which the trial of the drug of interest to the sponsoring industry was presented was also more frequent among trials involving drugs without generics, 11/13 versus 2/13 (p=0.006). Trials with outcomes favorable to the test drugs that showed statistical evidence according to the p-value were significantly more frequent when involving drugs without generics (p<0.001).

Table 2. Test of equality of proportions of variables in relation to groups of drugs with and without generics

Analyzed variables	Proportion in trials involving drugs without generics	Proportion in trials involving drugs with generics	Difference between proportions	95%CI for the difference between proportions	<i>p</i> -value
Favorable outcomes	90.9% (50/55)	90.9% (20/22)	0	-14.2-14.2%	1.000
Favorable outcomes with <i>p</i> -value	80.6% (29/36)	19.4% (07/36)	61.2%	42.8-79.4%	0.000
Favorable outcomes with no <i>p</i> -value	61.8% (21/34)	38.2% (13/34)	23.6%	0.04-4.7%	0.052
Placebo control	85% (17/20)	15% (3/20)	70%	47.9-92.1%	0.000
Sponsorship of the interested industry	76.9% (10/13)	23.1% (3/13)	53.8%	21.5-86.2%	0.006
Trials with an author in conflict	85.7% (36/42)	14.3% (6/42)	71.4%	56.5-86.4%	0.000
Declaration of conflict, if any	66.9% (23/36)	83.3% (5/6)	-19.4%	-53.1-14.2%	0.350

Table 3 shows the set of therapeutic categories of the 28 involved drugs per number of clinical trials. We can observe that the largest number of clinical trials were immunosuppressants and immunomodulators, most in the form of monoclonal antibodies, representing 28.6% of the total of studied drugs.

Antidiabetics, with 27.3%, antineoplastics, with 13% of trials, and anti-inflammatory drugs, with 10.4%, complete the group of the most involved categories. Together, they accounted for 79.2% of all involved drugs. In the remaining 20.8% of clinical trials, with the exception of just one trial involving an antiviral drug,

the tested drugs also involved therapeutic categories aimed at chronic degenerative conditions.

Table 3. Number of trials per therapeutic class of the involved drugs.

Therapeutic class	Number of trials
Antianginals and vasodilators	3
Platelet antiaggregants, anticoagulants and antithrombotics	5
Antidiabetics	21
Antineoplastics	10
Anti-inflammatory drugs	8
Antiparathyroids	4
Antilipemics	2
Antiviral	1
Immunosuppressants and immunomodulators	22
Neuroleptics	1
Total	77

Discussion

In this study, the proportion of surveyed trials in which authors were in a situation of conflict of interest was 59.7%, almost 10% lower than that found by Thompson and collaborators 27, when they investigated 335 abstracts in international gynecology congresses and found 69% of trials with authors in conflicts of interest. Conversely, the 33.3% of omission regarding declaration of conflict of interest was lower than that reported in previous international studies. Gray and collaborators 28 and Luce and Jackman 29 also studied medical conferences and congresses and found an omission of declaration in 48% and 45.5% of the presentations, respectively, in authors with financial ties to the industry. In the study by Thompson and collaborators 27, the omission of declaration remarkably reached 93% of the presented trials.

This considerable difference may be related to the rigor with which the scientific committees of the congresses assess the compliance with this ethical requirement and the way in which the declaration requirement is defined in the country's deontological and health resolutions. In Brazil, the Resolution 1,595/2000, of the Brazilian Federal

Council of Medicine (CFM) ³⁰, and the Resolution RDC 96/2008, of the National Health Agency (Anvisa) ³¹ are in force, both requiring declaration of conflicts of interest at events.

An original finding of this article, which was not found in other national or international studies, was the comparison of the occurrence of conflict of interest in relation to trials involving test drugs with and without generics. This aspect is considered important, as it has already been well-demonstrated that the largest marketing investments by the industries are directed to drugs in the process of being launched on the market or to those that still have patents ³².

In this sense, for the authors of the present article, it is paramount to prove the central hypothesis by demonstrating the statistical significance of the greater occurrence of authors with conflicts of interest in the group of drugs without generics. When comparing these variables, though the final sample size of 42 trials with which the comparison was performed is not very expressive, the confrontation of the proportions 34/42 versus 6/42 allowed to obtain a value of p<0.001, which indicates a very low probability of having found this result by chance, that is, of having committed a type I error.

A similar situation occurs in relation to the finding of greater confirmation of favorable outcomes by demonstrating the *p*-value in trials with drugs without generics. However, we are aware that a conclusion of greater generalizing strength would depend on an expansion of this sample size.

