Editorial

*Use of placebos and post-trial benefits**

Brazilian legislators have not yet enacted any laws regarding the use of placebos and the duties of assistance to research subjects. As a result of this omission, public administrative authorities have to deal with the subject on a regular basis, oriented by fundamental rights and judicial supervision. Against that backdrop, CNS (National Health Council)[2], speaking through CONEP (National Research Ethics Committee)[3], ANVISA (Healthcare Surveillance Agency)[4], the CFM (Federal Medical Council)[5], the CNJ (National Justice Council)[6] and the STF (Federal Supreme Court)[7] have expressed their opinions on the subject in a consistent manner.

A comparative analysis about the use of placebos and post-trial benefits in Brazil and the United States should therefore re-examine the fundamental rights in question (for example, the right to human dignity), not only according to the 2013 version of the World Medical Association's Helsinki Declaration[8], but also the case law of the Inter-American Court of Human Rights and the European Court of Human Rights, since Brazil is heavily influenced by the public law of Continental Europe.

In addition, certain premises may not accurately reflect Brazilian reality. I wish to point out three of them that might be explored in greater depth:

1. Avoid the possibility of confusion between research and treatment. Indeed, research is not treatment and many believe clinical trials are a sort of game of chance or gamble for volunteers. In fact they may be harmed (adverse events) without any insurance coverage or compensation for damages, or not receive any treatment at all (placebo) and his illness may deteriorate. Why decide to play such "Russian roulette" when well-proven treatments are available from SUS [Unified Health System] at no extra charge?
2. Is all research for the purpose of advancing science? It is undeniable that most research is substantially for an economic purpose. The idea is to maximize the profit of the sponsor (company) at minimal risk, and the subject may be considered a "useful innocent" in this context.
3. Is research in the best interests of governments because it relieves them of the burden of providing care for the subjects in question? Not in Brazil, because the number of volunteers is negligible compared to the 200 million patients funded by SUS, which ends up paying for the costs and consequences of the adverse events that occur in the research, because they do not have real coverage for such claims.

It is also important to remember that the socioeconomic and educational levels of Brazilian research volunteers are fundamentally different from those of their US counterparts, in that the Brazilian government has to provide greater protection for those who are considered psychologically vulnerable. Illiteracy, old age and mental deficiencies make it difficult for subjects to understand the scope and consequences of the study they are undergoing, as well as to understand the Informed Consent Form and consent to participate in a free and informed manner. In general, the insurance provided by the sponsor, which is mandatory according to the manual of good practices in clinical research, is only effective in the sponsor's country of origin and rarely covers adverse events or deaths that occur in the other countries that may participate in a multicenter, multinational research.

There is no specific legislation in Brazil that regulates the funding of research studies by the pharmaceutical industry. However, the notion that administrative authorities must remain independent and impartial is incompatible with the possibility of private financing of any activity that might result in an administrative decision that could directly or indirectly harm or benefit the sponsor.

In any case, it is well known that all the research carried out in order to register a drug is sponsored by the company that holds the patent. It would therefore be important to discuss the topic from a comparative perspective of Brazil and the United States, considering the fundamental principles of administrative law, especially in terms of the independence and impartiality of the authorities. On the one hand, it may seem utopian to expect the State to have specific funds to conduct cutting-edge research; on the other, it is necessary to examine in greater detail whether the authorities in charge of registering new technologies and incorporating them (into SUS) should be dependent on structurally biased technical testing.

Finally, regarding the breakdown of the research committees that monitor the nature and specificities of the project, it is mandatory to examine the type of committee being considered, as suggested by UNESCO[9]: a normative or advisory committee; a committee of professional associations; a hospital or medical ethics committee; or a research ethics committee. The specialisation of committees does not appear to create any great difficulties; however, even subcommittees are acceptable, provided that they are justified by a sufficient number of claims. Whether they are centralised or decentralised and exercise general or specific powers,

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it is important for all such committees to maintain structural coherency and, above all, a high level of autonomy, independence, impartiality and technical expertise.

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