

The bill submitted to the Brazilian Senate for ethical regulation of clinical research is contrary to the interests of research subjects

A proposta de regulamentação ética da pesquisa clínica apresentada ao Senado Brasileiro não interessa aos participantes de pesquisa

La propuesta de regulación ética de la investigación clínica presentada al Senado brasileño no interesa a los participantes de la investigación

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The system for ethical review of scientific research in Brazil is currently under threat. A bill of law submitted to the National Congress aims to regulate the conduction of clinical trials in the country. The bill only refers to the current system under the CEP-CONEP (Ethics Research Committee-National Council for Research Ethics) when it attempts to justify dismantling the system, based on two arguments: (1) a purported legislative gap on the matter, claiming that the existing guidelines are “non-statutory provisions”; (2) that the ethical review process for research currently in force is “inefficient, anachronistic, and laced with serious distortions” ¹. Furthermore, the bill fails to express any concern regarding scientific research conducted in Brazil, but only clinical trials involving health products slated to enter the Brazilian market in the future. The bill appears to be directly influenced by the *Document of the Americas* ², drafted in 2005 at the 4th Pan-American Conference on Harmonization of Pharmaceutical Regulation. The working group consisted of one representative from each of seven countries, one from the Caribbean community, and two from the pharmaceutical industry, the latter thus representing twenty per cent of the group. If the purpose of the *Guidelines for Good Clinical Practices* (which should actually say “good practices in clinical research”, i.e., what the bill is about) is to establish “a series of criteria

for the planning, implementation, auditing, conduction, analysis, and reporting of clinical trials in order to ensure their reliability” ² (p. 5), and “the objective of the Document of the Americas is to propose guidelines for good clinical practices that can serve as the basis for regulatory agencies, researchers, institutional review boards, universities, and companies” ² (p. 6), is so clear that the document that inspired the Brazilian bill of law evidently never intended to set ethical guidelines for evaluating clinical research (or any other research).

Such misappropriation is an improper extrapolation of the initial document, which aimed at minimum technical standardization of clinical trials in order to ensure credibility for those conducted in the Americas. Proponents of the bill fail to mention its hidden agenda, namely the interests served by it, quite different from those of research subjects.

According to article 30 of the *Declaration of Helsinki* as approved in 2000, “at the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic, and therapeutic methods identified by the study”. In June 2005, amid on-going discussions on access to the medicines after conclusion of trials and the use of placebo, Lurie & Greco ³ stated that the FDA (U.S. Food and Drug Administration) and the pharmaceu-

tical industry were actively fighting these two items in the *Declaration of Helsinki*, to the point of proposing that developing countries should not be covered by the declaration, but only by the GCP (good clinical practices) guidelines issued by the International Harmonization Conference, which convenes regulatory agencies and the pharmaceutical industry for international harmonization of research procedures. The Brazilian bill of law takes precisely this tone: prioritization of GCP to the detriment of the international ethical discussion. The bill thereby clearly favors the interests of the international pharmaceutical industry, represented in Brazil by Interfarma (Associação da Indústria Farmacêutica de Pesquisa). The circle is thus complete. While the ethical regulations are drafted by organizations and individuals that effectively discuss (or seek to discuss, or should discuss) the ethical issues involved in research practices, in the International Harmonization Conference discussions for defining GCP, the pharmaceutical industry and health surveillance agencies are the protagonists, with their main concerns focused on the technical dimensions of the process. It is impossible to ignore the blatant conflicts of interests, much less confuse the technical and ethical dimensions in the process.

Posts on the internet show that the bill's proponents base their arguments on the erroneous notion that industry and the vulnerable population have the same interests, and that cancer patients who have lost all hope should trust in a new drug that might have some impact on the evolution of their illness, thus justifying their enrollment in the trial. It is a mistake to assume that every patient enrolled in a clinical trial will be treated with the most recent drug. Testing a drug involves comparison of the new drug with the safest and most effective existing treatment, or as some would have it, with the absence of treatment. In other words, every patient entering a trial may be treated with the new drug, or with existing treatment, or even with placebo. It is also

a mistake to believe that participation in a trial solves the problem of access to treatment. We refuse to go along with such barbarianism. The Brazilian Constitution provides that all patients must have access to treatment, and we must demand this from government, not from the pharmaceutical industry.

All over the world, in order for medicines to be sold in pharmacies, they must submit to a series of tests, precisely to prove their efficacy and safety. We all obviously want to have increasingly better medicines to fight every disease that causes suffering. Still, Brazilian society cannot allow these medicines to be tested in humans without adequate protection, according to the interests of those who are not research subjects themselves. Who should orient society on the risks of smoking? The tobacco industry? And on the risks associated with alcohol? The beverage industry? And on healthy eating? The fast food industry?

Researchers and academics from a wide range of countries admire Brazil's system for ethical review of clinical trials, precisely because it is a system rather than a set of committees working in isolation. They admire it because it is linked to an independent social control system and relies on democratic participation by researchers, regulatory bodies, patients, universities, and health services. The system's dynamics are constantly being improved and fine-tuned, as is appropriate. An example was the recent revision of the basic regulation dealing with guidelines and principles for conducting studies in all areas, crowned by a public hearing with active participation by the various stakeholders. Such a system should not be destroyed by those who have proven incapable of demonstrating that their proposals are better for defending patients' interests. The interests and protection of study subjects cannot be overridden in the name of commercial interests from any sector whatever, when what is at stake is the very quality of life of study subjects, or any other of their legitimate interests.

Contributors

Both authors planned, wrote, and approved the final version of the article.

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