The low number of identification of sponsorships for congresses in which drug trials of interest to the sponsoring industries were presented, in a total N of 13, does not allow us to state that the verified p-value, even though far from the significance parameter (p=0.006), statistically confirms the greater tendency to sponsor trials of drugs without generics or similar options. Nonetheless, the presentation of the data is relevant as, from the author's perspective, this low number demonstrates the omission of information on sponsorship of industries for congresses. There was no information about congress sponsorship in any of the 22 studied proceedings, contrary to RDC 96/2008, which explicitly mentions the mandatory nature of this information in congress proceedings 31.

Likewise, it is noteworthy that, on the website of Interfarma, declarations of support for scientific events, which are also legally required, are exclusively aimed at small events, such as small meetings of academic associations and local events, without any report of large congresses ³³.

What makes this finding intriguing and legitimate to assume the omission of information by the industries and by the associations of specialists responsible for the congress is the indisputable empirical fact, already consensually accepted in the literature, that the great national and international congresses of medical specialties do not occur without industry financial support. Domingos Neto, Bajerl and Serodio ³⁴, in quick consultations on Brazilian congresses of three ongoing medical specialties, found an average of 50 sponsors for each one, of which 88% were pharmaceutical industries.

Despite this low number of confirmations, the industry's commitment to conflicts of interest was already widely demonstrated in this study, considering the financial ties between these companies and the authors of the trials in 59% of the 77 studied trials, in which about 40% of these conflicts were travel assistance, payment of honoraria or research funding, in addition to employment relationships or consulting contracts.

Another finding that is in line with reports in the literature is the frequency of favorable outcomes to the test drug in industry-funded studies. This study found that positive outcomes occurred in 90.9% of trials. We may argue that this data would be a bias caused by the selection of trials by the scientific committees of the congress, and not the responsibility of the industries. Although we found no studies that investigated this trend of trials favorable to the test drug specifically in congresses, with regard to publication in journals, studies have pointed out that this selection bias of positive results favors, by itself, the interests of industries ^{10-12,15,19}.

In a recent publication, Lexchin and collaborators ³⁵ compiled a series of studies that demonstrated selective reporting of data in clinical trials published in journals, with potential to induce conclusions of efficacy and safety that did not correspond to the reality, which the authors called "promotional presentation of clinical trials." The authors also state that, until the date of the study (2018), a large number of clinical trials with

unfavorable outcomes remained unpublished, a situation they consider as "shameful," considering that the inaccessibility of negative results brings a false impression of superiority of newer drugs and allows clinical trials involving risks for human beings to be repeated due to the lack of knowledge of the failure of previous attempts. The authors subsequently discuss recommendations for improvements in the review of articles, including planning and performing the statistical analysis. It is believed that the same concerns should be present in the evaluation of trials to be presented at conferences.

It is worth mentioning that, in the sample of this study, 48.6% of the abstracts of the 70 trials with favorable outcomes to the test drug did not even have the p-value; nevertheless, they highlighted the relevance of the findings, some of them using impact expressions such as: "significant reduction of symptoms," "beneficial result," "proved to be effective," and "safe option." Among the 24 abstracts that declared a conflict of interest, only one mentioned, in its conclusion, that it obtained a "nonsignificant" result. These findings seem to corroborate the strong statement by Lexchin and collaborators 35 that industry funding for medical events is a means of controlling healthcare and research practices, being capable of producing such serious biases that they turn disadvantages into advantages. For these authors, many positive results in clinical trials in the industry are based not on evidence, but rather on the production of a "compelling medical discourse."

It seems evident that the scientific committees of congresses have acted in a similar way to what has been denounced in the literature concerning some science editors as for the near exclusivity of publishing trials favorable to new drugs, even if their statistical confirmation is not evident. This indicates the existence of a vast space in the surveyed Brazilian congresses for the so-called "promotional presentations of clinical trials," as reported by Paul and Tauber ³⁶.

In a study comparing clinical trials sponsored by the National Institute of Health (NIH) and those sponsored by the pharmaceutical industry, out of a total of 226 trials, Riaz and collaborators ³⁷ demonstrated, by accurate calculations, that the industry trials were favorable to the test drug between four and seven times more than those

funded by the NIH. In Brazil, it has also been demonstrated how different types of conflicts of interest potentiate findings favorable to the test drug ^{38,39}. In the meta-analysis performed by Belkeman, Li and Gross ¹⁹ involving eight literature review articles, in addition to 1,140 original clinical trials published in journals, a strong, statistically significant association was found between industry sponsorship and pro-industry conclusions. In the same study, industry sponsorship was also associated with restrictions on publishing negative outcomes and sharing data.

