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Conflicts of interests in the medical and pharmacological research

Ricardo Pires de Souza [1], Abrão Rapoport [2], Rogério Aparecido Dedivitis [3], Cláudio Roberto Cernea [4], Lenine Garcia Brandão [5]

Resumo

A pesquisa médico-farmacológica clínica corresponde à aplicação experimental de determinada droga em seres humanos. Seu controle visa proteger os sujeitos de efeitos adversos inaceitáveis e de ineficiência do medicamento testado diante de outras possibilidades mais eficientes. Parcerias entre a indústria farmacêutica e pesquisadores externos estabelecem potenciais conflitos de interesses. Consulta bibliográfica realizada neste estudo indica que pesquisas com financiamento da indústria farmacêutica têm proporção mais alta de resultados favoráveis e que os conflitos de interesses representam vieses, podendo alterar resultados. Há estudos que comparam a eficácia de diferentes drogas e outros que comparam seus custos. Mesmo resultados negativos devem ser publicados. Conclui que o setor privado deve financiar a ciência para beneficiar o ser humano, especialmente no combate à doença; no entanto, deve manter empenho em financiar as pesquisas sem influenciar seus desenhos, resultados e destinações, caminhando em direção ao respeito à dignidade da pessoa.
Palavras-chave: Conflito de interesses. Pesquisa biomédica. Experimentação humana. Má conduta profissional. Má conduta científica.

Resumen

Conflicto de interés en la investigación médico-farmacológica

La investigación médico-farmacológica clínica corresponde a la aplicación experimental de determinado fármaco en seres humanos. Su control tiene como objetivo proteger los sujetos de efectos adversos inaceptables e ineficaces del fármaco probado. Relaciones entre la industria farmacéutica e investigadores externos establecen potenciales conflictos de intereses. En una consulta bibliográfica llevada a cabo en este estudio indica que investigaciones con financiación de la industria farmacéutica tienen proporción más elevada de resultados favorables y que los conflictos de intereses representan sesgos que pueden cambiar los resultados. Hay estudios que la eficiencia de distintos fármacos, mientras otros comparan sus costos. Todos los resultados obtenidos deben ser publicados, incluyendo cuando se los obtienen negativos. Se concluye que el sector privado deberá financiar la ciencia para beneficio del hombre, especialmente en el combate a la enfermedad. Sin embargo, La industria debería mantener su empeño en financiar las investigaciones sin influenciar su diseño, resultados y destinación caminando hacia a la comprensión de la persona en su dignidad.
Palabras-clave: Conflicto de intereses. Investigación biomédica. Experimentación humana. Mala conducta profesional. Mala conducta científica.

Abstract

Conflicts of interest in the medical and pharmacological research

The clinical medical pharmacological research corresponds to the experimental application of specific drug in human beings. Such application aims to protect them from unacceptable adverse effects and its inefficiency when comparing with other possibilities, more efficient. Partnerships between the pharmaceutical industry and external researchers establish potential conflict of interest. Literature use for this work indicates that researches performed under the sponsorship of pharmaceutical industry have a high rate of favorable results, and the conflicts of interest represent gaps which may interfere the result. There are studies that compare the efficiency of different drugs, whereas others compare their costs. All results should be published, even when negative. The present work concludes that the private sector must sponsor the science in order to improve human beings, especially to avoid diseases. However, it must keep its engagement in sponsoring the research with any influence on its methods, results and application, for a respectful understanding of the dignity of a person.
Key words: Conflict of interest. Biomedical research. Human experimentation. Professional misconduct. Scientific misconduct.

1. Doctor ricapires@uol.com.br – Hospital Heliópolis. **2.** Lecturer arapoport@terra.com.br – Universidade de São Paulo, Hospital Heliópolis **3.** Lecturer dedivitis.hns@uol.com.br – Universidade de São Paulo **4.** Lecturer cerneamd@uol.com.br – Universidade de São Paulo **5.** Lecturer leninegb@uol.com.br – Universidade de São Paulo, São Paulo/SP, Brazil.

Correspondence
Abrão Rapoport – Rua Cônego Xavier, 276 CEP 04231-030. São Paulo/SP, Brazil.

They declare that there is no conflict of interests.

The medical and pharmacological research corresponds to the application, experimentally, of a determined drug whose actions are requested to study in human beings, under a controlled way. The control of application aims to protect patients of clinical tests, both from unacceptable adverse effects as the inefficiency of the medicine tested in front of other more efficient possibilities, and the process of research can be interrupted at any time if it is detected, by partial results, its inadequacy. Such control requires a permanent and straight monitoring of external and exempt supervisors.

The pharmaceutical industry needs to establish partnerships with institutions and external medical researchers, in order to fill in personnel for the clinical stage of test with any drug regarding which one needs an authorization of government to commercial deployment. And that is when the conflicts of interests are established in a medical and pharmacological research. The way which pharmaceutical industry should promote the clinical phase of the research in partnership with institutions and external medical researchers which are responsible for them is financing the studies by providing material and money.

The pharmaceutical industry may contract Consulting firms which have among their personnel medical researchers able to assess specific products. On other occasions, the works are carried out by independent medical researchers – who are frequently doctors, post-doctors and lecturers – which have legal personality to receive pharmaceutical industry's funding. In any case, however, the eventual benefits of the studies for the institutions should not influence the methodological attitude of their researchers, the design, the assessment and dissemination of results.

The remuneration of medical researchers and their team regarding funding is still undefined. The crucial issue is if the financial relation can interfere in the application of the methodology by conditioning the research findings. Supposedly, there are no reasons to work for free, which include the medical researcher and his team. In these cases, the value of remuneration is a subject that, according to the memorandum, concerns only the contracting parties.

Thus, by taking into account the ethical principles of the *Declaration of Helsinki,* dated of 1964, and their subsequent changes (until 2008), and since the methodological strictness can be met, always supervised by autonomous collegiate bodies and fulfilling legal prerogatives, there is no problem that a medical researcher carries out tests clinically, with the request of pharmaceutical industry, a determined drug which aims its commercial deployment and he is remunerated for this work, as well as his team.

The researcher takes the commitment, under any circumstances, of respecting ethical principles and keeping methodological exemption, by applying the criteria defined by the study with the best possible ethical and scientific accuracy. In this sense, the findings achieved by the researcher should be immediately revealed to the academic community, no matter if they are favorable or unfavorable to the funder.

The favorable result may mean a new patent and profit. On the other hand, the unfavorable result may represent a significant loss of investment, time and expectation of profit. Ideally, this should not influence medical researchers and it is expected that the proportion of favorable and unfavorable results could not be much different among works supported by the pharmaceutical industry and the ones come from independent sources, which are generally produced in academic institutions. But, as will be observed below, it is not what happens [1].

Conflicts of interests in the research

There are evidences in literature that researches carried out with support of pharmaceutical industry has a better proportion of favorable results than the ones carried out by independent institutions [2,3,4]. Jang *et al* [2] assessed 236 economic analyses on use of drugs presented in American congresses of oncology and hematology with conflicts of interests; and they identified that 89.9% of those analyses were directly or indirectly favorable to research sponsors. Although the results are varied in literature, there are strong evidences that the presence of conflicts of interests is prevalent [3,4].

The conflicts of interests may represent a powerful bias in scientific research, by changing the result, producing bad science and, even more seriously, by affecting negatively the health of participants, since unexpected adverse effects and the absence of a planned action may come from fake results. This bias can be predicted or it can be involuntary, in a larger or shorter proportion, but, no matter how it takes, such situation exists and it should be taken into account. The experimenter is part of the experiment and his alleged exemption, as well as the inflexibility of scientific method, and he is only an ideal, not a real thing.