Miguelote and Camargo ⁴⁰ drew attention to the threat to the credibility of clinical trials for new drugs, as the development and performance of research in this field, as well as the dissemination of results, were dominated by private interests and marketing practices, which was transforming the very production of knowledge into a commodity. Souza and collaborators ³⁹ add that, by doing so, the pharmaceutical industry becomes a producer of altered results and bad science, with direct repercussions on the health of patients.

The data obtained from this study on the privileged therapeutic categories in relation to production also corroborate other studies that show a concentration of production in two main niches, drugs aimed at chronic-degenerative diseases and high-cost drugs, maintaining negligence in relation to other morbid conditions ^{4,7,10}.

In the sample of this study, drugs aimed at chronic degenerative diseases accounted for 57.2% of the trials, whereas high-cost drugs represented 41.6% of the 22 involved in the clinical trials presented at the congresses. However, considering that the chosen specialties are also among those that preferentially deal with chronic-degenerative diseases, the first part of these results would already be expected. Nonetheless, the finding of 41.6% in high-cost drugs, especially monoclonal antibodies, corroborates the growing trend of production of this pharmacological category, already addressed in the literature. In a recent publication, Urquhart⁸ showed that the ten best-selling drugs in 2017 yielded USD 75.3 billion, and six of them were monoclonal antibodies, responsible for 69% of this revenue. The results obtained in the study by Urguhart⁸ are similar to those in the study by Hoefler and collaborators 9 on new drugs registered between 2004 and 2016 in Brazil, demonstrating that among 253 new drugs registered in the period, the high-cost ones, such as antineoplastics and immunosuppressants, followed by antidiabetics, were among the most frequent registrations.

The results of these studies point to the seriousness of conflicts of interest involving medical congresses regarding the promotion of new drugs. The findings strengthen the concerns and complaints that have emerged in the scientific literature in recent years about the ethical consequences for professional conduct and the technical implications for decision-making related to therapeutic choices.

Final considerations

The results obtained from this study brought as an original finding, not yet explored in the Brazilian literature, the demonstration of a greater occurrence of conflicts of interest in clinical trials involving drugs without generics or similar options. Moreover, findings regarding the systematic lack of information on industry sponsorship of congresses in the 22 studied proceedings, as well as on the websites of the pharmaceutical industries, are also noteworthy.

Likewise, it is worth noting the omission of a declaration of conflict in more than a third of the trials in which at least one of the authors had some kind of financial tie with the industry responsible for the analyzed drug. All these conducts imply negligence in terms of complying with Brazilian regulations.

Conversely, the confirmation in the Brazilian context of the concentration of drugs in production niches already duly identified in the international literature is yet another demonstration that the production strategy of industries is globalized and independent of the socioeconomic reality and health priorities of the countries where clinical trials are carried out.

It is necessary to recognize, however, that, even though 407 abstracts were analyzed in the 22 proceedings that composed the study corpus, the final sample size, after meeting the exclusion criteria, was only 77 trials, which is the main limitation of this study. Even so, the statistical significance in some of the comparisons made by the authors—among them, the one that confirmed the central hypothesis of greater occurrence of conflicts of financial interests in trials with drugs

without generics or similar options—is relevant and acceptable, considering the effect size and the difference between the groups.

In these cases, the significant and very small *p*-value (non-borderline) indicated a very low probability of having found the results by chance. Nevertheless, we recognize that future studies with a significant expansion of the spectrum of surveyed congresses will be necessary to obtain a sample size that produces more safe, generalizable, and definitive conclusions. All in all, we consider that this study greatly contributes to the reflection on the issue of conflicts of interest in medical events in the Brazilian context.

The analysis of the findings and of other recent studies published in the literature led us to demand that the scientific committees of the congresses begin to adapt to the scope of oral communications and publication of abstracts in proceedings the use of some of the criteria already established by the Council of Science Editors, especially those dealing

with clarity in the presentation and interpretation of statistical data, space for trials with unfavorable outcomes to the test drug, and greater rigor in the requirement of declaration of conflicts of interest.

The omission of statistical calculations and the inaccessibility of raw data may be understood as a betrayal, on the part of those responsible for clinical trials, of the trust placed by patients who were willing to participate. Ultimately, these procedures do not enable to distinguish science from advertising, as without access to calculations and raw data it is not possible to prove the reproducibility of the results, one of the central criteria of scientificity in natural sciences, nor carry out meta-analyses, the safest method for asserting the efficacy and safety of new drugs.

We believe that the solution to the problem must include a stricter regulation on the part of schools and councils of medicine and pharmacy aimed at organizing congresses and other academic-educational events.

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Participation of the authors

Cláudio Fortes Garcia Lorenzo and Milton Luiz Nascimento conceived the research idea and performed data collection. Mauro Sanchez participated in the analysis of the data and in the discussion of the results. The three authors wrote and reviewed the text to be published.

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