The research in the pharmaceutical industry avoids systematically, in the clinical stage, testing a new medicine, and comparing it to other similar existing drug, so it is preferable comparing this medicine to a placebo[5]. This fact itself represents a bias in the design of research, which is a consequence come from the conflict of interest. On the other hand, in the economic analyses carried out by the pharmaceutical industry, comparisons of cost-benefit analyses intended to the paying sources use to compare directly their product with the direct or indirect competitors, by trying to show the inefficiency, in a last financial analysis, of competing products.

A fact which also calls the attention is that, in papers presented in congresses and articles published in specialist journals, conflicts of interests are usually not declared [2]. Jang *et al* identified 27 economic analyses on use of drugs in a sample universe of 356 analyses, in which the authors were employed or external consultants of pharmaceutical industry, but they did not declare conflict of interests [2]. Currently, the statement regarding conflict of interests is made by the author himself (or authors) voluntarily, with no external strict control as a counterpoint.

The issue regarding unfavorable results not published by the pharmaceutical industry can contribute to the discrepancy of favorable works regarding the academic institutions of research. This is not a bad fact which is inherent to researches conducted by the pharmaceutical industry, but it seems to be more predictable in this context.

Final considerations

The consortium among technology, science and commerce is inherent to the industrial development itself and it is part of foundations of contemporary civilization. The symbiosis among all these elements and the power also supports the symbolic structures and the behavior of the current societies based on the Western way of life. When the commerce supports science and technology in the sense of alleviating the human suffering, promoting their welfare, extending their existence and even improving it, the commerce acts within a high ethical aspect. With regard to its non-ethical aspect, the commerce allies to the power in search of exceeding profit and it ends up, among other possibilities, producing bad science and potentially dangerous technologies.

Generally, the biotechnological research and, particularly, the medical and pharmacological research deal with the dignity of the person in their most crucial moment: confronting death, which imposes peculiarities to the symbioses above described. Although fostering and funding of the medical and pharmacological research by the pharmaceutical industry are simultaneously desirable and inevitable, their non-ethical aspect should be preventively contained with strictness. Bioethics and justice are, in this context, the fundamental bases of this containment.

Clinical tests are experimentation *in anima nobile*. If their supervision is currently very strict, this strictness should be taken to the extreme. The design of the clinical tests should be submitted to an external and exempt collegiate under the control of government agencies. In this sense, for example, studies with placebo should be avoided or proscribed [6,7].

Studies with declared conflicts of interests should be paid pay a double attention or the same specific treatment by the editorial boards of specialist journals and the scientific committees of the congresses. The characterization of the types of conflict of interests, in each case, should be clear, which includes a declaration of remuneration by independent medical researchers. When there is no statement regarding conflict of interests, it should be dealt with respect. Case-by-case, method and results of any biomedical research should be compulsorily communicated.

A space in which case-by-case, method and results of non-published works are obligatory deposited and consulted by specialists should exist. Such place could be a virtual one and it should be under control of the States. Metanalyses should be systematically updated, with comparison of drug results, emphasis of works under conflict of interests and use of non-published material, and deposited in an appropriate place, as suggested above. In the relation between pharmaceutical industry and the medical and pharmacological research in its clinical stage, ideally, the industry should keep the effort of supporting the research by giving up proactively and completely any possibility of influence in their designs, results and editorial destinations. It is possible that, in the future, any different attitude of the expressed above on the part of the pharmaceutical industry can be interpreted as a rupture of the memorandum.

Nowadays, we live with our contradictions towards the comprehension of the individual in his dignity as a supreme value of the civilization. Each human individual noted as unique and unrepeatible whose existence is *beyond any price*. From the

search of the universality, the justice is born. Finally, many of the analyses and reflections here expressed may extended without any difficulty to all the biotechnological research.

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Participation of the authors

Abrão Rapoport: structuring of the text; Ricardo Pires de Souza and Rogério Aparecido Dedivitis: literature review and formatting of the text; Cláudio Roberto Cernea and Lenine Garcia Brandão: critical review and formatting of the text.

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